



STATE OF DELAWARE
STATE COUNCIL FOR PERSONS WITH DISABILITIES

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MEMORANDUM

DATE: October 25, 2013

TO: Ms. Deborah Harvey
Division of Public Health

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

RE: 17 DE Reg. 397 [DPH Prop. Medical Facilities Performing Invasive Procedures Reg.]

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 new regulation regarding facilities that perform invasive procedures using anesthesia. The proposed regulation was published as 17 DE Reg. 397 in the October 1, 2013 issue of the Register of Regulations. SCPD provided commentary on the initial set of proposed regulations in April 2013 and has the following observations on the revised version.

1. In §2.0, definition of "accredited facility", second sentence, SCPD recommends insertion of "the" between "from" and "facility".
2. In §2.0, definition of "accredited organization", second sentence, SCPD recommends the following revision - "...organization requires facilities to complete self-assessments and expert surveyors to conduct thorough reviews."
3. In §2.0, the definition of "certified registered nurse anesthetist" is simply "an individual currently licensed under 24 Del.C. Ch. 19." This definition is problematic since it would literally mean anyone licensed under that chapter (LPN; RN; APN) qualifies as a nurse anesthetist under the regulations. There is no separate license or certification of a nurse anesthetist mentioned in Chapter 19, only a passing reference in §1902(b)(1).
4. In §2.0, definition of "general anesthesia", SCPD recommends not capitalizing "(t)he in Par. (2) and inserting "and" before "(4)".

5. In §2.0, definition of “invasive medical procedure”, the reference to “major conduction anesthesia or sedation” is surplusage since the terms are included in the definition of “anesthesia.

6. In §2.0, definition of “minimal sedation, SCPD recommends inserting “and” before “(2)”.

7. In §2.0, the definitions of “physician” and “physician assistant” are identical. Consider the following revisions:

“**Physician**” means an individual currently licensed as a physician under 24 Del.C. Ch. 17.

“**Physician Assistant**” means an individual currently licensed as a physician assistant under 24 Del.C. Ch. 17.

8. In §2.0, definition of “time-out”, the reference to “site” is not intuitive. It suggests that the team does not know its location.

9. In §3.2, insert a comma after “anesthetist”.

10. In §3.5.1.11, delete “and”.

11. In §3.5.1.12, substitute a semicolon for the period.

12. In §3.5.1.13, insert “which” between “cart” and “include”.

13. In §3.5.1.13.2, substitute a semicolon for the period. Compare §6.2.2.2.

14. In §3.5.2, substitute “; and” for the period.

15. In §4.6, substitute “prohibit licensed individuals” for “prohibit a licensed individual” since there is otherwise a plural pronoun (“their”) which refers back to a singular noun (“individual”).

16. In §4.11, delete the comma after “accreditation”.

17. In §5.1, delete the comma after “environment”.

18. In §6.2.7, add a semicolon.

19. In §6.2.8, delete “and”.

20. In §6.2.9, insert a semicolon.

21. Delete §§6.2.10.1 and 6.2.10.2 while amending §6.2.10 to read as follows: “A separate

anesthesia record for each administration of anesthesia which must include:”

22. Renumber §§6.2.10.2.1 through 6.2.10.2.9 as 6.2.10.1 through 6.2.10.9. Substitute “; and” for the period after the renumbered 6.2.10.9.

23. Delete the comma after “near”.

24. Section 8.2.1.1.1 categorically caps the duration of an order of closure to 90 days in the absence of a request for continuance of the date of a Departmental hearing. This is problematic.

A. Under §§8.3.3.3.1 and 8.3.3.3.1.1, a hearing could routinely occur on the 80th day after issuance of the closure order and §8.3.3.3.1.3 suggests that the hearing decision could be issued on the 110th day. During days 91-109, the closure order would no longer be in effect and the facility could reopen. If a continuance were granted per 8.2.1.1.1, this time period would be extended and the facility could reopen for an even longer period.

B. Under §8.3.3.1, if the facility takes no action on an order of closure, the order of closure remains in effect. It is not capped at 90 days per §8.2.1.1.1.

25. Section 9.3.1 addresses unannounced inspections. SCPD recognizes that §9.3.1.1 mirrors the statute. However, the Department’s licensing authority might also authorize unannounced inspections at any time. As written, §9.3 would arguably bar the Department from initiating an unannounced inspection in the absence of a complaint or DPR referral. The Division may wish to add a catch-all provision (§9.3.1.3) to read as follows: “Anytime as otherwise authorized by law or applicable regulation.”

26. The exclusion in §9.5.1.1 is contrary to the statutory definition of “facility”. See Title 16 Del.C. §122(3)y.3.C. If the Stockley Center, Mary Campbell Center, or other long-term care facility engaged in invasive procedures (including dental and podiatry procedures), they should be required to comply with the regulation.

Thank you for your consideration and please contact SCPD if you have any questions or comments regarding our observations 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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