# STATE OF NEW YORK

1029

2019-2020 Regular Sessions

# IN SENATE

January 10, 2019

Introduced by Sen. RIVERA -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law, in relation to the provision of informed consent, by patients or their representatives, to medical and surgical procedures; and to repeal certain provisions of such law relating thereto

**The People of the State of New York, represented in Senate and Assembly, do enact as follows:**

Section 1. The public health law is amended by adding a new article 17 to read as follows:

**ARTICLE 17**

**INFORMED CONSENT**



**§ 1700. Definitions. As used in this article:**

**1. "Emergency" means a circumstance in which a patient's condition is such that a failure to provide hospitalization, medical treatment and/or surgery to a patient would result in undue suffering, death or substantial impairment of physical or mental function.**

**2. "Informed consent" means the legally effective knowing consent of a patient or his or her legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion. With regard to consent to a medical procedure or surgery, the elements of information necessary for consent include:**

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

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(a) a fair and understandable explanation to the patient or his or her legally authorized representative of the procedures to be followed and their purposes, including identification of any procedures which are experimental;

(b) a description of any attendant pain, discomfort and material risks possible and those that are reasonably expected;

(c) a description of any benefits reasonably to be expected;

(d) a disclosure of any appropriate alternative procedures that may be advantageous to the patient;

(e) a disclosure of the risks, benefits, pain and discomfort of election to refuse any procedure;

(f) an offer to answer any inquiries by the patient or his or her legally authorized representative concerning any and all information provided pursuant to this subdivision;

(g) a comprehensive inquiry by the health care provider to ensure that the patient or his or her legally authorized representative has sufficient understanding of the information provided pursuant to this subdivision so as to understand the medical procedures and/or surgery that the patient will undergo; and

(h) an instruction that the patient or his or her legally authorized representative is free to withdraw his or her consent and discontinue a medical procedure or surgery at any time.

3. "Invasive procedure" means a medical procedure involving a skin incision or puncture, or insertion of an instrument or foreign material into the body.

4. "Material risk" means a risk that a health care provider knows would be regarded as significant by a reasonable person in the patient's position when deciding to accept or refuse the recommended medical procedure or surgery.

5. "Surgery" means a medical procedure performed to structurally alter the human body by the incision or destruction of human tissue; or for diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue.

6. "Unexpected complication" means an emergency in which care is immediately necessary and presents an imminently life threatening risk to the patient or to prevent a substantial impairment of physical or mental function, which care exceeds that which was agreed to in an informed consent.

§ 1701. Notice of right to informed consent. Every health care provider and health care facility which performs medical procedures or surgery, shall, at the site on which such procedures or surgery is performed, conspicuously post the following notice:

"Every patient has the right to be informed of any surgical or medical procedure to be performed upon them, and shall have the right to consent to or refuse such procedure. To assure informed decision making and consent, patients or their legally authorized representatives must have information on the patient's medical status, diagnosis and prognosis. Informed consent is required to be documented prior to proceeding with any medical or surgical procedure."

§ 1702. Duty to obtain informed consent. It shall be the duty of the health care provider who orders or performs any medical procedure or surgery to obtain, in writing, the informed consent of the patient or his or her legally authorized representative. The obtaining of such consent shall include the provision and discussion of all information necessary for such consent, and the documentation in the patient's

medical record that all requirements for informed consent have been complied with. No medical procedure or surgery shall be performed without informed consent, and the health care provider who ordered such procedure or surgery shall be solely responsible for ensuring informed consent is obtained.

§ 1703. Procedures and surgery requiring informed consent. The following medical procedures shall require the obtaining of informed consent prior to the performance thereof:

1. all surgery, except simple laceration repairs and dermatological procedures performed on an outpatient basis;

2. experimental procedures or treatments;

3. administration of blood or blood products;

4. electroconvulsive therapy;

5. administration of neuroleptic medication for treatment of a mental illness or a developmental disability;

6. any medical treatment necessary to preserve the life or health of a person committed to a facility pursuant to the mental hygiene law;

7. radiation therapy;

8. invasive medical imaging;

9. procedures involving moderate to deep sedation where there is a risk of the loss of protective reflexes;

10. invasive procedures;

11. circumcision; and

12. sterilization.

§ 1704. Surgery; informed consent not required. 1. In the event that an emergency makes it impossible or impractical to obtain informed consent without jeopardizing the life or health of a patient, medical treatment may be provided to preserve the life or health of such patient without informed consent. In each such instance, the health care provider providing such treatment shall document, in the patient's medical record, the facts which establish that such situation was an emergency. Such treatment may continue until the patient or his or her legally authorized representative is able to provide informed consent. The provisions of this subdivision shall not apply to any patient who has previously made known in a document filed with his or her health care provider that he or she does not wish to receive such emergency treatment under the circumstances which exist.

2. In the event a medical complication arises in the course of a medical procedure or surgery, a health care provider may provide such treatment as is necessary to preserve the patient's life without informed consent.

3. The provisions of this article shall not apply to any medical procedure or surgery ordered by a court of competent jurisdiction. A copy of such court order shall be included in the patient's medical record.

§ 1705. Capacity to provide informed consent. Absent a court finding or legal documentation providing to the contrary, every person who is eighteen years of age or older shall be deemed to be competent to provide informed consent. Absent the designation of a legally authorized representative, only such person may grant informed consent. Except as otherwise provided in statutory or case law, unemancipated persons under the age of eighteen years shall not be authorized to grant informed consent, and such consent may only be provided by the minor's parent or legal guardian.

§ 1706. Scope of informed consent. 1. The following shall be addressed prior to the provision of informed consent to a medical procedure or surgery:

(a) a description of the proposed medical procedure or surgery, including any anesthesia proposed to be administered;

(b) the indications for the proposed medical procedure or surgery;

(c) material risks and benefits to the patient from the proposed procedure or surgery;

(d) treatment alternatives, and the risks and benefits thereof;

(e) consequences for declining the proposed or alternative treatments;

(f) designate the health care providers who will be engaged in the provision of the medical procedure or surgery to the patient, and the qualifications of such health care providers; and

(g) an ample opportunity for the patient or his or her legally authorized representative to ask questions and have such questions clearly and fully answered relating to the proposed treatment of the patient.

2. Each informed consent shall be confined to those medical procedures and surgeries that were discussed by the health care provider and the patient or his or her legally authorized representative. Every informed consent shall state the subjects discussed and the procedures and surgeries that were agreed to. An informed consent may be rescinded at any time prior to the performance of the medical procedure or surgery.

3. Every executed informed consent shall be included in the medical record of the patient to whom it relates and shall include:

(a) the name of the facility at which the medical procedure or surgery is to be performed;

(b) the designation of the medical procedure or surgery to be performed and for which consent is given;

(c) the names of the health care providers performing the medical procedure or surgery;

(d) a statement that the provisions of subdivision one of this section have been complied with;

(e) the signature of the patient or his or her legally authorized representative;

(f) the date and time the consent was executed;

(g) the name of the health care provider who discussed treatment with the patient or his or her legally authorized representative;

(h) the signature of a person who witnessed the execution of such consent, and the date and time thereof;

(i) the name of the patient; and

(j) statements of whether medical students will be viewing the procedure or surgery, whether such procedure or surgery will be recorded, and as to the removal, testing and disposition of tissue.

§ 1707. Patient involvement in their care. Every patient and their legally authorized representative shall have the right to be informed of and involved in the decision making process relating to such patient's medical care. To the extent practicable, all information provided pursuant to this section shall be provided in clear and easily understandable terms. Where medically significant alternatives for care and treatment exist, the patient shall be so informed.

§ 2. Subdivision 4 of section 2404 of the public health law is REPEALED.

§ 3. Subdivision 4 of section 2404-a of the public health law is REPEALED.

§ 4. Section 2442 of the public health law is REPEALED.

§ 5. Section 2499 of the public health law is REPEALED.

§ 6. Subdivision 4 of section 2783 of the public health law is REPEALED.

§ 7. Section 2805-d of the public health law is REPEALED.

§ 8. Subdivision 2 of section 2444 of the public health law, as added by chapter 450 of the laws of 1975, is amended to read as follows:

2. The human research review committee in each institution or agency shall require that institution or agency to promulgate a statement of principle and policy in regard to the rights and welfare of human subjects in the conduct of human research, and the committee and the commissioner shall approve that statement prior to its taking effect. The committee shall review each proposed human research project to determine (1) its necessity; (2) that the rights and welfare of the human subjects involved are adequately protected, (3) that the risks to the human subjects are outweighed by the potential benefits to them or by the importance of the knowledge to be gained; (4) that the voluntary informed consent is to be obtained by methods that are adequate and appropriate, and (5) that the persons proposed to conduct the particular medical research are appropriately competent and qualified. The committee shall periodically examine each existing human research project with regard to the proper application of the approved principles and policies which the institution or agency has promulgated. The committee shall report any violation to the commissioner. [~~In addition to the voluntary informed consent of the proposed human subject as required by section twenty-four hundred forty-two of this chapter, the~~] **The** consent of the committee and the commissioner shall be required with relation to the conduct of human research involving minors, incompetent persons, mentally disabled persons and prisoners.

§ 9. This act shall take effect on the first of January next succeeding the date on which it shall have become a law; provided, however, that effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized and directed to be made and completed on or before such effective date.