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(1) Agency Department of Health		INDEPENDENT REGULATORY REVIEW COMMISSION IRRC Number: 2623
(2) I.D. Number (Governor's Office Use) 10-184		
(3) Short Title Home Care Agencies and Home Care Registries		
(4) Pa Code Cite 28 Pa. Code Chapter 611	(5) Agency Contacts & Telephone Numbers Primary Contact: Janice Staloski, Director Bureau of Community Program Licensure and Certification (717) 783-8665 Secondary Contact: Karin S. Simpson, Senior Counsel (717) 783-2500	
(6) Type of Rulemaking (Check One) <input checked="" type="checkbox"/> Proposed Rulemaking <input type="checkbox"/> Final Order Adopting Regulation <input type="checkbox"/> Final Order, Proposed Rulemaking Omitted		(7) Is a 120-Day Emergency Certification Attached? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes: By the Attorney General <input type="checkbox"/> Yes: By the Governor
(8) Briefly explain the regulation in clear and non-technical language. These regulations set minimum standards for the operation and licensure of home care agencies and home care registries. Act 2006-69, signed by Governor Rendell on July 7, 2006, amended the Health Care Facilities Act (35 P.S. §§ 448.101 – 448.904b) to require the Department of Health to license home care agencies and home care registries. Agencies employ direct care workers and registries contract with direct care workers to provide home care services to consumers in their home or other independent living environment. Home care services include assistance with activities of daily living (e.g. bathing, dressing and feeding) and instrumental activities of daily living (e.g. housekeeping, shopping, meal preparation and transportation). These regulations establish consumer protections and require criminal background checks, child abuse clearance, communicable disease screens and training for direct care workers.		

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(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

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

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

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

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

These standards are intended by the Department to assure safe, adequate and efficient home care agencies and home care registries, and to promote the health, safety and adequate care of consumers of services provided by home care agencies and home care registries.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

Consumers prefer home care to institutional care. Home care permits consumers to age-in-place. These licensure standards are the only means available to the Department to ensure the delivery of quality care to consumers of services provided by home care agencies and home care registries. The proposed regulations require criminal background checks, child abuse clearance and health screenings for individuals employed by a home care agency or referred by a home care registry to provide care to consumers. The proposed regulations also impose hiring and training requirements.

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(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The regulations will benefit all future recipients of services provided by home care agencies and home care registries. Based on partial data collected by the Department to date, this will include approximately 650 home care agencies and home care registries and approximately 800,000 consumers.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

No one will be adversely affected by the regulation.

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

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

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

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

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consult with the Health Policy Board when promulgating regulations.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures that may be required.

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

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures that may be required.

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

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulations, including legal and accounting or consulting procedures that may be required.

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

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Some, but not all, of the cost of the licensure program will be offset by licensure fees paid by home care agencies and home care registries. The Department anticipates an offset in the form of licensure fees in the approximate amount of \$650,000 per year.

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

	Current FY Year	FY +1 Year	FY +2 Years	FY +3 Years	FY +4 Years	FY +5 Years
SAVINGS	\$	\$	\$	\$	\$	\$
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
TOTAL SAVINGS	0	0	0	0	0	0
COSTS						
Regulated Community	750,000	650,000	650,200	650,400	650,400	650,400
Local Government	0	0	0	0	0	0
State Government *	447,000	1,008,000	1,056,036	1,106,451	1,168,122	1,168,122
TOTAL COSTS						
REVENUE LOSSES:						
Regulated Community						
Local Government						

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State Government						
Total Revenue Losses						

(20a) Explain how the cost estimates listed above were derived.

Estimates for the impact on the regulatory community are explained in question 17. The increase in FY 1, 2 and 3 are based on additional facilities being established with a leveling out in years 4 and 5.

*State government costs for current year and 07/08 fiscal years was based on estimates calculated by the DOH budget office. For all out years, personnel costs include the proposed salary increases for 08/09, 09/10 and 10/11 fiscal year.

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

Program	FY - 3	FY - 2	FY - 1	Current FY
Home Health	801,644.22	1,051,829.00	1,136,123.00	942,510.00

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

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

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

No non-regulatory alternatives were considered in light of the legislative mandate to promulgate regulations.

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(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

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

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

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

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

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

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

The proposed regulations may affect the licensure program for home health agencies under 28 Pa. Code Chapter 601. To be licensed under Chapter 601, home health agencies must be staffed and equipped to provide skilled nursing services and at least one therapeutic service (e.g. physical therapy, occupational therapy, speech pathology, medical social services or home health aides). The home health agency, although staffed and equipped to provide skilled care, also may

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provide assistance with activities of daily living and instrumental activities of daily living. Home care agencies and home care registries provide assistance with activities of daily living and instrumental activities of daily living but do not provide skilled care. The Department anticipates that certain entities seeking licensure as a home care agency also may provide skilled care, in which case those entities must be licensed as home health agencies.

(27) Will any public hearings or information meetings be scheduled? Please provide the dates, times, and locations, if available.

Act 2006-69 required the Department to develop these regulations in consultation with the Department of Public Welfare and other advisory groups that represent persons in the home health care industry, persons with physical disabilities and the aging community. The Department also was required to take into consideration the preferences and philosophies of persons with physical disabilities who receive services through the home and community-based waiver 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 held in Harrisburg on December 7, 2006, in Muhlenberg on December 12, 2006 and in Pittsburgh on December 15, 2006. The Department also met with representatives of what was Pennsylvania Protection and Advocacy and is now the Disabilities Rights Network of Pennsylvania and with other individuals representing organization serving the disability community on January 26, 2007.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports that will be required as a result of implementation, if available.

Existing paperwork requirements, applicable to licensure of other health care facilities under the Health Care Facilities Act will now apply to home care agencies and home care registries. Existing forms will be revised and altered as necessary to accommodate the home care agency and home care licensure process.

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

The proposed regulations define "home care agency" and "home care registry" to exclude entities that provide only financial management services to consumers of publicly funded home and community-based services. "Financial management services" is defined as one or more of five specified services associated with meeting the payroll and other responsibilities of a consumer of home care services who is also the employer of the individual providing the home care services. This language was developed to meet the needs of certain members of the disability community who are consumers of publicly funded home and community based

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services and who employ their own care-givers and utilize the services of an agency only for payroll and other employer-related functions. The language is intended to support Section 903.1 of Act 2006-69, addressing non-applicability. That section states that nothing in the act shall apply to a private contract or arrangement entered into by a consumer and caregiver, provided that the caregiver was not supplied, arranged, scheduled or referred to the consumer by a home care agency or home care registry.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

Section 809.1 of Act 2006-69 required the Department to promulgate regulations to implement §§ 806(d.1) (relating to home care agency and home care registry licensure requirements) and 806.3 (relating to consumer protections) and to publish the regulations in the *Pennsylvania Bulletin* within one year of the effective date of § 809.1. Section 809.1 became effective when the act was signed on July 7, 2006. Thus, the Department anticipates that the regulations will become effective on July 7, 2007, or as soon thereafter as the regulatory review process permits. The proposed regulation would permit the entity operating as a home care agency or home care registry as of the effective date of the regulation to continue to operate after the effective date provided the entity submits an application for a license in accordance with timeframes to be announced via the *Pennsylvania Bulletin* and the Department's web site.

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

The regulations will be reviewed and updated as appropriate.

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<p>Copy below is hereby approved as to form and legality. Attorney General.</p> <p><i>Amey W. Elliott</i> BY DEPUTY ATTORNEY GENERAL <u>JUL 20 2007</u> DATE OF APPROVAL</p> <p>9 Check if applicable. Copy not approved. Objections attached.</p>	<p>Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:</p> <p>DEPARTMENT OF HEALTH (AGENCY)</p> <p>DOCUMENT/FISCAL NOTE NO. <u>10-184</u> DATE OF ADOPTION: _____</p> <p><i>Calvin B. Johnson</i> BY: <u>Calvin B. Johnson, M.D., M.P.H.</u></p> <p>TITLE: <u>SECRETARY OF HEALTH</u></p>	<p>Copy below is hereby approved as to form and legality. Executive or independent Agencies.</p> <p><i>Andrew C. Clark</i> BY <u>JUN 5 2007</u> DATE OF APPROVAL</p> <p>(Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title)</p> <p>9 Check if applicable. No Attorney General approval or objection within 30 days after submission.</p>
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NOTICE OF PROPOSED RULEMAKING

TITLE 28. HEALTH AND SAFETY

DEPARTMENT OF HEALTH

SUBPART H. HOME CARE AGENCIES AND HOME CARE REGISTRIES

CHAPTER 611. HOME CARE AGENCIES AND HOME CARE REGISTRIES

Notice is hereby given that the Department of Health, Bureau of Community Program Licensure and Certification, Division of Home Health (Department), proposes to amend 28 Pa. Code to add a new Subpart H, Chapter 611, to govern licensure of home care agencies and home care registries. The proposed regulations are set forth in Annex A hereto.

PURPOSE OF THE REGULATION

The purpose of these regulations is to set minimum standards for the operation of home care agencies and home care registries. Act 2006-69, signed by Governor Rendell on July 7, 2006, amended the Health Care Facilities Act (35 P.S. §§ 448.101 – 448.904b) to require the Department 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 home 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 home or other independent living environment. Services provided by home care agencies and home care registries include assistance with activities of daily living (e.g. bathing, dressing and feeding) and instrumental activities of daily living (e.g. housekeeping, shopping, meal planning and preparation, and transportation), companionship, respite care and other non-medical services.

These proposed standards are intended by the Department to assure safe, adequate and efficient home care agencies and home care registries, and to promote the health, safety and adequate care of the consumers of services provided by home care agencies and

home care registries. These proposed regulations provide consumer protection by establishing oversight, by requiring criminal background checks, child abuse clearance and communicable disease screens, and by imposing hiring and training requirements for individuals employed by a home care agency or referred by a home care registry to provide care.

STATUTORY AUTHORITY

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

SUMMARY

Act 2006-69 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. The Department also is required 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 (PP&A), and is now known as 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, in accordance with the Department's obligation to consult with the Health Policy Board when promulgating regulations under the Health Care Facilities Act. 35 P.S. § 448.803(1).

The proposed regulations are divided into several sections. The first section contains general provisions including definitions pertinent to the proposed regulations. The next three sections address the Department's proposed licensure process, inspection and survey activities, and sanctions and corrective actions. These three proposed sections reflect the Department's existing practices and protocols for licensure and enforcement of licensure standards for all health care facilities covered by the Health Care Facilities Act. The final proposed section on governance and maintenance would address the substantive requirements set forth in the statute that a home care agency or home care registry must

meet in order to obtain and maintain a license. This proposed section would address hiring and training of direct care workers employed or on contract, background checks, child abuse clearances, and consumer protections.

Proposed § 611.1 would explain the statutory authority for and the purpose of the regulations. Proposed § 611.2 would explain that the regulations affect home care agencies and home care registries that meet the definition included in the regulations, and would establish the time frame within which existing home care agencies and home care registries must come into compliance. Proposed § 611.3 would explain the obligation of the home care agency and home care registry to comply with existing laws and regulations addressing environment, health, sanitation and professional licensure standards imposed by Federal, State and local authorities.

Proposed § 611.4 would be the definitional section and would include definitions of terms used in the proposed regulations. Terms used in the proposed regulations that are defined in the Act are not defined again in these proposed regulations except to the extent that a definition has been expanded to clarify or interpret compliance obligations for the home care agencies and registries. Thus, the proposed regulations include definitions of “home care agency” and “home care registry” in order to clarify that entities providing only “financial management services” to consumers of home and community-based services through Medicaid waiver or other publicly funded programs would not be subject to these regulations. The terms “home care agency” and “home care registry” would be defined to exclude an entity designated under Section 3504 of the Internal

Revenue Code and either IRS Revenue Procedure 70-6 or IRS Revenue Procedure 80-4 that provides only “financial management services” to consumers of home and community-based services through Medicaid waiver or other publicly funded programs. These proposed regulations would define “financial management services” to mean one or more of five specified services associated with meeting the payroll and other responsibilities of a consumer of home care services who is also the employer of the direct care worker. If the entity provides only financial management services to a consumer of home and community-based services, then the entity would not be a covered entity for licensure purposes. The corollary, of course, is that if the entity provides more than financial management services, the entity would not be automatically excluded and would have to examine its operations to determine if it were subject to the licensure requirements.

The proposed definitional section also includes a definition of “inspection,” also defined in the act, in order to clarify the means by which the Department would determine the agency’s or registry’s compliance with licensure standards, and to establish that the inspection might or might not be on-site. The remaining definitions are self-explanatory.

The licensure section of the proposed regulations sets forth requirements for the licensure process that would be consistent with those of the Department for all health care facilities that the Department licenses. (See proposed §§ 611.5 – 611.13). This section of the proposed regulations does contain several provisions, however, that would be specific to home care agencies and home care registries. The proposed regulations would require

that to the extent that an entity operates a home care business from more than one location, each physical location of the agency or registry must be separately licensed. (See proposed § 611.5(a)). The proposed regulations also address the possibility that an entity could be operating as both a home care agency and a home care registry. (See proposed § 611.5(b)). That is, the entity might offer employees as direct care workers to consumers, and the entity might also offer a roster of individuals who are independent contractors for a consumer to choose from in order to receive services. In that case, the entity would be required to apply for a license to operate as a home care agency and a home care registry. This proposed section also addresses how existing home care agencies and home care registries would transition from non-licensed to licensed status. (See proposed § 611.5(c)). The proposed regulation would permit the entity operating as a home care agency or home care registry as of the effective date of the regulation to continue to operate after the effective date provided the entity submits an application for a license in accordance with timeframes to be announced in the Pennsylvania Bulletin and on the Department's website. (Id.)

The inspection and survey activities section also would contain requirements that would be consistent with those of the Department for all health care facilities that the Department licenses. (See proposed §§ 611.14 – 611.16). There are no proposed provisions in this section that vary the inspection and survey process for home care agencies and home care registries. Subsection (e)(4) of proposed § 611.14 (relating to inspections), however, would define access to the agency or registry to include private interviews with the consumer, with the consumer's consent. This proposed language is

intended to address concerns expressed during the stakeholder process that the Department might insert itself in the consumer and care-giver relationship without appropriate regard for the consumer's privacy. This provision would make clear that the Department's approach with regard to home care agencies and home care registries would be the same as it is for all other health care facilities. In all circumstances and in all settings in which the services of licensed entities are being assessed for regulatory compliance, the Department does not seek to interview the recipient of regulated services or observe direct care without that person's consent.

Finally, the sanctions and corrective actions section of the proposed regulation, which would address sanctions for deficiencies, reasons for revocation or nonrenewal of a license, notice and form of notice of sanctions to be imposed, and request for hearing, also reflects the Department's practices and procedures for all health care facilities that the Department licenses. (See proposed §§ 611.17 – 611.21). Much of what is proposed in this section, most notably the reasons for revocation or nonrenewal of a license, is pulled directly from the Health Care Facilities Act, whose provisions apply to all facilities covered by the Act.

The final section of the proposed regulations under "Governance and Maintenance" would address the substantive requirements set forth in the statute applicable to home care agencies and home care registries. Proposed § 611.22 (relating to hiring of direct care workers) would require that, before a home care agency may hire a direct care worker or a home care registry may enter into a contract with and place an individual on

a list of available direct care workers (e.g. roster the individual), the agency or registry conduct a face-to-face interview with the individual, obtain satisfactory references, and require the individual to submit a criminal history report and a ChildLine verification, if necessary. Agencies and registries would be required to include documentation of the face-to-face interview, references obtained, and criminal background check and child-line verification in a personnel file for the direct care worker.

Proposed § 611.23 (relating to criminal background checks) would address the criminal background check requirement and would include requirements that mirror those found in regulations promulgated at 6 Pa. Code Chapter 15 (relating to Protective Services for Older Adults) to implement the criminal background check requirements under the Older Adults Protective Services Act (35 P.S. §§ 10225.101 – 10225.5102) (OAPSA). Thus, this proposed section would require that the criminal history report, listed as a prerequisite for hire or roster under § 611.22, be obtained at the time of the application or within 1 year immediately preceding the date of the application. (See proposed subsection (a)). This proposed section also would require that the applicant for employment or roster submit a State Police criminal history record if the individual has been a resident of Pennsylvania for 2 years preceding the date of application. (See proposed subsection (b)). If the individual has not been a resident of Pennsylvania for the requisite 2-year period, the applicant would be required to follow the procedures at 6 Pa. Code § 15.144(b) (relating to procedure) to obtain a federal criminal history record and a letter of determination from the Department of Aging, based on the individual's Federal

criminal history record, regarding the individual's eligibility for hire or roster. (See proposed subsection (c)).

These proposed regulations anticipate that the Department of Aging, based on an inter-agency agreement to be developed between the Department and the Department of Aging, will expand its work under OAPSA for nursing care facilities, home health agencies, hospice and other health care providers, and review federal criminal history records for individuals applying to work for home care agencies and home care registries and issue letters of determination. The Department of Aging would review the federal criminal history record to determine whether the record lists a prohibited conviction (listed at 6 Pa. Code § 15.143 (relating to facility responsibilities)), and then issue a letter of determination.

Under proposed § 611.23(e), the home care agency or home care registry would not be permitted to hire or roster an individual if the State Police criminal history record revealed a prohibited conviction or if the Department of Aging letter of determination stated that the individual is not eligible for hire or roster. Until such point as OAPSA may be amended, in light of *Nixon v. The Commonwealth of Pennsylvania*, 576 Pa. 385, 839 A.2d 277 (2003), and the life-time prohibition against hire or the list of prohibited convictions revised, the Department is proposing that the regulations to implement the background check provisions of Act 2006-69 should mirror the existing background check provisions and prohibitions applicable to other health care providers under OAPSA.

The proposed regulation on criminal background checks would require persons who are employed by or rostered by a home care agency or home care registry as of the effective date of the regulation to obtain and submit a State Police criminal history record or Department of Aging letter of determination, as applicable, to the home care agency or home care registry within 120 days of the effective date of the regulations. This requirement would not apply if the home care agency or home care registry obtained a criminal history report meeting the requirements of the regulation when the individual was hired or rostered and a copy of the report is included in the individual's personnel file. (See proposed subsection (j)).

Under proposed § 611.24 (relating to child abuse clearance, a home care agency or home care registry that serves persons under 18 years of age would need to 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 verification regarding whether that individual is named in the Department of Public Welfare's Statewide Central Register as the perpetrator of a founded or indicated report of child abuse as defined at 55 Pa. Code § 3490.4 (relating to definitions). (See proposed subsection (a)). The home care agency or home care registry would be prohibited from hiring or rostering an individual named in the Statewide Central Register as the perpetrator of a founded or indicated report of child abuse. (See proposed subsection (b)). Persons currently employed or rostered as of the effective date of the regulation would have 120 days to comply, except that a person for whom a ChildLine verification had been obtained when the person was hired or rostered

need not obtain another verification as long as a copy of the verification is contained in the individual's personnel file. (See proposed subsection (d)).

During the stakeholder process, the Department received many suggestions that the Child Line clearance requirement should apply only to those direct care workers employed or rostered specifically to provide care to an individual under 18 years of age. Act 2006-69 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 register, 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 Department is not permitted to promulgate a regulation less stringent than the law on which the regulation is based.

Proposed § 611.25 would permit a home care agency or home care registry to hire an applicant for employment or referral on a provisional basis, pending receipt of a criminal history report or a ChildLine verification, as applicable, if certain listed conditions are met. (See proposed subsection (a)). The applicant would be required to apply for a criminal history report and ChildLine verification, as applicable, to affirm in writing that the applicant is not disqualified from employment because of a criminal background or history of child abuse, and to have the training required by the proposed regulations. The home care agency or home care registry would be required to monitor the provisionally

hired applicant through random, direct observation and consumer feedback. The period of provisional employment cannot exceed 120 days.

During the stakeholder process, a number of participants suggested that the concept of provisional hiring should be eliminated from the regulations. The Department emphasized then, and again points out, that the proposed regulation would permit, but would not require, provisional hiring. A home care agency or home care registry would be free to assess the risks associated with provisional hiring and to determine that the risks would outweigh the benefits. This proposed regulation is meant to establish the parameters within which provisional hiring might occur for those home care agencies or home care registries that would choose to provisionally hire.

Proposed § 611.26 would address training requirements and would allow the home care agency or home care registry several different options for ensuring that the direct care worker is appropriately trained. The proposed regulation would provide that a direct care worker who would provide only assistance with activities of daily living and instrumental activities of daily living may demonstrate competency by successfully completing a competency examination approved by the Department. (See proposed subsection (b)).

The proposed regulation also would provide that any direct care worker will have satisfied the training requirements if the direct care worker has a valid nurse's license or has successfully completed one of listed training programs or other training program approved by the Department and published in the Pennsylvania Bulletin. (See proposed subsection (c)). The proposed regulation includes required core elements in order for the

competency examination or other training program to be approved by the Department. (See proposed subsection (d)). In response to recommendations made during the stakeholder process by individuals representing persons with physical disabilities and persons who receive services through publicly funded home and community-based programs, the Department has proposed to include among the core elements for competency testing consumer control and the independent living philosophy.

Proposed § 611.26(e) would state, in part, that documentation of satisfactory completion of training prerequisites is transferable from one home care agency or registry to another home care agency or registry, provided the break in the individual's employment or roster status does not exceed 12 months. (See proposed subsection (f)). The proposed regulation would require periodic reassessment of the individual's competency to perform assigned duties. Reassessment would occur annually and more frequently when discipline or other sanction is imposed because of a quality of care infraction. (Id.) Finally, the proposed regulation would permit existing home care agencies and registries 2 years from the regulation's effective date to achieve compliance. (See proposed subsection (g)).

Proposed § 611.27 (relating to health evaluations) would require the home care agency or home care registry to ensure that each individual employed by an agency or rostered by a registry, and other office staff or contractors with direct consumer contact, prior to beginning work, provide documentation to be included in the individual's personnel file evidencing a screening assessment performed by a qualified health professional within

180 days prior to the individual's start date. The term "qualified health professional" would be defined within the regulation as an individual who holds a license or certification issued by the Commonwealth which allows for the performance of a physical examination, evaluation or assessment. (See proposed §611.4 (relating to definition of a "qualified health professional"). The term would include a physician, a physician's assistant, a registered nurse, and a certified registered nurse practitioner. (Id.)

The screening assessment would need to show that the individual was evaluated for tuberculosis risk factors and tested as necessary, and screened for the listed communicable diseases and conditions. (See proposed subsection (a)). The proposed regulation would prohibit the home care agency or home care registry from referring a direct care worker if the agency or registry suspects the direct care worker has one of the listed communicable diseases or conditions until the direct care worker has been evaluated by a qualified health professional and cleared to return to work. (See proposed subsection (b)). The regulation would require the home care agency or home care registry to require the individual to obtain an updated screening assessment annually. (See proposed subsection (c)).

Proposed § 611.28 (relating to consumer protections) would be divided into three subsections. The first subsection would address consumer rights, the second would address prohibitions for the home care agency and home care registry, and the third would list information that the home care agency and home care registry must provide to the consumer in advance of providing services. (See proposed subsections (a), (b) and (c)). The proposed requirements of this proposed section were taken directly from the

statute. The proposed regulation would require the home care agency to provide a disclosure, addressing the employee or independent contractor status of the direct care worker, and the resultant respective tax and insurance obligations and other responsibilities of the consumer, in a format to be published by the Department within 60 days of the effective date of the regulation. (See proposed subsection (c)(7)).

FISCAL IMPACT

State Government

The licensure program for home care agencies and home care registries would 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 would 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 ongoing 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 would 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 would issue a hard copy license which the agency or registry must post at the licensed location. The Department also would issue hard copy statement of deficiencies which would be required to be available for public inspection, along with any plan of correction.

Local Government

There would be no additional paperwork requirements for local government.

Public

Consumers of home care services would receive paperwork as a result of these regulations. Consumers would receive written notice of termination of services.

Consumers also would receive written notice of 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. Consumers also would 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 would 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 would need to notify the department in writing prior to any change in ownership, change in officers, directors, members, partner or principals, or change in management. They would need to create and maintain certain personnel files 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 training prerequisites and the annual reassessment. The personnel file also would be required to contain documentation of a health evaluation obtained prior to employment or roster.

Home care agencies and home care registries would be required to provide written notice to the consumer of the intent to terminate services. Finally, home care agencies and home care registries would 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 would be required to 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 would 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. § 745.5(a), the Department submitted a copy of the proposed regulations on August 6, 2007, to the Independent Regulatory Review Commission and to the Chairman of the House Committee on Health

and Human Services, the House Committee on Aging and Older Adult Services, the Senate Committee on Public Health and Welfare and the Senate Committee on Aging and Youth. In addition to submitting the regulation, the Department has 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.

If the Commission has any objections to any portion of the proposed regulations, it will notify the Department within 30 days of the close of the public comment period. Such notification shall specify the regulatory review criteria which have not been met by that portion. The Act specifies detailed procedures for review, prior to final publication of the regulation, by the Department, the General Assembly, and the Governor, of objections raised.

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 A, Harrisburg, PA 17104-1579, (717) 783-8665, within 30 days after publication of this notice in the Pennsylvania Bulletin. If you are a person with a disability, comments, suggestions, or objections regarding the proposed regulations may also be submitted to Ms. Staloski in alternative formats, such as by audio tape, Braille, or by using TDD: (717) 783-6514. If you are a person with a

disability and require an alternative format of this document (i.e., large print, audio tape, Braille), please contact Ms. Staloski so that she may make the necessary arrangements.

Annex A

Title 28. Health and Safety

Part IV. Health Facilities

Subpart H. Home Care Agencies and Home Care Registries

Chapter 611. Home Care Agencies and Home Care Registries

GENERAL

§ 611.1. Legal base.

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

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

- (a) This subpart applies to home care agencies, home care registries and to entities that meet both definitions, profit or nonprofit, operated in this Commonwealth, as defined in this subpart.
- (b) Existing home care agencies and home care registries which were home care agencies or home care registries prior to the effective date of this subpart shall be required to meet the same standards as home care agencies and home care registries created after the effective date of this subpart.

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

- (a) A current copy of this chapter shall be maintained at the home care agency or home care registry.
- (b) Home care agencies and home care registries licensed under this chapter shall comply with applicable environmental, health, sanitation and professional licensure standards which are required by Federal, State and local authorities.
- (c) If there is a difference in applicable State or local standards, the standards established under State statutes apply for the purpose of compliance with this chapter.

§ 611.4. Definitions.

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

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

ChildLine – An organizational unit of the Department of Public Welfare which operates a state-wide toll-free system for receiving reports of suspected child abuse established under section 6332 of the Child Protective Services Law, 23 Pa. C.S. §§ 6301 – 6385 (relating to establishment of Statewide toll-free telephone number), refers the reports for investigation and maintains the reports in the appropriate file,

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

Consumer – Individual to whom services are provided.

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

Department- The Department of Health of the Commonwealth.

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

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

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

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

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

Home care agency – An organization that supplies, arranges or schedules employees to provide assistance with activities of daily living or instrumental activities of daily living, companionship services or specialized care on an hourly, shift or continual basis to a consumer in the consumer's place of residence or other independent living

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

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

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

Nurse – A registered nurse or a licensed practical nurse.

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

Roster – To place an individual on a list of individuals eligible to be referred by a home care registry to provide services to an individual in the individual’s home or other independent living environment or the list of individuals eligible to be referred by a home care registry to provide services to an individual in the individual’s home or other independent living environment.

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

LICENSURE

§ 611.5. License required.

- (a) Except as set forth in subsection (c), no entity or organization shall operate, maintain, or hold itself out as operating or maintaining a home care agency or home care registry without first having obtained a license from the Department in accordance with this chapter. Each physical location of the home care agency or home care registry must be separately licensed.

- (b) The license shall specify whether the entity is licensed as a home care agency, a home care registry, or both, the term of the license, and any conditions or limitations imposed on the license.
- (c) An entity operating a home care agency or home care registry or both as of the effective date of this subpart may continue to operate after the effective date of this subpart provided it submits an application for a license to the Department in accordance with instructions published in the Pennsylvania Bulletin and posted on the Department's website on or within 60 days of the effective date of this subpart. An entity that has submitted an application for licensure in accordance with the requirements of this subsection may continue to operate the home care agency or home care registry until such date as the Department may refuse the application for licensure. If the Department grants the application for licensure, the home care agency or home care registry may continue operation of agency or registry in accordance with the requirements of this chapter.

§ 611.6. Application for license.

- (a) The applicant shall obtain the application for a license to operate a home care agency or home care registry from the Pennsylvania Department of Health, Division of Home Health.
- (b) The applicant shall submit an application or renewal form to the Department with the fee required by Section 807 of the Act (35 P.S. § 448.807). The applicant shall submit a renewal form not less than 60 days prior to the expiration date on

the license. There will be no rebate, refund, or prorating of any application fee.

The applicant shall complete a separate application and pay a separate application fee for each separately licensed home care agency or home care registry that it intends to operate.

- (c) The applicant shall provide any documentation required by the Department in connection with the application and shall complete and submit all forms specified by the Department and any additional information required by the Department so that the Department can determine if the applicant is a responsible person and otherwise qualified to obtain a license to maintain or operate a home care agency or home care registry.
- (d) The applicant shall specify on its application the type of facility for which it is seeking a license.

§ 611. 7. Ownership.

The owner of a home care agency or home care registry may be an individual, partnership, association, corporation or a combination of these forms of ownership. The following requirements apply to a home care agency and a home care registry according to the mode of ownership:

- (1) *Individual Ownership.* A complete list of names and addresses of the owners of the home care agency or home care registry shall be submitted with the application.
- (2) *Partnerships.* A complete list of names and addresses of the owners, general partners and partners responsible for the management of the

home care agency or home care registry shall be submitted with the application.

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

§ 611. 8. Issuance of license.

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

§ 611.9. Posting of license.

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

§ 611.10. Non-transfer of license.

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

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

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

§ 611.12. Change in ownership or management.

- (a) The home care agency or home care registry shall notify the Department in writing at least 60 days prior to any anticipated change in ownership, form of ownership, or name, and immediately prior to any unanticipated change in

ownership, form of ownership, or name. A change in ownership shall mean any transfer of the controlling interest in the facility.

- (b) The home care agency or home care registry shall notify the Department in writing at least 60 days prior to any anticipated change in officers, directors, members, partners or principals, and immediately prior to any unanticipated change in officers, directors, members, partners or principals.
- (c) The home care agency or home care registry shall notify the Department in writing at least 30 days prior to any transfer involving five percent (5%) or more of the stock or equity in the entity that operates the home care agency or home care registry.
- (d) The home care agency or home care registry shall notify the Department in writing no later than 30 days following a change in management.
Management includes any individual responsible for oversight of day-to-day operations in the facility.
- (e) Information regarding an anticipated change in ownership, change in form of ownership, or transfer involving five percent (5%) or more of the stock or equity in an entity subject to the regulations of the Federal Securities and Exchange Commission will not be considered a public record and will remain confidential until the transaction is complete.

§ 611.13. Void license.

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

- (1) The license term expires.

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

INSPECTION AND SURVEY ACTIVITIES.

§ 611.14. Inspections.

- (a) Prior to issuance of an initial license or renewal of a regular or provisional license, representatives of the Department will conduct an inspection of a home care agency or home care registry. Whenever the Department has received any complaint or has other reasonable grounds to believe that a deficiency exists, the Department may conduct an inspection to determine whether a deficiency exists.
- (b) The Department will make reasonable efforts to prevent duplication of inspections by state and federal regulatory agencies and will coordinate inspections whenever practical.
- (c) Inspections to investigate complaints or other allegation of regulatory deficiency will be prioritized in accordance with the level of perceived threat to the health and welfare of consumers.

- (d) Prior to the inspection by the Department, the Department may request from the home care agency or home care registry any documents or records of the home care agency or home care registry including those held by other organizations or agencies, or other information necessary for the Department to prepare for the inspection. The home care agency or home care registry shall provide any and all information requested.
- (e) Upon presenting a Department identification card, authorized agents of the Department shall have access to the home care agency or home care registry to determine compliance with this chapter. Such access shall include:
- (1) Entry to the premises.
 - (2) Examination of all of the facilities, buildings, grounds, files, policies and procedures, records, documents, offices, computer files, quality assurance files, risk management documents, governing body and management documents.
 - (3) Private interviews with any staff, employees, and direct care workers.
 - (4) Private interviews with the consumer, with the consumer's consent.

§ 611.15. Retention of records.

All documentation required by this chapter and all documentation with respect to establishing that the home care agency or home care registry is in compliance with all applicable federal, state, and local requirements shall be retained by the home care

agency or home care registry on site. Documentation shall be retained for four years after termination of services to a consumer unless otherwise required by applicable federal and state laws and regulations. Personnel records required under § 611.22 (relating to hiring of direct care workers) shall be retained for at least four years following termination of employment or roster status of a direct care worker. Documentation and records shall be retained even if the home care agency or home care registry discontinues operation. Documentation includes paper and electronic information.

§ 611.16. Statement of deficiencies and plan of correction.

- (a) After completion of the inspection, the Department will evaluate all relevant information gathered during the inspection and formulate its compliance findings and determinations. In the event that the Department makes a determination of noncompliance with any provision of this chapter, the Department will issue to the home care agency or home care registry a statement of deficiencies.
- (b) Upon receipt of a statement of deficiencies, the home care agency or home care registry shall provide the Department, within the timeframe set by the Department, a plan of correction. The plan of correction shall address all deficiencies cited in the statement of deficiencies and shall identify the corrective action to be taken, the individuals responsible for the corrective action, and the timeframes within which the corrective action will be accomplished. The plan of correction shall be attested to by the individual given signature authority by the home care agency or home care registry.

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

SANCTIONS AND CORRECTIVE ACTIONS

§ 611.17. Sanctions for deficiencies.

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

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

§ 611.18. Reasons for sanctions.

- (a) The Department may refuse to renew a license, may suspend, revoke or limit a license of a home care agency or home care registry for any of the following reasons:

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

(b) The Department may issue a provisional license when there are numerous deficiencies or a serious specific deficiency which has a substantial impact on governance and management or services, which indicates that the home care agency or home care registry is not in compliance with applicable statutes, ordinances or this chapter, and the Department finds that:

- (1) The applicant is taking appropriate steps to correct the deficiencies in accordance with a timetable submitted by the applicant and agreed upon by the Department.
- (2) There is no pattern of deficiencies over a period of 2 or more years.
- (3) There is no danger to the health or safety of the consumers.

(c) The Department may issue a provisional license for a specific period of not more than 6 months. A provisional license may be renewed three times.

§ 611.19. Notice.

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

§ 611.20. Form of notice.

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

which the home care agency or home care registry must file its appeal with the Department.

§ 611.21. Request for hearing.

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

GOVERNANCE AND MANAGEMENT

§ 611. 22. Hiring or rostering of direct care workers.

- (a) Hiring or rostering prerequisites. Prior to hiring or rostering a direct care worker, the home care agency or home care registry shall:
 - (1) Conduct a face-to-face interview with the individual.

- (2) Obtain not less than two satisfactory references for the individual.
 - (3) Require the individual to submit a criminal history report, in accordance with the requirements of § 611.23 (relating to criminal background checks), and a ChildLine verification, if necessary, in accordance with the requirements of § 611.24 (relating to child abuse clearance).
- (b) Personnel files. Personnel files for direct care workers employed or rostered shall include documentation of the date of the face-to-face interview with the individual and of references obtained. Personnel files also shall include all other information as required by § 611.23 (relating to criminal background checks), § 611.24 (relating to child abuse clearance), if applicable, § 611.26 (relating to training), and § 611.27 (relating to health evaluations).

§ 611. 23. Criminal background checks.

- (a) General rule. The home care agency or home care registry shall require each applicant for employment or referral to submit a criminal history report obtained at the time of application or within 1 year immediately preceding the date of application.
- (b) State Police criminal history record. If the applicant for employment or referral has been a resident of this Commonwealth for 2 years preceding the date of application, the applicant shall submit a State Police criminal history record.

- (c) Federal criminal history record. If the applicant for employment or referral has not been a resident of this Commonwealth for the 2 years immediately preceding the date of the application, the home care agency or home care registry shall require the applicant to follow the procedures at 6 Pa. Code § 15.144(b) (relating to procedure) to obtain a federal criminal history record and a letter of determination from the Department of Aging, based on the individual's Federal criminal history record, regarding the individual's eligibility for hire or roster.
- (d) Proof of residency. The home care agency or home care registry may require an applicant for employment or referral to furnish proof of residency, including any one of the following documents:
- (1) Motor vehicle records, such as a valid driver's license.
 - (2) Housing records, such as mortgage records or rent receipts.
 - (3) Public utility records and receipts, such as electric bills.
 - (4) Local tax records.
 - (5) A completed and signed, Federal, State or local income tax return with the applicant's name and address preprinted on it.
 - (6) Employment records, including records of unemployment compensation.
- (e) Prohibition. The home care agency or home care registry may not hire or roster an individual if the State Police criminal history record reveals a prohibited conviction listed at 6 Pa. Code § 15.143 (relating to facility responsibilities), or if the Department of Aging letter of determination states that the individual is not eligible for hire or roster.

- (f) Records maintained. The home care agency or home care registry shall maintain personnel records for individuals employed or rostered which include copies of State Police criminal history records or Department of Aging letters of determination regarding Federal criminal history records. The personnel records shall be available for Department inspection.
- (g) Confidentiality. The home care agency or home care registry shall keep the information obtained from State Police criminal history records and Department of Aging letters of determination regarding Federal criminal history records confidential and use it solely to determine an applicant's eligibility to be hired, rostered or retained.
- (h) Opportunity to appeal. If the decision not to hire, roster or retain an individual is based in whole or in part on State Police criminal history records, Department of Aging letters of determination regarding Federal criminal history records, or both, the home care agency or home care registry shall provide an affected individual with information on how to appeal to the sources of criminal history records if the individual believes the records are in error.
- (i) Exceptions. An individual employed or rostered who has complied with this section and who transfers to another agency or registry owned and operated by same entity is not required to submit another criminal history report. An individuals who is employed or rostered by an entity that undergoes a change of ownership is not required to submit another criminal history report.
- (j) Individuals currently employed or rostered. A person who is employed by or rostered by a home care agency or home care registry as of the effective date of this

chapter shall obtain and submit a State Police criminal history record or Department of Aging letter of determination, as applicable, to the home care agency or home care registry within 120 days of the effective date of this chapter. This subsection shall not apply if the home care agency or home care registry obtained a criminal history report meeting the requirements of this subsection when the individual was hired or rostered and a copy of the report is included in the individual's personnel file.

§ 611. 24. Child abuse clearance.

- (a) General rule. A home care agency or home care registry that serves persons under 18 years of age shall require each applicant for employment or referral as a direct care worker, and each member of the agency or registry office staff to request a ChildLine verification regarding whether the applicant or member is named in the Statewide Central Register as the perpetrator of a founded or indicated report of child abuse as defined at 55 Pa. Code § 3490.4 (relating to definitions).
- (b) Prohibition. In no case shall a home care agency or home care registry employ or roster an individual where ChildLine has verified that the applicant is named in the Statewide Central Register as the perpetrator of a founded or indicated report of child abuse.
- (c) Records maintained. The personnel records maintained by the home care agency or home care registry for each individual employed or rostered and for each member of the office staff shall include copies of the ChildLine verification. The

agency or registry shall maintain copies of the ChildLine verification for the agency or registry owners, which shall be available for Department inspection.

- (d) Individuals currently employed or rostered. A person who is employed by or rostered by the home care agency or home care registry as of the effective date of this chapter shall obtain and submit a ChildLine verification to the home care agency or home care registry within 120 days of the effective date of this chapter. This subsection shall not apply if the home care agency or home care registry obtained a ChildLine verification when the individual was hired or rostered and a copy of the verification is included in the individual's personnel file.

§ 611.25. Provisional hiring.

- (a) General rule. The home care agency or home care registry may hire an applicant for employment or referral on a provisional basis, pending receipt of a criminal history report or a ChildLine verification, as applicable, if the following conditions are met:
- (1) The applicant shall have applied for a criminal history report and ChildLine verification, as applicable, and provided the home care agency or home care registry with a copy of the completed request forms.
 - (2) The home care agency or home care registry shall have no knowledge about the applicant that would disqualify the applicant under 18 Pa.C.S. § 4911 (relating to tampering with public record information).
 - (3) The applicant shall swear or affirm in writing that the applicant is not disqualified from employment or referral under this chapter.

- (4) The provisionally hired applicant shall meet the requirements of § 611.26 (relating to training requirements).
- (5) The home care agency or home care registry shall monitor the provisionally hired applicant through random, direct observation and consumer feedback. The results of monitoring shall be documented in the individual's personnel file.
- (6) The period of provisional hire shall not exceed 120 days.
- (b) Termination. If the information obtained from the criminal history report or ChildLine verification, or both, reveals that the individual is disqualified from employment or referral under § 611.23 (relating to criminal background checks) or under § 611.24 (relating to child abuse clearance), the individual shall be terminated by the home care agency or removed from the home care registry's roster immediately. If the individual fails to provide the ChildLine verification or criminal history report or both within the 120-day period permitted for provisional hire, the individual shall be terminated by the home care agency or removed from the home care registry's roster.

§ 611. 26. Training requirements.

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

- (b) A direct care worker who will provide to a consumer only assistance with activities of daily living and instrumental activities of daily living may demonstrate competency by successfully completing a competency examination approved by the Department.
- (c) Any direct care worker, including a direct care worker providing only assistance with activities of daily living and instrumental activities of daily living, will satisfy the training requirements if the direct care worker has a valid nurse's license or has successfully completed one of the following:
- (1) The home health aide training program described at 42 CFR 484.36 (relating to the Conditions of Participation: home health aide services).
 - (2) The nurse aid certification and training program approved by the Department of Education.
 - (3) Other training programs, approved by the Department, notice of which shall be published in the Pennsylvania Bulletin and posted on the Department's website.
- (d) To be eligible for approval by the Department, a competency examination or other training program must address, at a minimum, each of the following subject areas:
- (1) Confidentiality.
 - (2) Consumer control and the independent living philosophy.
 - (3) Recognizing changes in the consumer that need to be addressed.

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

- (e) The home care agency or home care registry shall include documentation of the individual's satisfactory completion of training requirements in the individual's personnel file. If the individual has a nurse's license or other licensure or certification as a health professional, the individual's personnel file shall include a copy of the individual's current license. Documentation of satisfactory completion of training requirements is transferable from one home care agency or registry to another home care agency or registry, provided the training meets the requirements of subsection (a) and the break in the individual's employment or roster status does not exceed 12 months.

- (f) The home care agency or home care registry also shall include documentation in the individual's personnel file that the agency or registry has periodically reassessed the individual's competency to perform assigned duties through direct observation, testing, training, or other method approved by the Department or through a combination of methods. Periodic reassessment shall occur not less than once per year after initial competency is established, and more frequently when discipline or other sanction, including a verbal warning, is imposed because of a quality of care infraction.
- (g) Individuals employed by a home care agency or rostered by the home care registry on the effective date of this subpart shall achieve compliance with the training requirements imposed by this subpart within 2 years of the effective date of this subpart.

§ 611.27. Health evaluations.

- (a) A home care agency or home care registry shall insure that each individual employed or rostered by the agency or registry and other office staff or contractors with direct consumer contact, prior to beginning work, provide documentation that is made part of the individual's personnel file, evidencing a screening assessment performed by a qualified health professional within 180 days prior to the individual's start date. The results of the screening assessment shall include information showing that the individual was evaluated for tuberculosis risk factors, in accordance with guidelines issued by the federal

Centers for Disease Control and Prevention, and tested as necessary, and was screened for the following communicable diseases or conditions:

- (1) Hepatitis A.
 - (2) Salmonella.
 - (3) Shigella.
 - (4) Shiga toxin producing Escherichia coli.
 - (5) Symptom caused by illness, infection or other source where symptom is associated with gastrointestinal illness such as diarrhea, fever, vomiting, jaundice, sore throat with fever.
- (b) A home care agency or home care registry shall not refer a direct care worker that is suspected by the home care agency or home care registry of having any of the communicable diseases or conditions listed in subsection (a). Subsequent referral shall be contingent on verification from a qualified health professional that the direct care worker is free from any of the communicable diseases or conditions listed in subsection (a).
- (c) A home care agency or home care registry shall require each individual employed or rostered by the agency or registry, and other office staff or contractors with direct consumer contact, to obtain an updated screening assessment every 12 months and provide those results to the agency or registry. The updated screening assessment shall be made part of the individual's personnel file.

§ 611.28. Consumer protections.

(a) Consumer rights. The consumer of services provided by a home care agency or through a home care registry shall have the following rights:

- (1) To be involved in the service planning process and to receive services with reasonable accommodation of individual needs and preferences, except where the health and safety of the direct care worker is at risk.
- (2) To receive at least 10 days advance written notice of the intent of the home care agency or home care registry to terminate services. Less than 10 days advance written notice may be provided in the event the consumer has failed to pay for services, despite notice, and the consumer is more than 14 days in arrears, or if the health and welfare of the direct care worker is at risk.

(b) Prohibitions. No individual as a result of the individual's affiliation with a home care agency or home care registry may assume power of attorney or guardianship over a consumer utilizing the services of that home care agency or home care registry. The home care agency or home care registry may not require a consumer to endorse checks over to the home care agency or home care registry.

(c) Information to be provided. Prior to the commencement of services, the home care agency or home care registry shall provide to the consumer, the consumer's legal representative or responsible family member an information packet containing the following information in a form that is easily read and understood:

- (1) A listing of the available home care agency or home care registry services that will be provided to the consumer by the direct care worker.
- (2) The hours when those services will be provided.
- (3) Fees and total costs for those services on an hourly or weekly basis.
- (4) Who to contact at the Department for information about licensure requirements for a home care agency or home care registry and for compliance information about a particular home care agency or home care registry.
- (5) The Department's Hot Line (1-800-222-0989) and the telephone number of the Ombudsman Program located with the local Area Agency on Aging (AAA).
- (6) The hiring and training requirements applicable to direct care workers employed by the home care agency or referred by the home care registry, a description of the manner and frequency of periodic reassessment of direct care worker competency, and documentation maintained by the home care agency or home care registry to confirm compliance with hiring and training requirements under § 611.22 (relating to hiring requirements) and § 611.26 (relating to training requirements).

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

Commonwealth of Pennsylvania



DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

August 6, 2007

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

Re: Department of Health – Proposed Regulations No. 10-184
28 Pa. Code Chapter 611
Home Care Agencies and Home Care Registries

Dear Mr. Kaufman:

Enclosed are proposed regulations for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§ 745.1-745.15). The purpose of these proposed regulations is to set minimum standards for the operation of home care agencies and home care registries. Act 2006-69, signed by Governor Rendell on July 7, 2006, amended the Health Care Facilities Act (Act), act of July 19, 1979 (P.L. 130, No. 48), 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 home and other independent living environment. Home care registries refer direct care workers who are independent contractors to provide home care services to individuals in their home or other independent living environment. Services provided by home care agencies and home care registries include assistance with activities of daily living (e.g. bathing, dressing and feeding) and instrumental activities of daily living (e.g. housekeeping, shopping, meal planning and preparation and transportation), companionship, respite care and other non-medical services.

These standards are intended by the Department to assure safe, adequate and efficient home care agencies and home care registries and to promote the health, safety and adequate care of the consumer of services provided by home care agencies and home care registries. These proposed regulations require criminal background checks, child abuse clearance and communicable disease screens and impose hiring and training requirements for individuals employed by a home care agency or referred by a home care registry to provide care.

Section 5(g) of the Regulatory Review Act, 71 P.S. § 745.5(g), provides that the Commission may, within 30 days after the close of the public comment period, convey to the

proposing agency and the Standing Committees any comments, recommendations and objections to the proposed regulations. A 30-day comment period is provided.

Section 5.1(a) of the Regulatory Review Act, 71 P.S. § 745.5a(a), provides that upon completion of the agency's review of comments, the agency shall submit to the Commission a copy of the agency's response to the comments received, the names and addresses of the commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

The Department will provide the Commission within 5 business days of receipt, a copy of any comment received pertaining to the proposed regulations. The Department will also provide the Commission with any assistance it requires to facilitate a thorough review of the proposed regulations. If you have any questions, please contact Brent Ennis, Director of the Office of Legislative Affairs, at (717) 783-3985.

Sincerely,



Calvin B. Johnson, M.D., M.P.H.
Secretary of Health

Enclosures

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

RECEIVED

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



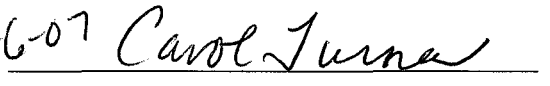
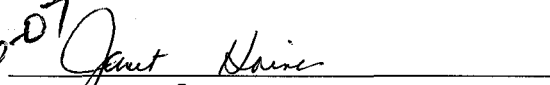
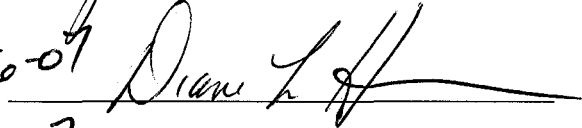
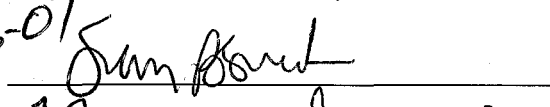
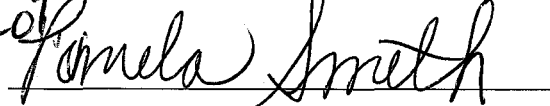
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INDEPENDENT REGULATORY
REVIEW COMMISSION

TYPE OF REGULATION

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

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
8-6-07		HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
8-6-07		
8-6-07		HOUSE COMMITTEE ON AGING & OLDER ADULT SERVICES
8-6-07		
8-6-07		SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
8-6-07		
8-6-07		SENATE COMMITTEE ON AGING & YOUTH
8-6-07		

8/6/07 Dr. Belmont

INDEPENDENT REGULATORY REVIEW COMMISSION

ATTORNEY GENERAL (for Final Omitted only)

8.6.07 Colyer

LEGISLATIVE REFERENCE BUREAU (for Proposed only)