STATE OF NEW YORK

2410

2019-2020 Regular Sessions

IN ASSEMBLY

January 22, 2019

Introduced by M. of A. PICHARDO -- read once and referred 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:

1 Section 1. The public health law is amended by adding a new article 17 2 to read as follows:

> ARTICLE 17 INFORMED CONSENT

5 Section 1700. Definitions.

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1701. Notice of right to informed consent.

1702. Duty to obtain informed consent.

1703. Procedures and surgery requiring informed consent.

1704. Surgery; informed consent not required.

1705. Capacity to provide informed consent.

11 1706. Scope of informed consent.

1707. Patient involvement in their care.

13 § 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 15 surgery to a patient would result in undue suffering, death or substantial impairment of physical or mental function.

17 18 2. "Informed consent" means the legally effective knowing consent of a 19 patient or his or her legally authorized representative, so situated as 20 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 21 or coercion. With regard to consent to a medical procedure or surgery,

23 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;
- 12 <u>(f) an offer to answer any inquiries by the patient or his or her</u> 13 <u>legally authorized representative concerning any and all information</u> 14 <u>provided pursuant to this subdivision;</u>
 - (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:
- 9 <u>1. all surgery, except simple laceration repairs and dermatological</u>
 10 <u>procedures performed on an outpatient basis;</u>
- 2. experimental procedures or treatments;
 - 3. administration of blood or blood products;
 - 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;
- 18 <u>7. radiation therapy;</u>

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- invasive medical imaging;
- 20 <u>9. procedures involving moderate to deep sedation where there is a</u> 21 risk of the loss of protective reflexes;
- 22 <u>10. invasive procedures;</u>
- 23 11. circumcision; and
- 24 <u>12. sterilization.</u>
- 25 § 1704. Surgery; informed consent not required. 1. In the event that 26 an emergency makes it impossible or impractical to obtain informed 27 consent without jeopardizing the life or health of a patient, medical treatment may be provided to preserve the life or health of such patient 28 29 without informed consent. In each such instance, the health care provider providing such treatment shall document, in the patient's medical 30 31 record, the facts which establish that such situation was an emergency. 32 Such treatment may continue until the patient or his or her legally authorized representative is able to provide informed consent. The 33 provisions of this subdivision shall not apply to any patient who has 34 35 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 treat-36 ment under the circumstances which exist. 37
- 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.
- 42 3. The provisions of this article shall not apply to any medical 43 procedure or surgery ordered by a court of competent jurisdiction. A 44 copy of such court order shall be included in the patient's medical 45 record.
- 46 § 1705. Capacity to provide informed consent. Absent a court finding 47 or legal documentation providing to the contrary, every person who is 48 eighteen years of age or older shall be deemed to be competent to provide informed consent. Absent the designation of a legally authorized 49 representative, only such person may grant informed consent. Except as 50 51 otherwise provided in statutory or case law, unemancipated persons under the age of eighteen years shall not be authorized to grant informed 52 consent, and such consent may only be provided by the minor's parent or 53

54 <u>legal guardian</u>.

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1 § 1706. Scope of informed consent. 1. The following shall be addressed 2 prior to the provision of informed consent to a medical procedure or 3 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;
- 7 (c) material risks and benefits to the patient from the proposed 8 procedure or surgery;
 - (d) treatment alternatives, and the risks and benefits thereof;
 - (e) consequences for declining the proposed or alternative treatments;
- 11 (f) designate the health care providers who will be engaged in the 12 provision of the medical procedure or surgery to the patient, and the 13 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;
- 29 <u>(c) the names of the health care providers performing the medical</u> 30 <u>procedure or surgery;</u>
 - (d) a statement that the provisions of subdivision one of this section have been complied with;
- 33 (e) the signature of the patient or his or her legally authorized 34 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.
- 51 § 2. Subdivision 4 of section 2404 of the public health law is 52 REPEALED.
- § 3. Subdivision 3 of section 2404-a of the public health law is 54 REPEALED.
 - § 4. Section 2442 of the public health law is REPEALED.
- 56 § 5. Section 2499 of the public health law is REPEALED.

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1 § 6. Subdivision 4 of section 2783 of the public health law is 2 REPEALED.

- § 7. Section 2805-d of the public health law is REPEALED.
- 8 8. This act shall take effect on the first of January next succeeding the date on which it shall have become a law. 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.