

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

Form #3

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2006 JUL 28 P 2:37

OFFICE WEST VIRGINIA
SECRETARY OF STATE

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

AGENCY: West Virginia Health Care Authority TITLE NUMBER: 65

CITE AUTHORITY: W.Va. Code § 16-2D-8(c)

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 17

TITLE OF RULE BEING AMENDED: Health Services Offered by Health Professionals

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: N/A

TITLE OF RULE BEING PROPOSED: N/A

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.


Authorized Signature

\$5.00

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: July 28, 2006

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) West Virginia Health Care Authority

100 Dee Drive, Charleston, West Virginia 25311

(304) 558-7000

LEGISLATIVE RULE TITLE: ~~Health Services Offered by Health Professionals~~

1. Authorizing statute(s) citation W.Va. Code § 16-2D-8(c)

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:
June 16, 2006

b. What other notice, including advertising, did you give of the hearing?
Notice of Public Comment Period on agency website

c. Date of Public Hearing(s) *or* Public Comment Period ended:
July 13, 2006, 5:00 p.m.

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.
Attached Comments (1) No comments received _____

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

July 28, 2006

- f. Name, title, address and **phone/fax/e-mail numbers** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Marianne Kapinos, General Counsel

100 Dee Drive, Charleston, West Virginia 25311

Phone: 558-7000 Fax: 558-4776

Email: mkapinos@hcawv.org

- g. **IF DIFFERENT FROM ITEM 'F'**, please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

same

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

N/A

b. Date of hearing or comment period:

N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

N/A

d. Attach findings and determinations and reasons:

Attached N/A

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.

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 reviewable. 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 JUL 28 P 2:38

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.



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WV HEALTH CARE
AUTHORITY

July 13, 2006

Marianne Kapinos
General Counsel
West Virginia Health Care Authority
100 Dee Drive
Charleston, WV 25311

Dear Ms. Kapinos,

On behalf of the West Virginia State Medical Association (WVSMA), I respectfully submit the following comments to the proposed changes to 65 C.S.R. § 7, Certificate of Need Rule and 65 C.S.R. § 17, Health Services Offered by Health Professionals.

First, I would like share the concern of the WVSMA regarding the process that the West Virginia Health Care Authority (Authority) underwent in filing and gaining approval of these Emergency Rules. On May 24 the Authority filed both rules with the Secretary of State seeking approval to implement them on an emergency basis. Secretary Ireland then approved them both on June 7. The public comment was not filed by your office until June 12, four days after the approval of both rules.

Though I recognize that the rules were posted in the State Register for 14 days before they were approved as Emergency Rules, this is the bare minimum required to meet the notice requirements of the law. Our organization was not in the habit of randomly perusing the weekly register in anticipation of discovering an unanticipated filing. We therefore missed the opportunity to comment to the Secretary of State in advance of her approval. At no time prior to the approval of the Emergency Rule by the Secretary of State on June 7, 2006, did the Authority's Board or staff contact me or my staff about the proposed changes to the rules. In fact, I was disappointed to realize when I checked the dates that the first time I was advised by Sonia Chambers of the planned rule changes was on June 8, 2006, one day after the Secretary of State approved the implementation of the rules as Emergency Rules.

I preface all of this with a reminder that the particular section of language in Series 17 which is being substantially modified (i.e. bringing CT Scanners under review and strengthening the review of diagnostic centers) was specifically negotiated between the Authority, the West Virginia Hospital Association and the WVSMA nearly seven years ago. The changes to the certificate of need rules significantly impact West Virginia physicians and other professional providers. I believe that the Authority is well aware that any modification to this section in particular would, at a minimum, raise the interest of the physician community and should have resulted in the courtesy of a notice before the filing and certainly before the approval of the rule.

West Virginia State Medical Association

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The Authority cites as a reason for seeking the approval of the Emergency Rules that there is a health care crisis due to the "unregulated proliferation of diagnostic imaging centers" and that without regulation CT services by hospitals and physicians will lead to the duplication of services throughout West Virginia which will in turn result in increased health care costs. The WVSMA questions whether there is an actual emergency that justified the promulgation of the emergency rules and the ultimate approval by the Secretary of State. At the same time as the Authority filed the Emergency Rules the Authority issued an immediate moratorium on the development of new CT services, except for the replacement or expansion of existing CT services. This 180 day moratorium served the purpose of halting any proliferation of CT services as alleged by the Authority in its support for the emergency issuance of the rules. Thus, no emergency existed regarding the further development of CT services in West Virginia.

Additionally, the WVSMA disagrees with the Authority's argument that the increased availability of diagnostic imaging centers and CT related services leads to skyrocketing health care costs. The Authority gives this as a basis for the emergency nature and filing of the rule changes to Series 7 and 17. The availability and better access to diagnostic imaging services may ultimately lead to further competition among providers, including hospitals, physicians and other health care professionals. The increased competition to provide the service can have a positive impact and actually reduce the cost of the service to the patient or patient's insurer. Moreover, there are cost savings recognized by having the service provided in a more convenient, cost effective matter. Often it is more efficient and convenient for diagnostic imaging services to be performed by the patient's physician in an office setting rather than having to refer the patient to another provider, including a hospital, to perform the particular diagnostic service.

Further, the Authority may have overstepped its statutory authority by adding CT services as a service subject to certificate of need review and regulation under Series 7 and 17. West Virginia Code § 16-2D-3(b)(5) requires the Authority to define the health services subject to certificate of need review based upon the certificate of need study that was conducted pursuant to W.Va. Code § 16-29B-19a. This study conducted by the certificate of need task force was used as the basis for changes to the certificate of need laws that came about as a result of Senate Bill 492. The study conducted specifically excluded CT as a health service subject to review. Based on the language of the last sentence of W.Va. Code § 16-2D-3(b)(5), the Authority is required to utilize the recommendations of the study to define the scope of the health services that are reviewable when creating the list of health services under 65 C.S.R. 7-28 and 65 C.S.R. 17-3. Instead, in contradiction with the statutory mandated language the Authority has now added CT scanning as a reviewable health service.

Following are additional specific comments on each of the proposed rule changes:

65 C.S.R. § 7, Certificate of Need Rule:

The Certificate of Need Rule has been modified to include CT (computed tomography) scanning under 65 C.S.R. 7-28.1.x. as a health service subject to certificate of need review if the service was not offered on a regular basis within the twelve month period prior to the time the service. As discussed above, this change to the certificate of need standards is outside the scope and

authority of the Authority based on the provisions of W.Va. Code § 16-2D-3(b)(5) which requires the Authority to use the study conducted by the certificate of need task force which specifically excluded CT services as a reviewable health service as the basis for the Addition of Health Services provisions under 65 C.S.R. § 7-28.

The WVSMA takes the position that this change to the certificate of need law has little direct impact on its members since Chapter 30 licensed professionals are generally exempt from the certificate of need law requirements under W.Va. Code § 16-2D-4(a)(1). However, the WVSMA objects to this modification to the rule to the extent that the Authority interprets the addition of this provision as meaning that Chapter 30 licensed professionals in West Virginia who desire to add, acquire or replace CT scanning equipment will now be subject to certificate of need review.

This rule change has little or no impact on the hospital community and other CT providers in West Virginia other than to protect the monopoly power on the provision of CT services within the state since the provisions only apply to the addition of CT services and does not impact the replacement of CT services by existing providers.

65 C.S.R. § 17, Health Services Offered by Health Professionals:

The WVSMA finds the rule changes to Series 17 much more problematic because these changes directly impact the ability of Chapter 30 licensed health professionals, including physicians, to acquire, develop or offer laboratory and diagnostic services. The Authority has made major changes to the definition of a "diagnostic center" under 65 C.S.R. § 17-2.1 and severely limited the ability of a Chapter 30 health care professional to offer laboratory or imaging services without first undergoing certificate of need review. In particular, the changes impede the ability of cardiologists and radiologists to offer diagnostic services to their patients.

Again, the WVSMA asserts that the addition of CT services as a reviewable health service is outside the scope and authority of the agency under W.Va. Code § 16-2D-3(b)(5). Further, proposed changes to the definition of "diagnostic center" under 65 C.S.R. § 17-2.1 result in many activities that would have been otherwise determined not reviewable under the private office practice exemption to now be reviewable and require certificate of need approval.

First, although the dollar threshold of \$2,000,000 was not changed under 65 C.S.R. § 17-2.1.a., the Authority has added the costs of the facility and any related construction of the facility to the calculation of whether or not the project exceeded the expenditure threshold. Prior to this change the cost of the equipment was the only cost used to calculate whether or not a particular diagnostic center project met the definition of a "diagnostic center" and was therefore required to undergo certificate of need review.

Second, under 65 C.S.R. § 17-2.1.b. the proposed changes do not define the term "primary purpose." This term seems extremely vague and subject to interpretation by the Authority. Also the nature of the service offered by a professional might change over time. At first the primary purpose of the facility might not be to offer lab or imaging services but after time the purpose may change. Will this mean that the owner of the facility has to constantly reexamine whether the services are subject to certificate of need review. Moreover, the prior language under this

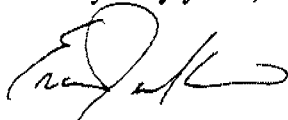
section which was negotiated between the WVSMA and the West Virginia Hospital Association was meant to reflect the idea that professional services offered outside the scope of the general practice or specialty of that professional should be subject to certificate of need review. The changes now focus on the services to be offered rather than the relationship of the services to the type of provider or specialist offering such service.

Third, under 65 C.S.R. § 17-2.1.c. the proposed changes significantly impact providers whose practice is largely a referral based practice. For example, radiologists rely exclusively on referrals. This change restricts any radiologist from providing diagnostic services since such services are typically referred by other licensed health care providers.

Fourth, the Authority under 65 C.S.R. § 17-2.1.d. and § 17-2.1.e. adds two new triggers for meeting the "diagnostic center" definition. Subsection 2.1.d. appears to restrict the ability of a health care professional to form a legal entity, not otherwise formed as an approved medical corporation or professional limited liability company to offer laboratory or imaging services. The WVSMA is not clear why this provision was added since any physician who forms another legal entity to provide health care services is required to first obtain approval for such entity through the West Virginia Board of Medicine. Subsection 2.1.e. again increases the ability of the Authority to find a basis on which to determine an otherwise nonreviewable project as reviewable under the "diagnostic center" definition. The professional owners or operators of a lab or imaging services must provide at least 75% of the services through the facility. The language appears to apply to all owners if there are multiple owners, so that if any one of them fall under the 75% threshold then the service becomes reviewable. Further, the Authority has built in multiple measurements (time spent, services billed or patient encounters) for calculating the 75% threshold all of which must be met to qualify as an exempt lab or imaging project.

The WVSMA would have liked to have had the opportunity to discuss our concerns addressed above prior to the implementation of the Emergency Rule and the filing of the comment period for the Proposed Rule; however, we were never given the opportunity. We request that in the future to the extent possible the Authority advise us of any rule changes that will likely impact the West Virginia physician community. Further, we request that the Authority involve the WVSMA in any future discussions involving the pending changes being made to Series 7 and 17 as they move through the legislative rule making review process.

Very truly yours,



Eyan H. Jenkins
Executive Director

cc: Sonia Chambers, Chair

The West Virginia Health Care Authority (HCA) received comments from the West Virginia State Medical Association (WVSMA) on July 14, 2006 regarding HCA's proposed changes to 65 C.S.R. § 7, Certificate of Need Rules and 65 C.S.R. § 17, Health Services Offered by Health Professionals. This was the only comment received with respect to the above referenced rules.

Based upon a review of WVSMA's comments, HCA has the following response:

- WVSMA takes issue that it was not provided with advance copies or notice of intent to change the above referenced rules. Such advance notice is not required by law. HCA complied with all applicable statutory provisions in filing and noticing the proposed emergency rules.
- WVSMA argues that HCA lacks authority to add computed tomography (CT), a reviewable service, since a study conducted approximately eight years ago recommended that CT services not be subject to Certificate of Need review. The health care field is dynamic and ever changing, HCA has the ability to respond to such market dynamics.
- WVSMA contends that the proposed definition of a diagnostic center results in many activities that would have been otherwise determined not subject to Certificate of Need review now to be reviewable. HCA's intent in making such changes was to clarify the definition of a diagnostic center and to clearly delineate what services are subject to Certificate of Need review.

Based upon WVSMA's comments, HCA does not have any changes to the proposed rules.