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I N S E N A T E

May 15, 2014

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:

3 ARTICLE 17
4 INFORMED CONSENT

5 SECTION 1700. DEFINITIONS.

- 6 1701. NOTICE OF RIGHT TO INFORMED CONSENT.
7 1702. DUTY TO OBTAIN INFORMED CONSENT.
8 1703. PROCEDURES AND SURGERY REQUIRING INFORMED CONSENT.
9 1704. SURGERY; INFORMED CONSENT NOT REQUIRED.
10 1705. CAPACITY TO PROVIDE INFORMED CONSENT.
11 1706. SCOPE OF INFORMED CONSENT.
12 1707. PATIENT INVOLVEMENT IN THEIR CARE.

13 S 1700. DEFINITIONS. AS USED IN THIS ARTICLE:

14 1. "EMERGENCY" MEANS A CIRCUMSTANCE IN WHICH A PATIENT'S CONDITION IS
15 SUCH THAT A FAILURE TO PROVIDE HOSPITALIZATION, MEDICAL TREATMENT AND/OR
16 SURGERY TO A PATIENT WOULD RESULT IN UNDUE SUFFERING, DEATH OR SUBSTAN-
17 TIAL IMPAIRMENT OF PHYSICAL OR MENTAL FUNCTION.

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
21 ANY ELEMENT OF FORCE, FRAUD, DECEIT, DURESS OR OTHER FORM OF CONSTRAINT
22 OR COERCION. WITH REGARD TO CONSENT TO A MEDICAL PROCEDURE OR SURGERY,
23 THE ELEMENTS OF INFORMATION NECESSARY FOR CONSENT INCLUDE:

24 (A) A FAIR AND UNDERSTANDABLE EXPLANATION TO THE PATIENT OR HIS OR HER
25 LEGALLY AUTHORIZED REPRESENTATIVE OF THE PROCEDURES TO BE FOLLOWED AND

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

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1 THEIR PURPOSES, INCLUDING IDENTIFICATION OF ANY PROCEDURES WHICH ARE
2 EXPERIMENTAL;

3 (B) A DESCRIPTION OF ANY ATTENDANT PAIN, DISCOMFORT AND MATERIAL RISKS
4 POSSIBLE AND THOSE THAT ARE REASONABLY EXPECTED;

5 (C) A DESCRIPTION OF ANY BENEFITS REASONABLY TO BE EXPECTED;

6 (D) A DISCLOSURE OF ANY APPROPRIATE ALTERNATIVE PROCEDURES THAT MAY BE
7 ADVANTAGEOUS TO THE PATIENT;

8 (E) A DISCLOSURE OF THE RISKS, BENEFITS, PAIN AND DISCOMFORT OF
9 ELECTION TO REFUSE ANY PROCEDURE;

10 (F) AN OFFER TO ANSWER ANY INQUIRIES BY THE PATIENT OR HIS OR HER
11 LEGALLY AUTHORIZED REPRESENTATIVE CONCERNING ANY AND ALL INFORMATION
12 PROVIDED PURSUANT TO THIS SUBDIVISION;

13 (G) A COMPREHENSIVE INQUIRY BY THE HEALTH CARE PROVIDER TO ENSURE THAT
14 THE PATIENT OR HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE HAS SUFFI-
15 CIENT UNDERSTANDING OF THE INFORMATION PROVIDED PURSUANT TO THIS SUBDI-
16 VISION SO AS TO UNDERSTAND THE MEDICAL PROCEDURES AND/OR SURGERY THAT
17 THE PATIENT WILL UNDERGO; AND

18 (H) AN INSTRUCTION THAT THE PATIENT OR HIS OR HER LEGALLY AUTHORIZED
19 REPRESENTATIVE IS FREE TO WITHDRAW HIS OR HER CONSENT AND DISCONTINUE A
20 MEDICAL PROCEDURE OR SURGERY AT ANY TIME.

21 3. "INVASIVE PROCEDURE" MEANS A MEDICAL PROCEDURE INVOLVING A SKIN
22 INCISION OR PUNCTURE, OR INSERTION OF AN INSTRUMENT OR FOREIGN MATERIAL
23 INTO THE BODY.

24 4. "MATERIAL RISK" MEANS A RISK THAT A HEALTH CARE PROVIDER KNOWS
25 WOULD BE REGARDED AS SIGNIFICANT BY A REASONABLE PERSON IN THE PATIENT'S
26 POSITION WHEN DECIDING TO ACCEPT OR REFUSE THE RECOMMENDED MEDICAL
27 PROCEDURE OR SURGERY.

28 5. "SURGERY" MEANS A MEDICAL PROCEDURE PERFORMED TO STRUCTURALLY ALTER
29 THE HUMAN BODY BY THE INCISION OR DESTRUCTION OF HUMAN TISSUE; OR FOR
30 DIAGNOSTIC OR THERAPEUTIC TREATMENT OF CONDITIONS OR DISEASE PROCESSES
31 BY ANY INSTRUMENTS CAUSING LOCALIZED ALTERATION OR TRANSPOSITION OF LIVE
32 HUMAN TISSUE.

33 6. "UNEXPECTED COMPLICATION" MEANS AN EMERGENCY IN WHICH CARE IS IMME-
34 DIATELY NECESSARY AND PRESENTS AN IMMINENTLY LIFE THREATENING RISK TO
35 THE PATIENT OR TO PREVENT A SUBSTANTIAL IMPAIRMENT OF PHYSICAL OR MENTAL
36 FUNCTION, WHICH CARE EXCEEDS THAT WHICH WAS AGREED TO IN AN INFORMED
37 CONSENT.

38 S 1701. NOTICE OF RIGHT TO INFORMED CONSENT. EVERY HEALTH CARE PROVID-
39 ER AND HEALTH CARE FACILITY WHICH PERFORMS MEDICAL PROCEDURES OR
40 SURGERY, SHALL, AT THE SITE ON WHICH SUCH PROCEDURES OR SURGERY IS
41 PERFORMED, CONSPICUOUSLY POST THE FOLLOWING NOTICE:

42 "EVERY PATIENT HAS THE RIGHT TO BE INFORMED OF ANY SURGICAL OR MEDICAL
43 PROCEDURE TO BE PERFORMED UPON THEM, AND SHALL HAVE THE RIGHT TO CONSENT
44 TO OR REFUSE SUCH PROCEDURE. TO ASSURE INFORMED DECISION MAKING AND
45 CONSENT, PATIENTS OR THEIR LEGALLY AUTHORIZED REPRESENTATIVES MUST HAVE
46 INFORMATION ON THE PATIENT'S MEDICAL STATUS, DIAGNOSIS AND PROGNOSIS.
47 INFORMED CONSENT IS REQUIRED TO BE DOCUMENTED PRIOR TO PROCEEDING WITH
48 ANY MEDICAL OR SURGICAL PROCEDURE."

49 S 1702. DUTY TO OBTAIN INFORMED CONSENT. IT SHALL BE THE DUTY OF THE
50 HEALTH CARE PROVIDER WHO ORDERS OR PERFORMS ANY MEDICAL PROCEDURE OR
51 SURGERY TO OBTAIN, IN WRITING, THE INFORMED CONSENT OF THE PATIENT OR
52 HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE. THE OBTAINING OF SUCH
53 CONSENT SHALL INCLUDE THE PROVISION AND DISCUSSION OF ALL INFORMATION
54 NECESSARY FOR SUCH CONSENT, AND THE DOCUMENTATION IN THE PATIENT'S
55 MEDICAL RECORD THAT ALL REQUIREMENTS FOR INFORMED CONSENT HAVE BEEN
56 COMPLIED WITH. NO MEDICAL PROCEDURE OR SURGERY SHALL BE PERFORMED WITH-

OUT INFORMED CONSENT, AND THE HEALTH CARE PROVIDER WHO ORDERED SUCH PROCEDURE OR SURGERY SHALL BE SOLELY RESPONSIBLE FOR ENSURING INFORMED CONSENT IS OBTAINED.

S 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. ABORTIONS;

4. ADMINISTRATION OF BLOOD OR BLOOD PRODUCTS;

5. ELECTROCONVULSIVE THERAPY;

6. ADMINISTRATION OF NEUROLEPTIC MEDICATION FOR TREATMENT OF A MENTAL ILLNESS OR A DEVELOPMENTAL DISABILITY;

7. ANY MEDICAL TREATMENT NECESSARY TO PRESERVE THE LIFE OR HEALTH OF A PERSON COMMITTED TO A FACILITY PURSUANT TO THE MENTAL HYGIENE LAW;

8. RADIATION THERAPY;

9. INVASIVE MEDICAL IMAGING;

10. PROCEDURES INVOLVING MODERATE TO DEEP SEDATION WHERE THERE IS A RISK OF THE LOSS OF PROTECTIVE REFLEXES;

11. INVASIVE PROCEDURES;

12. CIRCUMCISION; AND

13. STERILIZATION.

S 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.

S 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.

S 1706. SCOPE OF INFORMED CONSENT. 1. THE FOLLOWING SHALL BE ADDRESSED PRIOR TO THE PROVISION OF INFORMED CONSENT TO A MEDICAL PROCEDURE OR SURGERY:

1 (A) A DESCRIPTION OF THE PROPOSED MEDICAL PROCEDURE OR SURGERY,
2 INCLUDING ANY ANESTHESIA PROPOSED TO BE ADMINISTERED;

3 (B) THE INDICATIONS FOR THE PROPOSED MEDICAL PROCEDURE OR SURGERY;

4 (C) MATERIAL RISKS AND BENEFITS TO THE PATIENT FROM THE PROPOSED
5 PROCEDURE OR SURGERY;

6 (D) TREATMENT ALTERNATIVES, AND THE RISKS AND BENEFITS THEREOF;

7 (E) CONSEQUENCES FOR DECLINING THE PROPOSED OR ALTERNATIVE TREATMENTS;

8 (F) DESIGNATE THE HEALTH CARE PROVIDERS WHO WILL BE ENGAGED IN THE
9 PROVISION OF THE MEDICAL PROCEDURE OR SURGERY TO THE PATIENT, AND THE
10 QUALIFICATIONS OF SUCH HEALTH CARE PROVIDERS; AND

11 (G) AN AMPLE OPPORTUNITY FOR THE PATIENT OR HIS OR HER LEGALLY AUTHOR-
12 IZED REPRESENTATIVE TO ASK QUESTIONS AND HAVE SUCH QUESTIONS CLEARLY AND
13 FULLY ANSWERED RELATING TO THE PROPOSED TREATMENT OF THE PATIENT.

14 2. EACH INFORMED CONSENT SHALL BE CONFINED TO THOSE MEDICAL PROCEDURES
15 AND SURGERIES THAT WERE DISCUSSED BY THE HEALTH CARE PROVIDER AND THE
16 PATIENT OR HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE. EVERY INFORMED
17 CONSENT SHALL STATE THE SUBJECTS DISCUSSED AND THE PROCEDURES AND
18 SURGERIES THAT WERE AGREED TO. AN INFORMED CONSENT MAY BE RESCINDED AT
19 ANY TIME PRIOR TO THE PERFORMANCE OF THE MEDICAL PROCEDURE OR SURGERY.

20 3. EVERY EXECUTED INFORMED CONSENT SHALL BE INCLUDED IN THE MEDICAL
21 RECORD OF THE PATIENT TO WHOM IT RELATES AND SHALL INCLUDE:

22 (A) THE NAME OF THE FACILITY AT WHICH THE MEDICAL PROCEDURE OR SURGERY
23 IS TO BE PERFORMED;

24 (B) THE DESIGNATION OF THE MEDICAL PROCEDURE OR SURGERY TO BE
25 PERFORMED AND FOR WHICH CONSENT IS GIVEN;

26 (C) THE NAMES OF THE HEALTH CARE PROVIDERS PERFORMING THE MEDICAL
27 PROCEDURE OR SURGERY;

28 (D) A STATEMENT THAT THE PROVISIONS OF SUBDIVISION ONE OF THIS SECTION
29 HAVE BEEN COMPLIED WITH;

30 (E) THE SIGNATURE OF THE PATIENT OR HIS OR HER LEGALLY AUTHORIZED
31 REPRESENTATIVE;

32 (F) THE DATE AND TIME THE CONSENT WAS EXECUTED;

33 (G) THE NAME OF THE HEALTH CARE PROVIDER WHO DISCUSSED TREATMENT WITH
34 THE PATIENT OR HIS OR HER LEGALLY AUTHORIZED REPRESENTATIVE;

35 (H) THE SIGNATURE OF A PERSON WHO WITNESSED THE EXECUTION OF SUCH
36 CONSENT, AND THE DATE AND TIME THEREOF;

37 (I) THE NAME OF THE PATIENT; AND

38 (J) STATEMENTS OF WHETHER MEDICAL STUDENTS WILL BE VIEWING THE PROCE-
39 DURE OR SURGERY, WHETHER SUCH PROCEDURE OR SURGERY WILL BE RECORDED, AND
40 AS TO THE REMOVAL, TESTING AND DISPOSITION OF TISSUE.

41 S 1707. PATIENT INVOLVEMENT IN THEIR CARE. EVERY PATIENT AND THEIR
42 LEGALLY AUTHORIZED REPRESENTATIVE SHALL HAVE THE RIGHT TO BE INFORMED OF
43 AND INVOLVED IN THE DECISION MAKING PROCESS RELATING TO SUCH PATIENT'S
44 MEDICAL CARE. TO THE EXTENT PRACTICABLE, ALL INFORMATION PROVIDED PURSU-
45 ANT TO THIS SECTION SHALL BE PROVIDED IN CLEAR AND EASILY UNDERSTANDABLE
46 TERMS. WHERE MEDICALLY SIGNIFICANT ALTERNATIVES FOR CARE AND TREATMENT
47 EXIST, THE PATIENT SHALL BE SO INFORMED.

48 S 2. Subdivision 4 of section 2404 of the public health law is
49 REPEALED.

50 S 3. Subdivision 3 of section 2404-a of the public health law is
51 REPEALED.

52 S 4. Section 2442 of the public health law is REPEALED.

53 S 5. Section 2499 of the public health law is REPEALED.

54 S 6. Subdivision 4 of section 2783 of the public health law is
55 REPEALED.

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

1 S 8. This act shall take effect on the first of January next succeed-
2 ing the date on which it shall have become a law; provided, however,
3 that effective immediately, the addition, amendment and/or repeal of any
4 rule or regulation necessary for the implementation of this act on its
5 effective date are authorized and directed to be made and completed on
6 or before such effective date.