**State of Board of Health**
**Agenda**
**October 23, 2009 – 9:00 a.m.**
**Virginia Hospital and Healthcare Association**
**4200 Innslake Drive**
**Glen Allen, Virginia 23060**

| | |
|---|---|
| Welcome and Introductions | Fred Hannett, Chairman |
| Review of Agenda | Joseph Hilbert, Executive Advisor |
| Approval of July 2009 Minutes | Fred Hannett |
| Commissioner's Report | Karen Remley, MD, MBA, FAAP<br>State Health Commissioner |
| State EMS Advisory Board Update | Jennie Collins, Chairman<br>State EMS Advisory Board |
| Break | |
| Commissioner's EMS Process Action Team Update | Gary Critzer, Chairman<br>EMS Process Action Team |
| Health Information Technology - Update | Kim Barnes, VDH Health<br>Information Technology Coordinator |
| Federal Health Care Reform Proposals – Overview | Joseph Hilbert |

Working Lunch

Board discussion of Federal Health Care Reform issues, facilitated by Board Chairman

Public Comment

<u>Regulatory Action Items</u>

| | |
|---|---|
| Regulations for the Licensure of Hospices<br>12 VAC 5-391<br>(Final Amendments) | Chris Durrer, Director<br>Office of Licensure and Certification |
| Regulations Governing the Virginia Nurse Educator Scholarship Program<br>12 VAC 5-545<br>(NOIRA) | Michael Royster, MD, MPH<br>Director, Office of Minority Health and Public Health Policy |

Regulatory Action Items (continued)

| | |
|---|---|
| Regulations for the Administration of the Virginia Hearing Impairment Identification and Monitoring System<br>12 VAC 5–80<br>(Proposed Amendments) | David Suttle, MD<br>Director, Office of Family Health Services |
| Regulations for the Onsite Sewage Indemnification Fund<br>12 VAC 5-612<br>(Final Regulations) | Bob Hicks, Director<br>Office of Environmental Health Services |
| Schedule of Civil Penalties<br>12 VAC 5-650<br>(Final Regulations) | Bob Hicks, Director<br>Office of Environmental Health Services |
| Member Reports | |
| Approval of 2010 Board Meeting Dates | Fred Hannett |
| Other Business | |
| Adjourn | |

Virginia
Regulatory
Town Hall

townhall.virginia.gov

# Final Regulation
# Agency Background Document

| | |
|---|---|
| **Agency name** | Virginia Department of Health |
| **Virginia Administrative Code (VAC) citation** | 12 VAC 5 – 391 |
| **Regulation title** | Regulations for the Licensure of Hospices |
| **Action title** | Amendments addressing hospice facilities |
| **Date this document prepared** | August 28, 2009 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) 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. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.*

In 2003(HB1822), the hospice community was permitted to establish dedicated hospice facilities licensed as assisted living facilities. Such dual licensure has proven problematic for hospice providers with facilities currently licensed under that legislation. The strengthening of the assisted living facility regulation in 2006 widened the disparity between assisted living facilities and the hospice philosophy. Enactment of HB1965 (CHAP0391, 2007) places oversight for hospice facilities with the Virginia Department of Health, the designated state oversight authority for hospice programs. The legislation establishes that the continuity in hospice services provided in a patient's home also be provided in a dedicated facility. This change in law necessitates amending Part IV (12 VAC 5-391-440 et seq.) to expand the scope and breadth of the current standards addressing patient care and safety in hospice facilities. Currently the regulations do not offer adequate protections for medically fragile patients receiving care in the dedicated facilities. The department is also taking this opportunity to address some omissions in the regulation revised in 2005.

## 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.*

Enter statement here

## 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 under the authority of § 32.1-162.5 of the Code of Virginia, which grants the Board of Health the legal authority "to prescribe such regulation governing the activities and services provided by hospices as may be necessary to protect the public health, safety and welfare." Therefore, this authority is mandated. The passage of HB1965(CHAP0397, 2007) requires that sections of 12 VAC 5-391 be subsequently amended.

## 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.*

This action will establish standards for those hospice providers seeking to establish dedicated board and care facilities for diagnosed terminally ill consumers receiving hospice care, but who can no longer remain in their own homes. The proposed regulations address patient care and safety, physical plant, maintenance and housekeeping, and emergency preparedness. The proposed amendments also rectify some omissions in the 2005 revised regulation.

## 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.*

12VAC5-391-10: Amended 'bereavement services' amended to reference federal regulation; added definitions of 'adverse outcomes' and 'separate and distinct entrance' to clarify intent of regulatory requirements.

12VAC5-391-120 C: Added primary caregiver or family to 'convenience' prohibition; D and E: Switched placement of regulations and added language to clarify intent of respite and symptom management regulation.

12VAC5-391-160 H: Modified to reflect statutory language; K: Added 'pandemic disease outbreaks' to emergency preparedness planning

12VAC5-391-180 B: Amended to include 'applicable state laws and regulations' and change name of JCAHCO

12VAC3-391-300 F: Subsection added.

12VAC5-391-395 A: Amended to require reporting of adverse outcomes to OLC/VDH.

12VAC5-391-440 J: Added 'separate and distinct entrance' to divert traffic and noise away from patient care areas.

12VAC5-391-445C: Amended food service reference as not all facilities will meet the commercial kitchen threshold.

12VAC5-391-450 B: Amended to stipulate protection from 'avoidable' accidents, injuries and infections

12VAC5-391-480: added note regarding family provision of patient meals; D: Amended to provide for employment of dietary consultation

12VAC5-391-500 B: Added exclusion for service animals; D: correct syntax

12VAC5-391-510 D: Amended to add 'patient rooms' to areas requiring telephone access.

## 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.*

---

Some members of Virginia's hospice community have wished to establish identifiable hospice facilities for some years. Until the passage of HB1965, those efforts proved unsuccessful because providers felt that dual licensure as an assisted living facility, nursing facility or hospital, as required, was

overly burdensome and that the facility licensure regulations were not sufficiently flexible to implement services reflecting the hospice philosophy of care.

The 2005 comprehensive revision to the hospice licensure regulations (12VAC5-391) included minimum facility related regulations since a hospice facility would also have to be licensed as a nursing facility, a hospital or an assisted living facility. With the passage of HB1965 (2007), it was necessary to fully develop the requirements for the physical plant and facility portion of 12VAC5-391. In developing these amendments, OLC/VDH relied on the hospice facility regulations from other states, as well as other long term care facility regulations within Virginia, and the hospice facility conditions for participation of the Centers for Medicare and Medicaid (CMS). Part of that development was recognizing that the intent of these facilities is to mirror a residence rather than the more complex physical plant of a nursing facility or assisted living facility. However, there remain certain standards that are inherent in any communal living situation, regardless of the size and complexity of that facility. This is especially true when that facility is dedicated to the provision of medical care services. As part of it efforts to involve the various interested parties, OLC/VDH convened a stakeholder meeting to reach consensus on issues such as staffing, physical plant requirements, dietary and housekeeping. Stakeholders included: The Virginia Association of Home Care and Hospice, The Virginia Association of Hospice, The Virginia Health Care Association, the Virginia Association of Nonprofit Homes for the Aging, the Alzheimer's Association, the State Fire Marshall's Office, and OLC/VDH staff. OLC/VDH believes this is the first time that hospice providers participated in such a regulatory consensus meeting. OLC/VDH is confident that the resultant amendments offered herein are a reasonable compromise that assure appropriate quality patient care in a communal setting while ensuring that the regulations are not a barrier or intrusive to the operation of a hospice facility that is limited by the Code of Virginia to 16 or fewer beds.

The requirement for a registered nurse on duty on all shifts was considered problematic for some hospice providers. The most often cited reason for objecting to the regulation is cost. However, hospice patient care advocates do not consider costs a legitimate reason for opposing the registered nurse on duty criteria. Advocates cite the complexities of terminal illnesses, such as Alzheimer's disease, and the potential for medication errors and adverse drug reactions as sufficient cause to require a registered nurse on duty on all shifts. Even though the regulation was consistent with hospice facility licensure provisions in other states as well as with federal hospice facility regulation, OLC/VDH agreed to reconsider the regulation. After conducting a pilot study, it was mutually agreed that appropriate care could be provided without an RN on duty if an RN was on-call within 20 minutes. The department believes that the agreed upon exception that a RN be available to respond to emergent calls within 20 minutes for those facilities with six beds or less appropriately addresses the concerns of both parties.

In addition to staffing, dietary/food services and pharmacy received attention during the public comment period, stating that such regulations were unnecessary and intrusive. OLC/VDH disagrees that such regulations are actually intrusive; rather they bring provider awareness to the complexities of operating a facility. That includes an awareness of various other Virginia laws and regulations that all facility providers, regardless of focus, must adhere to. Such laws and regulations have been legislatively established for the common welfare of Virginia's citizens. Exception was also taken to the requirement that adverse medication outcomes be reported to the department and that providers implement an active pressure ulcer reduction program. OLC/VDH considers both these issues important to the overall quality of care delivered. In light of national studies on medication errors and adverse outcomes, many states have implemented adverse event reporting requirements as one of their tools for monitoring compliance to nationally accepted standards of practice. OLC/VDH believes Virginia should be no different and cites §32.1-19C as its legal authority for establishing reporting requirements. Therefore, OLC/VDH is adding adverse event reporting as it revises all its program licensure regulations. Medication errors can indicate a system failure within a provider's organization that can also have serious quality of care consequences. The intent is to use the reports as a survey preparation tool, for data analysis for targeted provider training, and to identify those providers needing additional oversight support. Patient advocates declare that all pressure ulcers are avoidable, however the national rate remains high and Virginia's rate is in excess of that. Since 2005, reduction of pressure ulcers has been a Governor's key performance reassure in VDH's strategic plan. As part of that ongoing requirement, OLC/VDH is adding a pressure ulcer regulation as it revises all its program licensure programs.

Even though the law provides for up to 16 beds, the size favored by most hospice providers appears to be 6 beds or less. OLC/VDH is mindful that history and experience have proven that smaller

size facilities such as the size preferred by most hospice providers are not of a sufficient capacity to provide significant economies of scale. This is especially true for facilities providing medical care services. As a comparison, the smallest nursing facility is 18 beds with an average size of 114 beds. OLC/VDH recognizes that the intent of these facilities is to resemble a residence. Since these facilities will be located in residential neighborhoods, OLC/VDH also focused on addressing appropriate quality patient care in a facility type that will not have the visibility experienced by their larger counterparts, i.e., assisted living facilities, nursing facilities or palliative care units in hospitals. Therefore, many of the regulations were modified to accommodate the planned smaller capacity of a hospice facility. The proposed regulations do not require that a hospice provider establish a hospice facility in order to operate in Virginia. That is a business decision determined by the hospice provider as an added service to their clients.

No particular locality is affected more than another by this regulation. Promulgation of these amendments to 12VAC5-391 creates no known advantages or disadvantages to the agency, the Commonwealth, or the hospice community. Every effort has been made to ensure the regulation protects the health and safety of patients receiving care in a hospice facility while allowing providers to be more responsive to the needs of their patients. Failure to implement the regulation will not negatively impact the overall provision of hospice care in Virginia.

## 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 | Definition of 'bereavement services' as taken from 42CFR418.3 in narrative | Definition amended to reflect 42CFR418.3<br><br>Added 'adverse outcomes' and 'separate and distinct entrance | Since many hospice providers are Medicare certified, and Medicare remains the primary payer source for hospice services, it makes sense to assure that Virginia's regulatory definition of bereavement services comports with the federal definition. By citing the applicable regulation, the definition can be changed or modified without having to subsequently amend the state regulation.<br><br>'Adverse outcomes' added to clarify for providers when it is necessary to report medication errors to OLC.<br><br>"Separate and distinct |

| | | | |
|---|---|---|---|
| | | | entrance' added to allow for administration of community hospice services from a facility, but traffic is to be diverted from patient care areas. |
| 120 | C: Convenience prohibition addresses only the hospice provider | C: Added 'primary caregiver' and 'family'<br><br>D/E: Placement of language switched. | Result of public comment, added reinforce that the decision to enter a hospice facility is between the patient and the physician.<br><br>Clarifies the intent that hospice facility providers are to accommodate the needs of those patients residing in their own dwellings that might need respite or symptom management to the extent that beds are available in the facility. |
| 160 | K: Includes only inclement weather and natural disasters to planning for emergencies | H: Amended to reflect statutory language<br><br>K: 'Pandemic disease outbreaks' added | Amended to comport with statute.<br><br>Adds pandemic diseases outbreaks to required planning for emergencies such as hurricanes or flu, conforms with Virginia's emergency planning efforts |
| 180 | Subsection D requires administrators to understand the interrelationship between state licensure programs and national and federal certification programs<br><br>References the Joint Commission on Accreditation of healthcare organizations | Amended to include an understanding of applicable state laws and regulations.<br><br>Amended to read: 'Joint Commission." | Ensures program administrators have knowledge of and a basic understanding of applicable Virginia laws and regulations and their interrelationship.<br><br>Technical name change by the organization |
| 300 | Did not include regulation on pressure ulcers | Added subsection pertaining to pressure ulcer prevention | This is part of a national and VDH initiative to reduce pressure ulcers in Virginia. Since 2005, reduction of pressure ulcers has been a Governor's key performance measure in VDH's strategic plan. As |

| | | | |
|---|---|---|---|
| | | | a part of that ongoing requirement, OLC/VDH is adding this regulation as it revises all its program licensure regulations. The national rate of pressure ulcers is one of 2 areas of focus by CMS. |
| 395 | Stipulates actions to be taken in the event of a medication error or drug reaction | Amended to require reporting medication related adverse outcomes to OLC. | As the mandated oversight authority for hospice provider, OLC/VDH has a vested interest in events relating to quality of care such as mediation errors and drug reactions. |
| 440 | Did not require a separate staff entrance for community hospice programs | J: Added 'Separate and distinct entrance' requirement | Addresses a public comment by allowing providers the flexibility to provide community based program services from a hospice facility; while requiring traffic be divert from patient care areas. |
| 445 | | Amended regarding food services applicability | Clarifies the applicability of the subsection as not all facilities will meet the commercial kitchen threshold of 13 or more unrelated persons. |
| 450 | Subsection B required that facility staff protect patients from accidents, injury or infection. | Amended to stipulate protection from avoidable accidents, injuries and infections | It was pointed out that it is an unrealistic expectation that staff protect patients from accident, injury or infection when caring for individuals whose physical condition may unavoidably result in an infection, injury or accident. However, some accidents, injuries and infections can be avoided if proper systems are in place. Therefore, the regulation was modified to reflect protections from avoidable accidents, injuries and infections. |
| 480 | Subsection D referenced only contracting for dietary | Added note on family involvement in meals provision<br><br>Allowed for employment of dietary consultation | The note clarifies that families bring or preparing food at the facility are not subject to the subsection.<br><br>The change provides clarification that a hospice |

| | | | |
|---|---|---|---|
| | consultation | | facility provider may contract with or employ dietary consultation. |
| 500 | Dies not address service animals | Added exclusion of service animals<br><br>Technical change in subsection D | Addresses a public comment that service animals are allowed anywhere the owner goes, including kitchens<br><br>Syntax correction |
| 510 | Subsection D requires a telephone in each area where patients' are admitted with additional phone as necessary. | Specifies that phones shall also be available in patient rooms as well as common areas and where needed. | The amendment clarifies the intent of the regulation. |

## 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 |
|---|---|---|
| Marcia Tetterton Executive Director, Virginia Association of Home Care and Hospice | Thank you for the opportunity to voice our support of the proposed regulations for the Licensure of Hospice [facilities]. As you are aware, a group of providers met several times to discuss the regulatory revision and the proposed regulations reflect the general nature of those meetings. The [Association] looks forward to moving forward with the regulations.<br><br>Additional modifications have been made to make the hospice facility regulations consistent with current health care practices, such as requiring reporting of medical errors and drug reactions, a pressure ulcer prevention program plan and a [clarification regarding] false advertising. These modifications are appropriate and should be made. | Thank you. |
| Brenda Clarkson Executive Director, Virginia Association for Hospices (VAH) | 12VAC5-391-10: Suggest: insert 'patient and/or family before and' after offered to the. | The definition has been amended to reference 42 CFR 418.3. |
| | 12VAC5-391-120.C: Replace | OLC/VDH disagrees and believes this |

| | | |
|---|---|---|
| | patient's physician with 'hospice [IDG]' | regulation as written is an important and vital requirement. In addition to the ethical concerns related to provider self-referral, in Virginia there are also legal prohibitions regarding self-referral to provider owned entities. OLC/VDH also believes that a patient's decision to move to a hospice facility is a decision between the patient and physician, without pressure from the provider who has a financial interest in the decision. Once the decision has been made by the patient and his physician, then the facility provider can become involved. |
| | 12VAC5-391-180: After Centers for, insert "Medicarcomments on the intended regulatory action e and Medicaid Services. Strike *JCAHO* as programs are choosing to obtain accreditation from other accrediting organizations. | OLC/VDH disagrees, the words 'such as' included in the regulation indicate the references to CMS and The Joint Commission are examples. It is apparent from the questions and comments that VDH staff routinely receive that many hospice providers, regardless of their size and organizational complexity, do not understand the relationship between licensure and national certification or accrediting organizations. Nor is there comprehensive understanding of the interrelationship with other applicable state laws and regulations. In Virginia, hospice programs *must* be licensed in order to conduct business. All certification or accrediting programs are voluntary on the part of the provider and are not necessary to operate a hospice business in Virginia. |
| | 12VAC5-391-300. [C. Replace] hospitals with 'facilities' and 'receiving short-term in-patient hospice care' allowing for admission to a nursing facility. | OLC/VDH disagrees. A nursing facility is not an appropriate admission setting for handling medical complications that might arise. |
| | 12VAC5-391-440.J.: Suggest adding 'and administrative offices of the hospice.' | OLC/VDH disagrees; the intent of the regulation is to limit the amount of non-facility patient traffic through patient care areas. However, we understand that some programs may want to consolidate administrative offices at the facilities. Therefore, the regulation has been amended to require a separate and distinct entrance when providing community based hospice care from the facility, so that traffic is diverted away from facility patient care areas. |
| | 12VAC5-391-450.C. Strike after 'to meet the needs of each patient.' | OLC/VDH disagrees. The regulation was discussed and the language carefully vetted at the public stakeholder meeting; consensus was reached on the proposed amendments to the regulation. |
| | 12VAC5-391-460.D.: [strike reference to consultant pharmacist], Insert: "ensure that the interdisciplinary group confers with | As stated in 12VAC5-391-130 regarding variances, OLC/VDH cannot waive the regulations of another state agency or to any requirements in federal, state or local laws. |

| | | |
|---|---|---|
| | an individual with education and training in drug management as defined in hospice policies and procedures, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs. The provided pharmacist services must include evaluation of a patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.' | |
| | 12VAC5-391-460.E.: Suggest [replacing] 'a pharmacist' with 'the pharmacist.' | There does not appear to be any advantage to such a change. |
| | 12VAC5-391-460.H.: Suggest [replacing] 'a pharmacist licensed in Virginia' with 'a licensed pharmacist.' | As stated in 12VAC5-391-130 regarding variances, OLC/VDH cannot waive the regulations of another state agency or to any requirements in federal, state or local laws. |
| | 12VAC5-391-480: VAH considers the entire chapter burdensome to the point of inhibiting the development of small hospice facilities that are designed to take the place of a person's own home and recommends it be eliminated. VAH recommends language similar to the new Medicare conditions of Participation | OLC/VDH disagrees. When a provider decides to offer facility services, the provider also accepts the responsibility to meet state and national standards for operating that facility. History and experience have shown that the smaller sized facilities preferred by most hospice providers are not of a sufficient capacity to provide significant economies of scale to operate a facility efficiently. That fact is not impacted by regulatory compliance requirements which are designed to protect the health, safety and welfare of hospice patients. |
| | 12VAC5-391-500.D.3: Strike: recommended or | OLC/VDH disagrees. This section as presented in the proposed regulation was expanded from the working draft at the request of VAH. Any pet residing in a communal environment such as a hospice facility should have all immunizations, recommended as well as required. |
| | 12VAC5-391-510: Replace: areas to which patients are admitted with 'patient room' | The regulation has been amended. |
| Sue Ranson<br>President<br>Good Samaritan Hospice<br><br>President of the Virginia Association of Hospices | 12VAC5-391-120.C: Replace patient's physician with 'hospice [IDG]' | OLC/VDH disagrees and believes this regulation as written is an important and vital requirement. In addition to the ethical concerns related to provider self-referral, in Virginia there are also legal prohibitions regarding self-referral to provider owned entities. |
| | 12VAC5-391-140: strike: dedicated | Thank you, but section 140 is not part of this regulatory action. However, note of the comment has been made for future regulatory amendments. |

| | | |
|---|---|---|
| | 12VAC5-391-120.E: strike to the extent possible Add: 'These services may be provided under contract with other facilities that meet regulatory requirements for short-term inpatient care.' | OLC/VDH disagrees. This regulation was discussed and the language carefully vetted at the public stakeholder meeting held to reach consensus on the proposed amendments. However, OLC/VDH believes there is confusion regarding this regulation and has amended it for clarity. The intent is to require those providers that also operate a hospice facility to provide any needed respite and symptom management for their patients remaining in their own homes, should the patient or family need such services in a facility. Regardless of the living situation of the patient, however, the hospice program is responsible for providing respite and symptom management to their clients. Failure to provide respite and symptom management may result in a cited deficiency or nonrenewal of a license. |
| | 12VAC5-391-180: Strike after state licensure add: 'governmental regulatory organizations' | OLC/VDH disagrees as explained above. |
| | 12VAC5-391-440J: Add: 'or for other hospice services provided by the hospice.' | The regulation has been amended to require a separate and distinct entrance when providing community based hospice care from the facility, so that traffic is diverted away from facility patient care areas. |
| | 12VAC5-391-445C: Strike this section | OLC/VDH disagrees. As stated in 12 VAC5-391-30, OLC/VDH cannot waive the regulation of another agency or any requirements of federal, state or local laws. Any facility with 13 or more beds must obtain a commercial kitchen license. Hospice facility law allows for up to 16 beds in which case compliance with becomes 12VAC5-421 is mandatory. However, OLC/VDH has modified the regulation for clarity. |
| | 12VAC5-391-450. Strike B and C. Replace with: 'The facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care. The nursing needs of patients may be met by the hospice's home care nursing staff as long as the patient's needs are met. A registered nurse must be available 24/7 and able to respond to emergent calls within twenty minutes.' | OLC/VDH disagrees. This regulation was discussed and the language carefully vetted at the public stakeholder meeting and consensus was reach on the proposed amendments. |
| | 12VAC5-391-460.Strike D. Replace with: Each facility shall ensure "that | As stated in 12VAC5-391-130 regarding variances, OLC/VDH cannot waive the |

| | | |
|---|---|---|
| | the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs." (42 CFR 418.106(a) The provided pharmacist services must include evaluation of the patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action." | regulations of another state agency or to any requirements in federal, state or local laws. |
| | 12VAC5-460.H. Strike | OLC/VDH disagrees. There is a need for such regulation in light of the numerous medications patients are given and the potential for severe adverse reactions or complications. OLC/VDH believes such reporting is essential to ensuring quality patient care. However, we have added a definition of adverse outcome to clarify when a report to the OLC is necessary. |
| | 12VAC5-391-480. B. Strike assigned food service | OLC/VDH disagrees and believes the regulation has been misinterpreted. For smaller bed facilities, it is expected that staff would wear many hats. The intent of the regulation is to assure that regardless of the size of the facility, staff and patients know who can assist in preparation of meals and snacks. For larger facilities, this might require dedicated food service staff. |
| | 12VAC5-391-480.[C] After: licensed by [VDH]. Insert: 'If meals are routinely provided by a food service establishment,' there | OLC/VDH disagrees. Unless food is prepared on the premises of the facility, all catered food shall be obtained from a food vendor licensed by the department. That is current law. OLC/VDH also believes this regulation is even more important in light of the recent increase in food borne illnesses affecting Virginians and any potential impact on compromised immune systems. However, this regulation does not apply to meals prepared by a patient's family members and brought to the patient. |
| | 12VAC5-391-480.D. After shall contract, insert 'or employ'; strike a consulting; strike food service personnel, insert 'staff'; strike shall, insert 'may'; | OLC/VDH agrees to add 'or employ'; however, other changes offered do not enhance or improve the regulation as currently written. |
| | 12VAC5-391-480. Strike E – O. Replace with "Food shall be stored, prepared, and served in an area and manner that promotes hygiene, safety and patient satisfaction.' | OLC/VDH disagrees. As explained under 'Issues' above, these regulations have been carefully considered and moderated to accommodate the smaller size facility preferred by providers, while still meeting the minimum |

| | | |
|---|---|---|
| | | national, state and community standards for facility operation, without being onerous or burdensome to providers. When a provider decides to offer facility services, the provider also accepts the responsibility for operating that facility in a manner that meets or exceeds standards or expectations. |
| | As I ponder the intention of regulations surrounding hospice facilities (which I see more as "residences"), my hope is that we can go back to the original conversations about why hospices want to have hospice residences: some hospice patients just cannot stay at home to die and prefer to be in a place that is like a home (not a facility) for the end of their journey. I do not question the need for regulations. I do wonder, however, if parts of these proposed regulations (especially those regarding food service), would more than likely discourage hospices from carrying forward their vision to have a residence, thus failing to meet a significant community need. I have a vision that someday Good Samaritan Hospice will have a hospice "residence", or a hospice "house" for 4-5 patients. It is also my hope that these regulations will encourage us to move forward with that vision. | OLC/VDH recognizes that the intent of these facilities is to look like a residence. However, these entities are medical care facilities as defined in the Code of Virginia. When a provider decides to offer facility services, the provider also accepts the responsibility to meet state, national and community standards for operating that facility. In developing the proposed regulations, OLC/VDH relied on the available hospice facility regulations of other states, replicating many of those standards in this endeavor. Since these facilities will be located in residential areas, OLC/VDH also focused on addressing appropriate quality patient care in a facility type that will not have the visibility experienced by their larger counterparts, i.e., assisted living facilities, nursing facilities or palliative care units in hospitals. Therefore, many of the regulations were moderated to accommodate the planned smaller capacity of a hospice facility. History and experience have shown that the smaller sized facilities preferred by most hospice providers are not of a sufficient capacity to provide significant economies of scale to operate a facility efficiently, regardless of focus. That fact is not impacted by regulatory compliance requirements. The proposed regulations do not require that a hospice provider establish a hospice facility in order to operate in Virginia. That is a business decision determined by the hospice provider as an added service to their clients. There is nothing in these regulations that prevents Good Samaritan from moving forward with their vision for a hospice facility. |
| Sharon Britt<br>Hospice of the Piedmont | 12VAC5-391-160.L: should read 'the hospice facility' not the hospice program | OLC/VDH disagrees. Section 160 and that regulation are applicable to all hospice providers, not just facility providers. |
| Pat Bishop<br>Blue Ridge Hospice | We agree with most of the comments that will be sent from the VAH. Some of the proposed regulations may be difficult and cost prohibitive for some hospices, especially smaller hospices…in particular the requirements for dietary services may be difficult for | OLC/VDH disagrees as explained previously. |

| | | |
|---|---|---|
| | smaller hospices to meet. | |
| Kathy Clement Hospice of the Rapidan | 12VAC5-391-120: This should be the decision of the patient and the caregiver in consultation with the hospice IDG and the patient's attending physician as needed. | OLC/VDH disagrees as explained previously. |
| | 12VAC5-391-180: Strike reference to JACHO. This may be seen as an endorsement by some hospices as the appropriate accrediting body | OLC/VDH disagrees, the words 'such as' included in the regulation indicate the references to CMS and The Joint Commission are examples. |
| | 12VAC5-391-300: To have a preventive pressure ulcer prevention program required by the state regulations seems to disregard the type of patients hospice programs are caring for. Suggest instead a program focused on decubitus ulcer prevention when possible and appropriate that is included in the regular teaching program that is done with families and caregivers to support them in their care for their loved ones. | OLC/VDH suggests that the suggested family/caregiver program would be part of any hospice program's overall program to prevent program acquired pressure ulcers. Patient advocates declare all pressure ulcers are avoidable, however the national rate remains high and Virginia's rate is in excess of the national rate. Since 2005, reduction of pressure ulcers has been a Governor's key performance measure in VDH's strategic plan. As a part of that ongoing requirement, OLC/VDH is adding this regulation as it revises all its program licensure regulations. The national rate of pressure ulcers is one of 2 areas of focus by CMS. |
| | 12VAC5-391-395: In order to obtain palliation of symptoms such as pain, hospice patients may receive high doses of medications with an occasional side effect, of that high dosing, being an undesirable outcome. What will be done with this report within [OLC/VDH], how will it be used and what authority rests… to collect this information. | OLC/VDH's understands that the combinations of medications used by some hospice patients can resulted in unintended outcomes through no fault of the provider. However, OLC also believes medication errors can indicate a system failure within a provider's organization that can have serious quality of care consequences and is adding adverse event reporting to all its program licensure regulations as they are revised. We cite §§ 32.1-19.C and 32.1-162.5 as the statutory authority to be informed when adverse outcomes result. The intent is to use the reports as a survey preparation tool, data analysis of type and frequency of medication errors for targeted provider training, and to identify those providers needing additional oversight support. To assist in determining when adverse outcomes should be reported, we have added a definition of 'adverse outcomes' in section 10. |
| | 12VAC5-391-440.I: Hospice providers should have the flexibility to … determine community need and what other parts of the program to place within the facility. | The regulation has been modified to allow for the provision for other hospice patient care services to be administered from the facility |
| | 12VAC5-391-440.J.: Suggest adding 'and administrative offices of the hospice.' Seems to be ruling out that program administrative offices | The reader is correct; the intent of the regulation is to limit non-facility related traffic, including the program's administrative office. The facility is a residence for terminally ill |

| | | |
|---|---|---|
| | and the facility can be together. | persons, not the administrative office for the program. However, the regulation has been amended to require a separate and distinct entrance when providing community based hospice care from the facility, so that traffic is diverted away from facility patient care areas. |
| | 12VAC5-391-450.C.: Suggest [ending] at "the hospice shall have sufficient numbers of trained and supervised staff to meet the needs of each patient.' | OLC/VDH disagrees as explained previously. |
| | 12VAC5-391-460.E.: Suggest [replacing] 'a pharmacist' with 'the pharmacist.' | OLC/VDH disagrees as explained previously. |
| | 12VAC5-391-460.H.: Suggest [replacing] 'a pharmacist licensed in Virginia' with 'a licensed pharmacist.' | OLC/VDH disagrees as explained previously. |
| | 12VAC5-391-460.J.: Suggest striking whole regulation or requiring that the drug container must be intact and sealed from the pharmacy with no signs of tampering. | OLC/VDH is unable to impose requirements on entities that are within the regulatory arena of another state agency, in this case, the Board of Pharmacy. |
| | 12VAC5-391-480: Suggest [using the food preparation language] that is closer to federal regulations … especially in some of our smaller rural areas. Much of this section reads… like regulations for nursing homes or assisted living facility.. does not take into account [hospice patients] with decreasing appetites and variable intake needs. | OLC/VDH's suggests there is some confusion regarding the focus of this section. OLC is aware that hospice patients have a decreased appetite and variable intake needs, especially those in the active stages of the dying process. The approach taken in developing this section was to assure proper food handling across the broad spectrum of potential hospice facility providers, from the small 4 bed facilities to the larger 16 bed facilities. Since these facilities will been caring for two or more unrelated persons, the regulations proposed are the minimum needed to assure proper food handling. |
| Beverley Soble<br>Vice President Regulatory Affairs<br>Virginia Health Care Association | 12VAC5-391-450.B: suggest inserting 'avoidable' after and protected from | OLC/VDH agrees and has made the change. |
| Judy Mathews, RN, MSN<br>Augusta Healthcare | [The 2005 revised regulation removed the Joint Commission deemed status provision.] I would like to see the exemption for licensure survey put back into the hospice regulations. | Thank you for the comment, however the provision was removed from regulation as deemed status is not permitted by law. |
| Becky Bowers-Lanier<br>Legislative Consultant<br>Macaulay & Burtch, PC | 12VAC5-391-300: after 'arise' insert: <u>that are unrelated to the terminal diagnosis or require treatment in a hospital.</u><br><br>This clarifies 'medical complications | OLC/VDH disagrees; medical complications are individual to each patient and subject to onsite observation and assessment of medical personnel providing care. |

| | | |
|---|---|---|
| On behalf of the Executive Director and the Board of Directors of the Virginia Association of Hospices and Palliative Care | and assists [providers] in determining the events that would necessitate transfer to hospitals. | |
| | 12VAC5-391-300.F: insert after 'ulcers': <u>whenever possible and palliate associated pain and discomfort</u> | OLC/VDH suggests that 'palliating associated pain and discomfort' would be part of any hospice program's overall program to prevent program acquired pressure ulcers. Patient advocates declare all pressure ulcers are avoidable, however the national rate remains high and Virginia's rate is in excess of the national rate. Since 2005, reduction of pressure ulcers has been a Governor's key performance measure in VDH's strategic plan. As a part of that ongoing requirement, OLC/VDH is adding this regulation as it revises all its program licensure regulations. The national rate of pressure ulcers is one of 2 areas of focus by CMS |
| | 12VAC5-391-395.A: strike the second sentence.<br><br>We believe tat creating a mandatory adverse drug reaction reporting system through regulation goes beyond the scope of statutory authority of the Board of health and therefore, we oppose the requirement on that basis. | OLC/VDH's understands that the combinations of medications used by some hospice patients can resulted in unintended outcomes through no fault of the provider. However, OLC also believes medication errors can indicate a system failure within a provider's organization that can have serious quality of care consequences and cites§§32.1-19.C and 32.1-162.5 as the statutory authority to be informed when adverse outcomes result. We have added a definition of 'adverse outcomes' to assist providers in determining when negative outcomes are appropriate for reporting. OLC is adding adverse event reporting to all its program licensure regulations as they undergo revision. |
| | 12VAC5-391-440 J: add after 'care': <u>and related hospice services</u> | The regulation has been modified to allow for the provision for other hospice patient care services to be administered from the facility |
| | 12VAC5-391-480.A: add:<br><u>The hospice must furnish meals to each patient that are:</u><br>1. <u>Consistent with the patient's plan of care, nutritional needs and therapeutic diet</u><br>2. <u>Palatable, attractive and served at the proper temperature</u><br>3. <u>Obtained, stored, prepared,</u> | OLC/VDH's suggests there is some confusion regarding the focus of this section. There is nothing in the section that prohibits families of hospice patients from providing favorite foods and beverages. In addition, OLC is aware that hospice patients have a decreased appetite and variable intake needs, especially those in the actively dying. The approach taken in developing this section was to assure proper food handling across the broad spectrum of potential hospice facility providers, from the |

| | | |
|---|---|---|
| | distributed and served under sanity conditions.<br>And striking subsections B and D through O<br><br>We recommend simpler language that is less burdensome for hospices and which does not prevent families from participating in providing favorite food and beverages to hospice patients. | small 4 bed facilities to the larger 16 bed facilities. Since these facilities will been caring for two or more unrelated persons, the regulations proposed are the minimum needed to assure proper and safe food handling. |
| Sherry Confer Deputy Director Virginia Office for Protection and Advocacy | The Virginia Office for Protection and Advocacy appreciates the Office of Licensure and Certification's (OLC) effort to enhance protections for patients receiving hospice services yet reinforcing efforts to maximize the patients' independence, and to require providers to exercise good business sense while providing a service that is based on dignity and respecting personal decisions of the patients. | Thank you. |
| | 12VAC5-391-120: VOPA recommends that this exemption include at the discretion of or for the convenience of the primary caregiver or family. That is not to say that we do not support using the hospice facility for respite services | OLC/VDH agrees and modified the regulations accordingly. |
| | 12VAC5-391-160.B: VOPA recommends that OLC specify the Americans with Disabilities Act, the Virginians with Disabilities Act, and the Health Care Decisions Act at a minimum. Providers may already be aware of the regulations and best practices specific to hospice services, but other laws and regulations impact the provision of services in general.<br><br>12VAC5-391-160.D: VOPA recommends that the OLC address including the patient, primary caregiver and family in the inspection process They could participate in determining compliance or investigating complaints. This will clarify that the inspection is much more than a document review. | The three Acts listed are certainly important to patient dignity and quality care. To list all applicable laws in regulation is not recommended lest an equally important reference be omitted. Compliance with all applicable laws and regulations is contained in the Virginia laws for hospice as well as within the regulation in 3 places. However, OLC/VDH will file this comment and monitor consumer complaints for potential future action.<br><br>OLC/VDH agrees that the inspection process is more than a document review exercise and believes that patients and families are given an opportunity to participate in the inspection process via the home visit as well as by filing complaints. Both these avenues to participate can be accomplished anonymously if desired. Consumers may also participate in the regulatory process via public participation as required in the APA. |

| | | |
|---|---|---|
| | 12VAC5-391-160.K: The Department of Health has taken the lead with educating the public about the H1N1 virus pandemic potential. VOPA suggests that the emergency preparedness plans include addressing pandemic and outbreak situations in addition to the natural disasters. | The regulation has been amended. |
| | 12VAC5-391-180.C: VOPA recommends that the OLC specify that addressing complaints and monitoring the complaint process be identified as a responsibility of the administrator. | OLC/VDH considers complaint monitoring part of the administrator's duty to organize and supervise the administrative functions of the organization. However, OLC/VDH will file this comment and monitor consumer complaints for potential future action. |
| | 12VAC5-391-300.C: VOPA recommends that the patient, primary caregiver, and family be made aware in advance that this agreement is in place. This will increase the patient's involvement in the planning of their care and will help to optimize their choice of hospital providers. | OLC/VDH considers that, in addition to being a critical aspect of quality patient care, a hospital transfer agreement serves as a marketing tool that should be part of any program's admission practices and public information program. However, OLC/VDH will file this comment and monitor consumer complaints for potential future action. |
| | 12VAC5-391-395: VOPA strongly supports the OLC in including these proposed regulations. This is an important safeguard that increases patient protection and requires the provider to review and modify if necessary procedures and duties; basic quality assurance strategies. | Thank you. |
| | 12VAC5-391-440: VOPA recommends that the ADA and VDA be noted here. Although the Uniform Statewide Building Code includes aspects of the ADA, the ADA also includes reasonable accommodations. | The Acts listed are certainly important to patient dignity and quality care. OLC/VDH can assure consumers that state and federal disability acts are inherent parts of national and state building codes as well as part of the AIA standards required by OLC/VDH. However, OLC/VDH will file this comment and monitor consumer complaints for potential future action. |
| | 12VAC5-391-450: VOPA strongly supports the OLC's effort to ensure that appropriate staffing levels are provided. Facility based hospice services are provided by people and people must be <u>at the facility</u> in order to provide the services. These patients are in the end-stages of terminal illnesses and conditions and they are individuals. There is no guarantee that a care plan can be developed to address every need of a unique individual as he or | Thank you. |

| | | |
|---|---|---|
| | she faces this phase of their life. Staff must be available to respond. In addition, this is a minimal safeguard in the event a patient wanders, a hydrating tube gets clogged, a smoke detector alarms and so on. | |
| | 12VAC5-391-500: There needs to be clarification that service animals for people with disabilities are not pets and are thus not confined in the same manner as other animals which are merely pets. Services animals are allowed in any area where the resident is allowed, including dining areas. Service animals must be permitted at every facility, regardless of its pet policy. | Thank you, the section has been clarified to allow for service animals. |
| | This portion of the Hospice regulations makes no mention of the need to prevent, monitor, and report incidents of alleged abuse, neglect, or exploitation. We recommend that OLC add such requirements while including language that alerts providers, patients, primary caregivers, and family members to these issues. Also, we recommend that OLC clarify the expectation that patient confidentiality be protected. | That is correct, only those portions of the regulation regarding the provision of care in a facility were opened for amendment. However, a hospice facility provider is subject to the regulations of the entirety of 12VAC5-391, abuse, neglect, and exploitation are covered elsewhere. This comment will be kept on file for review when we seek to revise the entire regulation. |
| | The proposed regulations specifically address accessibility issues regarding physical barriers (12VAC5-391-440A), they fail to address non-physical barriers. Of particular concern are effective communication access issues for persons with low-literacy abilities and those who are deaf or hard of hearing. Hospices and their staffs have an obligation to provide effective communication between the Hospice staff and the patient, the primary caregiver, and other family members – including the need to use sign language interpreters, language translators, and low-level reading materials as necessary. We think that the regulations should directly acknowledge this effective communication obligation. | Thank you for the suggestion. Only those portions of the regulation regarding the provision of care in a facility were opened for amendment. However, a hospice facility provider is subject to the regulations of the entirety of 12VAC5-391, patient rights are covered elsewhere. OLC is adding patient communications to all its program licensure regulations as they undergo revision. This comment will be kept on file for review when we seek to revise the entire regulation. |

Enter any other statement here

## 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 | | Definitions | Added 'hospice facility' based on passage of HB1965;<br><br>Amended 'inpatient' for consistency between regulatory chapters and to clarify meaning of inpatient care for hospice providers<br><br>Added 'medication error' in response to added new section |
| 120 | | Addresses in the required interface for dual licensure as a hospice provider and as assisted living, a nursing facility or hospital. Also addresses regulations specific to the provision of hospice facility care. | Amended the section to repeal interface with other licensing criteria;<br><br>Adds a requirement that hospice facilities provide respite and symptom management services to their community patients needing such services. This reinforces a basic tenet of hospice patient care. |
| 150 | | Addresses circumstances under which a licensed must be returned to VDH | Adds hospice facility to the list of circumstances, so that VDH is aware of changes affecting a provider's license. |
| 160 | | Addresses management and demonstration of the hospice | Adds hospice facility to the list of changes under which to notify VDH of changes to a hospice license;<br><br>Adds a requirement that a facility encourage and facilitate the availability of flu shots to correct an omission in the 2005 revised regulation in support of state and national flu prevention initiatives. |
| 180 | | Addresses the requirements for individuals hired as administrator and designated assistant administrators | Adds a requirement that the administrator have operational knowledge of state hospice laws and regulations and the interrelationship between such laws/regulations and voluntary accreditation/certification by national organizations. Believed to be necessary |

| | | | |
|---|---|---|---|
| | | | knowledge to effectively operate and hospice program.<br><br>Amends (relaxes) the criteria for the individual serving as backup to the administrator. Consistent with the criteria for the assistant administrator for home care organizations. |
| 300 | | Addresses the overall provision of hospice services in the community | Clarified transfer to a hospital as a result of provider confusion and passage of HB1965;<br><br>Added transportation in cases of emergency, moved from 12VAC5-391-440. |
| | 395 | | Section added to address an omission in the 2005 revised regulation. With the numbers and types of medications prescribed to hospice patients, there is the concern for medication errors. The section provides expectations regarding actions when such errors occur. |
| 440 | | Addresses general facility requirements | Adds criteria regarding design and construction of hospice facilities consistent with the 2006 standards of the American Institute of Architects addressing hospice facilities, Consistent with similar regulations for nursing facilities and hospitals.<br><br>Adds stipulation that hospice facilities can provide only hospice care to assure that the facilities are not used for other purposes to generate revenue. Determined necessary in response to provider emphasis on costs of operation. |
| | 445 | | New section added to address additional building regulations and standards as a result of passage of HB1965. Consistent with facility criteria for other licensed facility types. |
| | 446 | | New section added addressing financial controls and patient funds as a result of passage of HB1965. Consistent with GAAP and patient funds accountability for other licensed facility types. |
| 450 | | Address required minimum staffing | Section amended to allow 1 licensed staff person for six or fewer beds; result of compromise between differing factions in the hospice industry. |
| 460 | | Addresses pharmacy services | Amended to assure consistency with pharmacy laws and regulations (18VAC110-20) |
| 480 | | Address dietary and food service | Section amended to added additional dietary requirements resulting from passage of HB1965. Consistent with dietary criteria for other licensed facility types. |
| | 485 | | New section added addressing maintenance |

| | | | |
|---|---|---|---|
| | | | and housekeeping as a result of passage of HB1965. Consistent with similar criteria for other licensed facility types. |
| | 495 | | New section added addressing transportation as a result of passage of HB1965. Consistent with similar criteria for other licensed facility types. |
| 500 | | Addresses pet care | Amended to provide clarity regarding expectations for pet visitors and resident pets. Section expanded at request of hospice facilities providers participating in work group discussions. |
| | 510 | | New section added, as a result of passage of HB1965, to address resident/staff safety and preparedness for emergencies resulting from natural or man-made disasters. Consistent with similar criteria for other licensed facility types. Supports state and national preparedness initiatives. |

| Section number | Requirement at proposed stage | What has changed | Rationale for change |
|---|---|---|---|
| 10 | Definition of 'bereavement services' as taken from 42CFR418.3 in narrative | Definition amended to reflect 42CFR418.3<br><br>Added 'adverse outcomes' and 'separate and distinct entrance | Since many hospice providers are Medicare certified, and Medicare remains the primary payer source for hospice services, it makes sense to assure that Virginia's regulatory definition of bereavement services comports with the federal definition. By citing the applicable regulation, the definition can be changed or modified without having to subsequently amend the state regulation.<br><br>'Adverse outcomes' added to clarify for providers when it is necessary to report medication errors to OLC.<br><br>"Separate and distinct entrance' added to allow for administration of community hospice services from a facility, but traffic is to be diverted from patient care areas. |
| 120 | C: Convenience prohibition | C: Added 'primary caregiver' and | Result of public comment, |

| | | | |
|---|---|---|---|
| | addresses only the hospice provider | 'family'<br><br>D/E: Placement of language switched. | added reinforce that the decision to enter a hospice facility is between the patient and the physician.<br><br>Clarifies the intent that hospice facility providers are to accommodate the needs of those patients residing in their own dwellings that might need respite or symptom management to the extent that beds are available in the facility. |
| 160 | K: Includes only inclement weather and natural disasters to planning for emergencies | H: Amended to reflect statutory language<br><br>K: 'Pandemic disease outbreaks' added | Amended to comport with statute.<br><br>Adds pandemic diseases outbreaks to required planning for emergencies such as hurricanes or flu, conforms with Virginia's emergency planning efforts |
| 180 | Subsection D requires administrators to understand the interrelationship between state licensure programs and national and federal certification programs<br><br>References the Joint Commission on Accreditation of healthcare organizations | Amended to include an understanding of applicable state laws and regulations.<br><br>Amended to read: 'Joint Commission." | Ensures program administrators have knowledge of and a basic understanding of applicable Virginia laws and regulations and their interrelationship.<br><br>Technical name change by the organization |
| 300 | Did not include regulation on pressure ulcers | Added subsection pertaining to pressure ulcer prevention | This is part of a national and VDH initiative to reduce pressure ulcers in Virginia. Since 2005, reduction of pressure ulcers has been a Governor's key performance measure in VDH's strategic plan. As a part of that ongoing requirement, OLC/VDH is adding this regulation as it revises all its program licensure regulations. The national rate of pressure ulcers is one of 2 areas of |

| | | | |
|---|---|---|---|
| | | | focus by CMS. |
| 395 | Stipulates actions to be taken in the event of a medication error or drug reaction | Amended to require reporting medication related adverse outcomes to OLC. | As the mandated oversight authority for hospice provider, OLC/VDH has a vested interest in events relating to quality of care such as mediation errors and drug reactions. |
| 440 | Did not require a separate staff entrance for community hospice programs | J: Added 'Separate and distinct entrance' requirement | Addresses a public comment by allowing providers the flexibility to provide community based program services from a hospice facility; while requiring that traffic be diverted from patient care areas. |
| 445 | | Amended regarding food services applicability | Clarifies the applicability of the subsection as not all facilities will meet the commercial kitchen threshold of 13 or more unrelated persons. |
| 450 | Subsection B required that facility staff protect patients from accidents, injury or infection. | Amended to stipulate protection from avoidable accidents, injuries and infections | It was pointed out that it is an unrealistic expectation that staff protect patients from accident, injury or infection when caring for individuals whose physical condition may unavoidably result in an infection, injury or accident. However, some accidents, injuries and infections can be avoided if proper systems are in place. Therefore, the regulation was modified to reflect protections from avoidable accidents, injuries and infections. |
| 480 | Subsection D referenced only contracting for dietary consultation | Added note on family involvement in meals provision<br><br>Allowed for employment of dietary consultation | The note clarifies that families bring or preparing food at the facility are not subject to the subsection.<br><br>The change provides clarification that a hospice facility provider may contract with or employ dietary consultation. |
| 500 | Does not address service animals | Added exclusion of service animals<br><br>Technical change in subsection D | Addresses a public comment that service animals are allowed |

| | | | |
|---|---|---|---|
| | | | anywhere the owner goes, including kitchens<br><br>Syntax correction |
| 510 | Subsection D requires a telephone in each area where patients' are admitted with additional phone as necessary. | Specifies that phones shall also be available in patient rooms as well as common areas and where needed. | The amendment clarifies the intent of the regulation. |

## Regulatory flexibility analysis

*Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

The hospice community in Virginia includes both large hospice organizations, generally associated with health care systems, and smaller independent or stand alone hospice organizations. However, the proposed regulations do not require that a hospice provider establish a hospice facility in order to operate in Virginia. That is a business decision determined by the hospice provider as an added service to their clients. In developing the proposed regulations, the state focused on addressing appropriate quality patient care, consistent with state and national standards of care, in a facility type that will not have the visibility experienced by their larger counterparts, i.e., assisted living facilities, nursing facilities or palliative care units in hospitals. Because these facilities will be located in residential areas, it is necessary to assure that the state and public/private entities recognize that the smaller sized facilities preferred by most hospice providers are not of a sufficient capacity to provide significant economies of scale to operate a facility efficiently.

## Family impact

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

There is no direct impact on the family or family stability.

**Project 964 - Proposed**

**DEPARTMENT OF HEALTH**
**Hospice Program Changes**

Part I
Definitions and General Information

**12VAC5-391-10. Definitions.**

The following words and terms when used in these regulations shall have the following meaning unless the context clearly indicates otherwise.

"Activities of daily living" means bathing, dressing, toileting, transferring, bowel control, bladder control and eating/feeding.

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient by (i) a practitioner or by his authorized agent and under his supervision or (ii) the patient at the direction and in the presence of the practitioner as defined in § 54.1-3401 of the Code of Virginia.

"Administrator" means a person designated, in writing, by the governing body as having the necessary authority for the day-to-day management of the hospice program. The administrator must be a member of the hospice staff. The administrator, director of nursing, or another clinical director may be the same individual if that individual is dually qualified.

[ "Adverse outcome" means the result of drug or health care therapy that is neither intended nor expected in normal therapeutic use and that causes significant, sometimes life-threatening conditions or consequences at some future time. Such potential future adverse outcome may require the arrangement of appropriate follow-up surveillance and perhaps other departures from the usual plan of care. ]

"Attending physician" means a physician licensed in Virginia, according to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia, or licensed in an adjacent state and identified by the patient as having the primary responsibility in determining the delivery of the patient's medical care. The responsibilities of physicians contained in this chapter may be implemented by nurse practitioners or physician assistants as assigned by the supervising physician and within the parameters of professional licensing.

"Available at all times during operating hours" means an individual is available on the premises or by telecommunications.

"Barrier crimes" means certain offenses specified in § 32.1-162.9:1 of the Code of Virginia that automatically bar an individual convicted of those offenses from employment with a hospice program.

"Bereavement service" means [bereavement] counseling [ ~~and support offered to the patient's family after the patient's death~~ as defined in 42 CFR 418.3 ] .

"Commissioner" means the State Health Commissioner.

"Coordinated program" means a continuum of palliative and supportive care provided to a terminally ill patient and his family, 24 hours a day, seven days a week.

"Core services" means those services that must be provided by a hospice program. Such services are: (i) nursing services, (ii) physician services, (iii) counseling services, and (iv) medical social services.

"Counseling services" means the provision of bereavement services, dietary services, spiritual and any other counseling services for the patient and family while the person is enrolled in the program.

"Criminal record report" means the statement issued by the Central Criminal Records Exchange, Virginia Department of State Police.

~~"Dedicated hospice facility" means an institution, place, or building providing room, board, and appropriate patient care 24 hours a day, seven days a week to individuals diagnosed with a terminal illness requiring such care pursuant to a physician's orders.~~

"Dispense" means to deliver a drug to the ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery as defined in § 54.1-3401 of the Code of Virginia.

"Employee" means an individual who is appropriately trained and performs a specific job function for the hospice program on a full or part-time basis with or without financial compensation.

"Governing body" means the individual, group or governmental agency that has legal responsibility and authority over the operation of the hospice program.

"Home attendant" means a nonlicensed individual performing personal care and environmental services, under the supervision of the appropriate health professional, to a patient in the patient's residence. Home attendants are also known as certified nursing assistants or CNAs, home care aides, home health aides, and personal care aides.

"Hospice" means a coordinated program of home and inpatient care provided directly or through an agreement under the direction of an identifiable hospice administration providing palliative and supportive medical and other health services to terminally ill patients and their families. A hospice utilizes a medically directed interdisciplinary team. A hospice program of care provides care to meet the physical, psychological, social, spiritual and other special needs that are experienced during the final stages of illness, and during dying and bereavement. Hospice care shall be available 24 hours a day, seven days a week.

"Hospice facility" means an institution, place or building as defined in § 32.1-162.1 of the Code of Virginia.

"Inpatient" means ~~services provided to a hospice patient who is admitted to a hospital or nursing facility on a short-term basis for the purpose of curative care unrelated to the diagnosed terminal illness. Inpatient does not mean services provided in a dedicated hospice facility~~ the provision of services, such as food, laundry, housekeeping and staff to provide health or health-related services, including respite and

symptom management, to hospice patients, whether in a hospital, nursing facility, or hospice facility.

"Interdisciplinary group" means the group responsible for assessing the health care and special needs of the patient and the patient's family. Providers of special services, such as mental health, pharmacy, and any other appropriate associated health services may also be included on the team as the needs of the patient dictate. The interdisciplinary group is often referred to as the IDG.

"Licensee" means a licensed hospice program provider.

"Medical director" means a physician currently licensed in Virginia, according to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia, and responsible for the medical direction of the hospice program.

"Medical record" means a continuous and accurate documented account of services provided to a patient, including the prescription and delivery of the treatment or care.

"Medication error" means one or more violations of the five principles of medication administration: the correct drug to the right patient at the prescribed time in the prescribed dose via the prescribed route.

"Nursing services" means the patient care performed or supervised by a registered nurse according to a plan of care.

"OLC" means the Office of Licensure and Certification of the Virginia Department of Health.

"Operator" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity responsible for the day-to-day administrative management and operation of the hospice.

"Palliative care" means treatment directed at controlling pain, relieving other symptoms, and focusing on the special needs of the patient and family as they experience the stress of the dying process. Palliative care means treatment to enhance comfort and improve the quality of a patient's life during the last phase of his life.

"Patient" means a diagnosed terminally ill individual, with an anticipated life expectancy of six months or less, who, alone or in conjunction with designated family members or representatives, has voluntarily requested admission and been accepted into a licensed hospice program.

"Patient's family" means the hospice patient's immediate kin, including spouse, brother, sister, child or parent. Other relations and individuals with significant personal ties to the hospice patient may be designated as members of the patient's family by mutual agreement among the patient, the relation or individual.

"Patient's residence" means the place where the individual or patient makes his home.

"Person" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that operates a hospice.

DRAFT

"Plan of care" means a written plan of services developed by the interdisciplinary group to maximize patient comfort by symptom control to meet the physical, psychosocial, spiritual and other special needs that are experienced during the final stages of illness, during dying, and bereavement.

"Primary caregiver" means an individual that, through mutual agreement with the patient and the hospice program, assumes responsibility for the patient's care.

"Progress note" means a documented statement contained in a patient's medical record, dated and signed by the person delivering the care, treatment or service, describing the treatment or services delivered and the effect of the care, treatment or services on the patient.

"Quality improvement" means ongoing activities designed to objectively and systematically evaluate the quality of care and services, pursue opportunities to improve care and services, and resolve identified problems. Quality improvement is an approach to the ongoing study and improvement of the processes of providing services to meet the needs of patients and their families.

[ "Separate and distinct entrance" means an entrance to the hospice facility other than the formal public entrance used by patients and family members. ]

"Staff" means an employee who receives financial compensation.

"Supervision" means the ongoing process of monitoring the skills, competencies and performance of the individual supervised and providing regular face-to-face guidance and instruction.

"Terminally ill" means a medical prognosis that life expectancy is six months or less if the illness runs its usual course.

"Volunteer" means an employee who receives no financial compensation.

**12VAC5-391-120. ~~Dedicated hospice~~ Hospice facilities.**

A. Providers seeking to operate a ~~dedicated~~ hospice facility shall comply with the appropriate facility licensing regulation as follows:

1. ~~Up to five patient beds, facilities shall be licensed as:~~ Facilities with 16 or fewer beds shall be licensed as a hospice facility pursuant to this chapter. Such facilities with six or more beds shall obtain a Certificate of Use and Occupancy with a Use Group designation of I-2; or

~~a. An assisted living facility pursuant to 22VAC40-71;~~

~~b. A hospital pursuant to 12VAC5-410; or~~

~~c. A nursing facility pursuant to 12VAC5-371; or~~

2. ~~Six or more patient beds, facilities shall be licensed as:~~ Facilities with more than 16 beds shall be licensed as a hospital pursuant to 12VAC5-410 or as a nursing facility pursuant to 12VAC5-371. Such facilities shall obtain the applicable Certificate of Public Need prior to the development or construction of the facility.

~~a. An assisted living facility, pursuant to 22VAC40-71 with a classified Use Group of I-2;~~

~~b. A hospital pursuant to 12VAC5-410; or~~

~~c. A nursing facility pursuant to 12VAC5-371.~~

~~Facilities to be licensed as a hospital or a nursing facility shall obtain the applicable Certificate of Public Need (COPN)~~.

B. Only patients diagnosed terminally ill shall be admitted to a ~~dedicated~~ hospice facility. The facility shall admit only those patients whose needs can be met by the accommodations and services provided by the facility.

C. To the maximum extent possible, care shall be provided in the patient's home. Admission to a ~~dedicated~~ hospice facility shall be the decision of the patient in consultation with the patient's physician. No patient shall be admitted to a hospice facility at the discretion of, or for the convenience of, the hospice provider [ , the primary caregiver or family ] .

D. [ ~~No dedicated hospice facility shall receive for care, treatment, or services patients in excess of the its licensed bed capacity.~~ ] ~~However, facilities licensed as a nursing facility may provide temporary shelter for evacuees displaced due to a disaster. In those cases, the facility may exceed the licensed capacity for the duration of that emergency only provided the health, safety, and well being of all patients is not compromised and the OLC is notified~~ [ All hospice providers operating a hospice facility shall use its facility to provide, to the extent possible, respite and symptom management services to all patients in the hospice program needing such services ] .

E. [ ~~All hospice providers operating a hospice facility shall~~ [ ~~use its facility to~~ ] ~~provide, to the extent possible, respite and symptom management services~~ ~~for their patients needing such services~~ No hospice facility shall receive for care, palliative treatment, respite or symptom management services patients in excess of its licensed bed capacity].

~~E.~~ F. No ~~dedicated~~ hospice facility provider shall add additional patient beds or renovate facility space without first notifying the OLC ~~and the applicable facility licensing authority~~. OLC notifications must be in writing to the director of the OLC.

~~F.~~ G. The OLC will not accept any requests for variances to this section.

**12VAC5-391-150. Return of a license.**

A. The circumstances under which a license must be returned include~~, but are not limited to~~:

~~(i) change~~ 1. A change in ownership or operator~~,~~;

~~(ii) change in hospice~~ 2. A change in program name~~,~~;

~~(iii) relocation~~ 3. The relocation of the administrative office~~,~~;

~~(iv) discontinuation~~ 4. The discontinuation of any core services~~,~~; and

~~(v) establishment of a dedicated~~ 5. The relocation of a hospice facility.

B. The licensee shall notify its patients and the OLC in writing 30 days prior to discontinuing any services.

DRAFT

C. If the hospice program is no longer operational, or the license is revoked or suspended, the license shall be returned to the OLC within five working days. The licensee is responsible for notifying its patients and the OLC where all medical records will be located.

Part II
Administrative Services

**12VAC5-391-160. Management and administration.**

A. No person shall establish or operate a hospice program or a hospice facility, as defined in § 32.1-162.1 of the Code of Virginia, without having obtained a license.

B. The hospice program must comply with:

1. This chapter (12VAC5-391);
2. Other applicable federal, state or local laws and regulations; and
3. The hospice program's own policies and procedures.

When applicable regulations are similar, the more stringent regulation shall take precedence.

C. The hospice program shall submit or make available reports and information necessary to establish compliance with this chapter and applicable law.

D. The hospice program shall permit representatives from the OLC to conduct inspections to:

1. Verify application information;
2. Determine compliance with this chapter;
3. Review necessary records and documents; and
4. Investigate complaints.

E. The hospice program shall notify the OLC 30 working days in advance of changes effecting the hospice program, including the:

1. Location of the administrative office or mailing address of the hospice program;
2. Ownership or operator;
3. Services provided;
4. Administrator;
5. Hospice program name;
6. Establishment or relocation of a ~~dedicated~~ hospice facility; and
7. Closure of the hospice program.

F. The current license from the department shall be posted for public inspection.

G. Service providers or individuals under contract must comply with the hospice program's policies and this chapter, as appropriate.

H. The hospice program shall not use any advertising that contains [ ~~false, misleading or deceptive statements or claims, or false~~ untrue, deceptive or misleading

DRAFT

statements or claims or untrue, deceptive ] or misleading disclosures of fees and payment for services.

I. The hospice program shall have regular posted business hours and be fully operational during business hours. Patient care services shall be available 24 hours a day, seven days a week. This does not mean that a hospice program must accept new clients on an emergency basis during nonbusiness hours.

J. The hospice program shall accept a patient only when the hospice program can adequately meet that patient's needs.

K. The hospice program must have an emergency preparedness plan in case of inclement weather [ ~~or~~ , ] natural disaster [ or pandemic disease outbreaks ] to include contacting and providing essential care to patients, coordinating with community agencies to assist as needed, and maintaining current information on patients who would require specialized assistance.

L. The hospice program shall encourage and facilitate the availability of flu shots for its staff and patients.

**12VAC5-391-180. Administrator.**

A. The governing body shall appoint as administrator an individual who has evidence of at least one year of training and experience in direct health care service delivery with at least one year, within the last five years, of supervisory or administration management experience in hospice care or a related health care delivery system.

B. The administrator shall have operational knowledge of Virginia's hospice laws and regulations and the interrelationship between state licensure and [ other applicable state laws and regulations as well as ] national certification or accrediting organizations such as the Centers for Medicare and Medicaid Services and [ ~~JCAHO~~ The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations) ] .

~~B.~~ C. The administrator shall be responsible for the day-to-day management of the hospice program, including but not limited to:

1. Organizing and supervising the administrative functions of the hospice program;

2. Maintaining an ~~on-going~~ ongoing liaison with the governing body, the professional personnel and staff;

3. Employing qualified personnel and ensuring adequate employee orientation, training, education and evaluation;

4. Ensuring the accuracy of public information materials and activities;

5. Implementing an effective budgeting and accounting system;

6. Maintaining compliance with applicable laws and regulations and implementing corrective action in response to reports of hospice program committees and regulatory agencies;

7. Arranging and negotiating services provided through contractual agreement; and

8. Implementing the policies and procedures approved by the governing body.

~~C. An individual who meets the qualifications of subsection A of this section shall be~~ D. The individual designated ~~in writing~~ to perform the duties of the administrator when the administrator is absent from the hospice program shall be able to perform those duties of the administrator as identified in subsection C of this section.

~~Hospice programs shall have one year from the effective date of this chapter to ensure that the individuals currently designated meet the qualifications of subsection A of this section.~~

~~D.~~ E. The administrator or alternate shall be available at all times during operating hours and for emergency situations.

Part III
Hospice Program Services

Article 1
Hospice Services

**12VAC5-391-300. Hospice services.**

A. Each hospice shall provide a coordinated program of services encompassing the hospice philosophy that:

1. The unit of care consists of the patient, the primary caregiver, and the patient's family;

2. Emphasizes in-home care;

3. A designated interdisciplinary group supervises the patient's care;

4. A patient's symptoms and physical pain will be appropriately assessed and managed;

5. Services are available 24 hours a day, 7 days a week;

6. Inpatient care is provided in an atmosphere as home-like as practical;

7. Bereavement services are available to the family after the death of the patient; and

8. Trained volunteers are utilized to perform specific job functions in the hospice service delivery system.

B. Specific services provided according to the plan of care shall include:

1. Nursing services;

2. Counseling services;

3. Medical social services;

4. Physician services;

5. Physical therapy, occupational therapy, speech-language pathology;

6. Home attendant services;

7. Short-term inpatient care; and

8. Medical appliances and supplies, including drugs and biologicals, relevant to the patient's terminal illness.

DRAFT

~~C. Inpatient services shall be provided in a licensed hospital or nursing facility.~~

~~D.~~ C. There shall be a written transfer agreement with ~~an inpatient facility for~~ one or more hospitals sufficiently close to the hospice's service area to permit the transfer of patients if medical complications arise. Such agreement shall include, but is not limited to, interagency communication processes and coordination of the patient's plan of care, and shall clearly identify the services to be provided by ~~the facility and the hospice~~ each entity while the patient is at the ~~inpatient facility~~ hospital.

D. Provisions shall be made to obtain appropriate transportation in cases of emergency.

E. All prescription drugs shall be prescribed and properly dispensed to patients according to the provisions of Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for the prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushed for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol.

[ F. The hospice program shall have an active program designed to prevent the occurrence of pressure sores or decubitis ulcers by the program's hospice clients. ]

**12VAC5-391-395. Medication errors and drug reactions.**

A. In the event of a medication error or adverse drug reaction, employees shall promptly notify the patient's physician, the medical director, the nurse and the patient's family and shall take action as directed. [ Adverse outcomes of medication errors or drug reactions shall also be reported to the OLC within 48 consecutive hours of the event.]

B. Actions taken shall be documented in the patient's record.

C. The hospice [ ~~facility~~ program ] shall review all medication errors at least quarterly as part of its quality assurance program.

Part IV
~~Dedicated~~ Hospice Facilities

**12VAC5-391-440. General facility requirements.**

~~A. In addition to the facility licensure requirements in 12VAC5-391-120, providers of dedicated hospice facilities shall maintain compliance with the standards of this section.~~

~~B.~~ A. All construction of new buildings and additions, renovations or alterations of existing buildings for occupancy as a ~~dedicated~~ hospice facility shall ~~comply with applicable state and federal laws and regulations~~ conform to state and local codes, zoning and building ordinances and the Uniform Statewide Building Code.

In addition, hospice facilities shall be designed and constructed according to section 4.2 of Part 4 of the 2006 Guidelines for Design and Construction of Health Care Facilities of the American Institute of Architects. However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence.

B. All buildings shall be inspected and approved as required by the appropriate regional state fire marshal's office or building and fire regulatory official. Approval shall be a Certificate of Use and Occupancy indicating the building is classified for its proposed licensed purpose.

~~C. The facility shall provide 24-hour nursing services sufficient to meet the total nursing needs according to individual plans of care, including treatments, medication, and diet as prescribed, of the patients and shall keep patients comfortable, clean, well-groomed, and protected from accident, injury, and infection.~~

~~D.~~ C. The facility must have space for private patient family visiting and accommodations for family members after a patient's death. Patients shall be allowed to receive guests, including small children, at any hour.

~~E.~~ D. Patient rooms shall not exceed two beds per room and must be at grade level or above, enclosed by four ceiling-high walls~~, and able to house one or more patients~~. Each room shall be equipped for adequate nursing care, the comfort and privacy of patients, and with a device for calling the staff member on duty.

~~F.~~ E. Designated guest rooms for family members or patient guests and beds for use by employees of the facility shall not be included in the bed capacity of a hospice facility provided such beds and locations are identified and used exclusively by staff, volunteers or patient guests.

Employees shall not utilize patient rooms nor shall bedrooms for employees be used by patients.

~~G.~~ F. Waste storage shall be located in a separate area outside or easily accessible to the outside for direct pickup or disposal. The use of an incinerator shall require permitting from the nearest regional permitting office for the Department of Environmental Quality.

~~H. The facility shall assist in obtaining transportation, when necessary, to obtain medical and psychiatric care, routine and emergency dental care, diagnostic or other services outside the facility.~~

~~I.~~ G. The facility shall provide or arrange for under written agreement, laboratory, x-ray, and other diagnostic services, as ordered by the patient's physician.

~~J.~~ H. There shall be a plan implemented to assure the continuation of essential patient support services in case of power outages, water shortage, or in the event of the absence from work of any portion of the workforce resulting from inclement weather or other causes.

I. No part of a hospice facility may be rented, leased or used for any purpose other than the provision of hospice care at the facility.

J. [ A separate and distinct entrance shall be provided if the program intends to administer and provide its community based hospice care from the facility so that such traffic and noise shall be diverted away from patient care areas. ]

K. ] The hospice facility shall maintain a complete set of legible "as built" drawings showing all construction, fixed equipment, and mechanical and electrical systems, as installed or built.

**12VAC5-391-445. Additional building regulations and standards.**

A. Water shall be obtained from an approved water supply system. Hospice facilities shall be connected to sewage systems approved by the Department of Health or the Department of Environmental Quality.

B. Each hospice facility shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations.

C. The hospice facility's food services shall comply with 12VAC5-421 [ , as applicable ] .

D. A hospice facility's pharmacy services shall comply with Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and 18VAC110-20.

**12VAC5-391-446. Financial controls and patient funds.**

A. All financial records, including resident funds, shall be kept according to generally accepted accounting principles.

B. Hospice facilities choosing to handle patient funds shall, upon receipt of a patient's written delegation of this responsibility:

1. Give the patient at least a quarterly accounting of financial transactions made on his behalf and shall permit the patient access to the records of financial transactions made on his behalf at least once a month;

2. Purchase a surety bond or otherwise provide assurance for the security of all personal funds deposited with the facility; and

3. Provide for separate accounting of patient funds.

C. In the event the hospice facility is sold, the provider shall verify that all patient funds have been transferred or returned to the patient and shall obtain a signed receipt from the new owner of all patient funds transferred. Upon receipt, the new owner shall provide an accounting of resident funds transferred to the respective patient.

D. When a patient with funds deposited with the facility leaves or is discharged, the facility shall give a final accounting, within 30 days, of those funds to the patient or the individual administering the patient's estate and, if appropriate, refund any money due.

**12VAC5-391-450. Required staffing.**

A. ~~Each shift must include at least one registered nurse providing direct patient care~~ There shall be an individual, designated in writing, responsible for the day-to-day management and operation of the hospice facility. Such individual shall report directly to the program administrator and shall be qualified to perform the duties identified in 12VAC5-391-180 C.

B. ~~Minimum staffing for a hospice facility with five patient beds shall consist of one registered nurse and one additional direct care staff member on duty at all times. Staffing for hospice facilities with six or more beds shall be based on the assessed needs of the patients in the facility~~ The facility shall provide 24-hour nursing services sufficient to meet the total nursing needs of its patients according to individual plans of care, including treatments, medication, and diet as prescribed, and shall keep patients

comfortable, clean, well-groomed, and protected from [ ~~accident, injury and infection~~ avoidable accidents, injuries and infections ] .

C. The hospice facility shall have a sufficient number of trained and supervised staff to meet the needs of each patient. At least two staff, one of which is a licensed nurse, must be on duty when patients are present. However, facilities with six or fewer beds may staff with a single licensed nurse provided compliance with subsection B of this section is maintained.

If the nurse on duty is not a registered nurse, then a registered nurse must be on call and able to respond to emergent calls within 20 minutes.

**12VAC5-391-460. Pharmacy services.**

A. ~~Provision shall be made for the procurement, storage, dispensing, and accounting of drugs and other pharmacy products. This may be by arrangement with an off-site pharmacy, but must include provisions for 24-hour emergency service~~ Whether medications and biologicals are obtained from community or institutional pharmacies, the hospice facility is responsible for assuring availability for medications and biologicals, including 24-hour emergency services, for its patients and for ensuring that pharmaceutical services are provided according to accepted professional principles and appropriate federal and state laws.

B. The ~~dedicated~~ facility shall comply with the Virginia Board of Pharmacy regulations related to pharmacy services in long-term care facilities, i.e., Part XII (18VAC110-20-530 et seq.) of the Virginia Board of Pharmacy Regulations.

C. Each ~~dedicated~~ hospice facility shall develop and implement policies and procedures for the handling of drugs and biologicals, including procurement, storage, administration, medication errors, self-administration ~~and~~, disposal and accounting of drugs and other pharmacy products.

D. Each facility shall have a written agreement with a qualified pharmacist to provide consultation on all aspects of the provision of pharmacy services in the facility.

The consultant pharmacist shall make regularly scheduled visits, at least ~~monthly~~ quarterly, to the facility for a sufficient number of hours to carry out the function of the agreement.

E. Each prescription container shall be individually labeled by the pharmacist for each patient or provided in an individualized unit dose system.

F. No drug or medication shall be administered to any patient without a valid verbal order or a written, dated and signed order from a physician, dentist or podiatrist, nurse practitioner or physician assistant, licensed in Virginia.

G. Verbal orders for drugs or medications shall only be given to a licensed nurse, pharmacist or physician.

H. Each patient's medication regimen shall be reviewed by a pharmacist licensed in Virginia. Any irregularities identified by the pharmacist shall be reported to the physician and the director of nursing, and their response documented.

DRAFT

I. Medication orders shall be reviewed at least every 60 days by the attending physician, nurse practitioner, or physician's assistant.

J. Prescription and nonprescription drugs and medications may be brought into the facility by a patient's family, friend or other person provided:

1. The individual delivering the drugs and medications assures timely delivery, in accordance with the facility's written policies, so that the patient's prescribed treatment plan is not disrupted;

2. Each drug or medication is in an individual container; and

3. Delivery is not allowed directly to an individual patient.

In addition, prescription medications shall be:

4. Obtained from a pharmacy licensed by the state or federal authority; and

5. Securely sealed and labeled by a licensed pharmacist according to 18VAC110-20-330 and 18VAC110-20-340.

**12VAC5-391-480. ~~Food~~ Dietary and food service.**

[ Note: This section is not applicable to family members preparing meals or bringing food into the facility. ]

A. The facility shall provide dietary services to meet the daily nutritional needs of patients.

B. ~~If the facility has patients requiring medically prescribed special diets, the menus for such diets shall be planned by a dietitian qualified according to Chapter 27.1 (§ 54.1-2730 et seq.) of Title 54.1 of the Code of Virginia, or shall be reviewed and approved by a physician. The facility shall provide supervision of the preparation and serving of any special diets~~ The hospice facility shall employ sufficient assigned food service personnel trained to provide a hygienic dietary service that meets the daily nutritional and special dietary needs of patients, and provides palatable and attractive meals.

C. When meals are catered ~~to a hospice facility~~, such meals shall be obtained from a food service establishment licensed by the Virginia Department of Health. There shall be a current written contract with the food service establishment pursuant to 12VAC5-391-230.

D. The hospice facility shall contract with [ or employ ] a consulting registered dietitian, who meets the qualifications of § 54.1-2731 of the Code of Virginia, to provide guidance to the facility's food service personnel on methods for maintaining the dietary service, planning of nutritionally balanced meals, and assessing the dietary needs of individual patients. The dietitian's duties shall include the following:

1. Developing menus, including therapeutic diets prescribed by a patient's physician;

2. Developing, revising, and annually reviewing dietary policies, procedures and job descriptions;

3. Assisting in planning and conducting regularly scheduled inservice training that includes, but is not limited to:

a. Therapeutic diets;

b. Food preparation requirements; and

c. Principles of sanitation.

4. Visiting patients on a regular basis to discuss nutritional problems, depending upon their needs and level of care, and recommending appropriate solutions.

E. Menus shall meet the dietary allowances of the Food and Nutritional Board of the National Academy of Sciences, as adjusted for age, sex, and activity level.

F. A copy of a diet manual containing acceptable practices and standards for nutrition must be kept current and on file in the food preparation area.

G. Food service facilities shall be located in a designated area and shall include the following rooms or spaces:

1. Kitchen;

2. Dishwashing;

3. Food storage; and

4. Dining room.

H. At least three meals, served at regular intervals, shall be provided daily to each patient, unless contraindicated as documented by the attending physician in the patient's medical record.

I. Special attention shall be given to preparation and prompt serving in order to maintain correct food temperatures for serving.

J. Between meal snacks of nutritional value shall be available upon request to each patient according to their plan of care.

K. Therapeutic diets shall be prepared and served as prescribed by the attending physician.

L. Employees assigned to other duties in the facility and visitors shall not be allowed in the food preparation area during food preparation and patient meal service hours, except in cases of emergency.

M. Weekly menus, including therapeutic diets, substitutes, and copies of menus, as served, shall be retained on file for 12 months.

N. Disposable dinnerware or tableware shall be used only for emergencies, for infection control, as part of special activities, or as indicated in a patient's plan of care.

O. For hospice facilities with 13 or more patient beds:

1. The dietary and food service operation shall meet all applicable sections of 12VAC5-421; and

2. There shall be a food service manager, qualified as allowed in 12VAC5-421-60, responsible for the full-time management and supervision of the dietary service.

DRAFT

**12VAC5-391-485. Maintenance and housekeeping.**

A. The hospice facility shall be maintained and equipped to provide a functional, sanitary, safe, and comfortable environment.

B. A documented preventive maintenance program shall be established to ensure that equipment is operative and that the interior and exterior of the building or buildings are maintained in good repair and free from hazards and litter.

C. The administrator shall designate an employee responsible for carrying out these functions and for training and supervising housekeeping and maintenance personnel.

D. The heating, ventilation and air conditioning system shall be capable of maintaining temperatures between 70°F and 80°F throughout patient areas.

E. The hospice facility shall have an effective pest control program either by maintenance personnel or by contract with a pest control company.

F. The hospice facility shall provide adequate space, equipment and supplies for any special services to be offered.

G. All furniture shall be kept clean and safe for use.

H. Over bed tables shall be available as needed.

I. Stretchers and wheelchairs shall be stored out of the path of normal traffic.

J. A sufficient number of wheelchairs and chairs shall be provided for patients whose physical conditions indicate a need for such equipment.

K. Refuse containers shall be emptied and cleaned at frequent intervals.

L. Hazardous cleaning solutions, compounds and substances shall be labeled, stored and kept under lock in a safe place separate from other materials.

**12VAC5-391-495. Transportation.**

The hospice facility shall assist a patient in obtaining transportation when it is necessary to obtain medical, psychiatric, dental, diagnostic or other services outside the facility.

**12VAC5-391-500. Pet care.**

A. ~~If the facility chooses to permit pets, then healthy animals that are free of fleas, ticks and intestinal parasites, that have been screened by a veterinarian prior to entering the facility, that have received required inoculations and that represent no apparent threat to the health, safety, and well-being of the patients may be permitted provided they are properly cared for and the pet and its housing or bedding are kept clean~~ The hospice facility shall implement policies regarding pets, whether the pet is visiting or in residence.

B. ~~Pets shall not be allowed near patients with pet allergies or patients choosing not to be disturbed by animals.~~ The hospice facility shall ensure that any patient's rights, preferences, and medical needs are not compromised by the presence of an animal. [ ~~Pets~~ Except for working service animals, pets ] shall not be allowed in dining and kitchen areas when food is being prepared or served.

C. All pets, whether visiting or in residence, shall be in good health, clean and well-groomed, show no evidence of carrying disease, have a suitable temperament, and pose no significant health or safety risks to patients, staff, volunteers, or visitors.

D. For pets in [~~residences~~ residence ] , the facility shall:

1. Disclose to potential and current patients the types of pets and the conditions under which pets are allowed in residence;

2. Maintain documentation of disclosure of pet policies in the patients' records;

3. Ensure that, before living in the facility, the pet's owner provides current documentation that the pet has had all recommended or required immunizations;

4. Ensure that regular pet examinations and immunizations are maintained; and

5. Ensure that resident pets are properly cared for and that the pet and its housing or bedding are kept clean.

**12VAC5-391-510. Safety and emergency preparedness.**

A. A written emergency preparedness plan shall be developed, reviewed, and implemented when needed. The plan shall address responses to natural disasters, as well as fire or other emergencies that disrupts the normal course of operations. The plan shall include, but not be limited to:

1. The continuation of essential patient support services in case of power outages, water shortages, or in the event of absences from work of any portion of the workforce resulting from inclement weather or other causes;

2. The preparation of patients for potential or imminent emergencies and disasters;

3. Alerting emergency personnel and sounding alarms;

4. Using, maintaining and operating emergency equipment;

5. Accessing patient emergency medical information;

6. Utilizing community support services;

7. A sheltering plan that addresses, but is not limited to:

a. Sheltering in place as well as off-site relocation arrangements;

b. Implementing evacuation procedures; and

c. A letter of agreement with off-site sheltering locations;

8. A transportation plan including:

a. Agreements with entities for relocating patients;

b. Number and type of vehicles required; and

c. Procedures for providing appropriate medical support and medications during relocation; and

9. A staffing plan for relocated patients, including:

a. The number and type of staff needed to provide appropriate care to relocated patients; and

b. Plans for relocating staff or assuring transportation to the sheltering facility.

DRAFT

B. All staff shall participate in periodic emergency preparedness training.

C. Staff shall have documented knowledge of, and be prepared to implement, the emergency preparedness plan in the event of an emergency.

D. At least one telephone shall be available in each area to which patients are admitted [ , in each patient room, ] [ ~~and~~ with ] additional telephones or extensions as are necessary to ensure availability in case of need.

E. In the event of a disaster, fire, medication error, suspicious death, emergency or any other condition that may jeopardize the health, safety and well-being of patients, the facility shall notify the department of the conditions and status of the patients and the hospice facility as soon as possible, but no later than 24 hours after the incident.

F. The hospice facility shall have a policy on smoking.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-391)

Personal Care Aide Training Curriculum, 2003, Department of Medical Assistance Services.

2006, Guidelines for Design and Construction of Health Care Facilities, The Facility Guidelines Institute, The American Institute of Architects Academy of Architecture for Health, 1-800-242-3837.

DRAFT

Virginia
Regulatory
Town Hall

townhall.virginia.gov

# Notice of Intended Regulatory Action (NOIRA)
# Agency Background Document

| | |
|---|---|
| **Agency name** | Virginia Department of Health |
| **Virginia Administrative Code (VAC) citation** | 12 VAC 5-545 |
| **Regulation title** | Guidelines for Nurse Educator Scholarship |
| **Action title** | Promulgating new regulations for the Commonwealth of Virginia Nurse Educator Scholarship |
| **Date this document prepared** | October 5, 2009 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

## Purpose

*Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.*

The Virginia General Assembly in the 2009 Appropriations Act [Department of Health (601), Higher Education Student Financial Assistance~Scholarships (10810)] appropriated $2,008,196 for health professional scholarships. Section D. states: "Out of this appropriation, $200,000 for the first year and $200,000 for the second year from the general fund is provided for scholarships and loan repayments for nursing students pursuing an advanced degree towards becoming nursing faculty at the college level. Priority shall be given to master's degree candidates who will teach in the community colleges." Pursuant to this legislative mandate, and under the authority of the *Code of Virginia* §32.1-122.5:1, regulations will be proposed for the "Advanced Degree Nursing Scholarship Program."

## 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 number(s), 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.*

Sections 23-35.9 and 32.1-122.6:01 of the *Code of Virginia* authorize the Board of Health to award annual scholarships for students enrolled in undergraduate and graduate nursing programs in the State of Virginia.

## Need

*Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.*

The intent of the Virginia Nurse Educator Scholarship program is to increase the number of nurse educators by providing master's and doctoral nursing students with financial support for advanced degree programs. Ten (10) nurse educator scholarships will be awarded annually. The teaching service requirement will be delineated within the regulations. The intent of this program will be fulfilled if the nurse educator supply increases and the Commonwealth's nursing programs have an expanded pool of nursing professionals to support their educational mission.

## Substance

*Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.*

The proposed regulation will establish provisions for the administration of the "Virginia Nurse Educator Scholarship Program." Those provisions will include: definitions, purpose, administration, variance, eligible applicants, scholarship amount, distribution of scholarships, contract provisions, repayment of scholarships, repayment of practice, cash repayment, cash repayment amount, cash repayment schedule and reporting requirements.

## Alternatives

*Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.*

The Virginia Department of Health is mandated by the *Code of Virginia* to develop regulations for the new Virginia Nurse Educator Scholarship program. There are no other alternatives for achieving this need.

## Public participation

*Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.*

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation.

Anyone wishing to submit comments may do so at the public hearing or via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email or fax to Aileen Edwards Harris, 109 Governor Street, Suite 1016-East, Richmond, VA 23219, (804) 864-7436 or fax (804) 864-7440, email: **Aileen.Harris@vdh.virginia.gov**. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by the last day of the public comment period.

In addition, the agency is seeking information on (1) the continued need for the regulation; (2) the complexity of the regulation; (3) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

A public hearing will be held and notice of the hearing may be found on the Virginia Regulatory Town Hall website (**www.townhall.virginia.gov**) and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

## Participatory approach

*Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.*

The Department of Health is not using the participatory approach because the law authorizing the scholarships provides sufficient guidance.

## Family impact

*Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

The Virginia Nurse Educator Scholarship program will have a positive impact on the family and family stability by strongly supporting increased access to quality nursing services within medical practices throughout the Commonwealth. Assisting nursing students with their educational expenses also increases their family earning potential and allows low and moderate income families to pursue advanced practice nursing careers.

**Project 2032 - none**

**DEPARTMENT OF HEALTH**

**Guidelines for the Nurse Educator Scholarship**

CHAPTER 545

GUIDELINES FOR THE VIRGINIA NURSE EDUCATOR SCHOLARSHIP PROGRAM

This chapter has been prepared to familiarize scholarship applicants, Deans/Directors of nursing programs, and Financial Aid Officers with the Virginia Nurse Educator Scholarship Program. The legislative authority for the scholarships in addition to the actual steps involved in the application process are reviewed.

Do not hesitate to contact the Virginia Department of Health, 109 Governors Street, Suite 1016 - East, Richmond, VA 23219, with any questions relating to the scholarship program. The phone number at the office is (804) 864-7435.

ALL SCHOLARSHIPS ARE AWARDED WITHOUT REGARD TO RACE, COLOR, RELIGION, SEX OR NATIONAL ORIGIN.

**12VAC5-545-10. Legislative authority and general information.**

Sections 23-35.9 and 32.1-122.6:01 of the Code of Virginia authorize annual nursing scholarships for students enrolled in undergraduate and graduate nursing programs. Undergraduate nursing programs are defined as those leading to an associate degree, diploma, or baccalaureate degree in nursing. Graduate nursing programs are those offering masters and doctoral degrees.

Under the law, all scholarship awards are made by an Advisory Committee appointed by the State Board of Health. The Advisory Committee consists of eight members: four deans or directors of schools of nursing, two former scholarship recipients, and two members with experience in the administration of student financial aid programs. Committee appointments are for two-year terms and members may not serve for more than two successive terms.

The Virginia Department of Health, Division of Primary Care and Rural Health serves as the staff element to the Advisory Committee and plays no role in the determination of scholarship recipients.

The basis for determining scholarship recipients is established by the Advisory Committee with due regard given to scholastic attainment, financial need, character, and adaptability to the nursing profession.

**12VAC5-545-20. Definitions.**

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise:

"Board" or "Board of Health" means the State Board of Health.

"Certified" means having passed an examination through a national certifying organization.

"Commissioner" means the State Health Commissioner.

"Interest at the prevailing bank rate for similar amounts of unsecured debt" means the prime lending rate as published in the Wall Street Journal on the last day of the month in which the decision to repay is communicated to the commissioner by the recipient, plus two percentage points.

"Recipient" or "scholarship recipient" means an eligible registered nurse who enters into a contract with the commissioner and receives one or more scholarship awards via the Virginia Nurse Educator Scholarship Program.

"Teaching service" means to teach as a nurse educator in a Virginia nursing school for two years for each year of a scholarship award.

**12VAC5-545-30. Administration.**

The Commissioner of Health shall act as fiscal agent for the board in administration of the scholarship program through a Nursing Scholarship Committee. All scholarship awards are made by a Nursing Scholarship Committee, appointed by the State Board of Health. The Nursing Scholarship Committee shall consist of five members or their designees: three faculty members representing nurse practitioner or nurse midwife education programs, one nurse practitioner actively engaged in practice, and one former scholarship recipient (commencing the third year of scholarship availability). Committee appointments shall be for two years and members may not serve more than two consecutive terms.

**12VAC5-545-40. Variance.**

Any requests for variance from this chapter shall be considered on an individual basis by the board in regular session.

**12VAC5-545-50. Eligible applicants.**

To be considered eligible for the Virginia Nursing Scholarship Program, all applicants must meet the following criteria:

1. Be a U.S. Citizen,

2. Be a Virginia resident,

3. Be a full/part-time student in a master's or doctoral level nursing program in Virginia, who will complete the degree requirements within two years or less.

4. Have submitted a completed application,

5. Have submitted all other required materials (transcript, CV, letters of reference), and

6. Have signed and submitted a written contract agreeing to serve via teaching in a Virginia School of Nursing that prepares students to become Registered Nurses in the Commonwealth.

Failure to comply with any of the above will cause the applicant to be ineligible to participate in the Commonwealth of Virginia Nursing Scholarship Program. Applicants will be evaluated and ranked by the Nursing Scholarship Program, and the most qualified applicants will be awarded.

**12VAC5-545-60. Scholarship amount.**

The amount for Virginia nurse educator scholarships available each year shall be as provided by the Virginia General Assembly in that year's Appropriation Act. Scholarships shall be awarded to the recipients upon or following the recipient's execution of a contract with the commissioner for scholarship repayment.

**12VAC5-545-70. Distribution of scholarships.**

Annually, the Nursing Scholarship Committee shall inform nursing schools of the availability of the nurse educator scholarships through the Division of Primary Care and Rural Health, Virginia Department of Health. The nursing scholarship committee shall convene annually for the purpose of reviewing applications and awarding scholarships. Scholarship awards shall be based upon majority vote of the nursing scholarship committee.

**12VAC5-545-80. Contract provisions.**

Prior to the payment of money to a scholarship awardee, the commissioner shall enter into a contract with the recipient. The contract shall:

1. Provide that the recipient will pursue the nurse educator program of the designated school until graduation and will pursue full-time teaching service as a nurse educator within three months (90 days) following completion of training and for a period of two years per annual scholarship award. The area of employment must be at a Virginia nursing school program.

2. Provide that the recipient will not voluntarily obligate himself for military service prior to completion of the repayment period.

3. Provide for termination of the contract by the recipient while the recipient is enrolled in school, upon the recipient's notice and immediate repayment to the Commonwealth of the total amount of the scholarship funds plus 9% interest, computed from the date of receipt of funds by the recipient.

4. Provide that if the recipient fails to maintain satisfactory academic progress, the recipient may, upon certification by the Nursing Scholarship Committee, be relieved of the contract obligation to engage in full-time teaching service upon repayment to the Commonwealth of the total amount of scholarship funds received plus 9% interest, computed from the date of receipt of funds by the recipient.

5. Provide that if the recipient is in default due to death or permanent disability so as not to be able to engage in teaching service, the recipient, or his personal representative, may be relieved of the obligation under the contract to engage in full-time teaching service upon repayment to the Commonwealth of the total amount of scholarship funds received plus 9% interest. For recipients completing part of the

teaching obligation prior to becoming permanently disabled, the total amount of scholarship funds received and owed shall be reduced by the amount of the annual scholarship award multiplied by the number of years practiced. Unusual hardship may be reviewed by the board on a case-by-case basis.

6. Provide that individual cases of extraordinary hardship may be considered by the commissioner for forgiveness of payment or service.

7. Provide that any recipient of a scholarship who defaults by evasion or refusal to fulfill the obligation to teach for a period of two years equal to the number of annual scholarships received shall reimburse the Commonwealth the total amount of scholarship funds received plus 9% interest, computed from the date of receipt of funds by the recipient.

8. Provide that for a recipient who fulfills only part of the contractual obligation, the total amount of scholarship funds received and owed shall be reduced by the amount of the annual scholarship, divided into months and multiplied by the number of months taught in a Virginia nursing program, and the remainder repayment to the Commonwealth of the total amount of scholarship funds received plus 9% interest.

**12VAC5-545-90. Repayment of scholarships.**

Unless repayment is forgiven as specified in subdivision 6 of 12VAC5-545-80, all scholarships shall re repaid to the Commonwealth, either by the recipient's teaching as a nurse educator or through cash repayments.

**12VAC5-545-100. Repayment by teaching service.**

It is the intent of the Virginia Nurse Educator Scholarship Program that recipients pay their scholarship obligation by teaching. Each recipient electing to repay by teaching obligation shall notify the commissioner in writing of his proposed location not more than

30 days following beginning of employment. Written approval of the teaching location will be sent to the recipient by the commissioner. A recipient will receive 24 months of credit toward fulfillment of his scholarship application for each 12 months of full-time continuous teaching. Absences from teaching in excess of seven weeks per 12-month practice period for maternity leave, illness, vacation, or any other purpose shall not be credited toward repayment and will extend the recipient's total obligation by the number of weeks of excess absence. Any recipient who partially completes a scholarship obligation will be required to fulfill the remainder of the scholarship obligation by cash repayment in accordance with 12VAC5-545-110. Credit for partial year(s) of service will be applied toward fulfillment of the scholarship obligation.

**12VAC5-545-110. Cash repayment.**

Cash repayment by recipients who terminate their contracts prior to the completion of training shall be made in accordance with subdivisions 3 and 4 of 12VAC5-545-80 and by recipients who become disabled before fulfilling the practice obligation in accordance with subdivision 5 of 12VAC5-545-80. Cash repayments by recipients who otherwise fail or refuse to fulfill their practice obligation shall be made in accordance with subdivisions 7 and 8 of 12VAC5-545-80.

**12VAC5-545-120. Cash repayment amount.**

The full amount to be repaid by a recipient who fails or refuses to fulfill the teaching obligation shall be determined in the following manner: the annual amount of the scholarship for the year the recipient obtained the scholarship plus 9% interest penalty.

**12VAC5-545-130. Cash repayment schedule.**

Any scholarship to be repaid in cash payments due to the recipient's failure to enter into an approved practice shall be repaid within 24 months of the date contract obligation

should commence. Any scholarship to be repaid in cash payment due after partial repayment by practice shall be paid within 24 months of the recipient's departure from his approved practice. Failure of any recipient to make any payment on his debt of restitution plus interest when it is due shall be cause for the commissioner to refer the debt to the Attorney General of the Commonwealth of Virginia for collection. The recipient shall be responsible for any costs of collection as may be provided in Virginia law.

**12VAC5-545-140. Reporting requirements.**

Reporting requirements of nursing schools and scholarship recipients are as follows:

1. Each nursing school shall maintain accurate records of the status of scholarship recipients until the recipients graduate and during any postgraduate year that a scholarship is awarded. The schools shall provide a report listing the academic status of each recipient annually to the Nursing Scholarship Committee.

2. Each scholarship recipient shall, at any time, provide information as requested by the commissioner to verify compliance with the teaching requirements of the scholarship contract. The recipient shall report any change of mailing address, change of academic standing, change of intent to fulfill his contractual obligation and any other information which may be relevant to the contract at such time as changes or information may occur. The recipient shall promptly respond with such information as may from time to time be requested by the commissioner.

3. The Nursing Scholarship Committee will report annually to the board the following: number of applicants for scholarships, number of scholarships awarded, number of Virginia residents awarded scholarships, number of minorities and students from medically underserved areas awarded scholarships, total funding awarded, the teaching

sites of former scholarship recipients, and the number of students making monetary repayment of scholarship with reasons for failure to practice identified.

4. Monitoring of teaching service by recipients shall be conducted on an on-going basis by Department staff. Teaching service verification forms will be submitted by the recipient to the Department semi-annually (every six months), countersigned bya representative of the teaching site certifying continuous full-time service by recipients.

Certification Statement:

I certify that this regulation is full, true, and correctly dated.

_____ (Signature of certifying official)

Name and title of certifying official:_____

Name of agency:_____

Date:_____

Virginia
Regulatory
Town Hall

townhall.virginia.gov

# Proposed Regulation
# Agency Background Document

| | |
|---|---|
| **Agency name** | Virginia Department of Health |
| **Virginia Administrative Code (VAC) citation** | 12 VAC 5 -80 |
| **Regulation title** | Virginia Hearing Impairment Identification and Monitoring System |
| **Action title** | Amend 12 VAC 5-80 "Virginia Hearing Impairment Identification and Monitoring System" as a result of periodic review. |
| **Date this document prepared** | 9-25-2009 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

## Brief summary

*In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.*

This regulation is being amended to reflect the most current Joint Committee on Infant Hearing Statement issued in 2007. Substantive changes include: moving risk factor criteria to identify infants at risk for hearing loss from definitions to a new section and placing detailed criteria for each category of risk under a guidance document; requiring infants who receive neonatal intensive care services for longer than five days to be tested with ABR screening technology; adding a new section to address birthing centers; and further defining reporting requirements which include provisions for confirming negative results.

## Acronyms and Definitions

*Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.*

## 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 number(s), 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 State Board of Health is authorized to make, adopt, promulgate, and enforce regulations by Section 32.1-12 of the Code of Virginia.

Section 32.1-64.1 of the Code of Virginia requires the State Health Commissioner to establish and maintain the Virginia Hearing Impairment Identification and Monitoring System.

Part E of Section 32.1-64.1 requires the Commissioner to appoint an advisory committee to assist in the design, implementation, and revision of this identification and monitoring system.

Part F of Section 32.1-64.1 requires that the Board of Health with assistance from the advisory committee promulgate rules and regulations as may be necessary to implement this identification and monitoring system. This part states "These rules and regulations shall include criteria, including current screening methodology, for the identification of infants (i) with hearing impairment and (ii) at risk of hearing impairment and shall include the scope of the information to be reported, reporting forms, screening protocols, appropriate mechanisms for follow up, relationships between the identification and monitoring system and other state agency programs or activities and mechanisms for review and evaluation of the activities of the system. The identification and monitoring system shall collect the name, address, sex, race, and any other information determined to be pertinent by the Board, regarding infants determined to be at risk of hearing impairment or to have hearing loss."

## Purpose

*Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.*

---

Part A of Section 32.1-64.1 of the Code of Virginia mandates the necessity of the Virginia Hearing Impairment Identification and Monitoring System to protect public health as such "In order to identify hearing loss at the earliest possible age among newborns and to provide early intervention for all infants so identified as having hearing impairment, the Commissioner shall establish and maintain the Virginia Hearing Impairment Identification and Monitoring System. This system shall be for the purpose of identifying and monitoring infants with hearing impairment to ensure that such infants receive appropriate early intervention through treatment, therapy, training and education."

Early identification of hearing loss through screening and identification and tracking of infants at risk for acquiring hearing loss is essential to the health, well-being, and eventual language development of infants and children in the Commonwealth. In the absence of hearing screening, hearing loss is not usually identified until two to three years of age and language development has already been impacted adversely. The average deaf or hard-of-hearing adult reads at a fourth grade level. Infants can be assessed and diagnosed with hearing loss by several months of age and fitted with hearing devices as early as one month of age. Research suggests that most preschool-age children with hearing loss will have language development within the normal range if diagnosis and intervention begins by 6 to 12 months of age. Early identification reduces costs associated with special education as well.

The Code requires regulation for this program and this particular action is necessary following a periodic review of 12 VAC 5-80 pursuant to Executive Order (EO) 36 (2006). This action will incorporate principles and changes in standards for newborn hearing screening from the Joint Committee on Infant Hearing

"Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs". The current regulations, which have not changed since 2001, refer to and are congruent with the American Academy of Pediatrics position statement "Newborn and Infant Hearing Loss: Detection and Intervention" published in 1999 which is now outdated.

The amended regulations will reflect changes in the nationally accepted standards for newborn hearing screening. The amended regulations will also reflect relevant changes in related state regulations and recommendations from the Attorney General's Government and Regulatory Reform Task Force. These changes will help improve the newborn hearing screening program in the Commonwealth.

## Substance

*Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)*

---

In order to be consistent with the most recent recommendations from the Joint Committee on Infant Hearing, substantive changes have been proposed for hearing screening methodology in Section 80 (Responsibilities of Hospitals). In this chapter, the type of screening methodology to be administered has been defined according to level and length of hospital newborn service provision. In addition, details on how to handle transfer and other circumstances are outlined. More details have been added regarding the specifics required for reporting.

Another substantive change relates to identification of infants at-risk for hearing impairment. These criteria have been moved out of definitions and into a separate Section 75. The section outlines the review timeline and process for identifying and maintaining the list of risk indicators. The section specifies the broad categories of risk indicators (for example, syndromes known to be associated with hearing loss) however, the details of the particular category will now be maintained and published as a guidance document. The guidance document will now detail the list of known syndromes associated with hearing loss that are tracked by the program. This is necessary to allow flexibility to change with rapidly changing advances in links between genetic disorders and hearing loss as well as new findings regarding the ototoxicity of certain medications.

Other substantive changes include the addition of several sections related to different types of service providers who are part of the system. Section 85 addresses birthing centers that currently do not fall under other regulations. The Virginia Department of Health has received grant funding to work with these providers and help develop reporting ability. These facilities typically do not conduct hearing screening but refer infants for hearing screening. The Department seeks to capture information regarding infants born in these type of facilities to identify those at risk for hearing impairment and to enter those infants in the tracking system. With the number of birthing centers in the state expected to increase, the importance of capturing those infants increases.

Section 100 addresses primary health care providers and simply states that they have a responsibility to receive results and communications from the Virginia Early Hearing Detection and Intervention Program. It may be possible in the future that this provider group will have the ability to electronically access hearing screening results.

Section 110 relates to the Virginia Department of Health statutory responsibility as a partner in the Part C system. The Virginia Early Hearing Detection and Intervention Program is a component of the multi-agency early identification and intervention system in the Commonwealth. As part of this system, certain statutes, regulations, and a formal interagency agreement provide additional guidance for program operations and relationships between service providers.

Definitions (Section 10) have been added to reflect current screening methodologies and affected parties and others have been modified to be consistent with other similar regulations or correct citations.

Responsibilities of the Virginia Department of Health (Section 90) have been further refined and provide more direction regarding the reporting system. References related to false-positive and false-negative rates have been deleted.

Amendments to definitions are proposed for certain definitions to update references to other state regulations which are referred to in these regulations (12 VAC 5-410 "Rules and Regulations for the Licensure of Hospitals in Virginia"). In addition amendments are proposed to make these regulations consistent with other relevant state regulations which have been repealed (12 VAC 5-70 "Regulations Governing the Newborn Screening and Treatment Program" and 12 VAC 5-190 "State Plan for the Provision of Children's Specialty Services") and replaced with new regulations within the past several years (12 VAC 5-71 "Regulations Governing Virginia Newborn Screening Services" and 12 VAC 5-191 "State Plan for the Children with Special Health Care Needs Program"). Recommendations from the Attorney General's Government and Regulatory Reform Task Force have also been adopted in the proposed text.

## 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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.*

---

The primary advantages to the public are to families with infants born in Virginia hospitals. By amending the regulations and program practices to be current with the most recent national standard of care recommendations, infants will continue to be screened for hearing loss using the most appropriate technology and assessed for other factors which may put them at risk for hearing loss. Early identification of hearing loss is beneficial to children and their families. Without newborn hearing screening, hearing loss is not typically identified until two to three years of age and serious delays in language and other areas of cognitive development are likely to have occurred. Infants who are diagnosed and enter early intervention between 6 and 12 months of age can achieve normal language development. In addition, families who have infants identified with hearing loss can be linked with family-to-family support programs, such as Guide by Your Side where families who have had children with hearing loss serve as mentors to those with a newly diagnosed child, and medical support programs such as the Hearing Aid Loan Bank.

The disadvantage to the public for families with infants born in Virginia hospitals would be if an infant or child required further audiological evaluation and the family did not have insurance coverage or could not find a provider willing to accept public insurance (FAMIS plans). Another disadvantage may be stress involved for families of infants who may be identified at risk for hearing loss. These infants may undergo further testing but not be found to have hearing loss at any point during childhood.

The primary advantage for providers of hearing screening (birthing hospitals) is clarified guidance from the state regarding their mandate and to have guidance which is consistent with most recent national standards of care. Changes in the reporting requirements and changes being made to the current electronic reporting system will provide basic demographic information to hospital users and reduce duplicative data entry.

The primary disadvantage will be for hospitals with neonatal intensive care services that will need to acquire ABR technology to meet the new standard.

The primary advantages to the agency and the Commonwealth are to have a well defined and managed program which successfully identifies infants with hearing loss as early as possible to meet the mandate in the Code of Virginia. Early identification is key to reducing negative impact on language and cognitive development. Infants who are identified with hearing loss and receive early identification and amplification by six months of age will be one to two years ahead of their later identified peers in first grade in the areas of language, cognitive, and social skills. Children with undetected hearing loss in one ear are more likely to be held back in school than those without hearing loss. It is estimated that $400,000 in special education costs are saved by high school graduation for a child identified early with hearing loss who receives appropriate educational, medical and audiological services.

There are no disadvantages to the agency and Commonwealth.

## Requirements more restrictive than federal

*Please identify and describe any requirement of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.*

---

There is no federal statute mandating newborn hearing screening. The only federal requirements are reporting requirements which are contingencies of receiving grant funding from the U.S. Department of Health and Human Services, Health Resources and Services Administration.

## Localities particularly affected

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

---

No locality will be particularly affected by the proposed regulation.

## Public participation

*Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.*

---

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email or fax to:
Susan Tlusty, Policy Analyst, Sr.
109 Governor Street 8th Floor
Richmond, Virginia 23220
Phone: (804) 864-7686
Fax: (804) 864-7722
e-mail: **Susan.Tlusty@vdh.virginia.gov**

Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.
A public hearing will not be held.

## Economic impact

*Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.*

| | |
|---|---|
| **Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.** | There is no additional cost to the state to implement and enforce the proposed regulation. |
| **Projected cost of the *new regulations or changes to existing regulations* on localities.** | There is no current or projected cost for the amended regulations for localities. |
| **Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.** | The entities affected by the amended regulations include all infants and their families born in Virginia hospitals, birthing hospitals in Virginia, birthing centers in Virginia, persons providing audiological services in Virginia, and the Department of Behavioral Health and Developmental Services (lead agency for Part C early intervention program). |
| **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. | Infants born in Virginia hospitals: 105,000 annually<br>Birthing hospitals in Virginia: 64<br>Birthing centers in Virginia: 2<br>Persons providing audiological services for infants and children: 107 |
| **All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and do include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.** | Two of the 64 birthing hospitals which have specialty neonatal intensive care services would have to purchase ABR equipment to test those infants with stays of greater than five days. It is estimated that new ABR equipment may cost between $15,000 to $25,000. The other hospitals with these types of neonatal intensive care services already have the capability or are using this equipment.<br><br>Birthing centers have not previously reported formally to the department although the Code of Virginia has a provision for birthing centers. Risk |

| | |
|---|---|
| | assessments and referrals for hearing screening are currently being done in practice. Reporting findings to the department may require staff effort of one to three hours per month. Birthing centers typically have 25 or fewer births per month.<br><br>Birthing hospitals currently perform testing on all infants. Reporting time will be decreased with provision by the department of certain existing demographic data from births and elimination of monthly report totals, however with the new modified risk indicator list and primary information or confirmation on infants assumed to pass, reporting time and effort may have a net increase by 2 to 30 hours monthly depending on the number of births at the facility. |
| **Beneficial impact the regulation is designed to produce.** | Increased early identification of hearing loss in infants and decreased delays in cognitive and language development among those infants with hearing loss will be the primary benefit. In addition, costs related to special education should be reduced. |

## 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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

There are no alternatives which would comply with the current Code of Virginia Section 32.1-64.1. This Section would need to be amended through the legislative process to make promulgation of regulations optional. This is not a desired or viable alternative.

## Regulatory flexibility analysis

*Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

Less stringent standards would not be consistent with the most current national recommendations and cannot be argued to be consistent with the intent of the law and the role of promoting health for infants

born in the Commonwealth. The time for certain reporting requirements actually has been extended by one week to allow for use of existing demographic birth data to reduce data entry. This is a reporting simplification due to prepopulation of certain data requirements. The proposed regulations place details of the required at risk criteria in a guidance document which will provide for more flexibility in administering the regulations and to amend specific criteria. Less stringent reporting requirements for risk categories would not be consistent with the most current national recommendations and would not be consistent with the intent of the law and the role of public health to track infants at risk for acquiring hearing loss.

## Public comment

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

| Commenter | Comment | Agency response |
|---|---|---|
| No public comments following publication of the NOIRA | | |

## Family impact

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

The proposed regulatory action will potentially strengthen parents' ability to assure appropriate education because early detection and treatment of hearing impairment can reduce learning disabilities which often result with delayed identification and treatment of hearing impairment. By reducing potential disability, economic self-sufficiency may be strengthened and lessen the potential erosion of disposable family income. Early intervention and treatment for hearing impairment has been demonstrated to save costs for both families and governmental institutions.

Parents maintain the right to refuse hearing screening under the Code of Virginia.

## Detail of changes

*Please detail all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if implemented in each section. Please detail the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations 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, rationale, and consequences |
|---|---|---|---|
| 10 | 10 | Definitions | Definitions added for current screening methodologies (ABR and OAE); acronyms used (CDC, EHDI); programs (Part C, Virginia Hearing Impairment Identification and Monitoring System, Family-to-Family support); services/providers (audiologist, birthing center, hospital, newborn services); and other entities (Board, guardian, newborn, and resident). Definitions modified for parent, neonatal intensive care services unit, and primary healthcare provider. These definitions were modified to be consistent with other regulations and to define terms within the regulation. |
| 20 | 20 | Authority | Minor edits made for grammar. |
| 30 | 30 | Purpose | Added statement that section is designed to be consistent with most recent recommendations of Joint Committee on Infant Hearing. |
| 40 | 40 | Administration | Edited to allow issuance of guidance documents. Removed reference to general application. |
| 80 | 80 | Responsibilities of chief medical officer | Section renamed to clarify the responsible party as defined in the Code. This section is revised to include separate screening methodologies for different levels of newborn care and how to handle screening failures in one or both ears. This section defines how to handle transfer infants. Reporting requirements are more detailed. The screening timeframe is reduced to one month of age, except for neonatal intensive care services, to be aligned with CDC national goals. References to the 1999 American Academy of Pediatrics statement and false-positive and false-negative rates are removed. |
| 90 | 90 | Scope and content of the Virginia Early Hearing Detection and Intervention Program | Section renamed to specify the program. This section is revised to detail responsibilities regarding developing and maintaining reporting system. In addition, responsibilities for communicating with Part C, developing and disseminating protocols, parent education materials, and maintaining list of approved audiologists are added. National performance measures required for grant funding are |

| | | | |
|---|---|---|---|
| | | | added. |
| 95 | 95 | Responsibilities of persons providing audiological services after discharge | Section edited to specifically name Part C program for referrals. |

For new chapters, use this chart:

| Section number | Proposed requirements | Other regulations and law that apply | Intent and likely impact of proposed requirements |
|---|---|---|---|
| 75 | Adds section on risk indicators associated with hearing loss. Previously risk factors were in definitions. Risk indicators have been updated to reflect the most current national standards. Certain risk indicators have been deleted (low birthweight, low Apgar scores, mechanical ventilation five days or longer). Other risk indicator categories have been added (neonatal intensive care services for five or more days, ototoxic chemotherapy, head trauma, syndromes associated with hearing loss, neurodegenerative disorders). Details regarding specifics for each category removed and put into guidance document to be reviewed at least biennially. | Part F of 32.1-64.1 of the Code of Virginia directs Board to establish criteria for determination of at risk for hearing impairment. | Intent is to reflect most current national standard for risk indicators.<br><br>Movement of details to guidance document will allow risk indicators to be amended as needed to keep up with current research without lengthy wait under regulatory process.<br><br>Likely impact could be change in numbers of infants identified at risk for hearing loss. |
| 95 | Adds section on birthing places or centers. It is proposed to have this group report risk indicators to the department and confirm that screening was not done and that infants were referred. | Part C of 32.1-64.1 of the Code of Virginia states that birthing places and centers shall identify infants at risk of hearing impairment. | Intent is to formally include birthing centers which are specified in the law but not currently reporting. This is important as more birthing centers are expected to open in the state to meet obstetrical need.<br><br>The department will work with birthing centers to facilitate reporting either by paper or electronically. |
| 130 | Adds section on responsibilities of primary healthcare providers. States that they will receive hearing screening results and program information. | Part G of 32.1-64.1 of the Code of Virginia states that anyone making determination that infant has hearing loss or is at risk of hearing loss shall notify the primary healthcare provider. | Intent is to formally include this important group of service providers as part of the overall screening system.<br><br>Change in current practice unlikely as primary healthcare providers do receive results. |

| | | | |
|---|---|---|---|
| 140 | Adds section on relationship to Part C. | Individuals with Disabilities Education Act of 2004 (20 U.S.C. §§ 1431-1444); 34 CFR Part 303; §2.2-5303 of the Code of Virginia.<br><br>Section 2.2-5300 and 5303 of the Code of Virginia. | Intent is to formally include relationship between program and Part C early intervention system. Participating Part C agencies, including the Virginia Department of Health, will continue to formalize relationships regarding referrals, service provision and outcomes, evaluation, and data exchange through interagency agreements as required by federal and state law. |

The current Form (Report of Follow-Up) and Document Incorporated by Reference (Newborn and Infant Hearing Loss: Detection and Intervention, Pediatrics Vol. 103, No. 2, February 1999, American Academy of Pediatrics) will be deleted.

CHAPTER 80
REGULATIONS FOR ADMINISTRATION OF THE VIRGINIA HEARING IMPAIRMENT IDENTIFICATION AND MONITORING SYSTEM

**12VAC5-80-10. Definitions.**

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

“ABR” means an objective, electrophysiologic measurement of the brainstem’s response to acoustic stimulation of the ear.

"At risk" means considered to be in a status with a significant probability of having or developing hearing loss as a result of the presence of one or more factors identified or manifested at birth.

“Audiological evaluation” means those physiologic and behavioral procedures required to evaluate and diagnose hearing status.

“Audiologist” means a person licensed to engage in the practice of audiology as defined in §54.1-2600 of the Code of Virginia.

“Birthing center” means a facility outside of a hospital that provides maternity services.

“Board” means the State Board of Health.

“CDC” means the Centers for Disease Control and Prevention.

"Child" means any person from birth to ~~age~~ 18 years of age.

"Commissioner" means the State Health Commissioner, his duly designated officer, or agent.

“Department” means the Virginia Department of Health.

~~"Diagnostic audiological evaluation" means those physiologic and behavioral procedures required to evaluate and diagnose hearing status.~~

"Discharge" means release from the hospital after birth to the care of the parent or guardian.

“EHDI” means Early Hearing Detection and Intervention.

“Family-to-family support” means the provision of information and peer support among families having experience with family members having hearing loss.

“Guardian” means a parent-, court-, or clerk-appointed guardian of the person.

"Hearing screening" means an objective physiological measure to be completed in order to determine the likelihood of hearing loss.

“Hospital” means any facility as defined in §32.1-123 of the Code of Virginia.

"Infant" means a child under the age of one year.

"Missed" means that an infant did not have a required hearing screening prior to discharge.

"Neonatal intensive care services" means those services provided by a hospital's newborn services that are designated as ~~both~~ either specialty level ~~and~~ or subspecialty level as defined in ~~subdivision D 2 of 12VAC5-410-440.~~ 12 VAC 5-410-443 (B) (3) and (B) (4) of the Rules and Regulations for the Licensure of Hospitals.

“Newborn” means an infant who is 28 days old or less.

“Newborn services” means care for infants in one or more of the service levels designated in subsection B of 12VAC5-410-443 of the Rules and Regulations for the Licensure of Hospitals.

“OAE” means an objective, physiologic response from the cochlea. This term may include transient evoked otoacoustic emissions and distortion product otoacoustic emissions.

"Parent" means ~~(i)~~ a biological ~~or~~, adoptive, or stepparent. ~~who has legal custody of a child, including either parent if custody is shared under a joint decree or agreement; (ii) a biological or adoptive parent with whom a child regularly resides; (iii) a person judicially appointed as a legal guardian of a child; or (iv) a person who exercises the rights and responsibilities of legal custody by delegation from a biological or adoptive parent, upon provisional adoption or otherwise by operation of law.~~

“Part C” means the state early intervention program which provides medically necessary speech and language therapy, occupational therapy, physical therapy and assistive technology services and devices for dependents from birth to age three who are certified by the Department of Behavioral Health and Developmental Services as eligible for services under Part C of the Individuals with Disabilities Education Act of 2004 (20 U.S.C. §§ 1431-1444).

"Primary ~~medical care~~ healthcare provider" means the person who is licensed to provide health care as part of his job responsibilities and to whom the infant will go for ~~routine medical~~ primary health care following hospital discharge.

“Resident” means an individual who resides within the geographical boundaries of the Commonwealth.

"Risk ~~factor~~ indicator" means a factor known to place an infant at increased risk for being born with or developing a hearing loss.~~, including, but not limited to, any one of the following:~~

~~1. Family history of hereditary, childhood sensorineural hearing loss;~~

~~2. In utero infection (e.g., cytomegalovirus, rubella, herpes, toxoplasmosis, syphilis);~~

~~3. Craniofacial anomalies including those with morphological abnormalities of the pinna and ear canal;~~

~~4. Birthweight less than 1500 grams;~~

~~5. Hyperbilirubinemia at a serum level requiring exchange transfusion;~~

~~6. Bacterial meningitis;~~

~~7. Apgar scores of 0 to four at one minute or 0 to six at five minutes;~~

~~8. Ototoxic medications, including but not limited to the aminoglycosides, used in multiple courses or in combination with loop diuretics;~~

~~9. Mechanical ventilation lasting five days or longer;~~

~~10. Stigmata or other findings associated with a syndrome known to include a sensorineural hearing loss, a conductive hearing loss, or both;~~

~~11. Neurofibromatosis Type II; and~~

~~12. Persistent pulmonary hypertension of the newborn (PPHN)~~.

"Virginia Hearing Impairment Identification and Monitoring System" means a coordinated and comprehensive group of services including education; screening; follow up; diagnosis; appropriate early intervention including treatment, therapy, training and education; and program evaluation managed by the department's Virginia Early Hearing Detection and Intervention Program for safeguarding the health of children born in Virginia.

**12VAC5-80-20. Authority ~~for regulations~~.**

Sections 32.1-64.1 and 32.1-64.2 of the Code of Virginia direct the commissioner to establish and maintain a system for the purpose of identifying and monitoring infants with hearing loss and direct the board ~~of Health~~ to promulgate the regulations necessary for implementation of the system.

**12VAC5-80-30. Purpose of chapter.**

This chapter is designed to provide consistent guidelines for implementation of this system in order to assure that infants with hearing loss are identified at the earliest possible age and that they receive appropriate, early intervention. This chapter is

designed to be consistent with the most recent recommendations of the Joint Committee on Infant Hearing.

**12VAC5-80-40. Administration ~~and application~~ of chapter.**

~~A. This chapter is promulgated to implement the system and amended as necessary by the State Board of Health. The State Health Commissioner or his designee is charged with its administration, and the Virginia Department of Health shall provide the staff necessary for its implementation.~~

~~B. This chapter has general application throughout the Commonwealth.~~

This chapter is administered by the commissioner.

The commissioner may issue a guidance document that interprets these regulations and provides guidance for their implementation. Such a document shall be reviewed and revised whenever the regulations of this chapter are reviewed and may also be amended or revised as needed to meet changing circumstances.

**12VAC5-80-50. [Repealed]**

**12VAC5-80-60 to 12VAC5-80-70. [Reserved]**

**12 VAC5-80-75 Risk Indicators associated with hearing loss.**

A. The Virginia EHDI Program shall maintain a list of specific risk indicators consistent with, but not necessarily identical to, the most recent recommendations from the Joint Committee on Infant Hearing to identify infants at risk of hearing loss.

B. The Virginia EHDI Program Advisory Group shall provide guidance with the development and maintenance of the list of specific risk indicators.

C. The list of specific risk indicators shall be maintained in a guidance document which shall be reviewed at a minimum biennially. The list of specific risk indicators may be changed or amended more frequently as needed to reflect changes in standards of care or updates to Joint Committee on Infant Hearing recommendations.

D. The guidance document shall contain specific assessment and reporting criteria for the following general categories of risk indicators associated with hearing loss:

1. Family history of permanent childhood hearing loss;
2. Caregiver concerns;
3. In utero and post natal infections;
4. Neonatal intensive care services;
5. Head trauma and craniofacial anomalies;
6. Syndromes, neurodegenerative disorders, and sensory motor neuropathies;

7. Stigmata or other physical findings associated with certain syndromes;
8. Ototoxic medications, treatments, and chemotherapies; and
9. Other indicators as needed.

E. All infants born in Virginia hospitals shall be assessed prior to hospital discharge after birth for risk indicators associated with hearing loss as outlined in this chapter and the corresponding guidance document.

**12VAC5-80-80. Responsibilities of the chief medical officer of hospitals.**

~~Hospitals with newborn nurseries and hospitals with neonatal intensive care services~~ The chief medical officer or his designee shall:

~~1. Prior to discharge after birth, but no later than three months of age, screen the hearing, in both ears, of all infants using objective physiologic measures. The methodology used for hearing screening shall have a false-positive rate and false-negative rate no greater than those recommended by the American Academy of Pediatrics in "Newborn and Infant Hearing Loss: Detection and Intervention" (Pediatrics Vol. 103, No. 2, February 1999). If the error rates exceed these recommendations, the hospital shall examine and modify its hearing screening methodology to reduce its error rates below these maximum rates;~~

A. Cause all infants to be given a hearing screening test prior to discharge after birth as appropriate for the level of newborn services provided as defined in subsection B of 12 VAC 5-410-443 of the Rules and Regulations for the Licensure of Hospitals;

1. Infants in general or intermediate newborn services shall have both ears screened for hearing using either ABR or OAE testing prior to discharge after birth, but no later than one month of age.

2. Infants in neonatal intensive care services who receive this level of newborn service care for more than five days shall have both ears screened using ABR testing prior to discharge after birth or transfer to a lower level of newborn services. Infants should receive newborn hearing screening as early as development or medical stability will permit such screening. The hearing screening performed for infants requiring neonatal intensive care services for more than five days using ABR testing shall be reported as the initial hearing screen regardless of whether the infant is transferred to another lower level of newborn services within the same facility or to another facility.

3. Infants in neonatal intensive care services who receive this level of newborn service care for five days or less shall have both ears screened for hearing using either ABR or OAE testing prior to discharge after birth, but no later than one month of age.

B. Identify all infants who fail hearing screening in one or both ears;

1. Infants who fail hearing screening in one or both ears using ABR testing shall not be rescreened using OAE testing. These infants shall be referred for an audiological evaluation.

2. Infants who fail hearing screening in one or both ears using OAE testing may be rescreened using ABR testing. If the infant fails subsequent ABR testing in one or both ears, the infant shall be referred for an audiological evaluation.

C. Identify all infants not receiving an appropriate hearing screening test;

1. For infants who did not receive a hearing screening test due to transfer to another facility, written notification shall be made upon transfer to the healthcare provider in charge of the infant's care that testing was not completed. The hospital discharging the infant after birth is responsible for conducting an appropriate hearing screening test, except for infants who have been transferred to a lower level of newborn service care from another facility providing neonatal intensive care services to that infant for more than five days.

2. ~~If an infant is missed,~~ For infants who did not receive a hearing screening test prior to discharge after birth, inform the parent or guardian prior to discharge of the need for hearing screening and provide a mechanism by which screening can occur at no additional cost to the family~~;~~ .

3. For infants who did not receive screening due to refusal by the parent or guardian because the screening conflicts with religious convictions, documentation shall be made in the medical record.

D. Cause all infants to be assessed for risk indicators associated with hearing loss prior to discharge after birth as defined in 12VAC5-80-75;

1. For infants who are found to have one or more risk indicators associated with hearing loss, inform the parent of the need for a diagnostic audiological assessment by 24 months of age.

~~3.~~ E. ~~Prior to discharge, give~~ Provide written information to the parent or guardian of each infant that includes purposes and benefits of newborn hearing screening, risk indicators of hearing loss, procedures used for hearing screening, results of the hearing screening, ~~the~~ recommendations for further testing, ~~and~~ where ~~the~~ further testing can be obtained~~;~~ ,and contact information for the Virginia EHDI Program;

~~4.~~ F. ~~Give written information to~~ Notify the infant's primary ~~medical care~~ healthcare provider, within two weeks of discharge after birth, the status of the hearing screening including if the infant was not tested, ~~that includes~~ procedures used for hearing screening, ~~the limitations of screening procedures,~~ identified risk indicators associated with hearing loss as defined in 12 VAC 5-80-75, the results of the hearing screening, and the recommendations for further testing in writing or through an electronically secure method that meets all applicable state and federal privacy laws~~;~~

~~5.~~ G. ~~Within one week of discharge, complete the Virginia Department of Health report~~ Provide the department with information, as required by the board pursuant to § 32.1-64.1 F of the Code of Virginia and in a manner devised by the department, which may be electronic, ~~on each infant who does not pass the hearing screening and send it to the Virginia Department of Health;~~ on the hearing screening and risk indicator status of infants born at their hospital. This information shall be provided within two weeks of discharge after birth unless otherwise stated and includes, but may not be limited to:

1. Demographic information on infants including name, date of birth, race, ethnicity, and gender;
2. Primary contact information including address, telephone, and relationship type;
3. Primary healthcare provider name, address and telephone;
4. Risk indicators identified as defined in 12 VAC 5-80-75;

5. Special circumstances regarding infants as needed by the department to provide follow up;

6. Screening methodology used, date screened, and both right and left ear results;

7. Screening status for pass with risk factor, fail, unable to test, refusal, and inconclusive results;

8. Status of infants not screened prior to discharge which includes, but may not be limited to, infants who were transferred to other facilities and parents who refused screening;

9. Hearing rescreening information including date, type of screening methodology used, results in both left and right ears, and further recommendations within two weeks after the hospital rescreening date; and

10. Confirmatory data on the status of all infants born in the hospital facility. The department shall receive confirmation that infants not reported as passed with risk, failed, transferred, refused testing, not tested prior to discharge, expired, or other final disposition have had a negative assessment for risk indicators and that physiological hearing screening was conducted with passing results in both ears within 30 days after birth.

~~6. On a monthly basis, send to the Virginia Department of Health a report of the total number of discharges, the total number of infants who passed the newborn hearing screening, the total number who failed, and the total number not tested~~

~~due to parents' exercise of their rights under § 32.1-64.1 H of the Code of Virginia; and~~

~~7.~~ H. Report to the ~~Virginia Department of Health~~ department, on a yearly basis, hospital specific information including the test procedures used by the newborn hearing screening program, the name of the program director, the name of the advising audiologist, equipment calibration records, screening protocols, and referral procedures;

I. Develop written policies and procedures to implement hearing screening in their facility in accordance with 12 VAC 5-80 including separate protocols for specialty and subspecialty newborn services; and

J. Assure that training of staff on newborn hearing screening test procedures, follow up, and reporting requirements is implemented in a way that an adequately trained and knowledgeable workforce is maintained to conduct hearing screening program requirements.

**12VAC5-80-85. Responsibilities of other birthing places or centers.**

The chief medical officer or his designee or the attending practitioner shall:

A. Cause all infants to be assessed for risk indicators associated with hearing loss as defined in 12VAC5-80-75;

B. Provide written information to the parent or guardian of each infant that includes purposes and benefits of newborn hearing screening, risk indicators for hearing loss, procedures used for hearing screening, providers where hearing screening can be obtained, and contact information for the Virginia EHDI Program;

C. Notify the infant's primary healthcare provider, within two weeks after birth, the status of the hearing screening including if the infant was not tested, identified risk indicators associated with hearing loss as defined in 12 VAC 5-80-75, and the recommendations for testing in writing or through an electronically secure method that meets all applicable state and federal privacy laws; and

D. Provide the department with information, as required by the board pursuant to §32.1-64.1 F of the Code of Virginia and in a manner devised by the department on the hearing screening and risk indicator status of infants born at their birthing center. This information shall be provided within two weeks after birth unless otherwise stated and includes, but may not be limited to:

1. Demographic information on infants including name, date of birth, race, ethnicity, and gender;
2. Primary contact information including address, telephone, and relationship type;
3. Primary healthcare provider name, address and telephone;
4. Risk indicators identified as defined in 12 VAC 5-80-75;

5. Special circumstances regarding infants as needed by the department to provide follow up;

6. Screening methodology used, date screened, and both right and left ear results if applicable;

7. Screening status for pass with risk factor, failures, unable to test, refusals, and inconclusive results if applicable;

8. Status of infants not screened which includes, but may not be limited to, infants who were transferred to other facilities and parents who refused screening;

9. Hearing rescreening information including date, type of screening methodology used, results in both left and right ears, and further recommendations within two weeks after the rescreening date if applicable; and

10. Confirmatory data on the status of all infants born in the birthing place or center. The department shall receive confirmation that infants not reported with a screening status have had a negative assessment for risk indicators and have been referred for a hearing screening.

**12VAC5-80-90. ~~Responsibilities of the Virginia Department of Health.~~ Scope and content of Virginia Early Hearing Detection and Intervention Program.**

~~The Virginia Department of Health shall:~~

A. The mission of the Virginia EHDI Program is to identify hearing loss at the earliest possible age and to assure that appropriate early intervention services are received to reduce the risk of developmental delays.

The scope of the Virginia EHDI Program shall include the following:

1. Provide hospitals and birthing centers with a secure reporting system which may be electronic that meets all applicable federal and state privacy statutes. This electronic system may include existing demographic data captured by other department population-based systems and the Commissioner may authorize hospitals required to report to view existing data to facilitate accurate reporting and increase the department's ability to conduct successful follow up and identify infants at risk for hearing loss pursuant to § 32.1-127.1:04 of the Code of Virginia;

~~1.~~ 2. Collect, maintain and evaluate ~~hospital~~ newborn hearing screening data ~~in a database~~ including, but not limited to, initial screening, risk indicators, rescreening, and diagnostic audiological evaluations, in a secure data management information system;

~~2.~~ 3. Provide follow-up for ~~all~~ infants ~~reported~~ whose results indicate screening failure, identified risk indicators, inconclusive or missing results, or other circumstances requiring follow up. Follow-up includes, but is not limited to:

a. Communicating with the parent ~~by mail~~ or guardian for those infants who failed the hearing screening, ~~those who had one or more risk factors identified and were not screened prior to discharge,~~ those who were not screened, and those who are at risk for ~~progressive~~ hearing loss in order

to advise of the need for audiological services as well as to provide information on locating an approved center that provides diagnostic audiological services or a licensed audiologist;

b. ~~Receiving results of both the audiological evaluations and the intervention referrals, and adding the information to the database; and~~ Communicating with audiologists, hospitals, birthing centers, primary health care providers, and others as needed to ascertain follow up status and receiving results of audiological evaluations and intervention referrals, including Part C services;

c. Communicating with the parent ~~by mail~~ or guardian for any child found to have a hearing loss in order to provide information about hearing loss and appropriate resources including family-to-family support and referral to the Part C program; and

d. Communicating to the Part C program regarding any child found to have hearing loss in order to facilitate early intervention services.

~~3. Supply the reporting format and written information to hospitals;~~

4. Provide training and technical assistance ~~on this program~~ to hospitals and birthing centers; ~~and~~

5. Develop and disseminate protocols for hospitals, audiologists, and primary healthcare providers;

6. Develop and disseminate parent education materials;

7. Maintain an approved list of audiological providers meeting program criteria;

~~5.~~ 8. ~~Conduct a review and evaluation of the~~ Evaluate Virginia Hearing Impairment Identification and Monitoring System components, including but not limited to ~~the false-positive rate, false-negative rate~~, screening, referral ~~rate~~, and follow-up ~~rate,~~ rates; referral mechanisms; and ~~effectiveness of~~ tracking indicators~~,~~ ; ~~and communicating~~

9. Communicate critical performance data to hospitals and birthing centers, on a ~~yearly~~ quarterly basis.

10. Collect and report data required annually for Title V national performance measures, CDC national EHDI goals, and other funding sources as needed that measure how well the system functions.

B. Title V national performance measures and the CDC national EHDI goals, as required by the Government Performance and Results Act (GPRA; Public Law 103-62), shall be used to establish newborn hearing screening goals. The following goals shall change as needed to be consistent with federally required performance measures:

1. All infants who are born in Virginia hospitals shall be screened for hearing loss prior to hospital discharge. Residents of Virginia who do not pass screening, do not receive screening, or who have an identified risk factor shall receive appropriate evaluation, diagnostic, follow up, and early intervention services. Infants who are not residents of Virginia and who do not pass screening, do not receive screening, or who have an identified risk factor will be referred to their

state of residence for appropriate evaluation, diagnostic, follow up, and early intervention services;

2. All infants born in Virginia shall receive a hearing screening prior to one month of age;

3. Infants who are referred shall receive a diagnostic audiological evaluation before three months of age; and

4. All infants identified with a hearing loss shall receive appropriate early intervention services before six months of age.

**12VAC5-80-95. Responsibilities of persons providing audiological services after discharge.**

Persons who provide audiological services and who determine that a child has failed to pass a hearing screening, was not successfully tested, or has a hearing loss shall:

1. Provide the screening or evaluation results, either in writing or in an electronically secure manner, to the parent or guardian and to the child's primary ~~medical care~~ healthcare provider;

2. Send a ~~Virginia Department of Health~~ report including screening methodology, test results, diagnosis, and recommendations to the ~~Virginia Department of Health~~ department, in a manner devised by the department, which may be electronic, within two weeks of the visit;

3. ~~Advise~~ Provide information to the parent or guardian about and offer referral for the child to local early intervention or education programs, including the Part C program; and

4. Give resource information to the parent of any child who is found to have a hearing loss, including but not limited to, the degrees and effects of hearing loss, communication options, amplification options, the importance of medical follow up, and agencies and organizations, including the Part C program, that provide services to children with hearing loss and their families.

**12VAC5-80-100 to 12VAC5-80-120. [Repealed]**

**12VAC5-80-130. Responsibilities of primary healthcare providers.**

Persons who provide primary healthcare services to infants shall:

1. Receive hearing screening, risk indicator findings, and evaluation results from hospitals, audiological providers, and the Virginia EHDI Program .
2. Receive information from the Virginia EHDI Program regarding available resources to assist practitioners and families whose child is at risk or diagnosed with hearing loss.

**12VAC5-80-140. Relationship to the Part C System**

A. The department is a participating agency in the state Part C system as defined in §2.2-5300 of the Code of Virginia. The Virginia Hearing Impairment Identification and Monitoring System is a component of this statewide system to identify infants and children who may be eligible for Part C early intervention services. The Virginia EHDI Program shall develop policies and operating procedures that are consistent with the Individuals with Disabilities Education Act of 2004 (20 U.S.C. §§ 1431-1444); 34 CFR Part 303; §2.2-5303 of the Code of Virginia ; and the most recent state interagency agreement.

B. The state interagency agreement shall contain policies and procedures related to identification of resources, coordination of services, resolution of interagency disputes, and data exchange activities necessary for the department and the Virginia EHDI Program to fulfill responsibilities and implementation activities required as part of the state early intervention system.

Virginia
Regulatory
Town Hall

townhall.virginia.gov

# Final Regulation
# Agency Background Document

| | |
|---|---|
| **Agency name** | Virginia Department of Health |
| **Virginia Administrative Code (VAC) citation** | 12 VAC5-612 |
| **Regulation title** | Regulations for the Onsite Sewage Indemnification Fund |
| **Action title** | Implement Title 32.1-164.1:01 of the Code of Virginia, the Onsite Sewage Indemnification Fund. |
| **Date this document prepared** | October 23, 2009 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) 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. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.*

The Virginia Department of Health administers the onsite sewage indemnification fund ("Fund"), which assists any Virginia real property owner holding a valid septic tank or other onsite sewage system permit when the system fails within three years of its construction from negligence by the Virginia Department of Health. The new regulations provide notice of the Fund, establish the procedures for applying to the Fund, and establish the procedures for investigating and processing requests for assistance.

During the 60-day comment period, one person commented on the regulations and the Virginia Department of Health did not identify a need to change the regulations.

## 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.*

The Board of Health met on October 23, 2009 and adopted final regulations to implement the Fund. More information about the Board of Health can be found at http://www.vdh.state.va.us/Administration/BOH/.

## 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.*

---

Title 32.1-164.1:01 of the *Code of Virginia* gives the Board of Health authority to adopt regulations and administer Virginia's onsite indemnification fund program. The Code states that "the Board may promulgate regulations pursuant to the Administrative Process Act (§ 2.2-4000 et seq.) for the administration of the Fund consistent with this chapter." The authority to promulgate regulations is discretionary.

## 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.*

---

Owners should have access to the rules, investigation process, and legal basis for decision-making before claims are filed to the Fund. With the statutory guidelines and the new regulations, the Commissioner can implement a fair, consistent, and predictable procedure for owners who seek assistance. Regulations will ensure that binding legal requirements are in place to administer the Fund.

## 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.*

---

Title 32.1-164.1:01 of the *Code of Virginia* creates the Onsite Sewage Indemnification Fund to assist Virginia real property owners whose onsite sewage systems fail within three years of construction from the negligence of the health department. In order to receive assistance from the Fund, the Commissioner must find that the real property owner meets the statutory requirements (e.g., valid permit, failure three years from installation, and negligent actions by the health department caused failure); files a complete application within one year of the date of failure; follows the requirements to repair or replace the failed system; and executes a release of claims against the Commonwealth related to the failed system.

On July 26, 2007, Dr. Robert Stroube, M.D., MPH, State Health Commissioner adopted Guidance Memorandum, and Policy #123.A (GMP #123.A) to explain how VDH would accept, process, and decide requests for indemnification under Title 32.1-164.1:01 of the Code of Virginia. The policy can be viewed at: http://www.vdh.state.va.us/onsite/GMPs/GMP123.A.pdf. The policy provides notice of the Fund, establishes the application procedure for Virginia real property owners to apply for assistance from the

Fund, and establishes the procedure for investigating and processing requests for assistance from the Fund. The regulations codify the substance of GMP #123.A by specifying what information must be included and which actions the owner must take to file a complete application. The regulations establish the conditions under which a review might occur when a financial hardship exists. The regulations include guidelines for appealing a decision and how final administrative actions are done.

## 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 State Health Commissioner has administered the Fund since its creation in 1994 by policy (Acts of Assembly Chapter 747 (2004)). In that time, over 200 claims for indemnification have been processed. Policies do not have the same binding legal authority as laws or regulations. Real property owners have in some cases endured a long, unpredictable review process. Cases with similar facts have had different outcomes depending on the trier of fact's willingness to adhere to a policy that did not carry the force of law or regulation.

The primary advantage to the public and the agency is a more streamlined review process. The regulations set clear expectations for filing a complete application to the Fund. Owners and the agency have a known procedure for evaluation. Similar facts should result in similar results because there will be a predictable process with a predictable evaluation. Owners can expect all final administrative actions to include required information, which should allow for clear and consistent decisions.

No disadvantage is foreseen because expectations, analysis, and final administrative decisions will be outlined by the regulations.

## 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.*

No changes made.

## 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 |
|---|---|---|
| Peter Brooks/PMBA, Inc. | Move 12 VAC5-612-40.B.7 and 12 VAC5-612-40.B.8 to 12 VAC5-612.40.C. | 12 VAC5-612-40 describes the necessary components of a complete application. The commenter did not identify why this language |

| | | |
|---|---|---|
| | | would be better placed in paragraph C instead of paragraph B under Section 40. The agency could not identify any added value of moving 12 VAC5-612-40.B.7 and 12 VAC5-612-40.B.8 to 12 VAC5-612.40.C. |
| Peter Brooks/PMBA, Inc. | Twelve months is not enough time for owners to complete the requirements of 12 VAC5-612-40.B.7 and 12 VAC5-612-40.B.8. | The *Code of Virginia* (Title 32.1-164.1:01) establishes the time allowed to complete an application (one year) so the agency has no discretion in changing the timeframe. The Fund is a reimbursement program so the agency must know what costs have been incurred to reimburse owners. |
| Peter Brooks/PMBA, Inc. | Delete 12 VAC5-612-90.C | This section describes what must be included in the Sewage Handling and Disposal Appeal Review Board's final administrative decision. The commenter noted that the agency's verbatim record is sufficient. The agency believes that owners will be better served when certain pertinent and necessary information is included in the final administrative decision. Owners will have a complete administrative decision that will not require them to review perhaps hundreds of pages of a verbatim record. This section ensures that owners can fully understand the basis of the final administrative decision.<br><br>Deleting Section 90.C would be inconsistent with the statutory requirements of Title 2.2-4020(E), which specifies what must be included in a case decision from a formal hearing. Findings and conclusions are required and essential for judicial review. |
| Peter Brooks/PMBA, Inc. | Delete 12 VAC5-612-90.D | This section provides the Sewage Handling and Disposal Appeal Review Board with an optional opportunity to hear argument and fact after a written case decision is made. The commenter suggested this optional review was unnecessary because either party can appeal final administrative decisions to circuit court. The agency disagrees: only the appellant can appeal final administrative decisions to circuit court. This regulation provides the Appeal Review Board with an optional and additional opportunity to resolve cases in accordance with applicable law and regulation. The agency cannot identify harm by allowing an optional review to ensure final administrative decisions are accurate and correct. |

## 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.*

No changes are being proposed.

## Regulatory flexibility analysis

*Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

---

The State Health Commissioner has administered the Fund since its creation in 1994 by policy. As noted above, policies do not have the same binding legal authority as laws or regulations and real property owners have in some cases endured a long, unpredictable review process. Cases with similar facts have had different outcomes.

Continuing to use a policy to implement the Fund would most likely result in long processes and unpredictable results for owners seeking assistance. The VDH believes regulations are the best way to ensure consistent and fair administration of the Fund.

## Family impact

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

---

The proposed regulatory action will have no anticipated or associated impacts on family rights to educate and supervise children. It will not discourage economic self-sufficiency and family responsibilities and commitments or decrease disposable family income.

**Project 1125 - Proposed**

**DEPARTMENT OF HEALTH**

**CH 0612 Regulations to Implement Title 32.1-164:1:01, the Onsite Sewage Indemnificatio**

CHAPTER 612

REGULATIONS FOR THE ONSITE SEWAGE INDEMNIFICATION FUND

**12VAC5-612-10. Purpose.**

The purpose of this chapter is to:

1. Provide notice of and administer the Onsite Sewage Indemnification Fund (hereinafter, the fund) as established by § 32.1-164.1:01 of the Code of Virginia.

2. Establish the application for Virginia real property owners to use for reimbursement from the fund.

3. Establish the procedure for investigating, processing, and evaluating requests for assistance from the fund.

**12VAC5-612-20. Definitions.**

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"An onsite sewage system that has been permitted by the Department of Health" means that the Department of Health issued an operation permit in accordance with the Sewage Handling and Disposal Regulations, 12VAC5-610, or its successor.

"Appeal Review Board" means the Sewage Handling and Disposal Appeal Review Board as established by § 32.1-166.1 of the Code of Virginia.

"Commissioner" means the Commissioner of Health, Virginia Department of Health.

"Date of first failure" means the date that a Virginia real property owner submits a repair application to the local health department or the date that a local health department sends a notice to the owner that acknowledges that an apparent failure exists, whichever occurs first.

"Date of system construction" means the date that the local health department inspected and approved the onsite sewage system's construction or the date that the contractor or person who installed the onsite sewage system certifies that the onsite sewage system was installed properly (as evidenced by a completion statement), whichever occurs first. The date of construction is not the date that the local health department issued a permit to operate the sewage system.

"Department" means the Virginia Department of Health.

"Division" means the Division of Onsite Sewage and Water Services, Virginia Department of Health.

"Holding a valid permit to operate an onsite sewage system" means that the Virginia real property owner received a valid operation permit for the onsite sewage system that failed.

"Onsite sewage system" means a treatment works approved in accordance with the Sewage Handling and Disposal Regulations, 12VAC5-610, or its successor.

"Onsite sewage system failure" means an onsite sewage system is not operating in a normal or usual manner as defined by the Sewage Handling and Disposal Regulations, 12VAC5-610, or its successor.

"Onsite sewage system component failure" means that a part or discreet element of the onsite sewage system is not operating in a normal or usual manner, which, when corrected, repaired, or replaced, will return the system to normal function.

"Specific actions of the department were negligent and that those actions caused the failure" means (i) the department had a duty to perform, (ii) the department breached or failed to perform the duty, (iii) the breach of duty or failure to perform the duty proximately caused the actual damage or injury, and (iv) the owner incurred damage or injury.

**12VAC5-612-30. Applicability.**

This regulation applies to construction permits issued and approved in accordance with the Sewage Handling and Disposal Regulations (12VAC5-610), or its successor. The department will look to the Sewage Handling and Disposal Regulations to resolve any technical issue associated with a request for reimbursement from the fund,

**12VAC5-612-40. Complete application.**

A. To file a request for reimbursement, the Virginia real property owner must submit a complete application within one year of the date that the system or components thereof failed. The request must be sent by certified mail in a form approved by the division. If the owner was under a disability at the time the cause of action accrued, the tolling provisions of § 8.01-229 of the Code of Virginia will apply. In any action contesting the filing of the request for payment, the burden of proof will be on the Virginia real property owner to establish mailing and receipt.

B. A complete application shall contain all information required by the division, including, but not limited to the following:

1. The owner's name, current address, telephone numbers, and property identification;

2. The property address where the sewage system failed;

3. The date the contractor installed the sewage system;

4. The date the health department approved the sewage system (issued an operation permit);

5. The date the Virginia real property owner filed an application to repair the failed system with the local health department;

6. The date the Virginia real property owner received a notice from the local health department indicating that the sewage system had apparently or actually failed;

7. The date(s) the Virginia real property owner made or hired a contractor to make repairs to the failed sewage system;

8. A description of the repairs made, the date for each repair, and the itemized cost for repairs on each date; and

9. The Virginia real property owner's signature.

C. The Virginia real property owner must attach a copy of receipts, invoices, bills of sale, and canceled checks to substantiate the costs incurred to repair the failed sewage system. The division may request original receipts, invoices, or canceled checks. The commissioner may withhold reimbursement to the Virginia real property owner pending submission of the original receipts, invoices, or canceled checks.

D. Except as provided in 12VAC5-612-50, the commissioner will not act on an incomplete application. A complete application means that the onsite sewage system or

components thereof that failed have been repaired or replaced in accordance with the Board of Health's applicable regulations.

E. By completing the application, the Virginia real property owner provides consent for the Virginia Department of Health, the division, the local health department, or other experts deemed necessary by the division to enter onto the property during normal business hours and to perform all tests and analysis deemed necessary to evaluate the request for assistance.

**12VAC5-612-50. Financial hardship.**

For situations where an application is incomplete because the Virginia real property owner cannot afford or does not have the financial ability to install the repair system or components thereof to comply with the Board of Health's regulations, then the commissioner may consider the incomplete application, subject to the following conditions:

1. The owner must substantiate and verify that he does not have the financial means to install the repair or components thereof. Acceptable verification of financial status may include, but is not limited to, the following: pay stubs, federal tax returns, written statements from employers, social security or retirement awards, unemployment compensation, child or spousal support from nondependant household members, or a bank loan denial letter.

a. For Virginia real property owners whose adjusted gross income is below 250% of the federal poverty guidelines as published each year in the Federal Register, the commissioner may review the incomplete application.

b. For owners whose adjusted gross income is 250% or greater than the federal poverty guidelines as published each year in the Federal Register, the

commissioner may review the incomplete application when the Virginia real property owner has been denied a loan. The bank loan denial letter must cite that the Virginia real property owner cannot qualify for a personal loan, a home equity line of credit loan, or any other loan offered by the bank for the amount needed to repair the onsite sewage system or components thereof.

2. The Virginia real property owner must submit three estimates from properly licensed contractors based on the repair permit issued by the local health department to install the repair system or components thereof. The commissioner may consider fewer estimates if requested by the Virginia real property owner and a sufficient reason is provided as to why three estimates cannot be obtained.

**12VAC5-612-60. Informal fact-finding conference.**

A. Following submission of a complete application, a Virginia real property owner may request an informal fact-finding conference in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) of the Code of Virginia to assist the division in gathering facts for an application to the fund.

B. A verbatim record of the informal fact-finding conference is not required. Any party may request a verbatim record and the requesting party is responsible for making a verbatim record. When a verbatim record is made at the commissioner's direction, it shall constitute the official record of the proceedings. The commissioner shall review the facts presented and render a case decision based upon those facts.

**12VAC5-612-70. Decision.**

A. The division will evaluate complete applications and provide a recommendation to the commissioner. Upon the commissioner's finding that (i) the onsite sewage system or components thereof failed within three years of construction; (ii) specific actions of the

department were negligent and that those actions caused the failure; and (iii) the owner filed a request for payment from the fund within one year from the date the system or components thereof failed, then the commissioner will reimburse the Virginia real property owner for the reasonable cost of following the Board of Health's regulations to repair or replace the failed onsite sewage system or components thereof and subject to the limitations and conditions in this chapter and § 32.1-164.1:01 of the Code of Virginia.

B. If the commissioner finds that (i) the Virginia real property owner's onsite sewage system was permitted by the department, (ii) the system failed within three years of construction, and (iii) the failure resulted from faulty construction or other private party error (the department's negligence, if any, did not cause the sewage system to fail), then the commissioner may assist the owner of the failed system in seeking redress from the system's builder or other private party. The assistance will be limited to providing expert services and information.

**12VAC5-612-80. Release and hold harmless agreement.**

Reimbursement from the fund is conditioned upon the Virginia real property owner completing a release and hold harmless agreement as required by the division and in a form approved by the division. The Virginia real property owner must release and hold harmless the Commonwealth, its political subdivisions, agencies and instrumentalities, and any officer or employee of the Commonwealth in connection with or arising out of the occurrence complained of.

**12VAC5-612-90. Appeal Review Board.**

A. The Appeal Review Board may review the commissioner's decision to reimburse or to deny reimbursement under this chapter. To request a review, the Virginia real

property owner must file a written request for review to the Appeal Review Board and in accordance with the Appeal Review Board's directives and authority.

B. In reviewing cases and rendering final administrative decisions, the Appeal Review Board is bound by statutes and the Board of Health's regulations in the same manner as implemented or directed by the department, the commissioner, or the local and district health departments.

C. The Appeal Review Board must cite in its written decision whether the appellant proved by a preponderance of the evidence that (i) the onsite sewage system or components thereof failed within three years of construction; (ii) specific actions of the department were negligent and that those actions caused the failure; and (iii) the owner filed a request for payment from the fund within one year from the date the system or components thereof failed. The decision must cite the date of construction, the date of first failure, and the date that the owner filed a request for payment from the fund. The decision must explain the specific actions of the department that were or were not negligent and how those actions did or did not cause the failure.

D. The Appeal Review Board may provide the Virginia real property owner and the department an opportunity to reconsider its written decision. Any party requesting a rehearing of the Appeal Review Board's decision must file a written request for rehearing to the secretary to the Appeal Review Board within 14 calendar days of the Appeal Review Board's decision. The request for rehearing must explain why it is requested and necessary. Upon such request, the Appeal Review Board may, at its own discretion, schedule a rehearing to reconsider or clarify its decision. The Appeal Review Board must notify the department and the Virginia real property owner within 14 calendar days of the request whether a rehearing will be granted or whether a new decision will be

made. If the Appeal Review Board grants a rehearing of the case decision, then the prior case decision will be vacated.

E. In accordance with § 32.1-166.1 of the Code of Virginia, the Appeal Review Board shall render the final administrative decision, which may be appealed by a named party to the appropriate circuit court in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

**12VAC5-612-100. Prohibitions and limitations.**

A. A Virginia real property owner cannot be reimbursed for both the cost of the failed system and the cost for repairs or components thereof. If the costs to repair the system or components thereof are less than the cost of the failed system, only the costs to repair the system or components thereof can be reimbursed.

B. If the cost to repair the system or components thereof exceeds the cost of the failed system, only those costs that are directly attributed to labor (which includes design) and equipment (which includes materials) will be reimbursed.

C. Virginia real property owners will not be reimbursed for consequential damages in accordance with § 32.1-164.1:01 E of the Code of Virginia.

D. Installing or modifying a sewage system without a valid construction or repair permit automatically voids any application for assistance from the fund. Any Virginia real property owner who did not possess a valid operation permit for the onsite sewage system's installation or who operated the onsite sewage system without a valid permit will not be entitled to assistance from the fund.

E. In issuing a construction permit pursuant to § 32.1-163.5 of the Code of Virginia, the Department of Health will not assume liability for actions and decisions made by private parties.

F. The fund will not reimburse any Virginia real property owner more than $30,000 for an onsite sewage system failure or component thereof.

G. In the event the fund is insufficient to meet requests for payment, the creation of the fund shall not be construed to provide liability on the part of the department or any of its personnel where no such liability existed prior to July 1, 1994.

H. Before payment or assistance is disbursed, the Virginia real property owner must:

1. Submit an application to repair the sewage system or components thereof to the local health department in the city, county, or town where the property is located.

2. Receive a repair permit from the local health department.

3. Complete the requirements in the repair permit and receive an operation permit unless exempted by 12VAC5-612-50.

4. Sign the required release and hold harmless agreement.

FORMS (12VAC5-612)

Release and Hold Harmless Agreement, IF (eff. XX/XX).

Application for Indemnification, IF 2 (eff. XX/XX).

Certification Statement:

I certify that this regulation is full, true, and correctly dated.

_____ (Signature of certifying official)

Name and title of certifying official:_____

Name of agency:_____

Date:_____

COMMONWEALTH of VIRGINIA
*Department of Health*
P O BOX 2448
RICHMOND, VA 23218
TDD 1-800-828-1120

# Application for Indemnification

Mail this completed application by certified mail to the Commissioner of Health, care of the Division of Onsite Sewage and Water Services, 109 Governor Street, 5th Floor, Richmond, Virginia 23219.

Owner(s): _____ Email: _____
_____ _____

Present Address: _____ Phone: (home) _____
_____ (work) _____
_____ (cell) _____

1. Provide a legal description of the property where the sewage system failed. In what county was the failed sewage system located? _____
_____
_____
2. Do you still own the property where the sewage system failed? _____ If NO, what date did you sell the property? ____
   List the current property owner's name, address, and phone number: _____
3. What is the date that the contractor installed the sewage system? _____.
4. What is the date that the health department approved the sewage system (issued an Operation Permit)? _____.
5. What is the date that you filed an application to repair the failed system with the local health department? _____.
6. What is the date that you received a notice from the health department indicating that the sewage system had apparently or actually failed? _____.
7. If known, what is the household's average daily water use? _____ gallons per day (GPD). If available, attach copy of previous 12 months of water use records.
8. Did the owner properly operate and maintain (O&M) the failed sewage system as required by the system's designer and/or the manufacturer? _____ If YES, attach the requirements. If NO, describe the O&M done.
_____
_____
9. List the date(s) that you made or hired a contractor to make repairs to the failed sewage system, describe what the repairs were on each date, and list the itemized cost for repairs on each date. Attach copy of receipts and invoices.

| Date of Repair | Describe the repair(s) | Cost of Repair |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

10. Has the local health department approved all of the repairs? _____ If YES, when did the local health department issue an operation permit for the repairs: _____ If NO, why not? _____

11. If you installed a new sewage system to replace the one that failed, has the local health department issued an operation permit for the new system? _____ How much did you pay to install the new system? _____ (Attach copy of receipts, invoices, canceled checks, bills of sale to substantiate the amount paid for a new system)

## Optional questions to help evaluate your claim:

12. What was the cost of the failed system? _____ Attach a copy of receipts, invoices, bills of sale, and canceled checks to substantiate the cost.

13. Was the failed sewage system installed in the correct location? _____ If NO, describe where it was located. If available, attach survey plat showing owner's house and the location of the sewage system. _____

_____

_____

14. Was the failed sewage system installed correctly? _____ If No, please describe what defects were present:

_____

_____

15. Did the site and soil conditions comply with the regulations where the contractor installed the failed sewage system? If NO, please describe how the soil conditions did not comply. _____

_____

_____

16. What specific actions by the health department do you believe caused the system to fail within three years of its construction date?

_____

_____

All information included with this application is true and complete to the best of my knowledge. I hereby give permission for Virginia Department of Health to enter on the above described property for the purpose of processing this application and investigating this claim.

Sign: _____ _____
(owner) (Date)

_____ _____
(owner) (Date)

This RELEASE, HOLD HARMLESS, and INDEMNIFICATION AGREEMENT is made and entered into this _____ Day of _____, 2007, by and between _____, their HEIRS, SUCCESSORS, DEVISEES, AGENTS, ASSIGNS, REPRESENTATIVES and INTERESTS (hereinafter the "Owners") and the COMMONWEALTH OF VIRGINIA, acting through the Department of Health, including, without limitation, any and all of its agencies, boards, and commissions, her insurer(s), officers, directors, employees, representatives, and agents, (hereinafter the "COMMONWEALTH OF VIRGINIA").

WHEREAS, Owners hold good title to a single family residence lying in _____County at _____, (hereinafter the "Residence"); and,

WHEREAS, Owners received a construction permit from the local health department to install an onsite sewage system; and,

WHEREAS, Owners installed the onsite sewage system in accordance with the construction permit on or about _____; and,

WHEREAS, Owners received a permit to operate the onsite sewage system on or about _____; and,

WHEREAS, Owners notified the local health department that the onsite sewage system for the Residence failed in _____, within three years of its construction date; and,

WHEREAS, Owners requested assistance from the Onsite Sewage Indemnification Fund (hereinafter the "Fund", § 32.1-164.1:01 of the Code of Virginia) administered by the Department of Health; and,

WHEREAS, the State Health Commissioner determined that Owners qualify for reimbursement from the Fund; and,

WHEREAS, Owners are the only persons entitled to reimbursement from the Fund; and,

WHEREAS, the Commissioner and Virginia Department of Health desire to protect public health and the environment and to resolve all matters in dispute, now and in the future with Owners,

NOW, THEREFORE, in exchange for the mutual promises contained herein, the COMMONWEALTH OF VIRGINIA and Owners agree as follows: That for and in consideration of $_____ (thousand dollars and cents) paid from the Fund, the Owners agree to, and hereby do, release and hold harmless the COMMONWEALTH OF VIRGINIA, from any and all claims, complaints, demands, actions, causes of action, liabilities and obligations, of whatever source or nature, whether administrative, legal or equitable, whether known or unknown, which Owners now have or will have in the future relating to or arising from the onsite sewage system that failed and which is the basis for reimbursement, including, without limitation, any and all claims due to the failure of any person to comply with federal, state, or local laws or regulations, claims under the Virginia Tort Claims Act, the Virginia Constitution, the United States Constitution and amendments thereto, or under common law. Furthermore, Owners expressly release and hold harmless the COMMONWEALTH OF VIRGINIA from any and all further claims, actions, causes of action, or obligations under the Fund related to the onsite sewage system that failed and which is the basis for reimbursement.

Owners also agree to indemnify and hold harmless the COMMONWEALTH OF VIRGINIA for any sum of money or judgment against the COMMONWEALTH OF VIRGINIA, as well as costs and reasonable attorney fees incurred in the defense of any action arising out of or related to the onsite sewage system that failed and which is the basis for reimbursement.

Severability. If any portion of this Agreement is held to be void or deemed unenforceable for any reason, the remaining portion shall survive and remain in effect, unless the effect of such severance shall defeat the parties' intent as set forth herein, with the parties asking the Court to construe the remaining portions consistent with the expressed intent of the parties.

Entire Agreement. Owners acknowledge that they may consult with an attorney concerning their rights and obligations, that they have been given time and opportunity to consider the Agreement with the COMMONWEALTH OF VIRGINIA, that they have read this Agreement, that they fully understand and agree to its terms and conditions, and that there exists no other promises, representations, inducements or agreements related to this Agreement, except as specifically set forth herein, and that this constitutes the entire agreement between Owners and the COMMONWEALTH OF VIRGINIA.

Accepted:

Date_____ _____(SEAL)
(Owners)

Accepted:

Date_____ _____(SEAL)
Program Manager for the Fund
Virginia Department of Health

COMMONWEALTH OF VIRGINIA

CITY / COUNTY OF _____.

The foregoing instrument was signed and acknowledged before me this day of _____, 2007, by _____.

Notary Public

My Commission expires:

Virginia
Regulatory
Town Hall

townhall.virginia.gov

# Final Regulation
# Agency Background Document

| | |
|---|---|
| **Agency name** | Board of Health (Virginia Department of Health) |
| **Virginia Administrative Code (VAC) citation** | 12 VAC 5-650 |
| **Regulation title** | Schedule of Civil Penalties |
| **Action title** | New regulation establishing a uniform schedule of civil penalties for violations of onsite sewage and alternative discharging sewage treatment system regulations. |
| **Date this document prepared** | October 23, 2009 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) 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. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.*

This regulation establishes a uniform schedule of civil penalties for violations of the Board of Health's (Board) regulations pertaining to conventional and alternative onsite sewage systems (12VAC5-610 or successor), and for violations of the Board's regulations pertaining to alternative discharging sewage treatment systems for individual single family homes (12VAC5-640 or successor).

## 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.*

The Board, at its meeting on October 23, 2009, approved the final adoption of the Schedule of Civil Penalties.

## 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.*

---

1) Code of Virginia § 32.1-164.J (2007 Acts of Assembly, Chapter 514); 2) Board of Health/Department of Health (Department); 3) mandatory.

## 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.*

---

1) The regulation, while fulfilling specific statutory requirements, will allow the Department to employ civil penalties to enhance existing regulatory programs for supervising and controlling the safe and sanitary treatment and disposal of sewage. 2) Currently, the Department may ask for criminal penalties (Class I Misdemeanor), may initiate civil proceedings, and may collect civil charges only with the consent of the affected party. Under the final regulation, the Department may charge civil penalties in amounts that are relatively small in comparison to existing penalties. The goal of the regulation is to enhance the Department's ability to protect public health and the environment by providing an enforcement tool that may be scaled to match the seriousness of a violation.

## 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.*

---

The regulation specifies uniform penalties for violations of the Board's regulations. The penalty for any one violation may not exceed $100 for the initial violation, $150 for each additional violation. Each day during which a violation is found to exist will constitute a separate offense, however violations arising from the same set of operative facts may not be charged more than once in any 10-day period. A series of violations arising from the same set of operative facts may not result in civil penalties exceeding a total of $3,000. The Department may not charge civil penalties in cases where an unoccupied structure does not contribute to pollution of public or private water supplies or to the contraction or spread of disease. The Department may pursue other remedies as provided by law, however civil penalties must be in lieu of criminal penalties except where a violation contributes to or is likely to contribute to the pollution of public or private water supplies or the contraction or spread of disease. The Department may issue a civil summons ticket as provided by law for a scheduled violation.

## 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.*

---

1) The primary advantage to the public comes from improving the Department's ability to protect citizens and the environment from the harmful effects of sewage. As the number of alternative onsite sewage systems in the Commonwealth continues to increase, citizens, local governments, regulators, and onsite sewage professionals agree that ongoing operation, maintenance, and monitoring of these systems is essential to assure that they function properly. When these systems are not properly maintained and operated, they may discharge untreated or partially treated sewage directly into the Commonwealth's ground and surface waters. The Board's regulations and policies increasingly require owners of alternative onsite sewage systems to perform certain activities, such as monitoring inspections and maintenance, to assure that systems are operating properly. The ability to assess civil penalties, as an alternative to criminal enforcement, is a more effective enforcement strategy to employ in such a "performance-based" regulatory program. A disadvantage, expressed by some in the regulated communities, is that Department staff may misuse or abuse the new penalties.
2) Civil penalties will improve the Department's ability to enforce the Boards regulations by providing another enforcement tool. Existing statutes provide for enforcement actions via the Administrative Process Act (APA) such as informal fact-finding conferences to make case decisions, e.g., permit suspension, revocation, the issuance of orders by the Board, civil actions in circuit courts, and criminal actions. These are relatively "heavy" actions that are appropriate in some cases. Currently, civil charges can only be collected with the consent of the affected party and are employed in conjunction with a consent order. Properly used, civil penalties can be viable alternatives when existing enforcement tools are too heavy-handed for many routine enforcement actions. Civil penalties are not intended to be punitive, but are intended to encourage compliance with environmental health regulations before a situation deteriorates to the point that heavier enforcement is warranted. A disadvantage to the agency will be the perceived drains on agency staff and resources required to implement the new civil penalties.
3) Civil penalties are particularly critical for managing the onsite sewage and alternative discharging sewage system programs. Several local governments have enacted ordinances requiring operation and maintenance of alternative onsite sewage systems. The Department is currently developing new regulations for the Board that will require routine monitoring, maintenance, and reporting for alternative onsite systems. These are already required in the alternative discharging system program. Typically, an owner is responsible for maintaining a contract with a private-sector provider to perform routine inspections, tests, and maintenance. The owner (or the provider) must forward inspection reports and test results to the Department. Criminal or other "heavy" enforcement actions are not appropriate for situations such as the failure to submit a report or keep a maintenance contract in effect. Civil penalties will provide options for the Department to scale its enforcement actions to the seriousness of a particular situation. The Department will develop administrative guidelines for implementing the civil penalties. These guidelines will seek to assure the penalties are not abused or misused by staff.

## 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.*

---

No changes have been made to the text of the regulation since publication of the proposed stage.

| Section number | Requirement at proposed stage | What has changed | Rationale for change |
|---|---|---|---|
| NA | | | |

## 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 |
|---|---|---|
| Sandra Gentry | **Define "modify" as it applies here**<br><br>The proposed text states that it will be a violation to "modify or cause to modify... an onsite or alternative discharging sewage system without a permit." What constitutes modification of a system? This needs to be defined. If it is already defined in other regulations, a reference needs to be made to this definition.<br><br>At what level is a permit required? Some may consider replacing a pump with another brand of pump or a float switch with another type to be a modification. Changing the timing of a distribution box or replacing that box if it has been damaged or replacing a control panel with another brand may be modification of the system. Without definite guidelines as to what can be done without a permit, those contractors who repair or maintain systems may be left wondering if their work could result in penalties. | The *Sewage Handling and Disposal Regulations* ( 12VAC5-610, the "SHDR") require a person to obtain a permit for "the…expansion or modification of a sewage disposal system." The Schedule of Civil Penalties applies to activities conducted under the SHDR (see § 30.B). For that reason, the interpretation of the permit requirements for system "modifications" will be the same as it is currently under the SHDR. The term is not defined in the SHDR, and is, therefore, subject to interpretation by the agency and any reviewing body such as a hearing officer or a court. The agency specifically did not propose a regulatory definition in the Schedule of Civil Penalties because it believes that preserving discretion in this area increases regulatory flexibility. Some activities that might not be considered "modifications" with one type of onsite system may clearly constitute "modifications" with another type or size of onsite system. If additional guidance is necessary in the future on this issue, the agency will provide such guidance either by amending the Schedule of Civil Penalties or through appropriate guidance document(s). |

## 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.*

No changes are proposed.

| Current section | Proposed new section | Current requirement | Proposed change and rationale |
|---|---|---|---|

| number | number, if applicable | | |
|---|---|---|---|
| NA | | | |

## Regulatory flexibility analysis

*Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

Because of the statutory requirement to establish a uniform schedule of civil penalties, the agency has not considered other methods.

## Family impact

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

The new regulation will have little direct impact on families in the Commonwealth. The action, by offering an alternative to existing criminal and civil enforcement, may encourage economic self-sufficiency and the assumption of responsibility on the part of regulated persons. The action is intended to improve the Department's enforcement capabilities, particularly in the area of operation and maintenance of alternative onsite sewage systems. As such, the agency expects that its efforts to protect public health and the environment (ground and surface water quality) will be improved and that families will benefit from a safer environment. The regulation will have a direct, short-term financial effect on a family that is in violation if a civil penalty is charged. This impact, however, should be balanced against the likelihood that in such cases a civil penalty will be in lieu of a potential criminal charge. Any civil penalties collected will be credited to the newly created Environmental Health Education and Training Fund. This fund is to be used to support training for private- and public-sector individuals in all areas of Environmental Health and may be used for research to improve public health and for protection of the environment. Family members may benefit directly from the improved availability of educational and training opportunities and indirectly from improved environmental and public health protection.

**Project 1522 - NOIRA**

**DEPARTMENT OF HEALTH**

**New regulation establishing a uniform schedule of civil penalties for violations of**

CHAPTER 650

STATE BOARD OF HEALTH SCHEDULE OF CIVIL PENALTIES

**12VAC5-650-10. Schedule of Civil Penalties for Onsite and Alternative Discharging Systems.**

**12VAC5-650-20. Definitions.**

The following words and terms used in this chapter have the following meanings unless the context clearly indicates otherwise:

"Board" means the State Board of Health.

"Department" means the Virginia Department of Health.

"Transportation of sewage or septage" means actions associated with removing septage, sludge, or sewage from an onsite sewage system, a sewerage system or other treatment works, including, but not limited to, using a pump or other device or gravity flow to collect septage, sludge, or sewage in a tank or other vessel intended to contain the septage, sludge, or sewage during transport to another location.

**12VAC5-650-30. Purpose and authority.**

The Board has promulgated this chapter to:

1. Establish a uniform schedule of civil penalties for violations of 12VAC5-610, the Sewage Handling and Disposal Regulations (or successor), and 12VAC5-

640, the Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings (or successor);

2. Support enforcement activities necessary to discharge the Board's responsibility to supervise and control the safe and sanitary collection, conveyance, transportation, treatment, and disposal of sewage as they affect the public health and welfare;

3. Support enforcement activities necessary to discharge the Board's responsibility to exercise due diligence to protect the quality of ground and surface waters; and

4. Guide the State Health Commissioner in charging civil penalties.

**12VAC5-650-40. Applicability.**

A. This Chapter applies only in those localities where the local government has entered into a contract with the Department for the operation of local and district health departments. It does not apply in any locality that has not entered into such a contract.

B. This chapter applies to those activities conducted pursuant to 12VAC5-610 and 12VAC5-640 or successor regulations promulgated by the Board as described herein. Except as provided in Va. Code § 32.1-164.J, this Chapter may not be construed to limit the Board's or the Commissioner's authority to enforce any law or regulation administered by the Board or to enforce any Order of the Board.

**12VAC5-650-50. Administration.**

This Chapter is administered as follows:

A. The Board has the responsibility to promulgate, amend, and repeal regulations necessary to ensure the safe and sanitary handling and disposal of sewage via onsite

sewage systems and alternative discharging sewage systems as these affect public health. Nothing in this Chapter may be construed to limit the Board's authority to enforce any law administered by it, any regulation promulgated by it, or any case decision rendered by it or by the Commissioner.

B. The State Health Commissioner is the chief executive officer of the Department. The Commissioner has the authority to act, within the scope of regulations promulgated by the Board, for the Board when it is not in session. The Department is designated as the primary agent of the commissioner for the purpose of administering this chapter. The Commissioner may delegate his powers under this chapter.

C. Va. Code § 32.1-30 requires each county and city to establish and maintain a local department of health which is responsible for enforcing all health laws of the Commonwealth and regulations of the Board. With the concurrence of each county and city government affected, the Commissioner may create a district health department composed of such local health departments. The Commissioner appoints the local or district health director in those localities that enter into a contract with the Department for the operation of the local or district health department. In such localities the local or district health director is responsible for implementing this chapter. The authority to implement this Chapter is hereby delegated to local and district health directors who are employees of the Department; such local and district health directors may delegate to subordinates as they deem necessary. Nothing in this section may be construed as limiting the Commissioner's authority to delegate his powers as provided in law.

**12VAC5-650-60. Conduct declared unlawful.**

The following conduct is hereby declared unlawful and subject to civil penalties in accordance with this Chapter:

1. Violation of any provision of 12VAC5-610, the Sewage Handling and Disposal Regulations or successor regulation promulgated by the Board, including failure to comply with the provisions, requirements, conditions, or standards contained in a construction permit or in an operating permit.

2. Violation of any provision of 12VAC5-640, the Alternative Discharging Sewage Treatment Regulations for Individual Single Family Dwellings or successor regulation promulgated by the Board, including failure to comply with the provisions, requirements, conditions, or standards contained in a construction permit or in an operating permit.

3. Failure to comply with any order issued by the Board or Commissioner.

**12VAC5-650-70. Uniform schedule of civil penalties.**

A. There is hereby established a uniform schedule of civil penalties for the following violations of the Board's regulations:

1. Install or cause to install, modify or cause to modify, use or operate an onsite or alternative discharging sewage system without a permit issued by the Commissioner- $100.00 for the first violation, $150.00 for each additional violation.

2. Discharge treated or untreated sewage on the surface of the ground or into the waters of the Commonwealth without a permit- $100.00 for the initial violation, $150 for each additional violation.

3. Fail to obtain or keep a contract for operation, maintenance, or monitoring of an onsite or alternative discharging system to the extent that such contract is a requirement of the Board's regulations - $50.00 for the initial violation, $100.00 for each additional violation.

4. Fail to submit to the Department a laboratory test result, or an inspection or other report to the extent that such report is a requirement of the Board's regulations- $50.00 for the initial violation, $100.00 for each additional violation.

5. To the extent such activities are not regulated by another agency of the Commonwealth, engage in unlawful transportation or handling of sewage or septage- $100.00 for the initial violation, $150.00 for each additional violation.

6. Any unlawful act described in 12VAC5-650-60 not specifically described in this subsection- $25.00 for the initial violation, $50 for each additional violation.

B. The Department may not charge civil penalties pursuant to this chapter for activities related to land development.

C. The Department may not charge civil penalties pursuant to this chapter for an unoccupied structure unless such structure contributes to the pollution of public or private water supplies or the contraction or spread of infectious, contagious, or dangerous diseases.

**12VAC5-650-80. Criminal prosecution precluded.**

In accordance with Va. Code § 32.1-164.J designation of a particular violation for a civil penalty pursuant to this chapter must be in lieu of criminal penalties, except for any violation that contributes to or is likely to contribute to the pollution of public or private water supplies or the contraction or spread of infectious, contagious, or dangerous diseases.

**12VAC5-650-90. Civil summons ticket.**

A. The Department must prepare a civil summons ticket for use in implementing this chapter.

B. In addition to any information the Department deems necessary, the ticket must contain the following information:

1. A statement notifying the recipient that he may make an appearance in person or in writing by mail to the Department prior to the date fixed for trial in court;

2. A statement that any person so appearing may enter a waiver of trial, admit liability, and pay the civil penalty established for the offense charged;

3. The physical address and hours of operation and the mailing address for the local or district health department responsible for issuing the civil summons;

4. A statement that civil penalties may be paid only by cashier's check or certified check made payable to the Treasurer of Virginia;

5. The date fixed for trial in general district court.

**12VAC5-650-100. Authority to issue civil summons ticket; penalties collected.**

A. Any employee of the Department who has been delegated authority pursuant to this chapter may issue a civil summons ticket in accordance with this chapter.

1. The civil summons ticket may be delivered in person after presentation of proper credentials.

2. The Department may deliver a civil summons ticket in any other manner provided by law.

B. All civil penalties collected pursuant to this chapter shall be credited to the Environmental Health Education and Training Fund established pursuant to Va. Code § 32.1-248.3.

**12VAC5-650-110. Requirements for civil summons ticket.**

A. Before the Department may issue any civil summons ticket pursuant to this chapter, the following must occur:

1. The Department shall notify the alleged violator as required in the Board's regulations;

2. At least thirty days shall have passed from the date the alleged violator received notice of the violation; and

3. The violation must remain uncorrected.

B. Violations arising from the same operative set of facts shall not be charged more than once in any 10-day period nor shall the Department charge more than one civil penalty from the same set of operative facts.

Certification Statement:

I certify that this regulation is full, true, and correctly dated.

_____ (Signature of certifying official)

Name and title of certifying official:_____

Name of agency:_____

Date:_____