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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 425 Session of 2021

INTRODUCED BY GORDNER, MENSCH, MARTIN, BAKER AND STEFANO, MARCH 15, 2021

SENATOR DISANTO, BANKING AND INSURANCE, AS AMENDED, APRIL 19, 2021

AN ACT

Amending the act of March 20, 2002 (P.L.154, No.13), entitled "An act reforming the law on medical professional liability; providing for patient safety and reporting; establishing the Patient Safety Authority and the Patient Safety Trust Fund; abrogating regulations; providing for medical professional liability informed consent, damages, expert qualifications, limitations of actions and medical records; establishing the Interbranch Commission on Venue; providing for medical professional liability insurance; establishing the Medical Care Availability and Reduction of Error Fund; providing for medical professional liability claims; establishing the Joint Underwriting Association; regulating medical professional liability insurance; providing for medical licensure regulation; providing for administration; imposing penalties; and making repeals," in medical professional liability, further providing for informed consent.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 504 of the act of March 20, 2002 (P.L.154, No.13), known as the Medical Care Availability and Reduction of Error (Mcare) Act, is amended to read:

Section 504. Informed consent.

(a) Duty of physicians.--Except in emergencies, a physician owes a duty<u>, which may be fulfilled by a physician or by a</u>

qualified practitioner under subsection (b), to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

(1) Performing surgery, including the related administration of anesthesia.

(2) Administering radiation or chemotherapy.

(3) Administering a blood transfusion.

(4) Inserting a surgical device or appliance.

(5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner.

(b) [Description of procedure] Requirements to obtain informed consent.--Consent is informed if the patient or the patient's authorized representative has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. [The physician] A physician may delegate the task of obtaining the informed consent of the patient or the patient's authorized representative to a qualified practitioner for a procedure under subsection (a) performed by a physician or performed by a qualified practitioner. If claims for failure to obtain informed consent are alleged, the physician or qualified practitioner shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician or qualified practitioner, acting in accordance with accepted medical standards of medical practice, would provide.

(b.1) Consent from another qualified practitioner.--A physician or qualified practitioner performing a procedure under

subsection (a) may rely on information provided by another qualified practitioner to obtain the informed consent of the patient or the patient's authorized representative.

(b.2) Evidence.--Information provided by another qualified practitioner under subsection (b.1) shall be competent evidence in a proceeding in which it is alleged that a physician or qualified practitioner performing a procedure under subsection (a) failed to obtain informed consent.

(b.3) Construction.--Nothing under this section shall be construed to require a physician to delegate the authority to obtain informed consent to a qualified practitioner~~.~~ OR PROHIBIT <-- A PATIENT OR THE PATIENT'S AUTHORIZED REPRESENTATIVE FROM REQUESTING THE PHYSICIAN, RATHER THAN THE DELEGATED QUALIFIED PRACTITIONER UNDER SUBSECTION (B.1), ANSWER A QUESTION CONCERNING THE PROCEDURE, RISKS OR ALTERNATIVES TO THE PROCEDURE OR OBTAIN INFORMED CONSENT. IF THE PATIENT OR PATIENT'S AUTHORIZED REPRESENTATIVE MAKES A REQUEST THAT THE PHYSICIAN ACT UNDER THIS SUBSECTION, THE PHYSICIAN SHALL OBTAIN INFORMED CONSENT.

(c) Expert testimony.--Expert testimony is required to determine whether the procedure constituted the type of procedure set forth in subsection (a) and to identify the risks of that procedure, the alternatives to that procedure and the risks of these alternatives.

(d) Liability.--

(1) [A physician is liable] Liability under this section for failure to obtain the informed consent only may be established if the patient proves that receiving such information would have been a substantial factor in the patient's decision whether to undergo a procedure set forth

in subsection (a).

(2) [A physician may be held liable] Liability may be established under this section for failure to seek a patient's informed consent if the physician or qualified practitioner knowingly misrepresents to the patient [his or her] the professional credentials, training or experience[.] of the physician or qualified practitioner who performs the procedure.

(e) Human research exception.--The requirements under this section shall be deemed satisfied if informed consent is obtained for human research conducted pursuant to approval by an institutional review board or similar entity in accordance with 21 CFR Pt. 50 (relating to protection of human subjects), 45 CFR Pt. 46 (relating to protection of human subjects) and any other applicable Federal laws and regulations.

(f) Applicability--A physician or qualified practitioner performing a procedure under subsection (a) shall not be required to obtain a separate or new informed consent from the patient or the patient's authorized representative, provided that informed consent was already obtained by a physician or another qualified practitioner with respect to the procedure.

(g) Definition.--As used in this section, the term "qualified practitioner" means a:

(1) "Physician assistant" as defined in section 2 of the act of December 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of 1985, or section 2 of the act of October 5, 1978 (P.L.1109, No.261), known as the Osteopathic Medical Practice Act;

(2) "Certified registered nurse practitioner" as defined in section 2(12) of the act of May 22, 1951 (P.L.317, No.69),

known as The Professional Nursing Law;

(3) "Midwife or nurse-midwife" as defined in section 2 of the Medical Practice Act of 1985; and

(4) Registered nurse under section 3 of The Professional Nursing Law who is authorized under the registered nurse's scope of practice to perform the procedure as delegated by the physician or a registered nurse authorized to administer anesthesia under 49 Pa. Code § 21.17 (relating to anesthesia) or a successor statute or regulation.

The term shall include another physician and a physician participating in a medical residency or fellowship training program. A qualified practitioner shall have knowledge of the patient's condition and the procedure enumerated under subsection (a) to be conducted on the patient and shall be acting under the supervision of, at the direction of, or in collaboration or cooperation with, the physician.

Section 2. The amendment of section 504 of the act shall apply to all pending litigation. The term "pending litigation" means any action in which a final order has not yet been entered prior to the effective date of this section.

Section 3. This act shall take effect immediately.