

8025

I N S E N A T E

June 6, 2016

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

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:

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

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

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

17 Exception shall be made to the general requirement that TNE be used
18 instead of sedated upper endoscopy in the event that: (a) the treating
19 physician determines that TNE is not an available or suitable procedure
20 in treating a patient; (b) the treating physician determines that
21 sedated upper endoscopy is a more suitable or effective procedure than
22 TNE in treating a patient; or (c) the patient, after being informed of
23 the upper endoscopic patient's bill of rights as set forth in section
24 three of this act and being advised of the respective risks and benefits
25 of both the TNE and sedated upper endoscopy procedures, elects to under-
26 go the sedated upper endoscopy procedure.

27 S 3. All upper endoscopy patients shall, before undergoing any type of
28 upper endoscopic procedure for which TNE is an available and suitable
29 method of procedure, be so advised and informed by their treating physi-

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

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1 cian that the upper endoscopic procedure can be performed without
2 sedation by the use of the TNE procedure, as opposed to a sedated upper
3 endoscopic procedure. The patient shall be further advised and fore-
4 warned of the risks attendant to sedated upper endoscopic procedures.

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

14 S 4. Within one hundred eighty days of the effective date of this act,
15 the commissioner of health shall promulgate rules and regulations to
16 govern the use of flexible fiberoptic endoscopic instruments in accord-
17 ance with the following provisions. For the purposes of this act, the
18 term "flexible fiberoptic endoscopic instrument" shall be deemed to
19 include flexible endoscopes together with any accessory instrument or
20 device used in conjunction with a flexible endoscopic instrument when
21 such accessory or device comes into contact, or may come into contact,
22 with a patient. Such rules and regulations shall apply to every use of a
23 flexible endoscopic instrument by any health care provider using such
24 flexible endoscopic instrument.

25 In order to prevent the transmission of infectious contagious disease,
26 and in particular highly contagious pathogens that result in creutz-
27 feldt-jakob disease and tuberculosis, these protocols demand reprocess-
28 ing by sterilization, or having all surfaces completely covered by a
29 protective single use sterile barrier device. Flexible endoscopic
30 instruments shall be sterilized or shall have all surfaces completely
31 covered by a protective single use sterile barrier device before each
32 use in accordance with such method as the commissioner of health shall
33 prescribe, which shall be no less stringent than that recommended by the
34 federal Food and Drug Administration, if such a recommendation has been
35 made. If sterilization or covering by a protective single use sterile
36 barrier is not possible, in lieu thereof a high-level disinfection meth-
37 od shall be used, which method shall be prescribed by such commissioner
38 and shall be no less stringent than that recommended by the federal Food
39 and Drug Administration, if such a recommendation has been made.

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

47 The "upper endoscopic patient's bill of rights", set forth in section
48 three of this act, shall include a provision advising the patient, when
49 sterilization is not possible, that no disinfected but not sterilized
50 flexible endoscopic instrument shall be used unless the patient executes
51 a written informed consent document acknowledging that the difference
52 between sterilization and disinfection has been explained to and under-
53 stood by such patient and that such patient consents to the use of a
54 disinfected but not sterilized flexible endoscopic instrument.

55 S 5. This act shall take effect immediately.