

**WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION**

Form #2

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2006 JUN 26 P 2:01

OFFICE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: Department of Health and Human Resources - OHFLAC TITLE NUMBER: 64

RULE TYPE: Hospice Licensure Rule CITE AUTHORITY: W. Va. Code 16-5I, et seq.

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 54

TITLE OF RULE BEING AMENDED: Licensure of Hospice Care Programs, West Virginia Department of Health and Human Resources Legislative Rules, 64 CSR 54, effective 1989

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 26, 2006 AT 10:30 am ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

Dr. Anita Barnhouse

John Wilkinson - BPH

OHFLAC

One Davis Sq., Ste 101

Charleston WV 25301

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

Martha Yeager Walker
Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

85.40

Summary of rule

This rule repeals and replaces the hospice licensure rule with the effective date July 1, 1989. It sets forth the requirements for hospices to be licensed in the state of West Virginia.

Statement of Circumstances which require the proposed rule

The hospice licensure rule has not been update since July 1, 1989. The proposed rule brings the licensing requirements for hospices in line with current practice and current Centers for Medicare and Medicaid Services regulations.

TITLE 64
LEGISLATIVE RULES
DEPARTMENT OF HEALTH

SERIES 54
HOSPICE LICENSURE RULE

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§ 64-54-1. General.

1.1. Scope - This legislative rule establishes general standards and procedures for the licensure of hospice programs in West Virginia.

1.2. Authority. - W. Va. Code §16-5I.

1.3. Filing Date. -

1.4. Effective Date. -

1.5. Repeal of Former Rule. - This legislative rule repeals and replaces Licensure of Hospice Care Programs, West Virginia Department of Health and Human Resources Legislative Rules, 64 CSR 54, effective 1989.

1.6. Applicability - This rule shall apply to any person, partnership, association or corporation and any local governmental unit or any division, department, board or agency thereof establishing, conducting, managing or operating a hospice. Compliance with the hospice standards herein shall be evaluated independently from compliance with other licensure standards. Sharing of staff, space, physical facilities and equipment or other components shall be permitted only if the requirements of each applicable rule are satisfied in full.

1.7. Enforcement - This rule is

enforced by the Secretary of the West Virginia Department of Health and Human Resources or his or her other lawful designee.

1.8. Purpose - The purpose of this rule is to ensure all West Virginia hospices conform to a common set of standards and procedures. All standards and procedures are minimum requirements whereby hospices may be surveyed and evaluated to ensure the health and safety of all patients treated in West Virginia hospices.

§ 64-54-2. Definitions.

2.1. Administrator - A qualified person who shall be a hospice employee and possesses education and experience as required by the hospice's governing body. The administrator reports to the governing body and is responsible for the day to day operation of the hospice.

2.2. Department- West Virginia Department of Health and Human Resources.

2.3. Director - The official designated by the Secretary of the West Virginia Department of Health and Human Resources as his or her designee unless otherwise specifically noted. This individual is the Director of the Office of Health Facility Licensure and Certification or his or her designee.

2.4. Governing Body - The designated persons assuming full legal authority and responsibility for the management of the hospice, the provision of all hospice services, its fiscal operations, and continuous quality assessment and performance improvement.

2.5. Hospice- A public agency or private organization or subdivision of either of these that is primarily engaged in providing care to terminally ill individuals.

2.6. Inpatient Hospice Facility- A hospice that provides inpatient care directly.

2.7. NFPA- National Fire Protection Association

2.8. Restraint- Any drug used as a restraint, manual method, physical or mechanical device, material, or equipment attached to the patient's body that he or she cannot easily remove and restricts freedom of movement or normal access to one's body.

2.9. Satellite Location- A location that provides hospice care and services within a portion of the total geographic area served by the hospice provider. The satellite location is part of the hospice and shares the same name, administration, and services in a manner that renders it unnecessary for the satellite location to independently meet the Centers for Medicare and Medicaid Services conditions of participation.

2.10. Secretary - The Secretary of the West Virginia Department of Health and Human Resources.

2.11. Terminally ill- An individual

who has a medical prognosis that his or her life expectancy is six months or less if the illness runs its normal course.

§ 64-54-3 State Administrative Procedures.

3.1. General Licensure Provisions

3.1.a. No person, partnership, association, corporation, or any local governmental unit or any division, department, board or agency thereof may operate a hospice, satellite location or inpatient facility in the State of West Virginia without first obtaining a license under this rule.

3.1.b. Neither an original nor a renewal license shall be issued under this rule for a project reviewable under W. Va. Code § 16-2D-1, *et seq.*, unless the State Health Planning and Development Agency has issued a finding, after a final conformance review, that the completed project conforms to the terms of the Certificate of Need decision issued for the project. Evidence of compliance shall be supplied with licensure applications.

3.1.c. A license shall be valid only for the premises and persons named and described in the application.

3.1.d. A license shall not be transferable or assignable.

3.1.e. A license shall be issued to applicants who are in compliance with the conditions of this rule, W. Va. Code § 16-51-1, *et seq.*, and the Hospice Conditions of Participation promulgated by the Centers for Medicare and Medicaid

Services.

3.1.f. A license shall be surrendered to the Director:

3.1.f.1. Upon written demand stating the cause for the demand; and

3.1.f.2. In the event the hospice ceases to provide services.

3.1.g. A proposed change of ownership, including a change in a controlling interest, must be reported to the Director a minimum of sixty (60) days prior to the change.

3.1.g.1. A new owner shall immediately apply for a new license.

3.1.g.2. A new owner application for a license has the effect of a valid license for three (3) months from the date the application is received by the Director.

3.1.h. A license shall state:

3.1.h.1. The specific name of the hospice to which it applies;

3.1.h.2. The date of issuance; and

3.1.h.3. The expiration date.

3.1.i. A hospice name change shall be shown in the next license issued.

3.1.j. The license shall be

posted in a conspicuous and public place of the hospice.

3.1.k. A hospice, satellite location or inpatient facility shall only use the name provided to the Director at the time of application for advertising purposes.

3.1.l. Notification and approval shall be received from the Director before a hospice may operate an inpatient facility or satellite location.

3.2. Initial License

3.2.a. An applicant shall submit a completed application to the Director, on a form prescribed by the Director, not less than thirty (30) days and not more than ninety (90) days prior to the date proposed for commencement of operation for a hospice office, satellite location or an inpatient facility. A nonrefundable fee of one hundred dollars (\$100) shall be submitted with the application for the initial license.

3.2.b. The hospice shall identify the following as part of the application:

3.2.b.1. The operating name, the office location, the mailing address and telephone number;

3.2.b.2. The name and title of the administrator or other contact person;

3.2.b.3. A listing of services the hospice intends to offer either directly or by contractual agreement;

3.2.b.4. Written evidence that the building or part of the building in which the hospice office, satellite location or inpatient facility is to be located is in compliance with applicable local zoning, building and fire safety laws and chapters;

3.2.b.5. The mailing address, phone number and location of each satellite location or inpatient facility;

3.2.b.6. A copy of a valid Certificate of Need or a letter of exemption from the West Virginia Healthcare Authority; and

3.2.b.7. Name, address, principal occupation and official position of all persons who have ownership interest in the hospice or the name, address, principal occupation, and official position of each member of the board of directors, if a corporation.

3.2.c. If, at the initial licensing survey, an agency has more than five (5) violations of any minimum requirements or if any of the violations are determined to be of such a serious nature that they may cause or have the potential to cause harm, the Director shall deny licensing until such time the hospice is found to be in substantial compliance with these rules.

3.2.d. An initial license shall be issued only after the Director inspects the hospice or inpatient facility and finds the hospice complies with this rule and W. Va. § 16-5I, *et seq.*

3.2.e. An initial license issued shall be valid for a period of one (1)

year from the date of issuance.

3.2.f. A satellite location or inpatient facility shall be inspected at the discretion of the Director prior to the issuance of a license.

3.3. Renewal License

3.3.a. An applicant for a renewal license shall submit a completed application to the director, on a form prescribed by the director, not less than sixty (60) days and not more than ninety (90) days prior to the scheduled expiration date of the current license. A nonrefundable fee of one hundred dollars (\$100) shall be submitted with the license renewal application for a hospice whose yearly caseload exceeds ten (10) or more patients, and fifty dollars (\$50) for a hospice whose yearly caseload is fewer than ten (10) patients.

3.3.b. The Director shall issue a renewal license when he or she finds the hospice is determined to be in compliance with this rule and the licensee submits a completed application and the correct renewal fee.

3.3.c. A renewal license shall be valid for a period of one (1) year from the date of issuance.

3.3.d. A renewal license shall be given to each hospice office, satellite location and inpatient facility.

3.4. Inspections

3.4.a. The Director shall inspect all hospices that are subject to the provisions of this rule and W. Va. Code §

16-5I, *et seq.* periodically and at least as often as required by the Centers for Medicare and Medicaid Services in order to determine compliance with the provisions of this rule, W. Va. Code § 16-5I-1, *et seq.* and the Hospice Conditions of Participation promulgated by the Centers for Medicare and Medicaid Services.

3.4.b. The Director shall inspect or investigate a main hospice office, satellite location or inpatient facility of a hospice as it deems necessary.

3.4.b.1. The Director shall conduct an unannounced inspection of a hospice, satellite location or inpatient facility. This inspection may include home visits with prior patient consent, interviews with agency staff and family members, review clinical records, environmental and life safety inspections and any other documents necessary for the determination of compliance with these rules.

3.4.c. The Director has the right to enter the premises of a hospice the Director has reason to believe is being operated or maintained as a hospice without a license.

3.4.c.1. If the owner or person in charge of a licensed hospice or of an unlicensed hospice which the Director has reason to believe is being operated as a hospice refuses entry pursuant to this rule, the Director shall petition the circuit court of Kanawha County for an inspection warrant.

3.4.c.2. If the Director finds on the basis of the inspection that any person, partnership, association or corporation and any local governmental unit

or any division, department, board or agency thereof is operating as a hospice without a license, the hospice shall apply for a license within ten (10) days, in accordance with the provisions of this rule.

3.4.d. A hospice that fails to apply for a license shall be subject to the penalties established by W. Va. Code § 16-5I, *et seq.*

3.4.e. A report of any inspection made pursuant to this rule shall be made in writing and shall be maintained on file by the Director.

3.4.f. The Director shall send a copy of the inspection report to the hospice.

3.5. Complaint Investigation

3.5.a. Any person may register a complaint with the Director alleging violation of applicable laws, rules or requirements by a hospice. A complaint shall state the substance of the complaint and shall identify the hospice involved.

3.5.b. The Director may conduct an unannounced inspection of a hospice, satellite location or inpatient facility to determine the validity of the complaint.

3.5.c. The Director shall notify the complainant and the hospice in writing of the results of the investigation no later than fifteen (15) working days after completing an investigation of a complaint. If the complaint is substantiated by the investigation as a violation of this rule or W. Va. Code § 16-5I, *et seq.*, the Director

shall require a plan of correction or may take other action authorized by state law or this rule.

3.6. Plans of Correction

3.6.a. A hospice, satellite location or inpatient facility found to have deficiencies based on an inspection or complaint investigation shall develop a plan of correction and submit it to the Director within ten (10) calendar days of receipt of the inspection report.

3.6.b. A plan of correction shall specify a reasonable time within which a hospice shall correct each deficiency cited in the report and in any case shall be no more than sixty (60) days after the date of the inspection.

3.6.c. A plan of correction submitted by a hospice, satellite location or inpatient facility shall be approved or rejected by the Director. The Director shall notify a hospice, satellite location or inpatient facility within fifteen (15) working days as to whether a plan of correction has been approved or rejected. If the Director rejects the plan, the reasons for the action shall be stated. When the Director rejects a plan of correction, up to ten (10) calendar days may be allowed for submission of a revised plan.

3.6.d. Upon failure of a hospice, satellite location or inpatient facility to submit an approved plan of correction or to correct any deficiency within the time specified in the approved plan of correction, the Director may initiate action in accordance with W. Va. Code § 16-5I, *et seq.*

3.7. Availability of Reports

3.7.a. The Director shall provide a copy of an inspection deficiency report upon written request. A fee may be charged to cover the cost of research and copying.

3.7.b. The Director shall treat a report of inspection as public information from the time a written plan of correction has been received and accepted by the Director.

3.7.c. If a hospice does not submit a written plan of correction within twenty (20) calendar days the report shall be made available to the public.

3.7.d. Nothing contained in this section shall be construed to require or permit the public disclosure of confidential medical, social, personal or financial records of any patients.

§ 64-54-4. Inpatient Facility.

4.1. If a hospice administers an inpatient facility the provisions of this section shall apply.

4.2. An inpatient facility shall have a full time administrator. The administrator shall designate an individual who shall act in his or her absence as needed.

4.3. An inpatient facility shall make reasonable efforts to safeguard personal property and promptly investigate complaints of such loss. A record shall be prepared of all clothing, personal possessions, and money brought by the patient to the inpatient facility at the time of

admission. The record shall be updated as additional personal property is brought to the inpatient facility.

4.4. If an inpatient facility keeps patient funds, such funds shall be kept in an account separate from the inpatient facility funds. Patient funds shall not be used by the inpatient facility.

4.5. An inpatient facility shall have a policy to admit only patients who meet the following criteria:

4.5.a. Has been diagnosed as terminally ill;

4.5.b. Has been certified by the medical director, in writing, to have an anticipated life expectancy of six (6) months or less; and

4.5.c. Has personally or through a legal representative, in writing, given informed consent to receive hospice care.

4.6. Any admission in excess of the licensed bed capacity is prohibited except when an emergency admission is approved by the Director.

4.7. Nursing requirements.

4.7.a. An inpatient facility shall provide nursing care and services by or under the direct supervision of a registered nurse at all times.

4.7.b. Nursing care and services shall be provided in accordance with the plan of care developed by the interdisciplinary team and as ordered by the

physician.

4.7.c. Nursing care, staffing and services shall meet the needs of the patients.

4.7.d. A registered nurse shall assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

4.7.e. Nursing care and services shall be provided in accordance with recognized standards of practice.

4.8. Pharmaceutical Services

4.8.a. The pharmaceutical services shall be under the direction of a licensed pharmacist.

4.8.b. There shall be a medicine room or drug preparation area at each nurses' station of sufficient size for the orderly storage of drugs, both liquid and solid dosage forms, and for the preparation of medications for patient administration within the unit. In the event that a drug cart is used for storage and administration of drugs, the room shall be of sufficient size for storage of the cart without crowding.

4.8.c. An inpatient facility shall develop policies to identify, monitor and track medication errors and adverse drug reactions. The results shall be reported to the quality assurance program.

4.9. Laboratory and Radiological Services.

4.9.a. An inpatient facility shall maintain or have available, whether directly or through a contractual agreement, adequate laboratory and radiological services available to meet the needs of the patients.

4.10. Food and Dietetic Services.

4.10.a. An inpatient facility shall comply with W. Va. Code § 64-17-1, *et seq.*

4.10.b. An inpatient facility shall designate a person, either directly or by contractual agreement, to serve as the food and dietetic services manager with responsibility for the daily management of the dietary services. An inpatient facility that does not provide the services of a certified dietary manager shall, at a minimum, train all employees through the county health departments' food managers training course or a comparable course.

4.10.c. There shall be a qualified dietitian, full-time or part-time who is responsible for the development and implementation of a nutrition care program to meet the needs of the patients. This person shall be available to assist in nutritional assessment, menu planning, in-servicing staff and evaluating safe food production.

4.10.d. Menus shall meet the needs of the patients. Special diets shall be prepared and served as ordered.

4.10.e. A current therapeutic diet manual approved by the dietitian and medical director shall be readily available to all medical, nursing and food service

personnel.

4.10.f. Families shall be allowed to store home cooked food for a patient. This storage shall be readily available and meet the same standards as foods prepared by a hospice. Food brought from home shall not be commingled with the food prepared by the hospice for other patients.

4.11. Restraints

4.11.a. The patient has the right to be free from a restraint of any form imposed as a mean of coercion, discipline, convenience or retaliation by staff.

4.11.b. The use of a restraint shall be:

4.11.b.1. Selected only when less restrictive measures have been found ineffective to protect the patient or others from harm;

4.11.b.2. Only used as ordered by the physician;

4.11.b.3. Implemented in the least restrictive manner possible not to interfere with the palliative care being provided;

4.11.b.4. In accordance with safe and appropriate restraining practices; and

4.11.b.5. Ended at the earliest possible time.

4.11.c. All inpatient facility staff shall have documented training in the

safe and effective management of behaviors and safe restraining techniques at least annually.

§ 64-54-5. Inpatient Physical Facilities, Equipment, and Related Items.

5.1. The provisions of this section shall apply to all hospice inpatient facilities. An inpatient facility licensed prior to the effective date of this rule shall be maintained in accordance with applicable standards of practice as referenced in "Sections 8 and 13" in the 2001 edition of The Guidelines for Design and Construction of Hospital and Healthcare Facilities as recognized by the American Institute of Architects Academy for Health.

5.2. The following documents are adopted as construction, equipment, physical facility, and related procedural standards for all inpatient facilities, new construction and any additions, alterations, renovations, or conversions of existing buildings:

5.2.a. "Section 8, Nursing Facilities," and "Section 13, Hospice Care" of the 2001 edition of The Guidelines for Design and Construction of Hospital and Healthcare Facilities as recognized by the American Institute of Architects Academy for Health with assistance from the United States Department of Health and Human Resources shall be used as planning standards;

5.2.b. The State Building Code, which is the 2000 Edition of the International Building Code;

5.2.c. Provisions applicable to nursing homes, electrical standards,

medical gas standards and patient care equipment standards and health care emergency management standards as defined in the applicable subsections in the 2005 Edition of NFPA 99, Standard for Health Care Facilities; and

5.2.d. The guidelines set forth in the Americans With Disabilities Act, 28 CFR Part 36.

5.3. An inpatient facility shall comply with applicable rules of the West Virginia State Fire Commission.

5.4. An inpatient facility shall ensure that patient rooms are designed and equipped for nursing care, as well as the dignity, comfort, and privacy of patients.

5.4.a. Maximum room occupancy shall be one patient unless justified by the hospice. In no case shall a patient room exceed two occupants.

5.4.b. All patient rooms shall provide a minimum of one hundred and twenty (120) square feet of clear floor space excluding toilet room space per patient. Each patient room shall have private toilet and bathing space.

5.4.c. A minimum of fifty (50) percent of the patient rooms shall meet the guidelines set forth in the Americans With Disabilities Act, 28 CFR Part 36.

5.5. The interior and exterior of the inpatient facility shall be maintained to provide a clean, safe, sanitary environment free of hazards for patients, staff, and visitors.

5.6. An inpatient facility shall have an emergency operations plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would affect a hospice's ability to provide care or interrupt normal operations.

5.6.a. There shall be a written emergency operations plan that all staff are familiar with developed in accordance with the standards identified in NFPA 99.

5.6.b. New employees shall be trained in emergency operations upon hire and annually thereafter in accordance with the requirements identified in NFPA 99.

5.6.c. The administrator shall review the emergency operations plan on an annual basis, which shall be verified by signature and date.

5.6.d. There shall be at least one (1) rehearsal of the emergency operations plan on a semiannual basis.

5.7. An inpatient facility shall develop procedures for managing the control, reliability, and quality of the physical facility. This shall include the light, temperature, humidity, ventilation and air exchanges, and air quality throughout the hospice.

5.8. An inpatient facility shall have adequate drainage, electricity, telephone, sanitation, water, and other necessary facilities available on or near the site.

5.9. An inpatient facility shall meet

local building codes and zoning restrictions. Where local codes or regulations permit lower standards than required by this rule, the standards contained in this rule shall take precedence.

5.10. Site conditions shall comply with the relevant sections of the 2001 Edition of The Guidelines for Design and Construction of Hospital and Healthcare Facilities as recognized by the American Institute of Architects Academy of Architecture for Health.

5.11. An inpatient facility shall request, in writing, an inspection of a proposed inpatient facility site and obtain approval for construction from the Director before beginning construction.

5.12. For new construction, renovations and alterations, an inpatient facility shall submit to the Director for review, complete construction drawings and specifications for the inpatient facility construction project which alters a floor plan, impacts life safety or requires approval under W. Va. Code § 16-2D-1, *et seq*, prior to beginning work on the project. An architect or engineer registered to practice in West Virginia shall prepare and sign the drawings and specifications including architectural, life safety, structural, mechanical, and electrical drawings and specifications.

5.12.a. Each new inpatient facility constructed after the effective date of this rule shall provide a private room for family members to place telephone calls.

5.12.b. Prior to starting any renovations an inpatient facility shall

complete an infection control and safety risk assessment and shall develop a plan to control exposure of patients, employees and the public. This plan shall be implemented prior to and during construction phases.

§ 64-54-6. Penalties.

6.1. Director's Authority

6.1.a. The Director is authorized to suspend or revoke a hospice license according to the provisions of W. Va. Code § 16-5I-1, *et seq.*, if he or she finds, upon inspection that there has been a substantial failure to comply with the provisions of this rule or with the laws of this state or with any other order or final decision of the Director.

6.1.b. The Director shall refuse to grant a license if he or she finds that the applicant has failed to be in substantial compliance with the provisions of this rule or the laws of this state or with or with any other order or final decision of the director.

6.1.c. When the Director takes action pursuant to the suspension or revocation of a license issued under this rule, he or she shall comply with the requirements and procedures set forth in W. Va. Code § 16-5I-1, *et seq.*

6.2. The Director shall assess a civil money penalty not to exceed fifty dollars (\$50) for each violation per day for operating a hospice without first obtaining a license or violation of any provisions of the code or any rule or regulation lawfully promulgated thereunder.

6.2.a. The Director may institute an action to restrain or prevent establishment or operation of any hospice, because of violation of any provision of the code or rules, in the circuit court of the county where the hospice is located or the circuit court of Kanawha County.

§ 64-54-7. Administrative Due Process.

7.1. Before revoking or suspending a hospice license, the Director shall serve the licensee with written notice of the grounds of the complaint, and the date, time and place set for the hearing of the complaint, which shall be more than thirty (30) days from the date notice is given.

7.1.a. Said notice shall be sent by certified mail to the licensee at the address where the hospice is located.

7.2. All hearings shall be governed by the "Rules of Procedure for Contested Case Hearings and Declaratory Rulings" 64 CSR § 1, *et seq.*, (1981), and "Rules for Hearings Under the Administrative Procedures Act" 69 CSR § 1, *et seq.*, (1990). These rules of procedure are incorporated herein by reference.

7.3. Any applicant or licensee dissatisfied with the decision of the Secretary may, within thirty (30) days after receiving notice of the decision, appeal to the circuit court of Kanawha County for judicial review of that decision.

7.4. The court may affirm, modify or reverse the decision of the Secretary and either the applicant, or licensee or the Secretary may appeal the court's decision to the Supreme Court of Appeals of West

Virginia.

§ 64-54-8. Severability.

8.1. The provisions of this rule are declared to be severable. If any provisions of this rule shall be held invalid, the remaining provisions of this rule shall remain in effect.

Repairs and Alterations			
Equipment			
Other			
2. Estimated Total Revenues	0	0	0

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

Memorandum

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

Date

Agency

Authorized Representative

Department of Health and Human Resources

Martha Walker
Secretary