Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-380 (current) 12 VAC 5-381 (proposed)
Regulation title	Regulations for the Licensure of Home Care Organizations
Action title	Repeal of the current regulation Promulgation of the proposed regulation
Document preparation date	Enter date this form is uploaded on the Town Hall

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Do ***not*** *state each provision or amendment or restate the purpose and intent of the regulation.*

12 VAC 5-381 Rules and Regulations for the Licensure of Home Care Organizations is a comprehensive revision of the Commonwealth's regulation addressing home care organizations (HCOs). Because of the extensive revision to the current regulation (12 VAC 5-380), the Department proposes replacing the current home care organization (HCO) regulation, adopted in 1990, with the proposed regulation. To accomplish this, it will be necessary to repeal the current regulation as the proposed regulation is promulgated.

Basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The regulation is promulgated by the Center for Quality Health Care Services and Consumer Protection of the Department of Health under the authority of § 32.1-162.12 of the Code of Virginia, which grants the Board of Health the legal authority to "prescribe such regulations governing the activities and services provided by home care organizations as may be necessary to protect the public health, safety and welfare." Therefore, this authority is mandated.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the proposed regulation is to protect and promote public health, safety and welfare through the establishment and enforcement of regulations that set minimum standards for the operation of organizations providing home-based care. In addition, the purpose of the regulation is to assure quality health care through appropriate review and inspection while protecting the right to privacy of patients without unreasonably interfering with the provision of that care. The intent of the proposed regulation is to be more reflective of the changes occurring in the industry in the last decade, while providing the necessary consistency in the provision of services in order to assure safe, adequate and efficient home care organization operation.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.)

As provided in § 32.1-162.12 of the Code, provisions of the proposed regulation include: (i) an informed consent contract, (ii) the qualifications and supervision of licensed and non-licensed personnel, (iii) a complaint procedure for consumers, (iv) the provision and coordination of treatment and services provided by the organization, (v) clinical records kept by the organization, and (vi) utilization and quality control review procedures and arrangements for the continuing evaluation of the quality of care provided. Additionally, the regulation "shall be appropriate for the categories of service" included in the definition of HCOs found in the Code.

In addition, the Department recognized the need to update the current regulation to address: i) home visits, ii) infection control practices, and iii) consumer complaint procedures. The regulation governs the licensure of home care organizations unless they are specifically exempt from licensure as allowed in §32.1-162.8 of the Code.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.
If there are no disadvantages to the public or the Commonwealth, please indicate.

The existing regulation governing HCOs was promulgated in 1990. With changes in the home care industry, medical technology, and the Code itself, the Department recognized the need to update the regulation to be more reflective of those changes. Because services are rendered in a patient's residence, home care providers are not subject to the same public scrutiny as more formal health care institutions, i.e., hospitals and nursing facilities, making regulatory oversight of home health services an important governmental function. State licensure programs provide citizens with low cost assurance programs that licensees are delivering quality care. However, a critical component of any licensure program is that the licensure standards reflect currently accepted standards of practice. Since the HCO regulation was promulgated over a decade ago, it no longer reflects "state of the art" criteria.

In 1991, the General Assembly amended the entire home health care section of the Code, i.e., Article 7.1 of Chapter 5 of Title 32.1 (§ 32.1-162.7 et seq.). Changes that affected the regulation include: i) redefining home care services specifying personal care services and pharmaceutical services to "individuals who have or are at risk of an illness, injury, or disabling condition," ii) additional exemptions from licensure, and iii) requiring a criminal record check for new employees. Those changes by themselves rendered the regulation out of step with the requirements of the law. However, the regulation reflects needed changes in many other sections as well, including but not limited to: i) eliminating duplicative standards, ii) reworking archaic language, and iii) expanding the licensure process explanation.

In addition to Code changes and regulatory expectations, the evolution of the home-based health care industry and advances in medical technology now allow the elderly, the disabled, and persons with higher disease acuity levels to remain in their own homes, rather than being admitted to medical care facilities. Providing more complex and potentially invasive procedures in a patient's home requires a strengthening of licensure standards in the areas of organization management, quality assurance, personnel requirements, and personal care services; and initiating new standards regarding infection control and home visits.

Responsible for implementing the medical care facilities and services regulatory program, the department recognized the need for stronger standards and a more user-friendly regulation to ensure the welfare and safety of individuals receiving home-based care. Much work was necessary in order to bring the entire regulation up to currently accepted standards and practice. The approach used in developing the proposed regulation was to strive for simplicity, to avoid being burdensome, to meet the requirements of the law, and to reflect the home care

industry's expansion into more medically oriented care. The primary advantage to the public as a result of that effort is the enhancements made to the regulation, which include:

1. Adding requirements for criminal record clearance for any compensated employee, a result of changes in the Code;
2. Detailing the consumer complaint procedures;
3. Including home visits to patients as part of the licensing inspection;
4. Instituting quality improvement assessment indicators and infection control practice standards;
5. Eliminating the geographic service areas;
6. Coordinating standards, thereby eliminating contradictions with federal certification (Medicare/Medicaid) requirements;
7. Updating the insurance and medical record criteria to reflect correct practices;
8. Adopting a biennial inspection protocol;
9. Deleting the medical supplies and medical appliance section of the current regulation and broadening the personal care services section, a result of changes in the Code;
10. Ensuring that the regulation is clearly understandable by updating the language and eliminating ambiguities; and
11. Reorganizing the regulation into an user-friendlier format. The new arrangement is logical and orderly, facilitating use of the regulation.

Additional adjustments include restructuring the fees charged for licensure (see discussion below) and changing the descriptive name from home "health" to home "care" to reflect the statutory name of the entity to be licensed.

The Department, in collaboration with a diverse group of individuals, has worked to replace the existing regulation with that which the Department is now proposing. To determine the readiness of the proposed regulation for the public approval process and gauge its impact on the licensed entities, the Department circulated preliminary drafts of the document to all licensed entities and interested parties. Currently, there are more than 150 home health agencies certified under Medicare that are exempt from state licensure, i.e., they do not have to maintain state licensure. This is an important distinction to make in any discussion on the impact of state licensure regulations on home care organizations. Since all the federally certified agencies were exempt from state licensure, and thereby not subject to the requirements of licensure, the Department does not believe it necessary to give those comments as much weight when determining the impact of the proposed regulation as those respondents who are directly impacted by the regulation, i.e., the licensed entities. Copies of the proposed regulation were obtained by the federally certified (Medicare) agencies and many of their comments were incorporated into the proposed regulation. Of the more than 200 preliminary draft copies and notices sent out by the Department, 17 responses were received. Nine responses were received from licensed organizations, eight from interested parties. An additional eighteen responses were received from the federally certified agencies. The Department, therefore, concluded that the low response rate from the licensed entities indicates the general acceptance of the regulation as proposed.

There were, however, three notable concerns: (i) implementing a requirement that a patient's primary care physician be licensed in Virginia, (ii) establishing service areas based on the statewide planning districts, and iii) the requirements for the organization's administrator.

HCOs took exception to the requirement, in the proposed definition of "primary care physician," that patient physicians be licensed in Virginia, stating that many home care patients residing near Virginia's borders utilize the services of physicians from bordering states who do not necessarily hold a Virginia license. In response to this concern, VDH received clarification from the Department of Health Professions that physicians from bordering states are not required to hold a Virginia license in order to provide services to Virginia's home care patients. However, a physician serving in the position of Director of Patient Care Services for a home care organization must be licensed in Virginia. Therefore, the definition of "primary care physician" was modified in the proposed regulation.

A goal of the revision process was to determine the viability of service areas. The current regulation has a service area requirement that the Department recognized as too restrictive and limiting in its scope as it had been implemented. Under the regulation, service areas are defined as "geographically limited to the county or independent city in which that agency's office is located and the counties and/or independent cities immediately contiguous to that location." The Department took under consideration the service areas prescribed by sister states and the federal government, the metropolitan statistical areas, and a travel distance for staff from the office to residence as possible determinates for service areas. In particular, the Department did not favor adopting the system in place for federal certification as that system was acknowledged to be vague and subject to interpretation. After further scrutiny, however, it was determined that none of these options was a workable solution in Virginia. Therefore, the Department decided to eliminate the service area requirement from the regulation, even though the majority of states that require HCO licensure mandate prescribed service areas for licensure. HCOs will be required to include their intended service areas when applying for and renewing licensure. The Department does, however, reserve the right to reinstate defined service areas if there is evidence, as indicated by survey results or by an increase in filed complaints, that organizations are not providing adequate supervision of paraprofessional staff, i.e., home attendants, or that medical care services are not provided as ordered by the patient's physician.

HCO's are concerned that new requirements for an organization's administrator are over burdensome and restrictive, claiming that many current administrators would not meet the criteria. The department disagrees with this assessment for several reasons: i) organizations have known for some time that the new requirements were coming and, therefore, have had ample time to assure current administrators meet the requirements; ii) since the start of the revision project, many of the administrators now meet the requirements by virtue of experience; iii) as described earlier, the acuity level of individuals receiving home based care has increased over the last decade requiring that providers have the knowledge and skills necessary to oversee the medical needs to the patients served by the organization; and iv) the department is allowing one year from the effective date of the regulation to assure that current administrators meet the new requirements.

As stated above, fees charged for licensure have been restructured. State general funds and licensure services fees, based on a HCO's annual budget, finance the home care licensure program. The Department conducts the annual licensure inspections of hospices, processes Medicare certification for home health and hospice organizations, investigates complaints filed against hospices and home care providers, and conducts the inspection program for HCOs. Historically, tax dollars have subsidized a disproportionate share of the licensure program through state general funds. A goal of recent Administrations has been to relieve the tax burden on Virginia's citizens. One way to achieve relief is to have state licensing programs become

more self-sufficient. The Department is increasing certain fees, establishing new fees, and adopting a biennial inspection protocol to better support the cost of the program. The Department acknowledges that the increases may seem dramatic, however, this is the first increase in fees since the regulation was first promulgated in 1990. Additionally, the Department believes the increased fee indicates an organization's financial ability to provide care to clients. The proposed fees are structured on the potential for action required by the Department regarding an organization's licensure status, i.e., issuing initial and renewal licenses, responding to requests for a modification to, or an exemption from, licensure. Since no comments related to the proposed fee structure were received, the Department concludes the proposed fees do not create an added burden to the licensed entities. In addition, each home care organization will be inspected periodically, but not less than biennially. While the Department anticipates that enforcement of the regulation requires no more inspection staff at present, future revisions to the Code could very likely result in the need for additional staff and a corresponding need for additional increases in licensure fees.

Small businesses or organizations under contract with an HCO will be affected by the proposed regulation, as they will be expected to comply with the regulation when doing business with an HCO. However, any increase in cost to small businesses or organizations is expected to be minimal.

No particular locality is affected more than another by this regulation. There are no disadvantages to the public, the Commonwealth, or the HCOs as a result of the proposed regulation. Every effort has been made to ensure the regulation protects the health and safety of patients receiving home care services while allowing providers to be more responsive to the needs of their patients. Failure to implement the regulation would cause the current regulation, which is outdated and not reflective of the industry today, to remain in effect.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	A combination of general funds (0100) and licensure fees (0200) support the home care organization (HCO) licensure program. Licensure fees currently generate $18,000 annually. Under the proposed regulation, the fee would be $500 and would generate $64,500 biennially, from the existing 129 licensed HCOs. The average cost of an HCO inspection is $1500. In FY 2005, expenditures in program 5610300 for the HCO program were approximately $110,000 in ongoing costs. Although the proposed regulation will reduce the frequency of inspections from an annual to a biennial inspection cycle, the proposal is considered to be "budget neutral" on the expenditure side. This is because the amount of onsite time required to complete an inspection is expected to increase due to new requirements in the licensing process. Examples of improvements that will increase onsite time are patient home

	visits, and the inclusion of other aspects of the Medicare home health survey process that have proven to be efficacious. These expenditures are ongoing.
Projected cost of the regulation on localities	None, unless the locality operates a HCO. None currently do.
Description of the individuals, businesses or other entities likely to be affected by the regulation	HCOs; small businesses and organizations doing business with a HCO.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are approximately 129 HCOs; all are considered small businesses as none have over 500 employees or a budget over $6 million. This includes HCOs associated with the state's major health care systems. HCOs operated by such entities require a separate internal organizational structure and licensure under the umbrella of the larger entity.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	The new licensure fee is $500. We believe the fee increase is an indicator of a provider's ability to be financially solvent, not just clinically able, to provide care to clients, in addition to better supporting the cost of the licensure program. Other than new and increased fees (the first since 1990), there are no additional projected reporting costs or record keeping costs than currently required of those HCOs licensed under 12 VAC 5-390, the current licensure regulation. Therefore, we believe implementation of the new standards to be cost neutral for current license holders. Some providers of "personal care" services argue that the "new" requirements, such as staff supervision and staff requirements, are too costly to implement. However, the staff supervision requirement is not new, and adjustments have been made addressing staff training. Additions to the regulation were the definitions of "chore," "companion" and "homemaker" services to distinguish these services from home care and personal care services. Such services are not required to be licensed; therefore, individuals not able to meet the requirements for licensure can opt to provide non-regulated services.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

The regulation is clearly and directly mandated by law. The proposed regulation honors the Department's statutory charge and is the least burdensome alternative available for adequately addressing the mandate of the law.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

No comments were received.

Impact on family

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact on the family, unless the family utilizes the services of a home care organization.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
10	10	Definitions	Definitions, were modified, deleted, or added to reflect the proposed regulation.

20	20, 40, 70, 130, 140, 150	General Information	Not adequate to properly inform applicants of administrative requirements for licensure; new sections added address respectively: responsibility of the department, exemption from licensure, changes to or re0issues of a license, variances, revocation or suspension of a license, and surrender of a license.
30	80	Application fees	Fees are not adequate to cover the costs of the licensing program. Fees were restructured and cover initial and renewal licenses, late fees, exemption processing fees, and license re-issue or replacement. Section realigned.
40	30, 160	Requirements, general	Not adequate to inform applicants of expectations as a licensed provider; new sections added clarify the license process and management and administration.
50, 60, 70	50, 60	Initial Licensure, License renewal, License reissue	Requirements were incorporated into one section (licensing process) and a new section (compliance with appropriate for type of HCO) added to clarify intent.
80	90, 110	On-site inspection	New section developed to address actual practice: on-site inspections and complaint investigations.
90	N/A	Plan of correction	Incorporated into new section on On-site inspections
N/A	100	N/A	New section added addressing home visits, a consumer quality of care enhancement.
N/A	120	N/A	New section added gives direction for obtaining a criminal record check for compensated employees. Result of a Code change.
100, 110	160	Governing Body, Responsibilities	Sections were consolidated into one section on the Governing Body. The sections was realigned to facilitate use of the document..
120	210	Insurance and bonding	Section was adjusted to remove incorrect application of law; now reflects appropriate requirements for assuring indemnity coverage and eases restrictive and overly burdensome criteria currently imposed on licensees. Section logically realigned to facilitate use of the regulation.
130	170	Administrative management	Section was realigned and updated to reflect industry standards for administering a home care organization.
140, 150, 160, 170, 230	180, 190, 200, 210	Polices and procedures, Administrative and financial records, Admission and discharge criteria, Service policies and procedures	Sections were consolidated and appropriately realigned.
180, 290	220	Contract services, contract nursing services	Sections consolidated, ambiguities removed; section logically realigned.

190, 220	2780,	Medical records, Record retention	Sections were consolidated, incorrect Code citation removed, ambiguities removed and language updated.
200	230, 240	Patient's rights	Section split, criteria modified to reflect industry standards, ambiguities removed, new section added on complaints.
210	250	Quality assurance	Section modified to reflect current industry standards regarding improvement of services to patients. Ambiguities removed and section logically realigned.
N/A	260	N/A	New section added addressing infection control
2240	280	Provision of services	Not adequate to inform applicants of expectations regarding the provision of home care services, contradictions with federal regulations eliminated, ambiguities were removed.
250, 260, 270	290	General, Nursing services, Licensed practical nurses	Sections combined; more reflective of industry practice and quality of care expectations.
280, 300	250, 310	Home health aides, treatments performed by home health aides	Did not provide adequate direction regarding home care aides. Sections were realigned and modified to reflect industry standards, quality of care expectations, and eliminate contradictions with federal regulation.
310	350	Other care assistants	Section updated to reflect law, current industry practice and eliminate contradictions with federal regulation. Section realigned and renamed Personal care services.
320, 330, 340, 350, 360, 370, 380, 390, 400, 570, 580, 590, 600	320	Article 2, Physical therapy; Article 3. Occupational therapy; Article 4, Speech therapy; Article 9. Respiratory therapy services.	Sections were repetitive and duplicative, sections consolidated. Section named Therapy services.
410, 420, 430, 440, 450	330	Article 5. Medical social services	Sections were consolidated and updated.
460, 470, 480	N/A	Article 6. Medical supplies and medical appliances	No longer subject to licensure, sections eliminated, no replacement.
490, 500, 510, 520, 530, 540, 550, 560	340	Article 7. Specialized nutrition support; Article 8. Intravenous therapy services	Sections were consolidated and updated to reflect current practices, section renamed Pharmacy services.