KEN HECHLER
Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

JAN CASTO
Deputy Secretary of State

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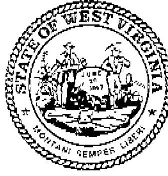

STATE OF WEST VIRGINIA

SECRETARY OF STATE

Building 1, Suite 157-K
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WILLIAM H. HARRINGTON
Chief of Staff

CATHERINE FREROTTE
Executive Assistant

JUDY COOPER
Director, Administrative Law

PENNEY BARKER
Supervisor, Corporations

(Plus all the volunteer
help we can get)

August 9, 1999

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

AGENCY: West Virginia Health Care Authority

RULE: Amendments, Series 7, Certificate of Need Rule

DATE FILED AS AN EMERGENCY RULE: June 30, 1999

DECISION NO. 11-99

Following review under W. Va. Code §29A-3-15a, it is the decision of the Secretary of State that the above emergency rule is **disapproved**. A copy of the complete decision with required findings is available from this office.

KEN HECHLER
Secretary of State

KEN HECHLER
Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

JAN CASTO
Deputy Secretary of State

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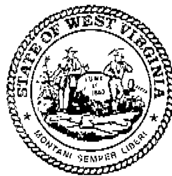

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(Plus all the volunteer help we can get)

EMERGENCY RULE DECISION
(ERD 11-99)

AGENCY: West Virginia Health Care Authority
RULE: Amendments, Series 7, Certificate of Need Rule
FILED AS AN EMERGENCY RULE: June 30, 1999

par. 1 The West Virginia Health Care Authority (HCA) has filed the above rule as a repealed and replaced emergency rule.

par. 2 W. Va. Code § 29A-3-15a requires the Secretary of State to review all emergency rules filed after March 8, 1986. This review requires the Secretary of State to determine: 1) whether the emergency rule was promulgated in compliance with W.Va. Code § 29A-3-15; 2) whether an emergency exists justifying promulgation of the rule; and, 3) whether the emergency rule exceeds the scope of the law authorizing or directing the promulgating thereof.

par. 3 Following review, the Secretary of State shall issue a decision as to whether or not such an emergency rule should be disapproved [§29A-3-15a].

par. 4 Procedural Compliance: W. Va. Code §29A-3-15 permits an agency to adopt, amend or repeal, without hearing, any legislative rule by filing such rule, along with a statement of the circumstances constituting the emergency, with the Secretary of State and forthwith with the Legislative Rule-Making Review Committee (LRMRC).

par. 5 If an agency has accomplished the above two required filings with the appropriate supporting documents by the time the emergency rule decision is issued or the expiration of the forty-two day review period, whichever is sooner, the Secretary of State shall rule in favor of procedural compliance.

par. 6 The HCA filed this emergency rule with supporting documents with the Secretary of State June 30, 1999 and with the LRMRC June 30, 1999.

par. 7 It is the determination of the Secretary of State that the HCA has complied with the procedural requirements of W. Va. Code §29A-3-15 relating to the adoption of an emergency rule.

par. 8 Statutory Authority -- W. Va. Code §16-2D-3(b)(5) reads:

(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.

par. 9 W. Va. Code further states in §16-2D-7(u):

Notwithstanding other provisions of this article, 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 establish a review process for nonhealth related projects. The review process shall not exceed forty-five days. The state agency shall specify in the rule which projects are eligible for this review.

par. 10 §16-2D-8(c) of the W. Va. Code states:

Subsequent amendments and modifications to any rule promulgated pursuant to this article may be implemented by emergency rule.

par. 11 W. Va. Code §§ 16-2D-3(b)(5) and 16-2D-7(u) authorize the HCA to promulgate emergency rules specifying those health services which are subject to certificate of need review and establishing a review process for nonhealth related projects. The proposal submitted by the HCA contains numerous changes from the existing rule which are beyond the scope of these legislative mandates. W.Va. Code § 16-2D-8(c) grants the HCA discretionary authority to amend or modify its legislative rules by emergency rule; however, it does not exempt the HCA from the requirements of W.Va. Code § 29A-3-15 relating to the issue of whether an emergency exists, and the HCA has failed to advance any grounds for an emergency other than the specific legislative directives discussed herein. Accordingly, it is the determination of the Secretary of State that the HCA has exceeded the scope of the law authorizing promulgation of this proposed rule as an emergency rule .

par. 12 Emergency -- W. Va. Code § 29A-3-15(f) defines "emergency" as follows:

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

par. 13 There are three classes of emergency set forth in W.Va. Code § 29A-3-15(f), and an agency must show, to the satisfaction of the Secretary of State, that there exists a nexus between the proposal and the circumstances creating at least one of the above three emergency categories.

par. 14 The facts and circumstances as presented by the HCA are as follows:

The 1999 Legislature passed SB 492 which directs the Health Care Authority to file emergency rules to implement certain changes within the certificate of need law. W. Va. Code §§16-2D-3(b)(5); 7(u) and 8(c) give the agency the authority to file this rule as an emergency rule.

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

par. 15 W.Va. Code §§16-2D-3(b)(5) and 7(u) establish time limitations and direct the HCA to promulgate emergency rules specifying those health services which are subject to certificate of need review and establishing a review process for nonhealth related projects. The proposal submitted by the HCA contains numerous changes from the existing rule which are beyond the scope of these legislative mandates. W.Va. Code § 16-2D-8(c) grants the HCA discretionary authority to amend or modify its legislative rules by emergency rule; however, it does not exempt the HCA from the requirements of W.Va. Code § 29A-3-15 relating to the issue of whether an emergency exists, and the HCA has failed to advance any grounds for an emergency other than the specific legislative directives discussed herein. Accordingly, it is the determination of the Secretary of State that the HCA has failed to show that an emergency exists with respect to this proposed emergency rule.

par. 16 In rendering this decision, it is important to note that the Secretary of State has not disapproved this proposed emergency rule on the basis that he disagrees with the underlying public policy established by the Legislature in enacting the supporting legislation or that he otherwise disagrees with the substance of the proposed emergency rule or the HCA's authority to advance the same.

par. 17 This decision shall be cited as Emergency Rule Decision 11-99 or ERD 11-99 and may be cited as precedent. This decision is available from the Secretary of State and has been filed with the West Virginia Health Care Authority, the Attorney General and the Legislative Rule Making Review Commission.

KEN HECHLER
Secretary of State

FILED 1999 JUL 14 11 03 AM
OFFICE OF SECRETARY OF STATE WEST VIRGINIA

Entered____________________

100 Association Drive
Charleston, WV 25311
(304)344-9744
FAX: (304)344-9745
Web Page: www.wvha.com

BY FAX

July 1, 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

Dear Mr. Secretary:

On behalf of the members of the West Virginia Hospital Association (WVHA) I am writing to make you aware of our opposition to an emergency rule filed on June 30, 1999 by the Health Care Authority (HCA). The emergency rule will amend §65-17 pertaining to the private office practice of health professionals to include changes to the certificate of need law which we do not believe were mandated by passage of Senate Bill 492.

This revision constitutes a major policy change 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, or to increase the costs of health care in our state.

We do not believe that this rule constitutes an emergency, nor do we believe that the HCA is correctly interpreting the legislation to give them the authority to change the Series 17 rule. We have retained attorney James Thomas to represent our members in this matter and he is preparing a petition which will outline our objections to the rule. In addition, the WVHA will prepare formal comments which we will submit for your consideration. We ask that you reject the proposed amendments to § 65-17 as not constituting an emergency.

Sincerely,

Patricia McGill

Patricia McGill
Vice President Legislative Policy

JUL 2 8 26 AM '99
OFFICE ... SECRETARY OF STATE

JACKSON & KELLY PLLC

ATTORNEYS AT LAW

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MEMBER OF LEX MUNDI, THE WORLD'S LEADING ASSOCIATION OF INDEPENDENT LAW FIRMS

Direct Dial No. 340-1319
e-mail: jthomas@jacksonkelly.com

July 22, 1999

Via Hand Delivery

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

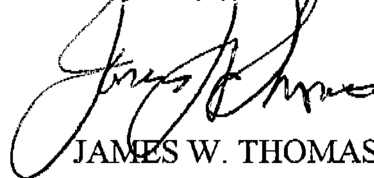
RE: Proposed Emergency Legislative Rule - Title 65, Series 7
Proposed Emergency Legislative Rule - Title 65, Series 17

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

Monongalia
General
Hospital

1200
J.D. Anderson Drive
Morgantown,WV
26505

(304) 598-1200

July 19, 1999

Ken Hechler, Secretary of State
Building 1, Suite 157-K
1900 Kanawha Boulevard E
Charleston, WV 25305-0770

Subject: Opposition to Proposed Certificate of Need Rules
CSR Title 65 Series 7 and Series 17

Dear Mr. Secretary:

During the past two years, the State had a series of study committees reviewing various healthcare policy areas. Then SB 492 was passed to cover these reviews.

At no time were changes to let physicians operate without a Certificate of Need in areas where a hospital must obtain Certificate of Need discussed.

Now we find that HCA has issued items under "Emergency Rules" that relax Certificate of Need rules for physicians, but not for hospitals. We are only looking for a level playing field.

We object for the following reasons:

1. No true emergency exists and the normal rules of Government with open review and hearings should apply.

2. The Health Care Authority has exceeded the mandates of SB 492. SB 492 only mandates emergency rule making to identify the reviewable list of services and process for reviewing non-health related services. The proposed rules go beyond those mandates and address other issues as well. HCA is using their discretionary power to promulgate rules through emergency rulemaking, rather than the standard rule-making process.
   The changes in these rules present major policy changes by the Authority and should be subject to the full standard rule-making process. These rules will have a significant negative impact on existing health care facilities throughout the state.

3. The changes will result in a very uneven playing field for hospitals.

4. The proposed CON rule governing physician office practice increases the threshold defining the acquisition of diagnostic equipment beyond the scope of what is a normal office practice and makes the practice a diagnostic health care facility. The rules will permit physicians to develop a diagnostic service costing

up to $2 million without obtaining a CON, while a hospital would still have to obtain a CON, regardless of the cost, if the service was developed off of campus.

5. The result of these "Emergency Rules" will be a proliferation of diagnostic centers in the state, which will have a dramatic impact on all existing health care providers by duplicating existing services and increasing the cost of health.

6. The relaxation of rules for physician offices on purchasing diagnostic equipment will result in "cherry picking" of the profitable services for insured populations thereby

   - Creating higher costs for local hospitals because of the revenue drained by cherry picking.
   - Causing higher costs to the State of West Virginia which pays a major share of health costs for many including PEIA.

Your leadership in rejecting these "Emergency Rules" will be appreciated by the majority of West Virginians.

Sincerely,

Robert P. Ritz
President/CEO

George Sarris
Chair, Board of Directors

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

JUL 22 2 35 PM '99

OFFICE [illegible] VIRGINIA
SECRETARY OF STATE

July 20, 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

Dear Mr. Secretary:

As president and CEO of Saint Francis Hospital 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, or to increase the costs of health care in our state.

I do not believe that this rules constitutes and emergency, nor do I believe that the HCA is correctly interpreting the legislation to give them the authority to change the Series 7 and 17 rules. I will prepare formal comments, which I will submit for you, consideration. I ask that you reject the proposed amendments to Title 65 Series 7 and Series 17 as not constituting an emergency.

Sincerely,

Daniel J. Lauffer
CEO

Putnam General Hospital

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

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

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

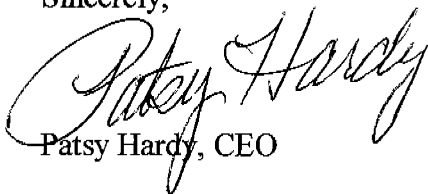
Dear Secretary Heckler:

I am writing to voice my opposition to two sets of emergency rules that were filed on June 30, 1999 by the Health Care Authority. The changes that the HCA is requesting your action upon have the potential to greatly damage the ability of my hospital to provide healthcare services to the community. Our hospital depends heavily upon the revenue that outpatient services, such as diagnostic testing, generates. The revenue generated by these services helps to offset the losses that we continue to see due to changing reimbursement rates.

While I too believe that our CON process needs to be reviewed, I do not believe that any action should be taken without thorough consideration of all possible consequences. 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 merit emergency status. I urge you to please send these measures back to the Health Care Authority and our Legislators for further review and consideration.

As a longstanding and faithful servant to our state, I trust that you will do the right thing. Thank you for your consideration.

Sincerely,



Patsy Hardy, CEO

July 19, 1999

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

Re: Health Care Authority
Emergency Rules Title 65
Series 7 and Series 17

Dear Mr. Secretary:

The West Virginia Primary Care Association wishes to go on record in opposition to filing, on June 30, 1999, by the Health Care Authority (HCA) of emergency rules. The amending of Title 65 Series 7 and Series 17 effect changes which will have a major impact on the rural health care infrastructure in our state. We feel that the legislative intent of Senate bill 429 which is being amended by these rules is being misinterpreted by HCA. We also do not believe that the proposed rules can be construed as an emergency. We request that you reject the proposed amendments to Title 65 Series 7 and Series 17.

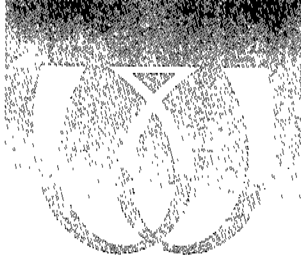
Sincerely,

Jill L. Hutchinson
Executive Director

JLH:lws

OFFICE OF WEST VIRGINIA SECRETARY OF STATE
JUL 21 9 31 AM '99
FILED

WEST VIRGINIA PRIMARY CARE ASSOCIATION, INC.
1219 Virginia Street, East • Charleston, WV 25301 • (304) 346-0032



WHEELING HOSPITAL
1 MEDICAL PARK
WHEELING, WV 26003-6300
304-243-3000
FAX 304-243-3060

JUL 20 12 27 PM '99
OFFICE OF SECRETARY OF STATE WEST VIRGINIA

July 8, 1999

Mr. Ken Heckler
Secretary of State
Building #1, Suite 157-K
1900 Kanawha Boulevard E.
Charleston, WV 25305-0770

Dear Mr. Heckler:

It is our understanding that the Health Care Cost Authority has filed with your office, proposed changes to its current rules as *Emergency Rule 65, CSR 7 and 17.* The purpose of this letter is to ask that these changes 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.

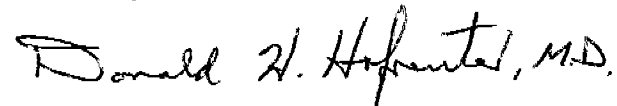
While the acquisition of equipment or development of an outpatient diagnostic center will increase a physician's practice revenue, it will result in a loss of that outpatient revenue from the local hospital. However, since the hospital must continue to offer these testing services to its inpatient population, 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.
Administrator/CEO

DHH/cjr

Wetzel County Hospital

3 East Benjamin Dr.
New Martinsville, WV 26155

Phone 304 455-8000

July 12, 1999

JUL 19 9 55 AM '99

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

RE: Health Care Authority Emergency Rules Title 65 Series 7 and Series 17

Dear Honorable Secretary Hechler:

I am writing to make you aware that Wetzel County Hospital is joining the West Virginia Hospital Association in opposition to two sets of emergency rules filed on June 30, 1999 by the Health Care Authority (HCA). The emergency rules will amend Title 65 Series 7 and Series 17 revising the CON Rule. 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 may result in a proliferation of diagnostic centers in West Virginia which is not needed. It is clear this was not the intent of the legislators, that is to increase the number of diagnostic centers, or to increase the costs of health care in our state and the citizens of Wetzel County and the surrounding areas.

The Hospital Association has retained Attorney James Thomas to outline all the objections to the said rule. We would ask that you review this information when received and we ask that you reject the proposed amendments to Title 65 Series 7 and Series 17 as not constituting an emergency.

Wetzel County Hospital Association

Your consideration in this matter is most appreciated. We attach some information prepared by the West Virginia Hospital Association and concur with those items set forth in the attached.

Sincerely,

Alvin R. Lawson, JD
CEO

enclosure

cc: Pat McGill, Vice President Legislative Policy, WVHA
Senator Mike Ross, Randolph County

ARL/cyg

July 13, 1999

Honorable Ken Hechler
Secretary of State
Building 1, Suite 157K
Charleston, WV 25305

Dear Mr. Hechler;

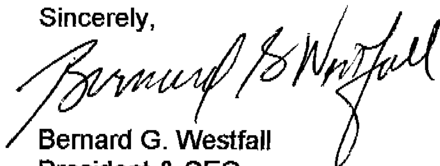
I am writing to ask that you not accept the emergency rules that were recently filed by the Health Care Authority. These rules are intended to implement changes to the Certificate of Need law in accordance with SB 492 that was passed by the Legislature during the past session.

Having participated as a member of the CON task force, I believe the agency has exceeded its authority by attempting to change the CON limits beyond what was recommended by that task force and beyond what was intended by SB 492. The revisions that were recommended by the task force were very specific and limited to that portion of the law that mandated limits for hospital services. The Agency has expanded the proposed rules to include other "Health Facilities" and particularly objectionable are those related to "diagnostic centers".

If the Agency wants to propose changes for CON limits for providers other than hospitals, they should follow the regular rulemaking process, rather than by using the emergency rule process that avoids an open and deliberate discussion of the proposed changes.

We urge that you give careful consideration to this matter and direct the Health Care Authority to stay within the confines of the legislative intent in amending its CON rules. We welcome the opportunity to work with them to change other sections of the regulations, but feel we must have open meetings with adequate preparation time in order to participate in a process that is legitimate.

Sincerely,



Bernard G. Westfall
President & CEO

cc: Senator Jon Hunter
Senator Michael Oliverio
Senator Roman Prezioso
Delegate Barbara Fleischauer
Delegate Cheryl Fletcher
Delegate Charlene Marshall
Delegate Nancy Houston

Office of the President

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WILLIAM T. KLINE
CHAIRMAN

ROBERT L. HARMAN
ADMINISTRATOR/CEO

REGIONAL HEALTH CARE CENTER
P.O. BOX 1019
PETERSBURG, WV 26847

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OFFICE OF SECRETARY OF STATE WEST VIRGINIA
JUL 15 9 22 AM '99
FILED

July 15, 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:

I have had the opportunity to review the above Emergency Rules, and I am very concerned about the content and scope of these two sets of rules. Senate Bill 492 which was passed by the Legislature in the most recently concluded session dealt with revisions to the CON legislation that had been recommended by a special Certificate of Need Study Committee convened by the Health Care Authority. The legislation mandated that the HCA promulgate emergency rules to deal with two specific areas addressed in this Bill. The first area occurs in 16-2D-3 (b) (5) and relates to the directive to establish rules for specifying the health services which are subject to certificate of need review. The second area occurs at 16-2D-6 (u) which mandates rules for establishing a review process for non-health related projects.

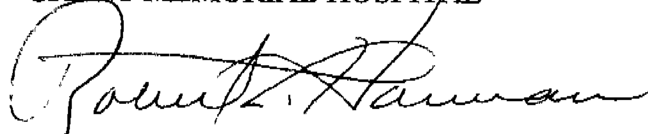
The Series 7 rules are intended to address the two areas mandated by the legislation; however, I believe that in these rules the HCA has addressed areas that were not envisioned by the Legislators. The Series 17 rules impact an area that was neither discussed nor debated by the Legislature when considering the passage of Senate Bill 492. The effect of the new Series 17 rules reflect a major policy change in the area of Certificate of Need that by all rights begs for further discussion and debate about the ramifications of this change in policy.

Senate Bill 492 at Section 16-2D-8 (a) states that the state agency ***may*** promulgate additional rules, but does not specifically direct the State Agency to address the issues that are posed in the Series 17 Rules. I strongly doubt that it was the intent of the Legislators to effect a major change in policy that could ultimately have a significant affect on the cost of health care services in this State, especially without debate and through the rule making process. It is my belief that a major portion of the proposed rules referenced above exceed the mandate of the Legislature for emergency rules, and I encourage you to reject these rules. I would ask that you remand these rules back to the Health Care Authority for revision, thereby providing an opportunity for broader debate on the policy issues contained in the proposed emergency rules.

Thanking you for your consideration on this issue, I remain,

Sincerely yours,

GRANT MEMORIAL HOSPITAL



Robert L. Harman
Administrator/CEO

RLH:mlh

FILED

JUL 16 9 22 AM '99

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

July 14, 1999

981 Maple Drive
Morgantown, WV 26505

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

RE: Opposition to Proposed Certificate of Need Rules
CSR Title 65, Series 17

Dear Mr. Secretary:

As an interested citizen of West Virginia, I am writing to you to express opposition to an emergency rule filed by the Health Care Authority (HCA).

The changes of the emergency rule that amend 65-17 pertaining to the private officer practice of health professionals to include changes to the Certificate of Need Law which I do not believe were mandated by passage of Senate Bill 492.

The proposed changes would constitute a major policy change, create an uneven playing field, and a proliferation of diagnostic centers in West Virginia. I do not think Legislators anticipated these changes.

I ask you to reject the proposed amendments to 65-17 at this time as no emergency exists and the changes are going above and beyond any emergency rules and will result in increased health costs to the State of West Virginia.

Sincerely,

William J. Hennessey

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. Hopen

July 14, 1999

Secretary of State Ken Hechler
State Capitol Building
Charleston, WV 25305

Dear Mr. Secretary:

I am writing to you today regarding the emergency rules that the Health Care Authority has filed to change Certificate of Need law in West Virginia. I am specifically calling your attention to the emergency rules that amend Title 65 Series 7. These changes will constitute a major policy change which will allow any health care facility to add diagnostic or laboratory equipment costing less than $2 Million and will permit other entities to develop diagnostic centers without obtaining approval as long as they stay under $2 Million.

As a member of the Task Force that served to develop the recommendations for Senate Bill 492 (which is being referenced by the Health Care Authority), I can say that at no time did I hear this as being the intent. Quite the opposite. I heard discussion saying that all parties must be treated the same. Finally, and most importantly, these rules are not being promulgated under an emergency situation. This will, however, create an emergency situation in health care in West Virginia. A system that is already stressed due to the severe limitations of the Balanced Budget Act and other reimbursement issues.

I urge you to reject the filing of these under an emergency basis and request that they be forwarded appropriately to the Legislative Rule-Making Review Committee. (It is my understanding that this organization recently asked HCA to withdraw the changes to the rules.) This is the forum for a more appropriate airing of these significant issues. AGAIN, NO EMERGENCY EXISTS. ONE WILL BE CREATED, HOWEVER, IF THESE RULES ARE APPROVED.

Respectfully,

Stephens Mundy
Chief Executive Officer

cc: Steven Summer

OFFICE SECRETARY OF STATE WEST VIRGINIA
JUL 16 9 22 AM '99

Raleigh General Hospital

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

FILED
JUL 16 9 02 AM '99
OFFICE ... VIRGINIA
SECRETARY OF STATE

July 14, 1999

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

Dear Mr. Secretary:

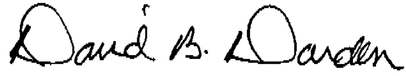
The Health Care Authority (HCA) has filed emergency rules that change the certificate of need law in a way that will result in proliferation of diagnostic health services in West Virginia. HCA submitted these emergency rules as a result of SB492.

The emergency rules amend Title 65 Series 7 and Series 17. I understand that the changes to the Series 7 rule constitute a major policy change which will allow any health care facility to add laboratory or diagnostic equipment costing less than $2 million, and will permit medical corporations to develop diagnostic centers without obtaining approval as long as they stay under the $2 million threshold. HCA is citing their authority to promulgate these rules as passage of SB492, which gave them permission to promulgate emergency rules to implement the Series 17 rules.

I also understand that this issue was debated thoroughly by the task force that developed the recommendations for SB492, and that the task force elected not to recommend changes to the physician practice section of the CON law. In addition, SB492 does not mandate revisions to the Series 7 rule. By revising the Series 7 rule, the HCA is clearly exceeding the authority granted them by the Legislature. The Legislative Rule-Making Review Committee is also concerned with HCA exceeding the legislative intent of SB492. In fact, Senator Mike Ross is including this matter on the agenda for the August interim since HCA failed to withdraw these emergency rules as he strongly suggested.

I am requesting that you not accept these rules, as there is no emergency that requires that they e promulgated under emergency rule making review. Your consideration of my request is appreciated.

Sincerely,



David B. Darden
President/CEO

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FAX: (304)344-9745
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BY FAX

July 2, 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:

On behalf of the members of the West Virginia Hospital Association (WVHA) 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, or to increase the costs of health care in our state.

We do not believe that this rules constitute an emergency, nor do we believe that the HCA is correctly interpreting the legislation to give them the authority to change the Series 7 and Series17 rules. We have retained attorney James Thomas to represent our members in this matter and he is preparing a petition which will outline our objections to the rule. In addition, the WVHA will prepare formal comments which we will submit for your consideration. We ask that you reject the proposed amendments to Title 65 Series 7 and Series 17 as not constituting an emergency.

Sincerely,

Patricia McGill

Patricia McGill
Vice President Legislative Policy

OFFICE OF WEST VIRGINIA SECRETARY OF STATE
JUL 2 1 14 PM '99

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

July 14, 1999

981 Maple Drive
Morgantown, WV 26505

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

RE: Opposition to Proposed Certificate of Need Rules
CSR Title 65, Series 17

Dear Mr. Secretary:

As an interested citizen of West Virginia, I am writing to you to express opposition to an emergency rule filed by the Health Care Authority (HCA).

The changes of the emergency rule that amend 65-17 pertaining to the private officer practice of health professionals to include changes to the Certificate of Need Law which I do not believe were mandated by passage of Senate Bill 492.

The proposed changes would constitute a major policy change, create an uneven playing field, and a proliferation of diagnostic centers in West Virginia. I do not think Legislators anticipated these changes.

I ask you to reject the proposed amendments to 65-17 at this time as no emergency exists and the changes are going above and beyond any emergency rules and will result in increased health costs to the State of West Virginia

Sincerely,

William J. Hennessey

STEPTOE & JOHNSON

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FACSIMILE (304) 624-8183

BANK ONE CENTER, SEVENTH FLOOR
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CHARLESTON, W. VA. 25326-1588
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WRITER'S DIRECT DIAL NUMBER
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deempd@steptoe-johnson.com

July 13, 1999

The Honorable Kenneth Hechler
Secretary of State of the State of West Virginia
Building One, Suite 157-K
1900 Kanawha Boulevard East
Charleston, West Virginia 25305-0770

Dear Mr. Hechler:

I am of the opinion that you should reject the emergency rules which have been recently promulgated and filed with your office by the West Virginia Health Care Authority pursuant to Senate Bill No. 492. I believe that these rules are not consistent with the mandates of this legislation and that their implementation will have a severe impact on community owned and operated not for profit hospitals in West Virginia. Accordingly, I would appreciate it if you would closely review the impact of these rules including their likely impact on the provision of appropriate health care services to all West Virginians.

Very truly yours,

Patrick D. Deem

PDD:jfk

CL543058.1

July 8, 1999

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

Dear Secretary Hechler:

I am writing to urge you not to approve as an "Emergency Rule" recent proposed rules filed by the West Virginia Health Care Authority which were filed with your office on June 30, 1999.

I am opposed to promulgation of Emergency Rules 65CSR7 and 17 for the following reasons:

1. HCA proposes to substantially revise Title 65 Series 7 and 17 Rules through Emergency Rule Making.
2. The HCA has substantially revised Series 7 set forth administrative procedures for conducting CON reviews. The Legislature did not mandate the revision of the Series 7 rules that only mandated that HCA adopt certain provisions pertaining to reviewable health services and reviews for non related health services as enacted by SB 492.
3. HCA proposes to significantly amend and liberalize existing Series 17 rules defining when certain activities undertaken by private office practice of a health professional are subject to review.
4. HCA is using their discretionary power to promulgate these rules through emergency rule making rather than the standard legislative rule making process.
5. Neither West Virginia Code 16-2D-1 et.seq. as amended by SB 492 nor the CON study subcommittee contemplated changes in the regulation of private office practice of physicians as set forth in Series 17.
6. The proposed CON rule governing private office practices increases the threshold defining when the acquisition of diagnostic equipment is beyond the scope of a normal office practice and becomes a diagnostic health care facility. That threshold for medical equipment is proposed to increase from $3 million to $2 million.
7. The proposed CON rule governing private office practices would also allow physicians to acquire CT scanners by removing CT from the list of restricted equipment in physician offices. This action is without legislative mandate or policy direction from the CON study committee.

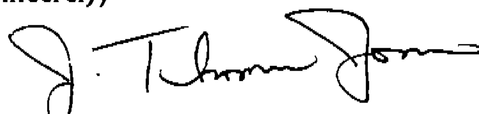
2900 First Avenue, Huntington, WV 25702 • (304) 526-1234

8. These new provisions enable physicians to develop diagnostic health care facilities anywhere in the state with virtually no restrictions (must cost less than $2 million) yet a hospital would still have to obtain a CON to develop any type of diagnostic center off of its own campus, regardless of whether it costs $2 or $2 million, and regardless of whether any equipment is included at all. This further results in an unlevel playing field between doctors and hospitals, allowing physician practices to become "outpatient hospitals".
9. These provisions also create the opportunity for organizations to partner with physicians under the auspices of medical corporations, resulting in health care dollars going out of the state to proprietary interests.
10. The result of these changes will be that diagnostic centers will proliferate throughout the state, having a dramatic negative impact on all existing health care providers, resulting is increased health care costs through unnecessary duplication and reduced utilization of existing services. Rural hospitals will suffer the most.
11. HCA has adopted an arbitrary definition in its Series 7 revisions which will allow any health care facility to add lab or diagnostic equipment costing less than $2 million.
12. HCA has exceeded legislative mandates by revising Series 7 in its entirety, including the changes to existing provisions related to "activities constituting an acquisition of a health care facility", diminishing due process provisions for CON applications and reviews; and defining circumstances involving hospital and physician relationships which are currently under review by an administrative law court in a pending case.
13. The HCA has made these regulatory changes purely at their discretion. There is no legal requirement for changing the rules pertaining to physician practices in Series 17. The regulation of physician practices has existed since 1992, which have articulated the specific and unique circumstances under with certain activities would go beyond the normal scope of a private office practice toward the development of a health care facility. The law allows HCA to specify what services are reviewable for physicians.
14. There was no direct legislative mandate to revise these rules and promulgate new emergency rules. Again, HCA has used it discretionary power to reverse long standing policy through emergency rules making, rejecting the normal legislative rule making process in order to make substantial changes to state health care policy.

I ask that you disapprove the revision of SCR Title 65 Series 7 and 17 as emergency rules pursuant to 29A-3-15(a)(1). There is no "emergency" to warrant revision of these rules through emergency rule making. The proposed revisions exceed the mandates enacted by the Legislature in Senate Bill 492.

Thank you for your attention to this matter.

Sincerely,



J. Thomas Jones
Executive Director/CEO

JUL 13 9 32 AM '99

OFFICE OF ... VIRGINIA
SECRETARY ... STATE

July 7, 1999

Ken Hechler, Secretary of State
Bldg. 1, Suite 157-K
1900 Kanawha Blvd. E.
Charleston, WV 25303-0770

RE: NEW PROPOSED CERTIFICATE OF NEED RULES

Dear Secretary Hechler:

As a United Hospital Center Trustee I am writing to register my opposition to the issue of Emergency Rules 65 CSR 7 and 17.

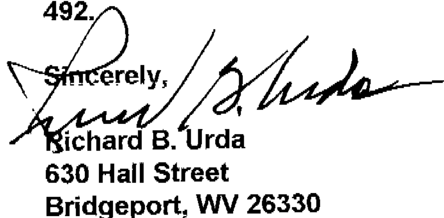
WV Code 16-2D-1 as amended by SB 492 nor the CON Study Subcommittee considered the changes to the regulation of private practice of physicians as set forth in Series 17 exempting physician practices from review as long as equipment acquisition does not exceed $2 Million. SB 492 nor CON Study Subcommittee called for this policy change. This change, is so significant, it should come through the standard legislative rule making process.

The CON rule pertaining to private office practices wherein the threshold for medical equipment proposes to increase from $300,000 to $2 Million exceeds normal office practice. This change will allow private practicioners to acquire CT scanners. It then follows that physicians will be able to develop diagnostic health care facilities anywhere in the state with little or no restriction. Hospitals on the other hand would still have to obtain CON to develop a sattelite diagnostic center whether or not any equipment is included.Not fair.

It then further follows that the result of these changes will see the proliferation of diagnostic centers throughout the state, which will have a dramatic, costly impact on all health care providers. Health care costs will increase due to duplication and reduced utilization of existing services. Rural hospitals, already sagging under the burden of the Medicare reduced reimbursements of the Balance Budget Act will see reduced services from health care facilities now available to our communities.

We ask you, Mr Secretary, to disapprove the revision of CSR Title 65 Series 7 and 17 as emergency rules. There is no "emergency" to justify revision of the rules through emergency rule making. The proposed revisions exceed the mandates enacted under SB 492.

Sincerely,



Richard B. Urda
630 Hall Street
Bridgeport, WV 26330

cc: Senator Mike Ross
Senator Joe Minard
Delegate Larry Linch
Delegate Sam Cann

Greenbrier Valley
Medical Center

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

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JUL 13 9 32 AM '99

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

July 6, 1999

Ken Hechler
Secretary of State
Building 1, Suite 157-K
1900 Kanwha Blvd., East
Charleston, WV 25305-0770

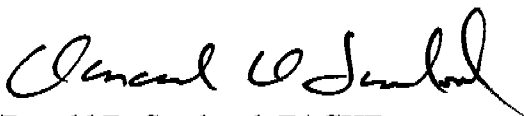
Dear Mr. Secretary:

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

APPALACHIAN
REGIONAL
HEALTHCARE

SERVING THE CENTRAL
APPALACHIAN COMMUNITIES OF
KENTUCKY VIRGINIA & WEST VIRGINIA

JUL 15 9 02 AM '99
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

July 13, 1999

BECKLEY ARH
HOSPITAL

Ken Hechler, Secretary of State
Bldg. 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

Dear Mr. Hechler:

The Health Care Authority has filed emergency rules that change the state's Certificate of Need (CON) laws in a manner that will undermine what I believe is the intent of the CON laws, i.e. the protection of the public interest. I am requesting that you not accept these revised CON rules until they can be thoroughly debated and revised to best protect the interests of all parties involved in the provision of healthcare services to the citizens of this state.

The Health Care Authority's emergency rules amend Title 65, Series 7 and Series 17 in such a manner as to allow a proliferation of freestanding diagnostic centers owned by medical corporations. These types of diagnostic centers typically serve insured clients while refusing care to the uninsured and underinsured. These less fortunate citizens are referred to public and not-for-profit hospitals for their care. While the mission of these charitable institutions, such as ours, is to provide charity care, we can only do this within the limits of our resources. We must treat paying customers in order to be able to afford to give charity care. The proposed emergency rules undermine this capability.

Please carefully review the Authority's emergency CON rules considering the ramifications of their adoption. The unintended consequences of adoption will be costly.

Thank you for your attention to this urgent matter.

Sincerely,

David R. Lyon
President
West Virginia ARH

306 Stanaford Road
Beckley, West Virginia 25801
(304) 255-3000

cc: Patricia McGill, Vice President Legislative Policy
West Virginia Hospital Association
100 Association Drive
Charleston, WV 25311

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FILED
JUL 13 9 32 AM '99
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

July 7, 1999
CarenbGE@steptoe-johnson.com

Writer's Direct Dial Number

(304) 353-8130

Honorable Ken Hechler
Secretary of State
State Capitol
Charleston, WV 25310

By Regular Mail and
Facsimile to (304) 558-0900

Dear Mr. Secretary:

We represent the United Hospital Center in Clarksburg, West Virginia, and on its behalf request that you exercise your authority under West Virginia Code § 29A-3-15a to disapprove the following emergency rules filed by the West Virginia Health Care Authority on June 30, 1999:

- 65 CSR 7: Certificate of Need Rule

- 65 CSR 17: Health Services Offered by Health Professionals

These rules should be disapproved because they violate two provisions of § 29A-3-15a:

- the rules violate subsection (b)(1) by exceeding the scope of the law authorizing their promulgation; and

- the rules violate subsection (b)(2) in that an emergency does not exist for the filing of the rules in the form in which they have been promulgated.

The rules were filed on an emergency basis purportedly to comply with Senate Bill 492, which was passed on March 13 and became effective June 12, 1999.

Although Senate Bill 492 amends the statutes on certificate of need and provides for the promulgation by the agency of certain rules on an emergency basis, the above rules go far beyond that which is authorized by the legislation.

65 CSR 7: Certificate of Need Rule

According to the Notice attached to the filing of this rule, the agency cites as its authority West Virginia Code §§ 16-2D-3(b)(5), 7(u) and 8(c).

An examination of two of these provisions demonstrates that the agency has exceeded its authority in the promulgation of this emergency rule.

West Virginia Code § 16-2D-3(b)(5) authorizes the agency to promulgate emergency rules to specify the health services subject to CON review, but requires the rule to specify "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." We believe that the emergency rule exceeds the recommendations of the study in several areas, and to that extent it violates this Code provision.

West Virginia Code § 16-2D-8(c) provides that "*subsequent* amendments and modifications to any rule promulgated pursuant to this article may be implemented by emergency rule." [Emphasis added.] Senate Bill 492 rewrote much of the language in this Code section, and the provision in subsection (c) is entirely new. The agency apparently has interpreted this provision to give it carte blanche to amend any existing rule by emergency rule. Such an interpretation is absurd, and the word "subsequent" should be read prospectively, so as not to deprive the public of its right to give interested persons an opportunity to offer written comments. Additionally, the agency states the emergency rule repeals and replaces the existing rule, so it is all the more apparent that the agency should comply with the preceding subsection (b) of section 8 which guarantees that the public shall have an opportunity to be heard.

65 CSR 17: Health Services Offered by Health Professionals

According to the Notice attached to the filing of this rule, the agency cites as its authority West Virginia Code §§ 16-2D-4(a)(1) and 8(c).

West Virginia Code § 16-2D-4(a)(1) is unchanged by Senate Bill 492, and offers no basis for revision of the rule on an emergency basis.

West Virginia Code § 16-2D-8(c) provides that "*subsequent* amendments and modifications to any rule promulgated pursuant to this article may be implemented by emergency rule." [Emphasis added.] As stated previously, Senate Bill 492 rewrote much of the language in this Code section, and the provision in subsection (c) is entirely new. The agency apparently has interpreted this provision to give it carte blanche to amend any existing rule by emergency rule. Such an interpretation is absurd, and the word "subsequent" should be read prospectively, so as not to deprive the public of its right to give interested persons an opportunity to offer written comments.

Promulgation on Emergency Basis Violates APA and Separation of Powers

At the same time the agency filed the above rules on an emergency basis, it also filed identical text as proposed legislative rules. It should be clear from a reading of both the Administrative Procedures Act and Senate Bill 492 that only those matters clearly set forth as necessary to comply with the provisions of Senate Bill 492 should be promulgated on an emergency basis. To do otherwise deprives the public of its role in the rulemaking process contemplated in Article 3, Chapter 29A of the West Virginia Code, as affected parties are unable to so much as comment on legislative rules that by definition have the force of law, supply the basis for imposition of civil or criminal liability or grant or deny a specific benefit.

The action of the Authority in promulgating the rules in this form on an emergency basis also deprives the Legislature, at least temporarily, from exercising its Constitutional authority to make substantive legislative change. In effect, therefore, the action of the Health Care Authority violates the separation of powers clause of Article V of the West Virginia Constitution and its action should be disapproved.

Very truly yours,

George Carenbauer

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General
Hospital

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26505

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JUL 22 2 15 PM '99
OFFICE ... SECRETARY ... VIRGINIA STATE

July 19, 1999

Ken Hechler, Secretary of State
Building 1, Suite 157-K
1900 Kanawha Boulevard E
Charleston, WV 25305-0770

Subject: Opposition to Proposed Certificate of Need Rules CSR Title 65 Series 7 and Series 17

Dear Mr. Secretary:

During the past two years, the State had a series of study committees reviewing various healthcare policy areas. Then SB 492 was passed to cover these reviews.

At no time were changes to let physicians operate without a Certificate of Need in areas where a hospital must obtain Certificate of Need discussed.

Now we find that HCA has issued items under "Emergency Rules" that relax Certificate of Need rules for physicians, but not for hospitals. We are only looking for a level playing field.

We object for the following reasons:

1. No true emergency exists and the normal rules of Government with open review and hearings should apply.

2. The Health Care Authority has exceeded the mandates of SB 492. SB 492 only mandates emergency rule making to identify the reviewable list of services and process for reviewing non-health related services. The proposed rules go beyond those mandates and address other issues as well. HCA is using their discretionary power to promulgate rules through emergency rulemaking, rather than the standard rule-making process.
   The changes in these rules present major policy changes by the Authority and should be subject to the full standard rule-making process. These rules will have a significant negative impact on existing health care facilities throughout the state.

3. The changes will result in a very uneven playing field for hospitals.

4. The proposed CON rule governing physician office practice increases the threshold defining the acquisition of diagnostic equipment beyond the scope of what is a normal office practice and makes the practice a diagnostic health care facility. The rules will permit physicians to develop a diagnostic service costing

MON GEN EXECUTIVE SVC. ID:304-598-1987 JUL 22'99 12:07 No.005 P.02

up to $2 million without obtaining a CON, while a hospital would still have to obtain a CON, regardless of the cost, if the service was developed off of campus.

5. The result of these "Emergency Rules" will be a proliferation of diagnostic centers in the state, which will have a dramatic impact on all existing health care providers by duplicating existing services and increasing the cost of health.

6. The relaxation of rules for physician offices on purchasing diagnostic equipment will result in "cherry picking" of the profitable services for insured populations thereby

   - Creating higher costs for local hospitals because of the revenue drained by cherry picking.
   - Causing higher costs to the State of West Virginia which pays a major share of health costs for many including PEIA.

Your leadership in rejecting these "Emergency Rules" will be appreciated by the majority of West Virginians.

Sincerely,

Robert P. Ritz
President/CEO

George Sarris
Chair, Board of Directors

MON GEN EXECUTIVE SVC. ID:304-598-1987 JUL 22,99 12:07 No.005 P.03

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AUG 2 9 45 AM '99

OFFICE ... SECRETARY OF STATE ... VIRGINIA

HOUSE OF DELEGATES
WEST VIRGINIA LEGISLATURE

BUILDING 1, ROOM M-212
1900 KANAWHA BLVD., EAST
CHARLESTON, WV 25305-0470
PHONE (304) 340-3200

NANCY HOUSTON
141 LAMPLIGHTER DRIVE
MORGANTOWN, WV 26508
PHONE: (304) 594-1468

Committees:
Constitutional Revision
Education
Health and Human Resources
Industry and Labor

July 28, 1999

Ken Hechler, Secretary of State
Building 1, Suite 157-K
1900 Kanawha Boulevard E
Charleston, WV 25305-0770

RE: Opposition to Health Care Authority Emergency Rules
Title 65, Series 7 and Series 17

Dear Mr. Secretary:

It has come to my attention that the Health Care Authority (HCA) has filed emergency rules that change the certificate of need law in a way that will result in a proliferation of diagnostic health services in West Virginia.

The emergency rules amend Title 65 Series 7 and Series 17. I have been informed that the changes to the Series 7 rule constitute a major policy change which will allow any health care facility to add laboratory or diagnostic equipment costing less than $2 million, and will permit medical corporations to develop diagnostic centers without obtaining approval as long as they stay under the $2 million threshold. The HCA is citing their authority to promulgate these rules as passage of SB 492, which gave them permission to promulgate emergency rules to implement the Series 17 rules.

I have been advised that this issue was debated thoroughly by the task force that developed the recommendations for SB 492, and that the task force elected not to recommend changes to the physician practice section of the CON law. In addition, SB 492 did not mandate revisions to the Series 7 rule. By revising the Series 7 rule, the HCA is clearly exceeding the authority granted them by the Legislature. I ask that you not accept these rules, as there is no emergency that requires that they be promulgated under emergency rule making review.

Sincerely,

Nancy Houston

Nancy Houston
Delegate 44th District

CC: William Hennessey, Director, Gov. Relations, Monongalia General Hospital
Bernard Westfall, President and CEO, WVU Health Care System

prefers interim mail, April through December, at home address

HOUSE OF DELEGATES
WEST VIRGINIA LEGISLATURE

BUILDING 1, ROOM M-212
1900 KANAWHA BLVD., EAST
CHARLESTON, WV 25305-0470
PHONE (304) 340-3200

LARRY A. WILLIAMS, Chair
COMMITTEE ON FOREST MANAGEMENT REVIEW
ASSISTANT MAJORITY WHIP
RT. 2, BOX 68-B
TUNNELTON, WV 26444
PHONE: (304) 568-2815

Committees:
Agriculture and Natural Resources
Education
Industry & Labor
Joint Pensions & Retirement

July 12, 1999

The Honorable Ken Hechler
West Virginia Secretary of State
Building 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

Dear Mr. Secretary:

As a legislator in West Virginia, I am writing to you to express my opposition to an emergency rule filed by the Health Care Authority.

The changes of the emergency rule that amend 65-17 pertaining to the private office practice of health professionals to include changes to the certificate of need law which I do not believe were mandated by passage of Senate Bill 492.

The proposed changes would constitute a major policy change, create an uneven playing field, and a proliferation of diagnostic centers in West Virginia. I never anticipated that these changes would come about, and I doubt my colleagues did either.

I ask that you reject the proposed amends to 65-17 at this time as no emergency exists.

Sincerely,

Larry A. Williams

Larry A. Williams

LAW:mrs

The Senate of West Virginia

Charleston

JUL 14 3 44 PM '99

OFFICE OF ... VIRGINIA SECRETARY ...

COMMITTEES:
Banking and Insurance
Finance
Health and Human Resources (Vice Chair)
Labor
Military (Chair)
Natural Resources

July 13, 1999

ROMAN W. PREZIOSO, JR.
1806 Dogwood Drive
Fairmont 26554

Phone: (304) 366-5308

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

RE: Opposition to Proposed Certificate of Need Rules
CSR Title 65, Series 17

Dear Mr. Secretary:

I am writing to you to express my concern to an emergency rule filed by the Health Care Authority (HCA).

On June 30, 1999, the Health Care Authority (HCA) filed an emergency rule that will amend 65-17 pertaining to the private practice of health professionals to include changes to the certificate of need law. This rule constitutes a major change which will result in the proliferation of diagnostic centers in West Virginia.

I would respectfully ask you to reject the proposed amendments to 65-17 at this time and suggest that you make this decision on the fact that no emergency exists.

If I can be of further assistance in this matter, please contact my office.

Sincerely,

Roman W. Prezioso, Jr.
Senator -- 13th District

RWP:dq

HOUSE OF DELEGATES
WEST VIRGINIA LEGISLATURE
BUILDING 1, ROOM M-212
1900 KANAWHA BLVD., EAST
CHARLESTON, WV 25305-0470
PHONE (304) 340-3200

FILED
JUL 14 3 04 PM '99
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

LARRY V. FAIRCLOTH
P. O. BOX 477
INWOOD, WV 25428
PHONE (304) 229-3193

Committees:
House Rules
Judiciary
Banking & Insurance
Rule-Making Review

July 14, 1999

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

Re: Health Care Authority Emergency Rules Title 65 Series 7 and Series 17

Dear Mr. Secretary:

It has come to my attention that the Health Care Authority (HCA) has filed emergency rules that change the certificate of need law in a way that will result in a proliferation of diagnostic health services in West Virginia.

The emergency rules amend Title 65 Series 7 and Series 17. I have been informed that the changes to the Series 7 rule constitute a major policy change which will allow any health care facility to add laboratory or diagnostic equipment costing less than $2 million, and will permit medical corporations to develop diagnostic centers without obtaining approval as long as they stay under the $2 million threshold. The HCA is citing their authority to promulgate these rules as passage of S.B. 492, which gave them permission to promulgate emergency rules to implement the Series 17 rules.

I have been advised that this issue was debated thoroughly by the task force that developed the recommendations for S.B. 492, and that the task force elected not to recommend changes to the physician practice section of the CON law. In addition, S.B. 492 did not mandate revisions to the Series 7 rule. By revising the Series 7 rule, the HCA is clearly exceeding the authority granted them by the Legislature. I ask that you not accept these rules, as there is no emergency that requires that they be promulgated under emergency rule making review.

Sincerely,

Larry V. Faircloth
Delegate -- 53rd District

prefers interim mail, April through December, at home address

JON BLAIR HUNTER
1265 Four-H Camp Road
Morgantown 26508-2458

Res. (304) 291-3782
Bus. (304) 292-5826
Senate (304) 357-7995

The Senate of West Virginia

Charleston

July 13, 1999

COMMITTEES:
Education
Energy, Industry and Mining
Health and Human Resources
Judiciary
Labor (Vice Chair)
Military

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

Dear Secretary Hechler;

RE: **Opposition to Proposed Certificate of Need Rules**
CSR Title 65, Series 17

As a State Senator from the 14th District, I am writing to you to express my concern for an emergency rule ruled by the Health Care Authority (HCA).

The changes of the emergency rule that amends 65-17 pertaining to the private office practice of health professionals to include changes to the certificate of need law which I do not believe were mandated by passage of Senate Bill 492.

The proposed changes would constitute a major policy change, create an uneven playing field, and a proliferation of diagnostic centers in West Virginia. I do not think these changes were anticipated by myself and other Legislators. In this regard, I believe the proposed changes should go through the normal rule making process to give us more time to examine the impact of these changes. For example, the proposed changes may lead to a proliferation of diagnostic centers throughout the state in an unplanned manner, which usually means placing them in more affluent settings and leaving rural, poor communities with less and inferior services.

Therefore, I ask you to reject the proposed amendments to 65-17 at this time as no emergency exists.

Sincerely,

Jon Blair Hunter
14th Senatorial District
JBH:cfb

JUL 30 9 30 AM '99
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

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

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

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

HARRISON COUNTY MEDICAL SOCIETY, INC.
P.O. BOX 2341
CLARKSBURG, WEST VIRGINIA 26302

PRESIDENT:
J. PATRICK GALEY, M.D.

PRESIDENT ELECT:
GLENN SNIDER, M.D.

SECRETARY:
SHIV NAVADA, M.D.

TREASURER:
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GERALD WEDEMEYER, M.D.

EXECUTIVE SECRETARY:
ALETHEA LARRY
(304) 624-2709
FAX (304) 624-2700

August 4, 1999
Re: Certificate of Need

RECEIVED
99 AUG -5 AM 9:22

Mr. Evan Jenkins
Executive Director
West Virginia Medical Association
P.O. Box 4106
Charleston, WV 25364

Dear Mr. Jenkins:

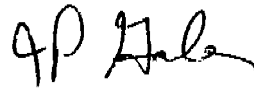
Following our conversation on the telephone I feel compelled to send you a follow-up letter regarding the proposed changes to the Certificate of Need regulations. If legislation was allowed to pass as written it would have an effect that would make it very difficult for not-for-profit hospitals in the state of West Virginia to continue to provide quality care to the patients in their community. Revenues from diagnostic imaging in particular would be lost which are used to offset the cost of giving free care in the community. If that did occur, then any revenues that would be made in excess of the operating revenues of the hospitals could not then be used to buy new capital equipment which would significantly affect the ability of medical physicians and surgeons to provide quality care to the people in their community.

I am certain Mr. Heckler is well aware of the implications of the Certificate of Need Bill but I felt it necessary to point out what would be a catastrophic side effect if the bill was allowed to pass.

Thank you very much for your concern in this matter.

I remain,

Yours Sincerely,



J. Patrick Galey, MD
President of the Harrison
County Medical Society

JPG/kf

cc: Mr. Ken Heckler, Sec. of State
Mr. Summers, Pres. of WV Hospital Assoc.

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July 30, 1999

OFFICE OF SECRETARY OF STATE WEST VIRGINIA
AUG 2 9 21 AM '99

VIA FACSIMILE

Judy Cooper, Executive Director
Administrative Law Division
Office of Secretary of State
Main Capitol Complex
1900 Kanawha Boulevard, East
Charleston, WV 25311

Re: West Virginia Health Care Authority Emergency Rule, 65 C.S.R. 7 "Certificate of Need Rule"

Dear Judy:

On or about June 30, 1999, the West Virginia Health Care Authority ("HCA") submitted an emergency rule to implement the provisions of Enrolled Senate Bill 492 passed during the 1999 Regular Session of the Legislature. Without commenting upon the merits of individual provisions in the rule, it is my opinion that unless the rule exceeds statutory authority, then the Secretary of State is required to approve the rule.[1] Other than the statutory mandate that the Health Care Authority shall promulgate emergency rules,[2] there is another reason why the Secretary of State should move forward in approving the proposed rules.

The purpose of Senate Bill 492, was to streamline the approval process for health related services and, more importantly, to exempt services from certificate of need review. Accordingly in 65 C.S.R. 7, Section 28, the HCA lists those new services requiring a certificate of need review. It is my contention that the exclusion of a particular service from the list, such as screening services

---

[1] W.Va. Code §29A-3-15a(b) states that the Secretary of State shall disprove an emergency rule if he determines that the rule exceeds the scope of the law authorizing or directing the promulgation of the rule; or that emergency does not exist justifying the promulgation of an emergency rule; or that the emergency rule was not promulgated in compliance with the provisions of W.Va. Code §29A-3-15.

[2] W.Va. Code §16-2D-7(u) provides that notwithstanding any other provisions of Article 2D the state agency shall promulgate emergency rules in accordance with W.Va. Code §29A-3-15, to establish a review process for non-health related projects. The review process shall not exceed 45 days. The state agency shall specify in the rule which projects are eligible for this review.

for osteoporosis, cardiovascular disease and strokes, would cause the service to be exempt from certificate of need review unless review is otherwise required.

One of our clients has recently received an order from the West Virginia Health Care Authority advising it that it needs to obtain a certificate of need prior to providing further screening services. The health care costs to West Virginians of delaying such screening services are real, and far outweigh the costs to provide such screening services. Indeed, our client does not charge Medicare or Medicaid for any of its screening services. Previous decisions of the West Virginia Health Care Authority have determined that no certificate of need was required for similar mobile services. Likewise, recent changes in the certificate of need statute pursuant to Senate bill 492 no longer requires certificate of need review for these services. West Virginians may go without screening services for several months until the regulatory hurdles are cleared. Given the clear and paramount policy in favor of screening our elderly for medical conditions, we believe that conflicting regulations must give way to reason and a creative solution found to deliver these screening services without unnecessary delay. Thus, the implementation of the emergency rule may assist in persuading the HCA that mobile screening services are exempt from certificate of need review.

For the foregoing reasons, we request the Secretary of State to approve the emergency rule to implement the exclusions and exemptions from certificate of need review. Should you have any questions or require additional input, please feel free to contact me.

Very truly yours,

Michael P. McThomas

MPM/skl

cc: Charles M. Johnson, Esquire

JACKSON & KELLY PLLC
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FAIRMONT, WEST VIRGINIA 26554
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WHEELING, WEST VIRGINIA 26003
TELEPHONE 304-233-4000

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TELEPHONE 303-390-0003

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TELEPHONE 606-255-9500

2401 PENNSYLVANIA AVENUE N.W.
WASHINGTON, D.C. 20037
TELEPHONE 202-973-0200

MEMBER OF LEX MUNDI,
THE WORLD'S LEADING ASSOCIATION
OF INDEPENDENT LAW FIRMS.

Direct Dial No. (304) 340-1319
e-mail: jthomas@jacksonkelly.com

August 10, 1999

OFFICE SECRETARY ... VIRGINIA
AUG 10 AM 9 09 '99

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

RE: Proposed Emergency Rules
West Virginia Health Care Authority
Title 65, Series 7 and 17

Dear Secretary Hechler:

The purpose of this correspondence is to provide final clarification of the position of the West Virginia Hospital Association regarding certain issues raised in the hearing yesterday on the proposed emergency rules filed on behalf of the West Virginia Health Care Authority (the "Authority") seeking to amend Title 65, Series 7 and 17.

The Authority argues under new W. Va. Code § 16-2D-8(c) that it has plenary authority to amend any provision of any Certificate of Need ("CON") rule by issuing an emergency rule pursuant to that subsection. In making this argument, the Authority cites the language in W. Va. Code § 29A-3-15(a)(1) which states the following:

> When the supporting statute specifically directs an agency to promulgate an emergency rule, or specifically finds that an emergency exists and directs the promulgation of an emergency rule, the emergency rule may not be disapproved pursuant to the authority granted by paragraph (B) of this subdivision.

It is clear, however, that the omnibus language contained in W. Va. Code § 16-2D-8(c) does not "specifically direct" the Authority to promulgate any emergency rule. It merely serves as a restatement of existing law, i.e., that the Authority may amend its existing rules through the emergency rule-making process. West Virginia Code § 16-2D-8(c) does not direct the Authority to promulgate any emergency rule, and was not the type of specific language contemplated by W. Va. Code § 29A-3-15(a)(1). The Authority's proposed interpretation of its powers would place it on a plane over and above all other agencies in the State of West Virginia not specifically exempted from the West Virginia Administrative Procedures Act, a result that certainly was never intended by the Legislature when enacting Senate Bill 492.

The Authority also argues that even if its broad construction of W. Va. Code § 16-2D-8(c) is not accepted, an emergency nevertheless exists to support the promulgation of its proposed emergency rules amending Title 65, Series 7 and 17. However, the only grounds for such an emergency cited by the Authority are the generalized legislative findings contained in its governing statute at W. Va. Code § 16-2D-1. While these legislative findings summarize important policy considerations to guide the Authority's actions, they do not and cannot form the basis of an emergency supporting the specific changes proposed to Title 65, Series 7 and 17 as required by W. Va. Code § 29A-3-15(f). If that were the case, then the requirements of W. Va. Code § 29A-3-15(f) would be meaningless, and the Authority (as well as any other agency) could promulgate any rule on an emergency basis without specific facts and circumstances to justify their immediate applicability prior to review by the legislative rule-making review committee. The Secretary of State's rule-making manual directs agencies to "[b]e specific about the facts and circumstances constituting the emergency," and the Authority has simply not met this requirement for anything other than the mandatory components of its proposed Series 7 rule.

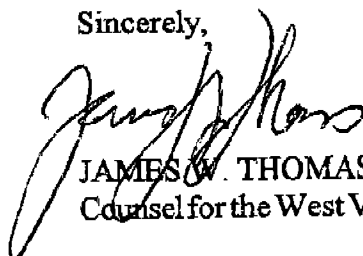
Once one rejects the Authority's unrealistic interpretation of W. Va. Code § 16-2D-8(c), and once one recognizes that the Authority has not identified specific facts and circumstances demonstrating that an emergency exists to justify the proposed amendments to Title 65, Series 17, it is clear that these rules must be rejected as beyond the scope of W. Va. Code § 29A-3-15. West Virginia Code § 16-2D-3(b)(5) withdrew CT scanning from the list of reviewable services for health care facilities and health maintenance organizations, while W. Va. Code § 16-2D-4(b)(5) did the same with respect to primary care centers. However, nothing in Senate Bill 492 addressed the scope of reviewable services by health professionals under W. Va. Code § 16-2D-4(a)(1). Therefore, one can only conclude that the amendments affecting health care facilities, health maintenance organizations, and primary care centers was not intended to similarly affect services provided by health professionals.

Finally, the Authority attempts to "boot strap" its filing of proposed emergency rules to amend Title 65, Series 7 by indicating that it had no choice but to include the many

discretionary policy changes in the same rules containing the mandatory changes required by Senate Bill 492 pursuant to W. Va. Code § 16-2D-3(b)(5) and § 16-2D-7(u). In fact, the Authority was not required to file all of its proposed changes in its proposed emergency rule. The Authority could have included the mandatory changes required by W. Va. Code § 16-2D-3(b)(5) and § 16-2D-7(u) in a proposed legislative rule as well as an identical proposed emergency rule. It then could have included all of the additional discretionary changes in a separate proposed legislative rule. Nothing in W. Va. Code § 29A-3-1 et seq. prohibits an agency from filing two separate and non-conflicting amendments of the same rule with the legislative rule-making and review committee. Such a procedure is in fact required when the discretionary amendments have not been justified by the agency as an appropriate emergency rule.

Thank you for your attention to these vitally important issues. If you require further information from the West Virginia Hospital Association, please do not hesitate to let us know.

Sincerely,



JAMES W. THOMAS
Counsel for the West Virginia Hospital Association

JWT/rs

cc: Robert L. Coffield, Esq.
George E. Carenbauer, Esq.
Larry Chafin, Esq.
T. R. Ross, II, Esq.
Todd Kruger, Esq.

CO305285

BEFORE THE WEST VIRGINIA SECRETARY OF STATE

In Re: Proposed Emergency Legislative Rule
West Virginia Health Care Authority
Title 65, Series 7 (Filed June 30, 1999)

PETITION FOR DISAPPROVAL OF
PROPOSED EMERGENCY LEGISLATIVE
RULE AMENDING TITLE 65, SERIES 7

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 7 entitled "Certificate of Need Rule." In 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 twofold: (1) to comply with the time limits set forth in Senate Bill 492 at W. Va. Code § 16-2D-3(b)(5), § 16-2D-7(u), and § 16-2D-8(c); and (2) to update the Certificate of Need ("CON") process to comply with the requirements of Senate Bill 492 passed by the 1999 West Virginia Legislature. For the reasons set forth below, the HCA's attempt to amend Title 65, Series 7 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 7 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 enactment this year of Senate Bill 492 amended in CON law in certain respects. Most notably:

a) it increased the capital expenditure threshold level from $1 million to $2 million;

b) it increased the major medical equipment threshold level from $750,000 to $2 million;

c) it required the HCA to promulgate an emergency rule by July 1, 1999, specifying which new services offered by health care facilities or health maintenance organizations will require CON review consistent with the findings of a recent CON study task force;

d) it deleted certain CON exemptions for health maintenance organizations;

e) it deleted certain CON exemptions for new services having annual operating costs less than $300,000;

f) it called for a review and modification of the State Health Plan within three (3) years;

g) it called for a study of the existing moratorium on nursing home beds in West Virginia;

h) it expanded the HCA's powers to order a moratorium upon new health services;

i) it required the HCA to promulgate an emergency rule by July 1, 1999, specifying a new review process for nonhealth-related projects of not more than 45 days; and

j) it clarified the CON appeal process.

The HCA's proposed emergency legislative rule to amend Title 65, Article 7 can be broken down into three (3) different components. The first component relates to provisions of the rule intended to comply with the July 1, 1999, time limitations set forth in Senate Bill 492 at W. Va. Code § 16-2D-3(b)(5) and § 16-2D-7(a). These are covered in §§ 2.8, 2.11, 2.16.e, 5.7, 10.4, 28.1.a-w, and 28.2. The petitioner recognizes that compliance with statutory time limitations does constitute an emergency under W. Va. Code § 29A-3-15(f)(2). Hence, although it may disagree with some of the policy choices made by the HCA in these provisions, it agrees that they may be validly promulgated as an emergency rule with the Secretary of State. The changes included in this first component therefore do not form the basis of the petitioner's objections.

A second component of the HCA's proposed emergency legislative rule relates to provisions in tended to comply with the changes in the law enacted by Senate Bill 492, as well as other legislative enactments and gubernatorial designations related to the CON appeal process. Examples of these provisions include, but are not limited to, §§ 2.16.f, 2.16.1, 12.4, 12.5, 15.1.f, 15.4, 18.1 through 18.9, and 19.1 through 19.3. While it is laudable that the HCA wishes to harmonize Title 65, Series 7 with the provisions of W. Va. Code § 16-2D-1 et seq.,

it is questionable whether such changes need to be made via an emergency rule. This is because the CON law contains the following provision at W. Va. Code § 16-2D-15:

> All rules previously promulgated to implement this article shall continue in force following the amendments to this article; except that, where such previous rules differ from the requirements of the amendments to this article, then such part of those rules are hereby abrogated and shall have no further legal effect. The state agency shall commence a review of such rules and shall promulgate revised rules.

Clearly, the above statute abrogates any provision of an existing rule that may differ from the statute without the need for an emergency rule amendment. The petitioner believes that he more appropriate procedure would be for the HCA to harmonize its rule with changes in the statute by the filing of a proposed legislative rule with the legislative rule-making review committee. The filing of an emergency rule appears unnecessary given the language of W. Va. Code § 16-2D-15. However, the provisions which make up this second component of the HCA's proposed emergency legislative rule to amend Title 65, Series 7 are not the focus of this petition.

The primary focus of this petition relates to the third component of HCA's proposed emergency legislative rules. This third component does not relate to any provisions of the rule that have time limitations set forth in Senate Bill 492, nor does it relate to provisions intended to comply with changes in the laws enacted by Senate Bill 492 or other previous legislative enactments or gubernatorial designations. Rather, the third component consists solely of specific policy changes that are discretionary in nature and that the HCA chose to include in its proposed emergency legislative rule. The amended provisions in this third component to which the petitioner specifically objects are found at §§ 2.1, 2.14, 8.1,

11.4, 11.4.b, 11.13, 11.21, 16.3, and 16.7. The petitioner also objects to the elimination of current §§ 10.4, 12.2, and 12.4.

The various amended provisions enumerated above which compose the third component of the HCA's proposed emergency legislative rule consist of a potpourri of issues. They may be summarized as follows:

a) the expansion of the definition of "acquire a health care facility" to include stock transactions;

b) the creation of a restrictive definition of "private office practice" despite a pending appeal seeking guidance on this issue from the courts;

c) the placement of strict limits upon the ability of applicants to submit additional evidence to the HCA in support of their CON applications or exemption requests;

d) the expansion of the grounds by which the HCA may declare a CON application incomplete due to a lack of all appropriate rate review filings;

e) a modification of the time frame in which prehearing motions can be filed with the HCA;

f) a modification of procedures which prohibits the filing of discovery materials with the HCA;

g) the elimination of a monthly batching alternative for certain CON applicants; and

h) the elimination of provisions which require the HCA to grant preference to CON applications that strengthen the effect of competition in the health care market.

Importantly, none of the third component changes have any relationship to the changes contained in Senate Bill 492, and cannot be justified by the HCA as emergency

updates to comply with that bill's requirements. Likewise, none of the time limitations in Senate Bill 492 are ever remotely related to any of these changes. Finally, and most significantly, the HCA has not set forth or even alleged any underlying emergency facts or circumstances justifying the changes included in this third component.

The law is clear as to what constitutes an emergency. W. Va. Code § 29A-3-15(f) requires a need to immediately preserve the public peace, health, safety, and welfare; to comply with statutory time limitations; or to prevent substantial harm to the public interest. While the HCA's amendments constituting the first component of its proposed emergency legislative rule meet the second qualification for an emergency under W. Va. Code § 29A-3-15(f), none of the rest of the amended provisions, especially those comprising the third component, are of an emergency nature. As a result, the HCA's proposed emergency legislative rule to amend Title 65, Series 7, is so tainted by its non-emergency, discretionary policy choices that it cannot withstand scrutiny under W. Va. Code § 29A-3-15a(b)(2). Moreover, the HCA exceeded the scope of Senate Bill 492's limited authorization of emergency rule-making in violation of W. Va. Code § 29A-3-15a(b)(1).

The Secretary of State cannot be reasonably expected to pick and choose specific provisions for approval and disapproval under W. Va. Code § 29A-3-15a. The better course would be for the HCA to withdraw its proposed emergency legislative rule in its current form, but simultaneously refile a substituted emergency legislative rule containing only those provisions meeting the requirements of W. Va. Code § 29A-3-15 and W. Va. Code § 29A-3-15a. If this is done, the HCA cannot be deemed to have failed to met its time limits established in Senate Bill 492 since those will have been fulfilled by one or the other of its filings with the Secretary of State.

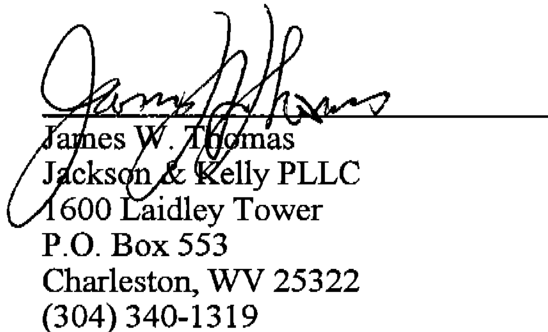
C. Conclusion.

In conclusion, significant portions of the HCA's proposed emergency legislative rule to amend Title 65, Series 7 cannot be justified as emergency rule-making. Not only do many of the provisions bear no relation to the time limits imposed by Senate Bill 492, but many also are not required to comply with the provisions of either that bill or previous bills enacted by the Legislature. 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 many of the revisions to Title 65, Series 7. Accordingly, the proposed emergency legislative rule, when read in its entirety, must be disapproved by the Secretary of State pursuant to W. Va. Code § 29A-3-15(b)(2) because an emergency does not exist, as well as pursuant to W. Va. Code § 29A-3-15a(b)(1) because the HCA exceeded the scope of Senate Bill 492's limited authorization of emergency rule-making.

Respectfully submitted,

WEST VIRGINIA HOSPITAL ASSOCIATION

By Counsel



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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.

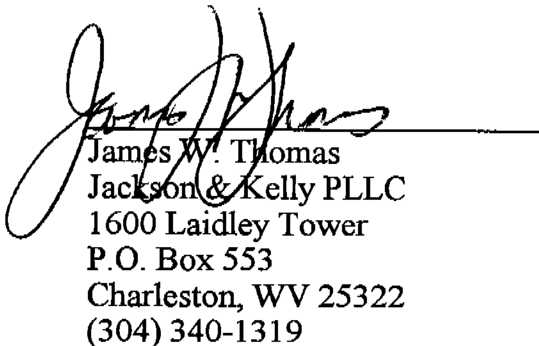
C. Conclusion.

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

By Counsel



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Cecil H. Underwood
Governor

WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES
HEALTH CARE AUTHORITY

D. Parker Haddix
Chairman

Board Members
Garry D. Black
Louie A. Paterno, Jr.

August 5, 1999

OFFICE SECRETARY OF STATE WEST VIRGINIA
AUG 5 3 24 PM '99

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

RE: Proposed Emergency Rule – Title 65, Series 7
Proposed Emergency Rule – Title 65, Series 17

Dear Secretary Hechler:

Attached please find the response of the West Virginia Health Care Authority (HCA) to the comments you have received opposing the above-referenced rules.

It is my understanding that a hearing is scheduled on these rules on Monday, August 9, 1999 at 1:00 p.m. The HCA will be present to answer any questions you may have regarding these rules.

If you have any questions prior to that time, please do not hesitate to contact Robert L. Coffield, Assistant General Counsel, at the phone number listed below.

Sincerely,

Marianne K Stonestreet

MARIANNE K. STONESTREET
General Counsel

MKS/dlg

Enclosures

cc: Judy Cooper, Director, Administrative Law
James W. Thomas, Esquire

100 Dee Drive, Suite 201 Charleston, West Virginia 25311-1692 Telephone: (304) 558-7000
FAX: (304) 558-7001
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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. <u>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.</u> [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. <u>Any rules promulgated pursuant to this subsection may be filed as emergency rules. . .</u> [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 <u>et seq.</u> 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 <u>general welfare and protection of the lives, health and property of the people</u> 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.

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[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.

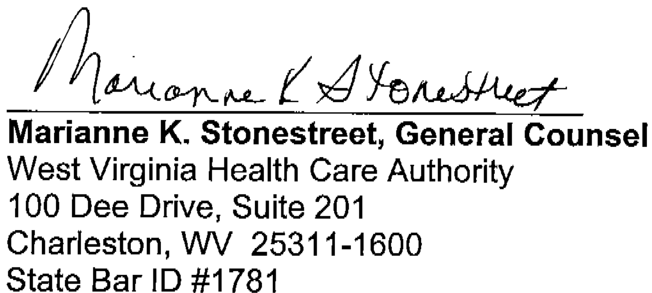
The opponents argue that the HCA was not required to remove CT from CON review for private office practices. However, Senate Bill 492 clearly authorized the agency to remove this service from CON review and did not authorize the agency to apply it selectively. It is the position of the HCA that

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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AUG 5 3 25 PM '99

OFFICE OF ... SECRETARY OF STATE ... WEST VIRGINIA

BEFORE THE WEST VIRGINIA SECRETARY OF STATE

In Re: **Proposed Emergency Legislative Rule**
West Virginia Health Care Authority
Title 65, Series 7 (Filed June 30, 1999)

RESPONSE OF THE HEALTH CARE AUTHORITY IN SUPPORT OF PROPOSED EMERGENCY RULE, "THE CERTIFICATE OF NEED RULE," TITLE 65, SERIES 7

A. Introduction.

During the 1999 legislative session, the Legislature passed 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 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 makes significant modifications to the current legislative rule, "The Certificate of Need Rule," 65 CSR 7. The changes were such that the proposed rule was filed as a replacement for current legislative rule, 65 CSR 7, as suggested by the Secretary of State's legislative rule, 153 CSR §6-7.

On July 22, 1999, the West Virginia Hospital Association ("WVHA") filed a Petition for Disapproval of Proposed Emergency Legislative Rule Amending Title 65, Series 7 ("Petition for Disapproval"). In addition, various comments were

submitted to the Secretary of State by member hospitals of the WVHA opposing the proposed emergency legislative rule.

The opponents of the proposed rule present two basic arguments against the approval of this rule as an emergency rule. First, 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). Second, they argue that the HCA has exceeded the scope of Senate Bill 492 and thus violated 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).

The comments received by the Secretary of State in opposition to the proposed emergency rule, "The Certificate of Need Rule," 65 CSR 7, argue that an emergency does not exist because the proposed emergency rule does not meet the required statutory criteria contained in W.Va. Code §29A-3-15(f). Thus, the opponents state that the Secretary of State should disapprove the proposed emergency rule on the grounds that an emergency does not exist under W. Va. Code §29A-3-15a(b)(2). This argument is without merit for the following reasons:

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

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 making an examination of legislative intent unnecessary. However, 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 CON Study which included the recommendations for the changes made by Senate Bill 492.[1] The purpose of this significant amendment was to grant the HCA authority to promptly amend the CON rules in order to update and clarify current HCA policy and to implement changes which have been made in the Code since 1991, the last time Series 7 was amended. 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 undergo 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, this Code section states:

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

[1] The CON Committee was formed in 1997 when the West Virginia Legislature 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 WVHA and Dayle Stepp, Director of the CON Division.

> 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 proposed emergency 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 specific 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 HCA to promulgate emergency rules.

It should be pointed out that the opponents of the rule do not specifically address W. Va. Code §16-2D-8(c) in the Petition for Disapproval. The reason they failed to address W. Va. Code §16-2D-8(c) is that it undermines the basic premise of their arguments. Why would the Legislature grant to 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 passage of W. Va. Code §16-2D-8(c) meaningless and clearly that was not 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 recognized agencies' statutory authorization to file emergency rules and has approved the rules as emergency rules without applying the additional criteria in W. Va. Code §29A-3-15(f). For example, 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. This rule was approved as an emergency rule by the Secretary of State on December 3, 1998.

The statutory authorization for filing the Benchmarking and Discount Contract 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, states as follows:

> (B). . . the board may promulgate rules, in accordance with the provisions of section eight 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. <u>Any rules promulgated pursuant to this subsection may be filed as emergency rules.</u> [Emphasis added.]

The emergency rate rule was similarly filed as a proposed legislative rule and was approved by the Legislative Rule Making Review Committee and passed by the Legislature in 1999. The issue of the HCA's authority to promulgate the rate rule as an emergency rule was never raised or questioned by the opponents of the CON rules or the Secretary of State. In fact, the opponents supported implementation of the Benchmarking and Discount

Contract Rule. The opponents' true objections to 65 CSR 7 are related to content and not to whether 65 CSR 7 meets the criteria for an emergency rule.

In addition, counsel for United Hospital Center argues in its comments that W. Va. Code §16-2D-8(c) should be read prospectively. They argue that the use of the word "subsequent" in the phrase "subsequent amendments and modifications . . . " should be read prospectively, so as not to deprive interested persons an opportunity to offer written comments. The HCA believes that this interpretation is wrong and that the word should be read in context and given its simple and clear meaning that all future amendments to any rule promulgated pursuant to the W. Va. Code §16-2D-1 et seq. can be implemented by emergency rule. The intent of the newly enacted language in W. Va. Code §16-2D-8(c) was to allow the HCA to amend any existing rule by emergency rule.

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

Although proposed emergency rule, 65 CSR 7, 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. W. Va. 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 7 is a CON rule filed pursuant to the CON 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 CON programs as follows:

> 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.]

The statutory language contained in the CON Act meets the criteria of both Code §29A-3-15(f)(1) and (3). Title 65, Series 7, 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 (1) the immediate preservation of the public health, safety and welfare; and, also (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. Furthermore, the basic premise behind the CON laws is the protection of the health and welfare of the public and the prevention of harm to the public. For these reasons, Series 7 meets the criteria of W. Va. Code §29A-3-15(f).

C. **The Proposed Emergency Rule Does Not Exceed the Scope of Senate Bill 492 Which Authorized the Amendments to 65 CSR 7 and the Secretary of State Should Not Disapprove the Proposed Emergency Rule under W.Va. Code § 29A-3-15a(b)(1).**

The major changes in 65 CSR 7 have been listed and discussed in the Petition for Disapproval filed in opposition to this rule by the WVHA. Although the HCA disagrees with most of the characterizations and descriptions contained within the discussion of 65 CSR 7 by the WVHA, none of that is relevant as it relates to this issue.

Essentially, the WVHA argues that the proposed rule is not valid because it is outside the scope of Senate Bill 492. The WVHA then proceeds to make a "wish list" of the items it finds acceptable, the items it finds somewhat acceptable and the items it finds unacceptable according to its interpretation of Senate Bill 492. The bottom line is it doesn't matter whether the WVHA finds the amendments to 65 CSR 7 acceptable. The issue is whether the rule complies with the requirements of W. Va. Code §29A-3-15a(b)(1). This Code section states as follows:

> (b) The secretary of state shall disapprove an emergency rule or an amendment to an emergency rule if he determines:
>
> (1) That the emergency rule or an amendment to the emergency rule exceeds the scope of the law authorizing or directing the promulgation thereof. . . [Emphasis added.]

The law authorizing the promulgation of this rule is W. Va. Code §16-2D-8(c) (also W. Va. Code §§16-2D-3(b)(5) and 7(u), as previously discussed). W. Va. Code §16-2D-8(c) states:

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

Thus, the scope of the authority to promulgate emergency rules extends to the entire CON Act, Chapter 16, Article 2D of the W. Va. Code. Contrary to the arguments of the opponents to this proposed emergency rule, the scope of 65 CSR 7 need not be limited to the specific items in Senate Bill 492. Indeed, one of the primary purposes of amending W. Va. Code §16-2D-8 of the Certificate of Need Act granting the HCA emergency rule making authority, was to allow the HCA to update 65 CSR 7 which had not been amended since 1991.

The overwhelming majority of items within 65 CSR 7 are a direct result of the passage of Senate Bill 492, as admitted by the WVHA. However W. Va. Code §29A-3-15a(b)(1) simply requires that the amendments be within the scope of the Certificate of Need Act. It is undisputed that the changes comply with this requirement.

In summary, Senate Bill 492 includes language under W. Va. Code §16-2D-8(c) allowing the HCA to make amendments and modifications to any existing rule by emergency rule. The HCA has made the modifications that it believes are necessary and they are not beyond the scope of the CON Act. For these reasons, the Secretary of State should not disapprove the proposed emergency rule under W. Va. Code §29A-3-15a(b)(1).

D. Conclusion.

The proposed emergency rule, "The Certificate of Need Rule," 65 CSR 7, is a valid emergency rule and meets all of the necessary requirements of W. Va. Code §29A-3-1 et seq.

Respectfully submitted,
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Certificate of Need Study

Prepared for:

Certificate of Need Committee

For Presentation to:

West Virginia Health Care Authority

Arthur Clark Company

September 1998

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West Virginia Health Care Authority
Certificate of Need Study

EXECUTIVE SUMMARY

During its 1997 Session, the West Virginia Legislature directed the West Virginia Health Care Authority (Authority) to conduct a study of the Certificate of Need (CON) program, including the following:

- The effects of any changes in the CON program on managed care and access for uninsured and rural consumers;
- Determining which services or capital expenditures should be exempt and why; and,
- The status of similar programs in other states.

The Legislature also directed the Authority to identify barriers or obstacles, if any, presented by the CON program or standards in the State Health Plan (SHP) to the need among health care providers to reduce excess capacity, restructure services, and integrate the health care delivery system.

To conduct this study, the Authority empanelled a Primary Task Force. The Task Force was comprised of a cross section of interests throughout the state, including consumers, government, health care providers, private industry, and health care payors. Members of the Task Force were also selected to serve on various subcommittees who were charged with addressing the directives established by the Legislature. Four specific objectives were established related to the CON study directives; these include the following:

1. Provide definitions of capital costs and determine the effectiveness for controlling capital expenditures and limiting the cost of health care services.
2. Determine the appropriateness and effectiveness of the SHP criteria "standards" and review services to determine if any should be exempt from the CON process, and, if so, develop criteria to accomplish that task.

3. Determine the effectiveness of the CON administrative review process, i.e., methodology and timing, and improvement thereof.
4. Determine the impact of the CON process on reduction of excess capacity, health care integration and shared resources.

To accomplish the objectives, a series of action steps was developed. The complete list of these objectives, as well as each action step, are included in Attachment 1.

At the beginning of its study, the Subcommittee considered the stringency of the scope of West Virginia's CON review relative to the stringency of programs in other states. West Virginia's CON program was listed as third most stringent in a ranking produced by the American Health Planning Association in 1998. The Subcommittee concluded that the West Virginia program was too stringent, and that a reduction in the scope of CON review was needed. The incremental changes in scope recommended by the Subcommittee would reduce the scope of CON review and drop West Virginia's ranking to 13. A summary of the recommended changes in the CON statute is provided below.

- The Subcommittee recommends that the capital expenditure threshold be increased from the current level of $1 million to $1.5 million in 1999; to $1.75 million in 2000; and to $2 million in the year 2001. Similarly, the Subcommittee recommends that the major medical equipment threshold be increased from the current level of $750,000 to $1.5 million in 1999; to $1.75 million in the year 2000; and to $2 million in 2001. The Subcommittee also recommends that the expenditure minimum for annual operating cost, which is currently $300,000, be eliminated.
- The Subcommittee recommends that the scope of review for new services be limited to a specific list of services that would be identified in regulation. This would reduce the scope of reviewable activities from the current level (any new service is reviewable). The proposed list includes 23 specific services.
- The Subcommittee recommends that the exemption for facilities and services developed by HMOs (WV Code 16-2D-4(b)) be eliminated.

- The Subcommittee recognized that steady increases in the size of the elderly population may create a need for additional nursing home beds. Therefore, the Subcommittee recommends that a task force be set up to study the need to continue the moratorium on the development of nursing facility beds, as well as the exemption for the conversion of acute care beds to SNF beds. It further recommends that the study consider the development of a methodology to assess the need for additional nursing facility beds in the state. The Subcommittee also recommends that the study consider requiring certification of new beds by both Medicare and Medicaid.
- The Subcommittee recommends that the Authority be enabled to impose a moratorium, for a period not exceeding 180 days, on the review of services for which proliferation might cause an adverse impact on the cost of health care and/or the health status of the public.
- The Subcommittee considered the objective to evaluate the appropriateness and effectiveness of the state health criteria, and determined that the magnitude of this task would require more time than what had been allotted to complete its work. The Subcommittee, however, recommends that a task force be established to rewrite the state health plan, and to consider the appropriateness and effectiveness of the CON standards. It also recommends that the rewriting be completed within two years of passage of the legislation in the 1999 Session to amend the CON statute.
- The Subcommittee recommends that the Authority establish a "fast track" process for review of projects not involving direct patient care; such a process would allow an expedited review (30 days, for example) of projects such as parking garages, information systems, and heating and ventilation systems, etc.
- The Subcommittee recognizes that the modification or creation of standards in the SHP might permit the Authority to grant a CON that would have been denied under the current standards. Thus, the Subcommittee recommends that the CON statute be modified to allow applicants in this special situation to re-file their proposals as soon as the new standards are effective.
- The Subcommittee recognizes that CON statute includes several provisions to foster integration of services among providers. The Subcommittee endorses efforts to promote integration, and recommends that the need and benefits of integration be addressed

explicitly in the SHP, and that specific standards giving preference to health service integration projects be developed.

- The Subcommittee favors the retention of a modified and less restrictive program over elimination of the program; however, it recommends that a task force be set up to study the cost-effectiveness of the program, and that the study be completed within two years of passage of CON legislation.

A description of the analyses conducted by the Subcommittee, including its findings, follows this summary.

OVERVIEW

During its 1997 Session, the West Virginia Legislature directed the West Virginia Health Care Authority (Authority) to conduct a study of the Certificate of Need (CON) program, including the following:

- The effects of any changes in the CON program on managed care and access for uninsured and rural consumers;
- Determining which services or capital expenditures should be exempt and why; and,
- The status of similar programs in other states.

The Legislature also directed the Authority to identify barriers or obstacles, if any, presented by the CON program or standards in the State Health Plan (SHP) to the need among health care providers to reduce excess capacity, restructure services, and integrate the health care delivery system.

To conduct this study, the Authority empanelled a Primary Task Force. The Task Force was comprised of a cross section of interests throughout the state, including consumers, government, health care providers, private industry, and health care payors. Members of the Task Force were also selected to serve on various subcommittees who were charged with addressing the directives established by the Legislature. Four specific objectives were established related to the CON study directives; these include the following:

1. Provide definitions of capital costs and determine the effectiveness for controlling capital expenditures and limiting the cost of health care services.
2. Determine the appropriateness and effectiveness of the SHP criteria "standards" and review services to determine if any should be exempt from the CON process, and, if so, develop criteria to accomplish that task.
3. Determine the effectiveness of the CON administrative review process, i.e., methodology and timing, and improvement thereof.
4. Determine the impact of the CON process on reduction of excess capacity, health care integration and shared resources.

To accomplish the objectives, a series of action steps was developed. The complete list of these objectives, as well as each action step, are included in Attachment 1.

At the beginning of its study, the Subcommittee considered the stringency of the scope of review of the West Virginia statute relative to that of other state programs. West Virginia's CON Program was ranked third most stringent in a comparison of state programs produced by the American Health Planning Association in 1998. The Subcommittee concluded that the scope of review in West Virginia is too high. Thus, the Subcommittee's study was guided by a determination to reduce the scope of CON review in West Virginia. The incremental changes recommended by the Subcommittee would drop West Virginia's ranking to 13.

EFFECTIVENESS OF CON PROGRAM (Objective 1.A.)

As shown in Attachment 1, Objective 1 entails developing a definition of capital costs and determining the effectiveness of CON in controlling capital expenditures and limiting the cost of health care services. In order to address this objective, the CON Subcommittee reviewed the West Virginia CON statute, as well as collected information from various studies concerning the retention, modification or elimination of the CON program, and the resulting effect on the availability of services and costs, etc. As an initial step, the Subcommittee considered the scope of review included in the West Virginia CON statute. A summary of the CON review thresholds is provided below.

- The construction, development, acquisition or other establishment of a new health care facility or health maintenance organization.
- The partial or total closure of a health care facility or health maintenance organization with which a capital expenditure is associated.
- Any capital expenditure made by or on behalf of a health care facility in excess of one million dollars, or an obligation of a capital expenditures made by any person to acquire a health care facility.
- A substantial change to the bed capacity of a health facility with which a capital expenditure is associated; the statute does not establish a minimum for the capital expenditure.

- The addition of a health service by or on behalf of a health care facility or HMO and which was not offered on a regular basis within the 12 month period prior to the time the services would be offered.
- The addition of ventilator services to any nursing facility by any health care facility or any HMO.
- The deletion of one or more health services previously offered by a health care facility or HMO which is associated with a capital expenditure.
- The acquisition of major medical equipment; major medical equipment means a single unit of medical equipment or a single system of components with related functions which cost in excess of $750,000.
- An expansion of the service area for hospice or home health services, regardless of the time period in which the expansion is made.

There are also several exemptions from CON review. These include the private practices of physicians, except where major medical equipment is used. In addition, the CON law exempts the creation of primary care services or centers that are located in medically underserved areas, as long as the centers do not utilize major medical equipment. Further, birthing centers sponsored by not-for-profit primary care centers may also be exempt. Such birthing centers must be located in an area which is medically underserved with respect to low risk obstetrical services. In addition, the birthing center must collaborate with a hospital in the county if the hospital is also eligible for the exemption for the development of a birthing center.

The CON statute also allows a waiver for any HMO that is proposing the development of a new service, acquisition of major medical equipment, or the obligation of a capital expenditure. To qualify for the exemption, the HMO must have an enrollment of at least 50,000 individuals. In addition, the proposed service or facility must be located in an area that is reasonably accessible to the individuals enrolled in the HMO. Moreover, at least 75 percent of the individuals expected to use the proposed service or facility must belong to the HMO.

Another waiver for the development of a new health facility service may be granted to any provider if projected annual operating costs are below $300,000, as long as there is no capital expenditure associated with the development of the new service. The statute also allows an exemption for mobile magnetic resonance imaging (MRI) or lithotripsy services if they are shared between two or more acute care facilities. However, no exemption may be granted if it is more cost-effective to provide a fixed unit. The statute also specifies that in no cases will a mobile cardiac cathaterization laboratory be exempt from CON review. An acquisition of a health care facility may also be exempt from review.

Another exemption is allowed for the conversion of the acute care beds to skilled nursing facility (SNF) beds if:

- The hospital is located in a non-metropolitan statistical area.
- The hospital's occupancy is lower than 50 percent during the 12 months preceding the date of the request for the exemption.
- The nursing home ratio in the county is less than 30 beds per 1,000 residents.
- The hospital converts no more than 25 percent of its total licensed acute care capacity to SNF beds.
- Upon completion of the project, the hospital must delete the SNF beds from its acute care license.
- Hospitals will only be allowed to add the beds back to the license with a new CON.

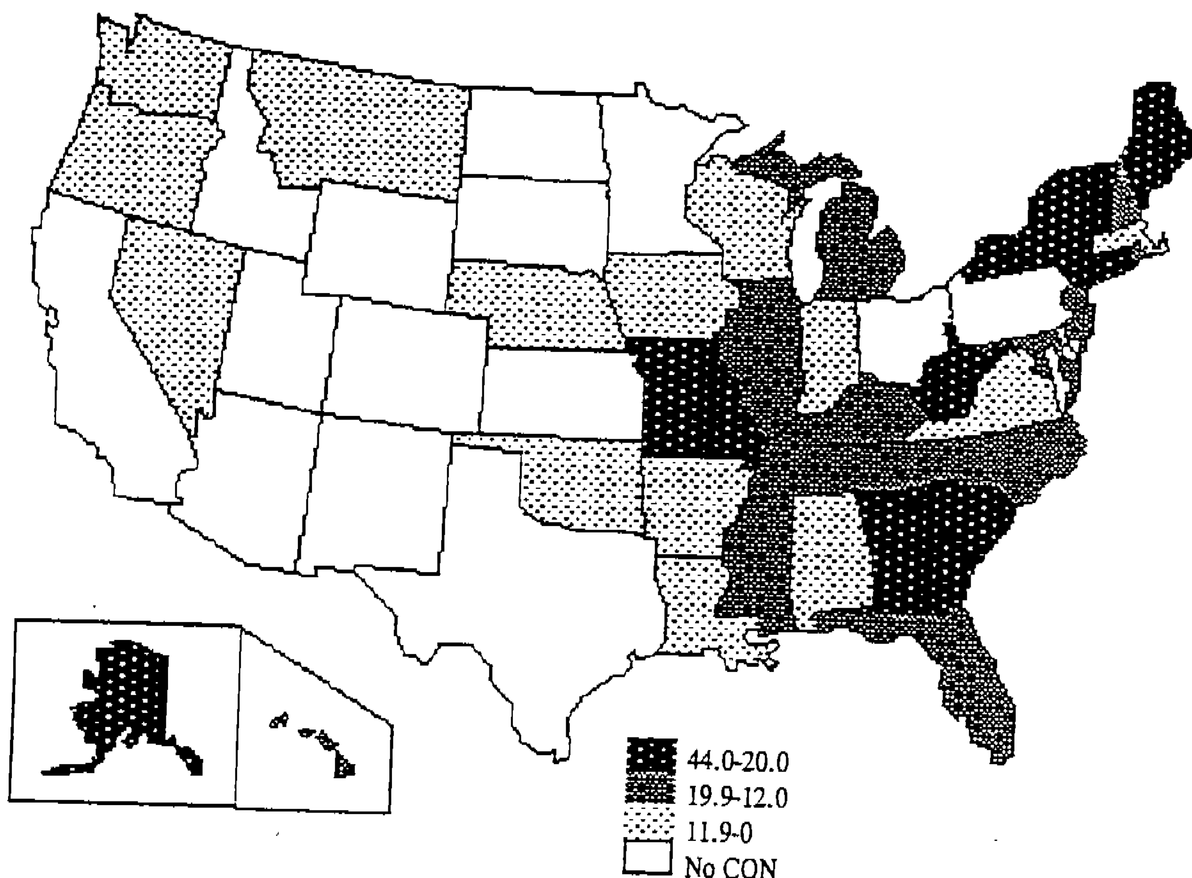
The CON statute also has imposed a moratorium on the addition of intermediate care facility (ICF) or SNF beds by any health care facility; this includes the development of intermediate care facility beds for the mentally retarded (ICF-MR). However, the statute does allow hospitals that propose conversion of acute beds to SNF to obtain a CON. The hospital must follow the following conditions in order to receive a CON.

- The SNF beds must be certified for Medicare only.
- The state agency may require that up to three acute care beds be converted to one SNF bed.
- The SNF beds must be permanently deleted from the acute care complement.

- The hospital must demonstrate a need for the beds prior to CON approval.
- The hospital must use existing space and cannot construct additional facility space in which to develop the SNF beds.

The CON Subcommittee considered the impact of changes in CON programs in other states on the availability and cost of services, as well as other parameters. Since the federal mandate for state CON programs expired in 1985, 14 states throughout the country have dropped their CON programs altogether; some of these states have, however, maintained a moratorium on long term care beds. Most of the states that have maintained a CON program are clustered in the eastern section of the country (See map below). However, Pennsylvania allowed its program to sunset in December 1996. Ohio passed legislation in 1995 to phase out its program over a three-year period from May, 1995 to March, 1998. Ohio maintained a restriction on additional long term care beds. While Pennsylvania did not impose any restrictions on the construction of new long term care beds, its Department of Public Welfare ceased offering new provider contracts for additional Medicaid beds. Both Ohio and Pennsylvania also have developed, or are in the process of developing, more comprehensive licensing standards; these standards are intended to require providers to meet specific criteria for quality, including achieving and maintaining specific utilization levels, as well as related to access for underserved populations.

STATE CON PROGRAMS BY STRINGENCY OF SCOPE



While some states have eliminated CON, there has been no clear trend among those states that have retained CON review. For example:

- In 1993, North Carolina lowered its review threshold for equipment, from $2.0 million to $750,000, except for all ambulances, cardiac catheterization and angioplasty suites, gamma knives, and several other services, which require review regardless of costs.
- Michigan reduced the scope of review to focus on proposed developments that exceed specific thresholds.
- Missouri increased its review thresholds to $1.0 million each for capital expenditures and equipment in 1997; in 1995, it brought assisted living (residential care) facilities into the scope of reviewable activities.

- Maryland increased its scrutiny of reviewable projects in part to address an inequity of its all payer system, which was believed to provide a pricing advantage to freestanding facilities over inpatient facilities.

A number of studies have been conducted over the years concerning the impact of the elimination and/or modification of CON on the availability and cost of services. Much of the research conducted during the past several years on the effectiveness of CON has been summarized in a study commissioned by the state of Delaware and carried out by researchers at Duke University. The study analyzed the impact of CON on a variety of parameters, including controlling spending and facility development/equipment acquisition; quality; access and distribution; and the dissemination of new technology. It also focused on the effectiveness of restricting the development of long-term care facilities. While the study was comprehensive, and questioned the overall benefits of CON programs, it included a review of numerous studies over the years that have provided contradictory or inconclusive results. In short, while the review of these studies was instructive, it did little to predict the impact of changes in the West Virginia CON law on managed care providers or on access for uninsured or rural populations. Thus, the Subcommittee was unable to determine the overall effect of changes in the statute.

While not explicitly directed by the Legislature to do so, the Subcommittee also considered the question of whether the CON program should be abolished altogether; this question was raised in light of the recommendation from the Rate Setting Subcommittee to phase that program out, and the lessening of restraints on price increases.

Countering this concern is the evidence presented by The Dartmouth Atlas Study, which is an analysis of healthcare utilization patterns among Medicare beneficiaries that was conducted jointly by the American Hospital Association and the Dartmouth Medical School. This study showed that higher concentrations and availability of healthcare facilities and services was correlated with higher levels of utilization among Medicare beneficiaries. The consensus of the Subcommittee was that incremental changes in CON were appropriate at this time.

The Subcommittee also reviewed information related to the development of facilities and services in Ohio since the CON law was phased out. As noted earlier, phase out or deregulation, began in May 1995. This information shows that significant activity has occurred, and is summarized below.

- Since March of 1998, when transplantation services were deregulated, four hospitals notified the state of their intent to add transplant programs; two are bone marrow transplant programs, and two are heart/lung transplant programs (these latter two hospitals already have heart transplant programs in place).
- Cardiac catheterization and open heart surgery services were deregulated in March, 1998. Since then, six hospitals have started open heart surgery programs, and two more are scheduled to open in 1999.
- MRIs and CT scanners were deregulated in existing hospitals in May, 1995; free standing imaging centers in urban areas were deregulated in May 1996, and in rural areas, in May, 1997. Between May 1996 - May 1997, 39 MRIs were added in Ohio; 15 MRIs were added since May 1997.
- Since deregulation in May of 1995, 12 new lithotripters were added; only five or six were available prior to the elimination of the CON requirement.
- Ten Level I obstetrics programs have opened since deregulation in May, 1995; several hospitals intend to upgrade their programs from Level I to II.
- 312 new psychiatric bed were added since May, 1995.
- 430 rehabilitation beds were added since May, 1995.

It should be noted that these developments may not represent all health service or facility development that have occurred since the law was phased out.

The Subcommittee did consider the expenditure thresholds established by other states for capital, equipment, and new services. This activity was undertaken largely through a survey conducted of 12 state agencies, and by a review of data compiled by the American Health Planning Association (AHPA) in its 1998 National Directory of Health Planning, Policy and Regulatory Agencies (Ninth Edition). The results of the AHPA data are provided in

Attachment 2. These data show the number of services reviewed, as well as the dollar thresholds. As Attachment 2 shows, the number of services reviewed ranges from a high of 27 in the state of Maine, to a low of only two services (Wisconsin, Oregon, Indiana, and Louisiana). Capital review thresholds range from $5.0 million in Virginia to $500,000 in Maine, Virginia, and Arkansas.

Review thresholds for medical equipment show a wide variation as well, ranging from $3,000,000 in Delaware to $400,000 in New Hampshire and Connecticut. For new services, some states review all, regardless of cost, while Alaska and Missouri review those services associated with expenditures exceeding $1,000,000.

The Subcommittee also examined the experience of other states in which CON was eliminated or substantially modified. Much of this review was conducted through a consideration of the Delaware study referenced earlier. The study presented some data that a surge in new health service development may occur when CON is repealed, and that states with stringent programs may experience a slower growth in facilities and services. Again, the studies referenced in the Delaware report were contradictory: some showed no impact of eliminating CON.

As noted above, the CON threshold for capital expenditure is currently $1,000,000, while that for equipment is $750,000. The CON Subcommittee recommends the thresholds for both capital and equipment be raised to 1.5 million dollars in 1999. In addition, the Subcommittee recommends that the thresholds be raised by $250,000 per year between 1999 and 2001, thus rising to $2,000,000 in 2001.

Current CON regulations require a review of any new service, regardless of capital expenditures needed to develop the service. The CON Subcommittee recommends that the scope of review for new services be limited to a specific list of services to be identified in regulation. Up until 1993, the CON regulations did, in fact, include a list of specific health care services that would be reviewed regardless of any capital expenditure or operating cost associated with them. The CON Subcommittee recommends that a list of reviewable services

be re-established; the recommended list is shown below. Thus, under the Subcommitee's recommendation, the only new services which would fall under CON review are those included on the list, or those exceeding the capital expenditure or equipment threshold. The proposed list is provided below.

RECOMMENDED LIST OF REVIEWABLE SERVICES

1. Alcohol and other drug treatment and rehabilitation offered in a discrete inpatient unit.
2. Ambulatory surgical facilities or ambulatory surgical centers; and diagnostic services
3. ~~Cardiac~~ catheterization
4. Comprehensive medical rehabilitation on an inpatient basis
5. End-stage renal dialysis stations and home training
6. Intermediate care facilities for the mentally retarded (ICF-MR)
7. Discrete units for long term care nursing beds
8. Lithotripsy
9. Magnetic resonance imaging (MRI)
10. Medical or surgical beds
11. Discrete obstetrical units
12. Organ and tissue transplants
13. Open heart surgery
14. Discrete pediatric units
15. Discrete inpatient psychiatric units
16. Special care units for burns, intensive care, cardiac care, neonatal intensive care, neonatal intermediate care, and pediatric intensive care.
17. Surgical services
18. Radiation therapy
19. Hospice
20. Home health
21. Positron emission tomography (PET)
22. In-home personal care services
23. Outpatient behavioral health services

The Subcommittee recommends that the Authority develop definitions, where needed, to clarify what is included in these services.

The development of the proposed list would obviate the need for the operating expense threshold. Thus, the Subcommittee recommends eliminating this requirement. It also recommends elimination of the exemption for facilities and services developed by HMOs. (WV Code 16-2D-4(b))

The Subcommittee considered projections in the growth of the elderly population in the state. The Subcommittee was concerned that continued increases in the elderly population may create a demand for additional nursing facility beds in the future. Thus, the Subcommittee

recommended that a task force be set up to study the need to continue the moratorium on the development of nursing facility beds. The study would embrace a number of issues, including eliminating the provision that allows hospitals to convert acute care beds to Medicare certified skilled nursing facility beds. It also recommends that a methodology to assess the need for additional nursing facility beds be considered. The methodology would assess bed need based on the age of the population, as well as the bed to population ratio and occupancy levels within a defined service area. Moreover, the study would evaluate other factors that might be considered in reviewing CON applications for the development of long term care beds; these may include the potential economies of scale and operational cost-effectiveness that might be achieved through the expansion of existing facilities. Such consideration may also include the need for critical access hospitals (CAH) to convert a segment of their facilities to long term care in order to maintain financial viability. Finally, the Subcommittee recommends that the study consider requiring that any new nursing facility beds be certified for both Medicare and Medicaid, and that Medicare certified hospital based skilled nursing beds also be certified for Medicaid.

The current CON statute allows the Authority to impose a moratorium on the review of services for which standards are either obsolete or nonexistent. The moratorium may last for no more than 180 days. The Subcommittee recommends that the Authority be granted the ability to impose a moratorium, for a period not exceeding 180 days, on the review of services for which proliferation might cause an adverse impact on the cost of healthcare, and/or the health of the public.

While the Subcommittee favors the retention of a modified and less restrictive CON program over elimination of the program, it also recommends that a task force be established to study of the cost effectiveness of the CON program, and that the study be completed within two years of passage of CON legislation in the 1999 session.

POTENTIAL EFFECTS OF INCREASED MANAGED CARE PENETRATION

(Objective 1.B)

As shown in Attachment 1, the action steps in support of this objective included analyzing studies from other states to include volume/capacity aspects of need methodologies; expenditure thresholds; and the experience of states that have eliminated or modified CON. The Subcommittee deferred consideration of the volume/capacity aspects of need methodologies because the time allotted for the CON study was not sufficient to address adequately the potential activity involved in this action step. The Subcommittee also recognized that the Authority will address this step as it revises the SHP.

MANAGED CARE PENETRATION, SERVICES, AND EXPENDITURES

(Objective I.C.)

The Subcommittee investigated the relationship between CON regulation and managed care penetration through its survey of other states. None of the states could describe any direct relationship between managed care development and CON.

In its 1997 report, the AHPA presented a ranking of CON programs by their review thresholds and numbers of services reviewed; at the time, West Virginia was ranked third most stringent (a subsequent review in 1998 dropped the ranking to 13).

Data compiled from the AHPA show no clear relationship between the level of CON review and managed care penetration, as presented in the table below.

Managed Care Penetration and CON Stringency

	CON* RANK	HMO** Penetration
Oregon	0.9	47.2%
Massachusetts	4.8	44.6%
Delaware	10.8	38.8%
Maryland	13.5	38.0%
New York	21	35.7%
Connecticut	32.4	34.7%
Dist. Of Columbia	18.4	34.1%
Missouri	33	30.2%
Florida	14.4	29.0%
New Jersey	21	27.5%
Kentucky	16.2	27.4%
Washington	9	25.1%
Hawaii	14.4	25.0%
Wisconsin	3.3	24.9%
New Hampshire	11.7	23.9%
Michigan	14	23.5%
Nevada	5.6	20.8%
Ohio	11.9	17.6%
Illinois	15.2	17.1%
Maine	42	15.9%
Virginia	8	15.7%
Nebraska	15.2	15.4%
Tennessee	18.4	15.3%
Louisiana	0.4	14.7%
North Carolina	18.4	14.6%
Georgia	24	12.7%
Oklahoma	7.5	12.4%
Rhode Island	17.6	11.8%
Alabama	7	9.8%
West Virginia	30.8	9.4%
Arkansas	8.4	8.7%
South Carolina	20.9	8.4%
Iowa	23.8	4.6%
Montana	8.1	3.1%
Mississippi	17	2.4%
Vermont	34	0.0%

*12/24/96 (Source: National Directory of Health Planning-1996)
**1/1/97 (Source: InterStudy)

As shown in the preceding chart, the relationship between managed care penetration and the stringency of CON programs is not clear cut. For example, Oregon has only limited CON review and high managed care penetration; in contrast, Alabama's CON program is of limited stringency, yet its managed care penetration is only 9.8 percent. Connecticut has a strong CON program and high managed care penetration.

APPROPRIATENESS AND EFFECTIVENESS OF STATE HEALTH PLAN CRITERIA "STANDARDS" (Objective 2)

The Subcommittee considered this objective and determined that its magnitude of the task would require more time than what had been allotted to the Subcommittee to complete its work. The Subcommittee also recognized that the review of the standards has already been started by the Authority in its efforts to revise the SHP. Thus, the Subcommittee decided to defer the completion of this objective to the Authority. However, the Subcommittee recommends that the rewriting of the SHP be completed within two years of passage of the legislation to modify the CON statute.

The CON statute now prohibits any applicant who is denied a CON from resubmitting an application for the same service for a 12-month period. The Subcommittee recognizes that the modification of standards in the SHP might permit the Authority to grant a CON that would have been denied under the current standards. The Subcommittee thus recommends that the CON statute be modified to allow applicants in this special situation to refile as soon as the new standards are effective.

EFFECTIVENESS OF CON ADMINISTRATIVE REVIEW PROCESS(Objective 3)

As noted above, the Subcommittee recommends that a list of services that would be reviewable regardless of cost be established. Additionally, the Subcommittee recommends that the Authority establish a "fast track" process for review of projects not involving direct patient care; such a process would allow an expedited review (30 days, for example) of projects such as parking garages, information systems, and heating and ventilation systems, etc. The review process would largely entail an analysis of financial data. Finally, the Subcommittee

recommends that providers needing to make emergency repairs due to fire, floods, or acts of God, be required to notify the Authority within a specified period of time of initiating the repairs. Attachment 3 includes a detailed description of the current CON review process in West Virginia.

IMPACT OF CON ON REDUCTION OF EXCESS CAPACITY, HEALTH CARE INTEGRATION, AND SHARED RESOURCES(Objective 4)

As shown in Attachment 1, this objective includes a consideration of those statutes, regulations and policies that do and do not promote the reduction of excess capacity, healthcare integration, and shared resources. Also included is the impact of the CON process on these three goals.

As shown in the review of the CON statute, exemptions from CON can be granted by the Authority for specific projects that involve sharing and integration of resources; these include the acquisition of mobile magnetic imaging and mobile lithotripsy services if they are shared among two or more acute care facilities, and if the services are more cost-effective than fixed units. Birthing centers may also be exempt if the center collaborates with the hospital in the county where the center would be located. The Subcommittee recommends that these exemptions continue.

In addition, the Authority may exempt from CON review financially vulnerable health care facilities located in underserved areas; these exemptions are available through the West Virginia Rural Health Systems Program, which was enacted to reduce excess capacity and duplication of services, to assure the continued provision of essential health services, and to promote linkages with secondary and tertiary services. State grants and loans are also available to transition and restructure the rural health care delivery system.

The Subcommittee endorses efforts to promote sharing and integration, where appropriate. In some instances, integration of services is an important strategy for providers to use in becoming more cost-effective and competitive in managed care contracting. The

Subcommittee recommends that the need for and benefits of integration be addressed explicitly as the SHP is rewritten, and that specific standards giving preference to health service integration projects be developed.

ATTACHMENT 1

CON Subcommittee

Objectives and Action Steps

Objective #1

A. Provide definitions of capital costs and determine effectiveness for controlling capital expenditures and limiting the cost of health care services;

1. Collect information from various studies concerning the elimination, modification or no changes to CON programs and the resultant effect on availability of services, costs, etc.

B. Examine the potential effects of increased managed care penetration on the CON process;

1. Analyze studies from other states to include:

a. volume/capacity aspects of need methodologies;
b. expenditure thresholds;
c. experience of states that have eliminated or substantially modified CON.

C. Perform comparative analyses of other State CON programs regarding managed care penetration, services and expenditures;

1. Review managed care penetration now and projected.

Objective #2

A. To determine the appropriateness and effectiveness of the State Health Plan Criteria "Standards" and review services to determine if any should be exempt from the CON process and, if so, develop criteria to accomplish this task.

1. Review each CON Standard and determine if any changes are needed and if they would require statutory changes;

2. Review process for development and approval of the State Health Plan Standards;

3. Review existing standards for potential amendments;

4. Examine need for standards for services and/or equipment for which none currently exist;

5. Review format of standards - do other things need to be added or deleted? e.g., need methodology continuum of care, quality, etc.

Objective #3

A. Determine the effectiveness of the CON administrative review process, i.e. methodology and timing; and possible improvement thereof;

   1. Review the process from the Letter of Intent through Decisions, including hearings

   2. Which areas require change and how does this take place?

      a. Statutory
      b. Regulation
      c. Administrative/Policy

   3. Which areas currently work effectively?

Objective #4

A. Determine the impact of the CON process on reduction of excess capacity, health care integration and shared resources;

   1. What statutes, regulations and policies promote these goals?

   2. What statutes, regulations and policies do not?

   3. What is the impact of the CON process on these goals?

ATTACHMENT 2

1998 Reviewability Threshold Comparison Chart for West Virginia Area

(this information is summarized from the 1998 National Directory of Health Planning, Policy and Regulatory Agencies, a ninth edition published by the American Health Planning Association)

Service categories: Acute Care, Air Ambulance, Amb Surg Ctrs, Burn Care, Business Cmptrs, Cardiac Cath., CT Scanners, Gamma Knives, Home Hlth, ICF/MR, Lithotripsy, Long Term Care, Med Off Bldg, Mobile Hi Tech, MRI Scanners, Neo-ntl Int Care, Obstetric Svcs, open Heart Svcs, Orgn Transplnt, PET Scnrs, Psychiatric Svsc, Rad Therapy, Rehab, Renal Dialysis, Res Care Fac, Subacute, Substance Abuse, Swing Beds, Ultra Sound

Rank (no. of svc. X weight)	Categories	Other items	Count (no. of services)	Capital	Med Eqpt	New Svc	Weight
37.8	Maine		27	500,000	1,000,000	155,000	1.4
36.1	Connecticut		27	1,000,000	400,000	any	1.3
33.6	West Virginia	Behavioral health	28	1,000,000	750,000	any	1.2
28.8	Georgia	Diagnostic Treatm	24	1,055,798	586,555	any	1.2
27.0	Alaska	All assisted living	27	1,000,000	1,000,000	1,000,000	1.0
24.2	New York	[illegible]	22	1,000,000	1,000,000	any	1.1
23.1	New Jersey	[illegible]	21	1,000,000	1,000,000	any	1.1
22.5	Vermont		25	1,500,000	500,000	300,000	0.9
22.0	South Carolina		20	1,000,000	600,000	400,000	1.1
22.0	Missouri	Emerging tech.	22	1,000,000	1,000,000	1,000,000	1.0
18.7	Mississippi		17	1,000,000	1,000,000	any	1.1
18.4	North Carolina	Intensive Care, M	23	2,000,000	750,000	n/a	0.8
18.4	Illinois	Post-surgical reco	23	2,548,285	1,270,086	any	0.8
17.6	Tennessee	LT acute, nursing	22	2,000,000	1,000,000	any	0.8
16.2	Kentucky	Mobile services	[illegible]	1,587,500	1,587,500	n/a	0.9
16.1	D. of Columbia	[illegible]	23	2,000,000	1,300,000	600,000	0.7
16.0	Rhode Island		20	2,000,000	1,000,000	750,000	0.8
16.0	Michigan	Hospice NH, Surg	20	2,188,000	any	any clin	0.8
15.3	Maryland	Acquisitions, merg	17	1,305,000	n/a	any	0.9
15.0	Hawaii		25	4,000,000	1,000,000	any	0.6
12.0	Alabama	ESRD, Assisted L	20	3,200,000	1,500,000	any	0.6
11.7	New Hampshire		13	1,500,000	400,000	any	0.9
9.1	Florida	Hospice and home	13	n/a	n/a	any	0.7
8.4	Arkansas	LT medical, perso	7	500,000	n/a	hm hlth	1.2
8.1	Washington	new beds in hospi	9	1,202,000	n/a	any	0.9
8.1	Iowa	No specific stds fo	9	1,500,000	1,500,000	500,000	0.9
8.0	Virginia	Gen Surgery, MSI	20	5,000,000	n/a	n/a	0.4
7.0	Oklahoma	Acquisitions of lon	5	500,000	n/a	any beds	1.4
6.3	Montana		7	1,500,000	n/a	150,000	0.9
6.0	Delaware	[illegible]	10	3,000,000	3,000,000	n/a	0.6
5.1	Massachusetts	OB II & III only	17	9,048,071	482,563	any	0.3
5.0	Ohio	[illegible]	10	5,000,000	2,000,000	n/a	0.5
4.9	Nevada		7	2,000,000	n/a	n/a	0.7
2.2	Wisconsin		2	1,000,000	600,000	any LTC	1.1
0.9	Nebraska		3	LTC/rehab	n/a	LTC/rehab	0.3
0.6	Oregon		2	any LTC	n/a	any LTC	0.3
0.4	Indiana		2	any LTC	n/a	any LTC	0.2
0.4	Louisiana		2	LTC/MR	n/a	LTC/MR	0.2

Disclaimer: Rank order relates to volume of items reviewed, NOT severity of analysis or conclusions which are based on Criteria and Standards at Source: Updated April 15, 1998 using information based on 4th Qtr. '97 responses.

ATTACHMENT 3

West Virginia

Health Care Authority

Certificate of Need

Workflow Procedure

Procedures for Applications

1. Letter of intent submitted by applicant.

2. Letter stamped "Received", along with date and time, at the front desk and forwarded to CON Division.

3. CON secretary assigns letter a CON file number.

4. Letter of intent forwarded to Supervisor.

5. Supervisor reviews letter and assigns project to an analyst.

6. Letter of intent placed in Agenda folder for next status meeting.

7. Agenda prepared for status meeting.

8. CON pre-status meeting is held mid-week, attended by CON Director, CON Analysts and other HCA staff.

9. CON status meeting is held with the HCA Board of Directors weekly, during which letters of intent are addressed.

    a. Board determines type of review, either standard or expedited.

        (1) Expedited Review - 65 day review cycle

        (2) Standard Review - 90 day review cycle

10. CON secretary prepares acknowledgment of letter of intent and mails to applicant along with application packet.

11. Applicant submits application and fee.

12. Application is stamped "Received", along with date and time, by the CON secretary; fee is verified.

    a. Copy of application mailed to affected and/or interested party, if any.

13. Letter acknowledging receipt of application and fee sent to applicant.

14. Application forwarded to analyst.

15. Analyst reviews application for completeness:

a. Application deemed complete:

(1) completeness letter prepared and forwarded to clerical for typing,

(2) completeness letter typed and returned to analyst for review:

(a) analyst makes corrections and returns letter to typist,

(b) typist corrects letter and returns it to analyst, **OR**

(c) analyst signs letter and returns to clerical for copying and distribution.

b. Analyst determines additional information is needed:

(1) Analyst prepares information request and forwards to clerical for typing.

(2) Request is typed and returned to analyst for review.

(3) Analyst reviews correspondence:

(a) makes corrections; returns to typist,

(b) typist corrects; returns to analyst, **OR**

(c) analyst signs and returns to clerical for distribution,

(d) clerical copies correspondence:

[1] original correspondence mailed to applicant,

[2] copy of letter mailed to interested/affected parties,

[3] copy sent to analyst.

(4) Upon receipt of additional information:

(a) information stamped "Received", along with date and time, by CON secretary and forwarded to analyst,

(b) analyst reviews information,

(c) if response is sufficient, analyst includes information submitted in application.

(5) Application deemed complete:

(a) completeness letter prepared and forwarded to clerical for typing,

(b) completeness letter typed and returned to analyst for review:

(1) analyst makes corrections and returns letter to typist,

(2) typist corrects letter and returns it to analyst, OR

(3) analyst signs letter and returns to clerical for copying and distribution.

16. Analyst prepares project description for Notice of Review.

17. Clerical types Notice of Review:

a. Copy of Notice of Review mailed to contact person listed on application.

b. Copy of Notice of Review mailed to affected and/or interested parties.

c. Notice of Review included in legal notice published in newspaper.

18. Project enters review cycle:

a. Expedited Review:

(1) 10th day of cycle - deadline for affected party to request that application undergo standard review,

(2) 30th day of cycle - deadline for affected party to request hearing (See No. 19: Hearing Requests). If no hearing requested, go to No. 20,

(3) 31st day of cycle - file closes if no hearing is requested,

(4) 65th day of cycle - on or before, decision is issued.

b. Standard Review:

(1) 30th day of cycle - deadline for affected party to request hearing (See No. 19: Hearing Requests). If no hearing is requested, go to No. 20,

(2) 75th day of cycle - file closes if no hearing is requested.

(3) 90th day of cycle - on or before, decision is issued.

19. Hearing Requests:

    a. Applicant or affected party requests public hearing,

    b. Prehearing and administrative hearing scheduled by HCA legal staff,

    c. Prehearing held,

    d. Administrative hearing held:

        (1) Briefing schedule established,

    e. Briefs submitted,

    f. Reply briefs submitted,

    g. Review by analyst.

20. Staff presentation prepared by analyst and forwarded to clerical for typing.

    a. presentation typed and returned to analyst for review,

    b. presentation reviewed by analyst and submitted as agenda item .

21. Analysts presentation submitted as agenda item at pre-status meeting.

22. Analysts presentation to HCA Board at status meeting for decision.

23. HCA Board determines if certificate of need is approved or denied.

24. Analyst writes decision; forwards to clerical:

    (a) CON secretary logs in decision and assigns for typing.

    (b) Decision typed, placed in folder with routing slip on front of folder, and returned to analyst for review.

25. Decision reviewed by:

    (a) Analyst:

(1) Analyst returns decision to clerical for corrections, **OR**

(2) Analyst signs routing slip, approving decision and forwards to supervisor.

(b) Supervisor:

(1) Supervisor returns decision to analyst for corrections, **OR**

(2) Supervisor signs routing slip, approving decision and forwards to legal staff.

(c) Legal Staff:

(1) Legal Staff returns decision to analyst for corrections, **OR**

(2) Forwards decision to HCA Board for signatures.

(d) HCA Board:

(1) Board returns decision to analyst for corrections, **OR**

(2) signs decision.

26. Decision returned to CON secretary for distribution.

Distribution Process:

1. Signed decision returned to CON clerical for mailing.

2. Decision is copied.

3. Envelopes prepared for mailing.

a. copies of decision mailed certified mail, return receipt requested, to applicant and affected parties,

(1) date noted on log in sheet,

b. copies of decision mailed regular mail to interested parties,

c. one copy of decision sent to Secretary of State's Office to be placed in the State Register,

d. one copy of decision sent to WV Department of Health & Human Resources, Office of Health Facility Licensure and Certification,

e. one copy of decision sent to Office of Hearings & Appeals, WV Tax Department,

f. one copy of decision sent to WV Insurance Commission, Consumer Advocacy Division,

g. one copy of decision filed in the HCA central filing system.

4. When return receipt is received by the HCA, original Decision, certified mail receipts, copy of State Registry letter, and copy of newspaper ad displaying Decision are filed with the application.

Letter of Intent

"Received" stamped at front desk, forwarded to CON

CON # assigned and forwarded to Supervisor

Supervisor reviews and assigns project to analyst

LOI placed in status meeting agenda folder

Agenda prepared

Pre-status meeting (CON staff)

Status meeting (CON staff and Board)

Board determines type of review (expedited or standard)

Acknowledgement prepared and mailed to applicant with application packet

Application and filing fee submitted

"Received" stamped at front desk, forwarded to CON

Fee verified, acknowledgement prepared and mailed

Application forwarded to analyst

Review for completeness

Additional information requested

Analyst prepares request, forwards for typing

Request is typed and returned to analyst for review

Analyst reviews request and returns to CON clerical for distribution

Receipt of additional information

Date stamped in, forwarded to analyst

Application deemed complete

Completeness letter prepared and forwarded for typing

Completeness letter typed and returned to analyst for review

Analyst signs and returns for distribution

Completeness letter copied for distribution

Analyst prepares project description for Notice of Review

Notice of Review prepared and distributed

Standard Review Cycle

Expedited Review Cycle

15th day of cycle - deadline for affected party to request standard review

Hearing request received

"Received" stamped at front desk, forwarded to Legal Staff

Legal staff reviews request and schedules prehearing conference and administrative hearing

Notice of Prehearing and Administrative Hearing prepared and distributed

Prehearing held

Administrative hearing held

Briefing schedule established

Briefs submitted

Reply briefs submitted

Review by analyst

GO TO -

30th day of cycle - deadline for affected party to request hearing

[illegible]

Staff presentation prepared by analyst and forwarded for typing

Presentation typed and returned to analyst for review

Presentation reviewed by analyst and submitted as agenda item

75th day of cycle - file closed

31st day of cycle - file closed

Pre-status meeting (CON staff)

Status meeting (CON staff and Board)

Analyst presentation to Board at status meeting

Board decision

Analyst prepares decision and forwards for typing

Decision log-in by CON clerical

Decision typed and returned to analyst for review

Analyst reviews and forwards to Supervisor

Supervisor reviews and forwards to Legal Staff

Legal Staff reviews and forwards to Board for signature

Board signs

Decision returned to CON for distribution

Copies made

Envelopes prepared

Decision mailed to applicant (certified), affected (certified)/interested parties

Date mailed noted on log-in sheet

90th day of cycle - decision due

45th day of cycle - decision due

Return receipt returned

File folder prepared and decision filed

Procedure for Request for Ruling on Reviewability

I. **Receipt of Request**:

1. Petitioner submits notarized request for ruling on reviewability.

2. Request is stamped "Received", along with the date and time it is received, at the front desk. The request is then forwarded to CON Division.

3. CON secretary assigns the request a CON file number and prepares and mails an acknowledgment of the receipt of the request.

4. Request is placed in a file folder to be placed on the agenda for the next CON status meeting.

5. Agenda is prepared for status meeting.

6. CON pre-status meeting is held mid-week, attended by CON Director, CON Analysts and other HCA staff and request is assigned to a CON analyst.

7. CON status meeting is held with the HCA Board of Directors weekly, during which requests are addressed.

8. Request is reviewed by the Board.

9. If it is determined that additional information is needed:

   a. Analyst prepares information request and forwards to clerical for typing.

   b. Request is typed and returned to analyst for review.

   c. Analyst reviews correspondence:

      (1) makes corrections; returns to typist

      (2) typist corrects; returns to analyst **OR**

      (3) analyst signs and returns to clerical for distribution

      (4) clerical copies correspondence:

(a) original correspondence mailed to petitioner

(b) copy of letter mailed to interested/affected parties

(c) copy sent to analyst

d. Upon receipt of additional information:

(1) information stamped "Received", along with date and time, at the front desk, and forwarded to analyst

(2) analyst reviews information

(3) if response is sufficient, analyst places item in status meeting folder for presentation at next meeting.

II. <u>Request determined NOT REVIEWABLE by HCA Board</u>:

1. Analyst writes Order; forwards to clerical for typing.

2. Order is logged in by CON secretary and is assigned to be typed.

3. Order typed, placed in folder with routing slip on front of folder, and returned to analyst for review.

4. Analyst reviews typed Order and:

   a. makes corrections and returns Order to typist

   b. typist corrects and returns Order to analyst, **OR**

   c. analyst initials routing slip, approving Order and forwards to supervisor

5. Supervisor reviews Order and:

   a. returns Order to analyst, **OR**

   b. supervisor initials routing slip, approving Order and forwards to legal staff

6. Legal staff reviews Order and:

   a. returns Order to analyst, **OR**

   b. forwards to HCA Board for signatures

7. HCA Board reviews Order and:

   a. returns Order to analyst, **OR**

   b. signs Order

8. Signed Order forwarded to CON for copying and distribution (See IV. Distribution Process).

III. <u>Request determined REVIEWABLE by the HCA Board</u>:

1. Analyst writes Order; accepts request as letter of intent; forwards to clerical for typing.

2. Order is logged in by CON secretary and is assigned to be typed.

3. Order typed, placed in folder with routing slip on front of folder, and returned to analyst for review.

4. Analyst reviews typed Order and:

   a. makes corrections and returns Order to typist

   b. typist correct and returns Order to analyst, **OR**

   c. analyst initials routing slip, approving Order and forwards to supervisor

5. Supervisor reviews Order and:

   a. returns Order to analyst. **OR**

   b. supervisor initials routing slip, approving Order and forwards to legal staff

6. Legal staff reviews Order and:

   a. returns Order to analyst, **OR**

   b. forwards to HCA Board for signatures

7. HCA Board reviews Order and:

   a. returns Order to analyst, **OR**

b. signs Order

8. Signed Order forwarded to CON for copying and distribution (See IV. Distribution Process).

9. Petitioner advised request for ruling found reviewable; request accepted as letter of intent, and application packet mailed to Petitioner.

IV. **Distribution Process**:

1. Signed Order returned to CON clerical for mailing.

2. Original request for determination removed from Agenda folder and clipped to original signed Order.

3. Order is copied.

4. Envelopes prepared for mailing.

   a. copies of Order mailed certified mail, return receipt requested, to petitioner and affected parties

   b. copies of Order mailed regular mail to interested parties

   c. one copy of Order sent to Secretary of State's Office to be placed in the State Register

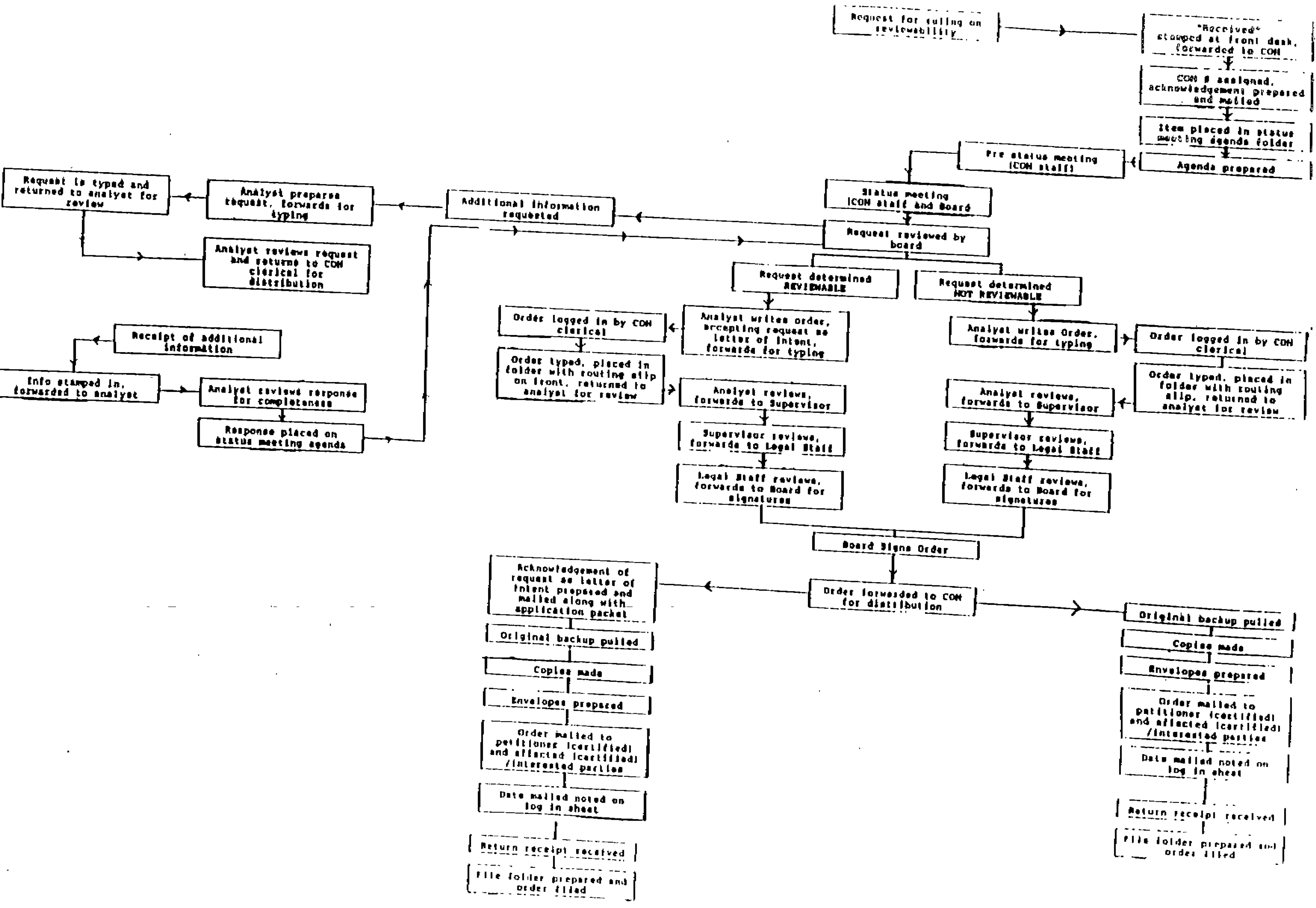
   d. one copy of Order and copies of all original request material are sent to WV Department of Health & Human Resources, Office of Health Facility Licensure and Certification

   e. one copy of Order and copies of all original request material are sent to Office of Hearings & Appeals, WV Tax Department

   f. one copy of Order and copies of all original request material are sent to WV Insurance Commission, Consumer Advocacy Division

   f. one copy of Order and copies of all original request material are filed in the HCA central filing system

5. When return receipt is received by the HCA, original Order, all original request information submitted, certified mail receipts, copy of State Registry letter, and copy of newspaper ad displaying Order are filed in "Determinations of Reviewability files"



Request for ruling on reviewability
"Received" stamped at front desk, forwarded to CON
CON # assigned, acknowledgement prepared and mailed
Item placed in status meeting agenda folder
Agenda prepared
Pre status meeting (CON staff)
Status meeting (CON staff and Board)
Request reviewed by board
Additional information requested
Analyst prepares request, forwards for typing
Request is typed and returned to analyst for review
Analyst reviews request and returns to CON clerical for distribution
Receipt of additional information
Info stamped in, forwarded to analyst
Analyst reviews response for completeness
Response placed on status meeting agenda
Request determined REVIEWABLE
Analyst writes order, accepting request as letter of intent, forwards for typing
Order logged in by CON clerical
Order typed, placed in folder with routing slip on front, returned to analyst for review
Analyst reviews, forwards to Supervisor
Supervisor reviews, forwards to Legal Staff
Legal Staff reviews, forwards to Board for signatures
Request determined NOT REVIEWABLE
Analyst writes Order, forwards for typing
Order logged in by CON clerical
Order typed, placed in folder with routing slip, returned to analyst for review
Analyst reviews, forwards to Supervisor
Supervisor reviews, forwards to Legal Staff
Legal Staff reviews, forwards to Board for signatures
Board Signs Order
Order forwarded to CON for distribution
Acknowledgement of request as letter of intent prepared and mailed along with application packet
Original backup pulled
Copies made
Envelopes prepared
Order mailed to petitioner (certified) and affected (certified) /interested parties
Date mailed noted on log in sheet
Return receipt received
File folder prepared and order filed
Original backup pulled
Copies made
Envelopes prepared
Order mailed to petitioner (certified) and affected (certified) /interested parties
Date mailed noted on log in sheet
Return receipt received
File folder prepared and order filed

ATTACHMENT 4

Certificate of Need Committee Members

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ATTACHMENT 5

CON COMMITTEE

✓ **Vote Tally results from meeting on September 9, 1998, 11:00 a.m., regarding Accepting Certificate of Need Study Report**

MEMBER	INTEREST GROUP	VOTE	SIGNATURE
Elizabeth Morgan	Governor's Office	Abstain	Via Telephone conference
Sen. Martha Walker Jerry Rouche	Senate (Designee)	Yes	Via Telephone conference
Delegate. Mary Pearl Compton	House of Delegates	Yes	Via Telephone conference
Gordon Copland	Business	Yes	Via Telephone conference
Charlene Farrell	Hospice Provider	Yes	Via Telephone conference
Robert Ritz	Hospital Industry	Yes	Via Telephone conference
Bernie Westfall	Hospital Industry	Yes	Via Telephone conference
Tim Gibbons	Consumer Interest	Yes	Via Telephone conference
George Rider	Medical Association	Yes	Via Telephone conference
Steven Summer	Hospital Industry	Yes	Via Telephone conference
Jill McDaniel	Hospital Industry	Yes	Via Telephone conference
John Wilkinson	Home Health	Not Available	Via Telephone conference
Paul Holdren	Managed Care	Not Available	Via Telephone conference
Jill Hutchinson	Primary Care	Not Available	Via Telephone conference
Neil Phillips	Consumer Advocate	Not Available	Via Telephone conference
Steve Barthelmess	Hospital Industry	Yes	Via Telephone conference
Al Mytty	Managed Care	Not Available	Via Telephone conference
Patsy Hardy	Hospital Industry	Not Available	Via Telephone conference
Alex Skaff	Medical Association	Not Available	Via Telephone conference

MEMBER	INTEREST GROUP	VOTE	SIGNATURE
Nora Antlake/Phil Shimer	Medicaid	Not Available	Via Telephone conference
Stephens Mundy	Hospital Industry	Yes	Via Telephone conference
Violet Burdette	Home Health	Not Available	Via Telephone conference
Kay Cotrill	Nursing Home	Not Available	Via Telephone conference
J. Thomas Jones	Business	Yes	Via Telephone conference
Jesse Samples	Nursing Home	Not Available	Via Telephone conference
Rich Kiley	Behavioral Health	Not Available	Via Telephone conference
David McWatters	Behavioral Health	Not Available	Via Telephone conference
Larry Malone	Business	Not Available	Via Telephone conference
D. Parker Haddix	WV Health Care Authority	Yes	Via Telephone conference
Gregory A. Burton	WV Health Care Authority	Yes	Via Telephone conference
Garry D. Black	WV Health Care Authority	Yes	Via Telephone conference
Dayle Stepp	WV Health Care Authority	Yes	Via Telephone conference
Raymond V. Shingler	WV Health Care Authority	Yes	Via Telephone conference

ATTACHMENT 6

PRIMARY TASK FORCE

✓ *Vote Tally results from meeting on September 16, 1998, 10:00 a.m., regarding Certificate of Need Study Report*

MEMBER	INTEREST GROUP	VOTE	SIGNATURE
Elizabeth Morgan	Governor's Office	Not Available	
Senator Martha Y. Walker	Senate	Not Available	
Senator Larry Kimble	Senate	Not Available	
Delegate Mary Pearl Compton	House of Delegates	Not Available	
Delegate Ron Walters	House of Delegates	No	[signature]
Steven J. Summer	Hospital Industry	Yes	[signature]
Rich Kiley	Behavioral Health Industry	Yes	[signature]
George Rider	Medical Association	No	[signature]
Jill Hutchinson	Primary Care	Not Available	
Phil Shimer	State Agencies	Not Available	
Neil Phillips	Consumer Advocate	Yes	[signature]
Jesse Samples	Nursing Home	Yes	[signature]
Paul Holdren	Managed Care	Not Available	
Bill Gavin	Third Party Payor	No	[signature]
Renate Pore	Public	~~Yes~~ No	[signature]
Thomas M. Boggs	Business Industry	Yes	[signature]
J. Thomas Jones	Business Industry	Not Available	
Charles Steinmetz	Business Industry	Not Available	

MEMBER	INTEREST GROUP	VOTE	SIGNATURE
D. Parker Haddix	WV Health Care Authority	YES	D. Parker Haddix
Gregory A. Burton	WV Health Care Authority	YES	[illegible]
Garry D. Black	WV Health Care Authority	Yes	[illegible]
Linda Sovine	WV Health Care Authority	Yes	Linda Sovine
Margi High	WV Health Care Authority	Not Available	
Dayle Stepp	WV Health Care Authority	Yes	Dayle O Stepp
Marianne K. Stonestreet	WV Health Care Authority	Not Available	
Raymond V. Shingler	WV Health Care Authority	Yes	Raymond Shingler

ATTACHMENT 7

Executive Summary of Primary Task Force Meeting on September 16, 1998 for Voting of Certificate of Need Study from the Certificate of Need Committee

During a meeting of the Primary Task Force, held on September 16, 1998 at the West Virginia Health Care Authority, the Certificate of Need Committee presented a draft of the Certificate of Need Study for review by the Primary Task Force.

During this meeting a number of issues were discussed by the Primary Task Force and an outline of those issues are as follows:

1. **Memorandum presented by Charles Steinmetz**

   Mr. Steinmetz presented a memorandum that suggested CON be abolished at the earliest possible opportunity and absence of that occurring that certain services be eliminated from review, except for certain tertiary services such as open heart surgery and transplantation. The memorandum agreed with the CON Study to review the State Health Plan and "fast-tracking" certain non-patient care projects.

   a. Mr. Steven Summers and Mr. Greg Burton commented that all of the issues spelled out be Mr. Charles Steinmetz had been discussed by the CON Committee and they stated how disappointed they were that this had not been brought up in the CON Committee meetings by Mr. Charles Steinmetz or one of the business representatives.

   b. Delegate Ron Walters spoke in favor of Mr. Charles Steinmetz's memorandum.

   c. Mr. Bill Gavin questioned if there was representation of the Kanawha Valley Employers Coalition on the CON Subcommittee. He also supported the memo's contention that CON programs function today as barriers to entry by new providers and therefore reduce competition. Mr. Greg Burton informed the Primary Task Force that there was a number of individuals representing business on the CON Subcommittee.

2. **Discussion on whether CON controls costs/services**

   There was a long discussion on this issue and the following topics were discussed:

   a. Ms. Renate Pore stated that there was evidence that CON does not control costs and she hoped the study proposed in the CON Committee Study would be able to answer the question.

b. Mr. Bill Gavin questioned whether CON truly controlled services since it was a one shot deal. Mr. Dayle Stepp of the WV Health Care Authority states that we could review a CON for three years after issue date and Mr. Greg Burton stated that if the CON was issued to a hospital, the rate applications filed by hospitals may allow for a continual review.

c. Mr. Bill Gavin also questioned whether hospitals/current providers having services could expand while another hospital/new providers would have to go through CON. The question about expansion of current services was not resolved during the meeting, although it was reported that existing regulations specifically require CON for expansion of certain cardic services. Mr. Greg Burton stated that we have CON to help control the number of providers so duplication of services does not occur. Further, Mr. Greg Burton stated that the expense of going through a CON could be minimal to the applicant if they would use the Authority staff to help prepare the application. He further stated the only extra expense would be the fees charged by the authority. Mr. Scott Buckley stated that the Dartmouth Atlas study showed that an increase of providers led to an increase in utilization.

d. Delegate Ron Walters agreed with Mr. Bill Gavin that barriers were being created for small rural hospitals with CON. Mr. Steve Summers stated that small rural hospitals were concerned that competition from other providers may upset the balance of care in their areas if CON were eliminated.

3. **Discussion on accepting the CON Committee Study**

a. The Primary Task Force discussed in length whether to accept the Study as presented, amend the Study or send it back with comments to the CON Committee for further study.

1. A motion to move the Study before the Primary Task Force was made and seconded and passed unanimously.

2. Mr. Bill Gavin made a motion that the Primary Task Force recommend that the scope of the review for new services be limited to those that exceed the expenditure limits($1.5 to $2 million) or those services, as identified in regulation, which are reimbursed in large part by the Medicaid program (eg. ICF-MR). Delegate Walters seconded the motion. During discussions, Mr. Greg Burton stated this motion would change the scope of the Study dramatically and he felt if this passed the report should be sent back to the CON Committee. The motion was rejected 11 to 4 with Mr. Bill Gavin, Delegate Ron Walters, Ms. Renate Pore and Mr. George Rider voting in support of the motion.

3. Ms. Renate Pore made a motion that the study recommended on page 4 be amended to state that the study should vigorously review the costs and the savings of having CON. The amendment passed unanimously.

4. **Motion to accept the Study**

a. A motion and second was made to accept the report as amended.

b. Discussion before the vote

1. Mr. George Rider stated he was not able to vote for the report because the report did not call for the elimination of CON.

2. Delegate Ron Walters stated he was encouraged by the work done but discouraged by the fact he felt rural hospitals would be put at a disadvantage.

3. Mr. Greg Burton commended all the hard work and effort put into the report and also added that he felt all issues had been addressed by the CON Committee.

c. Vote on acceptance

1. The Primary Task Force voted to accept the report as amended 11 to 4 with Mr. Bill Gavin, Delegate Ron Walters, Ms. Renate Pore and Mr. George Rider voting no.