

April 25, 2013

Deborah Harvey
Division of Public Health
417 Federal Street
Dover, DE 19901

RE: DPH Proposed Medical Facility Regulation [16 DE Reg. 1033 (April 1, 2013)]

Dear Ms. Harvey:

The Governor's Advisory Council for Exceptional Citizens (GACEC) has reviewed the Division of Public Health (DPH) proposal to adopt a regulation to implement House Bill No. 47 and House Bill No. 144 enacted in 2011. That legislation authorized the Department to issue regulations covering medical facilities where invasive medical procedures using anesthesia are performed. The regulation is comprehensive and prescriptive. Council would like to share the following observations.

First, the regulation contains inconsistent standards for adverse events. Compare §§1.4.2 and 2.1 (definition of "adverse event"). The latter definition is based on the statutory definition in House Bill No. 47. The inconsistency will lead to confusion and errors in reporting. For example, initiation of criminal investigation is covered by the latter definition but not mentioned in §1.4.2. It would be preferable to adopt a single standard.

Second, §3.3.7 lacks a verb.

Third, §6.1 contains the following requirement:

The medical facility must post written notice of patient rights in a place or places within the facility likely to be noticed by patients (or their representatives, if applicable) waiting for treatment.

This posting standard could be improved. For example, the notice could be small (not prominent) and the text could be in 8 point type without violating the regulation. In contrast, §8.1.4 contains a more robust posting standard:

The accreditation certificate shall be posted in a conspicuous place on the Level II or III medical facility premises at or near the entrance in a manner which is plainly visible and easily read by the public.

Consider the following substitute standard in §6.1:

The medical facility must post written notice of patient rights near the entrance and places within the facility likely to be noticed by patients (or their representatives, if applicable) waiting for treatment. Such notices shall be plainly visible, at least 8 ½ X 11 inches in size,

and easily read by the public.

Council would also ask that consideration be given to posting patient rights compilations in a variety of methods to include Braille, Spanish, 14 point type font and/or review of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) patient rights posting standards.

Fourth, consider requiring facilities to honor patient requests for copies of patient rights compilations.

Fifth, §6.2.9 confers a patient right to “be free from all forms of abuse, mistreatment or harassment.” Section 1.4.2 requires the reporting of “abuse, neglect or mistreatment”. The Division could consider adding a reference to “neglect” to §6.2.9. “Neglect” is a distinct from “mistreatment”. Compare Title 16 Del.C. §1131.

Sixth, §7.2.1.1.1 categorically caps the duration of an order of closure to 60 days in the absence of a request for continuance of the date of a Departmental hearing. This is problematic.

A. Under §§7.3.3.3.1.1 and 7.3.3.3.1.3 a hearing could be convened on the 60th day and a hearing decision issued on the 90th day. Literally, since the closure order is “capped” at 60 days, the facility could reopen during days 61-89.

B. Under §7.3.3.1, if the facility takes no action on an order of closure, the order of closure remains in effect. It is not “capped” at 60 days per §7.2.1.1.1.

Seventh, in §9.0, the reference to “clause or section” is unduly narrow. The more common term for a severability section is “provisions or application”. Compare House Bill No. 35 in 147th General Assembly.

Thank you for your time and consideration of our comments and recommendations. Please feel free to contact me or Wendy Strauss should you have any questions.

Sincerely,

Dafne A. Carnright
Vice Chairperson

DAC:kpc