

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:

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

ARTICLE 17 INFORMED CONSENT

Section 1700. Definitions.

3 1701. Notice of right to informed consent.

4 1702. Duty to obtain informed consent.

5 1703. Procedures and surgery requiring informed consent.

6 1704. Surgery; informed consent not required.

7 1705. Capacity to provide informed consent.

8 1706. Scope of informed consent.

9 1707. Patient involvement in their care.

10 § 1700. Definitions. As used in this article:

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

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

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

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

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

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

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

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

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

15 (g) a comprehensive inquiry by the health care provider to ensure that
16 the patient or his or her legally authorized representative has suffi-
17 cient understanding of the information provided pursuant to this subdi-
18 vision so as to understand the medical procedures and/or surgery that
19 the patient will undergo; and

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

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

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

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

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

40 § 1701. Notice of right to informed consent. Every health care provid-
41 er and health care facility which performs medical procedures or
42 surgery, shall, at the site on which such procedures or surgery is
43 performed, conspicuously post the following notice:

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

51 § 1702. Duty to obtain informed consent. It shall be the duty of the
52 health care provider who orders or performs any medical procedure or
53 surgery to obtain, in writing, the informed consent of the patient or
54 his or her legally authorized representative. The obtaining of such
55 consent shall include the provision and discussion of all information
56 necessary for such consent, and the documentation in the patient's

1 medical record that all requirements for informed consent have been
2 complied with. No medical procedure or surgery shall be performed with-
3 out informed consent, and the health care provider who ordered such
4 procedure or surgery shall be solely responsible for ensuring informed
5 consent is obtained.

6 § 1703. Procedures and surgery requiring informed consent. The follow-
7 ing medical procedures shall require the obtaining of informed consent
8 prior to the performance thereof:

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

11 2. experimental procedures or treatments;

12 3. administration of blood or blood products;

13 4. electroconvulsive therapy;

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

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

18 7. radiation therapy;

19 8. invasive medical imaging;

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

22 10. invasive procedures;

23 11. circumcision; and

24 12. sterilization.

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
28 treatment may be provided to preserve the life or health of such patient
29 without informed consent. In each such instance, the health care provid-
30 er providing such treatment shall document, in the patient's medical
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
33 authorized representative is able to provide informed consent. The
34 provisions of this subdivision shall not apply to any patient who has
35 previously made known in a document filed with his or her health care
36 provider that he or she does not wish to receive such emergency treat-
37 ment under the circumstances which exist.

38 2. In the event a medical complication arises in the course of a
39 medical procedure or surgery, a health care provider may provide such
40 treatment as is necessary to preserve the patient's life without
41 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
49 provide informed consent. Absent the designation of a legally authorized
50 representative, only such person may grant informed consent. Except as
51 otherwise provided in statutory or case law, unemancipated persons under
52 the age of eighteen years shall not be authorized to grant informed
53 consent, and such consent may only be provided by the minor's parent or
54 legal guardian.

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:

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

6 (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;

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

10 (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

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

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

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

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

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

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

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

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

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

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

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

40 (i) the name of the patient; and

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

44 § 1707. Patient involvement in their care. Every patient and their
45 legally authorized representative shall have the right to be informed of
46 and involved in the decision making process relating to such patient's
47 medical care. To the extent practicable, all information provided pursu-
48 ant to this section shall be provided in clear and easily understandable
49 terms. Where medically significant alternatives for care and treatment
50 exist, the patient shall be so informed.

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

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

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

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

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

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

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

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

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