

Summary of changes to Title 65 Series 17 Health Services Offered by Health Professionals

This rule specifies which health services, major medical equipment and/or facilities acquired, offered or developed by health professionals are subject to Certificate of Need review and regulation.

The proposed changes to this rule are found in sections two and three. The changes proposed in section two clarify that the facility costs shall be included in the overall costs of the project, provide a definition of facility, and further clarify the definition of a diagnostic center. The sole change in section three includes Computed Tomography (CT) scanning as a reviewable or regulated service.

- Section 2.1.a. clarifies that the total cost of the project shall include the cost of the facility as well as the cost of the equipment.
- Section 2.1.b. clarifies that if a facility's primary purpose is to offer laboratory or imaging services, then it is a diagnostic center.
- Section 2.1.c. clarifies that if another physician refers a patient to any facility owned or operated by one or more health professionals licensed, authorized or organized pursuant to Chapter 30 of the West Virginia Code, for the purpose of obtaining laboratory or imaging services, then this is a diagnostic center.
- Section 2.1.d. contains new language which indicates that any facility owned or operated by one or more health professionals, licensed, authorized or organized pursuant to Chapter 30 of the West Virginia Code which offers laboratory or imaging services to patients and which is not organized as a sole practitioner, a partnership or licensed professionals, a professional limited liability company authorized by the appropriate licensing board pursuant to Chapter 30 of the West Virginia Code is a diagnostic center.
- Section 2.1.e. contains new language which indicates that any facility owned or operated by one or more health professionals licensed, authorized or organized pursuant to Chapter 30 of the West Virginia Code which offers laboratory or imaging services to patients through an entity for which any owner furnishes less than seventy-five per cent of his or her patient care services is a diagnostic center.
- Section 2.3. defines facility as any health care facility or private office practice, freestanding or attached to another building, stationary or mobile.
- Section 3.3.j. includes CT scanning as a health service subject to Certificate of Need review and regulation.

ATTACHMENT A

The facts and circumstances constituting the emergency are as follows:

In order to preserve public welfare and to prevent substantial harm to the public interest, the West Virginia Health Care Authority (Authority) proposes to regulate the development, acquisition or other establishment of computed tomography (CT) and to clarify the standards for the development of diagnostic centers in this state. The rising costs of healthcare attributable to diagnostic imaging services, such as CT, are unaffordable and unsustainable. These high costs often place an insurmountable burden on businesses, uninsured or underinsured patients and State and private payors. The uninsured and underinsured are particularly disadvantaged and often do not receive such testing because it is cost prohibitive.

Utilization of diagnostic imaging services has grown at a particularly rapid rate as evidenced by a March 2005 report to Congress by the Medicare Payment Advisory Commission (MedPAC) which concluded that volume for diagnostic imaging services has increased 15 to 20 percent from 1999 to 2003. In March 2006, MedPAC concluded that between 2003 and 2004 per capita volume for diagnostic imaging tests grew more than any other medical service.

In addition to the volume of diagnostic imaging services increasing, the proliferation of diagnostic imaging centers is a serious threat to the public welfare and the cost attributable to this proliferation will cause substantial harm to the public in the form of sky-rocketing health care costs. Currently, CT is the highest cost imaging modality not regulated by HCA and other high cost imaging procedures, such as MRI and PET are regulated. In addition, the unregulated proliferation of diagnostic imaging centers raises serious concerns about the quality of care provided. Without regulation, CT can be offered by any hospital or physician without restriction. This leads to the duplication of services throughout the State, which in turn increases health care costs. In non regulated states, such as Ohio, the number of diagnostic imaging centers has increased by 748 percent, from 27 to 229 from 1997 to 2000. In Pennsylvania, diagnostic imaging centers have increased 47 percent from 1999 to 2001.

For all these reasons, West Virginia citizens are facing a health care crisis and it is essential that an emergency rule be issued to protect the public welfare.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Health Services Offered by Health Professionals

Type of Rule: Legislative Interpretive Procedural

Agency: West Virginia Health Care Authority

Address: 100 Dee Drive, Charleston, West Virginia 25311

Phone Number: (304) 558-7000 Email: mkapinos@hcawv.org

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

There will be no fiscal impact on the costs and revenues of state government.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			
Personal Services			
Current Expenses			
Repairs & Alterations			
Assets			
Other			
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: _____

Rule Title: Health Services Offered by Health Professionals

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

There will be no increase or decrease in fees as noted above.


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.

The proposed rule will not have a fiscal impact because it merely makes the development, acquisition or other establishment of computed tomography (CT) services reveiwable. Current staff will review these applications and no additional hiring or other expenditures to process applications will be necessary.

Date: May 24, 2006

Signature of Agency Head or Authorized Representative



FILED

TITLE 65
LEGISLATIVE RULE
HEALTH CARE AUTHORITY

2006 JUN 12 P 3:25

SERIES 17
HEALTH SERVICES OFFERED BY HEALTH PROFESSIONALS

OFFICE WEST VIRGINIA
SECRETARY OF STATE**§65-17-1. General.**

1.1. Scope. -- This legislative rule specifies which health services, major medical equipment, and/or facilities acquired, offered or developed by health professionals are subject to certificate of need review.

1.2. Authority. -- W. Va. Code, §§16-2D-4(a)(1), 16-2D-8(c).

1.3. Filing Date. -- May 5, 2000.

1.4. Effective Date. -- July 1, 2000.

§65-17-2. Definitions.

As used in this legislative rule, all terms that are defined in W. Va. Code §16-2D-1 et seq. have those same meanings which are in some cases further clarified herein. All terms not defined in W. Va. Code §16-2D-1 et seq. have the following meanings unless the context expressly requires otherwise.

2.1. "Diagnostic center" means:

2.1.a. Any private office practice of one or more health professionals licensed, authorized, or organized pursuant to Chapter 30 of the West Virginia Code which offers laboratory or imaging services and in which the total cost of all the facilities and equipment required to provide these services exceeds \$2,000,000; In determining whether the total cost of facilities and equipment exceeds \$2,000,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the construction of the facilities and acquisition of the equipment shall be included; If the facilities and equipment ~~is~~ are acquired for less than fair market value, the term "cost" includes fair market value; The term "cost" also includes a series of expenditures which exceeds \$2,000,000 if the State agency determines that the sum total constitutes a single expenditure subject to review under the provisions of the Health Care Authority's legislative rule, "Certificate of Need," 65 CSR 7, subdivision 3.6.a., 3.6.b., and 3.6.c.;

2.1.b. Any facility owned or operated by one or more health professionals licensed, authorized, or organized pursuant to Chapter 30 of the West Virginia Code ~~which~~ whose primary purpose is to offers laboratory or imaging services ~~in a setting that is not ancillary to and functionally integrated with the private office practice of the health professionals,~~ regardless of the cost associated with the proposal;

2.1.c. Any facility owned or operated by one or more health professionals licensed, authorized, or organized pursuant to Chapter 30 of the West Virginia Code which offers laboratory or imaging services to patients that are ~~not examined and evaluated in the same manner as any other patient of the private office practice of~~ referred by other licensed health professionals for the purpose of obtaining such laboratory or imaging services, regardless of the cost associated with the proposal; ~~or~~

2.1.d. Any facility owned or operated by one or more health professionals licensed, authorized, or organized pursuant to Chapter 30 of the West Virginia Code which offers laboratory or imaging services to patients, and which is not organized as a sole practitioner, a partnership of licensed professionals, a professional limited liability company authorized by the appropriate licensing board pursuant to Chapter 30, or a professional corporation authorized by the appropriate licensing board pursuant to Chapter 30, regardless of the cost associated with the proposal;

2.1.e. Any facility owned or operated by one or more health professionals licensed, authorized, or organized pursuant to Chapter 30 of the West Virginia Code which offers laboratory or imaging services to patients through an entity for which any owner furnishes less than seventy-five percent (75%) of his or her patient care services as measured by either time spent, services billed, or patient encounters, regardless of the cost associated with the proposal; or

2.1.d.f. Any facility owned or operated by one or more health professionals licensed, authorized, or organized pursuant to Chapter 30 of the West Virginia Code which offers laboratory or imaging services to patients, and which facility is either licensed by the Office of Health Facility Licensure and Certification of the Department of Health and Human Resources, or accredited by the Joint Commission for the Accreditation of Healthcare Organizations, regardless of the cost associated with the proposal; provided however, that certification of a facility for any reason under Title 42 of the United States Code, including but not limited to certification of a facility as a rural health clinic under the Medicare or Medicaid programs shall not result in a facility being classified as a diagnostic center.

2.2. "State agency" means the West Virginia Health Care Authority which is designated to administer the certificate of need program by W. Va. Code §16-29B-11.

2.3. "Facility" means any health care facility or private office practice, freestanding or attached to another building, stationary or mobile.

§65-17-3. Health Services, Major Medical Equipment and/or Facilities.

3.1. One or more health professionals licensed to practice in this state pursuant to the provisions of Chapter 30 of the West Virginia Code who wish to acquire, offer or develop one or more of the health services, major medical equipment and/or facilities listed in subsection 3.3 of this rule shall follow the procedures set forth in the Health Care Authority's legislative rule, "Certificate of Need," 65 CSR 7.

3.2. If a health service, major medical equipment and/or facility is one set forth in subsection 3.3 of this rule, the proposed acquisition, development or offering of that service, equipment and/or facility by a licensed health professional is subject to review regardless of the cost associated with the proposal, except for diagnostic centers as set forth in subdivision 3.3.i of this rule.

3.3. The list of health services, major medical equipment and/or facilities subject to review pursuant to W. Va. Code §16-2D-4(a)(1) is as follows. This list is all inclusive and may not be altered except by amendment to this legislative rule.

3.3.a. End-stage renal dialysis stations and home training.

3.3.b. Lithotripsy.

3.3.c. Radiation therapy.

- 3.3.d. Magnetic resonance imaging (MRI).
- 3.3.e. Proton emission tomography (PET).
- 3.3.f. Cardiac catheterization.
- 3.3.g. Birthing centers.
- 3.3.h. Ambulatory surgical facilities or ambulatory surgical centers.
- 3.3.i. Diagnostic centers.
- 3.3.j. CT (computed tomography) scanning.

§65-17-4. Batching Category.

All applications received pursuant to this rule shall be considered by the state agency in the applicable batching category as described in the Health Care Authority's legislative rule, "Certificate of Need," 65 CSR 7.