

Regulatory Analysis Form

(Completed by Promulgating Agency)



IRRC

Independent Regulatory Review Commission

SECTION I: PROFILE

(1) Agency:

Department of Health

(2) Agency Number: 10

Identification Number:

10-184

(3) Short Title:

Home Care Agencies and Home Care Registries

IRRC Number:

2623

(4) PA Code Cite:

28 Pa. Code Chapter 611

(5) Agency Contacts (List Telephone Number, Address, Fax Number and Email Address):

Primary Contact: Janice Staloski, Director
Bureau of Community Program
Licensure and Certification
(717) 783-8665

Secondary Contact: Karin S. Simpson, Senior Counsel
(717) 783-2500

(6) Primary Contact for Public Comments (List Telephone Number, Address, Fax Number and Email Address) – Complete if different from #5:

(All Comments will appear on IRRC'S website)

(7) Type of Rulemaking (check applicable box):

- Proposed Regulation
- Final Regulation
- Final Omitted Regulation
- Emergency Certification Regulation;
 - Certification by the Governor
 - Certification by the Attorney General

(8) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

RECEIVED
JAN 24 10 51 AM '13
INDEPENDENT REGULATORY REVIEW COMMISSION

Regulatory Analysis Form

These regulations set minimum standards for the operation and licensure of home care agencies and home care registries. Act 2006-69, signed by Governor Rendell on July 7, 2006, amended the Health Care Facilities Act (35 P.S. §§ 448.101 – 448.904b) to require the Department of Health to license home care agencies and home care registries. Agencies employ direct care workers and registries contract with direct care workers to provide home care services to consumers. Home care services include assistance with activities of daily living (e.g. bathing, dressing and feeding) and instrumental activities of daily living (e.g. housekeeping, shopping, meal preparation and transportation). These regulations establish consumer protections and require background checks, health screenings and training or testing for direct care workers to establish competency.

(9) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments:

The proposed regulations were published on August 11, 2007. The 30-day public comment period ended on September 10, 2007.

B. The date or dates on which public meetings or hearings will be held:

Stakeholder meetings were held in December, 2006, and January, 2007. The regulations also were presented at public meetings of the Department's Health Policy Board, as proposed on March 14, 2007, and in final format on July 30, 2008.

C. The expected date of promulgation of the proposed regulation as a final-form regulation:

September, 2009

D. The expected effective date of the final-form regulation:

Upon publication in the *Pennsylvania Bulletin* in final.

E. The date by which compliance with the final-form regulation will be required:

Immediately upon publication.

F. The date by which required permits, licenses or other approvals must be obtained:

Section 611.2 of the regulation states:

Regulatory Analysis Form

An entity operating a home care agency or home care registry or both as of the effective date of this chapter may continue to operate after the effective date of this chapter provided it submits an application for license to the Department in accordance with instructions published in the *Pennsylvania Bulletin* and posted on the Department's website on or within 60 days of the effective date of this chapter. An entity that has submitted an application for licensure in accordance with the requirements of this subsection may continue to operate the home care agency or home care registry until such date as the Department may refuse the application for licensure. If the Department grants the application for licensure, the home care agency or home care registry may continue operation of the agency or registry in accordance with the requirements of this chapter.

(10) Provide the schedule for continual review of the regulation.

The regulations will be reviewed and updated as appropriate.

SECTION II: STATEMENT OF NEED

(11) State the statutory authority for the regulation. Include specific statutory citation.

Section 803(1) of the Health Care Facilities Act, 35 P.S. § 448.803(1), authorizes the Department, after consultation with the Health Policy Board, to promulgate regulations necessary to carry out the purposes and provisions of the Act. Also, Act 2006-69 includes a provision at § 809.1 expressly authorizing the Department to promulgate regulations to implement §§ 806(d.1) (addressing licensure standards) and 806.3 (addressing consumer protections).

(12) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are

Regulatory Analysis Form

there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

Section 809.1 of Act 2006-69 requires the Department to promulgate regulations to implement §§ 806(d.1) (addressing home care agency and home care registry licensure requirements) and 806.3 (addressing consumer protections) and to publish the regulations in the *Pennsylvania Bulletin* within one year of the effective date of § 809.1. Section 809.1 became effective when the act was signed on July 7, 2006.

(13) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

These standards are intended by the Department to assure safe, adequate and efficient home care agencies and home care registries, and to promote the health, safety and adequate care of consumers of services provided by home care agencies and home care registries. The regulations will benefit all future recipients of services provided by home care agencies and home care registries. Based on partial data collected by the Department to date, this will include approximately 650 home care agencies and home care registries and approximately 800,000 consumers.

(14) If scientific data, studies, references are used to justify this regulation, please submit material with the regulatory package. Please provide full citation and/or links to internet source.

No scientific data, studies or references were used to justify this regulation.

(15) Describe who and how many will be adversely affected by the regulation. How are they affected?

Regulatory Analysis Form

No one will be adversely affected by the regulation.

(16) List the persons, groups or entities that will be required to comply with the regulation. Approximate the number of people who will be required to comply.

These regulations will affect home care agencies and home care registries and the individuals hired by the agencies or referred by the registries to provide services to individuals in their homes or other independent living environment.

SECTION III: COST AND IMPACT ANALYSIS

(17) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are approximately 650 home care agencies and home care registries. Each one will be required to pay an annual licensure fee of \$100.00. Agencies and registries also will incur costs connected with coming into compliance with licensure requirements; i.e. ensuring competency of direct care workers, developing and maintaining documentation demonstrating compliance with hiring, training and health screening prerequisites, developing documentation to be supplied to consumers in advance of providing services, and adding necessary hardware and software to permit electronic submission of required reports to the Department. The agency or registry will incur start-up costs connected with establishing systems and procedures that comply with the regulation and on-going costs of doing business in the manner dictated by the regulation. The regulation does permit choices, however, and the choice will have an impact on overall costs. Establishing competency of a direct care worker through a competency examination, for example, may cost less than establishing competency through a training program developed and implemented by the home care agency or registry.

Regulatory Analysis Form

The increase in FY 2 and 3 are based on additional facilities being established with a leveling out in years 4 and 5.

(18) Provide a specific estimate of the costs and/or savings to **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There will be no costs and/or savings to local government associated with compliance with these regulations.

(19) Provide a specific estimate of the costs and/or savings to **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

As outlined in the next section, the licensure program for home care agencies and home care registries will cost approximately \$1,060,000 for the first full year of the program. This figure represents costs associated with hiring and equipping the necessary staff to implement a new licensure program. The Department will also incur certain start-up costs associated with training of surveyors or inspectors and updating the Department's computer system through which the Department coordinates and manages its licensure function. The Department and its staff use the system to schedule and track surveys or inspections of all facilities, track surveyor time and efforts and track complaints about facilities. The system also includes a function through which a statement of deficiencies, in the event of regulatory violations identified during an inspection, can be generated. The system also allows the facilities to submit its plan of correction electronically. This system will need to be revised to include the home care agency and home care registry licensing function.

State government costs for current year and 09/10 fiscal years were based on estimates calculated by the DOH budget office. For all out years, personnel costs include the proposed salary increases for 10/11, 11/12 and 12/13 fiscal years.

Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community	650,000	650,000	650,200	650,400	650,400	650,400
Local Government	0	0	0	0	0	0
State Government	1,060,000	1,114,000	1,171,000	1,232,000	1,297,000	1,366,000
Total Costs						
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

(20a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
Quality Assurance	16,057,000	15,557,000	17,308,000	19,063,000

(21) Explain how the benefits of the regulation outweigh any cost and adverse effects.

Regulatory Analysis Form

These regulations support consumers' choice and preference to remain in their own homes. With the shift from institutional to home and community based services, it is imperative to have the basic consumer protections to be imposed by these regulations. Failure to insure quality of care results in persons needing higher level of care i.e. institutionalization with increased costs to the Commonwealth.

(22) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

Act 2006-69 required the Department to develop these regulations in consultation with the Department of Public Welfare and other advisory groups that represent persons in the home health care industry, persons with physical disabilities and the aging community. The Department also was required to take into consideration the preferences and philosophies of persons with physical disabilities who receive home and community-based services through the Medicaid waiver or other publicly funded programs. The Department distributed a set of draft regulations to the Department of Public Welfare, the Department of Aging, other designated stakeholders and interested persons in advance of stakeholder meetings in Harrisburg on December 7, 2006, in Muhlenberg on December 12, 2006 and in Pittsburgh on December 15, 2006. The Department also met with representatives of what was then Pennsylvania Protection and Advocacy and is now the Disability Rights Network of Pennsylvania and with other individuals representing organizations serving the disability community on January 26, 2007. Following meetings with stakeholders and receipt of comments on the draft regulations, the Department revised the regulations based on comments received and presented the regulations to the Department's Health Policy Board on March 14, 2007, in accordance with the Department's obligation under Section 803(1) of the Health Care Facilities Act, 35 P.S. § 448.803(1), to consult with the Health Policy Board when promulgating regulations. On August 11, 2007, the Department published notice of proposed rulemaking. The Department provided a 30-day public comment period. After preparation of the regulations in final, the Department again presented the regulations to the Department's Health Policy Board at its public meeting on July 30, 2008.

(23) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory schemes were considered. The proposed regulations implement the mandatory language of the statute.

Regulatory Analysis Form

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

Home care agencies and home care registries are not subject to federal standards at this time.

(25) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete with other states?

Thirty-five other states have licensure programs in place for home care services. Home care agencies and home care registries are not likely to avoid doing business in Pennsylvania because Pennsylvania is adopting a licensure program for home care services. While the cost of doing business in Pennsylvania may be a little higher than in a state that does not have a licensure program, the advantages of providing home care services in a state with such a high elderly population remain.

(26) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The proposed regulations may affect the licensure program for home health agencies under 28 Pa. Code Chapter 601. To be licensed under Chapter 601, home health agencies must be staffed and equipped to provide skilled nursing services and at least one therapeutic service (e.g. physical therapy, occupational therapy, speech pathology, medical social services or home health aides). The home health agency, although staffed and equipped to provide skilled care, also may provide assistance with activities of daily living and instrumental activities of daily living. Home care agencies and home care registries provide assistance with activities of daily living and instrumental activities of daily living but do not provide skilled care. The Department anticipates that certain entities seeking licensure as a home care agency also may provide skilled care, in which case those entities must be licensed as home health agencies.

Regulatory Analysis Form

(27) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

Existing paperwork requirements, applicable to licensure of other health care facilities under the Health Care Facilities Act will now apply to home care agencies and home care registries. The revised forms for home care agency and home care licensure are attached. Only those paperwork requirements already applicable to other health care facilities are being imposed on home care agencies and home care registries.

(28) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The proposed regulations define "home care agency" and "home care registry" to exclude entities that provide only financial management services to consumers of publicly funded home and community-based services. "Financial management services" is defined as one or more of five specified services associated with meeting the payroll and other responsibilities of a consumer of home care services who is also the employer of the individual providing the home care services. This language was developed to meet the needs of certain members of the disability community who are consumers of publicly funded home and community based services and who employ their own care-givers and utilize the services of an agency only for payroll and other employer-related functions. The language is intended to support Section 903.1 of Act 2006-69, addressing non-applicability. That section states that nothing in the act shall apply to a private contract or arrangement entered into by a consumer and caregiver, provided that the caregiver was not supplied, arranged, scheduled or referred to the consumer by a home care agency or home care registry.

**COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH**

**INFORMATION REQUESTED OF HEALTH CARE PROVIDERS APPLYING FOR
A LICENSE TO OPERATE A HEALTH CARE FACILITY**

(APPLIES TO APPLICATIONS FOR INITIAL LICENSURE OF A HEALTH CARE FACILITY AND
TO APPLICATIONS FOR LICENSURE AS A RESULT OF CHANGE OF OWNERSHIP OF AN
EXISTING HEALTH CARE FACILITY)

BUSINESS STRUCTURE

1. A description of the business structure of the health care provider ("Applicant") applying for a license to operate a health care facility, as defined in the Health Care Facilities Act, Act of July 19, 1979, P.L. 130, as amended, 35 P.S. §§448.101 - 448.904b.

OWNERSHIP AND/OR CONTROLLING INTEREST

2. (a) Identify the persons and entities with 5% or greater direct or indirect ownership or controlling interest in the Applicant (see attached definitions).

(b) Provide the information requested in questions 1, 4, 5 and 8 with respect to all persons and entities identified in (a).

DOCUMENTATION

3. (a) A copy of the Applicant's articles of incorporation, certificate of registration, certificate of incorporation, charter, certificate of organization, or other articles, statements or documents establishing the legal existence of the business entity that will hold the license. This submission shall include applicable Pennsylvania Department of State filings and approvals. For foreign entities, provide a copy of the applicable Pennsylvania Department of State filings and approvals to conduct business in Pennsylvania.

(b) A copy of the applicant's by-laws, operating agreement, partnership agreement, or other rules adopted for the regulation or management of the business entity applying for licensure, regardless of the name used to describe those rules.

*IDENTIFICATION OF INDIVIDUALS WITH MANAGEMENT AND OPERATIONAL
AUTHORITY*

4. (a) A list of the names, addresses and health care experience of the individuals who are responsible for the overall business direction of the Applicant

(b) A list of the names, addresses and health care experience of the individual[s] to be appointed by the Applicant to act on its behalf in the overall management and operation of the health care facility regardless of form of ownership.

- (c) The names, addresses and health care experience of the individual[s] who will have responsibility for day-to-day operations and who will provide immediate direction and control over the manner of delivery of health care services to individuals served by the health care facility.

LOCATION OF APPLICANT

5. Address of the Applicant's headquarters. If the Applicant has out-of-state headquarters, the Applicant also shall supply the address where the Applicant may be served with legal documents within Pennsylvania.

HEALTH CARE SERVICES TO BE PROVIDED BY APPLICANT

6. (a) A description of the health care services the Applicant intends to offer through the health care facility.
- (b) If the application for licensure is the result of a change of ownership, the health care provider should provide a description of
- i. any actual or anticipated change from the health care services currently offered,
 - ii. any actual or anticipated change in the present staff, or in the composition of the staff, and
 - iii. a description of any anticipated innovations in the manner of delivery of health care services.

BACKGROUND OF APPLICANT

7. *The Applicant's previous experience in operating health care facilities inside or outside Pennsylvania, including:*
- (a) the type of health care facilities currently or previously owned, managed or operated by Applicant
 - (b) the names and addresses of facilities currently or previously owned, managed or operated by Applicant and persons and entities identified in 2(a)
 - (c) a description of any adverse action taken by any state or federal agency against any of the facilities identified in 7(b), and any documentation regarding the action taken and its resolution.
8. Have any of the facilities identified in 7(b) or any of the individuals identified in 4(a), (b) or (c):
- (a) Been subject to criminal or civil fraud charges; or
 - (b) Ordered to pay a civil monetary penalty (other than those listed in response to 7(c); or
 - (c) Convicted of Medicare or Medicaid fraud and abuse?

If yes, please provide documentation regarding the action taken and its resolution.

9. Are there any ongoing fraud and abuse investigations at any facility identified in 7(b)?

INTENTIONS WITH RESPECT TO CHARITY CARE

10. A description of the Applicant's intentions with respect to the level of charity and uncompensated care to be provided.

DIRECTIONS AND DEFINITIONS FOR PROVIDING THE INFORMATION REQUESTED OF HEALTH CARE PROVIDERS APPLYING FOR A LICENSE TO OPERATE A HEALTH CARE FACILITY

BUSINESS STRUCTURE

1. Please provide as much information as necessary to provide a complete description of the business structure of the Applicant. While you may choose to provide an organizational chart outlining chain of command or lines of decision-making authority for the Applicant, that is not the primary purpose of this question. The purpose of this question is to obtain a detailed explanation of the business entity that is seeking a license to operate a health care facility. The business entity may be a business corporation, professional corporation, nonprofit corporation, limited liability company, general partnership, limited partnership, limited liability partnership, restricted professional company, unincorporated association, professional association, sole proprietorship, trust, estate, joint stock company, insurance company, the Commonwealth or political subdivision or instrumentality (including a municipal corporation or authority) or other government entity. The description of the business structure of the entity applying for a license should include information about those entities or persons that have an ownership interest in the Applicant. The explanation of the business structure should include information about a parent corporation, a holding company, or the corporate or individual members of a limited liability company.

OWNERSHIP AND/OR CONTROLLING INTEREST

2. Please see the definitions to determine the direct/indirect ownership/control of the Applicant. Please include "parent" corporations, sole members or any entities that have a relationship with the Applicant that results in ownership or control as defined below.

DOCUMENTATION

3 (a) Please provide the documentation that demonstrates the legal existence of business entity that is seeking a license to operate a health care facility. The technical form of that documentation may vary. If the Applicant is a corporation, the documentation will be the Articles of Incorporation. If the Applicant is a limited liability company, the documentation will be a Certificate of Authority. If the Applicant is a Partnership, the documentation will be the Partnership Agreement. If the business entity that will operate the health care facility is a sole proprietorship, there will be no documentation to supply. A foreign corporation shall supply a copy of the corporation's application for a Certificate of Authority to do business in Pennsylvania.

(b) Please provide the documentation necessary to describe the rules for the regulation, management and operation of the Applicant as a business entity. The form of that documentation may vary. If the Applicant is a corporation, the documentation may be titled "by-laws." If the Applicant is a limited liability company, the operating agreement will include the rules for operation of the company. If the Applicant is a partnership, the partnership agreement will include the operating rules for the partnership. If the business entity that will operate the health care facility is a sole proprietorship, there is no requirement for documentation setting forth the rules for running the business.

**IDENTIFICATION OF INDIVIDUALS WITH MANAGEMENT
AND OPERATION AUTHORITY**

4. (a) The names included in the response to this question should include any and all persons who have overall responsibility for business direction of the Applicant. The title of these persons may vary depending upon the form of business entity that will operate the health care facility. In a corporation, these persons often are referred to as "directors." In a limited liability company, these persons often are referred to as "members."

(b) The names included in the response to this question should include any and all persons appointed by the health care provider to act on its behalf in the overall management and operation of the health care facility. The title assigned to these persons may vary depending upon the form of the business entity that will operate the health care facility. In a corporation, these persons often are referred to as "officers." In a limited liability company, the members may fill the roles described in (a) and (b), or the members may appoint an individual to manage the company, and may be referred to as "manager." This person or persons also may be referred to as the "general partners," "managing partners," "chief executive officer," or "chief operating officer."

(c) The name provided in the response to this question should be, for example, the individual who is licensed as a nursing home administrator, or the individual named as the administrator, director of nursing, medical director, or executive director for the health care facility.

It is possible that the same persons will have responsibility for the business direction of the health care facility, for the overall management and operation of the facility, and for direction and control over the manner of delivery of health care services. In the event of repetition of names in response to (a), (b), and (c) above, simply supply all names in response to this question 4 and list the responsibilities of each.

LOCATION OF APPLICANT

5. An applicant with an out-of-state address must supply an in-state address to which the Department or one of its divisions may deliver correspondence including notice of an adverse action or other legal documentation.

HEALTH CARE SERVICES TO BE PROVIDED BY APPLICANT

6. Self-explanatory.

BACKGROUND OF APPLICANT

7. The term "adverse action" refers to an adverse licensure or certification action by a state or federal agency, including civil monetary penalties.

8, 9. Self-explanatory.

INTENTIONS WITH RESPECT TO CHARITY CARE

10. A response to this question is solicited merely as a means of collecting information. An answer indicating an unwillingness to provide charity care will not affect the Department's decision with regard to the application for licensure.

IF YOU ARE UNSURE HOW TO ANSWER ONE OF THE QUESTIONS OR WHAT KIND OF DOCUMENTATION YOU MUST PROVIDE, PLEASE CONTACT THE OFFICE OF LEGAL COUNSEL FOR THE DEPARTMENT OF HEALTH AT (717) 783-2500.

DEFINITIONS

“Direct Ownership” means an interest through the possession of stock, equity in capital or any interest in the profits of the Applicant.

“Indirect Ownership” means an interest in an entity that has direct or indirect ownership interest in the Applicant. The amount of indirect ownership in the Applicant that is held by any other entity is determined by multiplying the percentage of ownership interest at each level. An indirect ownership interest must be reported if it equates to an ownership interest of 5 percent or more in the Applicant.

“Control” means the ability to control operational direction or management of the Applicant which may be maintained by any or all of the following devices: the ability or authority, expressed or reserved, to amend or change the corporate identity (e.g. joint venture agreement, unincorporated business status) of the Applicant; the ability or authority to nominate or name members of the Board of Directors or Trustees of the Applicant; the ability or authority, expressed or reserved, to amend or change the by-laws, constitution, or other operating or management rules of the Applicant; the right to control any or all of the assets or other property of the Applicant upon the sale or dissolution of that entity; the ability or authority, expressed or reserved, to control the sale of any or all of the assets to encumber such assets by way of mortgage or other indebtedness, to dissolve the Applicant, or to arrange for the sale or transfer of the Applicant to new ownership or control.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH
DIVISION OF HOME HEALTH

CIVIL RIGHTS SURVEY

Agency Name: _____ Provider No: _____

NOTE: The word "discrimination" shall be understood to mean "discrimination on the basis of race, color, national origin, religious creed, ancestry, sex, age or handicap" as used in the Pennsylvania Human Relations Act of 1955, as amended.

1. Is a non-discrimination policy which states services are provided, referrals are made, and employment actions are made without regard to race, sex, color, national origin, ancestry, religious creed, handicap, or age, posted conspicuously in the agency?

YES ___ If yes, provide a copy and indicate where postings are located.

NO ___ If no, state what corrective steps will be taken to assure a non-discrimination policy is developed and posted.

2. Does the agency include the non-discrimination policy in brochures, media notices, and posters?

YES ___ If yes, identify publications and media communications means used.

NO ___ If no, state what corrective steps will be taken.

3. Describe methods and materials used to orient patients and staff to civil rights compliance requirements.

4. Are residents and staff informed that complaints of discrimination may be filed with the Office of Equal Opportunity, Pennsylvania Department of Health, and/or the Pennsylvania Human Relations Commission?

YES ___ If yes, explain the contents of the information and how it is disseminated.

NO ___ If no, provide corrective steps to be taken.

5. Are there non-English speaking, or speech impaired persons who you provide services to?

YES ___ NO ___

If yes, list the languages / impairments.

COMMENTS:

6. Are bilingual interpreters and materials available to serve individuals in the appropriate language listed above?

YES ___ NO ___

If yes, list specific languages, organizations/persons utilized or available.

COMMENTS:

7. If there are hearing or visually impaired patients, what methods are used to assure communication with them? (For example, application forms, responding to daily needs, emergency situations, etc.)

8. Does the non-discrimination policy statement include that reasonable accommodation is to be provided for handicapped employees?

YES ___ If yes, describe its content and how it is disseminated.

NO ___ If no, specify reasons or corrective actions to be taken.

9. Within the past 12 months, have there been any complaints of discrimination filed against this agency?

YES ___ NO ___

If yes, for each complaint registered, please show date of the complaint; the sex and race/national origin of the complainant; major allegations made in the complaint; agency with which the complaint was registered; and the finding of either cause or no cause by the investigating agency.

**COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH
INITIAL
HOME CARE AGENCY/REGISTRY LICENSURE SURVEY**

Name of Entity: _____

DBA: _____

Address: _____

Application Type: Home Care Agency _____ Home Care Registry _____ Both _____

Name of Administrator: _____

Contact Person if any Questions

Phone

LICENSURE SURVEY QUESTIONS

1. List the number of direct care workers employed and/or rostered by the agency.
2. Describe or attach your agency or registry's prerequisites for hiring and/or rostering of direct care workers. If attached, please label as exhibit A.
3. Criminal background checks are required for all employed or rostered direct care workers. Describe your agency or registry's policy for requiring background checks and prohibiting individuals with a prohibited conviction or Department of Aging ineligibility determination from being hired or rostered. If attached, label as exhibit B.
4. Does the agency or registry provide services to consumers less than 18 years of age?
5. If services are provided to consumers less than 18 years of age, have all staff, including office staff had child abuse clearances completed or initiated?
6. If services are provided to consumers less than 18 years of age, please describe or attach a copy of the process in place that ensures all staff employed and/or rostered receive child abuse clearances. If attached, label as exhibit C.

7. Do you hire or roster individuals on a provisional basis pending the outcome of a criminal background check and ChildLine verification, if necessary?

If so, describe or attach the provisional hiring process, which must include termination procedures if a criminal history or ChildLine verification indicates a prohibited offense or occurrence and the system in place for monitoring provisionally hired or rostered individuals. If attached, label as Exhibit D.

8. Describe or attach an outline of your agency or registry's training program and/or competency exam process. If attached, label as Exhibit E.

- a. If direct care workers are not directly trained or tested for competency by the agency or registry, describe or attach a copy of the process used to verify the individual has successfully completed a training program approved by the Department. If attached, label as Exhibit F.

9. All individuals employed and/or rostered who have direct consumer contact are required to have a health screening prior to employment or referral and annually thereafter. Describe or attach you policy that addresses this process. If attached, label as Exhibit G.

10. Describe or attach your policy that addresses termination of consumer services. If attached, label as Exhibit H.

11. All individuals affiliated with the home care agency and/or registry are prohibited from assuming power of attorney or guardianship over a consumer utilizing your services. Describe or attach you policy that addresses this. If attached, label as Exhibit I.

12. Agencies and registries are prohibited from allowing a consumer to endorse a check over to the home care agency or registry. Describe or attach your policy that addresses this. If attached, label as Exhibit J.

13. Attach a sample(s) copy of the information packet which will be provided to the consumer prior to the commencement of services. (Label as Exhibit K.) **THE PACKET MUST INCLUDE THE FOLLOWING:**
- a. A form or other document that will show a list of services to be provided to the consumer and the hours when they will be provided.
 - b. Cost of the services to be provided on an hourly or weekly basis.
 - c. Department of Health contact information for inquires about licensure requirements and agency/registry compliance.
 - d. Department of Health hotline and local AAA Ombudsman telephone numbers.
 - e. Hiring/Training requirements of direct care workers.
 - f. The manner and frequency that direct care workers will be reassessed for competency and the method in which it will be documented.
 - g. Disclosure addressing employee or independent contractor status of the direct care worker providing services to the consumer, and the resultant tax and insurance obligations and other responsibilities of the consumer.

**NOTE: PLEASE COMPLETE LICENSURE SURVEY
AFFIRMATION BELOW**

Application is made to operate a home care agency and/or home care registry in accordance with the Health Care Facilities Act (35 P.S. §§448.801a – 448.904b).

I affirm that all of the information provided herein is COMPLETE and TRUE. Incomplete or inaccurate information will result in licensure denial

I further agree to conduct said facility in accordance with the laws of the Commonwealth of Pennsylvania and with the rules and regulations of the Department of Health.

Signature of Agency Administrator

Date



**APPLICATION FOR HOME CARE AGENCY OR
HOME CARE REGISTRY LICENSE**

Please check the one that applies:

- Home Care Agency
- Home Care Registry

IDENTIFYING INFORMATION

Name of Entity: _____

D/B/A: _____

Mailing Address: _____
Street City Zip Code

Site Address: _____
Street City Zip Code

County: _____

Telephone (Including area code): () _____ Fax: () _____

E-mail address (if available): _____

Administrator (local): _____

PAYMENT

A CHECK OR MONEY ORDER PAYABLE TO "COMMONWEALTH OF PENNSYLVANIA" FOR THE AMOUNT OF THE FEE MUST ACCOMPANY THIS APPLICATION. CURRENCY IS NOT ACCEPTABLE. THE REGULAR FEE PER LICENSE IS \$100.00.

Mail check or money order, along with the completed application to the Pennsylvania Department of Health, Division of Home Health, 132 Kline Plaza, Suite A, Harrisburg, PA 17104.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH
DIVISION OF HOME HEALTH

INSTRUCTIONS FOR COMPLETING DISCLOSURE OF OWNERSHIP AND CONTROL INTEREST
STATEMENT

These instructions are designed to clarify certain questions on the licensure form. Instructions are listed in question order for easy reference. No instructions have been given for questions considered self-explanatory.

IT IS ESSENTIAL THAT ALL APPLICABLE QUESTIONS BE ANSWERED
ACCURATELY AND THAT ALL INFORMATION IS CURRENT.

Item A – Under identifying information, specify in what capacity the entity is doing business as (DBA), example, name of trade or corporation.

Please answer all questions as of the current date. If the Yes block for any item is checked, list requested additional information under Remarks on Page 2, referencing the item. If additional space is needed, use an attached sheet.

Item C – List the names of all individuals and organizations having direct or indirect ownership interests, or controlling interest separately or in combination, amounting to an ownership interest of five percent (5%) or more in the disclosing entity.

Direct ownership interest is defined as the possession of stock, equity in capital or any indirect ownership interest in the disclosing entity. The amount of indirect ownership in the disclosing entity that is held by any other entity is determined by multiplying the percentage of ownership interest at each level. An indirect ownership must be reported if it equates to an ownership interest of 5 percent or more in the disclosing entity. Example: If A owns 10 percent of the stock in a corporation that owns 80 percent of the stock of the disclosing entity, A's interest equates to an 8 percent indirect ownership and must be reported.

Controlling interest is defined as the operations direction or management of a disclosing entity which may be maintained by any or all of the following devices: the ability or authority, expressed or reserved, to amend or change the corporate identity (i.e., joint venture agreement, unincorporated business status) of the disclosing entity; the ability or authority to nominate or name members of the Board of Directors or Trustees of the disclosing entity; the ability or authority expressed or reserved, to amend or change the by-laws, constitution or other operating or management direction of the disclosing entity; the right to control any or all of the assets or other property of the disclosing entity upon the sale or dissolution of that entity; the ability or authority, expressed or reserved to control the sale of any or all of the assets, to encumber such assets by way of mortgage or other indebtedness, to dissolve the entity, or to arrange for the sale or transfer of the disclosing entity to a new ownership or control.

Item F – If there has been a change in ownership within the last year or if you anticipate a change, indicate the date in the appropriate space.

Changes in Provider Status. Change in provider status is defined as any change in management control. Examples of such changes would include: A change in medical or nursing director, a new administrator, contracting the operation of the facility to a management corporation, a change in the composition of the owning partnership which under applicable State law is not considered a change in ownership, or the hiring or dismissing of any employees with 5 percent or more financial interest in the facility or in an owning corporation, or any changes of ownership.

If the Yes box is checked, list additional information requested under Remarks. Clearly identify which item is being continued.

Item G – If the answer is Yes, list name of the management firm and employer identification number (EIN), or the name of the leasing organization. A management company is defined as any organization that operates and manages a business on behalf of the owner of that business, with the owner retaining ultimate legal responsibility for operation of the facility.

Item H – If the answer is Yes, identify which has changed (Administrator, Medical Director, or Director of Nursing) and the date the change was made. Be sure to include the name of the new Administrator, Director of Nursing or Medical Director, as appropriate.

Item I – A chain affiliate is any freestanding health care facility that is either owned, controlled or operated under lease or contract by an organization consisting of two or more freestanding health care facilities organized within or across State lines which is under the ownership, or through any other device, control and direction of a common party. Chain affiliates include such facilities whether public, private, charitable or proprietary. They also include subsidiary organizations and holding corporations. Provider based facilities, such as hospital-based home health care agencies, are not considered to be chain affiliates.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH
DIVISION OF HOME HEALTH

DISCLOSURE OF OWNERSHIP AND CONTROL INTEREST STATEMENT

A. Identifying Information

Name of Entity	D/B/A	Telephone No.
Street Address	City, County, State	Zip Code

B. Answer the following questions by checking "Yes" or "No." If any of the questions are answered "yes", list names and address of individuals or corporations under Remarks on Page 2. Identify each item number to be continued.

1. Are there any individuals or organizations having a direct or indirect ownership or control interest of 5% or more in the institution, organizations, or agency that have been convicted of a criminal offense related to the involvement of such persons, or organizations in any of the programs established by Titles XVIII, XIX, or XX?

Yes No

2. Are there any directors, officers, agents, or managing employees of the institution, agency or organization who have ever been convicted of a criminal offense related to their involvement in such programs established by Titles XVIII, XIX, or XX?

Yes No

C. List names, address for individual, or the EIN for organizations having direct or indirect ownership or a controlling interest in the entity. List any additional names and addresses under "Remarks" on Page 2. If more than one individual is reported and any of these persons are related to each other, this must be reported under "Remarks."

Name	Address	EIN

D. Type of Entity: Sole Proprietorship Partnership Corporation
 Unincorporated Other
 Associations

1. If the disclosing entity is a corporation, list names, address of the Directors and EINs for the corporation under "Remarks."

E. Check appropriate box for each of the following questions:

1. Are any owners of the disclosing entity also owners of other Medicare/Medicaid facilities? (Example, sole proprietor, partnership or members of Board of Directors) If "yes", list names, addresses of individuals and provider number

___ Yes ___ No

Name	Address	Provider Number
------	---------	-----------------

F. Has there been a change in ownership within the last year? Yes No

If yes, give date _____

Do you anticipate any change of ownership or control within the year? Yes No

If yes, when? _____

G. Is this facility operated by a management company, or leased in whole or part by another organization? Yes No

If yes, give date of change in operations _____

H. Has there been a change in Administrator, Director of Nursing or Medical Director within the last year? Yes No

I. Is this facility chain affiliated? (If yes, list name, address of Corporation, and EIN) Yes No

Name EIN

Address

If the answer to the above question is No, was the facility ever affiliated with a chain? (If yes, list name, address of corporation and EIN) Yes No

Name EIN

Address

WHOEVER KNOWINGLY AND WILLFULLY MAKES OR CAUSES TO BE MADE A FALSE STATEMENT OR REPRESENTATION OF THIS STATEMENT, MAY BE PROSECUTED UNDER APPLICABLE FEDERAL OR STATE LAWS. IN ADDITION, KNOWINGLY AND WILLFULLY FAILING TO FULLY AND ACCURATELY DISCLOSE THE INFORMATION REQUESTED MAY RESULT IN DENIAL OF A REQUEST TO PARTICIPATE OR WHERE THE ENTITY ALREADY PARTICIPATES, A TERMINATION OF ITS AGREEMENT OR CONTRACT WITH THE STATE AGENCY.

Name of Authorized Representative (Typed) Title

Signature Date

Remarks

Please **type** or **print**

Provider/License Number: _____

PASSWORD AGREEMENT

I, _____ hereby certify that I am the Administrator/
Director/Chief Executive Officer for _____, ("Facility")
and that I am responsible for submitting a Plan of Correction in response to deficiencies cited
by the Pennsylvania Department of Health on HCFA Form 2567.

1. I acknowledge receipt of the facility identification number and my individual password (which will be provided after receipt of this agreement) from the Pennsylvania Department of Health.
2. I agree to maintain the confidentiality of both the facility identification number and my password.
3. I recognize and acknowledge that the use of my password to electronically submit a Plan of Correction, in response to deficiencies cited on a HCFA Form 2567, identifies me as the signer of the Plan of Correction.
4. I further recognize and acknowledge that the use of my password, in conjunction with the submission of a Plan of Correction, authorizes the Pennsylvania Department of Health to conclusively accept that electronic Plan of Correction as my authorized submission.

I have had the opportunity to review this Agreement and hereby agree to the above statements.

E-mail address (**type or print legibly**)

Signature of Administrator/CEO/Director

Signature of Witness

Date

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED
AUG 24 PM 3:13
LEGISLATIVE COUNCIL
SECRETARY

DO NOT WRITE IN THIS SPACE

<p>Copy below is hereby approved as to form and legality. Attorney General.</p> <p>BY _____ DEPUTY ATTORNEY GENERAL</p> <p>_____ DATE OF APPROVAL</p> <p>9 Check if applicable. Copy not approved. Objections attached.</p>	<p>Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:</p> <p>DEPARTMENT OF HEALTH (AGENCY)</p> <p>DOCUMENT/FISCAL NOTE NO. <u>10-184</u> DATE OF ADOPTION: _____</p> <p>BY: <u>Everette James</u> Everette James</p> <p>TITLE: <u>Secretary of Health</u></p>	<p>Copy below is hereby approved as to form and legality. Executive or independent Agencies.</p> <p>BY: <u>Andrew C. Clark</u> <u>AUG - 7 2009</u> DATE OF APPROVAL</p> <p>(Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title)</p> <p>9 Check if applicable. No Attorney General approval or objection within 30 days after submission.</p>
---	---	--

NOTICE OF FINAL RULEMAKING

TITLE 28. HEALTH AND SAFETY

DEPARTMENT OF HEALTH

SUBPART H. HOME CARE AGENCIES AND HOME CARE REGISTRIES

CHAPTER 611. HOME CARE AGENCIES AND HOME CARE REGISTRIES

The Department of Health (Department) hereby amends 28 Pa. Code by adding Subpart H, Chapter 611, to govern licensure of home care agencies and home care registries. The regulations are set forth in Annex A.

PURPOSE OF THE REGULATIONS

The final regulations set minimum standards for the operation of home care agencies and home care registries. Act 2006-69 (Act 69), signed by Governor Rendell on July 7, 2006, amended the Health Care Facilities Act (Act) (35 P.S. §§ 448.101 – 448.904b) to require the Department to license home care agencies and home care registries. Home care agencies employ direct care workers to provide home care services to individuals in their place of residence or other independent living environment. Home care registries refer direct care workers who are independent contractors to provide home care services to individuals in their place of residence or other independent living environment. Home care services include assistance with bathing, dressing and feeding, housekeeping, shopping, meal planning and preparation and transportation, and also include companionship services, respite care, and specialized care.

Section 803(1) of the Act, 35 P.S. § 448.803(1), authorizes the Department, after consultation with the Health Policy Board, to promulgate regulations necessary to carry out the purposes and provisions of the Act. The Act 69 amendments also include a provision expressly authorizing the Department to promulgate regulations to implement §§ 806(d.1) (addressing licensure standards) and 806.3 (addressing consumer protections). Act 69 requires the Department to develop regulations in consultation with the Department of Public Welfare and other advisory groups that represent persons in the home health care industry, persons with physical disabilities

and the aging community, and to take into consideration the preferences and philosophies of persons with physical disabilities who receive home and community-based services through Medicaid waiver or other publicly funded programs.

The Department distributed a set of draft regulations to the Department of Public Welfare, the Department of Aging, other designated stakeholders and interested persons in advance of stakeholder meetings in Harrisburg on December 7, 2006, in Muhlenberg on December 12, 2006, and in Pittsburgh on December 15, 2006. The Department also met on January 26, 2007, with representatives of what was, at that time, the Pennsylvania Protection and Advocacy, Inc. (PP&A), and is now the Disability Rights Network of Pennsylvania, and with other individuals representing organizations serving the disability community. Following meetings with stakeholders, and receipt of comments on the draft regulations, the Department revised the draft based on comments received and presented the proposed regulations to the Department's Health Policy Board on March 14, 2007. On August 11, 2007, the Department published notice of proposed rulemaking . The Department provided a 30-day public comment period. After preparation of the regulations in final, the Department presented the regulations to the Department's Health Policy Board at a public meeting on July 30, 2008.

DISCUSSION OF COMMENTS

During the public comment period the Department received over 200 individual comments from more than 40 commentators, including members of the Legislature, the public, advocacy groups serving the disability community, and trade associations representing providers of home care services. Many of the comments were critical of some aspect of the Department's proposed

regulations, although some commentators did express support for specific provisions of the proposed regulations.

While the bulk of the comments received were in response to the substantive requirements for licensure as a home care agency or home care registry (i.e. hiring and training or testing of direct care workers employed or on contract, background checks, child abuse clearances, health evaluations and consumer protection), the Department also received a number of comments on the Department's proposed procedural provisions addressing the licensure process for home care agencies and registries, inspection and survey activities, and sanctions and corrective actions. The three proposed sections addressing the procedural aspects of the licensure process were intended to incorporate and expand upon the requirements in 28 Pa. Code Chapter 51 (relating to general provisions), promulgated in 1998, applicable to all health care facilities required to be licensed under the Act, and to clarify procedural requirements for home care agencies and registries.

Upon further consideration, the Department has determined not to address in these regulations the Department's practices and protocols for licensure and enforcement of licensure standards as applied, specifically, to home care agencies and home care registries. The Act addresses the application process, issuance of a license, inspections, notice of violations, and possible sanctions as a result of violations for all "health care facilities" required to be licensed by the Department. See 35 P.S. §§ 448.807 – 448. 814. Moreover, the Department plans a comprehensive revision of Chapter 51 to address the licensure process for all health care facilities.

For these reasons, the Department has deleted the provisions under “Licensure,” “Inspection and Survey Activities,” and “Sanctions and Corrective Actions.” Portions of what had been included in §§ 611.11 (relating to licensed required) and 611.12 (relating to application for license) are now in § 611.2. The remaining regulations in the “General” section have been renumbered accordingly. Section 611.2 advises of the licensure requirement generally as applied to new and to existing home care agencies and home care registries, states that the licensure requirement applies to all physical locations of home care agencies and home care registries, and informs the reader where to submit the application and the application fee of \$100.

Because the Department has chosen not to adopt the bulk of the provisions under the proposed regulations labeled “Licensure,” “Inspections and Survey Activities,” and “Sanctions and Corrective Actions,” this preamble does not include a discussion of comments received in response to those proposed provisions.

The Department received comments on each of the provisions in the proposed “Governance and Management” section, but most comments focused on the proposed § 611.55 that dealt with training and on the proposed § 611.56 that dealt with health evaluations. Many commentators expressed concern that if the Department required all direct care workers to receive training or establish competency in all 16 subject areas listed in the proposed regulation, the pool of individuals willing to become a direct care worker and provide home care services would decline dramatically and the cost of home care services to the consumer would increase. Commentators explained that many potential direct care workers are individuals who have been homemakers for many years who wish to earn an income by providing some, but not all, levels of home care

services. These individuals have little interest in providing the kind of hands-on care for which more intensive training is required. According to the commentators, if these individuals are required to become trained or establish competency in skills they do not intend to use, they will decline the training and the work-for-pay opportunity being offered to them.

In response to the comments received, the Department reevaluated the statute and determined that it allows for differing levels of competency; one for persons who will provide the full gamut of home care services, up to and including personal care, and another for those who will provide only companionship and assistance with tasks such as laundry, shopping, making and keeping appointments, paying bills, and engaging in social and leisure activities. Therefore, the final regulation, § 611.55 (relating to competency requirements), includes a list of 10 mandatory subject matter areas to be included in any training program or competency examination developed by a home care agency or home care registry. If, however, the direct care worker will provide personal care, including assistance with eating, ambulating, transferring, positioning, toileting and with personal hygiene and with self-administration of medications, § 611.55 provides that the direct care worker must receive training, or establish competency through testing, in 6 additional subject matter areas.

The Department retained other options, per the statute, for ensuring competency, prior to assignment or referral if the agency or registry does not choose to create its own training program or competency examination; e.g., a current nurse's license, the home health aide training program outlined at 42 C.F.R. 484.36 or the nurse aid certification and training program offered by the Department of Education. In response to a suggestion from a commentator, the

Department also added, in § 611.55, as an additional method for ensuring competency, training that conforms to training standards imposed on the agency or registry by virtue of the agency's or registry's participation as a provider of home and community based services funded by a Medicaid waiver or other publicly funded program. Thus, if the direct care worker is trained to provide services funded through the Medicaid waiver or other publicly funded program, the direct care worker is competent to provide home care services.

Commentators also almost unanimously objected to the proposed health evaluation section, which would have required a screening assessment to establish that the individual had been screened, and tested as necessary, for tuberculosis, and for 5 other communicable diseases or conditions which were listed in the proposed regulation. There was widespread confusion regarding the meaning of the term "screening assessment" and consternation that direct care workers would need to undergo more onerous scrutiny as to their health status than other workers actually engaged in providing health care services.

In response to comments received, the Department has revised the regulation at § 611.56 (relating to health screening) to require the direct care worker and other office staff or contractors with direct consumer contact to provide documentation that the individual was screened for and is free from active tuberculosis. The individual need not be screened for other communicable diseases.

The Department's response to the comments received on the specific provisions of the proposed regulation follows:

GENERAL

Section 611.1. Legal Base.

The Independent Regulatory Review Commission (IRRC) suggested that the references in this section to “subpart” should be changed to “chapter.” The Department agreed and made the suggested change in this section and elsewhere within the regulation where the term “subpart” was used.

Section 611.2. Licensure.

This section contains portions of what had been included in proposed §§ 611.11 and 611.12.

This section alerts new and existing home care agencies and home care registries of the need to obtain a license for each physical location of the agency or registry, where to obtain the application, where to submit the completed application and the amount of the application fee. In accordance with a suggestion from IRRC, the Department inserted the actual fee amount for an initial license or license renewal in the final regulation. The Department also included a statement that the Department will conduct an inspection prior to issuing an initial license or a license renewal.

Several commentators suggested that the Department eliminate the requirement that each physical location of the home care agency or home care registry be separately licensed. One commentator suggested that the “central office” for the agency or registry be licensed, and that license would cover or include all physical locations of the agency or registry. IRRC has asked the Department to explain why it is necessary to separately license each physical location of an agency or registry.

The Act contemplates that the Department will separately license each health care facility. See § 808 of the Act, 35 P.S. § 448.808. The Department, per the statute, prior to issuing a license, must determine that the entity that will provide services is a responsible person; that the entity will provide safe and efficient services which are adequate for the care, treatment and comfort of patients; and that there is substantial compliance with the rules and regulations adopted by the Department pursuant to the Act. 35 P.S. § 448.808. For health care facilities that have a physical plant at which health care services are delivered, the Department also must establish that the place to be used as a health care facility is adequately constructed, equipped, maintained and operated to safely and efficiently render the services offered.

The Act also states that a separate license shall not be required for different services within a single health care facility except that home health care, home care, hospice or long-term nursing care will require separate licenses. Thus, the Act contemplates a license for each physical location of a health care facility, and specifically requires a separate license for home care services even though services might be offered in conjunction with services provided by, or located in, a facility also required to be licensed under the Act.

The Department does allow branch offices of home health care agencies, and does not require the branch offices to be separately licensed, provided the licensure requirements specifically applicable to branch offices are met. The Department's licensure regulations for home health care agencies mirror the Federal requirements for participation in the Federal Medicare and Medicaid programs. Both Federal certification standards and the State licensure standards permitting branch offices assume that a parent home health care agency will operate within a

limited geographic area within the Commonwealth, and that the branch offices are in close physical proximity to the parent agency such that the parent agency can and does exercise administrative control and supervision, as defined in the regulations, over the branch offices. If the home health care agency has branch offices or “subunits,” appropriate administrative records must be maintained for each subunit. 28 Pa. Code § 601.21(a). If the subunit, by virtue of the lack of accessibility between it and the parent agency, is not capable of sharing administration, supervision and services with the parent agency, the subunit must be separately licensed. *Id.*

The Act does not give the Department authority to impose geographical limits on home care agencies or registries. The Department may permit branch offices at some point, if the Department is granted the authority to impose administrative and oversight responsibilities to a parent home care agency or registry, which would operate, along with its branch offices, within a defined geographic area within the Commonwealth.

Senator Corman suggested that a standardized fee schedule could be implemented to avoid escalating cost if a company has an agency and a registry and satellite offices of each. The Act contains a fee schedule and requires a fee of \$100 to accompany each application for a license to operate a home care agency or home care registry. The Act does not permit an alternate fee schedule.

One commentator asked how the Department will determine geographic limits for each agency. As pointed out above, the Act does not authorize the Department to, and thus the regulations do not, set geographic limits for an agency or registry. An agency or registry licensed in the State

will be permitted to provide or offer home care services throughout the State. The agency or registry will determine its geographic limits, and the business and organizational structure needed to serve the chosen geographic area.

Section 611.3. Affected home care agencies and home care registries.

IRRC suggested that the Department should move to this section that portion of the definitions of “home care agency” and “home care registry” that exceeds the statutory definitions and attempts to distinguish covered from non-covered entities. In accordance with the suggestion from IRRC, the Department incorporated within this section a listing of those entities to which this Chapter does not apply. Thus, this section now states that the Chapter does not apply to a home health care agency, a durable medical equipment provider, a volunteer provider, or an entity providing financial management services or supports coordination services or both. The Department added “supports coordination services” in response to a comment received that the regulations should include a specific exemption for financial management *and other supports coordination services* for consumer/employers who self-direct their services. The Department agreed the language was necessary in order to accomplish a more complete description of the kinds of services potentially offered by the non-covered entity. The definitional section also has been revised to include a definition of “supports coordination services.”

One commentator suggested that the proposed definitions of “home care agency” and “home care registry” should be revised to delete the word “only” used in reference to “financial management services.” Upon relocating the language referred to in this comment, the Department has accepted the suggestion, and the word “only” prior to “financial management

services” has been deleted. The Department determined that use of the term is inferred. In other words, an entity that supplies services in addition to financial management services or supports coordination services, as those terms are defined, is no longer an excluded entity, and that entity will have to examine its operations to determine whether it meets the definition of home care agency or home care registry, and, therefore, needs to apply for a license.

One commentator inquired whether the licensure requirement applies only to organizations, and not to consumer employers. The licensure requirements apply to entities that meet the definition of home care agency or home care registry. The licensure requirements, per the statute, do not apply to a private contract or arrangement entered into by a consumer and caregiver, provided that the caregiver was not supplied, arranged, scheduled or referred to the consumer by a home care agency or home care registry. 35 P.S. § 448.903a. Thus, if the consumer enters into an arrangement with a caregiver not supplied, arranged, scheduled or referred by a home care agency or home care registry, the caregiver is not subject to the requirements in this Chapter. If, however, the consumer enters into an arrangement with a caregiver supplied, arranged, scheduled or referred by a home care agency or home care registry, the caregiver is, in essence, a direct care worker subject to the requirements of this Chapter. Ensuring that the direct care worker meets the requirements of this Chapter, however, is the responsibility of the home care agency or registry that employed or rostered the direct care worker.

Two commentators suggested that the regulations do not address the unique place of consumer-driven organizations nor the philosophies that oppose medical oppression in personal assistance

services. In any set of regulations that a Commonwealth agency, such as the Department, promulgates to accomplish the objective set out by the General Assembly in the authorizing legislation, the agency must strive to address the safety and well-being of all individuals the regulations are intended to reach. Moreover, regulations promulgated must be objective in their application. Regulations must include the requirements to meet the statutory objectives. When the regulations regulate licensure, they must specify the minimum standards that need to be met to qualify for and retain a license. Thus, these regulations address minimum requirements for licensure of entities that provide or supply direct care workers to provide home care services. Every consumer receiving home care services supplied, arranged, scheduled or referred by a home care agency or registry must receive those services from an individual who has had a background check, is competent to provide home care services, and has been screened for tuberculosis and other communicable diseases as appropriate. Moreover, every consumer receiving services is entitled to certain basic consumer protections including notice of services to be provided, the cost of those services, and the identity of the individual who will provide the services. These are basic protections to which all consumers are entitled.

One commentator commented that the Department failed to meet the statutory requirement that the Department take into consideration the preferences and philosophies of persons with physical disabilities. The Department met on January 26, 2007, with representatives of what was, at that time, the Pennsylvania Protection and Advocacy, Inc. (PP&A), and is now the Disability Rights Network of Pennsylvania, and with other individuals representing organizations serving the disability community. The Department sought input from the individuals present at that meeting and engaged in an on-going dialogue in the process of drafting language to ensure the regulations

were not more far-reaching than had been intended. The language exempting entities that supply financial management services or supports coordination services or both to consumers of home and community-based services through Medicaid waiver or other publicly funded programs was developed through dialogue with representatives of organizations serving the disability community. Other changes included in these regulations, such as inclusion of a training program meeting training standards for providers participating in the Medicaid waiver or other publicly funded programs as an option for satisfying competency requirements, are a direct result of input from the disability community through the public comment process.

Section 611.4. Requirements for home care agencies and home care registries.

IRRC commented that proposed subsection (b) references other Federal, State and local standards and recommended that, to clearly guide the regulated community, the Department should identify the specific standards in the final-form regulations or maintain a list of applicable standards on the Department's website. The Department cannot list all applicable Federal, State and local standards in the final-form regulations or on the Department's website. It is the home care agency's or registry's responsibility to be aware of all the laws that affect the agency or registry, and any changes to those standards. The Department, in its regulations for health care facilities governed by the Act, routinely requires compliance with all applicable Federal, State and local standards, in accordance with § 813 of the Act (35 P.S. § 448.813). This requirement is included in order to apprise facilities that the inspection process could encompass a requirement included in another law to which the facility is subject. For example, the Department uses this provision in order to cite facilities subject to but not in compliance with the requirements of the Older Adult Protective Services Act (OAPSA) (35 P.S. §§ 10225.101 –

10225.5102). The Department of Aging, assigned responsibility for implementation of OAPSA, does not have the authority to conduct inspections of facilities to confirm compliance.

Compliance is confirmed by the State agency required to conduct facility licensure inspections.

The Department confirms compliance with OAPSA by nursing facilities, home health care agencies and hospices. Any deficiencies in compliance are cited pursuant to the provision in the applicable licensure regulations requiring the facility to be in compliance with all applicable Federal, State and local standards.

One commentator inquired whether a home care office needs to be ADA compliant. The Department believes the reference is to the Americans with Disabilities Act, 42 U.S.C. §§ 12101 et seq., which prohibits discrimination on the basis of disability in defined sectors of the economy. As noted above, it is the responsibility of each home care agency and home care registry to be aware of all Federal, State and local standards that apply.

One commentator inquired whether a home care agency seeking to be licensed in Pennsylvania must have a physical office in Pennsylvania. Since this regulation requires inspection to determine compliance with regulatory requirements, which is confirmed through, among other means, review of required documentation, a physical office in Pennsylvania is necessary.

Section 611.5. Definitions.

IRRC commented that the terms “activities of daily living” and “instrumental activities of daily living” are defined in the Act but are not found in this section and that they should be added to this section with a cross-reference to the statutory definition. One

commentator also suggested that the terms should be defined in the regulation as they are defined in the Act.

The term “instrumental activities of daily living” has been added to the definitional section and the definition references the Act. The term “activities of daily living” has not been defined because it is not used in the regulation. The term is not used in the regulation because the statutory definition is not in accord with the industry standard. The statutory definition states that “activities of daily living” include home management activities, respite care, companionship services and personal care, including, but not limited to, assistance with self-administered medications, feeding, oral, skin and mouth care, shaving, assistance with ambulation, bathing, hair care and grooming, dressing, toileting and transfer activities. The statutory definition also states that the term “activities of daily living” includes “instrumental activities of daily living.” The industry standard is that assistance with activities of daily living means assistance with self-administered medications, feeding, oral skin and mouth care, assistance with ambulation, bathing, hair care, grooming, dressing, toileting and transfer activities. The industry standard for assistance with activities of daily living does not include assistance with instrumental activities of daily living. Similarly, respite care and companionship services are separate from assistance with activities of daily living. To avoid confusion created by the statutory definition that is at odds with the industry standard, the Department has included the term “home care services” to refer to the gamut of services referenced in the statutory definition of “activities of daily living.” Because the term “activities of daily living” has a particular meaning, per the statute, the Department has selected the term “personal care” to refer to those services routinely associated, per the industry, with the term “assistance with activities of daily living.” The definition of the

term “personal care” in this section reflects this meaning. Throughout the regulation, the term “personal care” is used when referring to the kinds of hands-on care associated with “assistance with activities of daily living.”

IRRC also commented that the definition of “direct care worker” uses the term “services.” IRRC suggested that the term “services” should be defined. The Department elected to use the term to “home care services” instead, and a definition of that term has been included. As stated above, the Department has defined “home care services” to include one or more of the range of services referenced in the statutory term “activities of daily living.” Thus, “home care services” has been defined to include “personal care,” “assistance with instrumental activities of daily living,” “respite care,” “companionship services,” and “specialized care.” Each of the terms used in the definition of “home care services” has been separately defined, as suggested by a commentator, and requested by IRRC.

As mentioned in the discussion under § 611.3 above, IRRC also suggested that the definitions of “home care agency” and “home care registry” should be revised to mirror the statutory definitions of the terms. IRRC suggested that the portions of the definitions seeking to distinguish covered entities from non-covered entities should be moved to § 611.2 (relating to affected home care agencies and home care registries). The Department followed IRRC’s suggestion and deleted subsection (ii) from each definition. The information provided in proposed subsection (ii) is now provided in § 611.2(a). The definitions, as revised, do include language not included in the statutory definitions, however; both definitions clarify that the home care agency or registry supplies, arranges, schedules or refers direct care workers to provide

home care services *as directed by the consumer or the consumer's representative*. The Department added this language to acknowledge that consumers must be permitted to self-direct their home care services.

The Department also added definitions of “consumer control” and “independent living philosophy” in accordance with the suggestion of a commentator. The same commentator also suggested defining the terms “consumer direction” and “disability cultural competency.” The Department has determined not to add a definition of “consumer direction” as the concept has been incorporated with the definitions of “consumer control” and “independent living philosophy.” The Department also has determined not to add a definition of “disability cultural competency.” The Department is aware of the considerable impact and effect of the competency requirements imposed by this regulation and has determined not to add a requirement for cultural competency, generally, or disability cultural competency, specifically, at this time. The Department will continue to monitor the need to add this competency requirement.

One commentator, voicing overall approval and support of regulation of the home care industry, has suggested that the definitions of home care agency and home care registry are overly broad to the extent that they encompass organizations that may supply, arrange, or schedule employees to provide assistance to residents or consumers who live on the same campus as the supplying entity; e.g. nursing homes or personal care homes.

If an entity with a personal care home license or a nursing care facility license provides health care services (including skilled nursing care) or home care services to individuals that do not

reside in the personal care home or nursing care facility, the entity will need to obtain a home health care agency license or a home care agency or home care registry license, as applicable.

One commentator suggested that the Department revise the definition of “financial management services” to reference “other supports coordination services.” The Department addressed this concern by adding the reference to “supports coordination services” at § 611.2, addressing affected home care agencies and home care registries. That section now indicates, as discussed above, that the licensure requirements in Chapter 611 do not apply to entities that provide financial management services or supports coordination services or both to consumers of home and community-based services through Medicaid waiver or other publicly funded programs. A definition of the term “supports coordination services,” based on a suggested definition included in comments received, has been incorporated in the definitional section.

The Department has deleted the definition of “qualified health professional” in accordance with revisions to § 611.56 (relating to health screening). That section has been revised to delete the requirement for a “health evaluation” by a “qualified health professional.” The health care agency or registry must ensure the direct care worker is screened for tuberculosis in accordance with CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Settings.

Finally, the Department revised the definition of “inspection” to address issues raised by IRRC in response to proposed § 611.31 (relating to inspections). In response to proposed § 611.31, IRRC recommended that the regulation make clear whether inspections would be announced or

unannounced. IRRC also recommended that the Department state in the regulation that inspections would be conducted during regular business hours, in accordance with the requirements of 35 P.S. § 448.806d.

The Department, historically, in accordance with its longstanding inspection authority under the Act pursuant to § 812 (35 P.S. § 448.812), has conducted unannounced and announced inspections. The Act, since its inception, has required the Department to conduct inspections to determine the adequacy of the care and treatment provided or the continuing conformity of the licensees to the Act and to applicable local, State and Federal regulations. The Act gives the Department full and free access to the records of the facility, to persons served by the facility, and to the individuals providing services and their records. The Act permits the Department to interview, inspect and examine the licensee as necessary to determine the licensee's compliance with law and regulations. The Act does not address whether the entity being inspected should be apprised that the inspection will occur. The Department believes that the integrity of the inspection process is dependent, to a great extent, on its ability to conduct unannounced inspections. An entity that is aware that it will undergo an inspection is able, at least to some limited extent, to affect the outcome of the inspection. The Department must have the ability to assess compliance without the complications introduced by the knowledge of when the inspection will take place. At the same time, there are situations in which the Department must give at least minimal notice that the inspection will occur in order that representatives of the business are available to provide the Department the access it requires and is entitled to, pursuant to the Act, in order to determine compliance. Therefore, the Department will, on occasion, give the licensee 2 to 3 days notice of an impending inspection so that the Department is assured that

representatives of the licensee will be available when the Department's inspectors arrive for the inspection. Also, on those occasions when the Department determines to review records only, it may ask the licensee to forward copies of records essential to the inspection, in which case the licensee will be aware in advance of the inspection.

Accordingly, the Department has revised the definition of inspection to apprise licensees that an inspection may be scheduled or unscheduled. The Department also has added language to address the IRRC's concern that the requirement at § 806d of the Act (35 P.S. § 448.806d) that inspections occur "during regular business hours" be included in the regulation. Lastly, the Department, in order to eliminate confusion, has eliminated language stating that the inspection may or may not be on-site. The language of the regulation as revised allows the Department to conduct an inspection via record review only. If the Department conducts a record review, the Department may opt to require the licensee to forward those records essential to the review to the Department. The Department will review the records and then inform the licensee of the results of its review.

Section 611.51. Hiring or rostering of direct care workers.

The Act, at section 806c(b)(7) (35 P.S. § 448.806c(b)(7)) (listing information to be provided to a consumer prior to commencement of services) requires "documentation from the home care agency or home care registry that demonstrates personal face-to-face interviews with all employees from a home care agency or independent contractors referred by the home care registry and documentation of at least two satisfactory reference checks prior to referral to the consumer." In accordance with the Act's requirements, the Department published a proposed

regulation listing hiring or rostering prerequisites, including a face-to-face interview with the direct care worker and “satisfactory references.” Many commentators questioned what was a “satisfactory reference.” IRRC also has suggested that the Department explain what qualifies as a “satisfactory reference.”

Commentators who questioned the meaning of the term also offered suggestions; sometimes, the suggestions also included questions or points for consideration.

Several commentators suggested that a satisfactory reference should consist of dates of employment from a previous employer and personal references, and that home care agencies and registries should be permitted to obtain verbal, as opposed to written, references, that are then documented in the direct care worker’s file. One commentator suggested that the applicant should have documentation of two years continuous prior employment. Another commentator suggested that because many employers have adopted policies to confirm only employment dates, requiring more could be problematic. Another commentator questioned how to proceed if there is no prior employer. One commentator suggested that references could be supervisory or personal references, but should not come from family.

In response to IRRC’s suggestion, and after considering public comments, questions and suggestions, the Department has inserted in the regulation language establishing what constitutes a satisfactory reference. The reference need not be from a prior employer, in the event there is no prior employer, and can, but need not, include dates of employment. The reference, either verbal or written, and either supervisory or personal, must be from someone not related to the

individual, must be verifiable, and must confirm the ability of the individual to provide home care services.

Commentators also were concerned with the way in which this requirement would impact and affect existing direct care workers, and how documentation of a face-to-face interview and satisfactory references could be included in the file for a direct care worker employed or rostered prior to the effective date of the regulations. One commentator asked how to handle documentation of direct care workers already on the roster for the registry.

Regulations have only prospective effect, unless the regulation specifically states that it applies retroactively. If the regulation applies retroactively, there must be support in the statute for the requirement. Thus, the requirement of a face-to-face interview and of documentation of at least 2 satisfactory references will be applied prospectively only. Files for direct care workers hired prior to the effective date of the regulations that do not contain evidence of a face-to-face interview or of 2 satisfactory references will not constitute a violation of the regulations. However, those files must contain documentation of completion of requirements for establishing competency, a criminal background check, and a child abuse clearance, as applicable, since the regulations (at §§ 611.55, 611.52 and 611.53, respectively) each require, per the statute, the agency or registry to meet the applicable requirements, within the time frame specified, for existing direct care workers.

One commentator was concerned with the use of “personnel” as the modifier for “file,” because the term “personnel,” in the commentator’s view, connotes an employment relationship between

the individual and the entity maintaining the file. Since registries do not employ direct care workers, the connotation, in the commentator's view, is not appropriate. *Webster's* defines "personnel" as "a body of persons usually employed (as in a factory, office, or organization)." Thus, employment is the usual, but not requisite, connection between the person and the organization. While continued use of the term "personnel" would not be wrong, it may lead to some confusion. Therefore, in this section, the Department has determined to substitute the modifier "direct care worker" for "personnel." The file required to be maintained for each caregiver being supplied, arranged, scheduled or referred by a home care agency or home care registry to provide home care services will be referred to as a "direct care worker file." The commentator recommended deletion of the term "personnel" in subsequent sections as well. The Department accepted the recommendation and has deleted the term "personnel" from subsequent sections.

A commentator has suggested that this section must require that files for direct care workers must include all documentation required under § 611.54 (relating to provisional hiring), and that the regulation must require the agency or registry to maintain in the file any other documentation required under the Act or any of its implementing regulations or rules. The commentator also suggested that the Department should include a reference with this Section to the proposed retention of records provision.

The Department has accepted the commentator's first suggestion and has included within subsection (b) of § 611.51 a reference to § 611.54 (relating to provisional hiring). Direct care worker files must contain documentation related to the worker's provisional hire, if applicable.

The Department elected not to include language in the regulation requiring the agency to include in direct care worker files any and all other documentation that might be required under the Act or any of its implementing regulations. To the extent the Act or any other regulations promulgated pursuant to the Act and applicable to a home care agency and home care registry require the agency or registry to maintain certain documentation, the agency or registry will be required to comply with the regulation. The agency and registry will be required to have the documentation, and be able to produce the documentation if requested by a representative of the Department conducting an inspection, but the Department will not require the agency or registry to keep the requisite documentation in direct care worker files. If the information is pertinent to the individual, and the agency or registry chooses to maintain that information in the individual's file, it is within the agency's or registry's discretion to do so, but will not be dictated by the Department in this regulation. Finally, the Department elected not to include a reference to the proposed retention of records provision, as that provision has not been included in the final form regulation.

Finally, one commentator suggested that the prerequisites for hiring or rostering of direct care workers should be revised to require, as an additional prerequisite, that the direct care worker hold a GED (General Education Development) test credential or be a certified nursing assistant (CNA). The Department does not have the authority, per the statute, to impose this additional requirement. The statute does require training or testing prior to assignment or referral of a direct care worker, but no minimum level of education is dictated. Thus, the regulation lists options for training and includes mandatory content for training or testing programs developed by the agency or registry, but does not dictate a minimum education level for all direct care

workers. As stated previously, these regulations contain minimum requirements that all agencies and registries must meet in order to be licensed. Certainly, it is within the agency's or registry's discretion to require, as a matter of policy, that any direct care worker employed or rostered by the agency or registry must meet a minimum education requirement as determined by the agency or registry.

Section 611.52. Criminal background checks.

IRRC inquired regarding the need for subsection (d) which states that an agency or registry may require an applicant to furnish proof of residency. IRRC stated that, if this provision is needed, that the circumstances when proof of residency would be required should be included in the final-form regulation.

The Act requires the Department, prior to licensing a home care agency or registry, to determine that all individuals employed by an agency or referred by a registry, staff working within each entity and the owner or owners have obtained criminal history record information, in accordance with the requirements of § 503 of the act of November 6, 1987 (P.L. 381, No. 79) (35 P.S. §§ 10225.101 – 10225.5102), known as the “Older Adults Protective Services Act,” and maintain that information on file in the home care agency or registry office. Thus, the Department proposed regulations that mirror the existing background check provisions and prohibitions applicable to other health care providers under the Older Adults Protective Services Act (OAPSA). OAPSA, in § 502, (35 P.S. § 10225.502), requires the following information in connection with a criminal background check: (1) a report of criminal history record information from the State Police or a statement from the State Police that their central repository contains no

information relating to the individual, (2) where the individual is not and for the two years immediately preceding the date of application has not been a resident of the Commonwealth, a report of Federal criminal history record information. Per the statute, the Department of Aging is the intermediary for purposes of the second method of conducting a criminal background check. 35 P.S. § 10225.502(a)(2).

Therefore, regulations at 6 Pa Code Chapter 15, promulgated by the Department of Aging to implement the statutory requirements under OAPSA, require the individual to submit a State Police criminal history record, unless the individual is not and, for the 2 years immediately preceding the date of application, has not been a resident of the Commonwealth, in which case the individual must submit a Federal Criminal History record. See 6 Pa. Code § 15.141. The same section states that facilities may require the individual to furnish proof of residency by submitting one of the documents listed in the regulation.

When the Department promulgated these regulations, we purposely mirrored the requirements in OAPSA and in Department of Aging regulations. Our regulations also dictate the type of criminal history record that must be obtained based on the length of time the individual seeking to be employed or rostered has been a resident of the Commonwealth. Our regulations also permit, but do not require, the agency or registry to require the individual to submit proof of residency. It is the agency or registry that will be inspected for compliance with the criminal background check requirements. Allowing the agency or registry to obtain proof of residency will allow the agency or registry to take steps to ensure compliance, if the agency or registry chooses to do so.

IRRC also inquired whether a state-issued identification would suffice to prove residency. A commentator also suggested adding a state-issued identification as another method by which residency could be established. The Department agreed with the suggestion, and has added state-issued identification as an optional method of establishing residency.

One commentator pointed out that the Act requires a criminal background check not only for direct care workers, but also staff working within a home care agency or registry, and the owners. The Department agreed and, therefore, revised the regulation to include in the final form regulations a statement affirming the applicability of the criminal background check requirement to staff and the owners. Because the criminal background check requirement has wider applicability than to an “applicant for employment or referral,” the Department changed the reference to “individual required to submit or obtain a criminal history report.”

The commentator also suggested that the Department clarify subsection (j) of § 611.52, addressing requirements for individuals currently employed or rostered, to affirm the applicability of subsection (f), addressing records maintained. The commentator suggested that the regulation, at subsection (j), should state that the criminal background check information obtained for existing employees must be included in the direct care worker’s file. The Department elected not to revise subsection (j) because subsection (f) applies to all individuals employed or rostered, regardless whether they were employed or rostered before or after the effective date of the regulations.

The commentator also suggested that subsection (j) should state that a person currently employed whose State Police criminal history record reveals a prohibited conviction listed in 6 Pa. Code § 15.143, or whose Department of Aging letter of determination states that the individual is not eligible for hire or roster must be immediately terminated from the agency's employment or removed from the registry's roster. In response to this comment, the Department revised subsection (e) to state that a home care agency or home care registry may not hire, roster *or retain* an individual if the State Police criminal history record reveals a prohibited conviction listed at 6 Pa. Code § 15.143 (relating to facility responsibilities).

The commentator also pointed out that OAPSA, at § 508(1) (35 P.S. § 10225.508(1)), exempts from the act's criminal background check requirement existing employees employed for one year or longer. The commentator suggested subsection (j) should be revised to exempt from the criminal background check requirement direct care workers who have been employed or rostered for one year or more.

The Department notes that the Legislature did not amend OAPSA to include home care agencies and home care registries as covered entities; rather, the Legislature amended the Health Care Facilities Act to include home care agencies and home care registries as facilities that must be licensed by the Department and imposed a criminal background check requirement for workers, staff and owners, in accordance with § 503 of OAPSA (35 P.S. § 10225.503), as one of the licensure criteria. The Legislature did not include, by reference, other sections of OAPSA. The Legislature did not incorporate by reference the section of OAPSA that limits the applicability of the criminal background check requirement and provides an exemption for existing employees

employed for more than one year. Accordingly, the Department did not include an exemption for existing employees in its regulations.

A commentator inquired whether, for workers who have not been a Pennsylvania resident for two years, if both the Federal criminal history record and the Department of Aging letter of determination were required, or whether the Department of Aging letter of determination “includes” the Federal criminal history record. The Department of Aging letter of determination is a letter advising the agency or registry, based on the Federal criminal history record, whether the individual for whom the report was prepared may be hired or rostered as a direct care worker. In effect, the Department of Aging letter “includes” the Federal criminal history record.

A commentator inquired how often criminal background checks must be conducted. Another commentator suggested that criminal background checks should be repeated every 2 to 3 years. Once a criminal background check is completed, the criminal background check need not be repeated. Of course, if the agency or registry has reason to know that another check should be conducted, the agency or registry is advised to conduct the check. The regulation, however, does not require routine or repeated background checks.

One commentator recommended deletion of the modifier “personnel” in the term “personnel file” for the same reasons outlined in prior paragraphs of this preamble. The Department made the recommended revision. The commentator also recommended that the Department substitute the term “direct care workers” for the phrase “individuals employed or rostered.” The Department agreed with the recommendation and made the substitution where appropriate.

Section 611.53. Child abuse clearance.

Numerous commentators stated that they support the concept of a child abuse clearance for direct care workers who will provide care to a child, and even for office staff who have access to the child's personal and medical information. Commentators insisted that direct care workers who have no contact with children and staff who have no access to the child's records should not be required to obtain a child abuse clearance. Commentators also expressed concern over the expense to the agency or registry or to the individual associated with obtaining the clearance. Finally, commentators suggested that this requirement will lead agencies and registries to refuse to extend the scope of the agency's or registry's consumer base to persons under 18 years of age.

The Department has no power to vary the requirement clearly imposed by statute. The Act requires that "prior to licensing a home care agency or home care registry which provides services to persons under 18 years of age, the department shall determine that all individuals employed by an agency or referred by a registry, all office staff working within each entity and the owner or owners have obtained clearance from the child abuse registry, in accordance with 23 Pa. C.S. Ch. 63 (relating to child protective services) and maintain that information on file in the home care agency or registry office."

The rules that govern promulgation of regulations do not permit the Department to promulgate a regulation with language less stringent than the language in the Act on which the regulation is based.

A commentator recommended that the Department substitute the term “registrant” for “applicant” when referring to registries. Thus, the commentator would have the Department revise subsection (a) to state that an agency or registry shall “require each applicant for employment *or registrant for referral* as a direct care worker . . . to request a ChildLine verification regarding whether the applicant or member is named in the Statewide central Register as the perpetrator of a founded or indicated report of child abuse. . . .” (Emphasis added.) The Department has not accepted this recommendation because the term “applicant” has been used elsewhere in the regulations, “applicant” does not necessarily infer “for employment,” and introduction of a new term in this section would be unnecessarily confusing to the reader.

The Disability Rights Network pointed out that the requirement for a child abuse clearance applies to direct care workers, staff working within each entity, and to owners. Subsection (a) makes clear that the agency or registry must require each applicant for employment or referral as a direct care worker, and each member of the agency or registry office staff to request a ChildLine verification. Subsection (c) requires that the records maintained by the agency or registry for each individual employed or rostered include a copy of the ChildLine verification. Subsection (c) also requires the agency or registry to maintain copies of the ChildLine verification for the agency or registry owners and to make those copies available to the Department for inspection. Thus the regulation requires a child abuse clearance for direct care workers, staff, and owners.

The same commentator also recommended clarification of subsection (d) to state that the subsection applies to direct care workers, office staff, and owners. The

Department accepted the recommendation and revised subsection (d) to incorporate a reference to member of the agency or registry office staff. The Department did not include a reference to owners, since subsection (c) states that a copy of the verification for the owners shall be available for inspection.

Finally, the same commentator recommended that subsection (d) must clarify that a person currently employed or rostered, including an office staff member, who is named in the Statewide Central Register as the perpetrator of a founded or indicated report of child abuse must be immediately terminated by the home care agency or immediately removed from the home care registry's roster. To meet the commentator's concern, the Department revised subsection (b) to state that the home care agency or home care registry shall not employ, roster, *or retain* an individual named in the Statewide Central Register as the perpetrator of a founded or indicated report of child abuse.

Section 611.54. Provisional hiring.

IRRC requested that the Department explain its authority for including this section in the regulation. IRRC also questioned how the Department determined that 120 days is the appropriate length of time for provisional hire. More than one commentator also questioned the length of time for provisional hire, and one commentator suggested that the provisional hiring of someone who may have a criminal history could allow such a person to move from employer to employer with no tracking or consequences for them. The commentator believed that the potential threat to consumers is too great, and that, based on the speed with which criminal background check information may be obtained, that, at a minimum, the Department should

shorten the period of permitted provisional hire. Another commentator pointed out that OAPSA permits only a 30 or 90 day period of provisional hire, depending upon whether the individual being provisionally hired is and has been a resident of Pennsylvania for at least 2 years. The commentator is correct, and the Department has revised the appropriate length of time for provisional hire to mirror requirements in OAPSA and in the Child Protective Services Law, on which the Department's provisional hire provisions are based. The explanation of the Department's statutory basis for the provisional hire provision follows.

The Act requires the Department to ensure for each direct care worker, a criminal background check in accordance with OAPSA (35 P.S. §§ 10225.101 – 10225.5102) and a child abuse clearance, as applicable, in accordance with the Child Protective Services Law (23 Pa.C.S. §§ 6301 – 6385). Both statutes referenced in the Act permit provisional hiring. The Department relied upon the statutes referenced in the Act for statutory authority for provisional hiring.

Section 506 of OAPSA (35 P.S. § 10225.506) permits provisional hiring for a period of 30 or 90 days, depending upon whether the applicant is and has been, for at least two years, a resident of Pennsylvania. Thus, OAPSA expects that a resident of Pennsylvania will obtain the results of a criminal history report within 30 days, and allows an applicant who is not a Pennsylvania resident and has not, for the two years preceding the date of application, been a resident of Pennsylvania, who must therefore obtain a criminal history record from the Federal Bureau of Investigation, 90 days to obtain the report. OAPSA imposes conditions upon provisional hiring; those conditions have been incorporated in the Department's regulation on provisional hiring.

Section 6344(m) of the Child Protective Services Law (35 Pa.C.S. § 6344(m)) permits provisional employment for a single period not to exceed 30 days, or for out-of-State applicants, a period of 90 days, provided certain conditions are met. Those conditions have been incorporated in the Department's regulation on provisional hiring. Specifically, the Child Protective Services Law does not permit the provisionally hired individual to work alone with children; the individual must work "in the immediate vicinity of a permanent employee." Thus, the Department's regulation requires the home care agency or home care registry to supervise, or assign another direct care worker to accompany, a provisionally hired individual who will provide home care services to a consumer less than 18 years of age.

IRRC inquired, as did a number of commentators, whether the Department's conditions for provisional hire prohibit the hire of someone on a provisional basis until the individual has received the necessary training or testing. One commentator suggested revision of the regulation to make clear that the training or testing was required prior to assignment or referral, but not prior to hiring on a provisional basis. The Department agreed with the comment, and revised the condition applicable to establishing competency for a provisionally hired individual to clarify that the individual may be provisionally hired before receiving the requisite training or testing but cannot be assigned or referred to provide home care services until he or she has received the requisite training or testing to establish competency.

One commentator inquired whether the provisional hiring provision allows an agency or registry to hire someone who has not yet obtained a criminal background check and child abuse clearance, as applicable, and that the direct care worker then has the period of permitted

provisional hire to obtain the necessary background check and child abuse clearance. The commentator's summary of the provision is correct.

One commentator stated that the period for provisional hire, even for an applicant who has not resided in Pennsylvania for at least 2 years, should be 30 days. The commentator believes that agency or registry should be required to submit a request for a letter of determination, for an individual who has not been a Pennsylvania resident for at least 2 years, to the Department of Aging within 30 days of the application.

The Department agrees that the process for obtaining the criminal history report should start almost immediately after the application for employment or referral is submitted. The Department anticipates, as did the Legislature when it enacted OAPSA, that a criminal history report for a Pennsylvania resident may be obtained from the Pennsylvania State Police within 30 days, provided there is not a significant backlog. Because, however, a criminal history report for an individual who has not been a Pennsylvania resident for the requisite 2-year period must be obtained from the Federal Bureau of Investigation and the Department of Aging must review the report to determine whether the report contains any prohibited convictions under Pennsylvania law, it is likely that process could very well take more than 30 days, which is the reason that both OAPSA and the Child Protective Services Law, and, as a result, the Department's regulations, permit a longer period of provisional hire for an individual who has not been a Pennsylvania resident for the requisite 2-year period. The provisional hire provisions do impose certain conditions meant to protect the consumer, however, including supervision or

oversight of the individual who has not yet obtained a criminal background check or child abuse clearance.

As the Department stated when it proposed the provisional hire provision, this provision permits, but does not require, provisional hiring. A home care agency or registry is free to assess the risks associated with provisional hiring and determine that the risks outweigh the benefits. If the agency or registry chooses to hire individuals on a provisional basis, however, this regulation establishes the parameters for provisional hiring.

Finally, a commentator suggested the addition of the word “immediately” at the end of the second sentence in subsection (b), to mirror the wording in the first sentence. The Department agreed with the comment, and made the suggested change.

Section 611.55. Competency requirements.

The first, and most immediately obvious, change to this regulation from proposed to final is the substitution of the term “competency” for “training” in the title and in the body of the regulation. The Department made this change not because the Act uses the term “competency,” not “training,” as was suggested by one commentator (the statutory provision does refer to training at § 806d.1(2) (35 P.S. § 448.806d.1(2))), but because the Department agreed that the statutory provision is directed at requiring competency, not training, prior to assignment or referral of a direct care worker. Training, received prior to or after hire or roster, is simply one method by which competency may be established. The Act also permits the agency or registry to verify, via

a competency examination, that the individual is competent to provide services. Regardless of the method used, however, basic competency is the goal.

The Department also agreed with the commentator who suggested the Department substitute “direct care worker” for “individual,” eliminate references to “personnel,” and substitute “review” for “reassessment” of competency. In the commentator’s view, “reassessment” implies oversight. The suggested changes have been incorporated. The same commentator suggested the Department add “consumer feedback” as a method of reviewing the direct care worker’s competency to provide home care services, and the Department accepted the recommendation.

As for the substantive requirements of the regulation, IRRC pointed out that Representatives Mundy and Hennessey and other commentators suggested that not all direct care workers should be required to establish competency for tasks listed in the proposed regulation at subsection (d), items (10) through (15) (e.g. bathing, shaving, grooming and dressing, hair, skin and mouth care, assistance with ambulation and transferring, meal preparation and feeding, toileting, and assistance with self-administered medications). Many commentators commented that ensuring that all direct care workers are able to provide personal care is an unnecessary expense, as many direct care workers prefer not to provide personal or “hands-on” care. One commentator said that the depth and scope of the subjects listed in the proposed rulemaking is excessive for caregivers who provide only homemaker-companion care. Commentators also pointed out that the already strained workforce would shrink, as potential direct care workers will decline the work opportunity if required to participate in training or be tested for skills the direct care worker has no intention of using. Several commentators stated that the requirements as set forth in the

proposed regulation would force agencies and registries to hire only individuals who had received training, or were certified, as certified nursing assistants. One commentator said that the scheme set forth in the proposed regulation would drastically reduce the number of people who will be able to provide care to clients, that it would eliminate older caregivers who might be willing to provide care for their peers but have no interest in training or competency examinations. The commentator inquired what might happen to the client who is very comfortable with her older caregiver who is not willing to take a competency examination.

As noted above, the Department agreed with comments suggesting that not all direct care workers must be competent to provide every possible home care service and revised the regulation accordingly. As revised, the training provision allows a direct care worker to establish competency by (1) having a valid nurse's license in this Commonwealth, (2) demonstrating competency by passing a competency examination developed by the home care agency or home care registry in accordance with regulatory requirements , or (3) successfully completing a training program developed by the agency or registry in accordance with regulatory requirements, the home health training program outlined at 42 C.F.R. 484.36, the nurse aid certification and training program sponsored by the Department of Education, the training program meeting the training standards of the Medicaid waiver or other publicly funded program, or other program identified by the Department by subsequent publication in the *Pennsylvania Bulletin* and on the Department's website.

Stakeholders and advocacy groups had inquired whether the competency requirements in these regulations would supersede the training requirements for providers serving clients of the

Medicaid waiver programs. An advocacy group also requested that the Department list the Medicaid waiver training program(s) in the regulation as an approved method of establishing competency. The Department reviewed the training requirements for the Medicaid waiver programs and determined that the training meets or exceeds the Department's minimum requirements to establish competency to provide home care services. Therefore, a training program meeting the training standards of the Medicaid waiver or other publicly funded program was added as another training program option.

The Department also has included language permitting the Department to add to the list of approved training programs without having to revise the regulation. The Department will be able to identify other training programs, as they are developed, by publishing notice in the *Pennsylvania Bulletin* and on the Department's website.

The Department did not include, in its listing of approved training programs, "a personal care worker training credentialing program." The Act includes "successful completion of a personal care worker training credentialing program approved by the department" as an optional method for meeting the Act's competency requirements. 35 P.S. § 448.806(d.1)(1)(iv). The Department was not able to locate a personal care worker training credentialing program for the Department to approve or disapprove; thus, that option was not included in the regulation.

If the agency or registry establishes its own training program or competency examination, the agency must ensure the direct care worker is competent in the home care services the direct care worker will provide. The final regulation now states that a competency examination or training

program developed by the agency or registry must address, at a minimum, the following subject areas: confidentiality; consumer control and the independent living philosophy; instrumental activities of daily living; recognizing changes in the consumer that need to be addressed; basic infection control; universal precautions; handling of emergencies; documentation; recognizing and reporting abuse and neglect; and dealing with difficult behaviors. These subject areas, with the exception of “instrumental activities of daily living,” were listed in the proposed regulation at subsection (d), items (1) through (9). The term “instrumental activities of daily living” was substituted for the term “home management,” listed in the proposed regulation as item (16). The competency examination or training program for a direct care worker who will provide personal care also must address the following subject areas pertinent to personal care: bathing, shaving, grooming and dressing; hair skin and mouth care; assistance with ambulation and transferring; meal preparation and feeding; toileting; and assistance with self-administered medications. These are the subject areas that had been listed in the proposed regulation at subsection (d), items (10) through (15).

The term “assistance with instrumental activities of daily living” was substituted for the term “home management” in response to questions from commentators regarding the meaning of the term “home management.” Since the intent was to refer to some portion of the services included in “instrumental activities of daily living,” the Department elected to use that term rather than create another term. “Instrumental activities of daily living” is defined in the regulation by reference to the Act. The Act defines the term to include meal preparation, shopping and errands, telephone use, light housework, laundry and transportation. 35 P.S. § 448.802a.

An advocacy group commented that the topics to be covered for all direct care workers should be expanded to include, in addition to “consumer control” and “independent living philosophy,” “consumer direction” and “disability cultural competency.” The Department has defined “consumer control” to incorporate the concepts embraced by the term “consumer direction.” The Department has determined not to require cultural competency training, generally, or disability cultural competency, specifically, at this time, for the reasons given in § 611.5 (relating to definitions).

The advocacy group also asserted that “consumer control” and the “independent living philosophy” not only must be separate mandatory subject areas for purposes of establishing competency of a direct care worker, they must be incorporated into every other subject area. The advocacy group proposed that “recognizing changes in the consumer that need to be addressed” should be revised to state that any recognized change will be communicated promptly to the consumer and that consumer control will be followed. The advocacy group also proposed that, because aspects of a person’s disability are often wrongly interpreted as difficult or confrontational, “dealing with difficult behaviors” should include communication skills. The advocacy group also commented that the regulation should make clear that the purpose for establishing competency in “home management” is to ensure that the consumer’s instructions regarding home management can be implemented. Finally, the advocacy group stated that it anticipated that the Department may develop guidelines for ensuring competency in each of the mandated subject areas and requested to have input in the development of those guidelines.

Home care agencies and registries are required to ensure competency in consumer control and the independent living philosophy. The Department has determined, at this juncture, to leave to agencies and registries the best method for ensuring competency in both areas. Certainly, neither topic can be addressed in a vacuum. The Department fully anticipates that both topics will be addressed in the context of providing home care services, and that once competency is established, direct care workers will understand how these concepts affect the manner in which home care services are provided to consumers. Compliance will be monitored during the Department's licensure inspections. If, subsequently, the Department determines that more direction is needed, the Department may consider preparing guidelines and will seek input and advice from stakeholders at that time.

The Department believes that the final form regulation addresses the needs and concerns of the industry, as expressed in comments the Department received. The final form regulation accommodates the commentator who said she would like the ability to create her own training program in order to reduce costs and the commentator who stressed that the agency or registry should have the ability to develop its own program to ensure competency prior to assignment or referral. The regulation meets the concern of the commentator who said that his or her agency did not have the physical space to provide training and suggested that the Department simply require a competency examination that could be designed by the home care agency or registry. The final form regulation also accommodates the commentator who suggested that there be the option for an examination or training geared to the individual who will provide homemaker/companion services, since getting the caregiver to the client in a timely fashion is crucial.

The final form regulation on training makes clear that there are options available to the agency or registry. If the individual is licensed as a nurse or is a certified nursing assistant, that individual is already qualified to provide home care services. If the individual is not already trained, the agency or registry can provide training, via its own program or another program listed in the regulation, or the agency or registry can administer a competency examination. The training provided or competency examination administered can vary depending upon the nature of the home care services the individual will provide.

The Department was not able to address all concerns raised by commentators. Many commentators had concerns regarding the cost to the agency or registry associated with ensuring direct care workers are competent to provide the care they are assigned or referred to provide. One commentator stated that it is cost prohibitive to pay future caregivers for hours of training before the agency or registry could begin to bill for the services to be provided by the caregiver. Another commentator suggested that if extensive classroom training is required, the result will be overbearing expense to the agency or registry that will be not reimbursed by public payment sources such as the Medicaid waiver programs. Another commentator was concerned that the agency or registry would incur the expenses associated with the training of a direct care worker who, once trained, would then leave the agency or registry to go to another agency or registry. Another commentator stated that if individuals must be paid to be trained, the administrative costs for the agency will rise, which would mean an increase in costs to the consumer.

Commentators also raised other concerns that the Department was not able to address. One commentator said that hours of training will cause too long a delay from the date of hire or roster

to the date when the individual can be assigned or referred in an environment in which agencies and registries struggle to find individuals to provide the care that is requested. Another commentator stated that individuals who intend to work only part-time, who might have one or more other part-time jobs, cannot commit to long training periods. Another commentator suggested that the most valuable training is training that occurs over a period of time as the direct care worker gains experience.

The Department concurs that as a direct care worker gains on-the-job experience, he or she will become more skilled. In addition, the agency or registry may wish to offer additional training, to hone skills and teach new ones, as part of overall direct care worker retention goals for the agency or registry. The Department encourages such efforts. Ongoing training, however, is not required by the regulation. Ensuring basic competency upon hire or roster prior to assignment or referral, either through training or a competency examination, and yearly review of skills, is required. As noted, ongoing training could make the review process go more smoothly.

The regulation, per the statute, requires the agency or registry to ensure that each direct care worker, prior to being assigned or referred to provide direct care services, has the basic skills needed to provide the home care services he or she has been assigned or referred to provide. The Department acknowledges there are costs associated with ensuring basic competency. The regulation, in accordance with the statute, contains options for meeting that requirement. Different options mean different costs. Providing training will mean more time and higher costs, but may be the better way to ensure competency. Agency and registry owners will need to weigh options and associated costs and make the decision that is best for the agency or registry.

Owners will need to decide whether the agency or registry will pay a direct care worker to be trained. That issue, like the issue of how to accommodate a part-time worker, will be a matter of discretion for the owner of the agency or registry, based upon the agency's or registry's own recruitment and retention goals or difficulties. The Department recognizes, as did the Legislature when it amended the Act to license agencies and registries and impose certain requirements in connection with licensure, that ensuring competency of a direct care worker, through training or testing, prior to assignment or referral, may mean increased costs for industry as a whole, which may be passed onto the consumer. The ultimate goal, however, is to promote the health, safety and adequate care of the consumers of services provided by home care agencies and home care registries and to assure safe, adequate and efficient home care agencies and home care registries.

IRRC pointed out that the proposed regulation required a competency examination to be "approved by the Department." IRRC inquired how approval would be accomplished. IRRC also pointed out that Senator Corman commented that it was not clear whether there would be a statewide test, and if so, how it would be graded or administered in a timely fashion so that new employees or contractors could begin employment. IRRC stated it agreed with Senator Corman's comment and requested that these issues should be clarified in the final-form regulation.

Other commentators made similar inquiries. One commentator inquired regarding a competency examination "approved by the Department," and asked whether there was an examination available that had been approved by the Department. Another commentator

inquired whether there will be guidelines, outlines, formats and suggested subject matter made available to agencies and registries by the Department. Another commentator asked that there be a list of accepted training programs and requested that the industry be involved in reviewing programs and assembling the list of accepted training programs. Another commentator inquired whether the Department has training programs or competency examinations that are available to agencies or registries to use. One of the trade associations recommended that the Department offer at least 3 pre-approved competency examinations to assist agencies and registries, and the trade association offered to assist in the preparation of the pre-approved competency examinations.

Commentators also inquired how to submit a competency examination for approval by the Department. One commentator inquired whether the competency examination could be a written examination. Another commentator asked if a written multi-question quiz on the topics listed as required subject matter would suffice.

In the final form regulation addressing competency requirements, the Department deleted language indicating the training program or competency examination developed by the agency or registry must be “approved by the Department.” The Department seeks to eliminate the notion that the training program or competency examination must be reviewed and approved by the Department prior to use. An agency or registry planning to develop its own training program or competency examination need not submit the training program or competency examination to the Department for approval prior to use. A training program or competency examination developed by the agency or registry that meets requirements of the regulation is an approved

training methodology. If an agency or registry opts to develop its own training program or competency examination, the Department will make the determination during inspection whether the training program or competency examination meets requirements of the regulation and whether direct care workers are appropriately trained prior to assignment or referral. If, upon inspection, the Department discovers that a direct care worker did not successfully complete the training or competency examination, or that the training program or competency examination does not meet the requirements of the regulation, or both, then the Department will cite the agency or registry for failure to comply with the competency regulation.

The agency or registry need not develop its own training program or competency examination. Per the statute, the Department has indicated in the regulation the existing programs which have the Department's approval, that the agency or registry may use as the agency's or registry's mechanism to ensure competency. An advocacy group has suggested that, because each training program option listed in the statute includes the language "approved by the department," the Department has the authority and must require each of those training programs to include, as part of the training program curriculum, training in consumer control and the independent living philosophy. The advocacy group also commented that the nurse aide program, per the statute, must be approved by the Department of Health, not the Department of Education, the agency referred to in the proposed regulation in connection with the nurse aide training program.

In the final regulation, the Department identifies the nurse aide training curriculum as one "sponsored" by the Department of Education, because it is the Department of Education that offers the curriculum. The Department of Health has no training programs appropriate for direct

care workers. The nurse aide training curriculum sponsored by the Department of Education is “approved” by the Department by virtue of its inclusion in the regulation.

The other training programs are also “approved” by the Department by virtue of their inclusion in the regulation. The Department has determined that the training programs will ensure the competency of the individual to provide home care services. No further action is anticipated. The Department has no authority to dictate the curriculum content for those training programs.

The Department also has given agencies and registries the parameters for development of the agency’s or registry’s own training or testing mechanism which will be examined upon inspection of the agency or registry. The Department will not be developing optional competency examinations for use by agencies or registries. The Department is willing, however, to receive recommendations of competency examinations or training programs that meet the requirements of the regulation that could be made available to all home care agencies and home care registries. If, upon review of the recommendation, the Department determines that the training program or competency examination does meet the requirements of the regulation, the Department will publish notice in the Pennsylvania Bulletin, for the benefit of the home care industry as a whole, of the availability of the competency examination or training program. Certainly, if a trade association wishes to develop a model competency examination or training program, the Department will review the examination or program developed by the trade association, and if the Department determines that the examination or program meets the requirements of the regulation, it will publish, for the benefit of the home care industry as a whole, notice of the availability of the training program or competency examination.

A commentator asked whether new caregivers will have 2 years to take and pass a competency examination since new caregivers cannot be on the caregiver roster until they have passed a competency examination and there is no approved examination. As the Department stated above, the Department will not be supplying an “approved” competency examination. If an agency or registry chooses to establish competency through administration of a competency examination, the agency or registry will need to develop or identify a competency examination that meets the regulatory criteria. This regulation takes effect upon publication. After the effective date, no new direct care worker may be assigned or referred to provide home care services prior to satisfying the competency requirement. Direct care workers employed or rostered prior to the effective date have 2 years from the effective date to satisfy the competency requirement.

A commentator pointed out that the regulation does not specify the number of hours of training that must be provided. The commentator stated that her agency requires its direct care workers to have 40 hours of orientation and an additional 12 hours of training each year. The commentator is correct; the regulation does not require a specific number of hours of training that must be provided, if the agency or registry chooses to provide its own training. The Department’s concern is that the required subject matter is covered. The Department will not dictate the time it should take to cover the required subject matter.

A commentator suggested that the regulation should require all direct care workers to meet the competency requirements within 30 days of the individual’s hire or roster date. The Department has declined to impose a time frame within which the competency requirement must be

accomplished after an individual is hired or rostered. The time frame within which the mandatory training or testing must be accomplished is within the discretion of the agency or registry.

An advocacy group has suggested that the regulation should be revised to state that the competency requirement applies to any person that has direct contact with a consumer, including specifically, an owner or member of the administrative staff for the agency or registry who, in an emergency, substitutes for the direct care worker who is unavailable. The Department has elected not to include an explicit statement in the regulation to this effect. If an office staff member is assigned or referred to provide care to a consumer, or the owner takes on the responsibility to provide care, the office staff member or owner becomes a direct care worker. Under the regulation, a direct care worker cannot provide home care services until he or she is competent to do so.

A commentator requested clarification of the provision that states that documentation of satisfactory completion of competency requirements is transferable from one home care agency or registry to another home care agency or registry. The commentator inquired how the documentation would be transferred from one agency or registry to another. The Department suggests that the direct care worker seeking to be employed or rostered by another agency or registry need simply provide a photocopy of what was included in the direct care worker's file maintained by the prior agency or registry. Another alternative is for the prior agency or registry to supply a letter either to the new agency or registry or to the direct care worker, verifying successful completion of competency requirements.

Lastly, a commentator stated that this section does not address those activities that the direct care worker is prohibited from providing; e.g. eye drops, fleet enemas, suppositories etc. This set of regulations establishes rules for licensure of home care agencies and registries that provide home care services. Home care services are defined to include personal care, assistance with instrumental activities of daily living, companionship services, respite care, and specialized care. Each term included in the definition of home care services also is defined. Home care services do not include nursing services or skilled care. If a home care agency or home care registry seeks to provide or offer nursing or skilled care, the agency or registry would need to be licensed as a home health care agency.

Section 611.56. Health screening.

Commentators almost unanimously objected to the proposed regulation requiring a health screening prior to referral or assignment of a direct care worker. The regulation as proposed would have required a “screening assessment” to establish that the individual had been screened for tuberculosis, and for 5 other communicable diseases or conditions which were listed in the proposed regulation. Commentators have inquired regarding the meaning of the term “screening assessment” and expressed concern that direct care workers would need to undergo more onerous scrutiny as to their health status than other workers in the health care field.

IRRC commented that Representatives Mundy and Hennessey, Senator Corman and several other commentators question how the “screening assessment” required by the proposed regulation would be accomplished. IRRC inquired whether a laboratory test would be required or whether a physical examination by a doctor would be sufficient. Many commentators

expressed concern that the Department was proposing an invasive procedure necessitating the use of blood and stool samples to detect communicable disease. Several commentators inquired whether the screening assessment could consist of a questionnaire. IRRC recommended that the Department amend this section to clearly state how the “screening assessment” must be completed.

IRRC also pointed out that commentators asserted that the list of conditions which must be screened for far exceed the screening required for employees of other licensed health care facilities. IRRC inquired how the Department determined that the health screenings in the proposed regulation are appropriate for use with agency or registry direct care workers.

One commentator said that prospective direct care workers do not have access to clinics that would provide the necessary health evaluation, and that home care agencies and registries do not have qualified health professionals on staff to perform the evaluation. The commentator said that lack of access to a qualified health professional would further exacerbate the growing shortage of direct care workers.

The Act requires that “prior to referral to consumers, all individuals and any other office staff or contractors with direct consumer contact must obtain documentation from a physician or other appropriate health care professional that the individual is *free from communicable disease, including, at a minimum, a tuberculosis screening* as outlined by the screening guidelines of the department.” 35 P.S. § 448.806(d.1)(5). (Emphasis added). Thus, in the draft regulations, circulated prior to publication of proposed regulations, the Department suggested that the direct

care worker should be screened for tuberculosis, in accordance with guidelines issued by the Federal Centers for Disease Control and Prevention (since these are the guidelines routinely used by the Department), and tested as necessary, and screened for “other communicable diseases.” Although the draft regulation did not provoke a great number of questions during the stakeholder process, the Department anticipated that once the regulations were in effect, the Department would receive questions about the kind of communicable diseases for which the individual must be screened, and the kind of communicable diseases for which the direct care worker must be screened.

In the process of revising the draft regulation dealing with health evaluations prior to publication of the regulation as proposed, the Department considered incorporating by reference a regulation included with the Department’s communicable disease regulations at 28 Pa. Code Chapter 27, such as 28 Pa. Code § 27.155 (relating to restrictions on health care practitioners) or 28 Pa. Code § 27.71 (relating to exclusion of children, and staff having contact with children, for specified diseases and infectious condition). The Department ultimately rejected incorporating by reference one of its communicable disease regulations. Ruling out infectious conjunctivitis, for example, listed in 28 Pa. Code § 27.71 (relating to exclusion of children, and staff having contact with children, for specified diseases and infectious conditions) during a physical examination conducted prior to the individual’s start date would not provide any assurance regarding the individual’s actual condition on the start date. Requiring a complete physical and potential testing of blood and stool samples to rule out all of the conditions listed at 28 Pa. Code § 27.155 (relating to restrictions on health care practitioners) would be cost prohibitive.

Ultimately, the Department included in the proposed regulation a list of communicable diseases for which the individual would be *screened* at the same time the individual was *screened* for tuberculosis risk factors. These diseases and conditions put the consumer at significant risk, and screening for these diseases and conditions sometime prior to the direct care worker's start date, in the Department's view, constituted a valuable and useful exercise.

As stated above, stakeholders were consistent in their criticism of the proposed regulation, although much of the criticism stemmed from the confusion over the meaning of the term "screening assessment." The County Commissioner Association of Pennsylvania supported the Department's attempt to protect consumers from workers with communicable diseases or conditions but believed that the proposed rulemaking applicable to annual screenings was excessive, intrusive and too expensive to implement. They pointed out, as did many other commentators, that the proposed screening far exceeded the kind of screenings required in other health care facilities licensed under the Act. The Association requested that the Department adopt a more broadly based regulation that would require home care agencies or home care registries to assure that employees do not have communicable disease or conditions but would not prescribe the process for doing so.

The Department also received many comments regarding the 180-day time frame in the proposed regulation. Several commented that achieving compliance was going to be challenging. Several commented that the health evaluation should be obtained in the one year prior to the start date.

As requested, the Department has revised the regulation. The final regulation has been titled “Health screening” and states that the home care agency or home care registry shall insure that each direct care worker and other office staff or contractors with direct consumer contact, prior to consumer contact, provide documentation that the individual is free from active mycobacterium tuberculosis. The regulation instructs that the determination regarding the individual’s status for tuberculosis should be made using the current CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Settings. The documentation must be dated not more than 1 year prior to the individual’s start date. The requirement that the direct care worker must obtain the documentation every 12 months has been deleted.

One commentator inquired whether a registered nurse could perform the health evaluation. A “health evaluation” is no longer required. The regulation now merely requires a health screening for tuberculosis. CDC guidelines do not require a physician, physician’s assistant, or certified registered nurse practitioner to conduct the screening for tuberculosis. Therefore, the Department has deleted the requirement that a “qualified health professional” provide the documentation regarding the direct care worker’s health status and deleted the definition of “qualified health professional” from the definitional section at § 611.5 (relating to definitions).

One commentator inquired whether the Commonwealth has a standard form that should be completed for the direct care worker. The Department will not be supplying a standard form or requiring a standard format. As long as the documentation establishes that the individual was screened for and is free from active tuberculosis, the documentation will suffice.

One commentator suggested the regulation should require agencies and registries to have a policy that workers should not present themselves for work if they have symptoms of acute illnesses such as fever, jaundice, or diarrhea. The Department considered the suggestion and determined not to impose the requirement for a policy as suggested by the commentator. The Department will not require the policy; however, the Department is in favor of such a policy and would encourage agencies and registries to put such policies in place.

One commentator said that if the agency must bear the cost of “testing,” the administrative costs for the agency will increase which will raise the hourly rate to the client. Other commentators also commented on the cost to the agency or registry. The regulation does not assign the cost of the health screening to the agency or registry. The regulation merely prohibits the agency or registry from assigning or referring a direct care worker to provide services until the documentation that the screening has been conducted has been obtained. If, in the interest of having the direct care worker prepared to begin providing services in a more prompt fashion, the agency or registry wishes to arrange and pay for the health screening, that is within the discretion of the agency or registry. The agency or registry also can choose to impose the obligation on the direct care worker to obtain and supply the necessary documentation to the agency or registry, as a condition of employment or roster.

Several commentators inquired whether the regulation will address the agency’s or registry’s obligations with regard to existing employees. After the effective date of the regulation, the home care agency or home care registry cannot assign or refer a direct care worker to provide home care services unless documentation of the health screening meeting the requirements of the

regulation is part of the individual's file. In accordance with the recommendation of one or more commentators, the regulation gives the agency or registry 180 days to obtain the necessary documentation for direct care workers employed or rostered as of the effective date of the regulation.

A commentator requested the Department delete references to "personnel." The Department made the changes as requested. The commentator also suggested that the Department replace "180 days" with "one year" prior to the individual's start date. The time frame, if not the exact wording, has been inserted in the final regulation. The commentator suggested the Department delete the five communicable diseases, in addition to tuberculosis, listed in the proposed regulation. The Department accepted this recommendation. The commentator suggested that the Department replace the reference in subsection (c) to "individual employed or rostered by the agency or registry" with "direct care worker." The Department accepted this recommendation.

Section 6 11.57. Consumer protections.

IRRC pointed out that commentators stated that there are situations when there is not time to get an information packet to the consumer or the consumer's family member prior to the start of services, when, for example, the consumer is being discharged from the hospital and is in immediate need of services and the family member requesting the services lives out of town. IRRC inquired whether the family member could give verbal permission for services to begin without having first received the required information, and asked that this be clarified in the final form regulation.

The Act requires that “each consumer or the consumer’s legal representative or responsible family member shall receive an information packet from the home care agency or home care registry *prior to the commencement of services. . . .*” 35 P.S. § 448. 806c(b). The information packet is to include a listing of available services that will be provided to the consumer, the hours when the services will be provided, fees and costs for the services on an hourly or weekly basis, Department contact information for agency and registry licensure requirements and for compliance information, information regarding the Department’s 24-hour hotline and the local ombudsman program, and information about the direct care worker who will be providing home care services, including information about the hiring process and training or testing to ensure competency. The information packet, per the statute, also must include a disclosure whether the direct care worker is an employee or an independent contractor and information regarding the respective employment and tax obligations of the consumer and the agency or registry.

The Department has no authority to alter the statutory requirement for written notice of the requisite items prior to the commencement of services.

One commentator suggested that the language in subsection (c)(6) of the proposed regulation requiring an agency or registry to provide, in advance of services, information regarding hiring and competency requirements applicable to direct care workers, a description of the manner and frequency of periodic reassessment of direct care worker competency, and information regarding documentation maintained by the home care agency or home care registry to confirm compliance with hiring and training requirements was not likely to be helpful to the consumer. The commentator suggested that the regulation should require the agency or registry to provide

information specific to the skills and abilities of the direct care worker and to list the services the direct care worker can and cannot provide.

Another commentator also commented on the awkward language in proposed subsection (c)(6), and suggested that the Department merely require the agency or registry to confirm for the consumer, prior to commencement of services, that all direct care workers referred have: (1) successfully completed a competency examination approved by the Department of Health; (2) acceptable reference checks; (3) a face-to-face interview, (4) a health screen completed by a licensed health care professional; and (5) a criminal background review conducted by the Pennsylvania State Police or the Federal Bureau of Investigation.

The Department agreed with the comments and has revised the proposed regulation to require general information regarding hiring and competency requirements applicable to direct care workers, and information about the specific services the direct care worker assigned to the consumer will provide. While the Department did not add language to the regulation requiring the agency or registry to include information about services the direct care worker will not provide, it is certainly with the discretion of the agency or registry to include this information in the packet to be given to the consumer or the consumer's family member or legal representative.

The same commentator also suggested that the Department clarify subsection (c)(2) which requires the agency or registry to provide information, in advance of the service start date, regarding the hours when direct care services would be provided. The commentator suggested

that the Department add the following language to the subsection: “Such hours that are requested by and agreed to by the consumer.”

The final form regulation now requires the agency or registry to provide the consumer or the consumer’s family member or legal representative a listing of the actual home care services to be provided to the consumer and the hours during which the services will be provided. The hours identified when services will be provided are those mutually agreed upon by the consumer and the agency or registry. The notice will serve as confirmation for the consumer.

One commentator suggested that the home care agency or registry, prior to commencement of services, must provide a full disclosure statement acknowledging the responsibilities of the agency or registry. The commentator went on to list the items the commentator believed should be included in the disclosure statement: the employment status of the direct care worker, specifically, an explanation of which party is responsible for payment the wages or salary of the direct care worker, paying federal social security taxes and state and federal unemployment taxes for the direct care worker, and procuring worker’s compensation or liability insurance covering injury to the direct care worker. The commentator also suggested that the disclosure statement should identify which party is responsible for supervising the direct care worker, assigning duties to the direct care worker, and for hiring, firing, and discipline of the direct care worker. The commentator stated that the disclosure statement should identify the party responsible and liable if a direct care worker is hurt on the job.

The commentator stated that it is critical that the disclosure form include a place for the consumer's signature and that the regulation require the consumer's signature on the disclosure form as a mechanism for acknowledging receipt and understanding of the information on the disclosure statement. The commentator stated that the home care agency or registry should be required to keep a copy of the signed disclosure statement in agency or registry files. Another commentator suggested that the regulation should require documentation of when consumer information was provided as well as dates informational packets were mailed.

The regulation states that information provided to the consumer must include a disclosure addressing the employee or independent contractor status of the direct care worker providing services to the consumer, and the resultant respective tax and insurance obligations and other responsibilities of the consumer and the home care agency and home care registry. The regulation states that the disclosure must be in the format as published by the Department in the *Pennsylvania Bulletin* within 60 days of the effective date of the regulation. As indicated by the outline of information required to be included in the disclosure statement, the Department fully intends that the disclosure statement will address the points listed by the commentator.

As for the suggestion that the Department should require the agency or registry to obtain the consumer's signature on the disclosure form, the Department will take into consideration the suggestion when drafting the disclosure form to be published in the *Pennsylvania Bulletin* following publication of the final form regulations. As for the suggestion that the regulation should require the agency or registry to maintain documentation to establish compliance with the requirements applicable to consumer protections, the Department has added a subsection (e) to

the regulation to require the agency or registry to maintain documentation on file at the agency or registry for verification by the Department of compliance with the requirements in the regulation.

One commentator requested that disclosure form to be drafted by the Department should be made available for public comment prior to publication in the *Pennsylvania Bulletin*. The Department will make every effort to obtain stakeholder input on the disclosure form prior to publication. The comment process will be brief, however, in light of the Department's obligation, per the language of the regulation, to publish the form within 60 days of the effective date of the regulations. The regulations are effective upon publication.

One commentator inquired whether the requirement that consumers be informed of tax obligations and employment responsibilities was pertinent only to registries and consumer employers. The responsibility to provide information listed above applies to home care agencies and registries. If a home care agency will assume all employment responsibilities and tax obligations associated with employment, this is information that should be provided to the consumer. The regulations do not apply to "consumer employers." "Consumer employer" is a term used in the Medicaid waiver and other publicly funded programs to refer to the individual receiving services who has elected to serve as employer of the individual providing the services to the consumer. A "consumer employer," most likely, does not meet the definition of a "home care agency" or "home care registry" as set forth in the Act and in the definitional section in these regulations. Only those entities who meet the definition, and are not excluded under the terms of the Act or these regulations (see § 611.3 (relating to affected home care agencies and

home care registries), need to obtain a license and comply with the requirements set forth in the Act and these regulations.

Another commentator inquired whether the requirement that information be provided to consumers concerning the services to be provided, the hours when services will be provided, and fees and costs for services applies only to private pay clients and not to clients whose services are paid by the Medicaid waiver or other publicly funded program. The requirement applies to all home care agencies and registries, regardless of the payment source for the services. For those clients or consumers whose services are paid by a Medicaid waiver or other publicly funded program, the information about specific fees and costs for the specific services to be provided to the client or consumer should reference the Medicaid waiver or other publicly funded program.

The Disability Rights Network commented that when a publicly funded program, such as the Medicaid Home and Community Based Waiver or the Act 150 Attendant Care Program, is involved, the home care agency or home care registry already is required to provide certain types of information and notices prior to the commencement of services. The commentator suggested that the regulation, therefore, also should require the home care agency or home care registry receiving public funds to comply with all information and notice requirements of the publicly-funded program.

The Disability Rights Network also commented that the Medicaid waiver and other publicly funded programs include due process requirements for reduction or termination of services. The

commentator suggested that, to avoid confusion, the Department should revise the regulation to require agencies and registries providing services to the publicly funded program recipients to follow the publicly funded program's due process requirements for termination of services. The commentator suggested that the requirements applicable to termination of services in the proposed regulation should apply only to agencies and registries with private-pay clients.

The Department cannot impose through *regulations*, having the force and effect of law, the requirements imposed by the Medicaid waiver or other publicly funded program through *contract* with the provider. Further, the Department can only promulgate regulations authorized by the statute. The Legislature has determined that *all* recipients of services provided by a licensed home care agency or home care registry are entitled to at least 10 days notice of termination of services, unless lack of payment or an immediate threat to the health or safety of the consumer or provider warrants less notice. If the home care agency or home care registry provides services to individuals who are beneficiaries of a publicly funded program, there may be additional or other requirements connected with termination or reduction of services to these individuals. A publicly funded program, subject to laws requiring due process in the event of termination or reduction of a public benefit, may require a participating provider to offer certain due process to the client or consumer as a condition of the provider's participation in the program. The Department has no authority to impose those requirements. Thus, an entity meeting the definition of a "home care agency" or "home care registry" that provides services to individuals and receives payment through the Medicaid waiver or other publicly funded program will need to be aware of and comply with licensure requirements in the Act and in these regulations, *and* they will need to be aware of and comply with any requirements imposed by the

Medicaid waiver or other publicly funded program as a condition of participation as a provider in the program.

FISCAL IMPACT

State Government

The licensure program for home care agencies and home care registries will cost approximately \$1,060,000 for the first full year of the program. This projection is based on the approximate cost to survey a home care agency or registry and the projected number of home care agencies and home care registries (650).

The Department also will incur certain start-up costs associated with hiring and training of surveyors or inspectors and updating the Department's electronic Survey Agency Information System (SAIS) through which the Department coordinates and manages its licensure functions. Through SAIS, the Department schedules and tracks surveys or inspections of all facilities, tracks surveyor time and efforts, and tracks complaints about facilities. The SAIS system also includes a function through which a statement of deficiencies, in the event of regulatory violations identified during an inspection, can be generated. The system also allows the facilities to submit its plan of correction electronically. The SAIS system will need to be revised to include the home care agency and home care registry licensing function.

Local Government

There would be no cost to local government.

Public

There may be a cost to the public in the form of higher charges for care because the home care agency or home care registry would need to recoup start-up and ongoing costs of compliance with licensure criteria.

Regulated Entity

Home care agencies and home care registries would incur costs as a result of these regulations.

To the extent an agency or registry currently does not have hiring policies and procedures in place equal to or more stringent than the hiring prerequisites contained in the proposed regulation, the agency or registry would incur the one-time cost of establishing systems and procedures that comply with the proposed regulation and the on-going cost of doing business in the manner dictated by the regulation. The proposed regulation would permit choices, however, and the choice made by an agency or registry would have an impact on overall costs.

Establishing competency of a direct care worker through a competency examination, for example, might cost less than establishing competency through a training program. The agency or registry also would be required to pay the annual licensing fee of \$100.

PAPERWORK REQUIREMENTS

State Government

The Department will have additional paperwork responsibilities connected with its role as the licensing agency. Much of the licensing paperwork is handled electronically through the Department's SAIS system. The Department will issue a hard copy license to the agency or registry. The Department also will issue a hard copy statement of deficiencies.

Local Government

There would be no additional paperwork requirements for local government.

Public

Consumers of home care services will receive paperwork as a result of these regulations.

Consumers will receive written notice of termination of services. Consumers also will receive written notice of services to be provided, the hours when those services will be provided, fees and costs associated with the services, and who to contact with complaints. Consumers also will receive a written description of the hiring and training requirements applicable to direct care workers and a written disclosure of the worker's status as an employee or independent contractor and the resultant respective tax and insurance obligations of the consumer and the agency or registry.

Regulated Entity

Home care agencies and home care registries will be required to submit paperwork in order to receive or renew a license. Home care agencies and home care registries would need to respond to any identified regulatory deficiencies in the form of a plan of correction. They will need to create and maintain files for direct care workers containing documentation of a face-to-face interview, references, a criminal history report and ChildLine verification, if necessary, and documentation of satisfactory completion of the competency prerequisites and the annual competency review. The files also will be required to contain documentation of a health evaluation obtained prior to employment or roster.

Home care agencies and home care registries will be required to provide written notice to the consumer of the intent to terminate services. Finally, home care agencies and home care registries will be required to provide written documentation to the consumer listing services to be provided, the hours when those services would be provided, fees and costs associated with the services, and who to contact with complaints. The written documentation also must describe the hiring and training requirements applicable to the direct care worker being sent to the consumer's home or other independent living environment and disclose the worker's status as an employee or independent contractor and the resultant respective tax and insurance obligations of the consumer and the agency or registry.

EFFECTIVE DATE

These proposed regulations will take effect immediately upon publication as final rulemaking.

SUNSET DATE

These proposed regulations would be continually monitored for their effectiveness and updated as needed. Therefore, no sunset date has been established.

REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act, 71 P.S. § 745.1 *et. seq.*, the Department submitted a copy of a Notice of Proposed Rulemaking, published at 37 Pa. B. 4431 on August 11, 2007 to the Independent Regulatory Review Commission and to the Chairman of the House Committee on Health and Human Services, the Senate Committee on Public Health and Welfare, the House Older Adult Services Committee, and the Senate Aging and Youth Committee. In

compliance with Section 5(c) of the Regulatory Review Act, the Department also provided IRRC and the Committees with copies of all comments received during the formal comment period, as well as other documentation.

In compliance with Section 5.1(a) of the Regulatory Review Act, the Department submitted a copy of the final-form regulations to IRRC and the Committees on August 24, 2009. In addition, the Department provided IRRC and the Committees with information pertaining to commentators and a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

In preparing this final-form regulation, the Department has considered all comments received from IRRC, the Committees and the public.

This final-form regulation was deemed approved by the House Health and Human Services Committee on _____, by the Senate Public Health and Welfare Committee on _____, by the House Older Adult Services Committee on _____, and by the Senate Aging and Youth Committee on _____. IRRC met on _____, and approved the regulation in accordance with Section 5.1(e) of the Regulatory Review Act.

CONTACT PERSON

Interested persons are invited to submit all comments, suggestions or objections regarding the proposal to Janice Staloski, Director, Bureau of Community Program Licensure and Certification, 132 Kline Plaza, Suite, Harrisburg, PA 17104-1579, (717) 783-8665, within 30 days after publication of this notice in the *Pennsylvania Bulletin*. Persons with a disability may submit questions in alternative format such as by audio tape, Braille, or by using V/TT (717) 783-6514 or the Pennsylvania At&T Relay Service at (800) 654-5984[TT]. Persons who require an alternative format of this document may contact Ms. Staloski at the above address or telephone numbers so that necessary arrangements may be made.

FINDINGS

The Department, after consultation with the Health Policy Board, finds that:

(1) Public notice of intention to adopt the regulations adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968(P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202), and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) The adoption of regulations in the manner provided by this order is necessary and appropriate for the administration of the authorizing statute.

ORDER

The Department, after consultation with the Health Policy Board, acting under the authorizing statute, orders that:

(1) The regulations of the Department at 28 Pa. Code are amended to add Subpart H, Chapter 611 as set forth in Annex A.

(2) The Secretary of Health shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(3) The Secretary of Health shall submit this Order, Annex A and a Regulatory Analysis Form to IRRC, the House Committee on Health and Human Services, the Senate Committee on Public Health and Welfare, the House Older Adult Services Committee and the Senate Aging and Youth Committee for their review and action as required by law.

(4) The Secretary of Health shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(5) This order shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

Annex A

Title 28. Health and Safety

Part IV. Health Facilities

Subpart H. Home Care Agencies and Home Care Registries

Chapter 611. Home Care Agencies and Home Care Registries

GENERAL

§ 611.1. Legal base.

- (a) This ~~subpart~~ CHAPTER is promulgated by the Department under the powers granted and the duties mandated by Section 809.1 of the Act (35 P.S. §§ 448.809.1) and by Section 803 (35 P.S. § 448.803).
- (b) The Department has the power and its duty is to promulgate the regulations necessary to implement the provisions of Chapter 8 of the Act (35 P.S. §§ 448.801a – 448.820) and to assure that its regulations and the Act are enforced.
- (c) The purpose of this ~~subpart~~ CHAPTER is to protect and promote the public health and welfare through the establishment and enforcement of regulations setting minimum standards for the operation of home care agencies and home care registries. The standards are intended by the Department to assure safe, adequate and efficient home care agencies and home care registries, and to promote the health, safety and adequate care of the consumers of services provided by home care agencies and home care registries.

§ 611.2. LICENSE REQUIRED.

- (A) EXCEPT AS SET FORTH IN SUBSECTION (C), NO ENTITY OR ORGANIZATION SHALL OPERATE, MAINTAIN, OR HOLD ITSELF OUT AS OPERATING OR MAINTAINING A HOME CARE AGENCY OR HOME CARE REGISTRY WITHOUT FIRST HAVING OBTAINED A LICENSE FROM THE DEPARTMENT IN ACCORDANCE WITH THIS CHAPTER. EACH PHYSICAL LOCATION OF THE HOME CARE AGENCY OR HOME CARE REGISTRY MUST BE SEPARATELY LICENSED. THE DEPARTMENT SHALL CONDUCT AN INSPECTION PRIOR TO ISSUING AN INITIAL LICENSE OR A LICENSE RENEWAL.
- (B) THE LICENSE SHALL SPECIFY WHETHER THE ENTITY IS LICENSED AS A HOME CARE AGENCY, A HOME CARE REGISTRY, OR BOTH, THE TERM OF THE LICENSE, AND ANY CONDITIONS OR LIMITATIONS IMPOSED ON THE LICENSE.
- (C) AN ENTITY OPERATING A HOME CARE AGENCY OR HOME CARE REGISTRY OR BOTH AS OF THE EFFECTIVE DATE OF THIS CHAPTER MAY CONTINUE TO OPERATE AFTER THE EFFECTIVE DATE OF THIS CHAPTER PROVIDED IT SUBMITS AN APPLICATION FOR A LICENSE TO THE DEPARTMENT IN ACCORDANCE WITH INSTRUCTIONS PUBLISHED IN THE *PENNSYLVANIA BULLETIN* AND POSTED ON THE DEPARTMENT'S WEBSITE ON OR WITHIN 60 DAYS OF THE

EFFECTIVE DATE OF THIS CHAPTER. AN ENTITY THAT HAS
SUBMITTED AN APPLICATION FOR LICENSURE IN ACCORDANCE
WITH THE REQUIREMENTS OF THIS SUBSECTION MAY CONTINUE TO
OPERATE THE HOME CARE AGENCY OR HOME CARE REGISTRY
UNTIL SUCH DATE AS THE DEPARTMENT MAY REFUSE THE
APPLICATION FOR LICENSURE. IF THE DEPARTMENT GRANTS THE
APPLICATION FOR LICENSURE, THE HOME CARE AGENCY OR HOME
CARE REGISTRY MAY CONTINUE OPERATION OF THE AGENCY OR
REGISTRY IN ACCORDANCE WITH THE REQUIREMENTS OF THIS
CHAPTER.

- (D) THE APPLICANT SHALL OBTAIN THE APPLICATION FOR A
LICENSE TO OPERATE A HOME CARE AGENCY OR HOME CARE
REGISTRY FROM THE PENNSYLVANIA DEPARTMENT OF
HEALTH, DIVISION OF HOME HEALTH.
- (E) THE APPLICANT SHALL SUBMIT AN APPLICATION OR
RENEWAL FORM TO THE DEPARTMENT WITH THE FEE OF
\$100.00. THE APPLICANT SHALL SUBMIT A RENEWAL FORM
NOT LESS THAN 60 DAYS PRIOR TO THE EXPIRATION DATE ON
THE LICENSE. THERE WILL BE NO REBATE, REFUND, OR
PRORATING OF THE APPLICATION FEE. 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.

- (F) THE APPLICANT SHALL SPECIFY ON ITS APPLICATION THE TYPE OF FACILITY FOR WHICH IT IS SEEKING A LICENSE.

§ 611.2.3. Affected home care agencies and home care registries.

- (a) This subpart CHAPTER applies to home care agencies, home care registries and to entities that meet both definitions, profit or nonprofit, operated in this Commonwealth, as defined in this subpart CHAPTER. THIS CHAPTER DOES NOT APPLY TO A HOME HEALTH CARE AGENCY, A DURABLE MEDICAL EQUIPMENT PROVIDER, A VOLUNTEER PROVIDER, OR AN ORGANIZATION OR BUSINESS ENTITY DESIGNATED UNDER 26 U.S.C. §3504 (RELATED TO ACTS TO BE PERFORMED BY AGENTS) AND EITHER IRS REVENUE PROCEDURE 70-6 OR IRS REVENUE PROCEDURE 80-4, THAT PROVIDES FINANCIAL MANAGEMENT SERVICES OR SUPPORTS COORDINATION SERVICES OR BOTH TO CONSUMERS OF HOME AND COMMUNITY-BASED SERVICES THROUGH MEDICAID WAIVER OR OTHER PUBLICLY FUNDED PROGRAMS.
- (b) Existing home care agencies and home care registries which were home care agencies or home care registries prior to the effective date of this subpart shall be required to meet the same standards as home care

agencies and home care registries created after the effective date of this subpart.

§ 611.3-4. Requirements for home care agencies and home care registries.

(a) A current copy of this chapter shall be maintained at the home care agency or home care registry.

(B) 28 PA CODE CHAPTER 51, APPLICABLE TO ALL ENTITIES LICENSED AS HEALTH CARE FACILITIES UNDER THE ACT, APPLIES TO HOME CARE AGENCIES AND HOME CARE REGISTRIES LICENSED UNDER THIS CHAPTER.

~~(b)~~(C) Home care agencies and home care registries licensed under this chapter shall comply with applicable environmental, health, sanitation and professional licensure standards which are required by Federal, State and local authorities.

~~(e)~~(D) If there is a difference in applicable State or local standards, the standards established under State statutes apply for the purpose of compliance with this chapter.

§ 611.4.5. Definitions.

The following words and terms, when used in this subpart, have the following meaning, unless the context clearly indicates otherwise:

Act- The Health Care Facilities Act (35 P .S. §§ 448.101 – 448.904b). ChildLine –

An organizational unit of the Department of Public Welfare which operates a state-wide toll-free

system for receiving reports of suspected child abuse established under section 6332 of the Child Protective Services Law, 23 Pa. C.S. §§ 6301 – 6385 (relating to establishment of Statewide toll-free telephone number), refers the reports for investigation and maintains the reports in the appropriate file.

ChildLine verification - Confirmation regarding whether an applicant for employment or referral by a home care agency or home care registry is named in the Department of Public Welfare's Statewide Central Register as the perpetrator of a founded or indicated report of child abuse (as defined at 55 Pa. Code § 3490.4).

COMPANIONSHIP SERVICES – SOCIALIZATION, SUPPORT AND ASSISTANCE WITH INSTRUMENTAL ACTIVITIES OF DAILY LIVING.

Consumer – Individual to whom services are provided.

CONSUMER CONTROL – CONTROL AND DIRECTION BY CONSUMER IN IDENTIFYING, EXERCISING CHOICE OF, AND MANAGING HOME CARE SERVICES IN ACCORDANCE WITH THE CONSUMER'S NEEDS AND PERSONAL PREFERENCES.

Criminal history report – A State Police criminal history record or a Department of Aging letter of determination of eligibility for hire or roster based on a review of a federal criminal history record.

Department- The Department of Health of the Commonwealth.

Department of Aging letter of determination – A written decision supplied by the Department of Aging regarding whether, based on the criminal history report from the Federal Bureau of Investigation, the applicant for employment by a home care agency or referral by a home care registry may be employed or rostered.

Direct care worker – The individual employed by a home care agency or referred by a home care registry to provide HOME CARE services to a consumer.

Direct consumer contact - Face-to-face interaction with the consumer in the consumer's place of residence or other independent living environment.

Financial management services – One or more of the following services:

- (a) Managing payroll including federal, state and local employment taxes for direct care workers recruited and retained by the consumer.
- (b) Processing the payment of workers' compensation, health and other insurance benefits for the direct care worker.
- (c) Assisting consumers in calculating and managing individual budgets for MEDICAID WAIVER AND OTHER publicly funded home and community based waiver services.
- (d) Monitoring the consumer's spending of public funds and any underage or overage in accordance with the consumer's approved budget.
- (e) Collecting, processing and maintaining time sheets for direct care workers.
- (f) Providing training to consumers related to employer-related tasks (e.g. recruiting, hiring, training, managing and discharging direct care workers and managing payroll and bill paying).

Home care agency – An organization that supplies, arranges or schedules employees to provide assistance with activities of daily living or instrumental activities of daily living, companionship services or specialized care on an hourly, shift or continual basis to a consumer HOME CARE SERVICES, AS DIRECTED BY THE CONSUMER OR THE CONSUMER'S REPRESENTATIVE, in the consumer's place of residence or other independent living

environment for which the organization receives a fee, consideration or compensation of any kind. The term shall not include a home health care agency, a durable medical equipment provider, a volunteer provider, or an organization or business entity designated under Section 3504 of the Internal Revenue Code and either IRS Revenue Procedure 70-6 or IRS Revenue Procedure 80-4 that provides only financial management services to consumers of home and community based services through Medicaid waiver or other publicly funded programs.

Home care registry – An organization or business entity or part of an organization or business entity that supplies, arranges or refers independent contractors to provide assistance with activities of daily living or instrumental activities of daily living, or specialized care, HOME CARE SERVICES, AS DIRECTED BY THE CONSUMER OR THE CONSUMER’S REPRESENTATIVE, in the consumer’s place of residence or other independent living environment for which the registry receives a fee, consideration or compensation of any kind. The term shall not include an organization or business entity designated under Section 3504 of the Internal Revenue Code and either IRS Revenue Procedure 70-6 or IRS Revenue Procedure 80-4 that provides only financial management services to consumers of home and community-based services through Medicaid waiver or other publicly funded programs.

HOME CARE SERVICES – THE TERM ENCOMPASSES THE FOLLOWING

ACTIVITIES:

- (a) PERSONAL CARE.
- (b) ASSISTANCE WITH INSTRUMENTAL ACTIVITIES OF DAILY LIVING.
- (c) COMPANIONSHIP SERVICES.
- (d) RESPIRE CARE.

(e) SPECIALIZED CARE.

INDEPENDENT LIVING PHILOSOPHY – A SYSTEM OF BELIEFS, CONCEPTS AND ATTITUDES THAT EMPHASIZE SELF-DIRECTION, CONTROL, PEER SUPPORT AND COMMUNITY INTEGRATION FOR INDIVIDUALS WITH DISABILITIES.

Inspection – An SCHEDULED OR UNSCHEDULED examination or assessment of a home care agency or home care registry DURING REGULAR BUSINESS HOURS, to determine compliance with requirements for licensure using one or more of the following means: inspection of records, interviews with office staff, consumers and direct care workers, and observation of the provision of services to consumers who have consented in advance to observation. The inspection may or may not be on-site.

INSTRUMENTAL ACTIVITIES OF DAILY LIVING – AS DEFINED AT 35 P.S. § 448.802a.

Nurse – A registered nurse or a licensed practical nurse.

PERSONAL CARE - THIS TERM INCLUDES, BUT IS NOT LIMITED TO, ASSISTANCE WITH SELF-ADMINISTERED MEDICATIONS, FEEDING, ORAL, SKIN AND MOUTH CARE, SHAVING, ASSISTANCE WITH AMBULATION, BATHING, HAIR CARE AND GROOMING, DRESSING, TOILETING AND TRANSFER ACTIVITIES.

RESPIRE CARE – PERSONAL CARE AND ASSISTANCE WITH INSTRUMENTAL ACTIVITIES OF DAILY LIVING PROVIDED ON A SHORT TERM BASIS BECAUSE OF THE ABSENCE OR NEED FOR RELIEF FOR THOSE PERSONS NORMALLY PROVIDING THE SERVICES.

Qualified health professional – An individual who holds a license or certification issued by the Commonwealth which allows for the performance of a physical examination, evaluation or assessment. The term includes a physician, a physician's assistant and a certified registered nurse practitioner.

Roster – To place an individual on a list of individuals eligible to be referred by a home care registry to provide HOME CARE services to an individual in the individual's home PLACE OF RESIDENCE or other independent living environment; or the list of individuals eligible to be referred by a home care registry to provide HOME CARE services to an individual in the individual's home PLACE OF RESIDENCE or other independent living environment.

SPECIALIZED CARE – NON-SKILLED SERVICES UNIQUE TO THE CONSUMER'S CARE NEEDS THAT FACILITATE THE CONSUMER'S HEALTH, SAFETY AND WELFARE, AND ABILITY TO LIVE INDEPENDENTLY.

Statewide Central Register – A register of child abuse established in the Department of Public Welfare, which consists of founded and indicated reports of child abuse.

SUPPORTS COORDINATION SERVICES – SERVICES TO CONSUMERS OF HOME AND COMMUNITY-BASED SERVICES THROUGH MEDICAID WAIVER OR OTHER PUBLICLY FUNDED PROGRAMS INCLUDING INTAKE SERVICES, NEEDS ASSESSMENT, AND ADVOCACY TO ENSURE COORDINATION OF MEDICAL, SOCIAL, EDUCATIONAL AND OTHER SERVICES AND MAXIMUM CONSUMER INDEPENDENCE.

LICENSURE

§ 611.11. License required.

- ~~(G) — Except as set forth in subsection (e), no entity or organization shall operate, maintain, or hold itself out as operating or maintaining a home care agency or home care registry without first having obtained a license from the Department in accordance with this chapter. Each physical location of the home care agency or home care registry must be separately licensed.~~
- ~~(H) — The license shall specify whether the entity is licensed as a home care agency, a home care registry, or both, the term of the license, and any conditions or limitations imposed on the license.~~
- ~~(I) — An entity operating a home care agency or home care registry or both as of the effective date of this subpart may continue to operate after the effective date of this subpart provided it submits an application for a license to the Department in accordance with instructions published in the Pennsylvania Bulletin and posted on the Department's website on or within 60 days of the effective date of this subpart. An entity that has submitted an application for licensure in accordance with the requirements of this subsection may continue to operate the home care agency or home care registry until such date as the Department may refuse the application for licensure. If the Department grants the application for licensure, the home care agency or home care registry may continue operation of agency or registry in accordance with the requirements of this chapter.~~

§ 611.12. Application for license.

- (a) ~~The applicant shall obtain the application for a license to operate a home care agency or home care registry from the Pennsylvania Department of Health, Division of Home Health.~~
- (b) ~~The applicant shall submit an application or renewal form to the Department with the fee required by Section 807 of the Act (35 P.S. § 448.807). The applicant shall submit a renewal form not less than 60 days prior to the expiration date on the license. There will be no rebate, refund, or prorating of any application fee. 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.~~
- (c) ~~The applicant shall provide any documentation required by the Department in connection with the application and shall complete and submit all forms specified by the Department and any additional information required by the Department so that the Department can determine if the applicant is a responsible person and otherwise qualified to obtain a license to maintain or operate a home care agency or home care registry.~~
- (d) ~~The applicant shall specify on its application the type of facility for which it is seeking a license.~~

§ 611.7. Ownership.

~~The owner of a home care agency or home care registry may be an individual, partnership, association, corporation or a combination of these forms of ownership. The following~~

requirements apply to a home care agency and a home care registry according to the mode of ownership:

- (1) ~~Individual Ownership. A complete list of names and addresses of the owners of the home care agency or home care registry shall be submitted with the application.~~
- (2) ~~Partnerships. A complete list of names and addresses of the owners, general partners and partners responsible for the management of the home care agency or home care registry shall be submitted with the application.~~
- (3) ~~Association or corporation. A complete list of names and addresses of the officers, directors, principal stockholders, either beneficial or of record, of the corporate owners and of the parent corporation, if applicable, and of the persons in charge who are responsible for the management of the home care agency or home care registry, shall be submitted with the application. Ownership interest of 5.0% or more direct or indirect shall be disclosed on the application.~~

§ 611.8. Issuance of license.

- (a) ~~The Department will issue a license to operate a home care agency or home care registry, or both, after the Department determines the applicant is a responsible person and an inspection conducted by the Department indicates that the applicant is in substantial compliance with this chapter.~~
- (b) ~~A license issued by the Department shall expire 1 year from the date of issue.~~

§ 611.9. Posting of license.

The home care agency or home care registry shall prominently post its license, or duplicate copy of the license, as requested and obtained from the Department, in a public and conspicuous location on the premises.

§ 611.10: Non-transfer of license.

A license shall not be transferred to another home care agency or home care registry, or to the purchaser or new owners of a home care agency or home care registry in the event of a change in ownership under § 611.12 (relating to change in ownership or management), and shall not extend to another home care agency or home care registry, or to another physical location of the home care agency or home care registry.

§ 611.11: Responsibility of owners of home care agencies and home care registries.

- (a) The owner shall be responsible for meeting the minimum standards for operation as set forth by the Department and by other State and local agencies responsible for the health, welfare and safety of the consumers of services.
- (b) The owner, administrator or designee shall immediately report to the Department any catastrophic incident, such as a fire or flood, or any incident that may cause interruption or cessation of the delivery of services, or another interruption of services which would affect the health and safety of the consumers of services.

~~(c) The owner, administrator or designee shall immediately report to the Department a relocation of the home care agency or home care registry or a change of address for the home care agency or home care registry.~~

§ 611.12. Change in ownership or management.

- ~~(a) The home care agency or home care registry shall notify the Department in writing at least 60 days prior to any anticipated change in ownership, form of ownership, or name, and immediately prior to any unanticipated change in ownership, form of ownership, or name. A change in ownership shall mean any transfer of the controlling interest in the facility.~~
- ~~(b) The home care agency or home care registry shall notify the Department in writing at least 60 days prior to any anticipated change in officers, directors, members, partners or principals, and immediately prior to any unanticipated change in officers, directors, members, partners or principals.~~
- ~~(c) The home care agency or home care registry shall notify the Department in writing at least 30 days prior to any transfer involving five percent (5%) or more of the stock or equity in the entity that operates the home care agency or home care registry.~~
- ~~(d) The home care agency or home care registry shall notify the Department in writing no later than 30 days following a change in management. Management includes any individual responsible for oversight of day to day operations in the facility.~~

- (e) Information regarding an anticipated change in ownership, change in form of ownership, or transfer involving five percent (5%) or more of the stock or equity in an entity subject to the regulations of the Federal Securities and Exchange Commission will not be considered a public record and will remain confidential until the transaction is complete.

§ 611.13. Void license.

A license shall be immediately void if any of the following occur:

- (1) The license term expires.
- (2) The facility adds, terminates, or otherwise changes the services it provides without notice to the Department required by § 611.11 (relating to responsibility of owners of home care agencies and home care registries).
- (3) The facility is transferred or sold, or substantially changes its ownership, form of ownership, or management without notice to the Department required by § 611.12 (relating to change in ownership or management).
- (4) The facility relocates to another site.

INSPECTION AND SURVEY ACTIVITIES.

§ 611.14. Inspections.

- (a) Prior to issuance of an initial license or renewal of a regular or provisional license, representatives of the Department will conduct an inspection of a home care agency or home care registry. Whenever the Department has received any complaint or has other reasonable grounds to believe that a

~~deficiency exists, the Department may conduct an inspection to determine whether a deficiency exists.~~

- ~~(b) The Department will make reasonable efforts to prevent duplication of inspections by state and federal regulatory agencies and will coordinate inspections whenever practical.~~
- ~~(c) Inspections to investigate complaints or other allegation of regulatory deficiency will be prioritized in accordance with the level of perceived threat to the health and welfare of consumers.~~
- ~~(d) Prior to the inspection by the Department, the Department may request from the home care agency or home care registry any documents or records of the home care agency or home care registry including those held by other organizations or agencies, or other information necessary for the Department to prepare for the inspection. The home care agency or home care registry shall provide any and all information requested.~~
- ~~(e) Upon presenting a Department identification card, authorized agents of the Department shall have access to the home care agency or home care registry to determine compliance with this chapter. Such access shall include:
 - ~~(1) Entry to the premises.~~
 - ~~(2) Examination of all of the facilities, buildings, grounds, files, policies and procedures, records, documents, offices, computer files, quality assurance files, risk management documents, governing body and management documents.~~~~

~~(3) — Private interviews with any staff, employees, and direct care workers.~~

~~(4) — Private interviews with the consumer, with the consumer's consent.~~

§ 611.15. Retention of records.

~~All documentation required by this chapter and all documentation with respect to establishing that the home care agency or home care registry is in compliance with all applicable federal, state, and local requirements shall be retained by the home care agency or home care registry on site. Documentation shall be retained for four years after termination of services to a consumer unless otherwise required by applicable federal and state laws and regulations. Personnel records required under § 611.22 (relating to hiring of direct care workers) shall be retained for at least four years following termination of employment or roster status of a direct care worker. Documentation and records shall be retained even if the home care agency or home care registry discontinues operation. Documentation includes paper and electronic information.~~

§ 611.16. Statement of deficiencies and plan of correction.

~~(a) — After completion of the inspection, the Department will evaluate all relevant information gathered during the inspection and formulate its compliance findings and determinations. In the event that the Department makes a determination of noncompliance with any provision of this chapter, the Department will issue to the home care agency or home care registry a statement of deficiencies.~~

~~(b) — Upon receipt of a statement of deficiencies, the home care agency or home care registry shall provide the Department, within the timeframe set by the Department, a plan of correction. The plan of correction shall address all~~

deficiencies cited in the statement of deficiencies and shall identify the corrective action to be taken, the individuals responsible for the corrective action, and the timeframes within which the corrective action will be accomplished. The plan of correction shall be attested to by the individual given signature authority by the home care agency or home care registry.

- (e) Copies of the statement of deficiencies and plan of correction will be readily available on the Department's website for the purpose of public inspection. The agency or registry also shall make available for inspection and examination by any person a copy of the most recent statement of deficiencies and plan of correction.

SANCTIONS AND CORRECTIVE ACTIONS

§ 611.17. Sanctions for deficiencies.

In the event of one or more regulatory deficiencies, in addition to requiring a plan of correction, the Department may impose a civil monetary penalty, not to exceed \$500 per deficiency per day, and the Department may take one of the following actions:

- (1) Suspend the license.
- (2) Revoke the license.
- (3) Refuse to renew the license.
- (4) Limit the license.
- (5) Issue a provisional license.

§ 611.18. Reasons for sanctions.

- (a) ~~The Department may refuse to renew a license, may suspend, revoke or limit a license of a home care agency or home care registry for any of the following reasons:~~
- (1) ~~A serious violation of this subchapter, the act or other statutes and regulations, which seriously threatens the health, safety and welfare of consumers.~~
 - (2) ~~Failure of an owner to submit a reasonable timetable for correction of deficiencies.~~
 - (3) ~~The existence of a pattern of cyclical deficiencies which extends over a period of 2 or more years.~~
 - (4) ~~Failure, by the holder of a provisional license, to correct deficiencies in accordance with a timetable submitted by the owner and agreed upon by the Department.~~
 - (5) ~~Fraud or deceit in obtaining or attempting to obtain a license.~~
 - (6) ~~Lending, borrowing or using the license of another, or knowingly aiding or abetting the improper granting of a license.~~
 - (7) ~~Incompetence, negligence or misconduct in operating the home care agency or home care registry or in providing services to consumers.~~
 - (8) ~~Mistreating or abusing consumers cared for by direct care workers employed by the home care agency or contractor referred by the home care registry to provide care.~~

- (9) — Serious violation of the laws relating to medical assistance or Medicare reimbursement.
- (10) — Serious violation of other applicable Federal or State laws.
- (b) — The Department may issue a provisional license when there are numerous deficiencies or a serious specific deficiency which has a substantial impact on governance and management of services, which indicates that the home care agency or home care registry is not in compliance with applicable statutes, ordinances or this chapter, and the Department finds that:
- (1) — The applicant is taking appropriate steps to correct the deficiencies in accordance with a timetable submitted by the applicant and agreed upon by the Department.
- (2) — There is no pattern of deficiencies over a period of 2 or more years.
- (3) — There is no danger to the health or safety of the consumers.
- (e) — The Department may issue a provisional license for a specific period of not more than 6 months. A provisional license may be renewed three times.

§ 611.19. Notice.

Whenever the Department proposes to impose a sanction for deficiencies, it will give written notice to the home care agency or home care registry by certified mail.

§ 611.20. Form of notice.

~~Notice under § 611.19 (relating to notice) will conform to 1 Pa. Code § 35.14 (relating to orders to show cause). The order will specify the reasons for the proposed action of the Department and will notify the home care agency or home care registry of its right to an appeal pursuant to 37 Pa. Code Chapter 197. The order will specify the time within which the home care agency or home care registry must file its appeal with the Department.~~

~~§ 611.21. Request for hearing.~~

- ~~(a) A finding by the Department that a home care agency or home care registry is in violation of the act or regulations of this chapter may not be appealed unless the Department also imposes a sanction under § 611.17 (relating to sanctions for deficiencies).~~
- ~~(b) Appeals relating to the Department's imposition of a sanction shall address the factual and legal bases asserted by the Department for imposing the sanction, and the facts and law upon which the health care facility relies and shall be made in accordance with 37 Pa. Code § 197.84 (relating to notice of appeal and answer) and 1 Pa. Code § 35.37 (relating to answers to order to show cause).~~
- ~~(c) A request for supersedeas of a sanction imposed by the Department must be made pursuant to 37 Pa. Code § 197.87 (relating to supersedeas).~~

GOVERNANCE AND MANAGEMENT

§ 611.51. Hiring or rostering of direct care workers.

(a) Hiring or rostering prerequisites. Prior to hiring or rostering a direct care worker, the home care agency or home care registry shall:

- (1) Conduct a face-to-face interview with the individual.
- (2) Obtain not less than two satisfactory references for the individual.

A SATISFACTORY REFERENCE IS A POSITIVE, VERIFIABLE REFERENCE, EITHER VERBAL OR WRITTEN, FROM A FORMER EMPLOYER OR OTHER PERSON NOT RELATED TO THE INDIVIDUAL THAT AFFIRMS THE ABILITY OF THE INDIVIDUAL TO PROVIDE HOME CARE SERVICES.

- (3) Require the individual to submit a criminal history report, in accordance with the requirements of § 611.23 (relating to criminal background checks), and a ChildLine verification, if necessary APPLICABLE, in accordance with the requirements of § 611.24 (relating to child abuse clearance).

(b) Personnel DIRECT CARE WORKER files. Personnel files FILES for direct care workers employed or rostered shall include documentation of the date of the face-to-face interview with the individual and of references obtained. Personnel DIRECT CARE WORKER files also shall include all other information as required by § 611.52, § 611.53, if applicable, § 611.54, § 611.55 and § 611.56 (relating to CRIMINAL BACKGROUND CHECKS, CHILD ABUSE CLEARANCE, PROVISIONAL HIRING; training COMPETENCY requirements; and health evaluations).

§ 611. 52. Criminal background checks.

- (a) General rule. The home care agency or home care registry shall require each applicant for employment or referral AS A DIRECT CARE WORKER to submit a criminal history report obtained at the time of application or within 1 year immediately preceding the date of application. AN APPLICANT FOR EMPLOYMENT AS A MEMBER OF THE OFFICE STAFF FOR THE HOME CARE AGENCY OR HOME CARE REGISTRY AND THE OWNER OR OWNERS OF THE HOME CARE AGENCY OR HOME CARE REGISTRY ALSO ARE REQUIRED TO OBTAIN A CRIMINAL HISTORY REPORT IN ACCORDANCE WITH REQUIREMENTS CONTAINED IN THIS SECTION.
- (b) State Police criminal history record. If the ~~applicant for employment or referral~~ INDIVIDUAL REQUIRED TO SUBMIT OR OBTAIN A CRIMINAL HISTORY REPORT has been a resident of this Commonwealth for 2 years preceding the date of ~~application~~ THE REQUEST FOR A CRIMINAL HISTORY REPORT, the ~~applicant~~ INDIVIDUAL shall ~~submit~~ REQUEST a State Police criminal history record.
- (c) Federal criminal history record. If the ~~applicant for employment or referral~~ INDIVIDUAL REQUIRED TO SUBMIT OR OBTAIN A CRIMINAL HISTORY REPORT has not been a resident of this Commonwealth for the 2 years immediately preceding the date of the ~~application~~ THE REQUEST FOR A CRIMINAL HISTORY REPORT,

the home care agency or home care registry shall require the applicant to follow the procedures at 6 Pa. Code § 15.144(b) (relating to procedure) to INDIVIDUAL SHALL obtain a federal criminal history record and a letter of determination from the Department of Aging, based on the individual's Federal criminal history record, regarding the individual's eligibility for hire or roster, IN ACCORDANCE WITH THE REQUIREMENTS AT 6 PA. CODE § 15.144(b) (RELATING TO PROCEDURE).

- (d) Proof of residency. The home care agency or home care registry may require REQUEST an applicant for employment or referral INDIVIDUAL REQUIRED TO SUBMIT OR OBTAIN A CRIMINAL HISTORY RECORD to furnish proof of residency, including THROUGH SUBMISSION OF any one of the following documents:
- (1) Motor vehicle records, such as a valid driver's license OR A STATE-ISSUED IDENTIFICATION.
 - (2) Housing records, such as mortgage records or rent receipts.
 - (3) Public utility records and receipts, such as electric bills.
 - (4) Local tax records.
 - (5) A completed and signed, Federal, State or local income tax return with the applicant's name and address preprinted on it.
 - (6) Employment records, including records of unemployment compensation.
- (e) Prohibition. The home care agency or home care registry may not hire, or roster OR RETAIN an individual if the State Police criminal history record reveals a prohibited conviction listed at 6 Pa. Code § 15.143 (relating to facility

responsibilities), or if the Department of Aging letter of determination states that the individual is not eligible for hire or roster.

- (f) Records maintained. The home care agency or home care registry shall maintain personnel records FILES for individuals employed or rostered DIRECT CARE WORKERS AND MEMBERS OF THE OFFICE STAFF which include copies of State Police criminal history records or Department of Aging letters of determination regarding Federal criminal history records. The personnel records FILES shall be available for Department inspection. THE AGENCY OR REGISTRY SHALL MAINTAIN COPIES OF THE CRIMINAL HISTORY REPORT FOR THE AGENCY OR REGISTRY OWNERS, WHICH SHALL BE AVAILABLE FOR DEPARTMENT INSPECTION.
- (g) Confidentiality. The home care agency or home care registry shall keep the information obtained from State Police criminal history records and Department of Aging letters of determination regarding Federal criminal history records confidential and use it solely to determine an applicant's eligibility to be hired, rostered or retained.
- (h) Opportunity to appeal. If the decision not to hire, roster or retain an individual is based in whole or in part on State Police criminal history records, Department of Aging letters of determination regarding Federal criminal history records, or both, the home care agency or home care registry shall provide an affected individual with information on how to

appeal to the sources of criminal history records if the individual believes the records are in error.

- (i) Exceptions. An individual employed or rostered A DIRECT CARE WORKER who has complied with this section and who transfers to another agency or registry owned and operated by same entity is not required to submit OBTAIN another criminal history report. An individual who is A DIRECT CARE WORKER employed or rostered by an entity that undergoes a change of ownership is not required to submit OBTAIN another criminal history report TO SUBMIT TO THE NEW OWNER.
- (j) Individuals currently employed or rostered. A person DIRECT CARE WORKER AND EACH MEMBER OF THE AGENCY OR REGISTRY OFFICE STAFF who is employed by or rostered by a home care agency or home care registry as of the effective date of this chapter shall obtain and submit a State Police criminal history record or Department of Aging letter of determination, as applicable, to the home care agency or home care registry within 120 days of the effective date of this chapter. This subsection shall not apply if the home care agency or home care registry obtained a criminal history report meeting the requirements of this subsection when the individual DIRECT CARE WORKER OR OFFICE STAFF MEMBER was hired or rostered and a copy of the report is included in the individual's personnel file.

§ 611. 53. Child abuse clearance.

- (a) General rule. A home care agency or home care registry that serves persons under 18 years of age shall require each applicant for employment or referral as a direct care worker, each **APPLICANT FOR EMPLOYMENT AS** A member of the agency or registry office staff to request a ChildLine verification regarding whether the applicant ~~or member~~ is named in the Statewide Central Register as the perpetrator of a founded or indicated report of child abuse as defined at 55 Pa. Code § 3490.4 (relating to definitions).
- (b) Prohibition. In no case shall a home care agency or home care registry employ, ~~or roster~~ **OR RETAIN** an individual where ChildLine has verified that the ~~applicant~~ **INDIVIDUAL** is named in the Statewide Central Register as the perpetrator of a founded or indicated report of child abuse.
- (c) Records maintained. The ~~personnel records~~ **FILES** maintained by the home care agency or home care registry for each individual employed or rostered and for each member of the office staff shall include copies of the ChildLine verification. The agency or registry shall maintain copies of the ChildLine verification for the agency or registry owners, which shall be available for Department inspection.
- (d) Individuals currently employed or rostered. A person who is employed by or rostered by the home care agency or home care registry, **INCLUDING EACH MEMBER OF THE AGENCY OR REGISTRY OFFICE STAFF**, as of the effective date of this chapter shall obtain and submit a ChildLine verification to the home care agency or home care registry within 120 days

of the effective date of this chapter. This subsection shall not apply if the home care agency or home care registry obtained a ChildLine verification when the individual was hired or rostered and a copy of the verification is included in the individual's personnel file.

§ 611.54. Provisional hiring.

(a) General rule. The home care agency or home care registry may hire an applicant for employment or referral on a provisional basis, pending receipt of a criminal history report or a ChildLine verification, as applicable, if the following conditions are met:

- (1) The applicant shall have applied for a criminal history report and ChildLine verification, as applicable, and provided the home care agency or home care registry with a copy of the completed request forms.
- (2) The home care agency or home care registry shall have no knowledge about the applicant that would disqualify the applicant under 18 Pa.C.S. § 4911 (relating to tampering with public record information).
- (3) The applicant shall swear or affirm in writing that the applicant is not disqualified from employment or referral under this chapter.
- (4) THE HOME CARE AGENCY OR HOME CARE REGISTRY SHALL NOT ASSIGN OR REFER The THE provisionally hired applicant shall meet UNTIL THAT PERSON HAS MET the requirements of § 611.26 (relating to training COMPETENCY requirements).

- (5) The home care agency or home care registry shall monitor the provisionally hired applicant AWAITING A CRIMINAL BACKGROUND CHECK through random, direct observation and consumer feedback. The results of monitoring shall be documented in the individual's personnel file.
- (6) THE HOME CARE AGENCY OR HOME CARE REGISTRY SHALL DIRECTLY SUPERVISE, OR ASSIGN ANOTHER DIRECT CARE WORKER TO ACCOMPANY, A PROVISIONALLY HIRED APPLICANT AWAITING A CHILD ABUSE CLEARANCE WHO WILL PROVIDE HOME CARE SERVICES TO A CONSUMER LESS THAN 18 YEARS OF AGE.
- (7) The period of provisional hire OF AN INDIVIDUAL WHO IS AND HAS BEEN, FOR A PERIOD OF 2 YEARS OR MORE, A RESIDENT OF PENNSYLVANIA, shall not exceed ~~120~~ 30 days. THE PERIOD OF PROVISIONAL HIRE OF AN INDIVIDUAL WHO HAS NOT BEEN A RESIDENT OF PENNSYLVANIA FOR TWO YEARS OR MORE SHALL NOT EXCEED 90 DAYS.
- (b) Termination. If the information obtained from the criminal history report or ChildLine verification, or both, reveals that the individual is disqualified from employment or referral under § 611.23 (relating to criminal background checks) or under § 611.24 (relating to child abuse clearance), the individual shall be terminated by the home care agency or removed from the home care registry's roster immediately. If the

individual fails to provide the ChildLine verification or criminal history report or both within the 120-day TIME period permitted for provisional hire, the individual shall be terminated by the home care agency or removed from the home care registry's roster IMMEDIATELY.

§ 611. 55. Training COMPETENCY requirements.

(a) Prior to assigning or referring a direct care worker to provide services to a consumer, the home care agency or home care registry shall ensure that the direct care worker has demonstrated competency in accordance with subsection (b) or has satisfied the training requirements in subsection (c), as applicable:

- (1) HAS A VALID NURSE'S LICENSE IN THIS COMMONWEALTH;
- (2) HAS DEMONSTRATED COMPETENCY BY PASSING A COMPETENCY EXAMINATION DEVELOPED BY THE HOME CARE AGENCY OR HOME CARE REGISTRY WHICH MEETS THE REQUIREMENTS OF SUBSECTION (b); OR
- (3) HAS SUCCESSFULLY COMPLETED ONE OF THE FOLLOWING:
 - (i) A TRAINING PROGRAM DEVELOPED BY A HOME CARE AGENCY, HOME CARE REGISTRY, OR OTHER ENTITY WHICH MEETS THE REQUIREMENTS OF SUBSECTION (b);
 - (ii) A HOME HEALTH AIDE TRAINING PROGRAM MEETING THE REQUIREMENTS OF 42 C.F.R. 484.36 (RELATING TO

THE CONDITIONS OF PARTICIPATION; HOME HEALTH
AIDE SERVICES);

- (iii) THE NURSE AID CERTIFICATION AND TRAINING
PROGRAM SPONSORED BY THE DEPARTMENT OF
EDUCATION AND LOCATED AT WWW.PDE.STATE.PA.US;
 - (iv) A TRAINING PROGRAM MEETING THE TRAINING
STANDARDS IMPOSED ON THE AGENCY OR REGISTRY
BY VIRTUE OF THE AGENCY'S OR REGISTRY'S
PARTICIPATION AS A PROVIDER IN A MEDICAID
WAIVER OR OTHER PUBLICLY FUNDED PROGRAM
PROVIDING HOME AND COMMUNITY BASED SERVICES
TO QUALIFYING CONSUMERS;
 - (v) ANOTHER PROGRAM IDENTIFIED BY THE DEPARTMENT
BY SUBSEQUENT PUBLICATION IN THE *PENNSYLVANIA
BULLETIN* OR ON THE DEPARTMENT'S WEBSITE.
- (b) ~~A direct care worker who will provide to a consumer only assistance with
activities of daily living and instrumental activities of daily living may
demonstrate competency by successfully completing a competency
examination approved by the Department.~~
- A COMPETENCY EXAMINATION OR TRAINING PROGRAM
DEVELOPED BY AN AGENCY OR REGISTRY FOR A DIRECT

CARE WORKER SHALL ADDRESS, AT A MINIMUM, THE
FOLLOWING SUBJECT AREAS:

- (1) CONFIDENTIALITY;
- (2) CONSUMER CONTROL AND THE INDEPENDENT
LIVING PHILOSOPHY;
- (3) INSTRUMENTAL ACTIVITIES OF DAILY LIVING;
- (4) RECOGNIZING CHANGES IN THE CONSUMER
THAT NEED TO BE ADDRESSED;
- (5) BASIC INFECTION CONTROL;
- (6) UNIVERSAL PRECAUTIONS;
- (7) HANDLING OF EMERGENCIES;
- (8) DOCUMENTATION;
- (9) RECOGNIZING AND REPORTING ABUSE OR
NEGLECT; AND
- (10) DEALING WITH DIFFICULT BEHAVIORS.

~~(e) — Any direct care worker, including a direct care worker providing only assistance with activities of daily living and instrumental activities of daily living, will satisfy the training requirements if the direct care worker has a valid nurse's license or has successfully completed one of the following:~~

- ~~(1) — The home health aide training program described at 42 CFR
484.36 (relating to the Conditions of Participation: home health
aide services):~~

~~(2) — The nurse aid certification and training program approved by the Department of Education.~~

~~(3) — Other training programs, approved by the Department, notice of which shall be published in the Pennsylvania Bulletin and posted on the Department's website.~~

A COMPETENCY EXAMINATION OR TRAINING PROGRAM
DEVELOPED BY AN AGENCY OR REGISTRY FOR A DIRECT
CARE WORKER WHO WILL PROVIDE PERSONAL CARE SHALL
ADDRESS THE FOLLOWING ADDITIONAL SUBJECT AREAS:

- (1) BATHING, SHAVING, GROOMING AND DRESSING;
- (2) HAIR, SKIN AND MOUTH CARE;
- (3) ASSISTANCE WITH AMBULATION AND
TRANSFERRING;
- (4) MEAL PREPARATION AND FEEDING;
- (5) TOILETING; AND
- (6) ASSISTANCE WITH SELF-ADMINISTERED
MEDICATIONS.

~~(d) — To be eligible for approval by the Department, a competency examination or other training program must address, at a minimum, each of the following subject areas:~~

- ~~(1) — Confidentiality.~~
- ~~(2) — Consumer control and the independent living philosophy.~~

- ~~(3) — Recognizing changes in the consumer that need to be addressed.~~
- ~~(4) — Basic infection control.~~
- ~~(5) — Universal precautions.~~
- ~~(6) — Handling of emergencies.~~
- ~~(7) — Documentation.~~
- ~~(8) — Recognizing and reporting abuse or neglect.~~
- ~~(9) — Dealing with difficult behaviors.~~
- ~~(10) — Bathing, shaving, grooming and dressing.~~
- ~~(11) — Hair, skin and mouth care.~~
- ~~(12) — Assistance with ambulation and transferring.~~
- ~~(13) — Meal preparation and feeding.~~
- ~~(14) — Toileting.~~
- ~~(15) — Assistance with self-administered medications.~~
- ~~(16) — Home management.~~

(e) (D) The home care agency or home care registry shall include documentation of the individual's DIRECT CARE WORKER'S satisfactory completion of training COMPETENCY requirements in the individual's personnel DIRECT CARE WORKER'S file. If the individual DIRECT CARE WORKER has a nurse's license or other licensure or certification as a health professional, the individual's personnel file shall include a copy of the individual's current license OR CERTIFICATION. Documentation of satisfactory completion of training COMPETENCY requirements is transferable from one home care agency or registry to another home care agency or registry, provided the training meets the

requirements of subsection (a) and the break in the individual's employment or roster status does not exceed 12 months.

(e) The home care agency or home care registry also shall include documentation in the ~~individual's personnel~~ DIRECT CARE WORKER'S file that the agency or registry has ~~periodically reassessed~~ REVIEWED the individual's competency to perform assigned duties through direct observation, testing, training, CONSUMER FEEDBACK or other method approved by the Department or through a combination of methods. ~~Periodic reassessment~~ THE COMPETENCY REVIEW shall occur not less than once per year after initial competency is established, and more frequently when discipline or other sanction, ~~including a verbal warning~~ INCLUDING, FOR EXAMPLE, A VERBAL WARNING OR SUSPENSION, is imposed because of a quality of care infraction.

(f) Individuals A DIRECT CARE WORKER employed by a home care agency or rostered by the home care registry on the effective date of this subpart shall achieve compliance with the ~~training~~ COMPETENCY requirements imposed by this subpart CHAPTER within 2 years of the effective date of this subpart CHAPTER.

§ 611.56. Health evaluations SCREENING.

(a) A home care agency or home care registry shall insure that each ~~individual employed or rostered by the agency or registry~~ DIRECT CARE WORKER and other office staff or contractors with direct consumer

~~contact, prior to beginning work-CONSUMER CONTACT, provide documentation that is made part of the individual's personnel file, evidencing a screening assessment performed by a qualified health professional within 180 days prior to the individual's start date. The results of the screening assessment shall include information showing that the individual was evaluated for tuberculosis risk factors, in accordance with guidelines issued by the federal Centers for Disease Control and Prevention, and tested as necessary, and was screened for the following communicable diseases or conditions:~~

- ~~(1) — Hepatitis A.~~
- ~~(2) — Salmonella.~~
- ~~(3) — Shigella.~~
- ~~(4) — Shiga toxin producing Escherichia coli.~~
- ~~(5) — Symptom caused by illness, infection or other source where symptom is associated with gastrointestinal illness such as diarrhea, fever, vomiting, jaundice, sore throat with fever.~~

~~THE INDIVIDUAL HAS BEEN SCREENED FOR AND IS FREE FROM ACTIVE MYCOBACTERIUM TUBERCULOSIS. THE SCREENING SHALL BE CONDUCTED IN ACCORDANCE WITH CDC GUIDELINES FOR PREVENTING THE TRANSMISSION OF MYCOBACTERIUM TUBERCULOSIS IN HEALTH CARE SETTINGS. THE DOCUMENTATION SHALL INDICATE THE DATE~~

OF THE SCREENING WHICH SHALL BE NOT MORE THAN ONE
YEAR PRIOR TO THE INDIVIDUAL'S START DATE.

~~(b) — A home care agency or home care registry shall not refer a direct care worker that is suspected by the home care agency or home care registry of having any of the communicable diseases or conditions listed in subsection (a). Subsequent referral shall be contingent on verification from a qualified health professional that the direct care worker is free from any of the communicable diseases or conditions listed in subsection (a).~~

~~(e) (B) A home care agency or home care registry shall require each individual employed or rostered by the agency or registry DIRECT CARE WORKER, and other office staff or contractors with direct consumer contact, to obtain an updated screening assessment UPDATE THE DOCUMENTATION REQUIRED BY SUBSECTION (A) NOT LESS THAN every 12 months and provide these results THE DOCUMENTATION to the agency or registry. THE 12 MONTHS SHALL RUN FROM THE DATE OF THE LAST EVALUATION. The updated screening assessment DOCUMENTATION REQUIRED BY SUBSECTION (A) shall be made part of INCLUDED IN the individual's personnel file.~~

(C) A DIRECT CARE WORKER EMPLOYED BY A HOME CARE AGENCY OR ROSTERED BY THE HOME CARE REGISTRY ON THE EFFECTIVE DATE OF THIS SUBPART SHALL ACHIEVE COMPLIANCE WITH THE HEALTH

EVALUATION REQUIREMENTS IMPOSED BY THIS CHAPTER WITHIN
180 DAYS OF THE EFFECTIVE DATE OF THIS CHAPTER.

§ 611.57. Consumer protections.

- (a) Consumer rights. The consumer of HOME CARE services provided by a home care agency or through a home care registry shall have the following rights:
- (1) To be involved in the service planning process and to receive services with reasonable accommodation of individual needs and preferences, except where the health and safety of the direct care worker is at risk.
 - (2) To receive at least 10 calendar days advance written notice of the intent of the home care agency or home care registry to terminate services. Less than 10 days advance written notice may be provided in the event the consumer has failed to pay for services, despite notice, and the consumer is more than 14 days in arrears, or if the health and welfare of the direct care worker is at risk.
- (b) Prohibitions. No individual as a result of the individual's affiliation with a home care agency or home care registry may assume power of attorney or guardianship over a consumer utilizing the services of that home care agency or home care registry. The home care agency or home care registry may not require a consumer to endorse checks over to the home care agency or home care registry.
- (c) Information to be provided. Prior to the commencement of services, the home care agency or home care registry shall provide to the consumer, the consumer's legal representative or responsible family member an

information packet containing the following information in a form that is easily read and understood:

- (1) A listing of the available home care agency or home care registry HOME CARE services that will be provided to the consumer by the direct care worker AND THE IDENTITY OF THE DIRECT CARE WORKER THAT WILL PROVIDE THE SERVICES.
- (2) The hours when those services will be provided.
- (3) Fees and total costs for those services on an hourly or weekly basis.
- (4) Who to contact at the Department for information about licensure requirements for a home care agency or home care registry and for compliance information about a particular home care agency or home care registry.
- (5) The Department's complaint Hot Line (1-866-826-3644) and the telephone number of the Ombudsman Program located with the local Area Agency on Aging (AAA).
- (6) The hiring and training COMPETENCY requirements applicable to direct care workers employed by the home care agency or referred by the home care registry, a description of the manner and frequency of periodic reassessment of direct care worker competency, and documentation maintained by the home care agency or home care registry to confirm compliance with hiring and training requirements under § 611.22 (relating to hiring requirements) and § 611.26 (relating to training requirements).

(7) A disclosure, in a format to be published by the Department in the Pennsylvania Bulletin within 60 days of the effective date of this chapter, addressing the employee or independent contractor status of the direct care worker providing services to the consumer, and the resultant respective tax and insurance obligations and other responsibilities of the consumer and the home care agency or home care registry.

(D) DOCUMENTATION. THE HOME CARE AGENCY OR HOME CARE REGISTRY SHALL MAINTAIN DOCUMENTATION ON FILE AT THE AGENCY OR REGISTRY OF COMPLIANCE WITH THE REQUIREMENTS OF THIS SECTION WHICH SHALL BE AVAILABLE FOR DEPARTMENT INSPECTION.

**LIST OF NAMES AND ADDRESSES OF COMMENTATORS
REQUESTING A COPY OF FINAL-FORM REGULATION 10-184**

JoAnn L. Knupp
Care For People
P. O. Box 359
Bellefonte, PA 16823

Mary Wagner, Director
Care For People
2220 Linwood Ave.
Williamsport, PA 17701

Nancy Bevan, Director
Care For People
R.R. #2, Box 2055
Lake Ariel, PA 18436

Susan Stuter, Director
Care For People
747 Woodland Drive
Reedsville, PA 17084

Kathryn Alven, President
Schuylkill Nursing Association, Inc.
P.O. Box 683
Schuylkill Haven, PA 17972

Kathleen Bailey, President
MediQuest Staffing & Homecare
600-E Eden Road
Lancaster, PA 17601

David Pareja
Chief Program Officer
Community Health Services of Hanover &
Spring Grove
440 North Madison Street
Hanover, PA 17331

Vicki M. Hoak
Executive Director
Pennsylvania Homecare Association
20 Erford Road, Suite 115
Lemoyne, PA 17043

Lori R. Griswold, Ph.D., M.S.G.
717 Bethlehem Pike, Suite 300
Erdenheim, PA 19038

Anita Weinberg
Office of Statewide Affairs
Bayada Nurses
1315 Walnut Street, Suite 1132
Philadelphia, PA 19107

Cheryl Dott R.N. M.Ed.
The Thorne Group, Inc.
Home Health Services
235 West Pittsburgh St.
Greensburg, PA 15601

Paula G. Sanders
Post & Schell
17 North Second Street
12th Floor
Harrisburg, PA 17101-1601

Silver Lining Home Health Care, Inc.
Attn: Jonathan Golluber
25 Washington Lane, Suite B-1
Wyncote, PA 19095

Marian Baldini
JEVS Human Services
1845 Walnut Street, 7th Floor
Philadelphia, PA 19103

Central Penn Nursing Care, Inc.
Attention: Eleanor H. Strayer, President
1910 Fruitville Pike, Suite #1
Lancaster, PA 17601

Betty L. Bollinger
Sun Home Health Services
61 Duke Street
P.O. Box 232
Northumberland, PA 17857

Donna M. Jenkins
Sun Home Health Services
61 Duke Street
P.O. Box 232
Northumberland, PA 17857

Commonwealth of Pennsylvania



DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

August 24, 2009

Mr. Kim Kaufman
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Department of Health – Final Regulations No. 10-184
Home Care Agencies and Home Care Registries

Dear Mr. Kaufman:

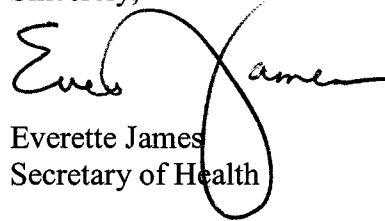
Enclosed is a copy of final-form regulations for review by the Commission pursuant to the Regulatory Review Act (Act)(71 P.S. §§745.1-745.15). Section 5.1(a) of the Act provides that, upon completion of the agency's review of comments following proposed rulemaking, the agency is to submit to the Commission and the Standing Committees, a copy of the agency's response to the comments received, the names and addresses of commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

Seventeen commentators have requested additional information relating to the final-form regulations. A list of the names and addresses of these commentators is enclosed. The Department received 38 comments to the proposed rulemaking. These comments, which discussed a number of provisions contained in the proposed regulations, were forwarded to the Commission upon receipt by the Department.

Section 5.1(e) of the Act provides that within 10 days following the expiration of the Standing Committee review period, or at its next regularly scheduled meeting, the Commission shall approve or disapprove the final-form regulations.

The Department will provide the Commission with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact Neil Malady, Director, Office of Legislative Affairs.

Sincerely,

A handwritten signature in black ink, appearing to read "Ever James". The signature is fluid and cursive, with a large loop at the end of the word "James".

Everette James
Secretary of Health

Enclosures

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT**



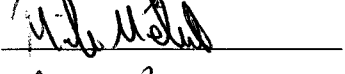
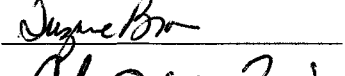
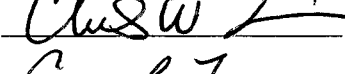
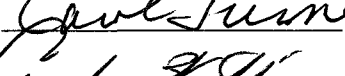

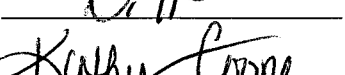
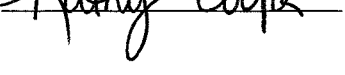
I.D. NUMBER: 10-184
SUBJECT: Home Care Agencies and Home Care Registries
AGENCY: Department of Health

TYPE OF REGULATION

- Proposed Regulation
- X Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
 - a. With Revisions
 - b. Without Revisions

RECEIVED
 DEPARTMENT OF HEALTH
 AUG 11 2009

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
8/24/09		HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
8/24/09		MAJORITY CHAIRMAN <u>Frank L. Oliver</u>
8/24/09		SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
8/24/09		MAJORITY CHAIRMAN <u>Edwin B. Erickson</u>
8/24/09		HOUSE COMMITTEE ON AGING & OLDER ADULT SERVICES
8/24/09		MAJORITY CHAIRMAN <u>Phyllis Mundy</u>
8/24/09		SENATE COMMITTEE ON AGING AND YOUTH
8/24/09		MAJORITY CHAIRMAN <u>Patricia H. Vance</u>
8/24/09		INDEPENDENT REGULATORY REVIEW COMMISSION
_____	_____	ATTORNEY GENERAL (for Final Omitted only)
_____	_____	LEGISLATIVE REFERENCE BUREAU (for Proposed only)