

**TITLE 64  
PROCEDURAL RULE  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES**

**SERIES 94  
WEST VIRGINIA ALZHEIMER'S DISEASE REGISTRY**

**§64-94-1. General.**

1.1. Scope -- This procedural rule sets forth and establishes procedures governing the West Virginia Alzheimer's Disease Registry as a central information database for policy and planning relative to Alzheimer's disease and related disorders, pursuant to the provisions of the West Virginia Administrative Procedures Act, 29A-3-1 et. seq.

1.2. Authority. -- W. Va. Code §16-5R-7.

1.3. Filing Date. -- November 27, 2007.

1.4. Effective Date.-- December 27, 2007.

1.5. Applicability. -- This rule applies to all hospitals, physicians, health care providers, health care facilities, Alzheimer's disease/dementia special care units and programs, clinics or other similar units diagnosing or providing treatment or care for individuals who are diagnosed by a physician to have Alzheimer's disease or a related disorder. These facilities include, but are not limited to, adult day care facilities, assisted living residences, behavioral health centers, nursing homes, and residential care communities.

1.6. Purpose. -- The West Virginia Alzheimer's Disease Registry will provide a database to evaluate the incidence and prevalence of Alzheimer's disease and related disorders in West Virginia. It will provide information for policy planning purposes and provide non-identifying data to support research on Alzheimer's disease and related disorders.

**§64-94-2. Definitions.**

2.1. Adult Day Care Facility - Any facility licensed as a medical adult day care center under WV Division of Health Legislative Rule,

Medical Adult Day Care Center licensure, 64 CSR 2 or any day care program maintained and operated by a nursing home, hospital or other licensed health care facility.

2.2. Alzheimer's Disease - A progressive, neurodegenerative disease leading to loss of mental functions such as memory and learning characterized by a loss of function and death of nerve cells in several areas of the brain. This disease is considered to be one of the most common forms of dementia.

2.3. Alzheimer's Disease/Dementia Special Care Units and Programs - Any facility licensed as an Alzheimer's Disease/Dementia special care unit or program under WV Division of Health Legislative Rule, Medical Adult Day Care Center licensure, 64 CSR 85 or any Alzheimer's Disease/Dementia special care unit or program maintained and operated by a nursing home, hospital or other licensed health care facility.

2.4. Assisted Living Residence - Any facility licensed as an assisted living residence under WV Division of Health Legislative Rule, Assisted Living Residence licensure, 64 CSR 14.

2.5. Behavioral Health Centers - Any facility licensed as a behavioral health center under WV Division of Health Legislative Rule, Behavioral Health Center licensure, 64 CSR 11.

2.6. Dementia - A deterioration of intellectual function and other cognitive skills, leading to a decline in the ability to perform activities of daily living.

2.7. Director - The Director of the West Virginia Alzheimer's Disease Registry or his or her designee.

2.8. Health care facility - Any hospital, nursing home, clinic, behavioral health center, adult medical day care facility, or other facility that provides health care or diagnostic services to individuals whether public or private.

2.9. Health care provider - Any physician, nurse, or other individual who provides medical, psychiatric, nursing, or other health care services of any kind to individuals.

2.10. Hospital - A facility licensed as a hospital under WV Division of Health Legislative Rule, Hospital Licensure, 64 CSR 12.

2.11. Medical Information - Data or other information regarding the history, examination, radiological or laboratory findings, diagnosis, treatment, or other clinical care for a person examined or treated for a suspected or actual illness.

2.12. Nursing Home - Any facility licensed as a nursing home under WV Legislative Rule, Nursing Home Licensure, 64 CSR 13, or any extended care facility operated in conjunction with a hospital.

2.13. Related Disorders - Dementias associated with vascular disease, mixed dementia and other medical conditions such as Parkinson's disease and Huntington's disease. These dementias also include senile dementia, presenile dementia, multi-infarct dementia, vascular dementia, alcoholic dementia, dementia with Lewy bodies, Creutzfeldt-Jakob disease, frontotemporal dementia, and medical diagnoses with dementia.

2.14. Residential Care Community - Any facility licensed as a residential care community under WV Division of Health Legislative Rule, Residential Care Community licensure, 64 CSR 75.

2.15. Registry - West Virginia Alzheimer's Disease Registry is a central information database concerning Alzheimer's disease and related disorders maintained by West Virginia University.

2.16. Board of Governors - West Virginia University Board of Governors.

**§64-94-3. Purpose: Required Reporting of Alzheimer's disease and related disorders.**

3.1. The Board of Governors shall establish the Registry and delegate to the Vice-President for Health Sciences at West Virginia University or their designee the responsibility for developing specific protocols for the reporting of Alzheimer's disease and related disorders to the Registry. The protocols shall include any information to be reported under this rule and any additional relevant information determined to be necessary for adequate reporting. All protocols must be approved by the West Virginia University Institutional Review Board.

3.2. The reports required by this rule shall be reported electronically or in paper format on forms available from or provided by the Registry.

**§64-94-4. Registry Contents.**

4.1. Information to be reported. Reports from health care providers and facilities, as defined in section 2 of this rule shall include the individual's:

4.1.a. Last name, first name and middle initial;

4.1.b. Birth date;

4.1.c. Gender;

4.1.d. Last four digits of the Social security number;

4.1.e. Maiden name( if female);

4.1.f. Race/ethnicity;

4.1.g. Address, including street, city, county, and zip code;

4.1.h. Contact information including secondary contacts;

4.1.i. Brief medical history;

4.1.j. History of Alzheimer’s disease and related disorders;

4.1.k. Physician’s name;

4.1.l. Physician’s contact information including address, phone, fax numbers, or email; and

4.1.m. Other information considered relevant for policy and planning relative to Alzheimer’s disease and related disorders.

4.2. Content and design of forms. The content and design of all forms for the Registry shall be consistent with the minimum information necessary to maintain the registry, pursuant to the provisions of W. Va. Code 16-5R-7(a).

4.3. Content and design of reports. The content and design of all reports for the Registry shall provide the most relevant and complete summary statistics and information required to advise policy development, pursuant to the provisions of W. Va. Code §16-5R-7(c).

**§64-94-5. Standard Operating Procedures.**

5.1. All aspects of data collection, management, and maintenance shall be governed by written standard operating procedures developed by the Registry.

**§64-94-6. Data Management.**

6.1. Registry data shall be managed in compliance with standard data management procedures.

**§64-94-7. Regulatory Compliance.**

7.1. The Registry shall comply with all applicable Department of Health and Human Resources requirements and rules.

**§64-94-8. Persons and Facilities, Required to Report.**

8.1. Health care Providers and Facilities. All health care providers and facilities, as

defined in section 2 of this rule, that diagnose Alzheimer’s disease or a related disorder or provide treatment or care for an individual who is diagnosed by a physician to have Alzheimer’s disease or a related disorder shall provide a report of each case of the disease or condition as required by this rule.

**§64-94-9. Distribution of Rule.**

9.1. The Registry shall distribute this rule to licensed health care providers or facilities, as defined in section 2 of this rule, which have a duty to report pursuant to the provisions of this rule. Local health departments may copy and distribute this rule to local health care providers or facilities, as defined in section 2 of this rule, at no cost. The rule shall also be available online from the Registry at [www.WVADR.hsc.wvu.edu](http://www.WVADR.hsc.wvu.edu).

**§64-94-10. Confidential Information, Utilization of Information, and Permitted Disclosures of Information.**

10.1. Confidential Information: Any information collected and maintained pursuant to this rule by the Registry which identifies an individual as having Alzheimer’s disease or a related disorder is “confidential information” and exempt from disclosure to third parties, pursuant to the provisions of all applicable state and federal laws, unless the disclosure is permitted pursuant to the provisions of subsection 10.3 of this section.

10.2. Use of non-identifying information:

10.2.1. The Registry may disclose non-identifying information for research purposes only.

10.3. Permitted Disclosures of Confidential Information:

10.3.1. Registry may release “confidential information” to the following:

10.3.1.a. The individual diagnosed with Alzheimer’s disease or a related disorder;

10.3.1.b. The individual’s representative, who has the legal authority to

access the individual's confidential information by virtue of a lawful written authorization or legal instrument or by virtue of an order from a court of competent jurisdiction;

10.3.1.c. A physician or other health care provider, if the request for confidential information is for the purpose of a medical evaluation or treatment of the individual;

10.3.1.d. Any individual or entity which provides the Registry with a lawful written authorization for the disclosure of confidential information from the individual diagnosed with Alzheimer's disease or related disorder or that individual's representative; or

10.3.1.e. Any individual or entity which provides the Registry with an order from a court of competent jurisdiction ordering the disclosure of confidential information.

10.4. In order to ensure patient confidentiality, patients will be assigned a unique identifying number. All patient information shall be stored as identified information and information with identification removed in two linked datasets on a secure, encrypted, password-protected database server. The Director of the Registry and his or her designee shall have the only means of linking the identified information and the information with identification removed.

**§64-94-11. Communication.**

11.1. Communication by the Registry with individuals, individual's representatives, and health care providers or facilities, as defined in section 2 of this rule, shall be made directly via U.S. mail, telephone, or e-mail to notify individuals and individuals' representatives about inclusion in the Registry and, if requested, to advise about research opportunities and to convey disease-related information.

**§64-94-12. Registry Director.**

12.1. The Board of Governors shall delegate to the President of West Virginia University or his or her designee the

responsibility for appointment of the Director of the Registry.

**§64-94-13. Registry Advisory Board.**

13.1. The Board of Governors shall delegate to the President of West Virginia University or his or her designee the responsibility for the appointment of an Advisory Board to the Registry.

13.1.1. The Advisory Board shall make recommendations to the Director about the implementation, coordination and oversight of the Registry.

13.1.2. The Advisory Board shall be comprised of, but not limited to, representatives from The Blanchette Rockefeller Neurosciences Institute, The Institute on Aging, West Virginia University, Marshall University, West Virginia Department of Health and Human Resources, and representatives of public and private entities and organizations and other individuals involved in Alzheimer's disease and related disorders. These shall include, but not be limited to, the Alzheimer's Association, West Virginia chapter, West Virginia State Medical Association, West Virginia Health Care Association, AARP (American Association of Retired Persons) West Virginia, West Virginia chapter of the National Association of Social Workers and other stakeholders as well as members of the community including a caregiver of a person with Alzheimer's disease or a related disorder.