STATE OF NEW YORK

529

2021-2022 Regular Sessions

IN SENATE

(Prefiled)

January 6, 2021

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

AN ACT relating to enacting the "Endoscope Reform Act"

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

Section 1. Short title. This act shall be known and may be cited as the "Endoscope Reform Act".

§ 2. Within one hundred eighty days of the effective date of this act, the commissioner of health shall promulgate rules and regulations to govern the practice of all upper endoscopic procedures. For the purpose of this act, "upper endoscopic procedures" shall be deemed to include all examinations of a patient's vocal cords, esophagus, and/or stomach by the use of a flexible endoscopic instrument.

In order to prevent the dangers of sedation and mitigate the risks involved in these upper endoscopic procedures, there shall be requirement that all upper endoscopic procedures be performed by the use of the transnasal esophagoscopy, hereinafter referred to as a TNE procedure, which is performed with the patient fully awake and upright, instead of the alternative method of upper endoscopic procedure, sedated upper endoscopy, which requires anesthesia, is significantly more dangerous, and much more expensive than the TNE procedure.

Exception shall be made to the general requirement that TNE be used instead of sedated upper endoscopy in the event that: (a) the treating physician determines that TNE is not an available or suitable procedure in treating a patient; (b) the treating physician determines that sedated upper endoscopy is a more suitable or effective procedure than TNE in treating a patient; or (c) the patient, after being informed of the upper endoscopic patient's bill of rights as set forth in section three of this act and being advised of the respective risks and benefits

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

LBD04386-01-1

of both the TNE and sedated upper endoscopy procedures, elects to undergo the sedated upper endoscopy procedure.

§ 3. All upper endoscopy patients shall, before undergoing any type of upper endoscopic procedure for which TNE is an available and suitable method of procedure, be so advised and informed by their treating physician that the upper endoscopic procedure can be performed without sedation by the use of the TNE procedure, as opposed to a sedated upper endoscopic procedure. The patient shall be further advised and forewarned of the risks attendant to sedated upper endoscopic procedures.

The commissioner of health shall promulgate and prescribe an "upper endoscopic patient's bill of rights", which bill of rights shall be in a standard written form and shall fully and clearly explain the respective risks and benefits of both the TNE and sedated upper endoscopic procedures, such to include but not be limited to the attendant risks of sedation and the respective costs of the TNE and upper endoscopic procedures. It shall be a requirement that treating physicians read and advise all upper endoscopic patients of the "upper endoscopic patient's bill of rights" in the form prescribed by the commissioner of health.

§ 4. Within one hundred eighty days of the effective date of this act, the commissioner of health shall promulgate rules and regulations to govern the use of flexible fiberoptic endoscopic instruments in accordance with the following provisions. For the purposes of this act, the term "flexible fiberoptic endoscopic instrument" shall be deemed to include flexible endoscopes together with any accessory instrument or device used in conjunction with a flexible endoscopic instrument when such accessory or device comes into contact, or may come into contact, with a patient. Such rules and regulations shall apply to every use of a flexible endoscopic instrument by any health care provider using such flexible endoscopic instrument.

In order to prevent the transmission of infectious contagious disease, and in particular highly contagious pathogens that result in creutzfeldt-jakob disease and tuberculosis, these protocols demand reprocessing by sterilization, or having all surfaces completely covered by a protective single use sterile barrier device. Flexible endoscopic instruments shall be sterilized or shall have all surfaces completely covered by a protective single use sterile barrier device before each use in accordance with such method as the commissioner of health shall prescribe, which shall be no less stringent than that recommended by the federal Food and Drug Administration, if such a recommendation has been made. If sterilization or covering by a protective single use sterile barrier is not possible, in lieu thereof a high-level disinfection method shall be used, which method shall be prescribed by such commissioner and shall be no less stringent than that recommended by the federal Food and Drug Administration, if such a recommendation has been made.

When sterilization is not possible, patients shall be so informed prior to use, and no disinfected but not sterilized flexible endoscopic instrument shall be used unless the patient executes a written informed consent document acknowledging that the difference between sterilization and disinfection has been explained to and understood by such patient and that such patient consents to the use of a disinfected but not sterilized flexible endoscopic instrument.

The "upper endoscopic patient's bill of rights", set forth in section three of this act, shall include a provision advising the patient, when sterilization is not possible, that no disinfected but not sterilized flexible endoscopic instrument shall be used unless the patient executes a written informed consent document acknowledging that the difference

between sterilization and disinfection has been explained to and understood by such patient and that such patient consents to the use of a disinfected but not sterilized flexible endoscopic instrument.

§ 5. This act shall take effect immediately.