



STATE OF DELAWARE  
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MEMORANDUM

DATE: April 26, 2013

TO: Ms. Deborah Harvey  
Division of Public Health

FROM: Daniese McMullin-Powell, Chairperson  
State Council for Persons with Disabilities

RE: 16 DE Reg. 1033 [DPH Proposed Medical Facility\_Regulation]

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health and Social Services/Division of Public Health's (DPH's) proposal to adopt a regulation to implement H.B. 47 and H.B. 144 enacted in 2011. That legislation authorized the Department to issue regulations covering medical facilities where invasive medical procedures using anesthesia are performed. The proposed regulation was published as 16 DE Reg. 1033 in the April 1, 2013 issue of the Register of Regulations. SCPD has 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 H.B. 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.

The Division should also consider utilization of type which is no less than 14 font and Braille and Spanish versions of the posting.

Fourth, §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.

Fifth, §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 60<sup>th</sup> day and a hearing decision issued on the 90<sup>th</sup> 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.

Sixth, 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 H.B. No. 35 in 147<sup>th</sup> General Assembly.

Thank you for your consideration and please contact SCPD if you have any questions or comments regarding our observations or recommendations on the proposed regulation.

cc: Dr. Karyl Rattay  
Mr. Brian Hartman, Esq.  
Governor’s Advisory Council for Exceptional Citizens  
Developmental Disabilities Council

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