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WEST VIRGINIA

SECRETARY OF STATE

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #3

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AUG 5 3 22 PM '99

OFFICE OF 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-3(b)(5), 4(a)(1), 4(a)(5) and 8

AMENDMENT TO AN EXISTING RULE: YES X 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 NEW RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

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.

D. Parke Hadley

Authorized Signature

$14.40

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: AUGUST 6, 1999

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) WEST VIRGINIA HEALTH CARE AUTHORITY
100 DEE DRIVE, SUITE 201
CHARLESTON, WEST VIRGINIA 25311-1600 (304) 558-7000

LEGISLATIVE RULE TITLE: HEALTH SERVICES OFFERED BY HEALTH PROFESSIONALS

1. Authorizing statute(s) citation W. VA. CODE §16-2D-3(b)(5), 4(a)(1), 4(a)(5) and 8

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

JUNE 30, 1999

b. What other notice, including advertising, did you give of the hearing?

AGENCY NEWSLETTER

c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

JULY 30, 1999

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached ____X____ No comments received _____

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

AUGUST 6, 1999

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 K. STONESTREET, GENERAL COUNSEL

WEST VIRGINIA HEALTH CARE AUTHORITY

100 DEE DRIVE, SUITE 201

CHARLESTON, WEST VIRGINIA 25311-1600

(304) 558-7000 - PHONE; (304) 558-7001 - FAX

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)

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

TITLE 65
LEGISLATIVE RULE
HEALTH CARE ~~COST REVIEW~~ AUTHORITY

SERIES 17
HEALTH SERVICES OFFERED BY HEALTH PROFESSIONALS

§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. -- ~~April 10, 1992~~

1.4. Effective Date. -- ~~April 10, 1992~~

§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 - a facility which offers laboratory ~~and~~/or imaging services and in which the total cost of all the laboratory and imaging equipment exceeds ~~$300,000.00~~ $2,000,000.00. In determining whether the medical equipment costs more than ~~$300,000.00~~ $2,000,000.00, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition of such equipment shall be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value.

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

§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 legislative rule "Certificate of Need," 65 C.S.R. 7.

3.2. If a health service, major medical equipment and/or facility is one set forth in subsection 3.3, 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 subdivision 3.3.9.

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 shall not be altered except by amendment to this legislative rule.

3.3.1. ~~Computerized tomography (CT).~~ End-stage renal dialysis stations and home training.

3.3.2. Lithotripsy.

3.3.3. Radiation therapy.

3.3.4. Magnetic resonance imaging (MRI).

3.3.5. Proton emission tomography (PET).

3.3.6. Cardiac catheterization.

3.3.7. Birthing centers.

3.3.8. Ambulatory surgical facilities or ambulatory surgical centers.

3.3.9. Diagnostic centers.

§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 65 C.S.R. 7. ~~Provided that, there is no expenditure minimum requirement for the inclusion of health services, major medical equipment and/or facilities offered, acquired or developed by health professionals.~~

BRIEF SUMMARY OF THE RULE

HEALTH SERVICES OFFERED BY HEALTH PROFESSIONALS PROPOSED RULE

SUMMARY: This proposed legislative rule, Health Services Offered by Health Professionals Rule, specifies which health services, major medical equipment, or facilities acquired, offered or developed by health professionals are subject to certificate of need review. Enrolled Senate Bill 492, which was passed by the legislature in 1999, made significant changes in the certificate of need law, necessitating the amendment to this rule.

This rule contains amendments which increases the threshold for major medical equipment/diagnostic center to $2,000,000.00 in accordance with the mandate contained in Enrolled Senate Bill 492. In addition, it deletes CT as a reviewable health service and adds end-stage renal dialysis as a reviewable activity in accordance with changes mandated by Senate Bill 492.

In summary, the proposed rule implements the provisions of Senate Bill 492 and updates this rule to comply with current requirements. The Authority will administer and enforce the rule. For further information contact: Marianne K. Stonestreet, General Counsel, Health Care Authority, 100 Dee Drive, Suite 201, Charleston, West Virginia 25311-1600, telephone number (304) 558-7000; fax (304) 558-7001.

TITLE 65
LEGISLATIVE RULE
HEALTH CARE COST REVIEW AUTHORITY

SERIES 17
HEALTH SERVICES OFFERED BY HEALTH PROFESSIONALS

§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.

1.3. Filing Date. -- April 10, 1992

1.4. Effective Date. -- April 10, 1992

§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 - a facility which offers laboratory and/or imaging services and in which the total cost of all the laboratory and imaging equipment exceeds $300,000.00. In determining whether the medical equipment costs more than $300,000.00, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition of such equipment shall be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value.

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

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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 legislative rule "Certificate of Need," 65 C.S.R. 7.

3.2. If a health service, major medical equipment and/or facility is one set forth in subsection 3.3, the proposed acquisition, development or offering of that service, equipment and/or facility by a licensed health professional is subject to review.

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 shall not be altered except by amendment to this legislative rule.

3.3.1. Computerized tomography (CT).

3.3.2. Lithotripsy.

3.3.3. Radiation therapy.

3.3.4. Magnetic resonance imaging (MRI).

3.3.5. Proton emission tomography (PET).

3.3.6. Cardiac catheterization.

3.3.7. Birthing centers.

3.3.8. Ambulatory surgical facilities or ambulatory surgical centers.

3.3.9. Diagnostic centers.

§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 65 C.S.R. 7. Provided that, there is no expenditure minimum requirement for the inclusion of health services, major medical equipment and/or facilities offered, acquired or developed by health professionals.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE TO BE FILED AS AN EMERGENCY

HEALTH SERVICES OFFERED BY HEALTH PROFESSIONALS PROPOSED RULE

The 1999 Legislature passed Enrolled Senate Bill 492 which directs the Health Care Authority (Authority) to file emergency rules to implement certain changes within the certificate of need law. W. Va. Code §§16-2D-4(a)(1) and 8(c) give the agency the authority to file this rule as an emergency rule.

The purpose of the certificate of need law is to contain or reduce increases in the cost of delivering health services. Furthermore, the agency is directed to protect the health and general welfare of the citizens of this state by ensuring that appropriate and needed institutional health services are made available for all citizens. See, W. Va. Code §16-2D-1

The purpose of this rule is to update the certificate of need process to comply with the requirements of Senate Bill 492.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: HEALTH SERVICES OFFERED BY HEALTH PROFESSIONALS

Type of Rule: X Legislative ____ Interpretive ____ Procedural

Agency WEST VIRGINIA HEALTH CARE AUTHORITY

Address 100 DEE DRIVE, SUITE 201

CHARLESTON, WV 25311-1600

1. Effect of Proposed Rule

	ANNUAL		FISCAL YEAR		
	INCREASE	DECREASE	CURRENT	NEXT	THEREAFTER
ESTIMATED TOTAL COST	$ 0	$ 0	$ 0	$ 0	$ 0
PERSONAL SERVICES	0	0	0	0	0
CURRENT EXPENSE	0	0	0	0	0
REPAIRS & ALTERNATIONS	0	0	0	0	0
EQUIPMENT	0	0	0	0	0
OTHER	0	0	0	0	0

2. Explanation of above estimates:

N/A

3. Objectives of these rules:

TO IMPLEMENT CHANGES IN THE CERTIFICATE OF NEED (CON) LAW MANDATED BY SENATE BILL 492 PASSED BY THE LEGISLATURE IN 1999.

Rule Title: HEALTH SERVICES OFFERED BY HEALTH PROFESSIONALS

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

N/A

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of Citizens.

N/A

C. Economic Impact on Citizens/Public at Large.

N/A

Date: JUNE 30, 1999

Signature of Agency Head or Authorized Reprensentative

RESPONSE TO COMMENTS RECEIVED TO "HEALTH SERVICES OFFERED BY HEALTH PROFESSIONALS" TITLE 65, SERIES 17

The West Virginia Health Care Authority ("HCA") received several comments to the proposed legislative rule, "Health Services Offered By Health Professionals," Title 65, Series 17. The comments received were from hospitals or their related organizations and were general in nature. However, the West Virginia Hospital Association ("WVHA") filed specific comments on July 30, 1999 which correspond to individual sections in the proposed rule. The specific comments filed by the WVHA incorporate all the general comments received by the HCA from the individual hospitals; therefore, the HCA's response corresponds to the specific 65 CSR 17 sections referenced by the WVHA.

Many of the arguments made by the WVHA are more appropriately made to the Secretary of State as they relate to emergency rule making authority. Because the WVHA has duplicated many of the arguments before the Secretary of State in its comments to the HCA, the HCA has attached a copy of its response filed with the Secretary of State. This response addresses the issues raised by the WVHA related to the ability of the HCA to implement emergency rules.

Following are the HCA's specific responses to the WVHA's comments filed with the HCA on July 30, 1999:

65 CSR §17-2.1. – The HCA's proposed amendment of the expenditure threshold for a "diagnostic center" under 65 CSR 17 is required by Senate Bill 492 due to the fact that the threshold minimum for "major medical equipment" under W. Va. Code §16-2D-2(s) changed from $750,000 to $2 million dollars. The HCA amended the dollar threshold in 65 CSR §17-2.1 so that it is consistent with the changes made by Senate Bill 492. The HCA does not have the ability to selectively apply the dollar threshold for "major medical equipment" which was

increased by Senate Bill 492 to $2 million dollars. The acquisition of "major medical equipment" is subject to review regardless of whether you are a hospital, physician, primary care center or other provider of health care services.

Moreover, the HCA has over the years consistently applied the "major medical equipment" threshold to the definition of "diagnostic center" in 65 CSR 17. The opponents argue that physicians should be limited to a $300,000 threshold for diagnostic equipment and that the change in Senate Bill 492 increasing the threshold for "major medical equipment" is not applicable to the definition of "diagnostic center" under 65 CSR 17. This assumption by the WVHA is clearly erroneous for the following reasons:

First, diagnostic equipment under the definition of "diagnostic center" is clearly "medical equipment". The definition of "diagnostic center" in 65 CSR §17-2.1 states "a facility . . . in which all the laboratory and imaging equipment exceeds . . . whether the medical equipment costs more than . . ." [Emphasis added.] Therefore, the HCA cannot by rule impose a different expenditure threshold than that which has been mandated by the Legislature in Senate Bill 492. The issue is simple – diagnostic equipment is a type of "major medical equipment" and therefore cannot be subjected to a different threshold.

In addition, the HCA's practice, policy and precedent dictate that the definition of "diagnostic center" be changed to be consistent with the statutory changes made by Senate Bill 492. In 1991, W. Va. Code §16-2D-4(a)(1) was enacted authorizing the HCA to promulgate 65 CSR 17. During that same year W.Va. Code §16-2D-2, the definition of "major medical equipment", was also amended and the threshold for "major medical equipment" was changed to $300,000. Accordingly, when the agency promulgated the rule, the threshold for "major medical equipment" within the definition of "diagnostic center" under 65 CSR §17-2.1 was listed as $300,000. The threshold for "major medical equipment" was next changed by the Legislature in 1997 when it was increased

to $750,000. Although the HCA did not formally amend 65 CSR 17 to comply with the new threshold at that time, the agency issued several CON decisions which recognized the new statutory threshold of $750,000 for "diagnostic center" and allowed an exemption from CON review for medical equipment purchased under the amount of $750,000. See Area Health Systems, Inc. d/b/a Tri-State Medical Center, CON File #97-2-6233-X; Beckley Oncology Associates, Inc., CON File #98-1-6410-X-1; Charleston Radiation Therapy Consultants PLLC, CON File #98-3-6513-X; Greenbrier Cardiovascular Associates, CON File #94-4-4856-X.

In Area Health Systems, Inc. d/b/a Tri-State Medical Center, CON File #97-2-6233-X, the HCA reviewed a request from a physicians group to determine if the acquisition of certain diagnostic medical equipment was subject to review. The HCA stated in the decision that "[I]n order to meet the definition of a diagnostic center, the equipment's fair market value must exceed the statutory threshold for major medical equipment." [Emphasis added.] This decision held that the threshold for "major medical equipment" applies directly to the definition of "diagnostic center" under 65 CSR §17-2.1. The HCA has consistently interpreted the threshold for major medical equipment within a "diagnostic center" to be the statutory threshold for "major medical equipment" since the Legislature increased it in 1997. For example, in Beckley Oncology Associates, Inc., CON File #98-1-6410-X-1, there was a request for reviewability for the private office practice to replace major medical equipment at a cost of $530,000. Although the project cost exceeded the $300,000 threshold in 65 CSR §17-2.1, the HCA found that the changes to the equipment were not new institutional health services (i.e. not major medical equipment over $750,000 as defined under W. Va. Code §16-2D-3(b)(9)). A similar decision was issued in Charleston Radiation Therapy Consultants PLLC, CON File #98-3-6513-X. The HCA held that the installation of enhancements to a linear accelerator, a cost of $490,000, was not reviewable.

The WVHA states in its Comments to Proposed Rule Making, Title 65, Series 17, the following:

> The proposed amendment to the capital expenditure threshold for a diagnostic center from $300,000 to $2 million will result in a proliferation and unnecessary duplication of laboratory and imaging services through the state. Effectively, licensed health professionals will be able to offer radiology, ultrasound, mammography, fluoroscopy, computerized tomography, nuclear imaging, densitometry studies, or other combinations thereof without any type of certificate of need review or oversight whatsoever.

First, the WVHA has inaccurately portrayed that the threshold is increasing from $300,000 to $2 million. As discussed above, the HCA is currently reviewing "diagnostic centers" under 65 CSR §17-2.1 at the $750,000 threshold level based upon prior precedent. The WVHA has misrepresented the increase in the threshold merely as a way to incite its member hospitals to oppose the HCA's actions.

Second, the HCA disagrees with the WVHA characterization that the increase will result in a proliferation and unnecessary duplication of laboratory and imaging services throughout the state. As a practical matter the HCA believes this will not happen or it would have already happened under the current state of the law. Currently, licensed health professionals (i.e., physicians) are able to offer radiology, ultrasound, mammography, fluoroscopy, nuclear imaging, densitometry studies, or some combination thereof without obtaining a CON, if they do not exceed the $750,000 expenditure threshold. Much of the diagnostic equipment (i.e., radiology, ultrasound, mammography, fluoroscopy, nuclear imaging, densitometry studies etc.) that the WVHA believes will proliferate if the threshold is increased to $2 million dollars can be purchased for less than $750,000. For example, a bone densitometry unit was purchased for approximately $70,000. Strategic Health Services, CON File #97-6189-X (1997); a nuclear medicine unit was purchased for approximately $235,000. Medical

Surgical Group, CON File #976184-X (1997); a mobile x-ray unit was purchased for approximately $150,000. Strategic Health Services, CON File #97-6252-X (1997); and a replacement for a mammography unit was purchased for approximately $166,995. Pleasant Valley Hospital, CON File #98-6435-X (1998). Each of these pieces of diagnostic equipment are well under the $750,000 threshold. Thus, one must express doubt about the arguments of the WVHA and inquire, under current law, why aren't "diagnostic centers" proliferating throughout the State of West Virginia?

Furthermore, the HCA believes that the proliferation cited by the WVHA will not occur because physicians will be faced with various restrictions on self-referral that exist under Stark I and Stark II (§ 1877 and 1903(s) of the Social Security Act). Very basically, the Stark provisions prohibit a physician from making a referral to an entity for the furnishing of certain designated health services (including clinical laboratory services, physical therapy services, occupational therapy services, radiology services including ultrasound, MRI and CT scans, radiation therapy services, durable medical equipment, etc.), for which Medicare may otherwise pay, if the physician (or an immediate family member) has a financial relationship with that entity. Due the restrictions placed upon physicians for self-referral – the HCA believes it will be very difficult for physicians to develop "diagnostic centers."

Further, the WVHA believes that hospitals and other nonprofessional providers will be placed at a competitive disadvantage compared to physicians who develop "diagnostic centers." The WVHA states that physicians will be able to provide services at freestanding locations while hospitals which wish to open up new freestanding locations will have to obtain a CON. (Comments, p. 3). This situation is not new. The law has not changed in this regard. Physicians have historically been exempt from CON law with several notable exceptions. Currently under existing law, physicians who wish to open up a diagnostic center at a cost of less than $750,000 may do so without obtaining a CON; whereas, a

hospital which wants to establish an off campus diagnostic service center is reviewable under W. Va. Code §16-2D-3(b)(1), regardless of the expenditure. Again the WVHA is bolstering its arguments by parading alleged (but imaginary) changes which it believes will have a negative effect upon health care in West Virginia.

In summary, the HCA believes it is statutorily required to raise the capital expenditure threshold to $2 million dollars for "diagnostic center" under 65 CSR §17-2.1. The HCA's practice, policy and precedent dictate that the definition of "diagnostic center" be changed to be consistent with the statutory changes made by Senate Bill 492. Furthermore, the HCA does not believe that the increase in the threshold will result in the drastic consequences alleged by the WVHA for the health care system in West Virginia.

65 CSR §17-3.2. – The HCA's proposed amendment to 65 CSR §17-3.2 which adds the phrase ". . . regardless of the cost associated with the proposal, except for subdivision 3.3.9." simply reflects the HCA's current practice and policy with regard to the health services major medical equipment and/or facilities offered by a license health professional that are subject to review." The proposed change by the HCA simply clarifies the language of the current rule.

Again, the Authority disagrees with the WVHA characterization of this amendment. The Authority did not, as the WVHA states in its comments, single out "diagnostic centers" for the "most lenient regulatory treatment." (Comments, p. 5). This is a blatant attack by the WVHA to confuse the issues. The HCA was merely clarifying the current language and intent of the rule.

65 CSR §17-3.3.1. – The HCA does not believe that it has the discretion to delete computerized tomography (CT) from the list of reviewable health services in Section 65 CSR 3.3.1, as argued by the WVHA. Rather, the HCA removed CT from the list of health services on the grounds that CT was also

removed from the list of reviewable services for all other CON matters. As previously stated, Senate Bill 492 mandated that the HCA promulgate emergency rules to specify the "health services which are subject to certificate of need review." Furthermore, W. Va. Code §16-2d-3(b)(5) states "the state agency shall specify by rule those health services subject to certificate of need as recommended by the certificate of need study. . .". The CON Study conducted by the HCA, WVHA and various other interested parties provides a list of specific reviewable services. The CON Study subcommittee recommended that the scope of review for new services be limited to a specific list of services rather than the CON law prior to Senate Bill 492 which required the review of any and all new services. W. Va. Code §16-2D-3(b)(5). In particular, the CON Study subcommittee recommended that CT be removed from the list of reviewable services. The CON Study did not recommend that physicians who wish to initiate CT should be treated differently than hospitals who wish to initiate CT. Nowhere did the CON Study make a distinction between services reviewable for physicians and services reviewable for hospitals.

Thus, the HCA believes that it was statutorily bound to remove CT from 65 CSR §17-3.3. Senate Bill 492 mandated the HCA to follow the recommendations in the CON Study. W. Va. Code §16-2D-3(b)(5). The HCA followed the recommendations from the CON Study and removed CT as a reviewable health service.

The WVHA states in its comments that "the deletion of computerized tomography (CT)" from Section 3.3.1. is a bad policy choice for West Virginia . . ." (Comments, p. 6). It is interesting and somewhat confusing to the HCA that the WVHA has taken this position due to the fact that it took the opposite position during discussions at meetings of the CON Study task force to develop the list of reviewable services. At that time, the WVHA took the position that CT should not be subject to CON review and that market forces should be allowed to drive the need for the service, determine utilization and in turn effect costs. In reality, the

WVHA is arguing that its member hospitals should be allowed to develop and offer CT without obtaining a CON, whereas licensed health professionals (i.e. physicians) would be required to obtain a CON to offer such services. This is the same type of "competitive disadvantage" that the WVHA so adamantly opposes. (Comments, p. 3).

BEFORE THE WEST VIRGINIA SECRETARY OF STATE

In Re: **Proposed Emergency Legislative Rule**
West Virginia Health Care Authority
Title 65, Series 17 (Filed June 30, 1999)

RESPONSE OF THE HEALTH CARE AUTHORITY IN SUPPORT OF PROPOSED EMERGENCY RULE, "HEALTH SERVICES OFFERED BY HEALTH PROFESSIONALS," TITLE 65, SERIES 17

A. Introduction.

During the 1999 legislative session, the Legislature enacted Senate Bill 492 which made significant changes in the Certificate of Need ("CON") law. The bill also authorized the Health Care Authority ("HCA") to promulgate emergency rules to implement certain changes in the law and to amend and modify current CON rules. The proposed legislative rule and the proposed emergency rule, which are identical, were filed with the Secretary of State and the Legislative Rule Making Review Committee on June 30, 1999. The proposed rule amends the current legislative rule, "Health Services Offered By Health Professionals," Title 65, Series 17, to comply with the requirements of Senate Bill 492.

On July 22, 1999, the West Virginia Hospital Association ("WVHA") filed a Petition for Disapproval of Proposed Emergency Legislative Rule Amending Title 65, Series 17 ("Petition for Disapproval"). In addition, various comments were submitted to the Secretary of State by member hospitals of the WVHA opposing the proposed emergency rule.

The parties opposing the emergency rule have targeted two substantive areas of concern. First, the increase in the major medical equipment threshold within the rule from $300,000[1] to $2 million dollars. Second, the elimination of computerized tomography (CT) from the list of reviewable services. Both of these changes are made by the HCA pursuant to the language in Senate Bill 492 and are addressed by the HCA in the following discussion of the issues.

Furthermore, the parties opposing the emergency rule have presented two procedural arguments in opposition to the approval of this rule as an emergency rule. One, they argue that the HCA has no authority to file this rule as an emergency rule pursuant to W. Va. Code §29A-3-15a(b)(2); and, two, the HCA has exceeded the scope of Senate Bill 492 pursuant to W. Va. Code §29A-3-15a(b)(1). These arguments are addressed separately below.

B. The Proposed Emergency Rule Meets the Criteria of W. Va. Code §29A-3-15 and the Secretary of State Should Not Disapprove the Proposed Emergency Rule under W.Va. Code § 29A-3-15a(b)(2).

Comments received by the Secretary of State in opposition to the proposed emergency rule, "Health Services Offered By Health Professionals," Title 65, Series 17, argue that an emergency does not exist and therefore the rule does not meet the required statutory criteria. This argument is without merit for the following reasons:

1. The proposed rule is authorized by W. Va. Code §16-2D-8(c).

[1] The dollar threshold for "major medical equipment" and "diagnostic centers" increased to $750,000 in 1997. Although the agency did not formally amend 65 CSR 17 in 1997 to comply with the new threshold at that time, the agency issued several CON decisions which recognized the new statutory limit and allowed an exemption from CON review for medical equipment purchased under the amount of $750,000 rather than $300,000. See, Area Health Systems, Inc. d/b/a Tri-State Medical Center, CON File #97-2-6233-X; Beckley Oncology Associates, Inc., CON File #98-1-6410-X-1; Charleston Radiation Therapy Consultants PLLC, CON File #98-3-6513-X; Greenbrier Cardiovascular Associates, CON File #94-4-4856-X.

One of the most significant changes in the CON law implemented by Senate Bill 492 is the change made to W. Va. Code §16-2D-8(c). This Code section states as follows:

> Subsequent amendments and modifications to any rule promulgated pursuant to this article may be implemented by emergency rule. [Emphasis added.]

This language is new and specifically grants the HCA the authority to amend or modify any CON rule by emergency rule. The language is clear and unambiguous and therefore reference to legislative intent is not necessary. It is interesting to note that this specific language was discussed and agreed upon by the co-chairs of the CON task force which reviewed and studied the existing CON law and submitted the recommendations for the changes made by Senate Bill 492.[2] The purpose of this significant amendment was to permit the HCA to make changes to the CON rules, to update and clarify current policy, and to implement various changes in the Code. Prior to the passage of Senate Bill 492, the HCA did not have specific authority to amend CON rules by emergency rule.

West Virginia Code §29A-3-15 specifies the process an agency must go through to implement emergency rules and also defines the criteria by which the Secretary of State must abide in determining whether an emergency rule may be approved. Specifically, W. Va. Code §29A-3-15(a) states:

> An emergency rule shall be effective for not more than fifteen months and shall expire earlier if any of the following occurs:

[2] The CON Committee was formed when the West Virginia Legislature in 1997 directed the HCA to conduct a study of the CON Program. The HCA empanelled a primary task force comprised of a cross section of interests, including consumers, government, health care providers, private industry, and health care payors. The co-chairs of the CON Task Force were, Steven J. Summer, President of the WV Hospital Association and Dayle Stepp, Director of CON. The CON Committee approved the Certificate of Need Study on September 16, 1998.

> (1) The secretary of state. . . disapproves the emergency rule because: (A) The emergency rule or an amendment to the emergency rule exceeds the scope of the law authorizing or directing the promulgation thereof; (B) an emergency does not exist justifying the promulgation of the emergency rule; or (C) the emergency rule was not promulgated in compliance with the provisions of this section. An emergency rule may not be disapproved pursuant to the authority granted by paragraphs (A) or (B) of this subdivision on the basis that the secretary of state or the attorney general disagrees with the underlying public policy established by the Legislature in enacting the supporting legislation. When the supporting statute specifically directs an agency to promulgate an emergency rule. . . the emergency rule may not be disapproved pursuant to the authority granted by paragraph (B) of this subdivision. . . An emergency rule may not be disapproved on the basis that the Legislature has not specifically directed an agency to promulgate the emergency rule, or has not found that an emergency exists and directed the promulgation of the emergency rule. [Emphasis added.]

The opponents of this rule cite W. Va. Code §29A-3-15(f) as the applicable Code section in this matter. This Code section defines an emergency for those agencies which do not have emergency rule making power. This Code section is not applicable in the present case since W. Va. Code §16-2D-8(c) specifically empowers the agency to promulgate emergency rules. The opponents fail to address W. Va. Code §16-2D-8(c) in the Petition for Disapproval because it makes no sense to grant an agency the authority to promulgate emergency rules and then impose the additional standards contained in W. Va. Code §29A-3-15(f). Such an interpretation would render the recent enactment of W. Va. Code §16-2D-8(c) meaningless and contrary to the intent of the legislation.

Furthermore, the HCA's filing of the proposed rule is consistent with its past practice and the rulings of the Secretary of State. The Secretary of State

has routinely approved emergency rules based upon statutory authorization of the agency and without applying the additional standards contained in W. Va. Code §29A-3-15(f). Specifically, the HCA filed an emergency rule with the Secretary of State in 1998 to implement changes in the agency's rate review process, "The Benchmarking and Discount Contract Rule," 65 CSR 26 ("Rate Rule"). The rate rule was approved by the Secretary of State on December 3, 1998, without the HCA being required to demonstrate an "emergency" for each and every amendment in the rule as the opponents believe should be shown for this proposed emergency rule.

The statutory authorization for filing the emergency rate rule is very similar to the authorization granted by Senate Bill 492 to amend the CON rules. West Virginia Code §16-29B-20(a)(2), the provision authorizing the rate rule, contains the following language:

> (B). . .the board may promulgate rules, in accordance with the provisions of section eight [§16-29B-8] of this article, that establish the criteria for review of discount contracts, which shall include that: (i) No discount shall be approved by the board which constitutes an amount below the cost to the hospital; (ii) the cost of any discount contained in the contract will not be shifted to any other purchaser or third-party payor; (iii) the discount will not result in a decrease in the hospital's average number of medicare, medicaid or uncompensated care patients served during the previous three fiscal years; and (iv) the discount is based upon criteria which constitutes a quantifiable economic benefit to the hospital. The board may define by rule what constitutes "cost" in subparagraphs (i) and (ii) of this paragraph; "purchaser" in subparagraph (iii) of this paragraph; and "economic benefit" in subparagraph (iv) of this paragraph. Any rules promulgated pursuant to this subsection may be filed as emergency rules. . . [Emphasis added.]

This emergency rate rule was also filed as a proposed legislative rule and was approved by the Legislative Rule Making Review Committee ("LRMRC") and the Legislature. The issue of the HCA's authority to promulgate the rate rule as an emergency was never raised by the current opponents of the proposed emergency CON rules. In fact, they supported its implementation.

2. Senate Bill 492 establishes July 1, 1999 as the deadline to specify the health services subject to CON review and the HCA has a duty to amend 65 CSR 17 as mandated in Senate Bill 492.

West Virginia Code §16-2D-3(b)(5) states as follows:

> The addition of health services as specified by the state agency which are offered by or on behalf of a health care facility or health maintenance organization and which were not offered on a regular basis by or on behalf of the health care facility or health maintenance organization within the twelve-month period prior to the time the services would be offered. The state agency shall promulgate emergency rules... by the first day of July, one thousand nine hundred ninety-nine, to specify the health services which are subject to certificate of need review. . . The state agency shall specify by rule those health services subject to certificate of need as recommended by the certificate of need study conducted pursuant to section nineteen-a, article twenty-nine-b of this chapter; [Emphasis added.]

This new subsection was passed as a direct result of the recommendations of the CON task force which reviewed the services previously subject to CON review and recommended that they be limited to those listed in proposed emergency rule, "The Certificate of Need Rule," 65 CSR 7. Although the opponents of this rule do not object to the removal of CT services from CON review for hospitals and primary care centers, they object to its exemption from review for licensed health professionals (i.e., physicians). However, the CON

task force did not recommend nor did the legislation specify that the services not on the list would continue to be subject to CON review for physicians. There is no language in the CON Study which supports the opponents' position that CT services should remain reviewable for physicians while CT services are removed from the list of reviewable services for hospitals. In the absence of specific authorization to differentiate among the different health care providers, the HCA applied the CON task force's recommendations and the subsequent legislation uniformly to all health care providers. The HCA believes that it has acted equitably by not favoring hospitals or physicians – instead the HCA applied the CON law uniformly to all health care providers.

As a result, the list of reviewable health services contained in 65 CSR 17 and 65 CSR 7 are consistent. There are some services listed in 65 CSR 7 which are not included in 65 CSR 17, however that is because these are not services offered by physicians. Specifically, the WVHA's main objection is the deletion of CT services from the list of services subject to review. Since the recommendation of the CON task force was to remove CT from CON review and Senate Bill 492 authorized the agency to remove CT from review, the agency did just that. The CON Study and Senate Bill 492 did not distinguish between CT offered by hospitals or by physicians. The deadline for specifying the list of health services subject to review was July 1, 1999 by emergency rule. The HCA filed the proposed emergency rules, 65 CSR 7 and 17, on June 30, 1999.

Thus, the opponents' argument that there is no time limit imposed by which to promulgate the emergency rule is not valid. The HCA had a duty to file emergency rules by July 1, 1999 specifying the list of health services subject to review. To implement this, the HCA submitted emergency rules revising the list of reviewable health services under 65 CSR 7 and 65 CSR 17.

3. An emergency exists as defined by W. Va. Code §29A-3-15(f).

Although proposed emergency rule, 65 CSR 17, is not required to comply with W. Va. Code §29A-3-15(f), the criteria contained within this Code section are met by this proposed emergency rule. This Code section supplements W. Va. Code §29A-3-15(a)(1), previously discussed, and defines what constitutes an emergency, absent statutory language authorizing the filing of emergency rules. West Virginia Code §29A-3-15(f) states in pertinent part:

> . . . an emergency exists when the promulgation of an emergency rule is necessary (1) for the immediate preservation of the public peace, health, safety or welfare, (2) to comply with a time limitation established by this code or by a federal statute or regulation, or (3) to prevent substantial harm to the public interest.

Title 65, Series 17 is a Certificate of Need rule filed pursuant to the Certificate of Need Act, W. Va. Code §16-2D-1 et seq. West Virginia Code §16-2D-1 defines the public policy of the State in regard to the certificate of need program and states:

> It is declared to be the public policy of this State:
>
> (1). . .to contain or reduce increases in the cost of delivering institutional health services.
>
> (2) That the general welfare and protection of the lives, health and property of the people of this State require that...new institutional health services within this State be subject to review and evaluation...in order that appropriate and needed institutional health services are made available for persons in the area to be served. [Emphasis added.]

This statutory language meets the criteria of both W. Va. Code §29A-3-15(f)(1) and (3). Title 65, Series 17, promulgated pursuant to the CON Act,

promotes the public policy of containment or reduction of health care costs and the general protection of the lives, health and property of West Virginians. Obviously this legislatively declared public policy is in accord with W. Va. Code §29A-3-15(f)(1), the immediate preservation of the public health, safety and welfare; and, also W. Va. Code §29A-3-15(f)(3), the prevention of substantial harm to the public interest. Specifically, the rule allows competition among health care providers as it relates to certain services. Increased competition can result in better access to health care and lower costs to the health care consumer. Thus 65 CSR 17 meets the criteria of W. Va. Code §29A-3-15(f).

C. Title 65, Series 17 Complies With The Requirements Of W. Va. Code §29A-3-15 and the Secretary of State Should Not Disapprove the Proposed Emergency Rule under W. Va. Code §29A-3-15a(b)(1).

The second argument made by the opponents of 65 CSR 17 is that the rule is beyond the scope of Senate Bill 492. Title 65, Series 17 was amended as a direct result of the new requirements of Senate Bill 492 and does not exceed the scope of Senate Bill 492 or the CON Act. The two main objections raised to 65 CSR 17 are the elimination of CT services as a reviewable service for physicians and the increase in the threshold for major medical equipment from $300,000[3] to $2,000,000. Both of these changes are authorized by Senate Bill 492. The opponents' arguments are without merit for the following reasons:

1. Senate Bill 492 does not authorize the HCA to apply the definition of "major medical equipment" selectively.

[3] The WVHA inaccurately cites in its arguments that the current threshold for major medical equipment for determining the reviewability for physicians is $300,000. Actually, the threshold for major medical equipment acquired by a physician is $750,000. (See, footnote 1.)

Senate Bill 492 increased the threshold for the acquisition of major medical equipment from $750,000 to $2,000,000. West Virginia Code §16-2D-2(s) states in pertinent part:

> "Major medical equipment" means a single unit of medical equipment or a single system of components with related functions, which is used for the provision of medical and other health services and costs in excess of two million dollars....[Emphasis added.]

West Virginia Code §16-2D-3(a) states that a "new institutional health service may not be acquired, offered or developed within this state except upon application for and receipt of a certificate of need..."

West Virginia Code §16-2D-3(b)(9) states that "'a proposed "new institutional health service" includes:

> (9) The acquisition of major medical equipment; . . .

West Virginia Code §16-2D-4(a)(1) states that the private office practice of health professionals is exempt from CON review except:

> . . .That such exemption from review. . .shall not be construed to include such practices where major medical equipment otherwise subject to review under the provisions of this article is acquired, offered or developed. . .[Emphasis added.]

In short, this means that the acquisition of "major medical equipment" is subject to CON review – period. The acquisition of "major medical equipment" is subject to review regardless of whether you are a hospital, physician, primary care center or other provider of health care services. If you acquire medical equipment with a fair market value in excess of $2 million dollars, this activity is subject to CON review pursuant to W. Va. Code §16-2D-3(b)(9).

West Virginia Code §16-2D-4(a)(1) of the CON law exempts the "private office practice" of medicine from CON review, unless the practice acquires "major medical equipment" or provides other services as discussed below. West Virginia Code §16-2D-4(a)(1) further provides that the exemption from CON review for private office practices does not include the:

> "acquisition, offering or development of one or more health services, including ambulatory surgical facilities or centers, lithotripsy, magnetic resonance imaging and radiation therapy by one or more health professionals.

The HCA is given the authority under W. Va. Code §16-2D-4(a)(1) to promulgate rules "pursuant to section 8 [W. Va. Code §16-2D-8] of this article" which specify the services subject to CON review. As previously stated, W. Va. Code §16-2D-8(c) states that the Authority has the authority to amend any rule by emergency rule. Thus, the Authority may amend the list of health services offered by private office practices that are subject to CON.

Title 65, Series 17 specifies the services subject to CON review as required by W. Va. Code §16-2D-4(a)(1). This list was originally developed in 1992 and is now being amended to comply with the new requirements of Senate Bill 492. The opponents of the proposed emergency rule object to the proposed amendment to the definition of "diagnostic center" (proposed, 65 CSR 17-2.1) which provides as follows:

> 2.1. Diagnostic center - a facility which offers laboratory ~~and/~~or imaging services and in which the total cost of all the laboratory and imaging equipment exceeds ~~$300,000.00~~ $2,000,000.00. In determining whether the medical equipment costs more than ~~$300,000.00~~ $2,000,000.00, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition of such equipment shall be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value.

The opponents argue that physicians should be limited to a $300,000 threshold for diagnostic equipment and that the change in Senate Bill 492 increasing the threshold for "major medical equipment" is not applicable to the definition of "diagnostic center". This is misguided for several reasons. First and foremost, diagnostic equipment is clearly "medical equipment" and therefore the HCA cannot by rule impose a different expenditure threshold than that which has been mandated by the Legislature in Senate Bill 492. This is a fundamental rule of law and the opponents' arguments should be put to rest here. Diagnostic equipment is simply a type of major medical equipment and therefore cannot be subject to a different threshold.

Secondly, the proposed rule, 65 CSR 17, as well as the current rule, expressly state that all terms used in the rule have the same meaning as those defined in W. Va. Code §16-2D-1 et seq. and are in some cases "further clarified herein." 65 CSR §17-2. This language alone shows the close link between 65 CSR 17 and W. Va. Code §16-2D-1 et seq. The opponents would have you believe that 65 CSR 17 should be changed only if language in W. Va. Code §16-2D-4 is changed by the Legislature.

Moreover, the proposed rule, 65 CSR 17 states:

> 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 legislative rule "Certificate of Need," 65 C.S.R. 7.
>
> 3.2. If a health service, major medical equipment and/or facility is one set forth in subsection 3.3, 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 subdivision 3.3.9.

> 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 shall not be altered except by amendment to this legislative rule. . .

The language of 65 CSR 17-3 is clear in that it states that a private office practice is subject to certificate of need review if it acquires, offers or develops one or more "health services, major medical equipment and/or facilities." These terms are defined by W. Va. Code §16-2D-1 et seq. For example, the definition of "major medical equipment" is found at W. Va. Code §16-2D-2(s) and the definition of "health services" is defined in W. Va. Code §16-2D-2(m). Because 65 CSR 17 relies upon the definitions used in W. Va. Code §16-2D-1 et seq. – when the definitions are changed, as they were by Senate Bill 492, then the related changes must be made to the pertinent rules. For these reasons, the HCA has not exceeded the scope of the law authorizing it to amend 65 CSR 17, as argued by the opponents. The HCA is only amending 65 CSR 17 to be consistent with the application of the CON law to all health care providers.

Third, agency practice, policy and precedent dictate that the definition be changed to be consistent with the statute. In 1991, W. Va. Code §16-2D-4(a)(1) was enacted authorizing the HCA to promulgate 65 CSR 17. West Virginia Code §16-2D-2, the definition of the "major medical equipment" threshold, was also amended that year and the threshold changed to $300,000. Accordingly, when the agency promulgated 65 CSR 17, the threshold for the major medical equipment within a "diagnostic center" was listed as $300,000. The threshold for major medical equipment was next changed by the Legislature in 1997 when it was increased to $750,000. Although the agency did not formally amend 65 CSR 17 to comply with the new threshold at that time, the agency issued several CON decisions which recognized the new statutory limit and allowed an exemption from CON review for medical equipment purchased under the amount of $750,000, rather than $300,000. See, Area Health Systems, Inc. d/b/a Tri-State Medical Center, CON File #97-2-6233-X; Beckley Oncology Associates,

Inc., CON File #98-1-6410-X-1; Charleston radiation Therapy Consultants, PLLC, CON File #98-306513-X; Greenbrier Cardiovascular Associates, CON File #94-4-4856-X.

In Area Health Systems, Inc. d/b/a Tri-State Medical Center, CON File No. 97-2-6233-X, the HCA reviewed a request from a physician group to determine if the acquisition of certain diagnostic medical equipment was subject to review. The HCA stated in the decision that "[I]n order to meet the definition of a diagnostic center, the equipment's fair market value must exceed the statutory threshold for major medical equipment." The HCA has consistently interpreted the threshold for major medical equipment within a diagnostic center to be the statutory threshold for major medical equipment since the Legislature increased it in 1997. For example, in Beckley Oncology Associates, Inc., CON File #98-1-6410-X-1, there was a request for reviewability for the private office practice to replace major medical equipment at a project cost of $530,000. Although the project cost exceeded the $300,000 threshold in 65 CSR 17-2.1, the Authority found that the changes to the equipment were not a new institutional health service (i.e. not major medical equipment over $750,000 as defined under W. Va. Code §16-2D-3(b)(9). A similar decision was issued in Charleston Radiation Therapy Consultants PLLC, CON File #98-3-6513-X. The Authority held the installation of enhancements to a linear accelerator at a cost of $490,000 was not reviewable.

The opponents of the proposed rule never challenged or appealed these CON rulings on the basis that the equipment cost was above the $300,000 threshold. It comes as a surprise that the opponents now challenge the proposed rule on the same basis. The decisions were all published in the State Register, Charleston Newspapers and the HCA newsletter. These decisions all reflect a simple principle. The threshold amount used in the definition of "diagnostic center" has always been the same amount used in the definition of "major medical equipment."

Fourth, the opponents argue that the CON law permits different standards for different providers and therefore a different major medical equipment threshold is permissible for physicians. The HCA agrees there are several examples of varying criteria for different providers within the CON law. However, they are specifically authorized by statute, unlike the current situation. For example, the very illustrations provided by the opponents to attempt to demonstrate that the HCA had not "harmonized" 65 CSR 17 demonstrate there are specific examples of different standards in the CON Act. The exemption for shared mobile services cited by the opponents is specifically limited by statute to acute care facilities. See, W. Va. Code §16-2D-4(d). Again the exemption for the creation of birthing centers is limited by statute to nonprofit primary care centers and hospitals. See, W. Va. Code §16-2D-4(a)(6). There is no corresponding statutory language in the present instance to authorize the creation of different major medical equipment thresholds for physicians. The Code is clear – the major medical equipment threshold is $2,000,000.

Finally, the opponents argue that the rule will have serious consequences to the hospital industry. Although this is not an appropriate argument to make to the Secretary of State due to his limited scope of review -- the HCA has two short responses. First, the HCA has not noticed any large increase in diagnostic centers since the Legislature increased the major medical equipment threshold to $750,000 in 1997 and for a number of reasons would not expect their proliferation in the future. If that does occur, the agency has the authority to declare a moratorium and to develop review criteria pursuant to W. Va. Code §16-2D-5(k). Furthermore, the Authority doubts that private office practices offering major medical equipment will spring up all over the state. Physicians developing such services will be faced with a myriad of legal issues including the limitations imposed by Stark I and Stark II and other self-referral law issues. Secondly, the CON task force which reviewed the CON law and made recommendations for legislation, recommended that the major medical

equipment threshold be increased gradually, over a three year period, to the present $2,000,000 threshold and this recommendation was embodied in the introduced version of Senate Bill 492. Significantly or not, the only substantive amendment made by the Legislature to the recommendations of the CON task force was to increase the threshold immediately rather than gradually.

2. The elimination of CT Services from CON review does not exceed the scope of the supporting legislation.

As previously discussed, the elimination of CT services from CON review was recommended by the CON task force and those recommendations were reflected in Senate Bill 492. Specifically new language appears in W. Va. Code §16-2D-3(b)(5) which states:

> The addition of health services as specified by the state agency which are offered by or on behalf of a health care facility or health maintenance organization and which were not offered on a regular basis by or on behalf of the health care facility or health maintenance organization within the twelve-month period prior to the time the services would be offered. The state agency shall promulgate emergency rules pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code [29A-3-15] by the first day of July, one thousand nine hundred ninety-nine, to specify the health services which are subject to certificate of need review. The state agency shall specify by rule those health services subject to certificate of need as recommended by the certificate of need study conducted pursuant to section nineteen-a, article twenty-nine-b of this chapter;

In addition, W. Va. Code §16-2D-4(a)(5) was amended by Senate Bill 492 to permit primary care centers to provide CT services without CON approval. Prior to the passage of Senate Bill 492, these services were specifically listed in this Code section as subject to CON review. This Code section currently states in pertinent part:

> . . .The exemption from certificate of need review of new primary care services provided by this subdivision shall not include the acquisition, offering or development of major medical equipment...or the acquisition, offering or development of major medical equipment otherwise subject to review under the provisions of this article or to include the acquisition, offering or development of ambulatory surgical facilities, lithotripsy, magnetic resonance imaging or radiation therapy. The office of community and rural health services shall define which services constitute primary care services for purposes of this subdivision, and shall, to prevent duplication of primary care services, determine whether a community is underserved with respect to certain primary care services within the meaning of this subdivision. Any organization planning to quality for an exemption pursuant to this subdivision shall submit to the state agency a letter of intent describing the proposed new services and area of service; and . . .

This Code provision relating to the exemption from CON review for primary care centers is now identical to the exemption language for private office practices contained in W. Va. Code §16-2D-4(a)(1), previously cited and discussed.

The passage of these two provisions required the HCA to specify the list of health services subject to review for health care facilities in 65 CSR 7 and to amend 65 CSR 17 to be consistent. No action was required to remove CT services from review for primary care centers since the removal of this service was done by statute. However, for other health care facilities and private office practices, it was necessary to make the changes by rule.

The opponents argue that the HCA was not required to remove CT from CON review for private office practices. However, Senate Bill 492 clearly authorized the agency to remove this service from CON review and did not authorize the agency to apply it selectively. It is the position of the HCA that

unless the statute specifically authorizes selective treatment of certain health care providers, that all entities subject to the CON Act must be treated uniformly.

D. Conclusion.

In conclusion, proposed emergency rule "Health Services Offered By Health Professionals," 65 C.S.R. 17, is a valid emergency rule and meets all of the necessary criteria under W. Va. Code §29A-3-1 et seq.

Respectfully submitted,
West Virginia Health Care Authority
By Counsel

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July 26, 1999

JUL 30 1999

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

Dear Ms. Stonestreet:

On behalf of the West Virginia Hospital Association and its 69 member hospitals and health systems, we submit to the Health Care Authority our comments on the proposed Title 65 Series 7 and Title 65 Series 17 emergency and legislative Certificate of Need rules.

Previously, WVHA filed petitions with the Secretary of State and the Health Care Authority objecting to the promulgation of the Series 7 and Series 17 as emergency rules. In accordance with the notice for public comment, WVHA now presents its concerns regarding the important policy issues which will implemented by the proposed Series 7 and Series 17 rules, as enclosed.

WVHA believes that the proposed Series 17 rules will create an unlevel playing field, by substantially deregulating health professionals who develop diagnostic centers, while maintaining strict control over the development of freestanding diagnostic services by hospitals and other non-professional providers.

The proposed policy changes are obviously not in the best interests of the health care consumers in West Virginia. The new policies are also not consistent with legislative intent to contain health care costs by avoiding duplication of services and will increase per-unit costs to payors, including the State's Medicaid and PEIA programs. Finally, these provisions pose a serious threat to the financial viability of our state's hospitals and community-based primary clinics, particularly the more vulnerable ones within the rural areas which could experience a substantial loss of patient revenue.

We are also concerned with the numerous changes to the Series 7 rule which were not mandated by SB 492, which are enumerated in the enclosed comments, including the definition of an "acquisition," and the definition of "diagnostic services."

WVHA believes that the promulgation of these rules through emergency rule making rather than the standard legislative rule making process is inappropriate for such significant policy changes. The proposed rules will likely result in a proliferation of outpatient diagnostic services throughout the state, in direct competition with existing health care facilities. The proposed rules will have a serious detrimental impact on already financially vulnerable rural hospitals and clinics, by unnecessarily duplicating existing services in rural communities.

Sincerely,

Steven J. Summer
President

SJS/jm

Enclosures:
1. Comments to Proposed Rule-Making Title 65, Series 7
2. Comments to Proposed Rule-Making Title 65, Series 17

cc. D. Parker Haddix
Garry D. Black
Louie A. Paterno, Jr.

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COMMENTS TO PROPOSED RULE-MAKING
TITLE 65, SERIES 17

The West Virginia Hospital Association ("Association") offers the following comments to the proposed emergency legislative rule and the proposed legislative rule promulgated by the West Virginia Health Care Authority ("Authority") seeking to amend Title 65, Series 17.

Section 2.1. The Authority's proposed amendment of the capital expenditure threshold for a "diagnostic center" under Title 65, Series 17 is not required, mandated, or contemplated in any way by Senate Bill 492 recently passed by the West Virginia Legislature. Rather, it constitutes a discretionary policy choice by the Authority that is inappropriately being proposed on an emergency rule-making basis. A more complete discussion of this procedural issue is contained in the Association's "Petition for Disapproval of Proposed Emergency Legislative Rule Amending Title 65, Series 17" ("WVHA's Petition") previously filed with the Secretary of State and with the Authority. This policy choice, if permitted to go forward, will have drastic consequences for the health care system in West Virginia.

Specifically, the proposed amendment to the capital expenditure threshold for a "diagnostic center" from $300,000 to $2 million will result in a proliferation and unnecessary duplication of laboratory and imaging services throughout the state. Effectively, licensed health professionals will be able to offer radiology, ultrasound, mammography, fluoroscopy, computerized tomography, nuclear imaging, densitometry

studies, or some combination thereof, without any type of Certificate of Need ("CON") review or oversight whatsoever. This is bad for the health care system in West Virginia for at least three (3) reasons.

First, a proliferation and unnecessary duplication of "diagnostic centers" statewide will decrease the utilization of these services already available at local community hospitals and primary care centers, thereby siphoning off revenues that may be used to support other necessary, but less profitable, services at these institutions. It is well known that the financial health of West Virginia hospitals is on the decline because of reimbursement cuts engendered by the federal Balanced Budget Act, as well as by other third-party payors. Those who will be hurt the most by such a dilution in utilization are the financially vulnerable rural hospitals in West Virginia. In general, however, all hospitals will have to increase rates to public and private payors, and their patients, in order to compensate for lost revenues on diagnostic services.

The second reason that the proposed amendment to Section 2.1 represents bad public policy is that it will add to health care costs in general, and specifically to the costs of the state's Medicaid and PEIA programs. The cost per unit of service at existing facilities will increase as these services proliferate. Meanwhile, new providers of these services will have invested millions of additional dollars that will ultimately have to be repaid by consumers and their third-party payors.

It is also noteworthy that studies conducted by the U. S. Office of Inspector General, the U. S. General Accounting Office, and the Florida Cost Containment Board

have all concluded that laboratories and imaging centers owned by physician investors are associated with higher (and potentially unnecessary) utilization rates as well as higher costs. See, Federal Register, Vol. 63, No. 6, Pg. 1661 (Jan. 9, 1998). Certainly, a health professional with a large financial investment in a "diagnostic center" has a strong incentive to refer patients to his or her center, and not to existing providers of services within the community. Historically, many such ventures also tend to attract out-of-state entrepreneurs with no stake in meeting the full range of health care needs within a particular community, and frequently cater to those patients with the most lucrative reimbursement plans. Lower paying and indigent patients are left to be served by the community hospitals and other providers.

The final reason why the proposed rule is bad public policy is that it will place hospitals and other nonprofessional providers at a competitive disadvantage compared to health professionals who develop "diagnostic centers". Health professionals will be able to provide these services at freestanding locations that are both convenient and highly visible to the public without any form of CON review. Conversely, a hospital or other non-professional provider wishing to offer diagnostic services in a similar freestanding location will have to apply for and receive a CON before doing so. Hospitals must also face a myriad of other regulatory requirements not applicable to health professionals, including rate review, financial disclosure, JCAHO accreditation, licensure, etc. The costs associated with these various regulatory requirements only widen the competitive gap faced by hospitals vis-a-vis health professionals insofar as

"diagnostic centers" are concerned.

In summary, logic dictates that a physician or other health professional who invests up to $2 million in a "diagnostic center" has gone beyond what has been commonly understood and accepted as the private office practice of medicine, and onto something qualitatively different. Such an investment should constitute an ambulatory health care facility, and should be reviewable under the CON law. This agency has the authority under the second proviso of W.Va. Code § 16-2D-4(a)(1) to rationally define what kinds of services offered by health professionals should be reviewable under the CON law in order to avoid unnecessary duplication and inordinately high health care costs, both of which are identified in W. Va. Code § 16-2D-1 as the primary purposes of the CON program. The Authority's proposed amendment of Section 2.1 of Title 65, Section 17 is nothing short of an outright abdication of its responsibilities under W.Va. Code § 16-2D-4(a)(1) and the CON law in general.

As an alternative to the Authority's proposed amendment to Section 2.1, the Association recommends that the Authority maintain the status quo until the issue can be further studied. At a minimum, the Authority should invoke its powers under W.Va. Code § 16-2D-5(k) to place a moratorium upon the offering or development of "diagnostic centers" statewide in order to examine the impact that their proliferation will have upon the cost of health care, particularly governmental payors, and upon the health status of the public.

Section 3.2. The proposed amendment to Section 3.2 of Title 65, Series 17 is again a discretionary policy choice that is not required, mandated, or contemplated in any way by Senate Bill 492. It is likewise an inappropriate subject for emergency rule-making. See, WVHA's Petition.

Beyond this objection, the Association believes that "diagnostic centers" are the facilities most likely to be unnecessarily proliferated statewide by health professionals, as well as the ones most likely to have an adverse impact upon existing providers and upon the cost of health care services. Despite this likely effect, "diagnostic centers" have been singled out by the Authority's proposed amendment to Section 3.2 for the most lenient regulatory treatment under Title 65, Series 17. The Association can identify no justification favoring such an amendment. Neither the Legislature in Senate Bill 492 nor the CON Study authorized by W. Va. Code § 16-29B-19a recommended changes to the statute or the policy underlying the Authority's regulation of "diagnostic centers".

Again, the Association recommends that the status quo be maintained under Section 3.2 of Title 65, Series 17. If the Authority wishes to add the "regardless of cost" language to Section 3.2, it should do so for all of the items set forth in Section 3.3, without exception.

Section 3.3.1. The proposed amendment to Section 3.3.1 of Title 65, Series 17 is a discretionary policy choice that is not required, mandated, or

contemplated in any way by Senate Bill 492. The Association can find no basis to support promulgation of this rule under Senate Bill 492 or its underlying CON Study. As such, it is an inappropriate subject for emergency rule-making. See, WVHA's Petition.

The deletion of computerized tomography ("CT") from Section 3.3.1 is a bad policy choice for West Virginia because it will only have the effect of increasing the scope and intensity of the problems outlined hereinabove in response to the proposed amendment to Section 2.1. Specifically, it will exacerbate the problems of unnecessary service proliferation, reduced utilization of existing providers, increased costs, and increased competitive disadvantages to hospitals and other nonprofessional providers. The Association recommends maintenance of the status quo, or at a minimum, the imposition of a general moratorium by the Authority upon "diagnostic centers" (including CT scanners within such centers) pursuant to W.Va. Code § 16-2D-5(k) in order to allow it time for further examine of the issue.

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THE WORLD'S LEADING ASSOCIATION
OF INDEPENDENT LAW FIRMS

July 22, 1999

Via Hand Delivery

Ms. Judy Cooper
West Virginia Secretary of State
State Capitol Complex
Charleston, WV 25305

RE: Proposed Emergency Legislative Rule - Title 65, Series 7
Proposed Emergency Legislative Rule - Title 65, Series 17

Dear Ms. Cooper:

Enclosed you will find two (2) Petitions filed on behalf of the West Virginia Hospital Association seeking disapproval of certain proposed emergency legislative rules recently filed with the Secretary of State on June 30, 1999, by the West Virginia Health Care Authority. The rules in question seek to amend Title 65, Series 7, as well as Title 65, Series 17.

Thank you for your review and consideration of these Petitions. If we can provide further information, please do not hesitate to give us a call.

Very truly yours,

JAMES W. THOMAS

JWT/rs
Enclosure
cc: Marianne K. Stonestreet, Esq. (w/enc.)

CO301818

BEFORE THE WEST VIRGINIA SECRETARY OF STATE

In Re: Proposed Emergency Legislative Rule
West Virginia Health Care Authority
Title 65, Series 17 (Filed June 30, 1999)

PETITION FOR DISAPPROVAL OF
PROPOSED EMERGENCY LEGISLATIVE
RULE AMENDING TITLE 65, SERIES 17

A. Background Information.

On June 30, 1999, the West Virginia Health Care Authority ("HCA") filed a proposed emergency legislative rule with the Secretary of State's office seeking to amend an existing legislative rule codified at Title 65, Series 17 entitled "Health Services Offered by Health Professionals." In the associated materials filed by the HCA with its proposed emergency legislative rule, the HCA stated that the facts and circumstances which required the rule to be filed on an emergency basis were threefold: (1) to update the Certificate of Need ("CON") process to comply with the requirements of Senate Bill 492 passed by the 1999 West Virginia Legislature; (2) to comply with the time limits set forth in Senate Bill 492 at W. Va. Code § 16-2D-3(b)(5), § 16-2D-4(a)(1), and § 16-2D-8(c); and (3) to contain or reduce increases in health service costs, and to promote the health and general welfare of the citizens of West Virginia by ensuring that appropriate and needed institutional health services are made available for all citizens. For the reasons set forth below, the HCA's attempt to amend Title 65, Series 17 by emergency rule must be disapproved by the Secretary of State as contrary to law under W. Va. Code § 29A-3-15a.

B. The HCA's Emergency Rule To Amend Title 65, Series 17 Violates W. Va. Code § 29A-3-15a.

The West Virginia CON law at W. Va. Code § 16-2D-1 et seq. establishes an administrative process which requires the review and approval of specified new health services and expenditures. The state agency designated to administer the CON law in West Virginia is the HCA. W. Va. Code § 16-2D-1 directs the HCA to avoid unnecessary duplication and to reduce increases in costs when evaluating and approving proposed new health care services and expenditures.

The legislative rule codified at Title 65, Series 17 relates specifically to health services offered by health professionals. Generally speaking, the private practice of medicine by licensed health professionals is exempted from CON review by W. Va. Code § 16-2D-4(a)(1). However, that statute contains two (2) provisos which require the review of certain expenditures and services offered by health professionals. W. Va. Code § 16-2D-4(a)(1) reads as follows:

> (a) Except as provided in subsection (b), subdivision (9), section three of this article, nothing in this article or the rules and rules adopted pursuant to the provisions of this article may be construed to authorize the licensure, supervision, regulation or control in any manner of the following:
>
> (1) Private office practice of any one or more health professionals licensed to practice in this state pursuant to the provisions of chapter thirty of this code: Provided, That such exemption from review of private office practice shall not be construed to include such practices where major medical equipment otherwise subject to review under the provisions of this article is acquired, offered or developed: Provided, however, That such exemption from review of private office practice shall not be construed to include the acquisition, offering or development of one or more health services, including ambulatory surgical facilities or centers, lithotripsy, magnetic resonance imaging and radiation therapy by one or more health professionals . The state agency shall adopt rules pursuant to

section eight of this article which specify the health services acquired, offered or developed by health professionals which are subject to certificate of need review; (Emphasis added).

The first proviso of the above-quoted language states that the exemption for health professionals does not apply to the acquisition of "major medial equipment" as defined elsewhere in the CON law. The CON law always required that certain medical equipment costing in excess of a certain threshold expenditure level constitutes "major medical equipment" which must undergo CON review, and licensed health professionals are not spared from this requirement by virtue of the first proviso. In the second proviso, the health professional exemption is deemed not to apply to the acquisition, offering, or development of one or more health services specified in a rule to be adopted by the HCA. Title 65, Series 17 is the very rule adopted by the HCA to implement the second proviso of W. Va. Code § 16-2D-4(a)(1) highlighted above.

On March 13, 1999, the West Virginia Legislature enacted Senate Bill 492. This bill amended certain portions of the CON law. No part of W. Va. Code § 16-2D-4(a)(1) relating to the private office practices of one or more licensed health professionals was directly amended by Senate Bill 492, although the expenditure threshold for "major medical equipment" was increased from $750,000 to $2 million elsewhere in the bill. See, W. Va. Code § 16-2D-2(s). Importantly, the special authority granted to the HCA by the second proviso to regulate the acquisition, offering, or development of specified health services by health professionals was not amended in any way by Senate Bill 492.

1. Senate Bill 492 Does Not Require Any Amendment to Title 65, Series 17.

As stated hereinabove, the HCA justified the filing of its proposed emergency rule amending Title 65, Series 17 on three (3) grounds. The first was the alleged necessity of

updating the rule to comply with the requirements of Senate Bill 492. However, as also stated hereinabove, Senate Bill 492 only impacted the first proviso of W. Va. Code § 16-2D-4(a)(1) by increasing the threshold expenditure level for "major medical equipment" from $750,000 to $2 million. The second proviso was left unaffected by Senate Bill 492. The HCA therefore retains full authority to regulate the acquisition, offering, or development of specified health services by health professionals via legislative rule. As a result, current Title 65, Series 17 is not inconsistent with any portion of Senate Bill 492, and no amendment of Title 65, Series 17 is needed to maintain consistency with current law.

The HCA may assert that it was required to change the threshold expenditure level for a "diagnostic center" under § 2.1 of Title 65, Series 17 from $300,000 to $2 million in order to harmonize it with the other changes to the threshold expenditure level for "major medical equipment" contained in Senate Bill 492. Likewise, the HCA may assert that it was required to delete computerized tomography ("CT") under § 3.3.1 of Title 65, Series 17 to harmonize it with the list of reviewable health services authorized by Senate Bill 492 under W. Va. Code § 16-2D-3(b)(5). Neither of these assertions, if made by the HCA, have any merit.

The second proviso of W. Va. Code § 16-2-4(a)(1) by its plain language does not require the HCA's exercise of its regulatory authority granted thereunder to be subservient to any other aspects of the CON law. That was never the intention of the Legislature in enacting the second proviso, nor has it ever been the case in practice by the HCA. In enacting the second proviso, the Legislature clearly understood that it had previously granted a broad CON exemption to licensed health care professionals; however, it also understood the wisdom of according some regulatory discretion to the HCA to designate and define certain services

offered by health professionals that, no matter what the cost, should remain subject to its review and approval process in order to avoid unnecessary duplication and inordinately high cost increases.

In its current form, Title 65, Series 17 provides greater restrictions upon licensed health professionals with respect to certain services than does Senate Bill 492, or the law prior to its enactment. For example, the threshold expenditure level for "diagnostic services" under § 2.2 is now only $300,000, whereas the threshold expenditure level for "major medical equipment" prior to Senate Bill 492 was $750,000. In addition, no attempt was ever made by the HCA to harmonize Title 65, Series 17 with the exemption available to hospitals for mobile magnetic resonance imaging ("MRI"), lithotripsy, and CT scanners, nor with the exemption available to hospitals and primary care centers for birthing centers. See, W. Va. Code § 16-2D-4(a)(6) and (d). In each of these instances, licensed health professionals are required by Title 65, Series 17 to undergo full CON review and approval before instituting such services, whereas other classifications of providers may obtain an exemption from CON to provide such services.

The fact that different classifications of providers face differing standards and levels of review under the West Virginia CON law should come as no great surprise. While the general purposes of the CON law to maintain cost containment and service availability may apply to all, the policies necessary to achieve these goals may vary from provider classification to provider classification. Such classifications are in fact permissible under the due process and equal protection guarantees of Article III, § 10 of the West Virginia Constitution. It is well established that legislative classifications involving economic-based rights are subjected to a minimum level of scrutiny, and that such classifications will be upheld if they are reasonably

related to the achievement of a legitimate state purpose. O'Dell v. Town of Gauley Bridge, 425 S.E. 2d 551 (W. Va. 1992); State ex rel. Boan v. Richardson, 482 S.E. 2d 162 (W. Va. 1996). The HCA's concern that it is legally constrained to apply all provisions in Senate Bill 492 equally to health professionals is just nonsense given the varying forms of regulation already provided for in the CON law, and the unqualified grant of discretion to the HCA by the second proviso of W. Va. Code § 16-2D-4(a)(1).

In summary, Senate Bill 492 has no impact upon the second proviso of W. Va. Code § 16-2D-4(a)(1). Accordingly, the HCA's proposed emergency legislative rule to amend Title 65, Series 17 amounts to nothing more than a discretionary policy choice unsupported by any underlying emergency facts or circumstances.

2. Senate Bill 492 Does Not Contain Any Time Limitations Applicable to Title 65, Series 17.

A second justification offered by the HCA for the filing of its proposed emergency legislative rule to amend Title 65, Series 17 was the alleged need to comply with the time limits set forth in Senate Bill 492 at W. Va. Code § 16-2D-3(b)(5), § 16-2D-4(a)(1), and § 16-2D-8(c). However, a close review of each of these provisions reveals that none have anything to do with the second proviso of W Va. Code § 16-2D-4(a)(1) or Title 65, Series 17.

W. Va. Code § 16-2D-3(b)(5) provides for CON review of the following:

> (5) The addition of health services as specified by the state agency which are offered by or on behalf of a health care facility or health maintenance organization and which were not offered on a regular basis by or on behalf of the health care facility or health maintenance organization within the twelve-month period prior to the time the services would be offered. The state agency shall promulgate emergency rules pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code by the

> first day of July, one thousand nine hundred ninety-nine, to specify the health services which are subject to certificate of need review. The state agency shall specify by rule those health services subject to certificate of need as recommended by the certificate of need study conducted pursuant to section nineteen-a, article twenty-nine-b of this chapter.

This subsection relates to new services provided by health care facilities and health maintenance organizations that are to be subject to CON review. It authorizes the HCA to promulgate an emergency rule by July 1, 1999, to specify which new services are to be reviewable. Licensed health professionals in private practice are not health care facilities or health maintenance organizations under the CON law, however. See, W. Va. Code § 16-2D-2(b),(j), and (i). As a result, the time limitations contained in W. Va. Code § 16-2D-3(b)(5) have no applicability to licensed health professionals or Title 65, Series 17.

Neither W. Va. Code § 16-2D-4(a)(1) nor § 16-2D-8(c) of Senate Bill 492 set forth any time limitations whatsoever. While the need to comply with a time limitation established by state statute is sufficient justification for the promulgation of an emergency rule according to W. Va. Code § 29A-3-15(f)(2), such justification does not exist in respect to Title 65, Series 17. As such, the HCA exceeded the scope of Senate Bill 492, which only authorized the filing of other, unrelated emergency rules.

3. The HCA Did Not Specify Any Other Facts and Circumstances Justifying the Filing of Its Proposed Emergency Rule.

The third justification alleged by the HCA for its filing was to contain or reduce increases in the cost of delivering health services, and to protect the health and general welfare of the citizens of the state by ensuring that appropriate and needed institutional health services are made available for all citizens. By the HCA's own admission, however, these items amount

to nothing more than a mere recitation of the general purposes of the CON law as set forth in W. Va. Code § 16-2D-1. They are applicable to all situations, and do not provide independent justification for the filing of the proposed emergency legislative rule in question. Moreover, the HCA made no effort to link these general purposes to the subject matter of the rule that it seeks to amend, namely, Title 65, Series 17.

Absent a time limitation imposed by state statute, an agency promulgating an emergency rule must demonstrate that such rule is necessary for the immediate preservation of the public peace, health, safety, or welfare, or to prevent substantial harm to the public interest. See, W. Va. Code § 29A-3-15(f)(i) and (f)(3). Other than erroneously asserting that the proposed emergency legislative rule is necessary to comply with the requirements of Senate Bill 492, no threat to the public peace, health, safety, welfare, or interest is even remotely alleged or identified by the HCA in its filing with the Secretary of State.

Title 65, Rule 17 has existed in its present form since April 10, 1992. It has apparently served the purpose of requiring licensed health professionals to undergo CON review of certain health services in order to avoid unnecessary duplication and inordinately high cost increases. The HCA did not identify any statewide shortage of CT scanners or diagnostic centers in its emergency filing that would demand an immediate relaxation of the rules of Title 65, Series 17 so as to allow licenced health professionals to provide these services with minimal or no review by the HCA. To the contrary, the immediate relaxation of the rules of Title 65, Series 17 will, in all likelihood, lead to unnecessary duplication of such services. Existing providers, such as hospitals and rural primary care clinics, will see their patient volumes diluted by this duplication of services, thereby leading to higher per procedure costs. Those potentially hurt by such a scenario will be the smaller, more rural facilities and their patients.

C. Conclusion.

In conclusion, none of the grounds asserted by the HCA as the basis for its filing of a proposed emergency legislative rule to amend Title 65, Series 17 can withstand legal scrutiny. Title 65, Series 17 is a legislative rule wholly unrelated to the changes and time limits set forth in Senate Bill 492. Not a single threat to the public peace, health, safety, welfare, or interest has been identified by the HCA in its filing with the Secretary of State to justify the promulgation of an emergency rule. Accordingly, the Secretary of State must disapprove this proposed emergency legislative rule pursuant to W. Va. Code § 29A-3-15a(b)(2) because an emergency does not exist, as well as pursuant to W. Va. Code § 29A-3-15a(b)(1) beause the HCA exceeded the scope of Senate Bill 492's limited authorization of emergency rule-making.

Respectfully submitted,

WEST VIRGINIA HOSPITAL ASSOCIATION

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COMMENTS TO PROPOSED RULEMAKING

TITLE 65, Series 7
Certificate of Need Rule

TITLE 65, SERIES 17
Health Services Offered by Health Professionals

United Hospital Center ("UHC") offers the following comments to the proposed legislative rules promulgated by the West Virginia Health Care Authority to amend Title 65, Code of State Regulations, Series 7, Certificate of Need Rule, and to amend Title 65, Series 17, Health Services Offered by Health Professionals.

UHC is a not-for-profit community hospital located in Clarksburg, West Virginia, with 373 licensed beds, and is a part of the West Virginia United Health System. It is a major provider of basic health care to the citizens of north central West Virginia, and offers essential services, including services to many who are unable to pay. Its continued viability is essential for citizens in the area to have access to quality health care services.

UHC previously, at the July 22, 1999 meeting of the Authority submitted comments on these same rules as promulgated on an emergency basis. On July 7, 1999, it filed a letter with the Secretary of State, asking him to disapprove the rules on an emergency basis, and on July 29, 1999 appeared before the Authority, asking that the emergency rule be withdrawn. In that request, we made it clear that the rules as promulgated do not constitute an "emergency" as that term is defined in Chapter 29A of the West Virginia Code.

UHC also has several policy concerns with these rules in their formulation as proposed legislative rules, because of the profound impact they will have on the ability to provide our citizens with access to health care. UHC has reviewed and endorses the comments on these rules submitted by the West Virginia Hospital Association, but also wants to offer the perspective of what implementation of the rules would mean to our facility and the people we serve.

Both rules were promulgated on June 30, 1999, ostensibly to comply with Senate Bill 492, enacted by the Legislature during the 1999 regular session. That legislation, in turn, was based

largely on the recommendations of a Certificate of Need Study conducted by the Authority pursuant to a previous legislative mandate. The Study's recommendations were carefully developed by a Task Force consisting of health care providers of various kinds, and representatives of government, business and consumers, and were issued in September 1998. Nonetheless, both proposed rules go far beyond the letter and intent of Senate Bill 492 and the underlying Study.

The most significant impact of the proposed rules that UHC wishes to address is that the effect of the proposed rules is to create an uneven playing field by which diagnostic services could be offered by physicians and others without CON review, but identical services offered by hospitals and related organizations would be subject to review. This phenomenon was not required, or even anticipated by either S.B. 492 or the CON Study, and results from the inter-relationship of following provisions of the proposed rules:

- 65-7-2.8: Definition of "diagnostic services"

- 65-7-2.14: Definition of "private office practice"

- 65-7-15.1.a: Exemption from CON review of a "private office practice"

- 65-7-28.1 and 28.1.b: Addition of certain health services offered by a health care facility, including diagnostic services

- 65-17-2.1: Increasing the threshold from $300,000 to $2 million for a diagnostic center

- 65-17-3.2 and 3.39: Establishing that the cost associated with a diagnostic center is an element in determining its reviewability

- 65-17-3.3.1: Eliminating computerized tomography (CT) as a reviewable item when offered, developed or acquired by health professionals

The net effect of these provisions is that without revision, the proposed rules will have a dramatic adverse effect on hospital revenues, will increase health care costs and will cause duplication of services. They will adversely affect the ability of community hospitals to survive long term and to continue to provide adequate care for the citizens of their respective communities, by forcing rate increases and a diminished capacity to provide indigent and uncompensated care.

One of the principal missions of the HCA is to prevent unnecessary duplication of services in order to curtail the increased cost of health care services. The proposed legislative rules will have the opposite effect.

While, with the exception of diagnostic centers, Magnetic Resonance Imaging ("MRI") remains subject to review under the proposed rules, Ohio's history with MRIs since their deregulation

in March 1996 for urban areas and May, 1997 for rural areas is instructive, with increases of 39 and 15 MRIs - a total of 54 - since those respective deregulation dates. To assume that similar duplication of other diagnostic services that are now effectively exempted from review when offered in a physician's office will not now occur in West Virginia is naive and unrealistic. It is self-evident that an increased supply in diagnostic services will result in a smaller demand for those services to each current provider, leaving the management of the current providers such as UHC no option but to try and replace the revenue lost as a result of the decreased demand, by raising its chargeable rates or reducing costs, which will lead to reductions in the quality of care provided, or both.

The proposed rules will allow entrepreneurial partnerships between doctors and venture capitalists to arise and establish lucrative diagnostic centers offering diagnostic services for private payors, without competition from hospitals or services for public employees or the indigent.

Under the rules as drafted, one can expect "diagnostic centers" to spring up with MRI, ultrasound, C/T scanners and nuclear cameras - all available for well under $2 million - and provide such services from 8 to 5, Monday through Friday, with a primary focus on lucrative insurance payors. Experience shows that such "cherry picking" operations are likely not to accept government pay patients, or provide indigent care, leaving the already strapped hospitals to continue to provide care to those groups. Under the proposed rules, all this would be accomplished without review by the state or consideration of the necessity for such services in the service area.

The proposed rules promulgated by HCA in 65 C.S.R. 17 do not incorporate the exemptions detailed in the recommendations from the CON Study, which were mandated to be incorporated into the proposed rules promulgated by the agency pursuant to S. B. 492. Rather, contrary to recommendations of the CON Study, HCA's proposed rules have inexplicably exempted from those services subject to review for physician practices only, CT scanners - a diagnostic service - despite the Study's specific recommendations that diagnostic services be subject to review regardless of cost and despite the fact that recommendations to exempt those services from review were expressly rejected by the subcommittee when it formulated its report. (See Recommended List of Reviewable Services at page 14 of the Study.)

Further contrary to the Study's recommendations to make diagnostic services reviewable regardless of cost (page 14), HCA has promulgated rules under Section 17 that would exempt diagnostic centers from review under the physician practices provisions unless the total cost of the diagnostic equipment and services offered are in excess of two million dollars, despite the subcommittee's express inclusion of diagnostic services on its Recommended List of Reviewable Services.

The clear effect of the agency's rules as promulgated in 65 C.S.R. 17 is to create a situation whereby physicians' practices and groups of physicians could provide diagnostic services and establish diagnostic centers offering new services or services already available in an area without CON review or rate review, thereby defeating the very purpose of the statute, which is to contain health care costs and to provide access to health care for West Virginia citizens regardless of ability to pay. In addition to creating an unfair competitive advantage for physicians and diagnostic centers by largely exempting

them from review while still subjecting hospitals to review of any services they might attempt to offer to compete for the market share that the new players in the diagnostics field will inevitably draw, the proposed rules will allow those new players to reduce the likelihood that hospitals will even be able to secure CONs for services they need and want to offer, but will not be able to show need because of entrepreneurial offerings that are secured without review.

The effect of the proposed rules will be to create duplication, remove revenue from hospitals, and increase cost to patients in West Virginia.

It is not an understatement to say that the revenue derived from diagnostic services at UHC is in large part the lifeblood of the hospital. In fact, the contribution margin of diagnostic services at UHC represents UHC's entire operating margin.

Assuming that a loss of 50% of the volume of UHC diagnostic services results from the anticipated proliferation of diagnostic services available through physician offices and diagnostic centers, the estimated effect on UHC alone would be to remove $4,308,055 annually of net contribution margin revenue that is currently being generated through the provision of diagnostic services. That figure is well in excess of half of UHC's total operating margin. A reduction of that size would require a 24.43% overall rate increase for the hospital to make up for that lost contribution margin. Should the anticipated revenue loss differ from the estimated 50% figure, a rate increase of approximately 5% would be required to recover a 10% increment of lost contribution margin. In light of the minimal rate increases that have been granted in the past, such an expectation is unrealistic.

The foregoing effect is brought into sharp focus when one considers that UHC historically provides uncompensated and indigent care that is between 7 and 8 percent of the total care provided when care is measured by the value of the services provided. No hospital can continue to provide uncompensated care at anywhere near that level in the face of the foregoing anticipated revenue losses.

Further, when the effects of the federal Balanced Budget Act are taken into consideration, resulting in Federal reimbursement revenue at more than two and one half percent less than expenses after inflation, resulting in an annual shortfall of an estimated two to two and one half million dollars for Medicare services provided at UHC, the adverse effects of the proposed legislative rules on the long-term viability of the hospital and the services it provides to the community only compound the difficulty that community hospitals are likely to experience because of the federal Balanced Budget Act's negative impact on revenues. In order for hospitals like ours to survive, either rates for the services that remain will have to rise dramatically or the amount of uncompensated care provided to the community must be reduced, or both.

The proposed rules may diminish quality of care for the selected services.

Another effect of the proposed rules in permitting certain freestanding diagnostic services to be developed is a potential diminution of the quality of care. It is questionable whether the quality of delivery of services can be maintained when services are delivered by doctors without the support

of specialists currently either employed by or contracted with West Virginia's hospitals. While we do not suggest that the physicians practicing in the various specialties are not capable of reading results of diagnostic tests, unless the physician offering a diagnostic service is a radiologist or has at his or her disposal the services of a radiologist, the level of service that can be provided to the patient will inevitably suffer.

Conclusion

Neither Senate Bill 492 nor the Certificate of Need Study was designed to create an uneven playing field by which certain services could be offered by freestanding operations without CON review, while the same services would be subject to such review if offered by hospitals.

Based on the intent of the Legislature and the Task Force which conducted the CON Study, the rules as proposed should be amended. In enacting Senate Bill 492, the Legislature did not change the language in West Virginia Code § 16-2D-4(a)(1), relating to the reviewability of services offered by a private office practice. Nor did the Task Force which conducted the CON Study for the Health Care Authority recommend a change in the playing field. In effect, the agency is attempting in the proposed rule to supersede the appeal in its recent decision in the Community Medical Associates matter, which is scheduled for oral argument on October 21, 1999.

Of greater consequence, however, is the drastic effect that implementation of the rules as proposed will have on community hospitals such as UHC, and we respectfully request that the proposed rules be amended to comport with Senate Bill 492, the recommendations of the CON Study, and the fundamental purpose of Articles 2D and 29B of Chapter 16 of the West Virginia Code, to ensure cost-effective high quality health care services to the people of our state.

Respectfully submitted,

Bruce C. Carter
President

BC/lc

Davis Health System

July 29, 1999

Ms. Marianne Stonestreet
West Virginia Health Care Authority
100 Dee Drive
Charleston, WV 25311

Dear Ms. Stonestreet:

I would like to have the enclosed letter addressed to the Secretary of State included as my comments on the Health Care Authority emergency rules Title 65 Series 7 and Series 17. Further, I urge the careful consideration be given to the legal brief filed by the West Virginia Hospital Association.

Sincerely,

Robert L. Hammer, II
President & CEO

RLH/jnl

Enclosure

▲ P.O. Box 1697 ▲ Elkins, West Virginia 26241
▲ (304) 637-3767 ▲ FAX: (304) 637-3184

Davis Health System

July 19, 1999

The Honorable Ken Hechler
West Virginia Secretary of State
Administrative Law Division
Building 1, Suite 157K
1900 Kanawha Boulevard, East
Charleston, WV 25305-0770

Subject: Health Care Authority emergency Rules Title 65 Series 7 and Series 17

Dear Mr. Secretary:

The Health Care Authority (HCA) has sent you emergency rules Title 65 Series 7 and Series 17 to revise the Certificate of Need (CON) Rule as a result of legislation (Senate Bill 492) passed in the 1999 session.

The Authority was authorized to issue new emergency rules to implement certain sections of the legislation. In the process HCA has revised the old procedural rules (65 CST 7 "Series 7") for CON and included the two mandated provisions of the legislation. However, in revising the old rule, the Authority also made some existing provisions more stringent, going beyond the emergency rule making requested by the Legislature.

For example, the rule has a definition for "diagnostic services" which would allow any health care facility to acquire lab or imaging services as long as the cost does not exceed $2 million. Davis Health System believes the emergency rule making is inappropriate for implementing the additional provisions which were not specifically authorized by the Legislature.

Another existing rule (65 SCR 17 "Series 17"), pertaining to the private office practice of health professionals was revised with a proposed emergency rule. The revisions would allow physician practices to be exempt from review as long as the acquisition of major medical equipment does not exceed $2 million, with some restrictions. This policy change was not mandated by the legislation and was a discretionary changes made by the Authority.

The result of this proposed rule will now allow any health professional to develop CT, diagnostic imaging and lab services anywhere as long as the $2 million threshold is not

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exceeded. However, existing healthcare facilities are prohibited from developing any new services "off campus". I can see "outside investors" opening "diagnostic centers" with healthcare dollars going to "stockholders" rather than re-invested in West Virginia to help take care of our people. In addition, we could have unnecessary duplication of existing services in rural communities.

My request is that you disapprove the emergency rules that reach beyond the legislative mandate and allow the normal legislative process to address these public policy issues.

Thank you for consideration of my views.

Sincerely,

Robert L. Hammer, II
President and Chief Executive Officer

RLH/bes

Camden-Clark Memorial Hospital
100 YEARS
For Your Lifetime

800 Garfield Avenue
P.O. Box 718
Parkersburg, WV 26102
(304) 424-2111

July 30, 1999

D. Parker Haddix Chairman
West Virginia Health Care Authority
100 Dee Drive, Suite 201
Charleston, WV 25311-1600

Re: Comments to Proposed Rule Making
Title 65, Series 7 and 17

Dear Chairman Haddix:

Camden-Clark Memorial Hospital (CCMH) wishes to provide the following comments with respect to the proposed emergency legislative rules and proposed legislative rules filed by the West Virginia Health Care Authority (Authority) to amend Title 65, Series 7 and Title 65, Series 17:

1. Title 65, Series 7 - The proposed rules to amend Title 65, Series 7 set forth a wide variety of issues and policy decisions. CCMH believes that Senate Bill 492 only contemplated emergency rules to define the list of health services which would be reviewable under W.Va. Code § 16-2D-3(b)(5), and to prescribe the procedure for the "fast track" review of non-health related projects pursuant to W. Va. Code § 16-2D-7(u). The remainder of the issues addressed by the Authority are not appropriate candidates for emergency rule making. Rather, many constitute discretionary policy-making by the Authority which should be considered by the Legislative Rule Making and Review Committee before becoming effective.

Included within the items which are unnecessary for emergency rule making are Section 2.1 (amended definition of "acquiring a health care facility"); Section 2.14 (proposed definition of a "private office practice"); Section 8.1 and 11.4 (drastically limiting the ability of a CON applicant to file additional information); Section 11.4.b (adding rate review non-compliance to the grounds under which the Authority may refuse to deem a CON application complete); and deleted Sections 12.2 and 12.4 (granting preference to CON applications which strengthen the effect of competition for health services). CCMH wishes to indicate its agreement with the West Virginia Hospital Association's (WVHA's) written comments opposing these amendments to Title 65, Series 7.

In addition, CCMH wishes to note its strong disagreement with the definition of "diagnostic services" proposed by the Authority in Section 2.8 of Title 65, Series 7. Proposed Section 2.8 defines "diagnostic services" as being reviewable only if an expenditure threshold of $2 million is exceeded. This is contrary to the intent of Senate Bill 492, and the CON Task Force Study completed earlier. Each of the listed services in proposed Section 28 to Title 65, Series 7 should be reviewable regardless of the level of capital expenditure associated therewith, including "diagnostic services." CCMH agrees with the proposed definition of "diagnostic services" included in the comments filed by the WVHA.

CCMH also believes that the review process for non-health related projects as set forth in proposed Sections 5.7 and 10.4 of Title 65, Series 7 are too restrictive. CCMH believes that applicants should not be required to file a full CON application for non-health related projects, but instead should be able to file an exemption application on such matters. CCMH believes that this was in fact the intention of the CON Task Force Study, which described the new process as a "fast track" one involving only the review of financial information.

2. Title 65, Series 17 - CCMH vehemently disagrees with the proposed amendment to the definition of a "diagnostic center" as set forth in proposed Section 2.1 of Title 65, Series 17. An increase in the capital expenditure minimum for a "diagnostic center" from $300,000 to $2 million will result in a proliferation of such facilities in our area. Specifically, CCMH believes that physicians in the Mid-Ohio Valley are likely to seek to develop free-standing mammography, ultrasound, radiology, fluoroscopy, CT, nuclear, and other imaging services to compete with those already provided by CCMH and other local hospitals. The proliferation of such centers will reduce utilization of such services at CCMH, and make it more difficult to provide other necessary, but less profitable, services. CCMH is also concerned about the built-in advantage for physicians under Title 65, Series 17 to develop such freestanding "diagnostic centers" without a CON, while hospitals would have to obtain CON approval to develop similar freestanding facilities.

Senate Bill 492 does not require any change to Title 65, Series 17. Accordingly, CCMH supports maintaining the status quo of that rule, including the current definition of a "diagnostic center" under Section 2.1. CCMH also supports retaining CT as a listed service under Title 65, Series 17.

Without a doubt, the Authority's proposed amendments to Title 65, Series 17 represent the single largest regulatory threat to hospitals in West Virginia in quite sometime. Since they are not required by law, they should not be made. Certainly, such drastic and potentially catastrophic changes should not be made on an emergency rule making basis by this agency. CCMH urges the Authority to reconsider its position, and to withdraw the proposed emergency rule amending Title 65, Series 17.

Thank you for your kind consideration of these comments. If we can provide further information, please do not hesitate to give us a call.

Sincerely,

Thomas J. Corder

Thomas J. Corder
President and Chief Executive Officer

TJC:mlm

St. Joseph's Hospital
In Affiliation with COLUMBIA/HCA™

1824 Murdoch Avenue P.O. Box 327
Parkersburg, West Virginia 26102-0327

General Information: **(304) 424-4111**
http://www.wvha.com/web/sjh

St. Joseph the Worker with the Child Jesus" - sculpture by William D. Hayden

July 29, 1999

Marianne Stonestreet, General Counsel
West Virginia Health Care Authority
100 Dee Drive, Suite 201
Charleston, WV 25311

Dear Marianne:

I am writing in reference to the proposed changes to certificate of need rules filed recently by the WV Health Care Authority, specifically Title 65, Series 7 (65CSR7) and Series 17 (65CSR17).

My primary concern relates to the definition of diagnostic services. In Series 7, I recommend the definition of diagnostic services be changed to include CT scanners. Proposed specific language to be included, bolded and underlined, reads:

> 65-7-2.8 "Diagnostic services" means, as referenced in subdivision 28.1.b of this rule, laboratory or imaging services **which include the addition of computed tomography (CT) equipment or** for which the total cost of all the equipment required to provide these services exceeds $2,000,000.00 ..."

In addition, I urge you to consider changing the language in Series 17 in Section 65-17-3.3.9 from "Diagnostic centers" to "**Diagnostic services**." I believe this would eliminate any confusion between the two rules.

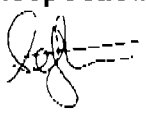
By changing this language to include CT scanners, patients will be ensured of continued quality of scans while the cost of equipment, supplies and patient charges are kept within reason. Additionally, allowing private practitioners to acquire CT scans without regard to need for the additional CT services, could result in a proliferation of unneeded equipment and increase the potential for hospitals to bear further financial loss. As you may be aware, hospitals have already been financial impacted by recent changes in Medicare reimbursement. If physicians acquire CT scanners, they have the option, which hospitals do not, of seeing only patients with insurance or the ability to pay. This could leave hospitals with a higher percentage of low income, uninsured patients with little or no ability to pay for the services.

It takes trained people to perform CT scans and read the results. CT techs have a lot of expertise, and we provide 24 hour a day, seven day a week service. If private practitioners perform CT scans, quality could be impacted. The quality of the result is very dependent on the quality of the CT scan. The cost of the equipment, coupled with the expense of hiring experienced CT techs, will be quite a financial undertaking for private practitioners. If these physicians cannot provide experienced staff to interpret scan results, quality of the scans will be diluted.

If you agree to the changes described above, I ask that the Health Care Authority also revise the emergency rules prior to their becoming effective, even if the rules must be withdrawn and then re-filed. It is possible that a re-filed emergency rule could be approved by the Secretary of State immediately, since there will have been a thirty-day comment period.

Thank you in advance for any consideration given to my recommendations on these rules. As always, I appreciate the willingness of the Authority to listen to concerns voiced by those of us who may be impacted by any changes made to the certificate of need rules.

Respectfully,



Stephens Mundy
Chief Executive Officer

Raleigh General Hospital

1710 Harper Road
Beckley, WV 25801
Telephone (304) 256-4100

July 28, 1999

Marianne Stonestreet
General Counsel
WV Health Care Authority
100 Dee Drive, Suite 201
Charleston, WV 25311

Re: Proposed Certificate of Need Rules

Dear Ms. Stonestreet:

As you well know, the West Virginia Health Care Authority (the Authority) proposed rule changes to the CON statutes, specifically Title 65, Series 7 and Series 17. As I understand it, these proposed rules were also submitted as emergency rules and may become effective immediately upon acceptance by the Secretary of State.

There is one significant area of concern that I have regarding the proposed emergency rules. This concern is the impact that the current language of the proposed rules have regarding computed tomography (CT). As I understand it, the proposed rules would only require providers interested in establishing CT services to submit an application should the cost of the project exceed two (2) million dollars. Should this become effective, I anticipate that a number of physicians will attempt to establish CT services in their own offices. On the surface this may not appear to be a reason of concern; however, I do not feel that there is a problem with access to this service currently. In addition, and more importantly, I feel that if this occurs there will be a significant loss of control of the quality of this service provided to patients as there is currently no monitoring process for physicians who offer this service.

To remedy this situation, I suggest the following changes to Series 7 and Series 17. First, the definition of diagnostic services included in Series 7 should be revised to include computed tomography equipment. This definition may read as follows: "Diagnostic Services" means, as referenced in subdivision 28.1.B. of this rule, laboratory or imaging services **which include the addition of computed tomography (CT) equipment or** for which the total cost of all equipment required to provide these services exceeds two (2) million dollars." In determining whether medical equipment exceeds two (2) million dollars, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition of equipment shall be included. If the

equipment is acquired for less than fair market value, the term "cost" includes fair market value.

Second, I suggest that the rules regarding Series 17 simply be revised to reflect the words diagnostic services as opposed to the current language which is diagnostic centers. I believe that this revision will clarify and avoid any confusion as a result of the difference in wording between these two series.

I appreciate the Authority's efforts in drafting rules which consistently and equitably apply to all providers. I do feel that the suggestions listed above, if accepted by the Authority, will reach the same goal.

I also appreciate the Authority's consideration for any revisions to these proposed rules. I also request that the Authority, if it agrees with these suggested revisions, strongly consider withdrawing the emergency rule and immediately refiling with the suggested revisions.

Your consideration in this matter is greatly appreciated. Should you have any questions, please feel free to contact me.

Sincerely,

David B. Darden

David B. Darden
President/CEO

DBD/sl

SAINT FRANCIS HOSPITAL
an affiliate of Columbia/HCA

333 Laidley Street
P.O. Box 471, Charleston, West Virginia 25322
Phone (304) 347-6500

July 30, 1999

Marianne Stonestreet, General Counsel
West Virginia Health Care Authority
100 Dee Drive
Suite 201
Charleston, WV 25311

Dear Mrs. Stonestreet,

As President and CEO of Saint Francis Hospital in Charleston, WV I am writing you regarding the two proposed CON rules (title 65, Series 7, and Series 17) recently filed by the Health Care Authority. As always, I appreciate the Health Care Authority's willingness to consider changes to proposed rules, and with that in mind I would like to make some comments and suggestions for your consideration.

The proposed rule changes provides the opportunity for the proliferation of expensive technical equipment such as CT scanners to be purchased by physician practices or other entities without regard for the potential harm that could be experienced by the hospital industry and the general public. Such proliferation of this technology without oversight or adherence to established quality health and safety standards could prove costly to consumers through repeat studies being performed due to poor quality or incomplete exams. Additionally, private practitioners or private entities accepting only paying patients for CT scanning services will drive charity or low income patients to hospital facilities already hit hard by Balance Budget Act changes. Finally, from a local perspective, does the Charleston Area really need additional CT services other than those provided for by the existing hospitals in the area?

Some suggestions that would correct and prevent the above issues from occurring would be to revise Series 7 Section 65-7-2.8 to define diagnostic services as laboratory services or imaging services **"which include the addition of computed tomography (CT) equipment "** or for which the total cost of all the equipment required to provide these services exceeds $2,000,000.

Additionally, Series 17 revisions to Section 65-17-3.3.9. should read **"Diagnostic Services"** rather than Diagnostic Centers. This change is needed so there is no confusion between the two rules.

If the Authority believes that these proposed changes have merit, I would ask that the authority revise the emergency rules prior to their being effective. I truly believe that the proposed policy changes I have outlined above have merit, and I ask the Health Care Authority to give serious consideration to these changes.

If you have any questions or comments please do not hesitate to call me at (304) 347- 6872. I appreciate your consideration in this matter.

Respectfully Submitted,

Daniel Lauffer, CEO

Faxed on July 30, 1999
Mailed on July 30, 1999

WHEELING HOSPITAL
1 MEDICAL PARK
WHEELING, WV 26003-6300

Donald H. Hofreuter, M.D.
Administrator / C.E.O.
304-243-3263 • Fax: 304-243-5045

July 28, 1999

Marianne Stonestreet
West Virginia Health Care Authority
100 Dee Drive
Charleston, WV 25311

Dear Ms Stonestreet:

The purpose of this letter is to ask that the changes to the current rules as *Emergency Rule 65, CSR 7 and 17* not be accepted as emergency rules as they have serious potential ramifications for the cost of health care in the State of West Virginia. Further, the changes do not represent an emergency and, therefore, should be subjected to the standard rule making process.

The primary area of concern is with the changes which would allow physicians to acquire expensive medical equipment without Certificate of Need (CON) approval. Currently, physician practices must obtain CON approval if the cost of the equipment exceeds $300,000. The proposed rules would exempt physician practices from CON review so long as the cost of the equipment did not exceed $2 million.

This would, in effect, allow physicians to purchase expensive pieces of medical equipment such as CT scanners, or develop complete ambulatory diagnostic centers without CON review. This has the potential to lead to the costly duplication of medical equipment and services without any corresponding increase in need or demand for the service.

Hospitals, on the other hand, would still be required to obtain CON approval for any diagnostic outpatient center off of its main campus, regardless of cost. This discrepancy provides an unfair business advantage to physician practices which would ultimately increase health care costs to everyone.

While the acquisition of equipment or development of an outpatient diagnostic center will increase a physician's practice revenue, it will result in a loss of that outpatient revenue from the local hospital. However, since the hospital must continue to offer these testing services to its inpatient population, it cannot reduce its staffing costs or eliminate the equipment costs associated with this service. Consequently, the hospital has no alternative but to increase its rates to the remaining payors and patients to cover these expenses and the lost revenue, resulting in higher health care costs overall.

As indicated above, most of a hospital's staffing and equipment costs are "fixed" because they are either required by regulatory agencies or are needed to care for the more seriously ill inpatient population. Therefore, it is important to fully utilize these units to the extent possible to spread these "fixed costs" over large volumes to keep the per test cost as low as possible. If a hospital loses its outpatient testing volume to a physician practice, it will not only duplicate equipment and staffing costs; but will also increase the per test cost to the hospital's remaining patients.

This is obviously not in the best interests of the health care consumers in the State. It s also not consistent with legislative intent to contain health care costs by avoiding duplication of services. Finally, this provision poses a serious threat to the financial viability of our State's hospitals, particularly the more vulnerable ones within the rural areas which could experience a loss of patient revenue.

We strongly urge that you disapprove these changes as emergency rules. If you would like to discuss this matter personally, please do not hesitate to call me at 304-243-3263.

Sincerely,

Donald H. Hofreuter, M.D.

Donald H. Hofreuter, M.D.
Administrator/CEO

DHH/ba

Putnam General Hospital

1400 Hospital Drive
P.O. Box 900
Hurricane, West Virginia 25526
FAX (304) 757-1732/Phone (304) 757-1700

July 28, 1999

Ms. Marianne Stonestreet, General Counsel
West Virginia Health Care Authority
100 Dee Drive, Suite 201
Charleston, WV 25311

Dear Ms. Stonestreet:

I am writing in response to the two certificate of need rules, 65CSR7 and 65CSR17, recently filed by the Health Care Authority. As the CEO of a small hospital, a nurse, a wife and a mother, I too want to make sure that the best medical care is within easy access to everyone in the state. However, I do not believe that the proposed changes will improve the quality or availability of these services to our most under-served neighbors, the uninsured and underinsured people of our state.

As they stand, the changes that you are considering have the potential to greatly damage the ability of my hospital, Putnam General Hospital, to provide healthcare services to our community. A large percentage of the people that we serve are Medicare and Medicaid. It is my fear that if the proposed changes are made, private practitioners will chose not to serve these patients and limit their practice to the insured. Since our hospital depends heavily upon the revenue that outpatient services, such as diagnostic testing, generates to offset the losses that we continue to see due to changing reimbursement rates, this diversion of resources will threaten our ability to care for underinsured patients.

I believe that making slight revisions to the proposed rules can lessen much of the negative impact. In 65CSR7, Section 65-17-3.3.9 should be revised to read:

> " 'Diagnostic Services' means, as referenced in subdivision 28.1.b of this rule, laboratory or imaging services **which include the addition of computed tomography (CT) equipment or**..."

In 65CSR17, Section 65-17-3.3.9, "Diagnostic centers" should be changed to read "**Diagnostic services.**"

Thank you for your time and consideration. I appreciate your willingness to consider changes to these rules.

Sincerely,

Patsy Hardy, CEO

Greenbrier Valley Medical Center

202 Maplewood Avenue
P.O. Box 497
Ronceverte, WV 24970
(304) 647-4411

July 15, 1999

Marianne K. Stonestreet, General Counsel
West Virginia Health Care Authority
100 Dee Drive, Suite 201
Charleston, WV 25311-1600

Dear Ms. Stonestreet:

I am writing to make you aware of our opposition to two sets of emergency rules filed on June 30, 1999 by the Health Care Authority (HCA). The emergency rule will amend Title 65 Series 7 and Series 17 revising the CON Rule and the rule governing the private office practice of health professionals. The revisions include changes to the certificate of need law which we do not believe were mandated by passage of Senate Bill 492.

These revisions constitute major policy changes which will result in a proliferation of diagnostic centers in West Virginia. Having actively lobbied for passage of SB 492 during the 1999 legislative session, I can assure you that legislators did not intend for this bill to increase the number of diagnostic centers, nor to increase the cost of health care in our state.

We do not believe that these rules constitute an emergency, nor do we believe that HCA is correctly interpreting the legislation to give them the authority to change the Series 7 and Series 17 rules. We ask that you reject the proposed amendments to Title 65 Series 7 and Series 17 as not constituting an emergency.

Sincerely,

Donald D. Sandoval, FACHE
Chief Executive Officer

DDS/sbf

CC: Steve Summer, President of West Virginia Hospital Association
Patricia McGill, Vice-President Legislative Policy at WVHA
Steve Barthelmess, Health Care Consultant