Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-381
Regulation title	Regulation for the Licensure of Home Care Organizations
Action title	Promulgation of final regulation
Document preparation date	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

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 is replacing the current home care organization regulation, adopted in 1990, with the proposed regulation (12 VAC 5-381). To accomplish this, it is necessary to repeal the current regulation as the proposed regulation is promulgated.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On September 2005 , the State Health Commissioner, in his capacity to act in lieu of the Board of Health when not in session, adopted the proposed regulation 12 VAC 5-381 (Rules and

Regulations for the Licensure of Home Care Organizations) and approved the repeal of the existing regulation 12 VAC 5-380.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter numbers, if applicable, and (2) promulgating entity, i.e., 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 it 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 existing regulation governing home care organizations (12 VAC 5-380) has not been revised since first promulgated in 1991. Since then, the home care industry has evolved and expanded. Responsible for regulating medical care facilities and related services, the department recognized the need to update the regulation to reflect changes that have occurred in the home care industry during the last decade. At the same time, the Department wanted to develop a more provider-oriented document. Simply revising the current regulation, however, would not achieve the goal of developing a document that could serve as a "customer service" manual while providing the necessary regulatory controls. The department, therefore, chose to replace the current regulation and promulgate a new regulation in its place. The approach used in developing the proposed regulation was to strive for clarity, simplicity, and avoid overly burdensome criteria while meeting the requirements of the law.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

As provided in § 32.1-162.12 of the Code, provisions of the proposed regulation include: (i) informed consent, (ii) the qualifications and supervision of licensed and non-licensed personnel, (iii) complaint handling procedures, (iv) the provision and coordination of services provided by

the organization, (v) client records, and (vi) the continuing evaluation of the quality of care provided. In addition, the regulation addresses: i) home visits, ii) infection control practices, iii) criminal records clearances, and iv) secondary office locations or "drop sites" for staff. As a result of the public comment period, substantive adjustments were made to the supervision of staff and qualifications of the assistant administrator. The criterion for supervision is now based on " the client's needs, the assessment of the nurse, and the organization's own policies, not to exceed 90 days." Persons appointed as assistant administrator must be able to perform the duties of the administrator, but no longer must have the same training and experience as the administrator. Other changes were technical in nature to provide further clarification, and do not alter the intent of the standard.

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.

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. 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. Criminal record clearance;
2. Consumer complaint procedures;
3. Home visits by state inspectors;

4. Quality improvement and infection control practice standards;

5. Coordinating standards with federal certification (Medicare/Medicaid) requirements;

6. Ensuring that the regulation is clearly understandable by updating the language and eliminating ambiguities; and

7. Reorganizing the regulation into a user-friendlier format. The new arrangement is logical and orderly, facilitating understanding of the regulation for providers and consumers.

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.

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. 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.

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.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
10	Definitions section	1. Added: "client record, "drop site, "functional limitations," "Licensed practical nurse," "Registered nurse," and "Skilled services." 2. Amended: "Activities of Daily Living or ADLs," "Administrator," "Barrier crimes," "Criminal record report," "Discharge or termination summary," "Dispense," " Home care organization," "Personal care services," "Primary care physician," "Sworn disclosure statement." 3. Deleted: "Bylaws," "Clinical note," "Direction," "Full-time," "Home care record," and "Immediately"	1. Definitions added to provide clarity; 2. Definitions amended (i) to provide added clarity, or (ii) are technical in nature and do not alter the intent of the definition. 3. Definitions deleted as they have a common understanding or are not used in the text.
	Responsibility of the department	Deleted section	Does not conform to regulatory guidelines; section unnecessary.
40	License application; initial and renewal	A. Amended to delete: "review an applicant's proposed program plans" and read "the survey process." E. Amended to read "make renewal applications available	Amended for consistency with current practices and acknowledges an operational change by the Center regarding licensure applications.
50	Compliance appropriate for type of HCO	Tile and section numbers amended	Technical changes made for clarity and relation to final text.
80	On-site inspections	A. "According to applicable law:" added	Amended for regulatory consistency.
100	Complaint investigation	Title amended to distinguish this section from section 250; subsection D amended to add provider response expectations.	Provider request
120	Variances	F. Sentence rewritten	Grammatical correction
140	Surrender of a license	"Return" substituted for "Surrender"	"Return" seen as less punitive and for regulatory consistency
150	Management and Administration	I. Amended for "on-call service" rather than "emergency services" J. Subsection amended deleting	I. Provider request J. In response to provider concerns to assure that

		possible needs L. Added flu shot requirement.	regulation addresses providers of skilled and non-skilled services. L. Added as result of constituent comment
160	Governing body	B. Bylaws deleted; Replaced with governing body responsibilities	Result of provider comment
170	Administrator	*C. Qualifications of assistant director amended.	Result of provider comment
180	Written policies and procedures	Technical amendments made	Result of provider comments
210	Indemnity coverage	Technical amendments made	Amended for regulatory consistency
220	Contract services	Technical amendments made	Result of provider comments
240	Complaints	Title amended to distinguish this section from section 100; subsection A amended deleting 2 procedure handling criteria.	Result of provider comment
250	Quality Improvement	Technical amendments made	In response to provider concerns to assure that regulation addresses providers of skilled and non-skilled services.
270	Drop sites	Section added describing elements of staff support offices	Section added as a convenience to providers to assure timely and appropriate client care.
280	Home care record system	Title changed and technical amendments made	In response to provider concerns to assure that regulation addresses providers of skilled and non-skilled services.
300	Home care services	Title changed and technical amendments made	Result of provider comments.
310	Nursing services	Proposed subsections A, B, and C replaced with new subsections A and B	New language offered by DHP to assure consistency with professional licensure standards.
320	Therapy services	1. Section amended to reflect appropriate professional qualifications; 2.subsections A and B combined; *3.subsection D addressing home attendant supervision added	1. Technical change to reflect appropriate professional credentials 2. Technical change 3. Result of provider comment and for regulatory consistency
330	Home attendants	1.Section moved within Part III; *2. Proposed subsections C and D were combined, text amended	1. Technical amendment for proper placement in the text 2. Subsections combined,

			as they were duplicative; Supervision requirements changed as a result of the public comment period.
340	Medical social services	Technical changes made	Amended for regulatory consistency
350	Pharmacy services	Technical changes made	Amended for regulatory consistency
360	Personal care services	A and B Technical change *E. Supervision of home attendant amended F. Deleted	A/B amended for regulatory consistency E. Amended as a result of public comment period F. Duplicative of subsection E and therefore, not needed.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Janet Faraone Senior Solutions of Richmond	I understand we've now added another layer between companion and personal care; and that companion and homemaker services will not be regulated by the Health Department. I think this leaves a large gray area that could easily be abused, and that many cases that should be personal care will be designated as homemaker to avoid regulation. I'm also concerned, because we witnessed it with companion agencies crossing into personal care, that some will fail to transition a homemaker case to personal care when necessary. I think conscientious agencies will still have a nurse (RN or LPN) open Homemaker cases, conduct visits and review weekly care notes. I also feel much more comfortable and feel the end user is better served by a nurse (RN/LPN) conducting an assessment if there is to be any "hands-on" care. I	To clarify, there have always been homemaker, chore, and companion services in addition to home care services, available to provide assistance to those persons needing help to remain independent and in their own communities. It is exactly because of the confusion that we have attempted to provide clarification through regulation. We recognize, and have the same concerns as licensed providers, the problems created by non-licensed providers that “cross over” into licensed activities or designate themselves as a provider of non-licensed services in order to avoid licensure. Such providers are in violation of the law and sanctions can be imposed. However, we must rely on local citizens and area licensed providers to bring these individuals to our attention. By working together to identify and educate these providers on the law, the licensed community and regulatory agency can ensure that Virginia’s vulnerable citizens are receiving the care and assistance they need.

Commenter	Comment	Agency response
	believe there needs to some sort of nursing supervision to determine when and if the case progresses to personal care so the client may be appropriately served.	
	381-80:Increasing the fee by 5 times seems excessive Perhaps a sliding scale based on gross income directly related to home care organization license.	As previously explained, the fees for licensure have not been increased since the regulation was first promulgated in 1991. The current fee structure, which is based on a HCO's annual budget, covers only 1/3 of the costs of the mandated licensure program, meaning that Virginia's taxpayers, many of whom do not utilize home care services, are carrying the burden of paying for the licensure and inspection program. The increase in fees is to address that inequity. In addition, fee increases are an indicator of an organization's ability to be financially solvent, not just clinically able, to provide care to clients it will admit to its services.
	391-90: Annual inspection, rather than bi-annual are most helpful as these provide an opportunity for consultation and improvement.	We are pleased that providers view the inspection process as an opportunity for consultation and improvement. However, biennial inspections assist in keeping program costs reasonable for providers and taxpayers, while not jeopardizing our oversight responsibility to assure quality care for Virginia citizens. However, there are other avenues for consultation and improvement for providers. For instance, we routinely provide presentations through the provider association conferences. Of course, providers are always welcome to call into or email the staff of the Center with their concerns and questions.
	381-120 A: Can we start the process of checking criminal records online with the state police? It allows us to run a criminal record check BEFORE placing them on a case and gives us much more peace of mind.	Yes, in fact, all home care providers should be accessing the State Criminal Records Bureau electronically, rather than continuing with surface mail options.
	381-220 B 1: Is blanket malpractice insurance required for non-medical home care companies?	Yes, since personal care providers are required to have an RN on staff. Malpractice insurance, as required by law, protects against errant practices by medical professionals. As with any insurance, it provides protection for the provider and the organization's staff from unexpected losses resulting from medical errors.

Commenter	Comment	Agency response
	381-260.B: Great data; will there be some training or guidance on collection of this data?	The request has been passed along to the Virginia Association for Home Care as a training topic for their members.
	381-270: Infection control, Does this apply to non-medical home care?	While infection and cross contamination prevention remain largely with medical home care providers, personal care providers will want to assure that staff are knowledgeable in infection control practices, such as universal precautions, to prevent the spread of illnesses. The provider community can be assured that Center staff recognize the difference between "non-applicable" and "out of compliance" regarding standards that may not be applicable to all providers.
	381-290 A: It is nice to see that we can use a nursing student as a home attendant. How do we document completion of clinical experience?	Evidence of completed clinical experience would be a transcript from the student's nursing school of the courses completed.
	381-360 F: We strongly disagree with changing from 60 day to 30day visits. In our experience and that of our RN (17+ years of home care), there isn't usually much change in a client in 30 days and if there is something of relevance then our DoN will make the determination to conduct a visit prior to the scheduled 60 day visit. 30 day visits would also be a financial hardship to our clients (senior citizens) and small agencies such as ours. It would double the compensation of a Director of Nursing, and force a rate increase upon our clients, most of whom are on fixed incomes.	As a result of the cogent arguments presented, we have amended the requirements to allow for supervision, not to exceed 90 days, based on the client's needs, the assessment by the RN, and the organization's policies. However, organizations should be aware that if inspectors determine that any of these conditions have not been addressed appropriately to assure client health, safety and welfare, the organization will be cited for noncompliance, which may result in suspension or revocation of a license.
	Thank you for taking the time to… make them more user friendly. I look forward to the trainings, better understanding them, and bringing them to fruition in our agency. My company is a small, non-medical company that caters to seniors. I don't anticipate expanding into skilled care. I believe there are many other non-medical home care agencies. It would be nice to see regulations tailored to non-medical	Thank you. We appreciate the recognition and support of our efforts on this project. A separate regulation focusing on non-medical care, while not unrealistic, would be improbable at this time. However, as a result of comments received from personal care providers, we have carefully reviewed the proposed regulation and made appropriate amendments to provide clarification between the 2 types of providers. We believe such efforts appropriately address the concerns expressed.

Commenter	Comment	Agency response
	home care.	
	I fully understand that we are not to dose or administer medication in the home. In most cases it is easy enough to find a family member, neighbor or friend who can predose medications into a medibox so that we can just remind folks to take their meds. However, the area of most frustration is with terminally ill patients. Often in end of life situations the Hospice will want to administer pain medications so that the client is comfortable, after all isn't that what quality end of life is all about? Liquid morphine is impossible to predose and sometimes family is not around to administer and the Hospice isn't willing to come out in the middle of the night. One of the options has been to remove our agency which is been providing reliable, compassionate and consistent care and has an established relationship with the client who doesn't have family around, in favor of an unskilled, untrained private hire who can administer medications. It doesn't seem right to make such an impersonal change in someone's final hours. It would be great if we could have med-techs administer medications in the home. We have nurses on-call 24 hours a day, just like an assisted living facility has an LPN available. I humbly ask that you consider a way to rectify this situation. I would be happy to serve on a task force to investigate options. Thank you!	We are concerned about the lack of cooperation you received from a hospice organization's RN. Any such incidences should be reported *immediately* to the Center and to the appropriate professional licensing board of the Department of Health Professions. Not only are such activities violations of provider and professional licenses, but possible evidence of patient abuse, a reportable action. We have conveyed this incident to the hospice community and will be addressing this during the upcoming training sessions on their revised regulation. We remind all providers of the strengthened adult abuse laws passed last year, which are applicable across the spectrum of adult services providers. This cannot be stressed enough to ALL home care providers. The potential of allowing personal care providers to utilize med techs will be taken under consideration and review.
Marcie Tetterton Virginia Association for Home Care	381-180 A: Remove the requirement that the individual appointed to serve in the absence of the administrator meet the same qualifications. Should be replaced with language that provides for the establishment of policies and procedures within the organization as to who is responsible for the operations in the event the administrator in not available.	The intent of the standard is to assure a smooth transition in the organization's management should the administrator be unable to continue in that capacity. We believe overall management of the organization to be an important facet of client care. However, we have amended the standard to state that the individual designated as assistant administrator shall be able to perform the duties of the administrator.

Commenter	Comment	Agency response
	381-250 6: After federal regulation insert: Home attendants of personal care services need only be evaluated on the tasks in 484.36 (b) as those relate to the personal care services to be provided.	Unfortunately, due to a technical error, the draft copy available on the Townhall website, did not contain the language suggested. However, *all* other copies of the draft available did contain the language regarding training of personal care staff. The language had not been deleted from the official draft, which is the *Virginia Register*, not the Townhall website.
	381-310 D and 381-350 F: Strongly suggest this language be consistent with Medicare standards which require supervisory visits of home attendants not less than once every 62 days.	As a result of the cogent arguments presented, we have amended the requirements to allow for supervision, not to exceed 90 days, based on the client's needs, the assessment by the RN and the organization's policies. However, organizations should be aware that if staff, upon inspection, determine that any of these conditions have not been addressed appropriately to assure client health, safety and welfare, the organization will be cited for noncompliance, which may result in suspension or revocation of a license.
	381-10: the definition of personal care services should clearly describe that the individual is "semi-dependent or dependent" on another person to perform activities of daily living.	The definition has been modified as contained in the law.
Leslie Ivy Heaven's Touch Nursing Svs, LLC	381-280: I believe LPN's should be allowed to make Medicaid Personal Care supervisor visits.	There seems to be some confusion, the draft under review is for the state's licensure program, not Medicaid program. The two programs are not synonymous.
John Devine Advantage Care of Shenandoah	12VAC 5-381-30---I routinely compete against unlicensed companion agencies who provide personal care services which by law require licensure. Penalties should be severe for operating without a license. VDH personnel should be assigned to make sure companion agencies do not perform services which require a license. If an agency does operate without a license they should not be allowed to secure a license for a period of 2 years if they are caught operating illegally. Many licensed agencies question why they should bother to be licensed.	It is exactly because of the confusion that we have attempted to provide clarification through regulation. We recognize, and have the same concerns as licensed providers, the problems created by non-licensed providers that "cross over" into licensed activities or designate themselves as a provider of non-licensed services in order to avoid licensure. Such providers are in violation of the law and sanctions can be imposed. However, we must rely on local citizens and area licensed providers to bring these individuals to our attention. By working together to identify and educate these providers on the law, the licensed community and regulatory agency can ensure that Virginia's vulnerable citizens are receiving the care and assistance they need. To strengthen the existing penalties would

Commenter	Comment	Agency response
		require legislative intervention.
	12VAC 5-381-80 ---Proposed licensure fee of $500.00 and the exemption fee of $75.00 are excessive and should be increased no more than $50.00.	As previously explained, the fees for licensure have not been increased since the regulation was first promulgated in 1991. The current fee structure, which is based on a HCO's annual budget, covers only 1/3 of the costs of the mandated licensure program, meaning that Virginia's taxpayers, many of whom do not utilize home care services, are carrying the burden of paying for the licensure and inspection program. The increase in fees is to address that inequity. In addition, fee increases are an indicator of an organization's ability to be financially solvent, not just clinically able, to provide care to clients it will admit to its services.
	12VAC 5-381-180 ----Remove the requirement that an administrator have at least one year, within the last five years, of supervisory or administrative management experience in home care or a related home health program. The requirement of one year experience in direct health care service delivery. The governing body should be given greater flexibility to hire administrative personnel to meet their company objectives without further restriction.	We disagree; the overall management of an organization is an important facet of client care. We believe the standard as written provides sufficient flexibility for the governing body "to hire administrative personnel to meet their company objectives."
	12VAC 5-381-360: Nurse supervisory visits should remain at 60 days and not be changed to 30 days. Medicaid was 30 and shifted to 90 days. Supervisory visits are done at no charge and existing rules are adequate.	As a result of the cogent arguments presented, we have amended the requirements to allow for supervision, not to exceed 90 days, based on the client's needs, the assessment by the RN and the organization's policies. However, organizations should be aware that if staff, upon inspection, determine that any of these conditions have not been addressed appropriately to assure client health, safety and welfare, the organization will be cited for noncompliance, which may result in suspension or revocation of a license.
Alexis Teitelbaum, Olivia Crawley Care Advantage, Inc.	We agree and fully support almost all of the changes made to the regulation to reduce archaic language and make them more up to date. This increase in appropriateness is helpful to only ensure the health and safety of the	Thank you. We appreciate the recognition and support of our efforts on this project.

Commenter	Comment	Agency response
	clients we work with, but to reduce the risk to clients and agency. We agree also that it is important for increased education for providers, to include their administrators so that we may be as educated as possible to best meet the needs of our clients and our community	
	Our issue with the regulation is the supervision requirement. We have a nurse that sees our clients every 30 to 90 days and as best practice completes these supervisory visits to our private pay client who are not regulated by licensure as well as our personal care clients. This supervision is increased or decreased per the client need and the nurse's assessment of what is needed. This 30 to 90 day supervision meets our client's need to ensure their health and safety and to reduce their risk of issue. This 30 to 90 day supervision also allows for the agency to provide the best service with an appropriate amount of cost effectiveness for our nurses and agency.	As a result of the cogent arguments presented, we have amended the requirements to allow for supervision, not to exceed 90 days, based on the client's needs, the assessment by the RN and the organization's policies. However, organizations should be aware that if staff, upon inspection, determine that any of these conditions have not been addressed appropriately to assure client health, safety and welfare, the organization will be cited for noncompliance, which may result in suspension or revocation of a license.
Louise Bodenstein Care Advantage Plus	381-160 E: don't always know 30 days in advance [of changes effecting the organization]	We disagree. The standard emphasizes the obligation of the providers to keep the Center informed of changes affecting the basis for their license. There are few instances when an organization does not know well in advance of the changes that need reporting, such as a change of ownership or an administrator leaving of their own accord. The sole reason for the standard is provider failure to inform the Center of such changes. The possible exception would be the immediate dismissal for cause of an administrator, in which case immediate notification to the Center after the dismissal would be acceptable.
	381-310 D: If the client is cognitively able and lucid the supervisory visit should not have to be every 30 days. Even Medicaid does not require this.	As a result of the cogent arguments presented, we have amended the requirements to allow for supervision, not to exceed 90 days, based on the client's needs, the assessment by the RN and the organization's policies. However, organizations should be aware that if staff, upon inspection, determine that any of these conditions have not been addressed appropriately to assure client health, safety and

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		welfare, the organization will be cited for noncompliance, which may result in suspension or revocation of a license.
	If you change the items required on care plans will you then in turn supply new forms with the new requirements. This should not be the responsibility of the agency that has already printed the forms at their expense.	There must be some confusion; the standard is not requiring any new requirements as asserted. We do not agree with the stated assertion; it is the responsibility of the provider to meet the conditions of the standard in order to be determined in compliance with the standard. If that means changing forms, then the provider is responsible for changing those forms. In addition, we recognize that each provider has a record system unique to their organization and has designed forms to best suit the needs of their record system and staff. To mandate a single format for all agencies would clearly be burdensome.
Tim Purcey, Neda McGuire, Karen Bonney, Toni Reinhart, Andrew Loehrer Comfort Keepers CK Franchising, Inc.	381-250 6: After federal regulation insert: Home attendants of personal care services need only be evaluated on the tasks in 484.36 (b) as those relate to the personal care services to be provided.	Unfortunately, due to a technical error, the draft copy available on the Townhall website, did not contain the language suggested. However, *all* other copies of the draft available did contain the language regarding training of personal care staff. The language had not been deleted from the official draft, which is the *Virginia Register*, not the Townhall website.
	381-310 D and 350 F: We would like the regulation to be kept at the current 60 day visit.	As a result of the cogent arguments presented, we have amended the requirements to allow for supervision, not to exceed 90 days, based on the client's needs, the assessment by the RN and the organization's policies. However, organizations should be aware that if staff, upon inspection, determine that any of these conditions have not been addressed appropriately to assure client health, safety and welfare, the organization will be cited for noncompliance, which may result in suspension or revocation of a license.
	We strongly encourage the change to eliminating the geographic restriction.	We believe that our effort to remedy service areas was misrepresented, even though states that have HCO licensure programs require such as does CMS. Instead, we have opted to require that the HCO identify their service areas when applying for initial or renewal licenses. As we stated in our initial discussion of the regulation, we reserve the right to reinstate defined services areas if there is evidence, as indicated by survey results or by an increase in filed complaints, that

Commenter	Comment	Agency response
		organizations are not providing adequate supervision of paraprofessional staff, i.e., home attendants, that medical care is not being provided as ordered by a client's physician, or that services are not being delivered as agreed.
	We are very excited about many of the changes that are proposed in the new regulations…We appreciate the Center helping to clarify and reflect changes that are occurring in the home care industry.	Thank you. We appreciate the recognition and support of our efforts on this project.
Cheryl Alston In-Home Family Care	381-10: Home maker services, delete: "assistance with bathing areas the client cannot reach," etc. this is general care.	We disagree. It is exactly because homemaker, chore, and companion services have not been defined in regulation that there has been much confusion in the lay provider community. In an effort to begin to rectify the situation across the spectrum of services, we were requested to provide clarification in the regulation. The agencies of the Secretary of Health and Human Resources spent much time in developing the definitions. It is expected that overtime, service parameters will become better understood, thereby alleviating any confusion.
	381-300 B: Delete: no need for primary care physician to review, approve & sign plan of care every 60 days for non-skilled agencies.	There must be some confusion; section 300 is not applicable to personal care providers.
	381-360 F: change supervisory visits to at least every 60 days.	As a result of the cogent arguments presented, we have amended the requirements to allow for supervision, not to exceed 90 days, based on the client's needs, the assessment by the RN and the organization's policies. However, organizations should be aware that if staff, upon inspection, determine that any of these conditions have not been addressed appropriately to assure client health, safety and welfare, the organization will be cited for noncompliance, which may result in suspension or revocation of a license.
Charles Mack Virginia Association of Personal Care Providers	381-10: Homemaker: Skills for these activities required some formalized training as outlined later in the proposed regulations to ensure client safety during activities and observations that should be made during these activities	While we may agree, homemaker services are not within the scope of our authority.

Commenter	Comment	Agency response
	381-80: The proposed fee increase is too great for smaller organizations that $500 fee will be very difficult to afford, margins are typically very low. Suggest fee schedule based on gross revenue as follows: < $400,000 = $100 $400,000 – 800,000 = $200 $800,001 – 1,200,000 = $300 $1,200,001 – 1,600,000 = $400 > $1,600,000 = $500	As previously explained, the fees for licensure have not been increased since the regulation was first promulgated in 1991. The current fee structure, which is based on a HCO's annual budget, covers only 1/3 of the costs of the mandated licensure program, meaning that Virginia's taxpayers, many of whom do not utilize home care services, are carrying the burden of paying for the licensure and inspection program. The increase in fees is to address that inequity. In addition, fee increases are an indicator of an organization's ability to be financially solvent, not just clinically able, to provide care to clients it will admit to its services.
	381-180 A: The requirement of 1 year of training and experience in direct health care delivery will exclude many competent individuals from assuming what is essentially a management function. If direct health care delivery were a prerequisite for health care management in general, many fine hospitals and health system CEO's would be deemed unqualified. It is unlikely such a regulation would safeguard consumers and will be interpreted so broadly it will be meaningless.	We disagree. The overall management of an HCO is an important facet of client care. The stated analogy to hospitals and health systems is not comparable.
	381-240 C 10: Suggest: Assured at least 5 days written notice prior to any discharge or referral in service, except when a medical emergency exists, when the patient's physician orders admission to an inpatient facility, or when discharge is determined by the Chief Administrative officer to be necessary to protect the health and welfare of the staff member providing services.	The intent of the standard is to assure that clients are given minimal notice of intended discharge or dismissal in order to make plans for continuing care. The examples cited, i.e., medical emergencies and a client's physician orders are beyond the control of the provider and therefore are not applicable to the standard. In addition, we believe the suggest language allowing the administrator to determine dismissal opens the door for arbitrary and capricious decision making.
	381-260: All HCO's do not provide all services, ex. an organization that provides only personal care services; #5 [medical records] would not be applicable.	The section has been amended for clarification.
	381-280 F 6: [medical plan of care] applicable only to clients receiving	The subsection has been amended for clarification between the 2 types of client

Commenter	Comment	Agency response
	skilled care, not obtainable for personal care only. F 9 [medication sheets]: Delete for personal care only	records.
	381-290 5: list the criteria as very difficult to read in the Code of Federal Regulation. Is this applicable to organization implementing competency program after August 14, 1990. The regulation should be spelled out.	We do not believe that listing the criteria is necessary. However, the Association is free to develop such a list as a service to its members.
	381-320 D and 360 F [supervision]: In personal care, supervisory visits are made as often as needed to ensure both quality and appropriateness of services. A minimum frequency of visits is every 30 days, not to exceed 90 days for clients who do not have any type of cognitive impairment. Supervisory visits for skilled care clients should be more frequent than for those clients receiving personal care only. Providers do not believe the aides should always be present when the supervisory visit is done.	We received many comments from providers regarding the staff supervision requirement. As a result of the cogent arguments presented, we have amended the requirements to allow for supervision, not to exceed 90 days, based on the client's needs, the assessment by the RN and the organization's policies. However, organizations should be aware that if staff, upon inspection, determine that any of these conditions have not been addressed appropriately to assure client health, safety and welfare, the organization will be sited for noncompliance, which may result in suspension or revocation of a license.
	381-360 G: We are concerned this may prove chaotic to administer. Personal care attendants work for different organizations, extended care facilities or individual employers, sometimes simultaneously, during any given year. Much less common for an aide to be employed by a single organization for extended periods.	We disagree and suggest that one reason there is such fluidity is because individuals are not offered incentives, such as training or opportunities to improve their skills, to remain with an organization. A common complaint across the spectrum for why individuals change jobs frequently is the lack of training or opportunities for advancement. We do not believe that 12 hours of in-service training is unreasonable, especially when training may be in conjunction with supervisory visits.
	Suggest a single term be used to describe the person providing the services for consistency in the regulation.	We certainly agree and that is our intent. The oversight on our part has been corrected.
Alexander Macaulay, Rebecca Argabrite Grove, Karen Smith Virginia Occupational	381-310 A 4, 310 C 3, and 360 C: Teaching of self-care techniques is not distinguishable from teaching activities of daily living. As indicated in [§ 54.1-2900 of the code], the delivery of education and training in	We disagree and believe the statement is an unfounded assumption of authority not granted by the Code of Virginia.

Commenter	Comment	Agency response
Therapy Association	activities of daily living is the unique province of occupational therapists. They are most qualified to "teach" self-care techniques for maximum patient benefit.	
	381-330 A and C 1: Therapists in Virginia are required to be licensed and occupational therapy aides are required to be certified by the National Board of Certification in Occupational Therapy.	The oversight regarding therapist credentials has been corrected.
Elaine Yeatts Virginia Department of Health Professions	References to RNs and LPNs should include the multi-state licensure privilege. Suggest adding 2 definitions as follows: Registered nurse/licensed practical nurse means "a person holding a current license issued by Virginia Board of Nursing or a current multi-state licensure privilege to practice nursing in Virginia." By adding the definitions, it would be unnecessary to repeat that language throughout.	We agree and have added definitions for registered nurse and licensed practical nurse to section 10.
	Section 310 is problematic and misleading because it implies that the nursing services listed could be delegated by an RN provided the tasks are performed under his supervision. However, many of the tasks listed cannot be delegated to an unlicensed person. Suggest: <u>All nursing services shall be directly provided by an appropriately qualified registered nurse or licensed practical nurse, except for those nursing tasks that may be delegated by a registered nurse in accordance with 18 VAC 90-20-420 through 18 VAC 90-20-460 of the regulations of the Virginia Board of Nursing and with a plan developed and implemented by the organization.</u>	We appreciate the assistance with crafting appropriate language that does not conflict with the Board of Nursing regulations.
	381-330: Therapists in Virginia are required to be licensed and occupational therapy aides are required to be certified by the National Board of Certification in Occupational Therapy.	The oversight regarding therapist credentials has been corrected.
Susan Ward		

Commenter	Comment	Agency response
Virginia Hospital & Healthcare Association	381-10: "Home care" is used ambiguously in the definition of "home care organization" and the regulation does not define home care. Suggest replace with "home health" a term defined by statute in 32.1-162.7.	The definition has been clarified.
	Because the terms are not clearly defined, it is unclear how new innovative services and technology fit into the regulations and consequently whether all procedural requirements under the regulations would apply.	We do not understand the intent of the comment, as the 2 issues are not synonymous. The use of new innovative services and technology, such as telemonitoring, are adjuncts to hands on care, not replacements for such care. We are happy to discuss developments in home medical care with providers, but do not consider them exclusive of the requirements of the law.
	Home care record should provide for electronic records	We do not believe the current definition precludes the use of electronic records, however, clarification has been provided.
	Personal care services should be consistent with the statutory definition in 32.1-162.7	The oversight has been corrected.
	381-40: Believe it would be much clearer and eliminate confusion in definitions to simply state that the regulations do not apply to any organization that is not a home care organization. There seem to be confusing overlaps in types of services that are considered (i) homemaker, shore, companion services, (ii) activities of daily living and (iii) instrumental activities of daily living	It is exactly because homemaker, chore, and companion services have not been defined in regulation that there has been much confusion in the lay provider community. In an effort to begin to rectify the situation across the spectrum of services, we were requested to provide clarification in the regulation. The agencies of the Secretary of Health and Human Resources spent much time in developing the definitions. It is expected that overtime, service parameters will become better understood, thereby alleviating any confusion.
	381-60: Spell out "HCO" or clarify in definitions what HCO means	The definition of home care organization was amended to include "or HCO."
	381-110: Complaint investigations are contained here and in section 250, suggest consolidating for clarification. The time frames in 110 D need clarification. Is the process the same as outlined in section 90. If so, some reference or consolidation of these provisions would provide clarity.	The titles to sections 110 and 250 have been amended to clarify between complaint investigations conducted by Center staff and handling of client complaints received by the organization. The 2 sections are not the same. A complaint inspection conducted by Center staff is handled no differently than an inspection. However, section 110 has been amended for clarification.
	381-160 E: Geographic limitations	We have opted to require that the HCO identify

Commenter	Comment	Agency response
	are removed; however changes in service area are to be reported to the Center. What is the purpose of such monitoring? Who establishes the areas? If not the HHA, how does it identify changes?	their service areas when applying for initial or renewal licenses. As we stated in our initial discussion of the regulation, we reserve the right to reinstate defined services 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, that medical care is not being provided as ordered by a client's physician, or that services are not being delivered as agreed.
	160 I: Agencies should not be required to provide emergency services, but "on-call" services based on agency policy.	The standard has been amended as suggested.
	381-170 B: Request clarification of the information sought in items 1 and 3.	The subsection has been amended for clarification.
	381-180: The back-up administrator should not be required to have the same qualifications as the administrator.	The intent of the standard is to assure a smooth transition in the organization's management should the administrator be unable to continue in that capacity. We believe overall management of the organization to be an important facet of client care. However, we have amended the standard to state that the individual designated as assistant administrator shall be able to perform the duties of the administrator.
	381-190: Suggest policies and procedures be reviewed every 3 years rather annually, or as required by Medicare CoPs.	We do not believe it is unreasonable that agencies review the policies and procedures annually, especially since staff is expected to follow those procedures when providing care or services. It would be unfortunate that an organization be cited for non-compliance regarding their own policies because those policies did not reflect staff practices.
	381-220: Libel is misspelled.	The spelling has been corrected.
	381-240 C 10: Suggest adding "for cause as set forth in agency policy."	We disagree. The intent of the standard is to assure that clients are given minimal notice of intended discharge or dismissal in order to make plans for continuing care. The suggest language opens the door for arbitrary and capricious decision-making.
	381-250 A 4: Are appeal rights required? What would they be? Suggest deleting, for consistency with Medicare CoPs.	Subsection A has been amended.

Commenter	Comment	Agency response
	381-260 B: Request clarification that the data is evaluated by the agency not the Center or another organization. It is unclear what some of the items refer to, especially items 2, 5 and 8. 260 C 1: Medicare permits oversight services by a physician or a registered nurse, requiring physician membership on the QI is excessive.	There seems to be some confusion; the standard does not indicate that Center staff would be evaluating the organizations data. Nor is that the intent. Subsection B has been reviewed and amended. The subsection has been amended.
	381-300: services are described in terms of services to be provided by a home attendant. This is confusing and seems to avoid the larger issue of defining the scope of the regulation. 300 A: a definition of respiratory therapy is needed.	Based on this comment, the whole of Part III has been reviewed and amended as appropriate. We disagree.
	381-330: Does home care include home medical equipment providers who provide clinical respiratory care through a respiratory therapist? We question whether there is authority for VDH to regulate respiratory therapy services.	Licensure of durable medical equipment (DME) was repealed in the early 1990's, for those DME providers that only deliver and set up the equipment, but do not provide clinical staff support. Those DME providers that do offer clinical support are required to be licensed as a home care provider. The inclusion of respiratory therapy as a facet of home care is not new and we question why VDH's authority to license such is now being disputed. Our research indicates that respiratory therapy delivered in the home has, and continues to be, considered part of home care services and, therefore, subject to licensure.
	381-350: Suggest including the statutory definition of pharmaceutical services	We disagree.
	381-360: DPB's EIA provides compelling arguments that RN or LPN supervision for personal care services is not supported by statute and imposes costs in complying with these supervisory requirements for what are non medical personal care services. 360 B: what is a personal care	As stated in our required response the DPB's EIA, we disagree with their assessment of the regulation. The law clearly mandates that clients be assessed for the care to be provided; only RNs can perform such assessments. That decision has been upheld by the Office of the Attorney General and supported by the Office of the Secretary of Health and Human Resources. It is expected that a record would be

Commenter	Comment	Agency response
	plan? Is this the same as a medical plan of care as defined in section 10?	established for each client in order to instruct staff on the care needs of the individual. However, the comment points to a confusion in the regulation and we have amended the applicable standards to clarify that confusion.
	It would be clearer to use the term "home attendant" throughout.	We certainly agree and that is our intent. The oversight on our part has been corrected.
Chris Head Home Instead Senior Care	381-180 A: The requirement of 1 year of training and experience in direct health care delivery will exclude many competent individuals from assuming what is essentially a management function. If direct health care delivery were a prerequisite for health care management in general, many fine hospitals and health system CEO's would be deemed unqualified.	We disagree. The overall management of an HCO is an important facet of client care. The stated analogy to hospitals and health systems is not comparable.
	381-240: Request the 5 day notice provision be amended to allow for termination on shorter verbal notice in cases where the safety of a home care worker is jeopardized. Aggressive pets, employee harassment and dangerously unsanitary conditions in the home are just a few of the situations that rightly justify more immediate terminations.	We disagree. The intent of the standard is to assure that clients are given minimal notice of intended discharge or dismissal in order to make plans for continuing care. The examples cited, i.e., aggressive pets and unsanitary conditions would be identifiable prior to providing services. Employee harassment could be a sign of a decline in client functioning triggering the need for medical care, not immediate dismissal from service. Dangerously unsanitary conditions are signs of client self-neglect and should be reported to the adult protective services unit of the local social services department. We remind all providers of the strengthened adult abuse laws passed last year, which are applicable across the spectrum of adult services providers. This cannot be stressed enough to ALL home care providers. In addition, we believe the suggested language, i.e., where the safety of the home care worker is jeopardized," opens the door for arbitrary and capricious decision making.
	381-260 C 1: suggest amending to read "Physician in a clinical medical specialty." Would object to any requirement that such a physician have some other formal affiliation with the HCO beyond membership on the committee.	Subsection C has been amended to clarify committee membership based on type of organization. There has been no discussion of any requirements that a physician have some formal affiliation with the HCO beyond the membership on the committee.

Commenter	Comment	Agency response
	381-280: Recommend that medication sheets not be required for clients receiving personal care services.	The subsection has been amended for clarification between the types of organizations.
	381-360: Request the VDH reconsider it proposed supervisory requirements for home attendants. Supervision every 30 days is excessive, unnecessary and intrusive for clients who are paying to have an alternative worker focusing on their needs. More over linking the frequency of supervision to a calendar period ignores the wide variations in intensity of care that exists between clients, ranging from an occasional visit to 24-hours to live-in care. Suggest changing to 90 days except in cases where a family member or other responsible party is not periodically in attendance, or reverting to the current 60-day interval.	The applicable sections have been amended as previously explained.
Bolling Scott Concordia Group, Inc.	381-10: Home attendant are also known as home care aide, home health aides, personal care aides, nurse aides, nursing assistant.	The comment highlights the difficulty we identified while developing the regulation. There are far too many names used to signify nonlicensed, paraprofessional staff. Therefore, we develop a generic term to use throughout the regulation and provided examples of the possible job titles used by an organization.
	381-80: The fee structure should be graduated	We disagree as explained previously.
	381-180: Delete requirement of direct health care delivery. This would eliminate many well qualified individuals	We disagree as previously explained.
	381-260: QI should not be so restrictive but should give loose guidance to incorporate services provided by the agency many listed to not apply to all agencies.	We do not believe the standards are restrictive, but provide the guidance suggested. However, we have amended the subsections to provide clarification.
	381-280 F: These are for skilled agencies only	The subsection has been amended as previously explained.
	381-290: Reference to federal regs should be spelled out and clearly state that competency was	There seems to be some confusion. The competency threshold of August 14, 1990 is applicable only for organizations seeking

Commenter	Comment	Agency response
	established on or before August 14, 1990. If I interpret the Code correctly, I could not use the competency program today.	federally certification, and is not applicable for state programs. This regulation is for licensure as a state program. To require such a standard in licensure would be counter-productive to the intent, which is to offer a broader scope of training for paraprofessional staff, specifically personal care.
	381-360: the supervisory visit is too onerous The in-service training requirements should be that agency should provide 12 in-services per year. The requirement that each aide must have 12 documented will be impossible with the way aides come and go.	The applicable sections have been amended as previously explained. We disagree as previously explained.
	Overall, I feel these regulations continue to try to "squeeze" personal care services into a skilled care model and tha's just not right. I feel strongly that the regulation should be completely separate from skilled services.	As explained previously, a separate regulation, while not unrealistic, is not possible at this time. However, as a result of comments received from personal care providers, we have carefully reviewed the proposed regulation and made appropriate amendments to provide clarification between the 2 types of providers. We believe such efforts appropriately address the concerns expressed.
Patty Anderson Visiting Angels, Inc.	Because the regulations still include skilled nursing care and personal care in the same set of regulations, they remain almost as confusing as the existing regs.	As explained previously, a separate regulation, while not unrealistic, is not possible at this time. However, as a result of comments received from personal care providers, we have carefully reviewed the proposed regulation and made appropriate amendments to provide clarification between the 2 types of providers. We believe such efforts appropriately address the concerns expressed.
	Personal care is strictly private pay. If we continue with regs such as these, the operational costs will be driven up, thereby increasing the rates charged to our seniors. In all other states, a company that provides only personal care services and companion services is considered non-medical.	We believe we have appropriately addressed the separation between personal care services, and home care services or pharmaceutical services. Perhaps the commenter missed section 50, which explains the applicability of the Parts of the regulation and the compliance expectations. Nevertheless, providers of personal care services are required by law to be licensed to operate in Virginia.
	381-320 [home attendant services]: Do we as personal care providers follow this?	This comment supports our belief that the commenter missed reading or understanding section 50, which explains the applicability of the Parts of the regulation. Section 320 is not applicable for Personal Care providers.

Commenter	Comment	Agency response
	381-360: The costs of hiring RNs and LPNs is exorbitant.	The law clearly mandates that clients be assessed for the care to be provided; only RNs can perform such assessments. The Personal Care section of the regulation stipulates that the provider need have only 1 RN on staff. If the provider chooses to have more then 1 professionally licensed nursing individual that is their decision.
	381-260: The cost of hiring a physician who will commit to this is difficult for most.	The subsection has been amended.
	What is required of companies that perform both personal care as well as companion care services? Must we perform nurse assessments, supervisory visits, and all other documentation for all of our clients, or just for the personal car clients?	We are not sure of the intent of the question. If a provider chooses to "carry over" personal care standards to their companion care clients that is certainly their option. To require such applicability, however, is beyond our scope of authority.
	These proposed regulations seem overzealous and harmful to the ethical organizations trying hard to follow the laws set the state, while failing to increase the safety and welfare of the care recipients.	We believe that a regulation that assures protections for clients, carries out the intent of the law, while addressing the concerns of providers, has been developed. It is unfortunate that the commenter disagrees.
Lori Griswold Griswold Special Care, Inc.	Clients receiving personal care, etc. do not require oversight by an RN or other health care professional and the required 30-day visits. We propose that the client be given the choice about whether they would like a nurse involved in the supervision of the ADL/IADL care or not and the decision shall be documented in the client's record.	The applicable sections have been amended as previously explained.
	381-10 definitions: Suggest changes to the following definitions: Activities of daily living, companion/homemaker services: home attendant, homemaker services, instrumental activities of daily living, and personal care services.	We disagree; the definitions of "activities of daily living" and "instrumental activities of daily living" are standardized throughout the industry and across the state's human services agencies. In addition, the definitions of "companion" and "homemaker services" were carefully crafted by the state's human services agencies. The definition of home attendant, as explained previously, was developed to provide clarity in the regulation; personal care services are defined in the law and cannot be changed without legislative intervention
	381-260: B 1 and 5, C 1, and D	The subsections have been amended for

Commenter	Comment	Agency response
	[quality improvement]: are appropriate for only for home care organizations.	clarification.
	381-270 Infection control: delete for agencies providing only personal care or as suggested only for home care providers.	We disagree and expect personal care service providers to be versed in universal precautions to prevent the spread of illnesses. However, the personal care organization can be assured that Center staff knows the difference between "non-appicable" and "out-of-compliance" situations.
	381-280 [home care record]: Only appropriate for home health licensed HCO's with skilled nursing duties.	We disagree; however, the section has been amended for clarity.
	381-290 [home attendants]: This definition is facially discriminatory and therefore unacceptable.	We disagree and believe the standard has been misinterpreted. There must be a common language by which management can communicate with staff and staff with their clients. The standard does not prevent foreign language speakers from being hired, and therefore, is not discriminatory. As a guarantee, we sought legal counsel and have been assured that "it is not unconstitutional or otherwise illegal to require that home attendants be "able to speak, read and write English…Nor is the English proficiency requirement designed to prevent foreign language speakers from serving as home attendants, rather, it merely requires English proficiency as it relates to the acts performed by the home attendant."
	381-300 Home care services. The title of this section should reflect the category of licensure described and also reflected in the stature	The section has been amended for clarification. However, it is not applicable to personal care providers.
	381-310 [nursing services]: appropriate only for home health providers	That is correct. As stated in section 50, section 310 is not applicable to personal care providers.
	381-360 A: It is shown in the statute and also by supportive documentation that a nurse supervisor for personal care services is not required. No statutory authority for such requirements. B2: Prefer "client service plan" vs. "personal care plan"	That is an incorrect statement. The provider is free to call the client's record any name they choose for the convenience of

Commenter	Comment	Agency response
		their staff as long as it contains the items stipulated in the regulation.
	C: A nurse is not required for writing a non-medical service plan.	We disagree, for the reasons previously explained.
	C1: "Assessment" reflects a medical act; "description" is more accurate	We point out that in order to place a *description* of the client's needs in the record, there must first be an *assessment* of those needs.
	D. A copy of the service plan is kept in the office and a copy given to the client and kept in a confidential location but accessible to the home attendant for review.	Nothing in the standard prevents the provider from continuing with those practices. However, we must point out that the record must be kept confidential *outside* the client's home.
	E. Home attendants providing only ADL and/or IADL services do not require the supervision of a nurse.	We disagree, as previously explained.
	F. Supervisory visits do not require nursing involvement. Such visits are usually not necessary more than every quarter.	The requirement regarding paraprofessional staff supervision has been amended as previously explained.
	G. A nurse is not necessary for supervision of personal care services. Such would have been listed in the statute if that was the legislative intent.	That is an incorrect statement. For example, §32.1-162.12 of the Code grants the Board of Health the 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."
	H. Requiring 12 hours of CEU's is not appropriate for this category of worker. It will result in an increased shortage of worker and increased turnover.	We disagree and believe the standard has been misrepresented. The standard does not require CEU's, but in-service training. The 2 are not synonymous. We also suggest that provision of training would curb the turnover rate some providers experience. A common complaint across the spectrum for why individuals change jobs frequently is the lack of training or opportunities for advancement. We do not believe 12 hours of in-service training is unreasonable, especially when training may be in conjunction with supervisory visits.

All changes made in this regulatory action

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

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.

As a result of the public comment period, which resulted in moving, deleting and adding sections, the regulation has been renumbered for continuity. Therefore, to avoid confusion with the proposed sections, the chart of the changes made since the public comment period has been added separately here.

Section number	Requirement at proposed stage	What has changed	Rationale for change
10	Definitions section	1. Added: "client record, "drop site, "functional limitations," "Licensed practical nurse," "Registered nurse," and "Skilled services." 2. Amended: "Activities of Daily Living or ADLs," "Administrator," "Barrier crimes," "Criminal record report," "Discharge or termination summary," "Dispense," " Home care organization," "Personal care services," "Primary care physician," "Sworn disclosure statement." 3. Deleted: "Bylaws," "Clinical note," "Direction," "Full-time," "Home care record," and "Immediately"	1. Definitions added to provide clarity; definition of "drop site" added for convenience of providers. 2. Definitions amended (i) to provide added clarity, or (ii) are technical in nature and do not alter the intent of the definition. 3. Definitions deleted as they have a common understanding or are not sued in the text.
	Responsibility of the department	Deleted section	Does not conform to regulatory guidelines; section unnecessary.
40	License application; initial and renewal	A. Amended to delete: "review an applicant's proposed program plans" and read "the survey process." and E. Amended to read "make renewal applications available	Amended for consistency with current practices and acknowledges an operational change by the Center regarding licensure applications.
50	Compliance appropriate for type of HCO	Tile and section numbers amended	Amended for clarity and relation to final text.
80	On-site inspections	A. "According to applicable law:" added	Amended for regulatory consistency.
100	Complaint investigation	Title amended to distinguish this section from section 250; subsection D amended to add provider response expectations.	Provider request
120	Variances	F. Sentence rewritten	Grammatical correction
140	Surrender	"Return" substituted for "Surrender"	"Return" seen as less punitive and for regulatory consistency
150	Management and Administration	I. Amended for "on-call service" rather than "emergency services" J. Subsection amended deleting possible needs L. Added flu shot requirement.	I. Provider request J. In response to provider concerns to assure that regulation addresses providers of skilled and non-skilled services. L. Added as result of constituent comment

160	Governing body	B. Bylaws deleted; Replaced with governing body responsibilities	Result of provider comment
170	Administrator	C. Qualifications of assistant director amended.	Result of provider comment
180	Written policies and procedures	Technical amendments made	Result of provider comments
210	Indemnity coverage	Technical amendments made	Amended for regulatory consistency
220	Contract services	Technical amendments made	Result of provider comments
240	Complaints	Title amended to distinguish this section from section 100; subsection A amended deleting 2 procedure handling criteria.	Provider request
250	Quality Improvement	Technical amendments made	In response to provider concerns to assure that regulation addresses providers of skilled and non-skilled services.
270	Drop sites	Section added describing elements of staff support offices	Section added as a convenience to providers to assure timely and appropriate client care.
280	Client record system	Technical amendments made	In response to provider concerns to assure that regulation addresses providers of skilled and non-skilled services.
300	Skilled services	Technical amendments	Result of provider comments.
310	Nursing services	Proposed subsections A, B, and C replaced with new subsections A and B added	New language offered by DHP to assure consistency with professional licensure standards.
320	Therapy services	1. Section amended to reflect appropriate professional qualifications; 2.subsections A and B combined; 3.subsection D addressing home attendant supervision added	1. Technical change to reflect appropriate professional credentials 2. Technical change 3. Result of provider comment and for regulatory consistency
330	Home attendants	1.Section moved within Part III; 2. Proposed subsections C and D were combined, text amended	1. Technical amendment for proper placement in the text 2. Subsections combined, as they were duplicative; Supervision requirements changed as a result of the public comment period.
340	Medical social services	Technical changes made	Amended for regulatory consistency

350	Pharmacy services	Technical changes made	Amended for regulatory consistency
360	Personal care services	A and B Technical change E. Supervision of home attendant amended F. Deleted	A/B amended for regulatory consistency E. Amended as a result of public comment period F. Duplicative of subsection E and therefore, not needed.

Family impact

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

There is no direct impact on the family as a result of the proposed regulation.