

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 4, 2007, the Department published notice of proposed rulemaking . The Department provided a 30-day public comment period.

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 to abandon current efforts to incorporate within these licensure 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 Department plans a comprehensive revision of the regulations in Chapter 51. The Department contemplates replacing Chapter 51 with several chapters that will address current requirements in significantly

greater detail and include requirements reflective of the Department's existing procedures and protocols. 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 will 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 elected not to use of the term “screening assessment” and has clarified the health evaluation requirements. The final regulation, § 611.56 (relating to health evaluations), requires the direct care worker and other office staff or contractors with direct consumer contact to provide documentation that a qualified health professional has determined that the individual is (1) free from active tuberculosis, and (2) free from other communicable diseases, as identified by the qualified health professional. The Department has not included the additional 5 communicable diseases and conditions listed in the proposed regulation. The final regulation leaves to the discretion of the qualified health professional those communicable diseases for which the individual should be evaluated.

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.

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 employed or rostered for more than one year, 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 convictions that are 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 is simply one method by which competency may be established.

The Act requires an agency or registry to ensure that the individual providing home care services is competent to provide those services, and gives the agency or registry a number of options to choose from in establishing that the individual is competent to provide the services. Most of the options center on training, received prior to hire or roster (evidenced via licensure or certification) or after, via an approved training mechanism identified in the statute or in regulation, or a training program developed and administered by the agency or registry. The Act also permits the agency or registry to verify that the individual is competent to provide services as assigned or requested by the

consumer through a competency examination. 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 care-givers 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 changed 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 training requirement. Direct care workers employed or rostered prior to the effective date have 2 years from the effective date to satisfy the training 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 training requirements within 30 days of the individual’s hire or roster date. The

Department has declined to impose a time frame within which the training requirement must be accomplished after an individual is hired or rostered. The time frame within which the mandatory training 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 the agency or registry could

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 evaluations.

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.

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).

When beginning to draft regulations, the Department quickly realized that establishing that an individual is “free from communicable disease” could be a very lengthy and expensive proposition. 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.

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 does not use the term “screening assessment.” The regulation 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 a qualified health professional has determined that the individual is free from active mycobacterium tuberculosis and that the individual is free from communicable diseases, as identified by the qualified health professional. 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 regulation leaves it to the discretion of the qualified health professional (defined as a physician, a physician’s assistant and a certified registered nurse practitioner) to identify the communicable diseases for which the individual should be evaluated. The direct care worker must obtain the documentation every 12 months and provide the documentation to the agency or registry to be included in the individual’s file.

One commentator inquired whether a registered nurse could perform the health evaluation. The regulation states that the health evaluation must be conducted by a qualified health care professional. The term “qualified health care professional,” per the definition, includes a physician, a physician’s assistant, and a certified registered nurse practitioner. A registered nurse is not qualified to perform the health evaluation.

One commentator inquired whether the Commonwealth has a standard physical examination form that should be completed for the direct care worker. Since the Department is leaving to the qualified health professional those communicable diseases, in addition to active tuberculosis, for which the individual should be evaluated, the Department will not be supplying a standard form or requiring a standard format. As long as the documentation establishes that the individual was evaluated for active tuberculosis and other communicable diseases, as identified by the qualified health professional, 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 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 an assessment of the direct care worker's health status before the worker is assigned or referred to

provide services. The Department has defined “qualified health professional” as broadly as possible in order to provide alternatives to individuals who will need to obtain documentation of the health evaluation.

Another 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 evaluation 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 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 evaluation, 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 evaluation 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 suggested that the Department replace “qualified” with “licensed” as the modifier for “health professional.” The Department has elected not to accept this suggestion. The term “qualified health professional” is a defined term in the regulation and lists individuals who are “qualified” to perform the health evaluation. The commentator 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 recommended that the health care professional determine the diseases for which the individual should be evaluated. The Department has accepted this recommendation. 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 \$1,008,000 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 ____ Pa. B. _____ 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 provided the Commission and the Committees with a copy of a 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*.