

MEMORANDUM

To: SCPD Policy & Law Committee

From: Brian Hartman

Re: Recent Regulatory Initiatives

Date: October 7, 2008

I am providing my analysis of nine (9) regulatory initiatives in anticipation of the October 9 meeting. Given time constraints, my commentary should be considered preliminary and non-exhaustive.

1. DOE Final Career Technical Education Program Regulation [12 DE Reg. 439 (October 1, 2008)]

The SCPD and GACEC commented on the proposed version of this regulation in August. I attach the August 27 SCPD letter for facilitated reference. The Councils noted that the proposed regulation contained confusing language in the context of the IDEIA, Section 504, and the ADA. The Councils submitted an alternative provision which accurately addressed these statutes and removed an authorization for the Career and Technical Education Teacher Coordinator to “trump” an IEP/MDT decision in favor of a more collaborative decision-making process.

The DOE adopted the Councils’ provision verbatim. The Councils may wish to send a “thank you” letter or email to the DOE for considering and adopting our recommended amendment.

2. DOE Final Education of Homeless Children & Youth Reg. [12 DE Reg. 444 (October 1, 2008)]

The SCPD and GACEC commented on the proposed version of this regulation in August. I attach a copy of the August 27 SCPD letter for facilitated reference.

The Councils recommended two (2) amendments.

First, the Councils favored a “calendar” rather than “business” day timetable to resolution of disputes. The DOE opted to retain the “business” day approach.

Second, the Councils objected to a provision which literally limited parental appeals from a district to the DOE Secretary. The Councils observed that parents are entitled to appeal district decisions to the State Board of Education by statute. The DOE did not change the regulatory provision but clarified in its commentary that the regulation does not preclude appeals to the State Board of Education. I continue to believe that the following provision is misleading in this context:

4.5.9. The determination of the Secretary or review official shall be final and is not subject to further appeal within the Department of Education.

Since the regulation is final, I recommend no further action.

3. DOE Final Medicaid Buy-in Regulation [12 DE Reg. 446 (October 1, 2008)]

The SCPD, DDC, and GACEC commented on the proposed version of this regulation in April, 2008. The Division of Medicaid & Medical Assistance (DMMA) has now adopted a final regulation incorporating some amendments prompted by the Councils' commentary.

First, the Councils noted that the "Summary of the Proposed Amendment" section could be construed as limiting eligibility to current Medicaid beneficiaries. The DMMA agreed to revise the section to clarify that eligibility is available to both current and new Medicaid beneficiaries.

Second, the Councils endorsed lack of a resource cap. DMMA acknowledged the endorsement.

Third, the Councils suggested an amendment to a table addressing premiums. DMMA felt the table was clear and effected no amendment.

Fourth, the Councils suggested addition of a section explicitly reciting that there are no resource or asset limits. DMMA agreed and added a new Section 17906 which recites "(a)II resources are excluded".

Fifth, the Councils recommended that DMMA reconsider a provision in Section 17904 which categorically required a new medical evaluation for non-SSI/SSDI beneficiaries. DMMA agreed and deleted the requirement.

Sixth, the Councils suggested reconsideration of some premium figures. DMMA clarified its rationale for adoption of the figures.

Seventh, the Councils suggested incorporation of a parental deeming reference in Section 17909. DMMA made no change.

Eighth, the Councils noted that DMMA's proposed \$800/month unearned income exclusion would preclude some SSDI beneficiaries from qualifying for the Medicaid Buy-in program. The Councils recommended excluding consideration of all income derived from the Social Security Administration (SSA). DMMA responded that the appropriation approved by the Legislature assumed that income derived from the SSA would be counted. Therefore, the DMMA declined to adopt a blanket exclusion of funds derived from the SSA. However, it did increase the exclusion based on inflation from \$800/month to \$904/month and noted that the cap would increase annually based on the SSA's Cost of Living Adjustment (COLA) effective each January. This is a major improvement.

Since the Division adopted multiple amendments prompted by the Councils' comments, a "thank you" letter or email should be considered.

4. HRC Final Equal Accommodation Reg. [12 DE Reg. 505 (October 1, 2008)]

The SCPD, DDC, and GACEC commented on multiple proposed versions of this regulation. The original version was published in May and a revised version, which incorporated some Council recommendations, was published in August. The proposed versions covered both equal accommodations and fair housing. The Human Relations Commission has now adopted a final regulation only for the equal accommodations regulation which essentially incorporates all Council suggestions. I attach the SCPD's August 28, 2008 memorandum for facilitated reference. The memorandum lists twenty-two (22) comments and identifies changes in the August version of the regulation prompted by the Councils. Since the amendments incorporated in the August version are already listed in the August 28 memo, I am only addressing the "holdover" recommendations by applicable paragraph.¹

5. The Councils noted that Section 2.6.3 was "underinclusive" by omitting "owner, lessee, proprietor, manager, or superintendent". The HRC agreed and inserted the terms to conform to the underlying statute.

6. The Councils recommended substituting §11.2 for §12.2 in Section 2.8. The HRC agreed and effected the substitution.

7. The Councils suggested substituting "attorney" for "attorneys" in Section 4.3. The amendment was made.

The Councils may wish to send a "thank-you" letter or email to the Commission for favorably considering Council commentary.

5. DSAMH Final Substance Abuse Facility Licensing Reg.[12 DE Reg. 464 (October 1, 2008)]

¹ The Human Relations Commission does manifest some confusion in its commentary on the regulatory changes reflected in the August version of the regulation. For example, the HRC recites that it rejected proposed amendments in Pars. 1 and 7 [12 DE Reg. at 508-509] but it actually incorporated the Councils' recommendations in the text of the regulation.

The SCPD, DDC, and GACEC commented on the proposed version of this regulation in October, 2007. I attach a copy of the SCPD's October 31, 2007 memorandum for facilitated reference. The Division of Substance Abuse & Mental Health also received extensive comments from other organizations. It has now adopted a final regulation which incorporates some Council recommendations. The regulation will be effective January 1, 2009.

1. The Councils recommended clarification of the applicability of the standards to children's facilities. The Division responded that the DSCY&F was consulted and that the regulation does apply to children's facilities.

2. The Councils recommended reconsideration of a provision limiting counseling to "face-to-face interaction. In its response, the Division agrees that videoconferencing would qualify as face-to-face interaction and that tele-conferencing could be permitted if the provider applied for a waiver.

3. The Councils endorsed inclusion of an affirmative reference to "head injuries" in the medical history standard. The Division responded as follows:

As the addictions field becomes more sophisticated in treating individuals with co-occurring disorders, providers have become more aware of the special needs of individuals with head injuries. DSAMH appreciates this recognition by the Council(s).

4. The Councils endorsed a requirement of compliance with the ADA. The Division acknowledged the endorsement.

5. The Councils noted the existence of some extraneous brackets "[]". The brackets were removed.

6. The Councils recommended that the Division retain discretion to limit the time period for a waiver to less than the full term of the license. DSAMH agreed and added a conforming sentence.

7. The Councils recommended that providers seeking a waiver be required to share the request with residents. DSAMH agreed and added the following standard applicable to both residential and non-residential facilities:

The waiver request shall be posted in a prominent place in the facility and outline a process approved by the Division whereby clients can offer comments and feedback specific to the waiver request. The Division's Licensing Unit shall make a recommendation of action to the Division Director or designee after reviewing the waiver request and any consumer input.

8. The Councils questioned the merits of requiring the Governing Board of a facility to meet only once annually. No change was made.

9. The Councils recommended the inclusion of a specific reference to reporting abuse, mistreatment, neglect, or financial exploitation as required by Title 16 Del.C. §2224. The Division agreed and added a reference.

10. The Councils recommended reconsideration of the qualifications of the Clinical Director and Clinical Supervisor positions. Eight organizations shared similar concerns. The Division agreed and amended the qualification section.

11. The Councils objected to the following eligibility exception:

No program shall deny any person equal access to its facilities or services on the basis of race, color, religion, ancestry, sexual orientation, gender expression, national origin or disability, unless such disability makes treatment offered by the program non-beneficial or hazardous.

The Division deleted the underlined exception.

12. The Councils recommended incorporation of a reference to advocacy organizations to comport with Title 16 Del.C. §2220(7). DSAMH declined to effect any amendment.

13. The Councils recommended adding a “catch all” provision requiring compliance with a bill of rights act. DSAMH agreed and added a conforming reference.

14. The Councils recommended stronger discharge planning standards comparable to those applicable to mental health facilities. DSAMH declined any amendment without sharing any rationale. This is unfortunate.

15. The Councils expressed concern that providers maintain records for only 12 months. DSAMH added an amendment to address retention periods for audits versus other purposes.

16. The Councils noted an extraneous reference in Section 8.1.2.2. No change was made.

17. The Councils observed that restrictions on phone usage could violate state statute. No change was made.

18. The Councils questioned a limit on access to opioid treatment. The Division responded that the limit was based on federal regulations.

19. The Councils questioned an ostensible limit on access to opioid treatment for persons leaving penal institutions. DSAMH responded that the Councils were misinterpreting the standard.

20. The Councils recommended addition of a requirement that persons denied admission to a program be provided with the reasons. DSAMH agreed in part and added a requirement that the reasons be provided “in writing to the client upon request”.

21. The Councils questioned a limit on access to opioid treatment. The Division responded that the limit was based on federal regulations.

22. The Councils recommended incorporation of standards for criminal background, adult abuse registry, and child abuse registry checks. DSAMH agreed and added a conforming sentence.

Since DSAMH incorporated many Council recommendations, a “thank you” letter or email could be considered.

6. DOE Prop. Teacher of Gifted/Talented Students Regulation. [12 DE Reg. 409 (October 1, 2008)]

The Department of Education proposes to adopt new standards applicable to teachers of students who are gifted and talented. I did not identify any concerns with the content of the standards. However, there are some weaknesses in grammar and format that merit attention.

First, in Section 4.2, there is a plural pronoun (their) with a singular antecedent (educator). The DOE may wish to consider one of the following alternatives:

- A. If the educator is applying for a first Standard Certificate... OR
- B. If the educator is applying for an initial Standard Certificate.

Second, in Section 4.2, the first line, the word “certificate” should be capitalized for consistency with other references.

Third, in Section 4.2, the reference to “14 DE Admin Code 1505 Standard Certificate 3.1.5.1” would benefit from the following amendment: “14 DE Admin Code 1505 Standard Certificate, §3.1.5.1, the required...”

Fourth, in Section 4.2, there is a reference to “14 DE Admin Code 3.1.5.1” which ostensibly omits “1505”. Consider the following amendment: “14 DE Admin Code 1505 Standard Certificate, §3.1.5.1”.

Fifth, in Section 4.2, the DOE should consider substituting a colon for the semi-colon after the word “areas”.

Sixth, in Section 4.3, there is a plural pronoun (their) with a singular antecedent (educator). The DOE may wish to consider the following alternative: “If the educator is applying for a second Standard Certificate...”

Seventh, in Section 4.3, the first line, the word “certificate” should be capitalized for consistency with other references.

Eighth, in Section 4.3, the reference to “14 DE Admin Code 1505 Standard Certificate 3.1.5” would benefit from the following amendment: “14 DE Admin Code 1505 Standard Certificate, §3.1.5.1, the satisfactory completion...”

Ninth, in Section 4.3, the DOE should consider substituting a colon for the semi-colon after the phrase “in the areas of”.

I recommend sharing the above observations with the Professional Standard Board, DOE and SBE.

7. DOE Prop. Graduation & Diploma Regulation [12 DE Reg. 401 (October 1, 2008)]

The Department of Education proposes to amend its standards applicable to graduation and diploma eligibility. I have the following observations.

First, in Section 1.0, the definition of “Core Course Credit” could be reconsidered. Literally, it would include courses that may be offered by districts but may not be “countable” towards the minimum credit requirements in these content areas. For example, several years ago the NCC Vo-Tech District adopted a policy of no longer counting physical science towards meeting the minimum science credits. Based on a check of its website, this is no longer the practice. However, in theory, a district could offer courses in the 4 identified content areas which would not “count” towards the minimum credit requirements. Moreover, under Section 3.1.1 a credit in a “business math” course may not qualify towards the required 4 math credits. Therefore, the DOE may wish to amend the definition of “core course credit” to only include courses which “count” towards the minimum requirements for these content areas under Sections 2.0 and 3.0. Otherwise, the accuracy of the assessment of whether a student is “on track to graduate” under Section 4.2.5 may be attenuated.

Second, Section 4.2.5 does not explicitly require a collaborative review with the student/family nor disclosure of the results to the student/family. Since Section 4.2.3 only requires annual updating with the student/family, if the update occurs between September and May the “end of year” review could occur without student/family knowledge. In Section 4.2.5, it would be preferable to include a specific requirement of inclusion of the student, student’s parent(s), guardian(s), or relative caregiver in the review. At a minimum, there should be a requirement of disclosure of the results of the review to the student and parent(s), guardian(s), or relative caregiver. This would facilitate timely recognition of any shortfall and timely consideration of summer school or other credit options.

Third, in Section 4.2.3 the DOE may wish to delete the extraneous bracket “[]” and, given the absence of commas, consider the following amendments: “the student’s parent(s), guardian(s), relative caregiver, and others as appropriate.”

I recommend that the above observations be shared with the DOE and SBE.

8. DOE Prop. Possession, Use, or Distribution of Drugs & Alcohol Reg. [12 DE Reg. 406 (10-1-08)]

The Department of Education proposes to adopt some minor amendments to its standards applicable to possession, use or distribution of drugs and alcohol.

First, the DOE adds several references to charter schools to clarify application of the standards to such schools.

Second, the DOE adds a requirement that districts and charter schools provide the Department with an electronic version of its policy on possession, use and distribution of drugs and alcohol. Districts and charter schools would also be required to forward revisions to the policy within 90 days of adoption.

I did not identify any concerns with the minor amendments. The Council could either take no action or comment that it reviewed the proposed regulation and did not identify any concerns with the discrete amendments. Since there are other aspects of the regulation (not part of the present amendments) with debatable merit, I am reluctant to recommend outright endorsement.

9. DPH Prop. Home Health Agency Regulations [12 DE Reg. 412 (October 1, 2008)]

The Division of Public Health proposes to adopt comprehensive revisions to its home health agency regulations. The 27–page first set of standards (Section 4406) apply to agencies which solely provide home health aides. The 30-page second set of standards (Section 4410) apply to agencies which offer not only home health aide services but skilled services as well. Both sets of regulations are generally well drafted. However, I have the following concerns with the proposed standards.

SECTION 4406: HOME HEALTH AGENCIES - AIDE ONLY LICENSURE

1. In Section 1.0, definition of “home health aide”, first sentence, I recommend insertion of “and/or patient” after the term “licensed nurse” to encompass patient-delegated services within the scope of Section 6.4 and Title 24 Del.C. §1921(a)(19)

2. In Section 1.0, the Division may wish to consider a revision of the definition of “immediate jeopardy” to comport with the terminology used in Section 2.4.4.1 (“immediate and imminent danger”). Otherwise, a provider could argue that the standard in Section 2.4.4.1 is either undefined or narrower than “immediate jeopardy”.

3. In Section 1.0, definition of “parent agency”, the requirement that the parent agency be located within 50 miles of any “branch” is difficult to justify. For example, if Easter Seal’s main office is in Georgetown, it could not have a branch in Wilmington. Delaware is such a small state that the

requirement that the parent agency be located in the State should suffice.

4. Section 2.1.4 requires any agency which “undergoes a change in ownership” ...to “reapply as a new agency”. This is “overbroad”. If the agency were a stock corporation, the change of 1 share of stock would “trigger” the need to reapply for a new license. Section 2.2.2.3.4 implies that ownership interests of less than 5% are so unimportant that they do not have to be disclosed to DPH. Moreover, Section 2.5 defines “modification of ownership and control” as encompassing only significant changes in ownership. For consistency, DPH should consider amending Section 2.1.4 to read as follows: “An agency that anticipates a modification of ownership and control as defined in Section 2.5 is required to apply as a new agency.”

5. In Section 2.3.1.1, I recommend the following amendment: “A probationary license shall be granted to every agency that completes the application process consistent with these regulations and whose policies and procedures ~~have demonstrated willingness to comply~~ demonstrate compliance with the rules and regulations...” The “willingness” reference suggests a subjective intent standard rather than an objective criterion. Contrast the DPH personal assistance services agencies regulations, Part 4469, Section 2.3.1.1: “A probationary license shall be granted for a period of ninety (90) calendar days to every agency that completes the application process consistent with these regulations.”

6. In Section 2.3.2.1, I recommend substituting “may” for “shall”. This is the approach adopted in the DPH personal assistance services agencies regulations, Part 4469, Section 2.3.2.1: “A provisional license may be granted to a period of less than one year to all personal assistance agencies that:...”. Use of the term “may” provides DPH with more discretion.

7. I recommend adding a reference to Section 2.4 prohibiting reprisal against any employee, contractor, patient, or patient’s representative for cooperating with a Departmental disciplinary investigation or proceedings. Although there is a limited reference protecting patients and representatives in Section 5.4.2.5, it would be prudent to include an explicit reference in Section 2.4 as well. Moreover, there is no other provision protecting employees and contractors who cooperate with the Department in investigations and disciplinary proceedings.

8. In Section 2.4.1.8, there is a lack of parallel form. All other subparts (Sections 2.4.1.1 through 2.4.1.9) begin with a verb. Consider the following amendment: “2.4.1.8. Committed a serious violation of statutes...” Alternatively, the same section in the proposed skilled home health agency regulations (Part 4410) recites as follows: “Violated any statutes relating to Medicaid...”

9. In Section 2.4.3.1.3, second sentence, consider deleting the comma between “based” and “shall”.

10. There is some “tension” between Section 2.4.4.1 and 2.4.4.2. The former section requires 24 advance oral or written notice of an emergency suspension of license. The latter section contemplates “forthwith” notice which must be in writing. The interrelationship between these

notices is unclear. Moreover, if DPH envisions a single notice, the regulations are inconsistent since the first regulation allows “oral” notice while the second regulation requires notice “in writing”. The Division may wish to clarify these sections to obviate any confusion.

11. In Section 2.4.4.5, second sentence, consider the following amendment: Upon a final decision of the Department, the order of temporary suspension ~~shall be vacated~~ may be vacated or superseded by disciplinary action ordered by the Department. This is more accurate since the Department could determine that its temporary suspension order was a mistake or was improvidently entered, justifying vacating of the order with no disciplinary action.

12. Section 2.7.1 contains no minimum frequency for inspection of home health agencies. DPH should consider adopting a standard requiring at least annual inspections.

13. Section 3.7 requires the director or clinical director to be “available at all times during the operating hours of the home health agency”. Since most agencies operate 24-hour shifts, this means that either the director or clinical director are on duty 24 hours/day. As a practical matter, if the director were out-of-town on vacation, and the clinical director was sick, the clinical director would still have to work. In contrast, the corresponding DPH personal assistance services regulations, Part 4469, Section 3.9, recites as follows: “The director or a designee of any agency shall be available to consumers at all times during the operating hours of the personal assistance services agency.” DPH could consider a compromise (e.g. “director, clinical director, or designee with full authority to act in their stead”). This would comport with Sections 5.1.4 and 5.2.4.

14. There is some “tension” between Sections 4.2.9 and 5.2.1. The former section contemplates governing body appointment of the clinical director. The latter contemplates agency director appointment of the clinical director.

15. Section 5.2.3.1 literally requires the clinical director to be available 24 hours/day, 365 days/year, for agencies with 24 hour shifts. This is an impractical standard. See discussion in Par. 13 above.

16. Section 5.4.2.5 disallows reprisal against patients and their representatives who complain to DHSS. Consistent with Par. 7 above, it would be preferable to include a similar provision protecting employees and contractors.

17. I recommend deletion of Section 5.4.2.6 since the content of this standard is already addressed in Section 3.10.

18. Section 5.7.10 requires annual competency testing of all employees. It is unclear if this applies to the director, clinical director, and other licensed supervisory personnel apart from home health aides. DPH may wish to clarify whether the requirement only applies to aides.

19. In Section 6.1.3.3 there is a lack of parallel form. Subsections 1-3 begin with a noun and are complete sentences. Subsection 4 is a clause. The next three subsections begin with a verb and are not sentences.

20. In Section 6.4.1.1, I recommend substituting “Title 24 Del.C. §1921(a)(19)” for “Del.C.”.

21. In Section 6.4.2, I recommend substituting Title 24 Del.C. §1921(a)(9)” for “Del.C.”.

22. In Section 6.5.1.6.3, at a minimum, consider adding a reference to “frequency”. See Section 6.3.3.1. See also the proposed skilled home health agencies regulations, Part 4410, Section 6.5.5, which contemplates recording the following for “all medication and treatment”: “date, time of day, type of medication/treatment, dose, route of self-administration/administration, by whom given and any reactions noted.”

23. In Section 6.6.3, authorizing 2 weeks notice of involuntary discharge of a patient by a provider is too short. Compare Title 16 Del.C. §1121(18). It may be very difficult for a consumer to obtain an alternative agency services plan within 2 weeks. A 30 day notice would be preferable and be consistent with Section 2.8.1 which requires 30 day notice of termination of services by agencies voluntarily going out of business.

24. Section 6.6.3.2 authorizes a provider to discontinue services immediately upon its unilateral determination that the patient should have a higher level of care. No notice would be required, leaving the consumer at great risk. In 2006, an assisted living agency unilaterally determined that a consumer (D.R.) exceeded the assisted living level of care and unilaterally terminated her services. The Division of Long-term Care Residents Protection conducted its own evaluation, determined the consumer eligible for assisted living services, and fined the provider who refused to reinstate services. Agencies make mistakes. If DPH allows abrupt, unilateral termination of services with no notice, this will create a huge “loophole for agencies who simply wish to stop services with no notice. Moreover, if a consumer has decompensated to the point of needing more care, an orderly transition period to a higher level of care would be more logical than complete termination of services. The DPH approach is akin to a nurse home determining that a resident needs a hospital level of care and abruptly discharging the resident to the street!

25. The exception of notice for even minor, minuscule “non-compliance” with the plan of care or non-payment (§6.6.3.3) is also highly objectionable. Contrast Title 16 Del.C. §1121(18), requiring 30 day notice of termination from long-term care facility for even non-payment. A provider could discharge a patient simply for contesting a \$10 charge that the patient feels is unjustified. Similarly, dispensing with notice “when care goals have been met” is subjective and objectionable. I recommend adoption of a 30 day notice period and deletion of exceptions (§§6.6.3.1-6.6.3.3) but for “emergency situations”, akin to Title 16 Del.C. §1121(18). Apart from notice, I also recommend some authorization for patient appeal of the decision.

26. Section 9.1 requires home health agencies to have “appropriate insurance coverage in force to compensate patients for injuries and losses resulting from services provided by the agency.” I recommend adding “or failure to provide services”. Otherwise, the insurance may cover negligent services but not omitted services (e.g. failure to turn patient resulting in bedsores; failure to assist with medications resulting in missed doses). Moreover, “appropriate” insurance is a subjective term. Contrast the DPH personal assistance services regulation, Part 4469, Section 7.0:

- 7.1 The personal assistance services agency shall have appropriate insurance coverage in force to compensate consumers for injuries and losses resulting from services provided by the agency.
- 7.2 The following types and minimum amounts of coverage shall be in effect at all times:
 - 7.2.1 General liability insurance covering personal property damages, bodily injury, libel and slander;
 - 7.2.1.1 \$1 million comprehensive general liability per occurrence; and
 - 7.2.1.2 \$500,000 single limit insurance.

27. Section 11.0, which covers “severability”, contains overlapping and incomplete references. It would benefit from editing.

SECTION 4406: SKILLED HOME HEALTH AGENCIES (LICENSURE)

28. In Section 1.0, definition of “home health aide”, first sentence, I recommend insertion of “and/or patient” after the term “licensed nurse” to encompass patient-delegated services within the scope of Section 6.4 and Title 24 Del.C. §1921(a)(19)

29. In Section 1.0, the Division may wish to consider a revision of the definition of “immediate jeopardy” to comport with the terminology used in Section 2.4.4.1 (“immediate and imminent danger”). Otherwise, a provider could argue that the standard in Section 2.4.4.1 is either undefined or narrower than “immediate jeopardy”.

30. In Section 1.0, definition of “parent agency”, the requirement that the parent agency be located within 50 miles of any “branch” is difficult to justify. For example, if Easter Seal’s main office is in Georgetown, it could not have a branch in Wilmington. Delaware is such a small state that the requirement that the parent agency be located in the State should suffice.

31. In Section 1.0, there is some tension between the definitions of “professional” and “social worker”. The definition of “professional” is limited to “licensed” persons. The definition of “social worker” does not require licensing. I recommend revision of the definition of social worker to only cover licensed social workers. See Title 24 Del.C. Ch. 39.

32. In Section 1.0, there is no definition or reference to “advanced practice nurse”, an individual who can maintain an independent practice with authority to issue prescriptions. See Title 24 Del.C. §1902(b). For example, there is no reference to “advanced practice nurse” in the definition of “professional”. The Division should consider correcting this omission.

33. Section 2.1.4 requires any agency which “undergoes a change in ownership” ...to “reapply as a new agency”. This is “overbroad”. If the agency were a stock corporation, the change of 1 share of stock would “trigger” the need to reapply for a new license. Section 2.2.2.3.4 implies that ownership interests of less than 5% are so unimportant that they do not have to be disclosed to DPH. Moreover, Section 2.5 defines “modification of ownership and control” as encompassing only significant changes in ownership. For consistency, DPH should consider amending Section 2.1.4 to read as follows: “An agency that anticipates a modification of ownership and control as defined in Section 2.5 is required to apply as a new agency.”

34. In Section 2.3.1.1, I recommend the following amendment: “A probationary license shall be granted to every agency that completes the application process consistent with these regulations and whose policies and procedures ~~have demonstrated willingness to comply~~ demonstrate compliance with the rules and regulations...” The “willingness” reference suggests a subjective intent standard rather than an objective criterion. Contrast the DPH personal assistance services agencies regulations, Part 4469, Section 2.3.1.1: “A probationary license shall be granted for a period of ninety (90) calendar days to every agency that completes the application process consistent with these regulations.”

35. In Section 2.3.2.1, I recommend substituting “may” for “shall”. This is the approach adopted in the DPH personal assistance services agencies regulations, Part 4469, Section 2.3.2.1: “A provisional license may be granted to a period of less than one year to all personal assistance agencies that:...”. Use of the term “may” provides DPH with more discretion.

36. I recommend adding a reference to Section 2.4 prohibiting reprisal against any employee, contractor, patient, or patient’s representative for cooperating with a Departmental disciplinary investigation or proceedings. Although there is a limited reference protecting patients and representatives in Section 5.5.2.5, it would be prudent to include an explicit reference in Section 2.4 as well. Moreover, there is no other provision protecting employees and contractors who cooperate with the Department in investigations and disciplinary proceedings.

37. In Section 2.4.3.1.3, second sentence, consider deleting the comma between “based” and “shall”.

38. There is some “tension” between Section 2.4.4.1 and 2.4.4.2. The former section requires 24 hour advance oral or written notice of an emergency suspension of license. The latter section contemplates “forthwith” notice which must be in writing. The interrelationship between these notices is unclear. Moreover, if DPH envisions a single notice, the regulations are inconsistent since the first regulation allows “oral” notice while the second regulation requires notice “in writing”. The Division may wish to clarify these sections to obviate any confusion.

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superseded by disciplinary action ordered by the Department. This is more accurate since the Department could determine that its temporary suspension order was a mistake or was improvidently entered, justifying vacating of the order with no disciplinary action.

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42. There is some “tension” between Sections 4.2.9 and 5.3.1. The former section contemplates governing body appointment of the clinical director. The latter contemplates agency director appointment of the clinical director.

43. Section 5.3.3.2 literally requires the clinical director to be available 24 hours/day, 365 days/year, for agencies with 24 hour shifts. This is an impractical standard. See discussion in Par. 41 above.

44. Section 5.5.2.5 disallows reprisal against patients and their representatives who complain to DHSS. Consistent with Par. 36 above, it would be preferable to include a similar provision protecting employees and contractors.

45. I recommend deletion of Section 5.5.2.6 since the content of this standard is already addressed in Section 3.10.

46. Sections 5.5.2..8.6 and 5.8.9 require annual competency testing of all employees. It is unclear if this applies to the director, clinical director, and other licensed supervisory personnel apart from unlicensed personnel. DPH may wish to clarify whether the requirement only applies to unlicensed personnel.

47. In Section 6.1.3.3 there is a lack of parallel form. Subsections 1-3 begin with a noun and are complete sentences. Subsection 4 is a clause. The next three subsections begin with a verb and are not sentences.

48. In Section 6.6.1.1, I recommend substituting “Title 24 Del.C. §1921(a)(19)” for “Del.C.”.

49. In Section 6.6.7, I recommend substituting Title 24 Del.C. §1921(a)(9)” for “Del.C.”.

50. In Section 6.7.2, at a minimum, consider adding a reference to “frequency”. It would also be preferable to adopt an equivalent standards for compilation of data as listed in §6.5.5 which contemplates recording the following for “all medication and treatment”: “date, time of day, type of medication/treatment, dose, route of self-administration/administration, by whom given and any reactions noted.”

51.. In Section 6.6.3, authorizing 2 weeks notice of involuntary discharge of a patient by a provider is too short. Compare Title 16 Del.C. §1121(18). It may be very difficult for a consumer to obtain an alternative agency services plan within 2 weeks. A 30 day notice would be preferable and be consistent with Section 2.8.1 which requires 30 day notice of termination of services by agencies voluntarily going out of business.

52. Section 6.8.3 authorizes a provider to discontinue services immediately upon its unilateral determination that the patient should have a higher level of care. No notice would be required, leaving the consumer at great risk. In 2006, an assisted living agency unilaterally determined that a consumer (D.R.) exceeded the assisted living level of care and unilaterally terminated her services. The Division of Long-term Care Residents Protection conducted its own evaluation, determined the consumer eligible for assisted living services, and fined the provider who refused to reinstate services. Agencies make mistakes. If DPH allows abrupt, unilateral termination of services with no notice, this will create a huge “loophole for agencies who simply wish to stop services with no notice. Moreover, if a consumer has decompensated to the point of needing more care, an orderly transition period to a higher level of care would be more logical than complete termination of services. The DPH approach is akin to a nurse home determining that a resident needs a hospital level of care and abruptly discharging the resident to the street!

53. The exception of notice for even minor, minuscule “non-compliance” with the plan of care or non-payment (§6.8.3.3) is also highly objectionable. Contrast Title 16 Del.C. §1121(18), requiring 30 day notice of termination from long-term care facility for even non-payment. A provider could discharge a patient simply for contesting a \$10 charge that the patient feels is unjustified. Similarly, dispensing with notice “when care goals have been met” is subjective and objectionable. I recommend adoption of a 30 day notice period and deletion of exceptions (§§6.8.3.1-6.8.3.3) but for “emergency situations”, akin to Title 16 Del.C. §1121(18). Apart from notice, I also recommend some authorization for patient appeal of the decision.

54. Section 9.1 requires home health agencies to have “appropriate insurance coverage in force to compensate patients for injuries and losses resulting from services provided by the agency.” I recommend adding “or failure to provide services”. Otherwise, the insurance may cover negligent services but not omitted services (e.g. failure to turn patient resulting in bedsores; failure to assist with medications resulting in missed doses). Moreover, “appropriate” insurance is a subjective term. Contrast the DPH personal assistance services regulation, Part 4469, Section 7.0:

- 7.1 The personal assistance services agency shall have appropriate insurance coverage in force to compensate consumers for injuries and losses resulting from services provided by the agency.

7.2 The following types and minimum amounts of coverage shall be in effect at all times:

7.2.1 General liability insurance covering personal property damages, bodily injury, libel and slander;

7.2.1.1 \$1 million comprehensive general liability per occurrence; and

7.2.1.2 \$500,000 single limit insurance.

I recommend sharing the above observations with the Division of Public Health. The SCPD could also consider forwarding a courtesy copy of the comments to the members of the Senate Health & Social Services Committee and the House Health & Human Development Committee emphasizing the Council's concerns outlined in Pars. 51 and 52.

Attachments

B: 1008bils.

F:pub/bjh/legis/2008p&l/1008bils