HEALTH

DIVISION OF CERTIFICATE OF NEED AND LICENSING

POLICY AND STRATEGIC PLANNING BRANCH

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

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

Proposed: May 1, 2017, at 49 N.J.R. 980(a).

Adopted: December 19, 2017, by Christopher R. Rinn, Acting 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.

Filed: December 19, 2017, as R.2018 d.049, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 26:8-40.27 et seq., particularly 26:8-40.32 and P.L. 2012, c. 17.

Effective Date: January 16, 2018.

Expiration Date: January 16, 2025.

Summary of Public Comments and Agency Responses:

The Department of Health (Department) received timely comments from the following commenters during the 60-day public comment period, which ended on June 30, 2017.

1. Mishael Azam, Esq., Chief Operating Officer and Senior Manager, Legislative Affairs, Medical Society of New Jersey

2. John D. Fanburg, Esq., Brach Eichler, LLC, on behalf of the Radiological Society of New Jersey

3. Pamela Graziadei, Capital Health Medical Center, Hopewell

4. Christopher Hughes, Assistant Vice President, Government Relations, Virtua

5. Sara Lechner, Vice President, Policy Development and Government Affairs, RWJ Barnabas Health

6. Jean Publiee, Whitehouse Station, NJ

7. Elizabeth A. Ryan, Esq., President and CEO, New Jersey Hospital Association

8. Kelly Tranes, Livingston, NJ

Quoted, summarized, and/or paraphrased below, are the comments and the Department's responses thereto. The numbers in parentheses following each comment below correspond to the commenters listed above.

General Comments

1. COMMENT: A commenter states that "[s]uffering the loss of a stillborn is a tragic time for the mother and family and hospitals strive to provide the best atmosphere possible during this time of grief. We appreciate the overall objectives of the Autumn Joy Stillbirth Research and Dignity Act. As noted in the proposal, "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. Hospitals embrace this flexibility to provide these families with the appropriate level of comfort during these difficult times." (7)

2. COMMENT: A commenter states that the Medical Society of New Jersey "appreciate[s] the circumstances under which the Autumn Joy Stillbirth Research and Dignity Act was passed and acknowledge[s] the importance of treating patients and their family with dignity and compassion when experiencing a stillbirth. We appreciate the opportunity to provide comments on the proposed regulations." (1)

3. COMMENT: A commenter "applauds the efforts and objectives of the Autumn Joy Stillbirth Research and Dignity Act in ensuring patients and families experiencing a stillbirth receive compassionate care along with emotional and psychological support ... Our goal has always been to provide the appropriate and necessary support during these difficult and emotional times in any individual's life." (4)

4. COMMENT: A commenter "recognizes the value of ensuring dignified and sensitive treatment of a patient and family experiencing a stillbirth." (2)

5. COMMENT: A commenter relates her own experience as the mother of a stillborn baby and thanks the Department for implementing the law, but notes that she wished the rules had been promulgated sooner. (8)

RESPONSE TO COMMENTS 1 THROUGH 5: The Department acknowledges the support of the commenters.

Individual's Concerns Regarding the Rules

6. COMMENT: A commenter believes that the "social effect is that many families may feel this latest govt intrusion into their personal issues is an insult and that these are personal matters primarily. The govt these days has a need to insert itself into every personal family matter through intrusion like listening to phone calls, etc. This is just

another intrusion. Many will not be happy about this govt intrusion into family lie [sic]." (6)

RESPONSE: While the commenter expresses her general viewpoint regarding the chapter, she does not suggest that any specific rule be amended or ask for clarification of a rule. Because the commenter is neither seeking amendment to any specific proposed rule nor asking for clarification, the comment is outside the scope of this rule proposal. Thus, the Department will not be making any changes to the proposed rules upon adoption in response to the comment.

Additionally, it should be noted that the Department is promulgating this rule chapter in order to effectuate the purpose and intent of the Autumn Joy Stillbirth and Dignity Act (the Act), N.J.S.A. 26:8-40.27 et seq., which requires the Department to establish mandatory protocols for health care facilities to follow when stillbirths occur "so that each child who is stillborn and each family experiencing a stillbirth in the State is treated with dignity." N.J.S.A. 26:8-40.27.

Notice of Proposal Impact Statements

Summary

7. COMMENT: In the notice of proposal Summary, the Department states that from its meetings with stakeholders, it "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." A commenter states that "[p]rocedures and practices

are evidence-based practice and best practice, not based solely on 'experience and interactions.'" (3)

RESPONSE: The Department agrees and notes that the proposed rules allow facilities to enhance the minimum standards established by the rules with their own best practices based on evidence of the validity of the practice.

Economic Impact

8. COMMENT: The commenter respectfully disagrees with the Department's statement that there will be a minimal economic impact resulting from the proposal. Specifically, the commenter respectfully disagrees with the minimal economic impact statement because 'the rules require education of all staff and potential changes in staffing levels." (7)

9. COMMENT: A commenter states that the Autumn Joy Stillbirth Research and Dignity Act, "specifically requires the creation of a comprehensive set of protocols; the assignment of one primary physician and one nurse to the patient in order to provide continuity for the patient; the creation and maintenance of a memory box; and the implementation of annual education and training for all staff in direct contact with patients experiencing a fetal stillbirth. As such, our system believes that these regulations will cause our facilities to experience more than a 'minor economic impact' in order to fully implement these requirements, both to the letter and the spirit of the law." (5)

10. COMMENT: A commenter states that “[m]any major costs are associated with care of a stillborn baby, mother and family of a stillborn such as performing/paying outside facilities for autopsies and alternatives to autopsy, payment of staff to report data from autopsy/evaluation to the State, costs of providing grief support by qualified professionals, education and training costs for nursing staff and providers, supplies for memory boxes/mementos, creating/printing pamphlets, and resources for contacting families regarding memory boxes after 1 year such as certified mail.” (3)

11. COMMENT: A commenter states that certain contents of the memory box “can be kept by the family instead of imposing this requirement on the hospital and costing [sic] the hospital to incur costs.” This commenter also states that “[a]s to economic impact the high costs of hospital care mean that the costs for hospital care for birth will go up. Nothing done in a hospital is cheap. Anything done in a hospital seems to cost thousands of dollars these days. The costs to hospitals of this additional work will be severe. And some will complain no matter what and seek money from govt and hospital agencies.” (6)

RESPONSE TO COMMENTS 8, 9, 10, and 11: The Department disagrees with the commenters. Although the Department cannot provide an exact figure for the costs associated with creating and keeping memory boxes, maintaining the required staffing levels, conducting autopsies training staff and reporting stillbirth data to the Department, the costs should be minimal because there are only an average of 700 stillbirths out of the approximately 100,000 births that occur each year in this State. With stillbirths representing only 0.7 percent of the yearly births in this State, hospitals and birthing facilities will not have to create and maintain a large number of memory boxes or report

a significant amount of stillbirth data to the Department each year. As such, these requirements should not create substantial financial burdens for the facilities. Furthermore, the amount of staff training and the levels of staff that are required under the proposed rules is minimal and, consequently, will not be a significant financial investment for the facilities.

Moreover, facilities are not required to shoulder the costs associated with performing the stillbirth autopsies. Indeed, the rules neither prevent hospitals from billing third-party payors, such as private insurance and government programs, that may pay for post mortem services nor prohibit a health care facility from billing the patient directly for the evaluation, if the patient consents to the procedure and it is not covered by insurance.

Even more, the Act requires the Department to ensure that health care facilities train their staff on caring for a patient and family experiencing a stillbirth, maintain certain staffing levels to care for the patient, offer families the opportunity to prepare a memory box with keepsakes and retain the keepsakes for one year if the family chooses not to take them at discharge, as well as report stillbirth data to the Department. See N.J.S.A. 26:8-40.28(b), 26:8-40.29, and 26:8-40.30. As such, these requirements are statutory mandates and are not optional. Accordingly, the Department will make no change upon adoption in response to the comments.

12. COMMENT: A commenter states that the rules “suggest a variety of radiologic and pathologic studies that might be used to determine the cause of the stillbirth, with no indication of what entity will pay for these tests.” (7)

13. COMMENT: A commenter states that "[s]ome hospitals pass the cost of autopsy on to the mother/family of the stillborn child. Depending on the autopsy facility, this cost may be more than $10,000. Costs associated with alternative evaluation may also be billed to the mother/family depending on the facility." (3)

14. A commenter states that "[t]he parents should be charged with the costs of any autopsy. Not the taxpayers of NJ." (6)

RESPONSE TO COMMENTS 12, 13, AND 14: These comments go beyond the scope of the rulemaking as payment for the costs of performing autopsies and alternative evaluations are not addressed in the Act or the proposed rule chapter. Moreover, the rules do not prevent hospitals from billing third-party payors, such as private insurance and government programs, that may pay for these services. Nor do the rules prohibit a health care facility from billing the patient directly for the autopsy or alternative evaluation, if the patient consents to one of these evaluations and it is not covered by insurance. Of course, if a third-party payor does not cover the cost of an autopsy or alternative evaluation, then the private pay cost for the procedures should be explicitly provided to the patient, so that she can make an educated decision on whether to proceed with the services. Accordingly, the Department will make no change upon adoption in response to this comment.

N.J.A.C. 8:35-1.3 Definitions

15. COMMENT: A commenter asserts that the "definition of 'alternative evaluation' should be amended to insert the word 'may' before 'includes a placental examination,

external examination, selected biopsies, X-rays, MRI and ultrasound as determined ...'" (7)

16. COMMENT: A commenter asks the Department to add an "or" in the definition of "alternative evaluation" before the term "MRI." Specifically, the commenter states that "[i]n order for pathologists and radiologists to continue to apply best practices, we ask for the definition of alternative evaluation to be amended as follows: ... X-rays, [or] MRI, and ultrasound ..." (2). Another commenter supports this requested revision. (1)

17. COMMENT: A commenter states that "'Alternative evaluation' is listed as MRI and ultrasound which ... would be of no benefit to stillbirth evaluation. Computerized Topography [sic] (CT Scan) is more appropriate ..." The commenter further states that "the pathologist performing the evaluation if autopsy is requested is out of state and would not have input into the imaging/evaluation that would take place prior to transfer of the stillborn baby's body. Alternative evaluation may also include chromosome evaluation." (3)

RESPONSE TO COMMENTS 15, 16, AND 17: The Department agrees with the commenters that the definition of "alternative evaluation" may be read in a manner that is more prescriptive than was intended as the only procedures included in the definition are those contained in the Act. The Department's intent was to include any evaluation method that is determined by the pathologist to be appropriate and consented to by the parents, as expressed in the requirement at N.J.A.C. 8:35-3.2(d), which incorporates the standards established by the American College of Obstetricians and Gynecologists when performing an alternative evaluation. To clarify this intent, the Department will make a non-substantive amendment to the definition upon adoption to state that the

alternative evaluation may include, but is not limited to, the methods listed in the definition, as determined appropriate by the pathologist performing the evaluation and the consenting parents. This non-substantive change will reflect the Department's intent to define alternative evaluation broadly in order to capture all appropriate methods of evaluation that are accepted within the medical community and determined by the pathologist to be the most effective for conducting the post-mortem examination.

18. COMMENT: A commenter states that the "[d]efinition of fetal death in legislation does not match the definition used by New Jersey. Certificate of fetal death, burial, cremation or removal permit is required over 20 weeks gestation at delivery regardless of weight." (3)

RESPONSE: Consistent with N.J.S.A. 26:8-40.27.a, the Department defined stillbirth or stillborn child to mean an unintended fetal death that occurs after 20 weeks of pregnancy or involves a fetus weighing 350 or more grams. The commenter may be confusing the definition of stillbirth set forth in the Act with the definition of fetal death for purposes of issuing a certificate of fetal death under N.J.S.A. 26:6-11. The Department makes no change on adoption in response to the comment.

19. COMMENT: With regard to the definition of memory box, a commenter states that the inclusion of a certificate of life in the box "is not appropriate as the child was born deceased. The mother/family may elect to request a certificate of birth resulting in stillbirth from the State. Permission from the mother is required from the mother to cut a lock of hair." (3)

20. COMMENT: A commenter states that the “proposed regulations set forth a number of definitions relevant to the new regulatory requirements, including that of a ‘memory box,’ consisting of keepsakes from a stillbirth. N.J.A.C. 8:35-1.3. Some of our facilities already have policies and procedures in place for the collection and maintenance of memory boxes, which contain many, if not all, of the keepsake items included in the definition. The definition already contains one item, photographs, which require patient permission to include in the keepsake box. We respectfully request the Department consider also requiring patient permission to include a handprint or footprint and a lock of hair in the memory box. The hair, in particular, requires hospital personnel to cut a lock from the baby and we believe that the patient should consent to its inclusion.” (5)

RESPONSE TO COMMENTS 19 AND 20: The certificate of life that may be contained in the memory box is a symbolic keepsake to memorialize evidence of the child’s existence and is not to be confused with or take the place of a certificate of birth resulting in stillbirth. The Department does not believe that a keepsake certificate of life is inappropriate. The definition of memory box at N.J.A.C. 8:35-1.3 was intended to require parental permission for both photographs and a lock of hair before they were taken and included in the memory box. The definition originally required permission for locks of hair to be taken from the stillborn child, but was omitted due to a technical error upon publication in the New Jersey Register. This error will be corrected upon adoption as a non-substantive change. Additionally, the Department does not believe parental consent is required for the taking of a handprint or footprint as these actions do not involve any alteration to the baby. However, if a facility would like to ask for parental permission before taking the handprint or footprint, then the facility is free to do so as

the rules do not prohibit requesting permission before creating this keepsake. The Department makes no change on adoption in response to the comment.

21. COMMENT: A commenter "appreciates the Department providing flexibility in its definition of 'one-on-one nursing care.' Permitting the assigned nurse to change with the end of each nursing shift allows hospitals to provide appropriate and professional coverage to the patient. Furthermore, we appreciate the flexibility for the assigned nurse to 'have additional duties and responsibilities during his or her shift.' While we interpret this to imply a nurse may also attend to other patients as necessary, and not limit his or her duties to only one patient, we believe the Department should amend the language to expressly state these additional duties and responsibilities include attending to other patients." (4)

22. COMMENT: A commenter "is appreciative that the Department, in these proposed regulations, has defined 'one-to-one nursing care' in a manner that clearly does not alter existing nurse staffing ratio requirements but also allows nurses assigned to the patient to also perform additional duties and responsibilities. See N.J.A.C. 8:35-1.3." (5)

RESPONSE TO COMMENTS 21 and 22: The proposed definition of "one-on-one nursing care" clearly and unambiguously permits the nurse who is assigned to care for a patient who experienced a stillbirth to perform duties and responsibilities other than those necessary to care for the grieving patient. Specifically, the definition provides that "the assigned professional nurse may also have additional duties and responsibilities during his or her shift." The broad nature of the phrase "additional duties and responsibilities" allows a facility to assign additional tasks, such as caring for other

patients, to the one-on-one nurse as it deems necessary and appropriate. Because the definition explicitly allows for the one-on-one nurse to perform duties in addition to his or her responsibility to care for the patient who experienced a stillbirth, the Department makes no change on adoption in response to the comment.

N.J.A.C. 8:35-2.2 Physician Responsibilities

23. COMMENT: Regarding N.J.A.C. 8:35-2.2(a), which requires the assignment of certain responsibilities to one primary physician when a stillbirth occurs, the commenter "would like to point out that in many births, a nurse midwife is the primary care provider and can also be assigned this responsibility, especially when the patient is cared for by the midwife during her pregnancy. Therefore, we respectfully request that 'midwife' is added after 'physician' in this section so that it applies to both." (7)

24. COMMENT: A commenter states that "[a]ny reference to 'physician' should also include certified nurse midwives as they are licensed independent practitioners. We suggest using the term 'provider(s).'" (3)

25. COMMENT: A commenter states that the Department "has added a provision in its proposed regulation, not specifically delineated in the statute, which requires the physician to advise the patient that a midwife or other healthcare professional may be present during any discussions." The commenter "is appreciative that the Department has included this fourth responsibility, ensuring that there is an option that another healthcare professional can be present during these delicate conversations. In practice, however, some parents elect to have a midwife provide maternity care without physician involvement. In those instances, our system would seek to ensure that the midwife, who

is a familiar and trusted resource to the patient, would fully participate in the care and coordination with the patient and family. Therefore, we ask the Department to consider amending proposed N.J.A.C. 8:35-2.2(a) to enable a midwife to be the primary point of contact with the patient and family, if the patient so chooses. This request would comply with statutory requirements that a primary physician be assigned to the case, but would provide needed flexibility to ensure that the patient is receiving care and communication consistent with the original birthing plan, if she so chooses." (5)

RESPONSE TO COMMENTS 23, 24, AND 25: N.J.S.A. 26:8-40.28.b(7) provides that facilities must have a policy and procedure setting forth the "protocols for **assigning primary responsibility to one physician**, who shall communicate the condition of the fetus to the mother and family, and inform and coordinate staff to assist with labor, delivery, and postmortem procedures." (Emphasis added). Because the statute expressly requires a physician to have these responsibilities, and not a midwife or other healthcare professional, the Department is without authority to contravene the statutory requirement by amending the rule in the manner suggested by the commenters. While the Department is unable to amend the rule due to the constraints of the statute, the rule as proposed addresses the commenters' concerns because it requires the physician to advise the patient that a midwife, or any other health care professional that provided her with care during the pregnancy, may be present during any discussions he or she has with the patient. This requirement ensures that the patient will have a trusted and familiar care provider present for the difficult discussions she will have with the primary physician. Accordingly, the Department makes no changes on adoption in response to the comments.

26. COMMENT: Noting that N.J.A.C. 8:35-2.2 requires the assignment of certain duties to one primary physician, a commenter asserts that "[p]roviders are on call and caring for an individual patient for, on average, 24 hours, after which another provider assumes care for the patient. While consistency in provider information is very important, it is not reasonable to assign this responsibility to one provider for the course of the patient's admission. Physicians do not address the coordination of facility staff or the preparation of the patient to view the stillborn infant. These are typically nursing responsibilities." (3)

27. COMMENT: A commenter believes that the "proposed regulation establishes the responsibilities that for which 'one primary physician' is responsible when a stillbirth occurs. The proposal, however, does not provide allowances so that a primary physician can effectuate a proper handoff at the end of a shift in instances in which a patient remains in the hospital for multiple shifts or multiple days." Therefore, the commenter "respectfully requests that the Department amend its proposal, at N.J.A.C. 8:35-2.2(a) to indicate that one primary physician per shift shall be assigned responsibility for overseeing the delineated responsibilities. We believe this change would be consistent with the definition of 'one-to-one nursing care,' which requires one professional nurse be assigned to the patient 'for the duration of each nursing shift.' N.J.A.C. 8:35-1.3." (5)

RESPONSE TO COMMENTS 26 AND 27: As stated in the Response to Comments 23, 24, and 25, N.J.S.A. 26:8-40.28.b(7) requires the Department to establish protocols for assigning primary responsibility to one physician for communicating the condition of the fetus to the mother and family and informing and coordinating staff to assist with labor,

delivery, and postmortem procedures, which the Department accomplishes in N.J.A.C. 8:35-2.2. Unlike one-on-one nursing care, which requires the assignment of duties to a nurse on a shift-by-shift basis, the patient has only one primary physician during her stay. The responsibilities assigned to the primary physician, which are communicating the condition of the fetus to the mother and family and coordinating orders addressing postmortem procedures, can and should be completed within the parameters of this one physician's shift. Because the duties can be completed within a normal shift, there is no need to transfer the responsibilities to a different physician when the primary physician's shift ends.

Regarding the comment that nurses and not physicians prepare the patient to view the stillborn child and coordinate facility staff, N.J.S.A. 26:8-40.28.b(7) requires a physician to perform these duties. As these duties are statutorily required to be performed by a physician, the Department is unable to delegate those tasks to other healthcare professionals, including nurses.

Based upon the foregoing, the Department makes no changes on adoption in response to the comments.

N.J.A.C. 8:35-2.3 Training for Direct Care Staff

28. COMMENT: Proposed N.J.A.C. 8:35-2.3 requires staff training on the effective and sensitive delivery of certain information to the patient, including the "importance of an autopsy." *See* N.J.A.C. 8:35-2.3(a)1iv. The commenter suggests "changing the term 'importance' of autopsy to 'value.'" (3)

RESPONSE: The use of the phrase “importance of an autopsy” mirrors the use of the phrase in the Act. Indeed, N.J.S.A. 26:8-40.28.b(7) requires the physician who is responsible for communicating with the family to discuss the “importance” of an autopsy. Consequently, proposed N.J.A.C. 8:35-3.2(b)2 also uses the phrase “importance of an autopsy.” Because the rule follows the language in the Act as it relates to the usage of “importance of an autopsy” at N.J.A.C. 8:35-3.2(b)2, it is logical to use the same phrase at N.J.A.C. 8:35-2.3(a)1iv. Moreover, the words “importance” and “value” are synonyms for one another. Thus, changing the term “importance” to “value” would be ineffectual. Therefore, the Department makes no changes on adoption in response to the comment.

29. COMMENT: A commenter suggests “that the Department clarify the availability of grief counseling because “’[c]ounseling’ is a term reserved for mental health professionals. ‘Grief support’ is the process provided by nurses and other educated professionals while the patient is in the hospital and post-discharge.” (3)
RESPONSE: Proposed N.J.A.C. 8:35-2.3(a)1ii requires staff training on effectively communicating the availability of “grief counseling” to the patient. Thus, the intent of the proposed rule is to ensure that staff members are able to sensitively broach the topic of grief counseling with the patient, not to specify who must provide the counseling. A hospital is free to define “grief counseling” as it deems appropriate and communicate that information to a patient in a sensitive manner required by the rule. Therefore, the Department does not believe that further clarification is necessary.

30. COMMENT: A commenter asks for clarification of the documentation required for training direct care staff members: “Is this documentation also required for providers (i.e. physicians and certified nurse midwives)?” (3)

RESPONSE: Under proposed N.J.A.C. 8:35-2.3, healthcare facilities are required to provide training appropriate for each direct care staff member who provides care to a patient who experiences a stillbirth and to document receipt of the training in the staff member’s personnel file. Proposed N.J.A.C. 8:35-1.3 defines direct care staff as “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.” (Emphasis added). Because the rule articulates who is considered “direct care staff,” which includes physicians and midwives, and clearly states that documentation of training provided to direct care staff must be placed in each staff member’s personnel file, the Department makes no change on adoption in response to the comment.

N.J.A.C. 8:35-2.4 Requirements for a Bereavement Checklist

31. COMMENT: A commenter “understands the Department’s desire to create a minimum set of standards for facilities to aid the parents of [a] stillborn child through the creation of a bereavement checklist. The proposed language indicates the bereavement checklist is to assist the facility in obtaining certain information which is ‘needed … to aid the patient and family with the grieving process.’ However, proposed N.J.A.C. 8:35-2.4(a)(1)(vi) requires the facility to inquire about the number of living children the

parents of the stillborn child have. Similarly, proposed N.J.A.C. 8:35-2.4(a)(1)(ix) requires the facility to inquire whether the parents suffered a previous loss of a stillborn child." The commenter "believes nothing should prevent facilities from inquiring about this type of information when the occasion is appropriate, but requiring facilities to broach the subject of number of living children or previous stillborn births during this emotional time will in fact be detrimental to the grieving process. Thus, we believe the Department should delete proposed N.J.A.C. 8:35-2.4(a)(1)(vi) and (ix)." (4) RESPONSE: N.J.S.A. 26:8-40.27.f requires patients and their families who suffer a stillbirth to be treated in a sensitive manner and the bereavement checklist, found at N.J.S.A. 26:8-40.28.b(3), is intended to assist the facility in this regard. The Department believes that a family's background, as it pertains to living children and past stillbirths, will help the facility in addressing the family's needs. The Department trusts that health care facilities will collect this information at appropriate times. The Department makes no change upon adoption in response to the comment.

32. COMMENT: A commenter states that "the requirements of proposed N.J.A.C. 8:35-2.4(a)(1)(xiii) are ambiguous. This language requires 'confirmation that the stillbirth information pamphlet … was provided to the family.' The language does not clearly state who must provide this confirmation: the provider or the patient." The commenter believes "an interpretation requiring the family to confirm receipt of the stillbirth information pamphlet would transform the process from one focused on compassion to one which is transactional in nature. Thus, we believe the Department should clarify the

ambiguity in this provision to require the provider to confirm the stillbirth information pamphlet was provided to the family." (4)

RESPONSE: Proposed N.J.A.C. 8:35-2.4(a) requires a healthcare facility to develop and implement a bereavement checklist that includes confirmation that the stillbirth information pamphlet was provided to the family. Therefore, the Department believes it is sufficiently clear that in implementing the checklist the health care facility staff would make an entry in the checklist confirming that the family received the pamphlet and then place a copy of the checklist in the patient's file, as required by proposed N.J.A.C. 8:35-2.4(b). The Department makes no change on adoption in response to the comment.

28. COMMENT: A commenter "does not understand why the address of the primary support person is required (N.J.A.C. 8:35-2.4(a)(1)(x)) and suggests that this be deleted. The telephone number of this individual is generally documented, but the address is not generally collected or documented." (3)

RESPONSE: The Department agrees with the commenter. The intent of N.J.A.C. 8:35-2.4(a)1x was for the facility to have a point of contact for the patient's primary support person in the event the facility needed to contact the support person with any issues regarding the care or emotional support of the patient. Because contacting the support person by telephone is a faster mode of communication and furthers the intent of the rule, the Department is making a non-substantive change to the rule upon adoption to require the collection of a telephone number rather than the address of the patient's primary support person.

29. COMMENT: With regard to a certificate of birth resulting in stillbirth, the commenter "suggests that 'requested' be changed to 'offered' (N.J.A.C. 8:35-2.4(a)1(xi)) as the patient may not make this choice while in the hospital." (3)

RESPONSE: N.J.A.C. 8:35-2.5(a)7 requires that, as part of the stillbirth informational pamphlet, the patient be advised of how to obtain a certificate of birth resulting in a stillbirth. It is the Department's intention that the bereavement checklist reflect whether the patient was offered information on obtaining this certificate. To clarify this intent, the Department will make a non-substantive amendment to N.J.A.C. 8:35-2.4(a)1xi upon adoption in response to this comment to change "requested" to "was offered information regarding how to obtain" in regard to whether the parents were offered a certificate of birth resulting in stillbirth on the bereavement checklist. This non-substantive change ensures that N.J.A.C. 8:35-2.4(a)1xi and 2.5(a)7 contain identical standards.

30. COMMENT: A commenter "suggests that 'postmortem activities' (N.J.A.C. 8:35-2.4(a)) be changed to 'bereavement care' as 'postmortem' activities are generally performed by medical and nursing professionals not by family members and siblings." (3)

RESPONSE: The Department disagrees with the commenter. Proposed N.J.A.C. 8:35-2.4(a)1xii requires that a healthcare facility's bereavement checklist include "whether the patient would like to include other family members, including siblings of the stillborn and visitors of their choosing, in postmortem activities." Although not defined in the rules, the ordinary meaning of the term "postmortem" as an adjective includes "of, pertaining to, or occurring in the time following death." See Random

House Kernerman Webster's College Dictionary, copyright 2010, by Random House. Another source defines post-mortem as "[o]ccurring or done after death." See American Heritage Dictionary of the English Language, Fifth Edition, copyright 2016, by Houghton Mifflin Harcourt Publishing Company. When the plain meaning of the term "postmortem" is used in the context of the rule, it becomes clear that family members, with the consent of the parents, may participate in the same post-death activities that the parents are entitled to participate in under these rules and does not mean family members would be performing activities executed by health care professionals, such as a postmortem examination to determine the cause of death. Accordingly, the Department will not be making any changes upon adoption to the proposed rule in response to this comment.

31. COMMENT: A commenter "suggests that 'the stillbirth information pamphlet' be changed (N.J.A.C 8:35-2.4(a)(1)xiii) to 'a stillbirth information pamphlet' as this pamphlet is not standardized throughout the State." (3)

RESPONSE: The Department does not believe it is necessary to change the reference to "the stillborn information pamphlet" in N.J.A.C. 8:35-2.4(a)1xiii. When N.J.A.C. 8:35-2.4(a)1xiii is read in conjunction with N.J.A.C. 8:35-2.5, which requires facilities to develop "a stillbirth information pamphlet," it becomes clear that each facility is required to develop its own information pamphlet. Thus, the Department makes no change on adoption in response to the comment.

N.J.A.C. 8:35-2.5 Stillborn Information Pamphlet

32. COMMENT: N.J.A.C. 8:35-2.5 requires a facility to develop a stillbirth informational pamphlet for distribution to a patient experiencing a stillbirth, which includes "[f]uneral and cremation options, including contact information for local funeral directors." A commenter "suggests removing 'funeral options' as these vary based on cost and personal preferences and are better provided by a funeral director. We suggest adding 'cremation' [as] an option along with burial options. This requirement is not stated in the legislation and would be better provided via fliers that could be updated and printed at a lower cost. Contact information for local funeral directors, community support groups, and grief counselors may change which would necessitate destroying unused pamphlets and reprinting the updated version of the entire pamphlet." (3)

RESPONSE: N.J.S.A. 26:8-40.28.b requires health care facilities to adhere to policies and procedures that include providing "an informational pamphlet to a family experiencing a stillbirth that includes information about funeral and cremation options." Consistent with this statutory provision, proposed N.J.A.C. 8:35-2.5 requires facilities to develop a stillborn information pamphlet that includes information on "funeral and cremation options, including contact information for local funeral directors." If funeral and support group information changes often, the proposed rule would not prevent a health care facility from including this information as an insert or attachment to the pamphlet. As the Department does not define the format of the informational pamphlet, facilities are permitted to format the pamphlet in a manner which works best for them. The Department makes no change on adoption in response to the comment.

N.J.A.C. 8:35-2.6 Patient and Family Support

33. COMMENT: A commenter states that proposed N.J.A.C. 8:35-2.6(a)2 "requires the following: 'The provision of one-on-one nursing care for the duration of the patient's stay at the facility.' Since the law was enacted, hospitals have been unable to interpret the intent of this section. It is our understanding from the legislative sponsor and the advocates of the bill that the intent is to require one nurse be assigned to that family during this difficult time. This will prevent multiple nurses and other healthcare professionals from delivering conflicting or confusing messages to the family, and to ensure the patient and her family that numerous healthcare providers will be asking her the same questions over and over again. However, some hospitals interpret this subsection to require one nurse be assigned to the family and be prohibited from caring for other patients. This staffing requirement would be incredibly burdensome on the hospital and the nurses of that unit. This also may be an unwelcomed intrusion into the grieving process of the family. Therefore, we respectfully request that this section be clarified that one-on-one nursing does not require a staffing level of 1:1 for that patient." (7).

34. COMMENT: A commenter asks for clarification of the provision of one-on-one nursing care. Specifically, the commenter asks that the term be clarified to require the "'provision of nursing care by one nurse per shift' as nurses are generally working approximately 12 hours per shift." (3)

RESPONSE TO COMMENTS 33 AND 34: As stated in the Response to Comments 21 and 22, proposed N.J.A.C. 8:35-1.3 defines one-on-one nursing care as "nursing services that are provided to a patient by one professional nurse assigned to that

patient for the duration of each nursing shift." The definition further provides that the "assigned professional nurse may also have duties and responsibilities during his or her shift," in addition to caring for the patient who experienced a stillbirth. The broad nature of the phrase "additional duties and responsibilities" allows a facility to assign additional tasks, such as caring for other patients, to the one-on-one nurse as it deems necessary and appropriate. Therefore, the proposed rule allows the assigned one-on-one nurse to care for other patients. And, contrary to the commenter's assertion, the rule already makes clear that the facility is to assign one professional nurse to the patient for the duration of the nursing shift. Accordingly, the Department will not be making any changes upon adoption to the proposed rule in response to the comments.

35. COMMENT: A commenter asks "[h]ow would staff determine 'a family's awareness and knowledge regarding the stillbirth process'?" (3)

RESPONSE: As set forth in proposed N.J.A.C. 8:35-2.6(a)1, a hospital is required to develop "[g]uidelines to assess a family's awareness and knowledge regarding the stillbirth process." Thus, it is the responsibility of the hospital to develop the guidelines by using its own expertise and best practices regarding stillbirths. The guidelines will then be used by the facility's staff caring for a patient and family experiencing a stillbirth so they are better able to provide appropriate and compassionate care. The Department makes no change on adoption in response to the comment.

N.J.A.C. 8:35-2.7 Memory Box

36. COMMENT: A commenter indicates that it "currently provides the families of stillborn children with keepsake boxes and appreciates the objective of providing a memory box as part of the grieving process. We additionally maintain contact with a number of patients who have not yet decided to obtain their memory box, sometimes even years later. While we do not believe the storage requirements will be difficult to comply with, we do have some concerns with the requirements of proposed N.J.A.C. 8:35-2.7(b)(2). This language requires the facility contact the patient by certified mail if the facility has not previously made contact by telephone, including informing the patient 'that failure to advise the facility of her wishes during this time period may result in the disposal of the box.' We interpret this language to mandate notifying the patient of potential disposal of the memory box, even if the facility has no intention to do so." The commenter "does not currently dispose of memory boxes related to stillborn or neonatal deaths, we believe mandatory language implying disposal of memory boxes is unwarranted as it could prompt additional emotional stress. Rather, we suggest the Department amend this section to require notifying a patient of potential disposal of a memory box via certified mail only when a facility actually intends to do so." (4)

RESPONSE: The Department agrees with the commenter. Proposed N.J.A.C. 8:35-2.7(b)2 requires a health care facility to retain the memory box that is created for the patient experiencing a stillbirth for a "minimum of one year from the date of the patient's discharge" if the patient elects not to take the box at the time of discharge. Thus, the Department's intent for the rule was to provide for a minimum retention period and not to prohibit a hospital from keeping the box for a longer period of time. The facility would not be required to contact the patient about the disposal of the box if it intends to

retain it beyond the one-year period. However, the facility would be required to contact the patient at the one-year anniversary of the patient's discharge to remind her of the existence of the box and to ascertain whether she wishes to receive it at that time. If the patient declines to receive it, then the facility may elect to retain the box for an additional amount of time. In the event the facility decides to dispose of the box at or after the one-year expiration, it is required to notify the patient 30 days prior to the date that it intends to dispose of the memory box to determine whether the patient wishes to receive it. The Department will make a non-substantive change to the rule clarifying this requirement.

37. COMMENT: A commenter states that: "Policy development is possible; however, it is important to note that patients often move within a year of discharge or provide inaccurate phone numbers and/or addresses when admitted to the hospital or same day surgery unit. It will not always be possible to contact the patient even immediately post-discharge." (3)

RESPONSE: Admittedly, it would be difficult to contact the patient about disposal of the memory box if she provides incorrect contact information or if her address changes and she fails to notify the facility of the change. However, if the health care facility attempts to contact the patient by telephone and by certified mail, as required under the proposed rule, and uses the contact information provided by her at the time of admission, it would satisfy its notification obligation set forth under proposed N.J.A.C. 8:35-2.7(c). The Department makes no change upon adoption in response to the comment.

38. COMMENT: A commenter states that "[d]ocumentation in the medical record post-discharge is often not possible as many hospitals utilize electronic medical records that cannot be reopened once closed by the Medical Records Department. If reopening the medical record is possible, materials sent to the Medical Records Department separate from the original record may be misfiled or misplaced." (3)

39. COMMENT: A commenter states that "the proposed regulation establishes a process by which the hospital must retain the memory box for a one-year period and must contact the patient, and document such contact, before disposing of the memory box. The proposed regulation, if promulgated, would require that all contacts and attempts to contact the patient must be documented in the patient's medical record. N.J.A.C. 8:35-2.7(c)." The commenter "agrees that documentation of all contacts, and attempted contacts, with the patient is important, particularly prior to the disposal of the memory box; however, the system does not believe that the medical record is always the most appropriate location to include this documentation. Particularly in the age of electronic medical records, a 'medical record' is opened and closed for each patient's inpatient and outpatient encounter with the facility. Therefore, a patient who is admitted to deliver a stillborn child would have a 'record' consisting of that one-or multiple-day stay during delivery and that record would be closed upon discharge." The commenter "believes that having to keep open for a year-long period, or re-open the medical record for that particular patient encounter may not always be appropriate; therefore, we are respectfully requesting flexibility in this area. Specifically, we request that the Department amend its proposal, at N.J.A.C. 8:35-2.7(c), to allow for documentation to be maintained in the patient's medical record or through another documentation

process, including but not limited to a log dedicated specifically to stillborn memory boxes." (5)

RESPONSE TO COMMENTS 38 AND 39: Pursuant to N.J.A.C. 8:43G-15.1, hospitals must maintain medical records for each patient and are required to have a "system for identifying medical records to facilitate their retrieval by patient identifier," as well as a "system of access to the medical records of all patients." Because hospitals are already required to have access to their patients' records, hospitals should not have an issue with incorporating additional information into a patient's closed file, as required under proposed N.J.A.C. 8:35-2.7. Furthermore, the Department believes it is necessary to maintain these contacts in the patient's medical record as the medical record is the history of the patient's stay related to the stillbirth, and all information relating to the stillbirth should be contained in the medical record. The Department makes no change upon adoption in response to the comment.

40. COMMENT: A commenter states that the public "should be told what contents of the memory box is purported to be and why that would need to be kept for one year." (6)

RESPONSE: The Act, as well as the proposed rules, describe the type of items that would be included in the memory box. See N.J.S.A. 26:8-40.28.b(6) (requiring facilities to "prepare a memory box with keepsakes, such as a handprint, footprint, blanket, bracelet, lock of hair, and photographs") and N.J.A.C. 8:35-1.3 (providing additional items to be included in the box). Additionally, N.J.S.A. 26:8-40.28.b(6) requires the facility to retain the box for one year if the patient elects not to accept it at discharge.

Therefore, the Department makes no change upon adoption in response to the comment.

N.J.A.C. 8:35-3.2 Autopsy and Alternative Evaluation

41. COMMENT: A commenter states that proposed N.J.A.C. "8:35-3.1 and 3.2 address data collection and autopsy/alternative evaluations. While we agree that we must use every opportunity possible to learn from these tragic events in order to clearly identify causes of stillbirths in order to reduce the incidence, and also to identify factors that might put the mother at risk for a future stillbirth, this is a very emotional time for mothers and families. Subsection 3.2 (b) addresses the information that is provided by the provider about autopsies and alternative evaluations, and the importance of these to research as to causes of stillbirth. Subsection 3.2 (f) then specifies the information included on the patient consent form. There is a concern that the details of the autopsy or alternative evaluation would lengthen and confuse the form for the patients. We would suggest that this information instead be included in the discussion, and documented in the medical record by the provider. Therefore, we respectfully request that the written details of the autopsy or alternative evaluation under 8.35-3.2(f) instead be provided orally when the physician meets with the patient in accordance with 8.35-3.2(b) and documentation of discussion placed into physician notes in medical record." (7)

RESPONSE: N.J.S.A. 26:8-40.28.b(7) provides that the Department shall require health care facilities to adhere to protocols to ensure that the physician assigned primary responsibility for communicating with the family discusses the importance of an

autopsy with the family, including the significance of autopsy findings on future pregnancies and the significance that data from the autopsy may have for other families. This proposed rule follows the requirements of the Act, and the Department believes that the family needs this information, so that it can make an informed decision regarding the autopsy or alternative evaluation. Setting forth the details of the autopsy or alternative evaluation in the consent forms ensures that the physician discussed the specific aspects of the evaluations with the patient and, as a result, is providing informed consent for the post-mortem examination. Accordingly, the Department will not make any change to the proposed rule upon adoption in response to the comment.

42. COMMENT: A commenter states that proposed N.J.A.C. 8:35-3.2(e) "addresses the development of a declination form for the patient to sign. This seems punitive in nature, especially at this period of time. Patients have a right to decline any procedure, and, in general, patients only sign forms to consent to procedures. It seems extraordinary to insist the mother sign a declination form in this instance. Therefore, we respectfully request a notation in the medical record instead of a formal declination form." (7)

RESPONSE: As set forth in the Act, a postmortem evaluation of a stillborn child can be of significant value to both the parents and the research community alike. Given the importance of the evaluation, it is essential that the patient experiencing a stillbirth fully understand the significance of the exam as explained to her by a physician. By requiring the patient to sign a declination form, as opposed to the facility simply marking the declination in the patient's file, there is an additional layer of assurance that the

facility complied with the rule and adequately explained the evaluation to the patient so that she could make an educated decision regarding the postmortem examination. Accordingly, the Department makes no change on adoption in response to the comment.

43. COMMENT: A commenter "suggests that the National Institute of Child Health and Human Development (NICHD), with its Stillbirth Collaborative Research Network (SCRN), be noted as a reference and resource as they continue to research the science of causes of stillbirths. They may develop more specific guidelines as to what should be considered at autopsy/alternative evaluation." (7)

RESPONSE: N.J.S.A. 26:8-40.29.b adopts the standards of the American College of Obstetricians and Gynecologists (ACOG) for stillborn autopsies and alternative evaluations. Thus, by statute, the autopsies and alterative evaluations must follow the OCOG guidelines. If the National Institute of Child Health and Human Development (NICHD) develops more specific guidelines as to what should be considered for the autopsy/alternative evaluation and those standards are adopted by the ACOG, then they would be implemented under the rule. The Department makes no change on adoption in response to the comment.

44. COMMENT: A commenter states "since there are very few pathologists in NJ who are qualified to do these autopsies, we hope that the Department may be of assistance in obtaining these services so that mothers and families do not have to expend unnecessary resources at this very emotional time." (7)

RESPONSE: The Act assigns responsibility to hospitals to follow the fetal death evaluation protocol at N.J.S.A. 26:8-40.29. Therefore, it is the responsibility of the hospitals to assist mothers and families in obtaining these services. As the Department does not regulate these services, Departmental staff are unable to provide assistance in locating them.

45. COMMENT: A commenter "appreciates the Department recognizing some grieving parents may not wish to have either an autopsy or alternative evaluation conducted on a stillborn child by permitting them to decline both. However, we are still concerned the manner in which physicians are to address autopsies or alternative evaluations could actually be counterproductive and place additional stress on already suffering patients and families. While the requirements of proposed N.J.A.C. 8:35-3.2(b) mirror the language of N.J.S.A. 26:8-40.28(b)(7), we believe physicians should provide the details of what each type of examination includes either after the family has chosen which type of examination they would prefer to have performed or if the family asks for the details of each type of examination while considering their decision. We believe requiring physicians to explain the importance of either type of medical procedure and the significance of the findings and data to a grieving family who has already expressed a desire to have neither an autopsy nor an alternative medical examination conducted on their stillborn child will only cause further emotional turmoil during the grieving process. We believe grieving parents should have an open-minded choice on how their stillborn child is treated, absent unnecessary influence suggesting the supposed benefits of one procedure compared to another, thus recognizing the fragile emotional state of the

parents. As such, we believe the Department should reallocate the requirements of proposed N.J.A.C. 8:35-3.2(b) to be subordinate to proposed N.J.A.C. 8:35-3.2(c) and (d), respectively, and include additional language requiring physicians to explain these examinations if requested by a parent." (4)

RESPONSE: N.J.S.A. 26:8-40.28.b(7) provides that the Department shall require health care facilities to adhere to protocols to ensure that the physician assigned primary responsibility for communicating with the family discusses the importance of an autopsy, including the significance of autopsy findings on future pregnancies and the significance that data from the autopsy may have for other families. Proposed N.J.A.C. 8:35-3.2(b) follows these statutory requirements of the Act. Furthermore, a family needs detailed information regarding the evaluations upfront, so that they can make an informed decision as to whether they desire a postmortem examination of their stillborn child. The Department will make no change on adoption in response to the comment.

46. COMMENT: A commenter believes that N.J.S.A. 26:8-40.29 "does not require all of these evaluations to be performed, but rather whichever evaluations are appropriate to obtain information similar to an autopsy needed for the database and for future child planning. We do not believe that radiologists can perform or read all of these evaluations, especially MRIs and ultrasounds. The Statute does not mandate a radiologist performance of MRI and ultrasound based on a pathologist's determination with parental consent. The Statute merely outlines the data required to be collected in the event of a stillbirth and if there is the performance of an alternative evaluation.

Currently, New Jersey radiologists do perform x-rays of stillborn children however, it is not the standard of care in New Jersey for radiologists to perform MRI or ultrasounds on post mortem stillborn children. At this time, there simply are no New Jersey pediatric radiologists adequately trained to perform these studies in non-research or academic settings. Additionally, there are no standardized imaging protocols. Further, reading post mortem scans is distinct from interpreting images of live patients as normal post mortem changes can simulate pathology which a facility's radiologist may not be able to accurately recognize." The commenter further states that "[d]ue to the specialist nature of stillborn MRI and ultrasound examinations ... that only professionals with dedicated skills should perform these assessments. The skills necessary include but are not limited to: Specific and detailed knowledge of pathology and patterns of diseases specific to infants; an understanding of fetal and infant development; familiarity with a wide range of genetic syndromes; extensive knowledge of congenital abnormalities including skeletal dysplasias; and post mortem imaging techniques as well as pathological issues. We believe these studies are only appropriate in research and academic settings." The commenter believes that a "laudable impetus for the Act and implementing regulation is to collect data to assist the patient (Mother) of the stillborn child regarding further pregnancies and to aid research to prevent stillbirths. However, utilizing radiological images and reports from radiologists not trained in this area will lead to faulty data which does not contribute to the goal of the Act and rule proposal and in fact may have a negative impact on research and a Mother's decisions regarding future pregnancies." The commenter also requests that the Department clarify "that the requirement of N.J.A.C. 8:35-3.2(c)1, a

formal report is to be made a part of the medical record, be the responsibility of the pathologist or primary physician in charge of the case and not the obligation of a radiologist." (2) Another commenter supports this comment. (1)

RESPONSE: Neither the Act nor the rules require a radiologist to perform MRIs or ultrasounds on stillborn children as part of a postmortem examination. Rather, the rules simply require the pathologist performing the alternative evaluation or autopsy to determine the procedures necessary for the exam. If the pathologist determines that an MRI or ultrasound is a necessary procedure for the evaluation, then it will be the facility's responsibility to coordinate the service. Additionally, the Department does not believe it necessary to amend the rule to provide that the pathologist or physician document the results of the autopsy in the medical record because the health care facility will assign this responsibility in accordance with the applicable regulations, including those promulgated by the New Jersey Board of Medical Examiners. The Department makes no changes on adoption in response to the comment.

47. COMMENT: A commenter "does not perform autopsies and therefore does not have a consent form. We utilize the consent from CHOP, our autopsy provider of choice. We cannot alter this consent to include the requested information as we do not own it. Could this requirement be documented on a separate form?" The commenter also states that it has "no control over which standards CHOP uses when doing a fetal autopsy." (3)

RESPONSE: Hospitals licensed in New Jersey are required to provide post-mortem services in accordance with N.J.A.C. 8:43G-25. If a hospital sends a stillborn child out-

of-State for an autopsy, the hospital must comply with N.J.A.C. 8:43G-25 and other applicable New Jersey law. The Department assumes that a hospital sending a stillborn child out-of-State would ensure, through contractual agreement with the out-of-State provider, that it complies with N.J.A.C. 8:43G-25 and N.J.A.C. 8:35. The Department makes no change on adoption in response to the comment.

48. COMMENT: A commenter states that the "Act requires that the provider discuss with the patient the 'significance' of an autopsy, both for future pregnancies and for other families. Should the parents not consent to an autopsy, an alternative evaluation can be performed, with consent. The proposed regulation essentially adopts those requirements. See N.J.A.C. 8:35-3.2. The list of alternative examinations in both Act and proposed regulation relate solely to tests to be performed on a stillborn child, many of which, for example an MRI or ultrasound, likely will not yield useful information as to why there was a fetal demise. Additionally, many facilities do not provide these services in-house, as the expertise required to perform and interpret these findings are specialized when related to evaluating a fetal stillborn. In many cases, the cause of a stillbirth remains unknown, and an examination of the baby will not often provide answers as to the cause of death. As such, other tests, such as chromosome evaluations or genetic testing of the parents, often yield more results as to the cause of the stillbirth." (5)

RESPONSE: The proposed rule defines the alternative evaluation to include the methods listed in N.J.S.A. 26:8-40.29.b, but would permit the pathologist to recommend other methods for the alternative evaluation that are appropriate. The rules do not

address tests for the parents, which the physician may of course recommend if medically appropriate. The Department makes no change on adoption in response to the comment.

49. COMMENT: A commenter "supports ensuring that information is provided to the patient about the availability [of] an autopsy and alternative examination ..." However, the commenter "is concerned that the requirements in the proposed regulations, if adopted as drafted, would provide incomplete information to the patient." Therefore, the commenter "respectfully requests that the Department consider amending proposed N.J.A.C. 8:35-3.2 to provide some additional discussion points that the provider may discuss with the patient. Specifically, we request that the Department add a new subsection (b)5, which would allow the physician to address the likelihood that an autopsy and alternative evaluations may not yield useful information to determining the cause of a fetal stillbirth and the availability of other tests, to be performed on the patient and other parent, if applicable, that could yield information. We believe that this additional language complies with the statutory language and intent of the Act, but also provides some additional flexibility to enable the provider to use his/her best judgment in having an open and honest conversation with the patient about potential causes of a fetal stillbirth and what tests – for both the stillborn baby and parents – could provide the most useful information." (5)

RESPONSE: The Act requires a facility to adhere to policies and procedures that include "protocols to ensure that the physician assigned primary responsibility for communicating with the family discusses the importance of an autopsy for the family,

including the significance of autopsy findings on future pregnancies and the significance that data from the autopsy may have for other families." N.J.S.A. 26:8-40.28.b(7). Proposed N.J.A.C. 8:35-3.2 reiterates these requirements, which are statutorily mandated discussion points between the physician and the patient. Beyond what is statutorily required, the physician is free to discuss other topics associated with an autopsy or alternative evaluation as the physician deems medically appropriate. Indeed, the rule does not foreclose a physician from discussing all aspects of an autopsy and alternative evaluation, including what they may or may not yield. And, as stated in the Response to Comment 48, the rules do not address tests for the parents, which the physician may recommend if medically appropriate. Accordingly, the Department makes no change on adoption in response to the comment.

50. COMMENT: A commenter believes that the "cause of death may be wrong and so lead to erroneous information being submitted. CDC does that all the time." (6)
RESPONSE: The Department has no evidence that autopsy results are wrong and would lead to erroneous information being submitted. Furthermore, the commenter has submitted no evidence to support this claim. The Department anticipates that the collection and analysis of fetal death data required by the Act and this chapter will lead to greater knowledge regarding the efficacy of stillbirth autopsy and alternative evaluation. The Department makes no change on adoption in response to the comment.

Federal Standards Statement

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

Full text of the adoption follows (additions to the proposal indicated in boldface with asterisks *__thus__*; deletions from proposal indicated in brackets with asterisks *[thus]*):

8:35-1.3 Definitions

The following word 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]* ***may include, but not be limited to,*** 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.

. . .

"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, ***and with the permission of the patient,*** lock of hair, when possible, and *[with the permission of the patient,]* photographs.

. . .

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. – ix. (No change from proposal.)

x. The name and *[address]* ***telephone number*** of the patient's primary support person;

xi. Whether the parents *[requested]* ***were offered information regarding how to obtain*** a certificate of birth resulting in stillbirth;

xii. - xiii. (No change from proposal.)

(b) (No change from proposal.)

8:35-2.7 Memory box

(a) (No change from proposal.)

(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]* ***Upon*** the expiration of the one-year-retention period, the facility shall:

1. - 2. (No change from proposal.)

***(c) In the event the facility elects to retain the memory box beyond the 30-day window provided for in (b)2 above and then elects to dispose of the memory box,**

the facility shall repeat the contact process in (b) above prior to disposing of the box.*

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