Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Department of Health (State Board of)
VAC Chapter Number:	12 VAC 5-380 (to be repealed) 12 VAC 5-381 (proposed)
Regulation Title:	Regulations for the Licensure of Home Care Organizations
Action Title:	Repeal of 12 VAC 5-380 Promulgation of 12 VAC 5-381
Date:	May 31, 2000

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

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

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

The regulation is promulgated under the authority of Title 32.1 of the Code of Virginia (Code), specifically: Section 32.1-162.9 provides that "no person shall establish or operate a home care organization without a license issued pursuant to [Article 7.1 of Chapter 5 of Title 32.1 of the Code] unless he is exempt from licensure pursuant to Section 32.1-162.8 through Section 32.1-162.10 of the Code authorizes the State Health Commissioner to cause each home care organization licensed under this article to be periodically inspected at reasonable times." Section 32.1-162.12 of the Code authorizes the Board to Aprescribe such regulations governing the activities and services provided by home care organizations as may be necessary to protect the public health, safety and welfare.

Article 7.1 of Chapter 5 of Title 32.1 of the Code, specifically sections 32.1-162.9, 32.1-162.8, and 32.1-162.10, are available through the Virginia Department of Legislative Services LIS web site (http://leg1.state.va.us/lis.htm).

The proposed regulation does not exceed federal minimum requirements. The Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the proposed regulation is to protect and promote public health, safety and welfare through the establishment and enforcement of regulations which set minimum standards for the operation of organizations providing home-based care. The intent of the regulation is to provide the necessary consistency in the provision of home health care services in order to promote health, safety and adequate care of patients receiving home care services and to assure safe, adequate and efficient home care organization operation. In addition, the purpose of the regulation is to assure quality health care through appropriate review and inspection while

protecting the right to privacy of patients without unreasonably interfering with the provision of that care.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

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

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 include a sentence to that effect.

The health and safety of the public are safeguarded through a regulatory program governing the activities of persons establishing or operating an HCO. Because of the vulnerability of individuals receiving services from an HCO, regulatory oversight of home health services is an important governmental function. The licensure program provides a low cost quality program that assures the public that HCO providers are maintaining quality assurance standards.

The existing regulation governing HCOs has not been revised since first promulgated in 1990. Since then, the General Assembly has made modifications to the entire section of the Code, Article 7.1 of Chapter 5 of Title 32.1 (ə 32.1-162.7 et seq.), pertaining to home care organizations. In addition, the home-based health care industry has evolved and expanded. Responsible for implementing the medical care facilities and services regulatory program, the Department recognized the need to update the regulation to be more reflective of the changes that have occurred in the last several years.

The Department, in collaboration with a diverse group of individuals, has been working to replace the existing regulation with those that it is now proposing. The approach used in developing the proposed regulation was to strive for simplicity and to avoid being burdensome, while meeting the requirements of the law. The primary advantage to the public as a result of that effort is the enhancements made to the regulation, which include:

1. Deleting the medical supplies and medical appliance section of the current regulation and establishing a personal care services section, a result of changes in the Code;

2. Adding the requirement for criminal record clearance for any compensated employee, a result of changes in the Code;

3. Including home visits to patients as part of the licensing inspection;

4. Expanding the geographic service areas for home care organizations utilizing the statewide planning districts;

5. Instituting quality improvement assessment indicators;

6. Coordinating standards, thereby eliminating contradictions, with federal certification (Medicare/Medicaid) requirements;

7. Updating the insurance and medical record criteria to reflect correct practices;

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

9. Reorganizing the regulation into an user-friendlier format. The new arrangement is logical and orderly, facilitating use of the regulation.

In 1991, the General Assembly modified the definition of home acre organization to include personal care services. As a result, personal care service requirements were broadened in the proposed regulation to include the qualifications for a personal care aide and the services that can be performed by a personal care aide. Additional adjustments include restructuring the fees charged for licensure (see discussion below) and changing the descriptive name from home "health" to home "care" to reflect the statutory name of the entity to be licensed.

The Department licenses 75 HCOs located statewide. The regulation governs the licensure of HCOs unless they are specifically exempt from licensure under ə 32.1-124 of the Code. Currently, there are more than 225 home health agencies certified under Medicare that are exempt from state licensure, i.e., they do not have to maintain state licensure. This is an important distinction to make in any discussion on the impact of state licensure regulations on home health agencies.

To determine the readiness of the proposed regulation for the public approval process and gauge its impact on the licensed entities, the Department circulated a preliminary draft of the document to all licensed entities and interested parties. In addition, copies of the proposed regulation were obtained by the federally certified (Medicare) agencies. Of the more than 100 preliminary draft copies sent out by the Department, ten responses were received. Four responses were received from licensed organizations, six from interested parties. An additional eighteen responses were received from the federally certified agencies. Since all the federally certified agencies were exempt from state licensure, and thereby not subject to the requirements of licensure, those comments were not given as much weight when determining their impact on the proposed regulation as those respondents who are directly impacted by the regulation, i.e., the licensed entities. The Department, therefore, concluded that the low response rate (four out of 75 possible responses) from the licensed entities indicates the general acceptance of the regulation as proposed. Two items did, however, elicit comment: (i) implementing a requirement that a patient's primary care physician be licensed in Virginia, and (ii) establishing service areas based on the statewide planning districts.

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

A major benefit to the Commonwealth will involve changes to the service areas. The existing regulation has a service area requirement that the Department recognized as too restrictive and limiting in its scope as it had been implemented. Therefore, a goal of the revision process was to determine another avenue for defining service areas. The Department firmly believes that service area boundaries are an integral part of ensuring quality of care to home bound patients by ensuring that an HCO does not "take on" patients to whom they cannot provide emergency treatment within a reasonable amount of time. Under the current regulation, service areas are defined as "geographically limited to the county or independent city in which that agency's office is located and the counties and/or independent cities immediately contiguous to that location."

The premise of home care is unique from other health care services. The services are brought to the location of the patient, in this case the patient's residence, unlike most other health care situations in which the patient goes to the service location, i.e., doctor's office or hospital. The problem the Department faced in determining the new service area requirements was to provide service area boundaries that addressed the desires of licensed entities to promote and expand their business, while maintaining geographic control essential to ensure quality patient care services. The subject of service areas was discussed during advisory committee meetings. The Department took under consideration the service areas prescribed by sister states and the federal government, the metropolitan statistical areas, and a travel distance for staff from the office to residence as possible determinates for service areas. After further scrutiny, however, it was determined that none of these options was a workable solution in Virginia. In particular, the Department did not favor adopting the system in place for federal certification as that system was acknowledged to be vague and subject to interpretation. Rather than divide the state yet again to establish viable service areas, the Department determined to utilize the planning districts that have been in place since 1970s.

The department believes that by utilizing the planning districts, the licensed entities and consequently the patients they provide care to, benefit in two ways. The established planning districts expand the geographic areas and potential patient base for the home care organization, while providing the potential to economize on office administration and overhead. That is, the patient base would expand, however licensed entities would not have to open additional offices to service those patients as is now required, unless the patient resides across a planning district boundary. At the same time, the planning districts also address the Department's concern that HCOs must be able to appropriately address patient care needs. The comments received in

opposition to using the planning districts as service area boundaries were received from federally certified agencies.

However, their objection that the planning districts would unfairly restrict business is not based on fact. In adopting the planning districts as home care service areas, the Department does not prohibit an HCO from crossing planning district lines to serve patients. However, in order to do so, the HCO would have to establish an office in the respective planning district; not unlike what is now required. The planning districts provide a larger geographic area for HCOs to operate prior to the need for opening and staffing additional offices. The Department does acknowledge, however, that there may be some initial disruption for some HCOs as they adjust to the service areas defined by the planning districts. To accommodate this change, the Department determined that an accommodation period would be needed for HCOs to comply with the requirement. Therefore, HCOs subject to state licensure will have a year from the effective date of the regulation to comply with the new requirement. In addition, the proposed regulation provides HCOs with the ability to request a variance identifying the special hardship if required to comply with the requirement. The Department could authorize a variance, either temporarily or permanently, provided the HCO satisfactorily proves that safety, patient care and services were not adversely affected.

The Department employs seven full-time inspectors to conduct the annual licensure inspections of HCOs, process Medicare certification for more than 225 agencies, investigate complaints filed against HCOs, and conduct the hospice licensure and certification program. State general funds and licensure service fees fund the annual HCO licensure program. Licensure service fees, established in 1990, average $17,000 annually. The average cost of an inspection survey is $1,500. Therefore, it has become necessary to increase certain fees and establish new fees to better support the cost of the program, thus relieving taxpayer burden via the General Fund.

To accomplish this, the existing fee structure, based on an organization's annual budget, was restructured. The proposed fee structure is based on the potential for action required by the Department regarding an organization's licensure status, i.e., issuing initial and renewal licenses, responding to requests for a modification to, or an exemption from, licensure. Since no comments related to the proposed fee structure were received, the Department concludes the proposed fees do not create an added burden to the licensed entities. While the Department anticipates that enforcement of the regulation requires no more inspection staff at present, future revisions to the Code could very likely result in the need for additional staff and a corresponding need for additional increases in licensure fees.

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

No particular locality is affected more than another by this regulation. There are no disadvantages to the public, the Commonwealth, or the HCOs as a result of the proposed regulation. Every effort has been made to ensure the regulation protects the health and safety of patients receiving home care services while allowing providers to be more responsive to the

needs of their patients. Failure to implement the regulation would cause the current regulation, which is outdated and not reflective of the industry today, to remain in effect.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

State General Funds (0100) and licensure service fees fund the annual HCO licensure program. Licensure service fees average $17,000 annually. In 1999, the program budget was $150,000; Program/subprogram: 561/03. In 1999, the cost of the licensure program was $150,000. The average cost of an inspection is $1500. The proposed new fees are: $500 for each initial and renewal license; $250 for each re-issuance request; $50 for late renewal applications; and one time processing fee of $75 for each exemption from licensure. These fees are nonrefundable.

There is no projected cost to localities unless the locality is an HCO licensee. HCOs, small businesses and organizations doing business with the HCO will be affected by the proposed regulation. Approximately 75 HCOs will be affected.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

Because of the comprehensive revision to the regulation, it is necessary to repeal the current regulation as the proposed regulation is promulgated. Generally speaking, the current regulation (12 VAC 5-380) was not logically organized. An objective of the revision project was to reorganize the regulation into an user-friendlier format. As a result, sections were logically moved within the document, some section titles were amended to better reflect section content, twenty-eight sections were combined, and eight sections were added. The proposed regulation is logical and orderly, facilitating use of the regulation. The specific changes are as follows:

12 VAC 5-380-10 was not reflective of the proposed regulation; therefore definitions were modified, deleted or added as needed to reflect proposed document (12 VAC 5-381-10 Definitions).

12 VAC 5-380-20 was not adequate to properly inform applicants of the administrative requirements for licensure as a home care provider. Sections (12 VAC 5-381-20 Responsibility of the department; 12 VAC 5-381-40 Exemption from licensure; 12 VAC 5-381-60 Modification of a license; 12 VAC 5-381-110 Variances; 12 VAC 5-381-120 Revocation or suspension of a

license; 12 VAC 5-381-130 Surrender of a license) were added and logically realigned to facilitate use of the regulation. The language was updated and ambiguities were removed. However, the text of the new sections does not indicate new requirements, but defines long-standing agency practice.

12 VAC 5-380-30 contained fees that are not adequate to cover the costs of the licensing program. Therefore, fees were restructured to better support the cost of the program. The proposed fee schedule (12 VAC 5-381-70 Licensing fees) will result in less draw from the General Fund to cover the cost of the program.

12 VAC 5-380-40 was not adequate to properly inform applicants of expectations as a licensed home care provider. Sections (12 VAC 5-381-30 License; 12 VAC 5-381-140 Management and administration) were added and logically realigned to facilitate use of the regulation. The language was updated and ambiguities were removed. The new text does not indicate new requirements, but defines long-standing agency practice. However, the current requirements for service areas were recognized as too restrictive and limiting in scope. Therefore, new service areas were defined, utilizing the established planning districts, thereby expanding the geographic areas and potential patient base while permitting administrative control.

12 VAC 5-380-50, 60, 70 were not adequate to properly inform applicants of expectations as a licensed home care provider and were eliminated. Requirements were incorporated into the proposed single section (12 VAC 5-381-50 Licensing process).

12 VAC 5-380-80 was not adequate to properly inform applicants of administration program requirements or expectations. Sections were added (12 VAC 5-381-80 On-site inspections; 12 VAC 5-381-100 Complaint investigation) and logically aligned to facilitate use of the regulation. The language was updated and ambiguities were removed.

12 VAC 5-380-90 was eliminated, requirements were incorporated into proposed single section (12 VAC 5-381-80 On-site inspections).

Current regulation does not provide a mechanism for VDH staff to interview individuals receiving the services of the organizations. Therefore, investigations were restricted. A new section (12 VAC 5-381-90 Home visits), based on federal regulation, provides a requirement for obtaining patient feedback regarding the services they receive from the organization.

12 VAC 5-380-100 and 12 VAC 5-380-110 were eliminated. Requirements incorporated into proposed single section (12 VAC 5-381-150 Governing body).

12 VAC 5-380-120 was modified to reflect the language of the law, see 12 VAC 5-381-200 Insurance.

12 VAC 5-380-130 was logically realigned to facilitate use of the regulation. The language was updated and ambiguities removed to provide clarity, see 12 VAC 5-381-160 Administrator.

12 VAC 5-380-140 was logically realigned to facilitate use of the regulation. The language was updated and ambiguities removed to provide clarity, see 12 VAC 5-381-170 Written policies and procedures.

12 VAC 5-380-150 eliminated. Requirements realigned and incorporated into proposed sections (12 VAC 5-381-170 Written policies and procedures and 12 VAC 5-381-180 Financial resources).

12 VAC 5-38-160 was logically aligned. The requirements were modified to reflect industry standards. The language was updated and ambiguities removed to provide clarity. A criterion for criminal record check, as required by law, was added. See 12 VAC 5-381-190 Personnel practices.

12 VAC 380-170 eliminated. Requirements were incorporated into proposed single section (12 VAC 5-381-170 Written policies and procedures).

12 VAC 5-380-180 was logically realigned to facilitate use of the regulation. The language was updated and ambiguities removed to provide clarity. See 12 VAC 5-381-210 Contract services.

12 VAC 5-380-190 was modified to reflect industry and regulatory standards. Incorrect code citation was eliminated. Language was updated and ambiguities removed to provide clarity. See 12 VAC 5-381-240 Home care record system.

12 VAC 5-380-200 was modified to reflect industry standards. The language was updated and ambiguities removed to provide clarity. See 12 VAC 5-381-220 Patient rights.

12 VAC 5-380-210 modified to reflect current industry standards regarding provision and improvement of services offered to patients. The language was updated and ambiguities removed to provide clarity. See 12 VAC 5-381-230 Quality improvement.

12 VAC 5-380-220 eliminated. Requirements incorporated into proposed single section (12 VAC 5-381-240 Home care record system).

12 VAC 5-230 eliminated. Requirements incorporated into proposed single section (12 VAC 5-381-170 Written policies and procedures).

12 VAC 5-380-240 modified to reflect industry standards and quality of care expectations, contradictions with federal regulation were eliminated. The language was updated and ambiguities removed to provide clarity. See 12 VAC 5-381-250 Home care services.

12 VAC 5-380-250 and 12 VAC 5-380-260 incorporated into proposed section (12 VAC 5-381-260 Nursing services). The proposed section is more reflective of industry practice and quality of care expectations.

12 VAC 5-380-270 retained. The language was updated and ambiguities removed to provide clarity. See 12 VAC 5-381-270 Licensed practical nurse.

12 VAC 5-380-280 modified to reflect industry standards, quality of care expectations, and eliminate contradictions with federal regulation. The language was updated and ambiguities removed to provide clarity. See 12 VAC 5-381-280 Home care aide services.

12 VAC 5-380-290 eliminated, requirements incorporated into proposed single section (12 VAC 5-381-210 Contract services).

12 VAC 5-380-300 eliminated. Requirements incorporated into proposed single section (12 VAC 5-381-280 Home care aide services).

12 VAC 5-380-310 was not reflective of home care law. Section was updated to reflect the law, current industry practice, and to eliminate contradictions with federal certification. The language was updated and ambiguities removed to provide clarity. See 12 VAC 5-381-320 Personal care services.

12 VAC 5-380-320, 330, 340, 350, 360, 370, 380, 390, 400 were repetitive and duplicative; therefore, sections eliminated. Requirements were incorporated into proposed single section (12 VAC 5-381-290 Therapy services) addressing therapy services. The language was updated and ambiguities removed to provide clarity.

12 VAC 5-380-410, 420, 430, 440, 450 eliminated. Requirements incorporated into proposed single section. The language was updated and ambiguities removed to provide clarity. See 12 VAC 5-381-300 Medical social services.

12 VAC 5-380-460, 470, 480, deleted, no longer subject to licensure. No replacement.

12 VAC 5-380-490, 500, 510, 520, 530, 540, 550, 560 eliminated. Requirements incorporated into proposed single section (12 VAC 5-381-310 Pharmaceutical services). Section was modified to reflect industry standard. The language was updated and ambiguities removed to provide clarity.

12 VAC 5-380-570, 580, 590, 600 were repetitive and duplicative of previous sections. Therefore, sections were eliminated. Requirements were incorporated into proposed single section (12 VAC 5-381-290 Therapy services).

Alternatives

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

The regulation is clearly and directly mandated by law. The proposed regulation honors the Department's statutory charge to protect public health and is the least burdensome alternative available for adequately carrying out the mandate of the law.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

No responses were received during the NOIRA comment period.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

One of the objectives of the revision of the current regulation was to clarify and eliminate ambiguous and outdated terminology and criteria. The proposed regulation is clearly written and understandable.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

Following adoption of the proposed regulation, it will be re-evaluated within three years to determine if it is continuing to meet its intended purpose. Mechanisms used for determining the continued effectiveness of the regulation will include: (i) any complaints received from service recipients, (ii) any variances to specific regulations requested by providers licensed under the regulation, and (iii) the Department's public participation process.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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 regulation does not directly impact the family unit in Virginia. However, it does impact those organizations desiring to provide home health care services to individuals in their place of residence. Indirectly, the proposed regulation will have a positive effect on those families

utilizing home health care services as it assures the necessary consistency in services provided by HCOs.

In addition, the regulation encourages the family unit to remain intact and reduces the financial burden to families by allowing for the provision of health care services in the home rather than the more institutional and expensive setting of a hospital or nursing home. Therefore, the proposed regulation does not erode the authority and rights of parents in the education, nurturing, and supervision of their children; discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, one's children and one's parents; it does not erode the marital commitment, and does not decrease a family's disposable income.

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