

ARTHUR COCCODRILLI, CHAIRMAN
ALVIN C. BUSH, VICE CHAIRMAN
DAVID J. DEVRIES, ESQ.
JOHN F. MIZNER, ESQ.
KIM KAUFMAN, EXECUTIVE DIRECTOR
LESLIE A. LEWIS JOHNSON, CHIEF COUNSEL



PHONE: (717) 783-5417
FAX: (717) 783-2664
irrc@irrc.state.pa.us
<http://www.irrc.state.pa.us>

INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

October 10, 2007

Honorable Calvin B. Johnson, M.D., M.P.H., Secretary
Department of Health
802 Health and Welfare Building
Harrisburg, PA 17108

Re: Regulation #10-184 (IRRC #2623)
Department of Health
Home Care Agencies and Home Care Registries

Dear Secretary Johnson:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact me.

Sincerely,

Kim Kaufman
Executive Director
wbg
Enclosure

cc: Honorable Ted B. Erickson, Chairman, Senate Public Health and Welfare Committee
Honorable Vincent J. Hughes, Minority Chairman, Senate Public Health and Welfare Committee
Honorable Frank L. Oliver, Majority Chairman, House Health and Human Services Committee
Honorable George T. Kenney, Jr., Minority Chairman, House Health and Human Services Committee
Honorable Patricia Vance, Chairman, Senate Aging and Youth Committee
Honorable LeAnna M. Washington, Minority Chairman, Senate Aging and Youth Committee
Honorable Phyllis Mundy, Majority Chairman, House Aging and Older Adult Services Committee
Honorable Tim Hennessey, Minority Chairman, House Aging and Older Adult Services Committee

Comments of the Independent Regulatory Review Commission

on

Department of Health Regulation #10-184 (IRRC #2623)

Home Care Agencies and Home Care Registries

October 10, 2007

We submit for your consideration the following comments on the proposed rulemaking published in the August 11, 2007 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the Department of Health (Department) to respond to all comments received from us or any other source.

1. Time for compliance with the regulation. – Implementation procedures.

This regulation will become effective upon publication of the final-form regulation in the *Pennsylvania Bulletin*. Senator Corman has asked that the regulated community be given enough time to comply with the requirements of the rulemaking. Will the Department provide the regulated community an opportunity to achieve compliance before penalties are imposed?

2. Section 611.3. Requirements for home care agencies and home care registries. – Clarity.

Subsection (b) references other Federal, State and local standards. To clearly guide the regulated community, the specific standards should be identified in the final-form regulation or a list of applicable standards should be maintained on the Department's website. Notice of this list should be included in the regulation.

3. Section 611.4. Definitions. – Consistency with statute; Clarity.

We have three concerns with this section.

First, the terms "activities of daily living" and "instrumental activities of daily living" are defined in the Health Care Facilities Act (35 P.S. §§ 448.101 - 448.904b) (Act), but are not found in this section. Because these terms are used in this regulation, they should be added to this section with a cross-reference to the statutory definition.

Second, the definition of "direct care worker" uses the term "services." "Services" is undefined and it is unclear exactly what would be considered a service. This term should be defined in the final-form regulation.

Finally, we have two concerns with the definition of "home care agency" (agency). First, Subsection (ii) goes beyond the statutory definition in the Act. The Preamble notes that the additional language is needed to clarify that certain entities would not be subject to the regulation. We recommend that the language contained in Subsection (ii) be moved to § 611.2, pertaining to affected home care agencies and registries. We have a similar concern with Subsection (ii) under the definition of "home care registry" (registry).

Second, the terms “specialized care” and “companionship services” are used in the definition. What is meant by these terms? We recommend that they be defined. We note that “specialized care” is also in the definition of “home care registry.”

4. Section 611.12. Application for license. – Implementation procedures; Reasonableness; Need; Fiscal Impact; Clarity.

Fees

The fee required for licensure as an agency or registry is contained in the Act. However, the fees are not referenced in the regulation. Similar to the Department’s regulations on home health care agencies (§ 601.11(b)), we recommend that the fee be included in the final-form regulation.

Subsection (b)

This subsection states that “The applicant shall complete a separate application and pay a separate application fee for each separately licensed home care agency or home care registry that it intends to operate.” Section 611.11(a) states, in part, “Each physical location of the home care agency or home care registry must be separately licensed.” Why is it necessary to separately license each physical location of agencies and registries? This should be explained in the Preamble to the final-form regulation.

Subsection (c)

We have two concerns with this subsection. First, it contains the phrase “...additional information required by the Department...” This requirement is vague. To clarify this requirement, we recommend that the Department specify what the additional information that may be requested pertains to.

Second, the term “responsible person” is used in this subsection and other sections of the regulation. We recommend that this term be defined in Section 611.4, pertaining to definitions.

5. Section 611.14. Issuance of license. – Implementation procedures; Clarity.

This section pertains to the issuance of a license. We have two recommendations. First, the procedures the Department will follow for issuing licenses should be included in the final-form regulation. The procedures should address how long the Department has to render a decision after an application is received, and what will happen if the application is not complete. The procedures should also explain the appeal rights for an applicant whose application was denied, and an explanation of the appeal procedures or a cross-reference to the applicable statutes pertaining to appeals of Departmental decisions.

Second, under Subsection (a), what is “substantial compliance”? Is this something less than complete compliance? This term should be defined in Section 611.4.

6. Section 611.17. Responsibility of owners of home care agencies and home care registries. – Reasonableness; Need.

Under Subsection (c), the Department must be notified immediately if the agency or registry relocates or has a change of address. Commentators assert that these providers should be given at least 30 days to submit a change in address to the Department. Why does the Department require an immediate notification of relocation?

7. Section 611.19. Void license. – Reasonableness.

A commentator asserts that relocation should not automatically void a license and recommends that Paragraph (4) be amended to add “without notice to the Department required by § 611.17(c).” We believe this recommendation is reasonable and recommend the Department add the suggested language.

8. Section 611.31. Inspections. – Implementation procedures; Clarity.

This section pertains to the inspections of agencies and registries. We have three concerns. First, it is unclear whether inspections will be announced or unannounced. Commentators have asserted that announced inspections should be allowed in order to ensure that someone is present at the office. The Department’s intention should be clearly stated in the final-form regulation.

Second, will inspections be limited to normal business hours, as required by Section 806.4(a) of the Act? If so, this should be specified in the regulation.

Third, Subsection (a) contains the phrase “...or has other reasonable grounds to believe that a deficiency exists...” What “other reasonable grounds” could make the Department believe that there is a deficiency? The types of circumstances that the Department would consider when determining if a deficiency exists should be included in the final-form regulation.

9. Section 611.32. Retention of records. – Reasonableness; Need; Implementation procedures; Clarity.

This section contains the following statement: “Documentation and records shall be retained even if the agency or registry discontinues operation.” What is the need for this provision? Who will keep these records if the agency or registry goes out of business? In what form should these records be retained? Why should these records be retained if the agency or registry is no longer in business?

10. Section 611.33. Statement of deficiencies and plan of correction. – Implementation procedures; Clarity.

Does the plan of correction referenced in Subsection (b) have to be approved by the Department? If so, the approval process should be set forth in the final-form regulation.

11. Section 611.41. Sanctions for deficiencies. – Statutory authority; Reasonableness; Implementation procedures.

We have two concerns with this section. First, what is the Department’s statutory authority for imposing penalties?

Second, this section allows the Department to impose civil monetary penalties “not to exceed \$500 per deficiency per day.” We question how these penalties will be applied. If an agency or registry has multiple deficiencies, the amount of the penalty could be substantial. As noted by Senator Corman, a detailed deficiency and penalty list is not included in the regulations, and it is not clear how monetary penalties will be applied. He further asserted that there should be a clearer delineation between minor deficiencies (such as a missing document in a personnel file) and fraud, neglect or mistreatment of consumers. We agree. The Department should consider adding a detailed deficiency and penalty list with a clear differentiation between minor and major deficiencies.

12. Section 611.42. Reasons for sanctions. – Statutory authority; Clarity.

Subsection (a)

Subsection (a)(1) contains the undefined term “serious violation.” The Department has indicated that it is applying the term as defined in the Health Care Facilities Act. Because this term is also used in Subsections (a)(9) and (a)(10), we recommend that this term be added to Section 611.4 with either a definition or a cross-reference to the Act.

Subsection (b)

This subsection pertains to provisional licenses. We have three concerns. First, what is the Department’s statutory authority for granting a provisional license?

Second, we recommend that language pertaining to provisional licenses be moved to either its own section or a section pertaining to licenses in general. We note that the term provisional license is also referenced in §§ 611.31(a) and 611.42(a).

Finally, this subsection contains the phrase “...numerous deficiencies or a serious specific deficiency...” This phrase is vague. The final-form regulation should specify how many deficiencies would be considered numerous and also define the term “serious specific deficiency.”

13. Section 611.51. Hiring or rostering of direct care workers. – Reasonableness; Implementation procedures; Clarity.

What qualifies as a “satisfactory” reference under Subsection (a)(2)? We recommend that the regulation include criteria that would allow an agency or registry to determine if a recommendation is satisfactory.

Commentators are concerned that the documentation of the interview required by Subsection (b) is retroactive. They assert that it is not possible to document some of the required items long after they have been completed. We agree that this could be problematic. The Department should explain if these documentation requirements are intended to apply to current employees. If so, it should explain why it is reasonable to require information that may or may not have been obtained in the past in a current personnel file.

14. Section 611.52. Criminal background checks. – Implementation procedures; Need; Clarity.

What is the need for Subsection (d), which states that an agency or registry may require an applicant to furnish proof of residency? If this provision is needed, we recommend that the circumstances when proof of residency would be required be included in the final-form regulation.

Also, would a state-issued identification card be sufficient to prove residency?

15. Section 611.54. Provisional hiring. – Statutory authority; Protection of public health, safety and welfare; Implementation procedures; Reasonableness; Clarity.

The concept of “provisional hiring” is not included in the Act. What is the Department’s authority for including this section in the regulation? How is public health adequately protected if “provisional hiring” is allowed?

If the Department has the authority to permit “provisional hiring,” we have two other concerns with this section. First, commentators question whether Subsection (a)(4) prohibits the hiring of someone provisionally until the individual has already received the necessary training. This should be clarified in the final-form regulation.

Second, Subsection (a)(6) permits a provisional hire to last up to 120 days. Commentators have suggested that this time period be shorter. How did the Department determine that 120 days is the appropriate length of time for a provisional hire?

16. Section 611.55. Training requirements. – Consistency with statute; Implementation procedures; Need; Clarity.

Subsection (b)

This subsection requires a competency examination to be approved by the Department. How is this approval accomplished? Further, Senator Corman stated that it is not clear if there will be a statewide test, how it will be graded or if it can be administered in a timely fashion so that new employees or contractors may begin employment. We agree. These issues should be clarified in the final-form regulation.

Subsection (c)

This subsection lists the various forms of training that would be acceptable for direct care workers. It references a “valid nurse’s license.” The corresponding section of the Act (§ 448.086(d.1)(1)(i)) references a “valid nurse’s license in this Commonwealth.” We recommend that the final-form regulation be amended to be consistent with Act. We have a similar concern with Subsection (e).

Subsection (c)(2) should be amended to reflect Act 69 at 35 P.S. 448.806(D.1)(1)(ii), which states that a nurse aide training program approved by the Department of Health (not the Department of Education) meets the training requirements.

Subsection (d)

Representatives Mundy and Hennessey and other commentators assert that employees that do not assist in activities of daily living (ADL) should not be required to prove competency for tasks described in Subsections (d)(10) through (15). Does the Department intend for ALL direct care workers, including those that do not assist in ADLs, to meet the competency standards in this section?

Under Subsection (d)(16), what is “Home management”?

Subsection (f)

The last sentence of this subsection is vague. It requires “periodic” reassessments “at least” once a year and “more frequently” when discipline or other sanctions have been imposed. To be clearer, the word “periodic” should be deleted. Further, the final-form regulation should specify exactly which types of discipline or other sanctions would result in a reassessment more frequently than once a year.

17. Section 611.56. Health evaluations. – Fiscal impact; Reasonableness; Need; Clarity.

Representatives Mundy and Hennessey, Senator Corman and several other commentators question how the “screening assessment” in Subsection (a) will be accomplished. Is a laboratory

test required or will a physical examination by a doctor be sufficient? The Department should amend this subsection to clearly state how the “screening assessment” must be completed.

Other commentators assert that the health screenings found in Subsection (a) far exceed the employee screenings required for employees of other licensed health care facilities. Some cite the requirements for long term care facilities found in 28 Pa. Code 201.22 (relating to prevention control and surveillance of tuberculosis). Others refer to the requirements for home health and hospice programs. How did the Department determine that the health screenings in the proposed regulation are appropriate for use with agency or registry direct care workers?

Subsection (c) requires an annual health screening. Commentators contend that an annual health screening is excessive, intrusive and expensive to implement. Has the Department considered the economic impact this requirement might have on direct care workers?

18. Section 611.57. Consumer protections. – Implementation procedures; Clarity.

Commentators have indicated that, under the requirements of Subsection (c), there are cases when there is no time to get an information packet to the family members, such as when the client is being discharged immediately or if the family member lives out of town and they want the services started immediately. Would the family be permitted to give verbal permission for the case to start without first having received the information packet? This should be clarified in the final-form regulation.

19. Miscellaneous clarity

- Section 611.1, pertaining to legal base, and other sections, refer to “this subpart.” Should the reference to “subpart” be changed to “chapter”?
- Under Section 611.4, pertaining to definitions, the citation found in the definition of “Act” should be (35 P.S. §§ 448.101—448.904**b**) (emphasis added).

Facsimile Cover Sheet



Phone: (717) 783-5417
Fax #: (717) 783-2664
E-mail: irrc@irrc.state.pa.us

INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

To: Yvette Kostelac
Regulatory Coordinator
Agency: Department of Health
Phone: 3-2500
Fax: 5-6042, 3-3794 or 2-6959
Date: **October 10, 2007**
Pages: 8

Comments: We are submitting the Independent Regulatory Review Commission's comments on the Health Department's regulation #10-184 (IRRC #2623). Upon receipt, please sign below and return to me immediately at our fax number 783-2664. We have sent the original through interdepartmental mail. You should expect delivery in a few days. Thank you.

Accepted by: Wally R. Os **Date:** 10/10/07