

TABLE OF CONTENTS

	<u>Page</u>
Motion for Declaratory Judgment	1
Demurrer	4
Order	6
Answer	8
Final Order	10
Plaintiff's Exhibit 1	
Letter dated 11-3-77.....	12
Letter dated 11-7-77	13
Letter dated 11-14-77	15
Letter dated 11-30-77	16
Letter dated 12-27-77	17
Letter dated 4-17-78	18
Letter dated 5-8-78	20
Letter dated 5-26-78 and 2 attachments	22
Letter dated 7-25-78	28
Letter dated 11-21-78	29
Letter dated 9-26-79	30
Plaintiff's Exhibit 2	
Letter dated 10-16-78 and 5 attachments	31
Plaintiff's Exhibit 3	
Letter dated 12-4-78.....	47
Plaintiff's Exhibit 4	
Certificate of Public Need	48
Letter dated 4-5-77	49
Plaintiff's Exhibit 5	50
Rules and Regulations of the Board of Health, Commonwealth of Virginia Virginia Medical Care Facilities Certificate of Public Need	
Plaintiff's Exhibit 6	74
Rules and Regulations of the Board of Health, Commonwealth of Virginia Virginia Medical Care Facilities Certificate of Public Need	

	<u>Page</u>
Defendant's Exhibit 1	
State Board of Health, Commonwealth of Virginia...	101
1979 State Medical Facilities Plan	
Argument of Phillips M. Dowding, Esquire	
Tr. p. 10, line 5 to p. 12, line 24	103
Argument of Robert T. Adams, Esquire	
Tr. p. 14, line 5 to p. 17, line 7	106
Testimony of Gerald R. Brink	
Tr. p. 7, line 1 to Tr. p. 35, line 17	110
Testimony of Dr. Walter H. Graham	
Tr. p. 35, line 10 to Tr. p. 48, line 13	137
Ruling of Honorable Henry D. Garnett	
Tr. p. 52, line 1 to Tr. p. 54, line 19	151

VIRGINIA: IN THE CIRCUIT COURT FOR THE CITY OF NEWPORT NEWS

NEWPORT NEWS GENERAL AND NON-SECTARIAN
HOSPITAL ASSOCIATION, INCORPORATED,

Plaintiff,

v.

Law # 5583-G

JAMES B. KENLEY,
Commissioner
Department of Health Commonwealth of Virginia
109 Governor Street
Richmond, Virginia,

Defendant.

MOTION FOR DECLARATORY JUDGMENT

Plaintiff respectfully represents unto this Honorable
Court as follows:

1. That this is an action for Declaratory Judgment pursuant to Sections 8.01-184 et seq, of the Code of Virginia, as amended.
2. That Plaintiff is a non-profit Virginia corporation which owns and operates Riverside Hospital, a general and non-sectarian hospital located at 500 J. Clyde Morris Boulevard, in the City of Newport News, Virginia.
3. That the Defendant is the Commissioner of the Department of Health for the Commonwealth of Virginia, and at all times herein mentioned was acting in the course of his official duties as an agent, servant and employee of the Commonwealth of Virginia.
4. That venue for this action is proper in this Court pursuant to Section 8.01-261 of the Code of Virginia, as amended.

5. That in connection with the operation of Riverside Hospital the Plaintiff has conducted and offered since 1972 a complete open-heart surgery program.

6. That the Defendant has erroneously and unlawfully undertaken to enforce the provisions of Sections 32.1-93 through 32.1-102, both inclusive, of the Code of Virginia, as amended, and the Rules and Regulations promulgated pursuant thereto, by requiring the Plaintiff to comply with the aforesaid provisions of Sections 32.1-93 through 32.1-102, both inclusive, of the Code of Virginia, as amended, as a condition precedent to continuing the operation of its open heart surgery program.

7. That Plaintiff alleges that the operation by it, at Riverside Hospital in the City of Newport News, Virginia, of an open heart surgery program is not subject to the requirements of Sections 32.1-93 through 32.1-102, both inclusive, of the Code of Virginia, as amended, and that compliance with the aforesaid statutes and the Rules and Regulations adopted pursuant thereto is not a condition precedent to the operation of its open heart surgery program.

8. That an actual justiciable controversy exists between Plaintiff and Defendant as to whether or not Plaintiff is required to comply with the conditions of Sections 32.1-93 through 32.1-102 of the Code of Virginia, as amended, and the Rules and Regulations promulgated pursuant thereto as a condition precedent to the operation by Plaintiff of an open heart surgery program at Riverside Hospital in the City of Newport News, Virginia.

WHEREFORE, Plaintiff moves the Court for a Declaratory Judgment Order adjudicating that it is not required to comply with the terms of Sections 32.1-93 through 32.1-102 of the Code of Virginia, as amended, as a condition precedent to the maintenance and operation of an open heart surgery program at Riverside Hospital, in the City of Newport News, Virginia, and for such other relief as the Court may deem necessary and proper.

NEWPORT NEWS GENERAL AND
NON-SECTARIAN HOSPITAL ASSOCIATION,
INCORPORATED

By 

Of Counsel

PHILLIPS M. DOWDING
Attorney at Law
12335 Warwick Boulevard
Newport News, Virginia 23606

Counsel for Plaintiff

VIRGINIA:

IN THE CIRCUIT COURT FOR THE CITY OF NEWPORT NEWS

NEWPORT NEWS GENERAL AND NON-SECTARIAN
HOSPITAL ASSOCIATION, INCORPORATED,

Plaintiff

v.

JAMES B. KENLEY, M.D.,
State Health Commissioner,

Defendant

LAW NO. 5583-G

DEMURRER

Defendant, by counsel, demurs to plaintiff's Motion for Declaratory Judgment on the basis that plaintiff has not alleged compliance with either the Administrative Process Act, 9-6.14:1-.14:20 of the Code of Virginia (1950), as amended, or Part 2A of the Rules of the Supreme Court of Virginia concerning timely appeals from case decisions.

Respectfully submitted,

JAMES B. KENLEY, M.D.
State Health Commissioner

By:

Robert T. Adams
Counsel

Marshall Coleman
Attorney General of Virginia

James E. Ryan, Jr.
Deputy Attorney General

Robert T. Adams
Assistant Attorney General
715 Madison Building
109 Governor Street
Richmond, Virginia 23219
(804) 786-1840

CERTIFICATE

I hereby certify that on this 10th day of June, 1980, I mailed, postage prepaid, a true copy of the foregoing Demurrer to Phillips M. Dowding, Esq., 12335 Warwick Boulevard, Newport News, Virginia 23606.

Robert J. Adams

RECEIVED SEP 5 1980

VIRGINIA: IN THE CIRCUIT COURT FOR THE CITY OF NEWPORT NEWS

NEWPORT NEWS GENERAL AND NON-SECTARIAN
HOSPITAL ASSOCIATION, INCORPORATED,

Plaintiff,

v.

Law #5583-G

JAMES B. KENLEY,

Commissioner

Department of Health Commonwealth of Virginia, Defendant.

O R D E R

This action came on this day to be heard on the
Demurrer filed herein by the Defendant and was argued by counsel.

UPON CONSIDERATION WHEREOF and for the reasons stated
from the Bench during oral argument, it is accordingly ORDERED
that the aforesaid Demurrer be, and the same hereby is,
overruled, to which action of the Court the Defendant, by
counsel, duly objected and excepted.

It is further ORDERED that the Defendant shall file
his Answer within twenty-one (21) days from the date of entry
of this Order.

ENTERED: 9/2/80

(s) Henry D. Garnett

Judge

I ASK FOR THIS:

(s) Phillips M. Dowding
Of Counsel for Plaintiff

SEEN:

(s) Robert T. Adams
Of Counsel for Defendant

A COPY. TESTE: H. J. Sturm, Jr., Clerk

By Linda Weatherly D. C.

IN THE CIRCUIT COURT FOR THE CITY OF NEWPORT NEWS

NEWPORT NEWS GENERAL AND NON-SECTARIAN)
HOSPITAL ASSOCIATION, INCORPORATED,)

Plaintiff)

v.)

LAW NO. 5583-G

JAMES B. KENLEY, M.D.,)
State Health Commissioner,)

Defendant)

ANSWER

1. The allegations contained in paragraph 1 of the Motion for Declaratory Judgment are not such as to require an answer, but to the extent that an answer may be required, the allegations contained therein are admitted.

2. The allegations contained in paragraph 2 of the Motion for Declaratory Judgment are admitted.

3. The allegations contained in paragraph 3 of the Motion for Declaratory Judgment are admitted.

4. The allegations contained in paragraph 4 of the Motion for Declaratory Judgment are not such as to require an answer, but to the extent that any answer may be required, the allegations contained therein are admitted.

5. The allegations contained in paragraph 5 of the Motion for Declaratory Judgment are denied.

6. The allegations contained in paragraph 6 of the Motion for Declaratory Judgment are denied.

7. The allegations contained in paragraph 7 of the Motion for Declaratory Judgment are denied.

8. The allegations contained in paragraph 8 of the Motion for Declaratory Judgment are denied to the extent

that it alleges that jurisdiction exists for this Court to consider this matter. For the reasons previously advanced and rejected by the Circuit Court concerning the defendant's demurrer, the defendant contests the jurisdiction of the Circuit Court. In all other respects, however, the allegations contained in paragraph 8 of the Motion for Declaratory Judgment are admitted.

Respectfully submitted,

JAMES B. KENLEY, M.D.
State Health Commissioner

By:


Counsel

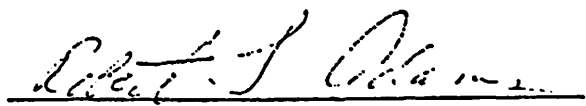
Marshall Coleman
Attorney General of Virginia

James E. Ryan, Jr.
Deputy Attorney General

Robert T. Adams
Assistant Attorney General
715 Madison Building
109 Governor Street
Richmond, Virginia 23219
(804) 786-1840

CERTIFICATE

I hereby certify that on this 15th day of September, 1980, I mailed, postage prepaid, a true copy of the foregoing Answer to Phillips M. Dowding, Esq., 12335 Warwick Boulevard, Newport News, Virginia 23606.



VIRGINIA: IN THE CIRCUIT COURT FOR THE CITY OF NEWPORT NEWS

NEWPORT NEWS GENERAL AND NON-SECTARIAN
HOSPITAL ASSOCIATION, INCORPORATED,

Plaintiff,

v.

Law #5583-G

JAMES B. KENLEY, Commissioner
Department of Health Commonwealth of Virginia,

Defendant.

FINAL ORDER

This action for Declaratory Judgment came on this day to be heard on the pleadings and exhibits previously filed, documentary evidence and testimony received and heard in open court and was argued by counsel.

UPON CONSIDERATION WHEREOF, and for the reasons stated by the Court from the Bench at the conclusion of the evidence and argument of counsel, it is ADJUDGED, ORDERED and DECREED that the finding of the Defendant, as set forth in his letter dated December 27, 1977 to Mr. Paul M. Boynton, Executive Director, Eastern Virginia Health Systems Agency, with copies to Bureau of Resources Development and Mr. Nelson St. Clair, is declared invalid and void ab initio, and that the Plaintiff, Newport News General and Non-Sectarian Hospital Association, Incorporated, trading as Riverside Hospital, is not required to comply with the terms of Sections 32.1-93 through 32.1-102 of the Code of Virginia, as amended, or any rules or regulations of the Board of Health of the Commonwealth of Virginia promulgated pursuant thereto, or any similar prior statutes and/or rules and regulations as a condition precedent to the maintenance and operation of a complete open heart surgery program at Riverside

Hospital in the City of Newport News, Virginia, to which action of the Court the Defendant, by counsel, duly objected and excepted.

In accord with Rule 5:9(a) of the Rules of Court, and by agreement of the parties as evidenced by the endorsement of counsel for both parties to this Order, it is further ADJUDGED, ORDERED and DECREED that the transcript of the hearing held herein on January 9, 1981 shall become a part of the record herein if filed in the Clerk's Office within sixty (60) days from the date of entry of this Order.

It is further ADJUDGED, ORDERED and DECREED that this action be, and the same hereby is, dismissed from the docket.

ENTERED: 1/26/81

Angie B. Bowers

I ASK FOR THIS:

Robert A. Dandridge
Of Counsel for Plaintiff

SEEN:

Robert A. Dandridge
Of Counsel for Defendant

A COPY TESTE: H. J. Sturm, Jr., Clerk

By *Denna L. Day* D. C.

EASTERN VIRGINIA HEALTH SYSTEMS AGENCY, INC.

11 KOGER EXECUTIVE CENTER / SUITE 20

NORFOLK, VIRGINIA 23502

Area Code (804) 461-1236

ROBERT W. WENTZ, JR.
President

PAUL M. BOYNTON
Executive Director



November 3, 1977

Mr. Nelson L. St. Clair
Executive Vice President
Riverside Hospital
J. Clyde Morris Boulevard
Newport News, Virginia 23601

Dear Mr. St. Clair:

As you may know, we are presently reviewing a Certificate of Public Need application for replacement of a cardiac catheterization lab at Norfolk General Hospital.


In performing this review, and in comparing present HSA V hospital operations with the proposed National Guidelines for Health Planning, it has come to our attention that the number of open-heart surgery cases at Riverside Hospital is much lower than the proposed standards. Our information indicates (see page 4 of enclosure) that during 1976 only 12 open-heart operations were performed at Riverside Hospital. This is well below the proposed standard of 200 procedures/annum.

Though admittedly these are only "proposed" standards and though the EVHSA has not at this point taken any formal position on them, nevertheless it seems to me that you might want to re-evaluate the need for this program at Riverside Hospital.

In any case, I would appreciate it if you could provide us with all pertinent information on the operation of this program from its inception to the present. This information will serve to update our records and to assist us in performing our COPN review functions.

Your cooperation in providing us with this information and any additional comments you might have is very much appreciated.

Sincerely,


P. M. Boynton
Executive Director

PMB/ks

Enclosure



(P)

RIVERSIDE HOSPITAL

J. Clyde Morris Boulevard
Newport News, Virginia 23601
Telephone 599-2000

November 7, 1977

Mr. Paul M. Boynton, Executive Director
Eastern Virginia Health Systems Agency
11 Koger Executive Center
Suite 203
Norfolk, Virginia 23502

Dear Mr. Boynton:

In response to your letter of November 3, 1977 requesting information concerning the Open Heart Surgery Program at Riverside Hospital, I would like to submit the following.

The program was initiated with approval of the Board of Trustees of Riverside Hospital on February 23, 1972. The program was put together with the support of a cardiologist, three thoracic surgeons on the medical staff at Riverside Hospital, and Dr. Lewis H. Boshier, Jr. from the Medical College of Virginia. The intent was that Dr. Boshier would assist with the design and establishment of the program, perform the open heart surgical cases at Riverside Hospital with the assistance of the thoracic surgeons until such a time that the thoracic surgeons were re-oriented to the program.

The first open heart surgery case was performed on February 2, 1973 and the cases progressed satisfactorily during the year. Throughout the years of 1974, 1975 and 1976 anesthesia was not available from Riverside Hospital and we had to use part-time personnel from MCV for anesthesia coverage.

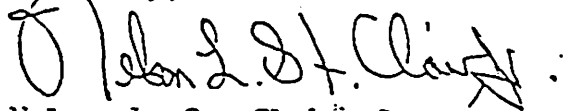
The last open heart surgical case performed at Riverside Hospital was on September 3, 1976. After that time the anesthesia coverage from MCV became non-existent and as a result the program ceased to function. A total of 77 cases were performed at Riverside Hospital between February, 1973 and September, 1976. These cases consisted of coronary arterial bypasses, aneurysmectomy, mitral commissurotomy, mitral valvular replacement, and enclosure of atrio-septal defects. All the patients were catheterized pre-operatively, and followed by a post-operative catheterization six to twelve months after surgery.

November 7, 1977

From September 3, 1976 to present the Open Heart Surgery Program has not functioned due to the lack of anesthesia coverage. In July of this year an anesthesiologist joined the staff of Riverside Hospital who is interested in providing anesthesia for open heart procedures and, therefore, we are re-activating the program. We also have an open heart surgeon who will be joining the staff in January of 1978.

We now have two hospital based cardiologists who have indicated to us that the potential of performing approximately 200 open heart surgical cases per year is a viable potential, given approximately three years to develop the program with a single surgeon performing the surgery. Even though the service has not been provided for 15 months, it is a service that has been provided by Riverside Hospital since 1973 and it appears to us that it will be a viable program in the near future.

Sincerely,



Nelson L. St. Clair, Jr.
Executive Vice President

NLSTC:ga

EASTERN VIRGINIA HEALTH SYSTEMS AGENCY, INC.

11 KOGER EXECUTIVE CENTER / SUITE 201

NORFOLK, VIRGINIA 23502

Area Code (804) 461-1236

PAUL M. BOYNTON
Executive Director

ROBERT W. WENTZ, JR.
President



November 14, 1977

Mr. Nelson St. Clair, Jr.
Executive Vice President
Riverside Hospital
J. Clyde Morris Boulevard
Newport News, Virginia 23601

Dear Mr. St. Clair:

Thank you for your November 7th letter responding to our earlier inquiry regarding Riverside's Open-Heart Surgery Program.

We have examined the information you have presented and are of the opinion that a Certificate of Public Need probably is required prior to reactivating this program. As you may know, the Federal Regulations which govern HSA review include as "new institutional services" those which have not been offered within the preceding 12 months.

Additionally, the performance of this program during the period in which it was active seems to fall far below the standards set forth in the proposed Federal Guidelines. In view of this fact and the fact that, according to 1976 data, Norfolk General Hospital only performed the minimum 200 open-heart procedures, it appears questionable to establish a "new" program when a geographically close existing program is only operating at a minimally efficient level.

By copy of this letter, I am requesting the advice of Commissioner Kenley on the appropriateness of a Certificate of Public Need review of this matter. Your cooperation is very much appreciated.

Sincerely,

P. M. Boynton
Executive Director

PMB/ks

cc: Commissioner James B. Kenley

EASTERN VIRGINIA HEALTH SYSTEMS AGENCY, INC.

11 KOGER EXECUTIVE CENTER / SUITE 203

NORFOLK, VIRGINIA 23502

Area Code (804) 461-1236

FRITZ W. WENTZ, JR.
President

PAUL M. BOYNTON
Executive Director

(R)

November 30, 1977

James B. Kenley, M.D.
State Health Commissioner
Virginia Department of Health
109 Governor Street
Richmond, Virginia 23219

Dear Commissioner Kenley:

I am writing you today to inquire as to the status of your deliberations concerning the potential reactivation of Riverside Hospital's open heart surgery program. By copy of my November 14th letter to Mr. St. Clair, I had requested your guidance as to the appropriateness of a COPN review of this matter.

In case the original correspondence was not received in your office or inadvertently overlooked, I am enclosing a copy of our complete file on this for your information and review. Anything you could do to assist us with this matter would be greatly appreciated.

I trust you had a good Thanksgiving, and my best wishes for a happy holiday season.

Sincerely,


P. M. Boynton
Executive Director

PMB/ks

Enclosures

cc: Mr. Nelson St. Clair



(S)

COMMONWEALTH of VIRGINIA

Department of Health
Richmond, Va. 23219

December 27, 1977

Mr. Paul M. Boynton, Executive Director
Eastern Virginia Health Systems Agency
11 Koger Executive Center - Suite 203
Norfolk, Virginia 23502

Dear Mr. Boynton:

This is in reference to your letter of November 14 and your followup letter of November 30 relative to re-instituting the open heart surgery service at Riverside Hospital. Based upon the advice provided by our legal counsel, who has researched this matter, it has been determined that if any services not provided by a hospital during its previous 12 months of operation is re-instituted, it is considered to be a new service and as such will require a Certificate of Public Need prior to implementation.

I hope this clarifies the matter. By copy of this letter I am informing Mr. St. Clair, Administrator of Riverside Hospital, of this finding.

If there are any questions, please contact Mr. Raymond O. Perry at 804-786-7463.

Sincerely,

James B. Kenley, M.D.
State Health Commissioner

cc: Bureau of Resources Development
Mr. Nelson St. Clair

(V)

April 17, 1978

Mr. Paul M. Boynton
Executive Director
Eastern Virginia Health Systems Agency
11 Koger Executive Center
Suite 203
Norfolk, Virginia, 23502

Dear Mr. Boynton:

In response to your letter of November 14, 1977 and Dr. Kenley's letter of December 27, 1977, we have re-examined the facts previously described in our letter to you of November 7, 1977, and find that some errors were made in the information provided by us and the interpretation of the definitions of cardiac surgery.

We have reassessed our information according to the guidelines established by the Intersociety Commission for Heart Disease Resources, Optimal Resources for Cardiac Surgery published in CIRCULATION, Volume 52, November, 1975. During the past 24 months, following the referenced guidelines, we have performed 134 cardiac surgical procedures at Riverside Hospital. Several of these operations required the availability of the open-heart pump. The last procedure was performed approximately one week ago. Also, during the same period, 119 additional cases were referred to other medical facilities for cardiac surgical procedures (see attached list). We, therefore, feel that we are in accordance with the federal and state regulation in that these cardiac surgical procedures have continued to be provided up to the present date and that the program was not discontinued as referenced in our letter of November 7, 1977.

Mr. Paul M. Boynton

-2-

April 17, 1978

We now have full anesthesia coverage, and a new cardiac surgeon who will be joining our staff. There is considerable pressure on the part of the Medical Staff to continue the cardiac surgical program, and expand it over the next two to three years within the guidelines for health planning. Our hospital based cardiologists have stated that the potential of performing approximately 200 open heart surgical cases per year along with approximately 90 to 100 non-pump cardiac surgery cases is a viable potential, given approximately three years to develop the program with a single surgeon performing the surgery.

I would appreciate your comments on and authorization to continue with our cardiac surgery program which would include open heart cases in line with the health planning guidelines without the necessity of applying for a Certificate of Need and/or a reinterpretation of the information by Dr. Kenley to assure that this is a continuous program and not a new service. Everything is available to continue the program with no major capital expenditures.

I am looking forward to your response.

Sincerely,

Gerald R. Brink
Executive Vice President

GRB:ga
Attachment

EAST VIRGINIA HEALTH SYSTEMS AGENCY, INC.

11 KOGER EXECUTIVE CENTER / SUITE 203

NORFOLK, VIRGINIA 23502

Area Code (804) 461-1236

ROBERT W. WENTZ, JR.
PresidentPAUL M. BOYNTON
Executive Director

May 8, 1978

(W)

Mr. Gerald Brink
Executive Vice President
Riverside Hospital
J. Clyde Morris Boulevard
Newport News, Virginia 23601

Dear Mr. Brink:

Thank you for your letter of April 17, 1978 and the information regarding Riverside Hospital's Cardiac Surgery Program.

In reviewing your question, it would be helpful if you could provide us with some additional information including:

1. The estimated amount of initial capital expenditure to continue the program.
2. A projected operating budget for the next two years.
(Show each year separately.)
3. A definition of the primary service area by city and county.
4. Will the surgery team be performing open heart procedures at any other institution in addition to Riverside?
5. Please indicate, by utilizing the following format, the types of procedures performed at Riverside for calendar years 1976, 1977, and 1978 to date. Indicate the same for those referred. Indicate yes or no if procedure requires availability of open-heart pump:

Performed at Riverside

		Calendar	Calendar	
	Pump	Year	Year	To Date
<u>Type Procedure</u>	<u>Assist</u>	<u>1976</u>	<u>1977</u>	<u>1978</u>

Referrals

		Calendar	Calendar	
	Pump	Year	Year	To Date
<u>Type Procedure</u>	<u>Assist</u>	<u>1976</u>	<u>1977</u>	<u>1978</u>

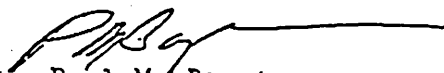
May 8, 1978

6. What percent (estimate) of those referred during the past two years went to the following institutions?

- (a) MCV _____
- (b) UVA _____
- (c) Norfolk General _____
- (d) Other _____

Your assistance in providing us with this additional information is very much appreciated.

Sincerely,


Paul M. Boynton
Executive Director

VMW



RIVERSIDE HOSPITAL

May 26, 1978

(X)

Mr. Paul Boynton, Executive Director
Eastern Virginia Health Systems Agency, Inc.
11 Koger Executive Center, Suite 203
Norfolk, Virginia 23502

Dear Mr. Boynton:

Per your letter of May 8, 1978 concerning our Cardiac Surgery Program, we submit the following additional information:

1. The estimated amount of initial capital expenditure to continue the program.

No new equipment will be needed.

2. A projected operating budget for the next two years.

	1979 (80-100 Cases)	1980 (130-150 Cases)
2 RN's in Operating Room	20,424	20,376
1 RN in Recovery Room	10,212	10,338
4.5 RN's in CCU	45,954	46,521
1 Pump Technician	18,000	18,000
1 Pump Assistant	-	14,000
Supplies	29,200	54,750
Total Operating Budget	\$123,790	\$166,023

3. A definition of the primary service area by city and county.

Planning Districts 17, 18 and 21 plus the Isle of Wight and Smithfield areas.

4. Will the surgery team be performing open heart procedures at any other institution in addition to Riverside?

The surgery team will work exclusively at Riverside.

5. Please indicate, by utilizing the following format, the types of procedures performed at Riverside for calendar years 1976, 1977, and 1978 to date. Indicate the same for those referred. Indicate yes or no if procedure requires availability of open-heart pump:

PERFORMED AT RIVERSIDE

<u>Procedure</u>	<u>Pump Assist</u>	<u>Pump Standby</u>	<u>Calendar Year 1976</u>	<u>Calendar Year 1977</u>	<u>To-Date 1978</u>
Insertion of Pacemaker	-	28 21 6	28	21	6
Pulse Generator Change	-	-	30	37	15
Pericardectomy	-	6	0	6	-
Coronary Vein Bypass Graft	13	-	13	-	-
Mitral Valve Commissurotomy	2	-	2	-	-
Repair of Atrial Septal Defects	1	-	1	-	-
Insertion of Vena Cava Umbrella	-	1	-	-	1
TOTAL			74	64	22

REFERRALS

<u>Procedure</u>	<u>Pump Assist or Standby</u>	<u>Calendar Year 1976</u>	<u>Calendar Year 1977</u>	<u>To-Date 1978</u>
Coronary Artery Bypass	Yes	35	40	15 (46)
Mitral Valve Replacement	Yes	2	4	1 (6)

REFERRALS (CONTINUED)

<u>Procedure</u>	<u>Pump Assist of Standby</u>	<u>Calendar Year 1976</u>	<u>Calendar Year 1977</u>	<u>To-Date 1978</u>
Ao Valve Replacement	Yes	3	3	2 (8)
Ao and MV Replacement	Yes	0	1	1
MV and Tricuspid Replacement	Yes	0	0	1 (1)
Ao and Cabs	Yes	0	4	2 (4)
MV and Cabs	Yes	0	1	1
Atrial Septal Defects	Yes	2	3	0
Mitral Commissurotomy	Yes	2	1	0 (1)
Patent Ductus Arterious	Yes	0	1	0
Coarctation of Ao	Yes	0	1	0
Transplant	Yes	0	1	0
Dissecting Thoracic Hemato	Yes	0	2	0

6. What percent of those referred during the past two years went to the following institutions?

- a) MCV.....80%
- b) UVA.....5%
- c) Norfolk General.....15%
- d) Other.....0%

Another factor to consider is the importance of having an efficient pump team available to the community and our Trauma Center. Discussions on categorization of Emergency Rooms have indicated that an area of our size should have pumping capabilities available. To have an efficient pump team, constant practice is necessary. This Open Heart Program would provide the community with the necessary expertise.

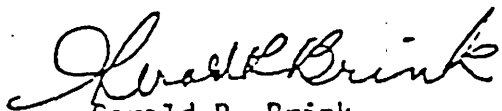
Mr. Paul Boynton

-4-

May 26, 1978

If you have any further questions concerning the program, please feel free to call me.

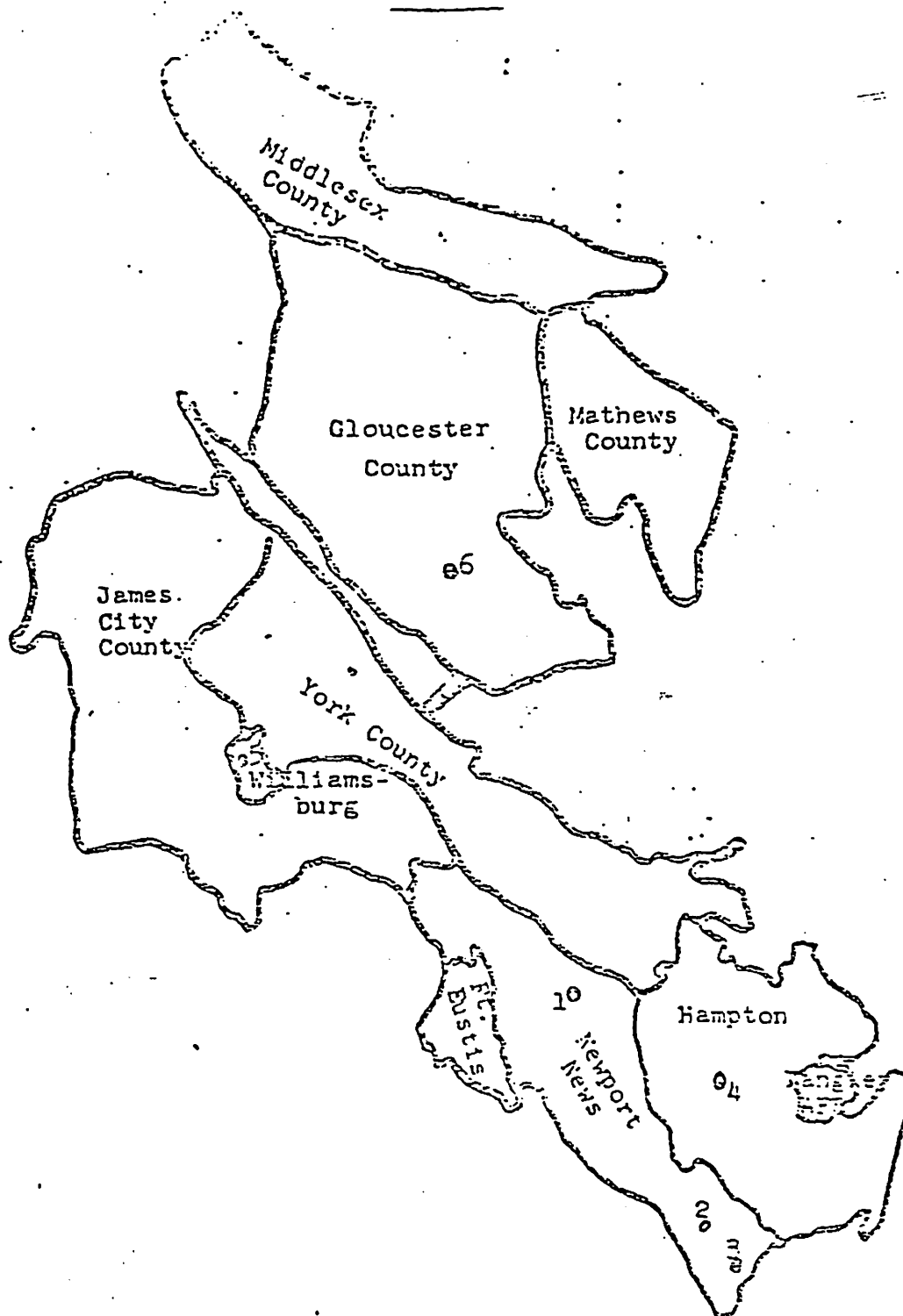
Sincerely,

A handwritten signature in cursive script, reading "Gerald R. Brink".

Gerald R. Brink
Executive Vice President

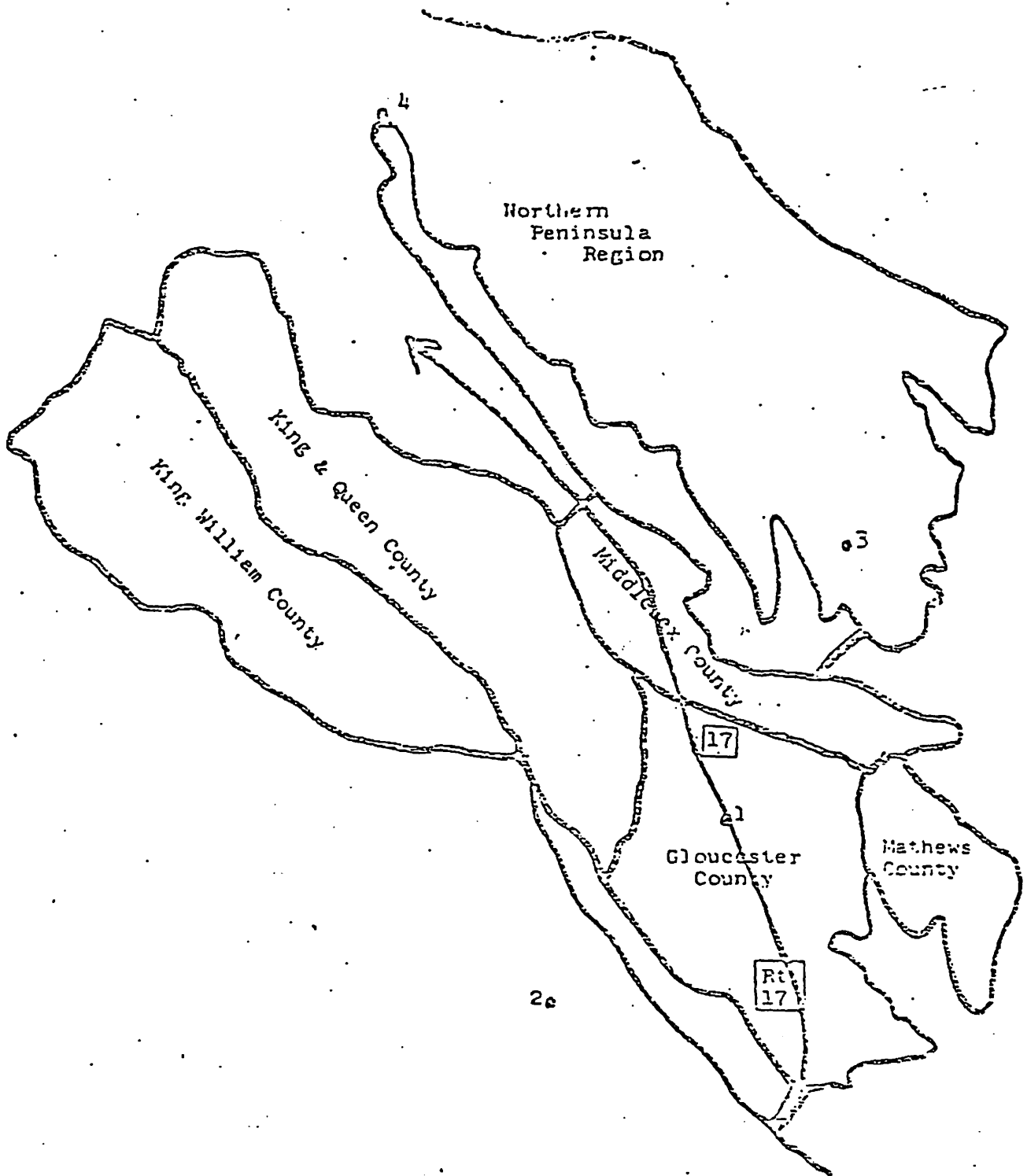
GRB:ga

1. RIVERSIDE HOSPITAL
 10. SERVICE AREA AND OTHER (VA HOSPITALS)



<u>Hospital</u>	<u>Beds</u>
1. Riverside Hospital	641
2. Whittaker Hospital	126
3. Mary Immaculate Hospital	116
4. Hampton General Hospital	369
5. Williamsburg Community Hospital	96
6. Walter Reed Memorial Hospital (proposed site)	71

Source: American Hospital Association, Guide to the Health Care Field, 1974 edition.



<u>Hospital</u>	<u>Beds</u>
1. Proposed Walter Reed Memorial Hospital site	71
2. Williamsburg Community Hospital	96
3. Proposed Hospital (Kilmarnock)	90-100
4. Tidewater Memorial (Tappahannock)	88

Source: American Hospital Association, Guide to the Health Care Field, 1974; State of Virginia Department of Health.

EASTERN VIRGINIA HEALTH SYSTEMS AGENCY, INC.

11 KOGER EXECUTIVE CENTER / SUITE 2C

NORFOLK, VIRGINIA 23502

Area Code (804) 461-1236

ROBERT W. WENTZ, JR.
President

PAUL M. BOYNTON
Executive Director

July 25, 1978

(Y)

Mr. Gerald R. Brink
Executive Vice President
Riverside Hospital
J. Clyde Morris Boulevard
Newport News, Virginia 23601

Dear Mr. Brink:

Thank you for the utilization information regarding Riverside Hospital's Cardiac Surgery Program.

After reviewing the information and consulting with medical advisors, it appears that the procedures which were performed during 1977 and 1978 to date, are not "open heart" procedures. Our analysis of the information you provided suggests that our earlier opinion was basically correct-- that a Certificate of Public Need would be required prior to reinstituting open heart procedures at Riverside. This opinion is based on the fact that those procedures performed do not use a heart-lung-bypass machine. This appears to be the accepted definition of open heart surgery as stated in the National Health Planning Guidelines (3-28-78). While in some cases it may be desirable to have the machine on hand, it does not appear to be medically necessary for those procedures performed at Riverside during 1977-78.

I regret the delay in responding to the information. Please keep us informed as to your plans.

Sincerely,



Paul M. Boynton
Executive Director

VMW

cc: Mr. Raymond O. Perry



COMMONWEALTH of VIRGINIA

Department of Health
Richmond, Va. 23219

MES B. KENLEY, M.D.
COMMISSIONER

November 21, 1978

Mr. Gerald R. Brink
Administrator
Riverside Hospital
500 J. Clyde Morris Boulevard
Newport News, Virginia 23601

Dear Mr. Brink:

This is in response to your letter of October 16, 1978, regarding Riverside Hospital's request to establish an open heart surgery program. I have reviewed the information provided and note the following:

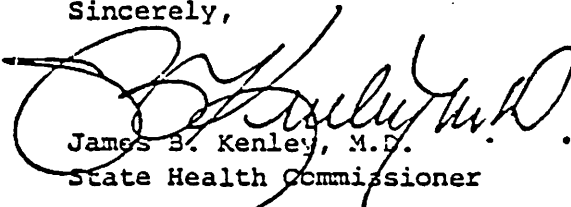
- During calendar year 1977 and year to date 1978, Riverside Hospital had a limited cardiac surgery program. This program performed pace-maker insertions, pulse generator changes, insertion of a vena cava umbrella and pericardiectomies.
- During this same time period, Riverside Hospital did not perform open heart surgical procedures.

The rules and regulations of the Virginia Certificate of Public Need program require that a Certificate of Need be obtained by the owner of a medical care facility prior to adding a new service which involves a capital expenditure in any amount. The rules further define a new service as "A distinct, identifiable modality, whether diagnostic, therapeutic. . . which has never been offered or has not been offered in the previous twelve (12) months by the medical care facility."

From this definition and the data provided, I conclude that:

- Riverside Hospital can continue to operate a cardiac surgery program for non-open heart procedures.
- Riverside Hospital must obtain a Certificate of Need prior to performing open heart surgery procedures.

Sincerely,



James B. Kenley, M.D.
State Health Commissioner

cc: Eastern Virginia Health Systems Agency

September 26, 1979

Dr. James B. Kenley, Commissioner
State Health Department
109 Governor Street
Richmond, Virginia 23219

Re: Open Heart Surgical Services ✓
Riverside Hospital
Newport News, Virginia

Dear Dr. Kenley:

Riverside Hospital is offering to the public the services of open heart surgery. In this connection, several cases have been scheduled during the next few weeks. The offering of these services will not involve any capital expenditures because all equipment and other facilities are available.

Riverside Hospital has been prepared to offer this service to patients for the past year. However, upon your direction, we did not perform this service and applied for a Certificate of Need.

It is our interpretation of the existing Statutes and Regulations that a Certificate of Need is not required because:

1. We do not consider the program as "new", as defined in Section 2.20.
2. The service does not require any capital expenditure.

Even though we are presently offering this program and believe that it does not need a Certificate of Need we would still like to receive Certificate of Need approval.

Sincerely,

Nelson L. St. Clair, Jr.
President

NLStCjr:ga



RIVERSIDE HOSPITAL

October 16, 1978

Dr. James Kenley
Health Commissioner
State Department of Health
109 Governor Street
Richmond, Virginia

RECEIVED	
STATE DEPT. OF HEALTH	
Office of the Commissioner	
OCT 20 1978	
Referred to	Perry
For	

Dear Dr. Kenley:

I would like to thank you and Ray Perry for the time you gave us on Wednesday, September 13, 1978, to explain our Cardiac Surgery dilemma. As a result of this meeting and our conversation, I would like to request that you reconsider your decision in your letter to Paul Boynton dated December 27, 1977, due to the discovery of new information which was not provided at the time for your review, and that you also consider our Cardiac Surgery Program as an ongoing program with a potential of performing up to the required standards.

Our letter of November 7, 1977 to Paul Boynton did not include a statistical breakdown of cardiac surgical cases when it stated, "From September 3, 1976 to present the Open Heart Surgery Program has not functioned due to the lack of anesthesia coverage." This statement did not consider the fact that six pericardiectomies were performed for chronic and sub-acute pericarditis in which the pump was primed and available to the operative field for immediate use. Other surgical procedures such as cardiac trauma and pacemaker implantation were also performed. A cardiac anesthesiologist was available, although he could not perform on a routine basis without proper back-up or relief. Please see attached statistics.

Our Cardiac Surgery Program, although at a reduced rate of surgery, has been ongoing during the troublesome developmental period. We maintain that we were in compliance with the guidelines existing at the time of the initial decision, November, 1977. We have delayed the provision of increased cardiac surgical services which has been ready for implementation since November 1977, while awaiting clarification of our service as a continuing program. Had this delay not occurred, we could have, in fact, performed over 100 cardiac surgical procedures within the last year, which would have placed us in full compliance with the Federal guidelines as published March 23, 1978. (Federal Register).

We have a cardiac surgeon, anesthesiology coverage, all necessary capital equipment and technical assistance available to continue the program. In

Dr. James Kenley

-2-

October 16, 1978

view of these facts and the continuing support and desire expressed by our medical staff for this service at Riverside Hospital, I again would like to request that you reconsider your decision as outlined in your letter to Paul Boynton on December 27, 1977. To clarify any questions concerning the program, I have a summary of statistics, an historical outline of the development of our program, a summary of our presentation on September 13, 1978 and copies of all correspondence. If you have any questions concerning this request or information provided, please call upon me. Thanking you in advance for your time and consideration.

Sincerely,

A handwritten signature in cursive script, reading "Gerald R. Brink". The signature is written in dark ink and is positioned above the printed name and title.

Gerald R. Brink
Executive Vice President

GRB:dsa

HISTORICAL DATA

- September 1971 - Director of Cardiology arrives at Riverside Hospital. The objective was to establish a cardiac catheterization laboratory and a cardiac surgical program.
- February 23, 1972 - Cardiac Surgery Program approved by the Board of Trustees. The program was put together with the support of a Cardiologist, three Thoracic Surgeons on the medical staff at Riverside Hospital and Dr. Lewis H. Bosher, Jr. from the Medical College of Virginia. The intent was that Dr. Bosher would assist with the design and establishment of the program, perform the open-heart surgical cases at Riverside Hospital with the assistance of the thoracic surgeons until such a time that the thoracic surgeons were re-oriented to the program.
- February 2, 1973 - The first cardiac surgery case was performed at Riverside and the cases progressed satisfactorily during the year. Throughout the years of 1974, 1975 and 1976, anesthesia was not available from Riverside Hospital, and we had to use part-time personnel from MCV for anesthesia coverage. The cardiac surgical cases which were deemed lower risk were performed at Riverside Hospital, while the higher risk cardiac surgical patients were transferred to the Medical College of Virginia. The purpose of this was to minimize the risk and maximize quality of care.
- The operating room suite expanded from eight to 12 operating rooms. A cardiac surgery room was now available for full-time scheduling.
- September 3, 1976 - Anesthesia coverage from MCV became non-existent, and it was decided that high-risk cardiac surgical procedures should be referred, while the shorter, less risky procedures could continue to be done at Riverside until an anesthesiologist trained in cardiac surgery could be recruited. During this period of somewhat limited activity, cardiac surgical procedures were performed such as pericardiectomy and pacemaker implantation, which required that the heart-lung bypass pump be primed and available to the operative field.
- September 1976 - During this period the number of cardiac catheterization cases performed at Riverside increased markedly to approximately 400 cases a year, precipitating about 100 referral cases to other facilities for cardiac surgery. This increase has also resulted in an approved construction project to provide a new cardiac catheterization laboratory adding to the cardiac surgery potential at Riverside.
- October 1977 - Two anesthesiologists with interest and expertise in cardiac anesthesia became available to the Riverside staff. In addition, an additional cardiac surgeon was recruited to assume responsibilities as Director of Cardiac Surgical Services and provide these services on a full-time basis.

HISTORICAL DATA

-2-

November 3, 1977 -

The Eastern Virginia Health Systems Agency inquired into the activity of the cardiac surgical program at Riverside. At this point in time, accurate statistics were not provided, which resulted in the December 1977 decision from Dr. Kenley, Health Commissioner; however, we considered our program to be an active cardiac surgical program, even though on a limited basis, through the performance of pericardiectomies and pacemaker insertions. This was based on the report of the Intersociety Commission for Heart Disease Resources, Optimal Resources for Cardiac Surgery, Guidelines of Program Planning and Evaluation, published in CIRCULATION, 52:8-23, November, 1975, which was the only document available defining the scope of cardiac surgery.

December 1977 -

A letter to Paul Boynton from Dr. Kenley indicated that a new institutional service was being initiated at Riverside Hospital, therefore requiring a Certificate of Public Need for Cardiac Surgery, the rationale being that we had not performed the service during the previous 12 months. Continued correspondence with the Eastern Virginia Health Systems Agency has resulted in no change of position, even though additional data has demonstrated that the cardiac surgical program was active during the period in question.

SUMMARY

1. Riverside Hospital has provided cardiac surgical services on a continuing basis since February 3, 1976. This was provided on a limited basis during the period of September 1976 though October 1978.
2. The capability for provision of full cardiac surgical services commensurate with the surgical cases generated by cardiac catheterization laboratory (100 surgical cases per year) has existed since October 1977. The potential for continued growth is certain.
3. Delay in the provision of increased services by this program since November 1977 has resulted from an interpretation of the guidelines based on incomplete data provided by Riverside Hospital.
4. Further capital expenditures would not be necessary for continuation of our program on a full scale. The cost per cardiac surgical case at Riverside Hospital would in all probability be the lowest in the state.
5. The General Medical Staff of Riverside Hospital has repeatedly expressed support for this program.
6. Nearly every patient referred to other centers following catheterization at Riverside Hospital has requested that their surgery be performed at Riverside Hospital if possible. This would not only decrease the cost to these patients' families, but would facilitate optimal follow-up care.
7. The current system of referral has resulted in unsatisfactory delay of surgery and less than optimal post-surgical care.
8. The provision of this service at Riverside Hospital will not significantly affect the operation of similar programs in our geographic area.
9. Riverside Hospital has the potential to meet all state and Federal standards for Open Heart Surgery.

SUMMARY
OF THE
RIVERSIDE HOSPITAL CARDIAC SURGERY PROGRAM

PRESENTED TO

DR. JAMES B. KENLEY, COMMISSIONER OF HEALTH

SEPTEMBER 13, 1978

BY

DR. J. A. HORGAN

SEPTEMBER 1971 THROUGH SEPTEMBER 3, 1976

In September of 1971 I became the Director of the Division of Cardiology at Riverside Hospital. The objectives of the Division of Cardiology were to establish a cardiac catheterization laboratory and a cardiac surgical program. The cardiac catheterization laboratory was established without difficulty, and has experienced a yearly increase in caseload. Dr. W. H. Graham was the cardiothoracic surgeon at Riverside Hospital. The cardiac surgical program was instituted under his direction. It was felt that in order to maximize the quality of care, consultation on each case would be obtained from Dr. Lewis H. Boshier, Professor of Cardiac Surgery at the Medical College of Virginia. Dr. Boshier agreed to be present at Riverside Hospital for each cardiac surgical case. Dr. Boshier would either personally perform the surgery, or act as a consultant to Dr. Graham. Dr. Boshier also agreed to provide anesthesia coverage from the staff at the Medical College of Virginia. The first cardiac surgical case was performed at Riverside Hospital on February 2, 1973. The cardiac surgical cases which were deemed lower risk were performed at Riverside Hospital, while the higher risk cardiac surgical patients were transferred to the Medical College of Virginia. Again, the purpose of this was to minimize the risk and maximize quality of care. The

2.

primary problems at this period in time involved anesthesia coverage and operating room availability. The Department of Anesthesia at Riverside Hospital felt that they were not qualified to administer anesthesia for cardiac surgical cases. Anesthesia coverage was provided by Dr. Bosher's staff. Initially, eight operating rooms were available at Riverside Hospital. Cardiac surgery increased the demand for the operating rooms. The Department of Anesthesia at Riverside Hospital indicated that they would attempt to solve the anesthesia problem. They initiated a search for anesthesiologists who were willing to provide anesthesia for cardiac surgery. This proved to be a difficult problem. Simultaneously, a construction program at Riverside Hospital was undertaken, and the operating room suite was expanded from eight operating rooms to 12 operating rooms. Thus, at the present time, there is no problem with availability of operating rooms, and one room has been designated as the cardiac surgical room. Also, the number of cardiac catheterization cases increased markedly during this period. The present cardiac catheterization volume is approximately 400 cases per year. There are now three hospital-based Cardiologists doing primarily cardiac catheterizations at Riverside Hospital. Due to the volume of cardiac catheterizations, a construction program was also undertaken to construct a new cardiac catheterization laboratory. It is estimated that this laboratory will be completed in January, 1979. A successful cardiac surgical program will be necessary for maximum utilization of this facility. All other hospital personnel and equipment necessary for the performance of cardiac surgery at Riverside Hospital are available. In spite of strong effort, the Department of Anesthesiology was unable to find an anesthesiologist who wanted to administer cardiac surgical anesthesia. In August, 1976, Riverside Hospital was notified by the Medical College of Virginia that the Medical College of Virginia would no longer be able to provide anesthesia coverage.

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At this point in time, it was felt that the more lengthy cardiac surgical procedures would have to be referred to the Medical College of Virginia, while the shorter, less risky procedures would continue to be performed at Riverside Hospital. These procedures included pacemaker implantation and pericardiectomies. The last lengthy cardiac surgical case was performed at Riverside Hospital on September 3, 1976.

AUGUST 3, 1976 THROUGH OCTOBER, 1977

During this period of time, the cardiac surgical program at Riverside Hospital was active, but had a limited caseload. The cases performed included pacemaker implantations, pericardiectomies and cardiac trauma. Six pericardiectomies were performed during this period for chronic and sub-acute constrictive pericarditis. During these cases the pump technician primed the cardiac bypass pump and the pump was prepared for immediate use with each case. During this period, great progress was made with regard to cardiac surgery. The Department of Anesthesia was successful in recruiting two anesthesiologists who were experienced and agreeable in performing cardiac surgical anesthesia. It was also felt that a cardiac surgeon should be recruited and given primary responsibility for the performance of the cardiac surgical cases. This was accomplished, and Dr. Dan Calhoun assumed the position of the Director of Cardiac Surgical Services. Subsequently, in October 1977, we were prepared at Riverside Hospital to continue our cardiac surgical program. Due to the growth in the cardiac catheterization studies to approximately 400 per year, 100 cardiac surgical cases were generated. It was felt that this would be an adequate caseload for the cardiac surgical program. It was also felt that there would be a rapid increase in the number of cardiac surgical cases performed to approximately 200 yearly within three years.

NOVEMBER 1977 THROUGH JANUARY 1978

In October 1977, the cardiac surgical program at Riverside Hospital was prepared to increase its volume of cardiac surgical cases, in that the anesthesia problem had been solved, and a cardiac surgeon with the primary responsibility of performing the cardiac surgical cases was present on a full-time basis at Riverside Hospital. The appropriate equipment and paramedical personnel were also available. On November 3, 1977, Riverside Hospital received its first inquiry regarding the cardiac surgical program from the Eastern Virginia Health Systems Agency, Inc. From September 1976, through October, 1977, 12 months, our cardiac surgical program was less active for the reasons previously enumerated. The report of the Intersociety Commission for Heart Disease Resources, Optimal Resources for Cardiac Surgery, Guidelines for Program Planning and Evaluation, published in CIRCULATION, 52:823, November, 1975, which was the only document available defining the scope of cardiac surgery, indicated that treatment of heart block and constrictive pericarditis constituted cardiac surgery. In view of these guidelines, we felt that from September 1976 to October 1977 the program was active, but with a reduced caseload. For these reasons, we continued in our efforts to attempt to solve the anesthesia problem. As soon as this was solved, then a cardiac surgeon was recruited. At that point in time, on November 3, the cardiac surgical program at Riverside Hospital was prepared to proceed with the full volume of cardiac surgical cases. Due to the inquiry by the Eastern Virginia Health Systems Agency, we awaited an opinion from your office. Unfortunately, in our first response to the Eastern Virginia HSA, we failed to include the pericardiectomies and only discussed treatment of heart block as cardiac surgery at Riverside Hospital. This was a misstatement. With this data, the HSA indicated that we would need a Certificate of Public Need, indicating that we had not offered cardiac surgical procedures within the preceeding 12 months,

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(Federal Register, January, 1977). They further stated that according to 1976 data, Norfolk General Hospital performed less than 200 cardiac surgical procedures. In truth, at the present time, 1977-78, Norfolk General Hospital performed 351 cardiac surgical procedures yearly. This data with regard to treatment of heart block without pericardiectomies was forwarded to your office. Your office felt that a Certificate of Need would be necessary in that cardiac surgery was not active for 12 months, from September 1976 to October 1977. We feel that we were in accordance with the guidelines stated in the report of the Intersociety Commission for Heart Disease Resources and the program was not inactive, but active on a limited basis.

FEBRUARY 1978 THROUGH JULY 1978

In April 1978 we requested the Eastern Virginia Health Systems Agency to again review the cardiac surgical program at Riverside Hospital. At this point in time, we corrected the original data, including the cases of pericardiectomies. This information was studied by the Eastern Virginia HSA, and they indicated on July 25, 1978 that they still felt that a Certificate of Need was necessary. At this point in time, they quoted the Federal Register published on March 28, 1978, which placed quotas and a strict definition of cardiac surgery. This definition indicated that cardiac surgery were those procedures requiring the use of a pump. It also indicated that at least 200 cases per year would have to be performed, and if a new program was instituted, the caseload by three years would have to equal 200. It also indicated that in each HSA area a new program would not be instituted unless programs already established would be doing at least 350 cases yearly. On the basis of this article in the Federal Register, the HSA felt that we again needed a Certificate of Need. I do not understand how they can make an article published in March 1978 retroactive to November, 1977. Even if we do apply the

6.

Federal Register Guidelines published in March 1978, Riverside Hospital will comply with these. During the period in question, September 1976 through October 1977, cardiac surgical procedures, pericardiectomies, were performed with the use of the pump. Also, Norfolk General Hospital during this time performed 351 cardiac surgical procedures as indicated by the Eastern Virginia Health Systems Agency. I feel that if it had not been for the HSA inquiry in November 1977 that the cardiac surgical program at Riverside Hospital would be operating with an adequate caseload. I feel that we will have no difficulty in performing at least 200 procedures by our third year of complete operation. I thus feel that we were, without question, a program which has continued to offer cardiac surgical procedures, but on a limited basis.

SUMMARY
OF THE
RIVERSIDE HOSPITAL CARDIAC SURGERY PROGRAM
PRESENTED TO
DR. JAMES B. KENLEY, COMMISSIONER OF HEALTH
SEPTEMBER 13, 1978
BY
DR. HUGH McCORMICK

CURRENT AVAILABILITY AND UTILIZATION

One has to consider the effects of a cardiac surgical program at Riverside Hospital on the two major referral areas. Norfolk General Hospital last year performed 351 cardiac surgical cases. They draw from a population base of 1.25 million people, which includes Norfolk, the Eastern Shore, Virginia Beach and portions of North Carolina. We refer very few surgical cases to Norfolk General Hospital. We also draw from a population base which is distinctly different from theirs, namely the middle Peninsula, including Gloucester, Mathews, York County, Williamsburg, Newport News and Hampton. There is also a small portion of patients from Isle of Wight County and Smithfield. This represents a population base of close to one-half million people, which is distinctly different from the Norfolk area; hence, we do not see that this will in any way influence the cardiac surgical program currently available in Norfolk. From the Peninsula area, we currently refer approximately 100 cardiac surgical cases per year. We anticipate that with the new surgical program, we will easily be able to realize a 200 caseload within a three year period.

The Medical College of Virginia performed 528 cardiac surgical cases last year. The majority of our cases were referred to the Medical College of Virginia to Dr. Lewis Bosher. There were several problems relating to this referral, which

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we understand were due to the following reasons:

1. There was sometimes a long delay of anywhere from two to four weeks before patients could be placed on the surgical schedule. We are told this was due to the non-availability of beds. There were no Intensive Care Unit beds available, nor any hospital beds. They also had considerable difficulty in arranging operating room time.
2. This also necessitated an early return to Riverside Hospital for patients who needed further hospital care. While the Medical College of Virginia maintains that it could provide services for 1200 cases per year, we seriously doubt this, and would anticipate even longer delays and diminishment in patient care. What impact our own surgical program would have on the program in Richmond is uncertain. Dr. Bosher performs the majority of our cardiac surgical cases. He is retiring from the Medical College within the next year. It is expected that some of these cases might well go elsewhere with his retirement.

With regard to the surrounding hospitals, we feel we could provide a better all-around service to these hospitals. We currently have a good working relationship with Hampton General Hospital, Williamsburg Community Hospital and Walter Reed Hospital. It is anticipated we would continue to service these areas. It is also anticipated with the new Mary Immaculate Hospital that an even larger relationship will develop with the Peninsula area. Currently, patients from these hospitals

3.

are referred to Riverside for diagnostic studies, and return to their primary hospital for further diagnostic studies and convalescence.

The population of the Peninsula strongly supports a complete cardiac surgical program. Many patients and their families object strongly to having to travel the distances during those critical periods of time when their loved ones are ill, and on critical lists. The medical community has also indicated its strong support. The medical staff has gone on record as actively supporting the continued cardiac program at Riverside Hospital.

A new cardiac surgeon, Dr. Daniel Calhoun, recently joined the staff at Riverside Hospital. He is well trained in all aspects of current cardiac surgery and comes highly recommended. He is not only well qualified, but very anxious to help develop and further support this program. Dr. Lewis Boshier of the Medical College of Virginia has indicated a strong desire to come to Newport News for a period of time after he leaves the Medical College of Virginia to further aid the development of a strong surgical program at Riverside Hospital. He has a long established reputation in Virginia, and has perhaps done more cardiac surgical cases in the state than any other current physician. The presence of these two gentlemen would insure the continued quality of care and excellence with regard to cardiac surgery.

We feel Riverside Hospital can perform this cardiac surgery at a lower cost than the other hospitals currently performing cardiac surgery, or seeking to develop such a program. We have on hand all the necessary equipment to continue to perform cardiac surgery at this hospital. Our per diem cost at Riverside Hospital is considerably lower than that of Norfolk General Hospital. Currently, the corrected per diem rate at Norfolk General Hospital is \$192.00 per day. At Riverside Hospital, it is \$133.00 per day. This can result in substantial savings to patients hospitalized for such procedures. Recently, the Eastern Virginia

4.

Health Systems Agency¹ published a report on cardiac catheterization services in Eastern Virginia, and showed that the fee for cardiac catheterization at Norfolk General Hospital was \$670.00 per patient. The cost at Riverside Hospital for the same patient was \$325.00. It is felt that with examples such as these and a long record of demonstrated careful administrative planning, we can extend this type of difference to all aspects of patient care. Recently, a study published in the New England Journal of Medicine² by Dr. Maurice MacGregor and his associates showed that the cost of open-heart cardiac surgical procedures is substantially reduced per patient when the number exceeds 100 cases per year. We feel that we already have that number available to begin a cardiac surgical program and that, along with our equipment, will not result in a major increase in initial cost.

¹ Cardiac Catheterization Services in Eastern Virginia, Eastern Virginia Health Systems Agency, Inc., August 7, 1978.

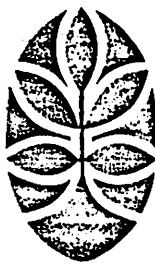
² MacGregor, M., et al, Planning of Specialized Facilities, Size vs. Cost Effectiveness in Heart Surgery, NEJM 299:179, 1978.

CARDIAC SURGICAL PROCEDURES - RIVERSIDE HOSPITAL

CALENDAR YEARS 1976, 1977, 1978

REFERRALS

<u>Procedure</u>	<u>Pump Assist or Standby</u>	<u>Calendar Year 1976</u>	<u>Calendar Year 1977</u>	<u>To-Date 1978</u>
Coronary Artery Bypass	yes	35	40	42
Mitral Valve Replacement	yes	2	4	2
Ao Valve Replacement	yes	3	3	8
Ao and MV Replacement	yes	0	1	1
MV and Tricuspid Replacement	yes	0	0	1
Ao and CABS	yes	0	4	4
MV and CABS	yes	0	1	1
Atrial Septal Defects	yes	2	3	0
Mitral Commissurotomy	yes	2	1	1
Patent Ductus Arteriosus	yes	0	1	0
Coarctation of Ao	yes	0	1	0
Transplant	yes	0	1	0
Dissecting Thoracic Hematoma	yes	0	2	0
TOTAL		44	62	60



RIVERSIDE HOSPITAL

RECEIVED	
DEPARTMENT OF HEALTH	
Office of Commissioner	
DEC 8 1978	
Approved	Perry
Refused	
File	

December 4, 1978

James B. Kenley, M.D.
State Health Commissioner
Virginia Department of Health
109 Governor Street
Richmond, Virginia 23219

Dear Dr. Kenley:

This is in response to your letter of November 21, 1978 regarding the Open Heart Surgery Program at Riverside Hospital. On the basis of your decision to require Riverside to obtain a Certificate of Public Need prior to continuing to perform open heart surgery, we hereby request the necessary materials to make application for Certificate of Need.

Thank you for your assistance.

Sincerely,

Gerald R. Brink
Executive Vice President

GRB:ga

COMMONWEALTH OF VIRGINIA
DEPARTMENT OF HEALTH
MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED

THIS CERTIFIES THAT NEWPORT NEWS GENERAL AND NON-SECTARIAN HOSPITAL ASSOCIATION, INC.

is authorized to initiate the proposal as described below _____

NAME OF FACILITY RIVERSIDE HOSPITAL

LOCATION J. CLYDE MORRIS BOULEVARD, NEWPORT NEWS, VIRGINIA

OWNERSHIP AND CONTROL NEWPORT NEWS GENERAL AND NON-SECTARIAN HOSPITAL ASSOCIATION, INC. - A VIRGINIA NON-PROFIT
CORPORATION

SCOPE OF PROJECT EXPAND, ADD AND CONSTRUCT X-RAY DEPARTMENT WITH WHOLE-BODY COMPUTERIZED AXIAL TOMOGRAPHY SCANNER,

CARDIOLOGY HEART STATION, EMERGENCY ROOM, NEW EKG AND RENAL DIALYSIS AREA, NEW GI LAB AND EMPLOYEE HEALTH SERVICE AREA.

TOTAL ESTIMATED COST OF PROJECT: \$3,545,600.



Pursuant to Title 32, Chapter 12.1, Sections 32.211.3 through 32.211.16, Code of Virginia (1950) as amended, and the policies and procedures promulgated thereunder, this Medical Care Facilities Certificate of Public Need is issued contingent upon substantial and continuing progress towards implementation of the proposal within (6) six months from the date of issuance. A progress report shall be submitted to the State Health Commissioner within six months from the date of issuance along with adequate assurance of completion within a reasonable time period. The Commissioner reserves the right not to renew this Certificate in the event the applicant fails to fulfill these conditions. This Certificate is non-transferable and is limited to the location, ownership, control and scope of project shown herein.

CERTIFICATE NUMBER VA-0198

SEPTEMBER 16, 1975

Date of Issuance

MARCH 16, 1979

Expiration Date


State Health Commissioner

COMMONWEALTH of VIRGINIA

Department of Health
Bldg. 1000, Richmond, VA 23219

April 5, 1977

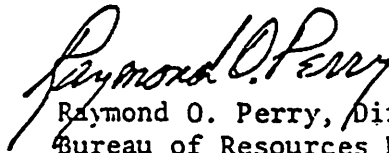
RE: Certificate of Need No. VA-0198
Riverside Hospital
Newport News, Virginia
Expansion & Addition of Services in
Radiology & EKG Departments

Mr. Gerald R. Brink, Administrator
Riverside Hospital
J. Clyde Morris Boulevard
Newport News, Virginia 23601

Dear Mr. Brink:

Enclosed is one copy of the progress report you have submitted regarding the above referenced project. This document represents official notification: that substantial and continuing progress toward completion of the above referenced project has been satisfactorily demonstrated; and that the original Certificate of Need issued for the project has been extended until September 16, 1977, at which time another progress report will be required.

Sincerely,



Raymond O. Perry, Director
Bureau of Resources Development

cc: Bureau of Medical and Nursing Facilities Services
Eastern Virginia Health Systems Agency

SA
**RULES AND
REGULATIONS
OF THE
BOARD OF HEALTH
COMMONWEALTH OF VIRGINIA**



**Virginia Medical Care Facilities
Certificate of Public Need**

Division of Planning, Evaluation and Research
Department of Health
James Madison Building
1109 Governor Street
Richmond, Virginia 23219

**RULES AND
REGULATIONS
OF THE
BOARD OF HEALTH
COMMONWEALTH OF VIRGINIA**

**Virginia Medical Care Facilities
Certificate of Public Need**

Division of Planning, Evaluation and Research
Department of Health
James Madison Building
109 Governor Street
Richmond, Virginia 23219

**Commissioner of Health
James Madison Building
109 Governor Street
Richmond, Virginia 23219**

Adopted pursuant to Chapter 1.1, Title 9 and Sections 32-6 and 32-211.6, Code of Virginia (1950), as amended. Medical Care Facilities Certificate of Public Need implementing Rules and Regulations.

Promulgated and adopted by the State Board of Health on December 4, 1974. Effective on February 1, 1975.

Table of Contents

Virginia Certificate of Public Need Law	1
Certificate of Public Need Rules and Regulations	
Section I Definitions	7
Section II Mandatory Participation Requirements	10
Section III Determination of Public Need	10
Section IV Application	11
Section V Standard Review Process	14
Section VI Administrative Review Process	15
Section VII Duration/Extension/Revocation of Certificates	16
Section VIII Exemptions	17
Section IX Appeal of Decision	18
Section X Sanctions	19
Section XI Severability Clause	20

Virginia Medical Care Facilities Certificate of Public Need Law

Chapter 12.1, Title 32, Code of Virginia, (1950), as amended

§32-211.3. This chapter may be cited as the "Medical Care Facilities Certificate of Public Need Law."

§32-211.4. The General Assembly finds that the unnecessary construction or modification of medical care facilities increases the cost of care and threatens the financial ability of the public to obtain necessary health, surgical, and medical services. The purpose of this chapter is to promote comprehensive health planning in order to help meet the health needs of the public; to assist in promoting the highest quality of health care at the lowest possible cost; to avoid unnecessary duplication by insuring that only those medical care facilities which are needed will be constructed; and to provide an orderly administrative procedure for resolving questions concerning the necessity of construction or modification of medical care facilities. Therefore, in the exercise of the sovereign powers of the Commonwealth to safeguard and protect the public health and general welfare of its citizens, the General Assembly declares that it is the public policy of the Commonwealth of Virginia to encourage, foster, and promote the planned and coordinated development of necessary and adequate health, surgical, and medical care facilities and that such comprehensive health planning and development shall be accomplished in a manner which is coordinated, orderly, timely, economical, and without unnecessary duplication of services and facilities.

§32-211.5. As used in this chapter, unless the context indicates otherwise:

- (1) "Advisory Hospital Council" means the Advisory Hospital Council appointed by the Governor in accordance with the provisions of Chapter 12, Title 32, of the Code of Virginia.
- (2) "Approved Areawide Comprehensive Health Planning Council" means a voluntary nonprofit or public agency or organization that is established pursuant to §314 (b) of United States Public Law 89-749, as amended, and approved by the State Comprehensive Health Planning Council to function as a health planning agency.
- (3) "Board" means the State Board of Health.
- (4) "Commissioner" means the State Health Commissioner.
- (5) "Department" means the State Department of Health.
- (6) "Medical Care Facilities" means any institution, place, building, or agency, whether or not licensed or required to be licensed by the State Board of Health or the State Hospital Board, by or in which facilities are maintained, furnished, conducted, operated, or offered for the prevention,

diagnosis or treatment of human disease, pain, injury, deformity or physical condition, whether medical or surgical, of two or more nonrelated mentally or physically sick or injured persons, or for the care of two or more non-related persons requiring or receiving medical, surgical or nursing attention or services as acute, chronic, convalescent, aged, physically disabled, or crippled, including, but not limited to, general hospitals, sanatorium, sanitarium, nursing home, intermediate care facility, extended care facility, health maintenance organization, mental hospital, mental retardation facility and other related institutions and facilities, whether operated for profit or nonprofit, and whether privately owned or operated, or owned or operated by a local governmental unit. This term shall not include a physician's office or first aid station for emergency medical or emergency surgical treatment.

- (7) "Project" shall mean a capital expenditure, which under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance and which (1) exceeds one hundred thousand dollars (\$100,000) or (2) changes the bed capacity of the facility with respect to which such expenditure is made, or (3) substantially changes the services of the facility with respect to which such expenditure is made. For purposes of clause (1) of the preceding sentence, the cost of the studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, expansion, or replacement of the plant and equipment with respect to which such expenditure is made shall be included in determining whether such expenditure exceeds one hundred thousand dollars (\$100,000).
- (8) "State Comprehensive Health Planning Council" means the duly authorized Statewide public planning agency established pursuant to § 314 (a) of United States Public Law 89-749, as amended.

§ 32-211.6. (a) In carrying out the purpose of this chapter, the Commissioner is authorized and directed:

- (1) To require such reports and make such inspections and investigations as he deems necessary;
- (2) To promulgate and prescribe such rules and regulations as he deems necessary;
- (3) To provide a method of administration, appoint a director and take such other action as may be necessary to effectuate the purposes of this chapter; and
- (4) To consult with and seek the advice of the Advisory Hospital Council and the State Comprehensive Health Planning Council in carrying out the administration of this

chapter.

(b) In making his determination whether a public need exists for the proposed project, the Commissioner shall consider the following:

- (1) The recommendation of the State Comprehensive Health Planning Council;
- (2) The contribution of the proposed project to the orderly development and proper distribution of adequate and effective health services for the people residing in the area to be served;
- (3) The size, composition, and growth of the population of the area to be served by the proposed project;
- (4) The number of existing and planned facilities of types similar to the proposed project and the extent of utilization thereof;
- (5) The availability of facilities or services, existing or proposed, which may serve as alternatives or substitutes to the proposed project;
- (6) The compatibility of the proposed project with the comprehensive State plan including the State Hospital construction program, developed pursuant to Chapter 12 of Title 32, Code of Virginia;
- (7) The availability of medical, nursing, and support personnel to staff such proposed project.

§ 32-211.7. Prior to the commencement of any proposed project, an application shall be submitted to the Commissioner for a certificate that there exists a public need for such project. The application shall be in such form and contain such information as the Commissioner may require and may be accompanied by any additional information or material relevant to a determination that a public need exists for such project. Upon receipt of an application, the Commissioner shall refer copies thereof to the State Comprehensive Health Planning Council which shall, within forty-five (45) days of the date of referral of the completed application, make known its recommendations to the Commissioner. The State Comprehensive Health Planning Council may seek the advice or assistance of the area-wide comprehensive health planning council, which advice shall be advisory only and shall not be binding upon the State Comprehensive Health Planning Council or the Commissioner.

If the Commissioner, after consideration of the above information and other relevant factors, finds that a public need exists for the proposed project, he shall approve the application and issue a certificate of public need to the applicant. The Commissioner shall make the above determination within ninety (90) days of the date of receipt of a completed application.

§ 32-211.8. The Commissioner shall afford every applicant for a certificate of public need an opportunity for a fair hearing in accordance with the Virginia General Administrative Agencies Act. Further, the action of the Commissioner in denying a certificate of public need for a proposed project shall be subject to de novo review by the State Board of Health. The Board shall thereafter afford any applicant, upon request made within thirty (30) days of the denial, a full and fair hearing before the full Board, or a majority of not less than two-thirds thereof, which shall make its final determination within such time limits as shall be prescribed by duly adopted regulations of the Board.

§ 32-211.9. Any applicant aggrieved by a final determination of the Board may, within thirty (30) days after receipt of notice of the Board's determination, obtain a review by the Circuit Court of the City of Richmond or by any court of record having chancery jurisdiction in the county or city where the proposed project is under construction or is intended to be constructed, located, or undertaken. Within five (5) days after the receipt of notice of appeal, the Board shall transmit to the appropriate court all of the original papers pertaining to the matter to be reviewed, and the matter shall be thereupon reviewed by the court or judge in vacation as promptly as circumstances will reasonably permit. The court may enter such orders pending the completion of the proceedings as are deemed necessary or proper. The court review shall be upon the record so transmitted, and any additional evidence presented on behalf of the parties thereto, and the court may request and receive such additional evidence as it deems necessary in order to make a proper disposition of the appeal. Upon conclusion of review, the court may affirm, vacate, or modify the final determination of the Board. Upon a judicial finding that the public need referred to herein presently exists, the Commissioner shall so certify. Any party to the proceeding may appeal from the decision of the court to the Virginia Supreme Court, in the same manner as appeals are taken and as provided by law.

§ 32-211.11. A certificate of public need shall be valid for such period of time, not to exceed two years from date of issuance, as may reasonably be required to complete preparation of detailed construction plans, secure necessary funds and building permits, and other details necessary for the completion of the project; provided, however, the Board may, in its sole discretion, renew the certificate for such additional periods of time as may

be reasonably necessary for completion of the project where the applicant has adequately shown that substantial and continuing progress towards completion of the project has been made. A certificate of public need shall not be transferable.

§ 32-211.12. Any court of record having chancery jurisdiction in the county or city where a proposed project is under construction or is intended to be constructed, located, or undertaken, and the Circuit Court of the City of Richmond shall have jurisdiction to enjoin, on petition of the Commissioner, the Board, or the Attorney General, any project which is constructed, undertaken, or commenced without the required certificate of public need as referred to herein.

§ 32-211.13. Any person, partnership, firm, company, trust, association, corporation, or other legal entity, which commences, constructs, or undertakes construction of a medical care facility project without having obtained a certificate of public need shall be guilty of a misdemeanor and upon conviction, shall be punished by a fine of not less than fifty dollars (\$50) nor more than one thousand dollars (\$1,000).

§ 32-211.14. If any clause, sentence, paragraph, subdivision, section or part of this chapter shall be adjudged by any court of competent jurisdiction to be invalid, the judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, subdivision, section or part thereof directly involved in the controversy in which the judgment shall have been rendered.

§ 32-211.15. Application of Chapter. — Unless exempt as hereinafter provided and only to the extent so exempt, any medical care facility which, on or after July one, nineteen hundred seventy-three, obligates itself by contract or otherwise, or commences, undertakes, or constructs a medical care facility project as defined herein shall be subject to all the provisions of this chapter. However, in the case of medical care facilities providing health care services as of December thirty-one, nineteen hundred seventy-two, which on such date is committed to a formal plan of expansion or replacement, the provisions of this chapter shall not apply with respect to such expenditure as may be made or obligations incurred for capital items included in such formal plans where preliminary expenditures (including payments for studies, surveys, designs, plans, working drawings, specifications and site acquisition, essential to the acquisition, improvement, expansion, or replacement of the medical care facility) of one hundred thousand dollars (\$100,000) or more had been made toward the plan of expansion or replacement during the three-year period ending December thirty-one, nineteen hundred seventy-two. Furthermore, in the case of new medical care facility construction projects as of December thirty-one, nineteen hundred seventy-two, which on such date was com-

mitted and lawfully obligated to a formal plan of construction, the provisions of this chapter shall not apply with respect to such capital items incurred in such plan where preliminary expenditures (including payments for studies, surveys, designs, plans, working drawings, specifications and site acquisition, essential to the initial construction of the medical care facility) of one hundred thousand dollars (\$100,000) or more had been made toward the plan of construction or legally obligated as of December thirty-one, nineteen hundred seventy-two. However, upon completion of the proposed expansion or replacement as specified herein or, in the case of new medical care facility construction, upon completion of the construction project referred to herein, all the provisions of this chapter shall apply to such medical care facilities not herein above specifically excluded.

§ 32-211.16. It shall be an improper practice for the governing body of a hospital which has twenty-five beds or more and which is required by State law to be licensed to refuse or fail to act within sixty (60) days of a completed application for staff membership or professional privileges or deny or withhold from a duly licensed physician staff membership or professional privileges in such hospital, or to exclude or expel a physician from staff membership in such hospital or curtail, terminate or diminish in any way a physician's professional privileges in such hospital, without stating in writing the reason or reasons therefor, a copy of which shall be provided to the physician. If the reason or reasons stated are unrelated to standards of patient care, patient welfare, violation of the rules and regulations of the institution or staff, the objectives or efficient operations of the institution, or the character or competency of the applicant, or misconduct in any hospital, it shall be deemed an improper practice. Such improper practice shall constitute grounds for suspension or revocation of license issued pursuant to Chapter 16, Title 32 of the Code. The provisions of this section shall not impair or affect any other right or remedy of the State. If the license is suspended or revoked on any of the above grounds, the hospital may appeal the decision of the Board to the circuit court of the county or city in which the hospital is located within thirty (30) days after the decision.

RULES AND REGULATIONS

Section I. Definitions

- A. "Applicant": The owner of an existing or proposed medical care facility submitting an application for a Certificate of Public Need.
- B. "Areawide Comprehensive Health Planning Council": A voluntary nonprofit or public agency or organization that is established pursuant to Section 314 (b) of United States Public Law 89-749, as amended, and approved by the State Comprehensive Health Planning Council to function as a health planning agency, in their respective geographic areas, or in the absence of such an agency, any agency approved by the State Comprehensive Health Planning Council for the purpose of conducting areawide comprehensive health planning.
- C. "Areawide Comprehensive Health Plan": A plan approved by an Areawide Comprehensive Health Planning Council and made available to the public.
- D. "Board": The State Board of Health
- E. "Certificate of Public Need": A document issued by the Commissioner indicating: (1) that the proposed project is in compliance with the intent, purposes and provisions of Chapter 12.1 of Title 32, Code of Virginia (1950), as amended, and (2) that a public need exists for the proposed project.
- F. "Commissioner": The State Health Commissioner.
- G. "Construction": Includes building new medical care facilities; the expansion, remodeling and alteration of existing medical care facilities; the initial and subsequent equipment of any such medical care facilities, including architect, engineer, and consultant fees.
- H. "Department": The State Department of Health.
- I. "Equipment": Items which are capitalized in conformance with generally accepted accounting principles and are necessary for provision of health or health-related services.
- J. "Hill-Burton Plan": A State Medical Facilities Construction Plan covering hospitals, nursing homes, rehabilitation facilities developed under Chapter 12 of Title 32, Code of Virginia (1950), as amended.

- K. "Inpatient Beds": Accommodations within a medical care facility with continuous support services (such as food, laundry, housekeeping) and staff to provide health or health - related services to patients who generally remain in the medical care facility in excess of 24 hours. Such accommodations include: nursing units, intensive care units, minimal or self-care units, isolation units, observation units equipped and staffed for overnight use, and pediatric units in a medical care facility, including pediatric bassinets and incubators located in a pediatric department. Bassinets and incubators in a maternity department and beds located in labor rooms, recovery rooms, emergency rooms, preparation or anesthesia inductor rooms, diagnostic or treatment procedures rooms, or on-call staff rooms are excluded from this definition.
- L. "Medical Care Facilities": Any institution, place, building or agency, whether or not licensed or required to be licensed by the State Board of Health or the State Board of Mental Health and Mental Retardation, by or in which facilities are maintained, furnished, conducted, operated or offered for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition, whether medical or surgical, of two or more non-related mentally or physically sick or injured persons, or for the care of two or more nonrelated persons requiring or receiving medical, surgical or nursing attention or services as acute, chronic, convalescent, aged, physically disabled, or crippled, including, but not limited to, general hospitals, sanatoria, sanatoria, nursing homes, intermediate care facilities and other related institutions and facilities, whether operated for profit or nonprofit, and whether privately owned or operated, or owned or operated by a local governmental unit. This term shall not include a physician's office or first aid station for emergency medical or emergency surgical treatment.
- M. "Medical Service Area": The geographic territory from which patients come or are expected to come to existing or proposed medical care facilities, the delineation of which is based on such factors as population characteristics, natural geographic boundaries, and transportation and trade patterns, and all parts of which are reasonably accessible to existing or proposed medical care facilities.
- N. "Modernization": Includes alteration, major repair, remodeling, replacement or renovation of an existing medical care facility, including initial and subsequent equipment thereof.

- O. "Operator": Any person, corporation, authority, commission, partnership, firm, association, trust, estate, public or private institution, group, agency, or political subdivision of the Commonwealth of Virginia having designated responsibility and legal authority to administer and manage a medical care facility, in accordance with all applicable state, federal and local laws, rules and regulations and ordinances.
- P. "Other Plans": Any formally recognized State plan which provides for the orderly planning and development of medical care facilities and services and is not otherwise defined in these Rules and Regulations.
- Q. "Owner": Any person, corporation, authority, commission, partnership, firm, association, trust, estate, public or private institution, group, agency or political subdivision of the Commonwealth of Virginia which has legal responsibility and authority to construct, renovate or equip a medical care facility as defined herein.
- R. "Progress": Evidence that actions have been accomplished which are required in a usual sequence of events incorporated in facility construction, including completion of studies or surveys, designs, plans or specifications, land zoning, arrangements for financing or actual initiation of physical construction.
- S. "Project": A planned capital expenditure, which under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance and which (1) exceeds one hundred thousand dollars (\$100,000) or (2) changes the bed capacity of the facility with respect to which such expenditure is made, or (3) substantially changes the service of the facility with respect to which such expenditure is made. For the purposes of clause (1) of the preceding sentence, the cost of studies, surveys, designs, plans, working drawings, specifications and other activities essential to the acquisition, improvement, expansion, or replacement of the plant and equipment with respect to which such expenditure is made shall be included in determining whether such expenditure exceeds \$100,000.
- T. "Physician's Office": Place of business owned or operated by a licensed physician or group of physicians for the purpose of providing diagnostic medical care and treatment for ambulatory patients on a fee for service basis; provided, however, such term shall not include independent laboratories, or specialized centers or clinics incorporated in the Commonwealth of Virginia for the provision of outpatient

or ambulatory surgery, renal dialysis therapy, cobalt therapy, or other medical or surgical treatments requiring the utilization of equipment not usually associated with the provision of primary health services.

- U. "Services": The delivery of health and health-related care by a functional division of a medical care facility, or by the staff of a medical care facility.
- V. "State Comprehensive Health Plan": A plan approved by the State Comprehensive Health Planning Council in accordance with Public Law 89-749, as amended.
- W. "State Comprehensive Health Planning Council": The duly authorized Statewide public planning agency established pursuant to Section 314 (a) of United States Public Law 89-749, as amended.

Section II. Mandatory Participation Requirements

- A. The owner of a proposed or existing medical care facility shall obtain a Certificate of Public Need prior to:
 - 1. Constructing, undertaking or commencing a medical care facility project involving a proposed capital expenditure in excess of \$100,000; or
 - 2. Changing the bed capacity of a medical care facility which involves a capital expenditure in any amount; or
 - 3. Adding a new service(s) to a medical care facility which involves a capital expenditure in any amount.
- B. Any proposed change(s) in a project for which a Certificate of Public Need has been issued shall be reported in writing to and subject to approval by the Commissioner prior to being implemented. A copy of such proposed change(s) shall also be forwarded to the appropriate Areawide Comprehensive Health Planning Council by the owner.

Section III. Determination of Public Need

In determining whether a public need exists for a proposed project, the Commissioner shall consider the following:

- A. The recommendation of the State Comprehensive Health Planning Council;
- B. The recommendation of the appropriate existing approved Areawide Comprehensive Health Planning Council;
- C. The compatibility of the proposed project with applicable State and areawide health service and facility construction plans, which plans have been approved by recognized health agencies and made available to the public, including the State Comprehensive Health Plan and the State Medical Facilities Construction Plan developed pursuant to Chapter 12 of Title 32, Code of Virginia (1950), as amended;
- D. The contribution of the proposed project to the orderly development and proper distribution of adequate and effective health services for the people residing in the area to be served;
- E. The size, composition, and growth of the population of the area to be served by the proposed project;
- F. The number of existing and planned facilities or services of types similar to the proposed project and the extent of utilization thereof;
- G. The availability of facilities or services, existing or proposed which may serve as alternatives or substitutes to the proposed project;
- H. The availability of medical, nursing, and support personnel to staff the proposed project;
- I. Other information deemed by the Commissioner to be pertinent to the determination of the public need for the project.

Section IV. Application

- A. To establish demonstrative need, the applicant must:
 - 1. Demonstrate that the services to be offered are not presently being offered by an existing facility to sufficiently satisfy the demand for the services;
 - 2. Demonstrate that the immediate growth projections reveal anticipated demands which cannot reasonably be met by existing facilities;

3. Identify the impact of the proposed project upon all other medical facilities operating within the service area, including the economic impact upon them and the effect upon the availability of both professional and non-professional staff to existing facilities;
 4. Demonstrate that completion of staffing will not result in higher costs to consumers, or that present lack of a competing facility in the area results in higher costs to the consumers.
- B. All applications for a Certificate of Public Need shall contain:
1. Data and information to show that the proposed project, upon completion, will meet either completely or partially a demonstrated or projected public need within the service area involved.
 2. Data and information on the services to be provided by the proposed project upon completion.
 3. A detailed description and an analysis of staffing patterns relative to the delivery of services upon completion of the project.
 4. A detailed analysis of the impact the project will have with respect to the operational cost and charge structure of the facility.
 5. Valid documentation, data, and information, that: (a) sufficient funds are or will be available to carry to completion the project proposal described in the application and (b) sufficient funds are or will be available to assure effective operation and maintenance of the facility for a period of not less than one year following completion of the project for which the Certificate of Public Need was issued.
 6. Data and information concerning the accessibility of the facility in terms of: (a) geographical location of the facility in reference to the proposed population to be served; (b) the proposed participation of the facility in public and private reimbursement programs;

(c) the adequacy and availability of services of the facility to all major segments of the population in terms of demographic and cultural groupings.

7. Data and information on the working relationships (i.e., linkages) of the proposed project with other health care providers in the service area.
8. A full disclosure of the names and addresses of all directors and owners or persons having a financial interest of five percent (5%) or more in the medical care facility. In the case of a corporate applicant, the name and address of the Registered Agent shall be provided.
9. A full disclosure of the name(s) and address(es) of the operator(s) of the medical care facility project, if such project is not to be operated by the owner. A copy of the contract or agreement between the owner and the operator of the medical care facility project shall be a part of the application.
10. The following assurances that the applicant will:
 - a. Carry through with the project as proposed; cause initiation of the work on the project within the period of time set forth in the Certificate of Public Need; pursue completion of the project with reasonable diligence;
 - b. Operate the facility within the scope of the proposed project as described in the application;
 - c. Operate the facility in accordance with all applicable state, federal and local laws, rules, regulations and ordinances;
 - d. Operate the facility in compliance with Title VI of the Civil Rights Act;
 - e. Design and construct the project in such manner as to assure easy access to services by persons confined to wheelchairs;

- f. Operate the facility in full compliance with the open staff requirements of state law.
- C. All of the data and information required must be presented in a format prescribed in the Procedures governing the administration of the Certificate of Public Need program. All applications shall be prepared in triplicate: two (2) copies to be submitted to the Department; one (1) copy to be submitted to the appropriate Areawide Comprehensive Health Planning Council.

Section V. Standard Review Process

A. Consideration of Applications:

Insofar as practical, in consideration of the time frames involved as defined in these Rules and Regulations, all applications for the same or similar projects in the same medical service area shall be reviewed concurrently by reviewing agencies.

B. Review for Completeness:

The applicant shall be notified by the Department within fifteen (15) days following receipt of the application that the application is acceptable as submitted, or that additional information is required to complete the application before the application can be accepted. No application shall be reviewed until it has been determined by the Department to be complete.

C. Review of a Complete Application:

Notification of acceptance of a complete application by the Department shall initiate the review process. The application shall be concurrently reviewed by the Bureau of Program Development and Evaluation and the appropriate Areawide Comprehensive Health Planning Council. Findings and recommendations of these agencies shall be forwarded to the State Comprehensive Health Planning Council. After review of all available data, findings, and recommendations, the State Comprehensive Health Planning Council shall make a recommendation to the Commissioner.

D. Amendment to an Application:

The applicant has the right to amend his application at any time during the review process prior to the Commissioner's decision, by submitting such amendment, in writing, to the Commissioner with a copy to the appropriate Areawide Comprehensive Health Planning Council. The extent of the modification(s) contained in such amendment, with respect to its impact on the project as originally proposed, may be cause for the Commissioner to determine the application to be subject to a new review cycle. All amendments to completed applications shall: (1) be received in writing; (2) reflect all substantive changes in the application; and (3) be signed by the applicant.

E. Withdrawal of Application:

The applicant has the right to withdraw his application at any time, without prejudice.

F. Action on Application:

1. Decisions as to approval or disapproval of applications for Certificate of Public Need are rendered by the Commissioner.
2. The Commissioner shall notify the applicant of approval or disapproval of an application within 90 days of notification of formal acceptance of the application. The Department may, however, request the applicant to grant additional time for review if circumstances warrant. Formal agreement by the applicant to such departmental request shall extend the time for notification of action as specified in the request.

Section VI. Administrative Review Process

- A. The purpose of the administrative review process shall be to permit appropriate consideration and response for those projects which would create minimal impact on the scope, quality or costs for health services to be provided by a health facility, or to permit required responsiveness at meeting emergency situations.
- B. The Administrative Review procedure may be applicable (1) to a capital expenditure of a medical care facility in excess of \$100,000 which does not change bed capacity

or replace existing beds, or does not substantially change the services offered by the facility, or (2) a capital expenditure of less than \$100,000 which does change bed capacity or replace existing beds or substantially change the services offered by the facility.

- C. Requests for Administrative Review shall be made by submission of data and information, by letter, to the Commissioner, with a copy to the appropriate Areawide Comprehensive Health Planning Council.
- D. The Areawide Comprehensive Health Planning Council shall, within twenty (20) days of receipt of a copy of the request for Administrative Review, notify the Commissioner of its recommendation with respect to the project for which an administrative review has been requested. If such Areawide Comprehensive Health Planning Council recommendation is unfavorable, the Commissioner shall so notify the applicant and require that a formal application be submitted pursuant to Section IV of these Rules and Regulations. Failure of the Areawide Comprehensive Health Planning Council to notify the Commissioner within the twenty (20) days allowed for such notification shall constitute a recommendation of approval by such Council. Failure of the applicant to submit appropriate data and information coincidentally to the Commissioner and to the appropriate Areawide Comprehensive Health Planning Council shall be cause for requiring the standard review.
- E. The Commissioner shall determine and notify the applicant within thirty (30) days following receipt of the request whether a Certificate of Public Need may be issued on the basis of this information or whether a formal application for a Certificate of Public Need is required.

Section VII. Duration/Extension/Revocation of Certificates

- A. The Commissioner shall issue a Certificate of Public Need to approved projects which shall be valid for a period of six months, renewable for additional periods, not to exceed two years. During the period the Certificate of Public Need is in force, the applicant shall demonstrate satisfactory progress toward completion of the project. Failure to initiate construction or otherwise demonstrate satisfactory progress toward completion of the project during the two years following the date of issuance of the Certificate of Public Need shall be cause for its revocation, unless due to

extenuating circumstances, the Board, in its sole discretion, extends the Certificate.

- B. An extension of Certificate of Public Need during the two years following the date of issuance may be obtained from the Commissioner by submitting satisfactory data and evidence of progress being made toward completion of the project for which the Certificate of Public Need was granted. Any application for an extension of a Certificate of Public Need beyond one (1) year shall be reviewed by the appropriate Areawide Comprehensive Health Planning Council and comments on the application by that Council will be solicited by the Commissioner before decision.
- C. Requests for extension, as described in Section VII-B above, shall be submitted in writing, at least thirty (30) days prior to the expiration date of the Certificate, which request shall be on a form issued by the Department.
- D. Extension of Certificate of Public Need by the Commissioner shall be made in the form of a letter from the Commissioner and shall become a part of the official file of the project. Extensions may be granted, assuming satisfactory progress has been demonstrated, for a period not to exceed two years from date of issuance.
- E. Failure of the applicant to meet all conditions and requirements stated in these Rules and Regulations shall constitute cause for which the Commissioner may revoke the Certificate of Public Need.
- F. An applicant, having had its Certificate of Public Need revoked by the Commissioner, may, without prejudice or preference, reapply, in accordance with these Rules and Regulations.

Section VIII. Exemptions

- A. Any person, formally committed and lawfully obligated to a medical care facility project, as defined herein, on or before December 31, 1972, shall be determined to be exempt from having to obtain a Certificate of Public Need.
- B. The determination of whether such medical care facility project is exempt, and the extent to which such exemption shall apply, shall be made by the Commissioner, based upon satisfactory evidence and documentation submitted

by such person to demonstrate such formal commitment and lawful obligation for a project amounting to \$100,000 or more.

- C. Any person who has received an exemption from securing a Certificate of Public Need shall report the progress toward completion of the exempt project within thirty (30) days of the effective date of these Rules and Regulations.
- D. Failure to report progress or failure to demonstrate that reasonable progress has been made toward the completion of projects exempt from having to obtain a Certificate of Public Need may be cause for the Commissioner to revoke the exemption.
- E. Any person having an exemption revoked and wishing to proceed with a project must obtain a Certificate of Public Need in accordance with these Rules and Regulations.

Section IX. Appeal of Decision

A. Appeal to Commissioner

- 1. Any applicant whose application for Certificate of Public Need has been disapproved may appeal such decision to the Commissioner in writing, within thirty (30) days after notification of the decision, requesting a fair hearing.
- 2. Any person whose exemption from having to obtain a Certificate of Public Need has been revoked or denied may appeal such decision to the Commissioner in writing, within thirty (30) days after notification of the decision, requesting a fair hearing.
- 3. Within thirty (30) days of receipt of notification of appeal, the Commissioner shall set a date and a place for such hearing.
- 4. Not later than 30 days following the hearing, the Commissioner shall issue a final order with respect to the disposition of the appeal.

B. Appeal to the State Board of Health

1. If the applicant is aggrieved following the final order of the Commissioner, he may within thirty (30) days, request a de novo hearing under the provisions of Section 32-311.8, Virginia (1950), as amended.
2. Such de novo hearing shall be conducted by the full Board or a majority of not less than 2/3 thereof at a time and place determined by the Board, which hearing shall be held within 120 days of receipt of notice.
3. The Board shall notify the applicant within thirty (30) days of final determination of its decision.

C. Appeal to Circuit Court

Any applicant aggrieved by the final decision of the Board may, within thirty (30) days after receipt of notice of the Board's decision, obtain a Circuit Court review in accordance with Section 32-211.9, Code of Virginia (1950), as amended.

D. Appeal to Virginia Supreme Court

The applicant may appeal the decision of the Circuit Court in accordance with provisions of Section 32-211.9, Code of Virginia (1950), as amended.

Section X. Sanctions

- A. Any person, partnership, firm, company, trust, association, corporation, or other legal entity, which commences, constructs, or undertakes construction of a medical care facility project without having obtained a Certificate of Public Need shall be guilty of a misdemeanor and upon conviction, shall be punished by a fine of not less than fifty dollars (\$50) nor more than one thousand dollars (\$1,000).
- B. Any person who shall violate, disobey, refuse, omit or neglect to comply with any of these Rules and Regulations shall be guilty of a misdemeanor. Such misdemeanor shall be punishable by fine not exceeding one thousand dollars (\$1,000), or by confinement in jail, not exceeding twelve (12) months, or both.

- C. Any court of record having chancery jurisdiction in the county or city where a proposed project is under construction or is intended to be constructed, located, or undertaken, and the Circuit Court of the City of Richmond shall have jurisdiction to enjoin, on petition of the Commissioner, the Board, or the Attorney General, any project which is constructed, undertaken, or commenced without the required Certificate of Public Need as referred to herein.

Section XI. Severability Clause

If any clause, sentence, paragraph, subdivision, section or part of these Rules and Regulations, shall be adjudged by any court of competent jurisdiction to be invalid, the judgement shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, subdivision, section or part thereof directly involved in the controversy in which the judgement shall have been rendered.

**RULES AND
REGULATIONS
OF THE
BOARD OF HEALTH
COMMONWEALTH OF VIRGINIA**



**Virginia Medical Care Facilities
Certificate of Public Need**

**Division of Health Planning and Resources Development
Department of Health
James Madison Building
109 Governor Street
Richmond, Virginia 23219**

As authorized by Sections 32-211 et seq., Chapter 12.1, and Section 32-6, Title 32, Code of Virginia, 1950, as amended, the Commissioner of Health and the State Board of Health have, in conformity with provisions of Chapter 1.1:1, Title 9, of the Code, adopted the Rules and Regulations for Virginia Medical Care Facilities Certificate of Public Need.

These are new regulations superceding the Rules and Regulations of the Board of Health, Commonwealth of Virginia, promulgated and adopted on December 4, 1974, which became effective February 1, 1975.

Preliminary approval by the Commissioner and the State Board of Health granted September 9, 1977.

Public Hearing was held October 11, 1977, in Richmond, Virginia.

Adopted by the Commissioner and the State Board of Health, December 1, 1977.

Effective date, January 2, 1978.

Copies may be obtained from Bureau of Resources Development, State Health Department, Suite 1001, 109 Governor Street, Richmond, Virginia 23219
(804) 786-7463

<u>Section</u>		<u>Page</u>
2.19.	Modernization.	5
2.20.	New Service.	5
2.21.	Operator	5
2.22.	Other Plans.	5
2.23.	Owner.	5
2.24.	Physician's Office	5
2.25.	Progress	6
2.26.	Project.	6
2.27.	Significant Change	6
2.28.	Statewide Health Coordinating Council.	6
2.29.	State Health Plan.	6
2.30.	State Medical Facilities Plan.	6
2.31.	Suspension of Certificate.	6
3.00	Mandatory Requirements	6
3.01.	Requirements for Medical Care Facilities . . .	6
	3.01.01. Capital Expenditure Limitation . .	7
	3.01.02. Bed Addition Limitation.	7
	3.01.03. Service Addition Limitation. . . .	7
	3.02. Requirements for Non-Institutional Providers .	7
	3.03. Significant Change Limitation.	7
4.00	Determination of Public Need (Required Considerations) .	7
5.00	Participation Requirements	8
	5.01. Applications	8
	5.02. General Data and Information Content	9
	5.03. Required Assurances.	9
6.00	Standard Review Process.	10
	6.01. Pre-Consultation	10
	6.02. Obtaining Application Forms.	10
	6.03. Review for Completeness.	10
	6.04. Ninety Day Review Cycle.	10
	6.05. Consideration of Applications.	10
	6.06. Review of Complete Application	10

<u>Section</u>		<u>Page</u>
	6.06.01. Review Cycle Time Frame.	10
	6.06.02. Health Systems Agency Required Notifications	11
	6.07. Participation by Affected Persons.	11
	6.08. Amendment to an Application.	11
	6.09. Withdrawal of an Application	11
	6.10. Action on an Application	11
	6.10.01. Commissioner's Responsibility. . .	11
	6.10.02. Notification Process-Extension of Review Time.	11
7.00	Administrative Review Process.	12
	7.01. Purpose.	12
	7.02. Applicability.	12
	7.03. Application.	12
	7.04. Process.	12
	7.05. Action on Application.	12
8.00	Duration/Extension/Revocation of Certificates.	12
	8.01. Duration	12
	8.02. Extension by Commissioner.	13
	8.02.01. Basis for Extension.	13
	8.02.02. Requests for Extension	13
	8.02.03. Health Systems Agency Review . . .	13
	8.02.04. Notification of Decision	13
	8.03. Demonstration of Progress.	13
	8.04. Extension by Board	14
	8.04.01. Basis for Extension.	14
	8.04.02. Requests for Extension	14
	8.04.03. Health Systems Agency Review . . .	14
	8.04.04. Notification of Decision.	14
	8.05. Revocation	15
	8.05.01. Lack of Progress	15
	8.05.02. Significant Unapproved Changes . .	15

<u>Section</u>		<u>Page</u>
	8.05.03. Failure to Initiate Construction .	15
	8.05.04. Misrepresentation.	15
	8.05.05. Non-Compliance with Assurances . .	15
	8.06. Reapplication.	15
9.00	Exemptions	15
	9.01. Eligibility.	15
	9.02. Determination by Commissioner.	15
10.00	Administrative Hearings and Appeals.	16
	10.01. Reconsideration of Initial Determination . . .	16
	10.01.01. Applicant Initiation	16
	10.01.02. Health Systems Agency Initiation .	16
	10.01.03. Notifications and Suspensions. . .	16
	10.01.04. Establishing Time, Date, Place . .	16
	10.01.05. Notification of Decision	16
	10.02. Formal Evidentiary Hearing	16
	10.02.01. Applicant Initiation	16
	10.02.02. Health Systems Agency Initiation .	17
	10.02.03. Notifications and Suspensions. . .	17
	10.02.04. Establishing Time, Date, Place . .	17
	10.02.05. Notification of Decision	17
	10.03. Formal Independent Hearing	17
	10.03.01. Applicant/Health Systems Agency Initiation.	17
	10.03.02. Notifications and Suspensions. . .	17
	10.03.03. Establishing Time, Date, Place . .	17
	10.03.04. Limitations of Review.	17
	10.03.05. Required Consideration	18
	10.03.06. Authority of Hearing Examiner. . .	18
	10.03.07. Notification of Decision	18
10.04.	Court Review	18

<u>Section</u>	<u>Page</u>
10.04.01. Appeal to Circuit Court.	18
10.04.02. Appeal to Supreme Court.	18
11.00 Sanctions	18
11.01. Violation of Virginia Medical Care Facilities Certificate of Public Need Law.	18
11.02. Violation of Rules and Regulations	18
11.03. Injunctive Relief.	18
12.00 Severability Clause	19

SECTION 1.00

GENERAL INFORMATION

- 1.01. Authority for Regulations - The Virginia Medical Care Facilities Certificate of Public Need Law, which is codified as Chapter 12.1 of Title 32, Section 32.211.3 to 32.211.17, Code of Virginia (1950), as amended, requires the owners of medical care facilities operating or sponsors of medical care facilities proposing to operate within the Commonwealth of Virginia to secure a Certificate of Public Need from the State Health Commissioner for the addition of beds, for new services proposed to be offered and for major capital expenditures proposed to be made. Section 32-6 of the Code of Virginia (1950), as amended, and the Act direct the Commissioner and the Board of Health to promulgate and prescribe such rules and regulations as are deemed necessary to effectuate the purposes of the Act.
- 1.02. Purpose of Rules and Regulations - The Commissioner and Board have promulgated these rules and regulations to set forth an orderly administrative process for making public need determinations and to identify explicitly those services and capital expenditures which require certification.
- 1.03. Administration of Rules and Regulations - These rules and regulations are administered by the following:
 - 1.03.01. State Board of Health - The Board of Health is the governing body of the State Department of Health, which has designated responsibility for implementing the Act.
 - 1.03.02. State Health Commissioner - The State Health Commissioner is the executive officer of the State Department of Health. The Commissioner is the designated decision maker in the process of determining public need under the Act.
 - 1.03.03. Statewide Health Coordinating Council - The Statewide Health Coordinating Council, established by gubernatorial Executive Order pursuant to Public Law 93-641, the National Health Planning and Resources Development Act, has the responsibility to review the public need for projects covered under the Virginia Medical Care Facilities Certificate of Public Need Law and to make advisory recommendations on such public need to the Commissioner, pursuant to its bylaws. The Council also has responsibility to advise the Commissioner relative to the administration of the Certificate of Public Need Program.
 - 1.03.04. Health Systems Agencies - Each Health Systems Agency, established pursuant to Public Law 93-641, the National Health Planning and Resources Development Act, has the responsibility to review the public need for proposed projects in its geographical area of concern under the Virginia Medical Care Facilities Certificate of Public Need Law and to make advisory recommendations on such public need to the Statewide Health Coordinating Council and the Commissioner.

Each Health Systems Agency also has the responsibility to conduct public hearings on proposed projects which are subject to review and the authority to request reconsideration by the Commissioner of any public need determinations which are contrary to their recommendations.

- 1.03.05. Public Meetings and Public Hearings - All meetings and hearings convened to consider any Certificate of Public Need application shall be open to the public in accordance with the provisions of the Virginia Freedom of Information Act, codified as Chapter 21 of Title 2, Section 2.1-340 et seq., Code of Virginia (1950), as amended.
- 1.03.06. Official Records - All analyses, staff evaluations, committee reports and written information developed or utilized during the course of determining public need shall be provided at the time of distribution to appropriate review groups and to each applicant and shall become part of the official project record maintained by the Department's Bureau of Resources Development. Correspondence received by the Commissioner concerning any application shall be deemed a part of the official record maintained by the Department's Bureau of Resources Development; such correspondence will not routinely be forwarded to appropriate review groups or to the applicant. All records are subject to the provisions of the Virginia Freedom of Information Act.
- 1.04. Application of Rules and Regulations - These rules and regulations have general applicability throughout the Commonwealth. The requirements of the Virginia Administrative Process Act, codified as Chapter 1.1:1 of Title 9, Section 9-6.14:1, et seq., Code of Virginia (1950), as amended, apply to their promulgation.
- 1.05. Effective Date of Rules and Regulations - These rules and regulations, or any subsequent amendment, modification, or deletion in connection with these rules and regulations, shall become effective thirty (30) days after the Commissioner and the Board have filed them in accordance with the Virginia Register Act.
- 1.06. Powers and Procedures of Regulations Not Exclusive - The Commissioner and the Board reserve the right to authorize any procedure for the enforcement of these regulations that is not inconsistent with the provisions set forth herein and the provisions of Chapter 12.1 of Title 32, Section 32-211.3 et seq., Code of Virginia (1950), as amended.

SECTION 2.00

DEFINITIONS

- 2.01. "Affected Person": Person(s) residing in an area proposed to be served by a project for which a Certificate of Public Need has been requested; medical care facility(ies) providing services or approved to provide services in an area proposed to be served by a project for which a Certificate of Public Need has been requested; or, any agency providing reimbursement to medical care facilities in an area proposed to be served by a project for which a Certificate of Public Need has been requested.
- 2.02. "Applicant": The owner of an existing medical care facility or the sponsor of a proposed medical care facility submitting an application for a Certificate of Public Need.
- 2.03. "Application": A prescribed format for the presentation of data and information deemed necessary by the Department for a determination concerning a project for which a Certificate of Public Need is required.
- 2.04. "Annual Implementation Plan": An annual regional plan developed by a designated Health Systems Agency in accordance with §1513(b)(3) of United States Public Law 93-641, or its successor, which describes objectives and established priorities among the objectives to achieve the goals set forth in its Health Systems Plan.
- 2.05. "Board": The State Board of Health.
- * 2.06. "Capital Expenditures": Any expenditure by or on behalf of a medical care facility which, under generally accepted accounting principles, is a capital expenditure. All acquisitions by or for medical care facilities under lease or comparable arrangement or through donation, bequest, or devise, which would require certification if such acquisition were made by purchase, are deemed to be capital expenditures. ? omit
- 2.07. "Certificate of Public Need": A document issued by the Commissioner which legally authorizes the initiation of a project as defined herein.
- 2.08. "Commissioner": The State Health Commissioner.
- 2.09. "Construction": The building of new medical care facilities and/or the expansion, remodeling, and alteration of existing medical care facilities, including the initial and subsequent equipping of any such medical care facilities.
- 2.10. "Construction, Initiation of": A project shall be considered under construction for the purpose of extension determinations upon the presentation of evidence by the owner of: (1) a signed construction contract; (2) evidence that short term and long term (permanent) financing has been completed, when applicable; (3) predevelopment site work has been completed; and (4) building foundations have been completed.

- 2.11. "Date of Issuance": The date of the Commissioner's decision awarding a Certificate of Public Need, or, where applicable, the date of reinstatement of a Certificate of Public Need following suspension.
- 2.12. "Department": The State Department of Health.
- 2.13. "Health Service Area": A geographic area of the State designated by the Secretary of the United States Department of Health, Education and Welfare pursuant to §1511 of United States Public Law 93-641, or its successor.
- 2.14. "Health Systems Agency": An entity organized and operated as provided in §1512 of United States Public Law 93-641 and designated as a health systems agency pursuant to §1515 of United States Public Law 93-641, or its successor.
- 2.15. "Health Systems Plans": A regional health plan developed by a designated Health Systems Agency in accordance with §1513(b)(2) of United States Public Law 93-641, or its successor, which sets forth in detail the goals of a healthful environment and the health systems in the geographical area it serves.
- 2.16. "Inpatient Beds": Accommodations within a medical care facility with continuous support services (such as food, laundry, housekeeping) and staff to provide health or health-related services to patients who generally remain in the medical care facility in excess of 24 hours. Such accommodations include, but are not limited to: nursing units, intensive care units, minimal or self care units, isolation units, observation units equipped and staffed for overnight use, and obstetric, medical, surgical, psychiatric, and pediatric units in a medical care facility, including pediatric bassinets and incubators located in a pediatric department. Bassinets and incubators in a maternity department and beds located in labor rooms, recovery rooms, emergency rooms, preparation or anesthesia inductor rooms, diagnostic or treatment procedures rooms, or on-call staff rooms are excluded from this definition.
- 2.17. "Medical Care Facilities": Any institution, place, building or agency whether or not licensed or required to be licensed by the State Board of Health or the State Mental Health and Mental Retardation Board, by or in which facilities are maintained, furnished, conducted, operated, or offered for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition, whether medical or surgical, of two or more non-related mentally or physically sick or injured persons, or for the care of two or more non-related persons requiring or receiving medical, surgical or nursing attention or services as acute, chronic, convalescent, aged, physically disabled, or crippled, including, but not limited to a general hospital, sanatorium, sanatorium, nursing home, intermediate care facility, extended care facility, health maintenance organization, mental hospitals, mental retardation facility and any other related institution and facility, whether operated for profit or nonprofit, and whether privately owned or operated or owned or operated by a local governmental unit or which is the recipient of reimbursements from third party health insurance programs or prepaid medical services plans. On and after July one, nineteen

hundred seventy-eight the term shall also include intermediate care facilities established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts. This term shall not include a physician's office; provided, however, the term "physician's office" shall not include independent laboratories or specialized centers or clinics developed for the provision of outpatient or ambulatory surgery, renal dialysis therapy, radiation therapy, computerized tomography (CT) scanning, or other medical or surgical treatments requiring the utilization of equipment not usually associated with the provision of primary health services, the cost of which exceeds two hundred thousand dollars (\$200,000) per unit of equipment. The term "medical care facility" shall not include a first aid station for emergency medical or emergency surgical treatment.

- 2.18. "Medical Service Area": The geographic territory from which at least seventy-five (75%) percent of patients come or are expected to come to existing or proposed medical care facilities, the delineation of which is based on such factors as population characteristics, natural geographic boundaries, and transportation and trade patterns, and all parts of which are reasonably accessible to existing or proposed medical care facilities.
- 2.19. "Modernization": The alteration, major repair, remodeling, replacement or renovation of an existing medical care facility, including initial and subsequent installation, replacement or alteration of equipment therein.
- * 2.20. "New Service(s)": A distinct, identifiable modality, whether diagnostic, therapeutic, rehabilitative, or preventive which has never been offered or has not been offered in the previous twelve (12) months by the medical care facility.
- 2.21. "Operator": Any person, corporation, authority, commission, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of the Commonwealth of Virginia or other legal entity having designated responsibility and legal authority to administer and manage a medical care facility.
- 2.22. "Other Plans": Any plan(s) formally adopted by a governmental agency or Health Systems Agency or the Statewide Health Coordinating Council, which provides for the orderly planning and development of medical care facilities and services and is not otherwise defined in these Rules and Regulations.
- 2.23. "Owner": Any person, corporation, authority, commission, partnership, firm, association, trust, estate, public or private institution, group, agency, or political subdivision of the Commonwealth of Virginia or other legal entity which has legal responsibility and authority to construct, renovate or equip or otherwise control a medical care facility as defined herein.

- 2.24. "Physician's Office": A place, owned or operated by a licensed physician or group of physicians practicing in any legal form whatsoever, designed and equipped solely for the provision of fundamental medical care to ambulatory patients whether diagnostic, therapeutic or rehabilitative. See also 2.17.
- 2.25. "Progress": Actions in a given period of time which are required in a usual sequence of events to complete a project for which a Certificate of Public Need has been issued.
- * 2.26. "Project": A capital expenditure, which under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance and which: (1) changes the bed capacity of the facility with respect to which such expenditure is made; or (2) substantially changes the services of the facility with respect to which such expenditure is made; or (3) exceeds one hundred fifty thousand dollars (\$150,000), except wherein Section 32-211.5(6) of the Code of Virginia (1950), as amended, provides for a \$200,000 threshold.
- 2.27. "Significant Change": Any alteration, modification or adjustment (including budget) to a project for which a Certificate of Public Need has been issued which: (1) changes the site; (2) increases the cost of the project in excess of twenty (20) percent more than the cost originally authorized by the Certificate of Public Need; (3) changes the number of beds originally authorized by the Certificate of Public Need; or (4) changes the service(s) proposed to be offered by the approved project.
- 2.28. "Statewide Health Coordinating Council": The duly authorized statewide health advisory agency established pursuant to §1514 of United States Public Law 93-641, or its successor, which is required to provide recommendations to the Commissioner regarding the public need for proposed medical facility projects.
- 2.29. "State Health Plan": A document prepared by the Statewide Health Coordinating Council in accordance with §1524(c)(2)(A) of United States Public Law 93-641, or its successor, which is made up of Health Systems Plans and sets forth goals for a healthful environment and health systems.
- 2.30. "State Medical Facilities Plan": A plan developed by the Department of Health, coordinated with Health Systems Agencies and reviewed for consistency with the State Health Plan by the Statewide Health Coordinating Council for use in the Virginia Medical Care Facilities Certificate of Public Need Program and for Title XVI of United States Public Law 93-641, or its successor.
- 2.31. "Suspension of Certification": A written order by the Commissioner issued for an approved project pending the conclusion of administrative hearings or appeals, which serves as notification to the project owner to cease temporarily and desist project development and temporarily relieves the owner of all performance requirements for development, and which shall terminate upon notification from the Commissioner that the suspended Certificate has been reinstated or revoked.

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SECTION 3.00

MANDATORY REQUIREMENTS

- 3.01. Requirements for Medical Care Facilities - The owner of a proposed or existing medical care facility shall obtain a Certificate of Public Need prior to:
- 3.01.01. Capital Expenditure Limitation - Constructing, undertaking, or commencing a medical care facility project, involving a proposed capital expenditure in excess of \$150,000; or
 - 3.01.02. Bed Addition Limitation - Changing the bed capacity of a medical care facility which involves a capital expenditure in any amount; or
 - * 3.01.03. Service Addition Limitation - Adding a new service(s) to a medical care facility which involves a capital expenditure in any amount.
- 3.02. Requirements for Non-Institutional Providers - Any physician or group of physicians or physician practice, of whatever legal form, shall obtain a Certificate of Public Need prior to purchase or lease of a unit of equipment, the cost of which equipment exceeds \$200,000.
- 3.03. Significant Change Limitation - No significant change in a project for which a Certificate of Public Need has been issued shall be made without prior written approval of the Commissioner, which shall be requested by the owner in writing with a copy to the appropriate Health Systems Agency, giving nature and purpose of the change. The Health Systems Agency shall review the proposed change in compliance with Section 7.04 of these regulations except that a public hearing shall be optional.

SECTION 4.00 DETERMINATION OF PUBLIC NEED (REQUIRED CONSIDERATIONS)

In determining whether a public need exists for a proposed project, the following shall be considered:

- 4.01. The relationship of the health services to be provided to the applicable health systems plan and annual implementation plan;
- 4.02. The relationship of the proposed project to the long-range development plan of the applicant providing or proposing such project;
- 4.03. The need that the population served or to be served by such project has for such project;
- 4.04. The availability of less costly or more effective alternative methods, existing or proposed, of providing such services;
- 4.05. The impact of the proposed project on the cost and charges for providing health services by the applicant and the financial capability to construct and/or maintain the proposed project;

- 4.06. The cost and utilization impact of the services proposed to be provided upon the existing health care system, including proposed facilities, of the area; 5.0.
- 4.07. The availability of resources (including, but not limited to health manpower, management personnel, and funds for capital and operating needs) for the provision of the services proposed to be provided and the availability of alternative uses of such resources for the provision of other health services;
- 4.08. The relationship, including the organizational relationship, of the proposed project to ancillary or support services;
- 4.09. Special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas. Such entities may include medical and other health professions schools, multidisciplinary clinics and specialty centers;
- 4.10. The special needs and circumstances of health maintenance organizations;
- 4.11. The special needs and circumstances of biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages;
- 4.12. In the case of a construction project, the costs and methods of the proposed construction, including methods of energy provision, and the probable impact of the construction project reviewed on the costs of providing health services by the person proposing such construction project;
- 4.13. The consistency of the proposed project with the facilities and services requirements of the current State Medical Facilities Plan;
- 4.14. The relationship of the proposed project to special criteria promulgated and adopted by the Board, as applicable.

SECTION 5.00

PARTICIPATION REQUIREMENTS

- 5.01. Applications - Applications for a Certificate of Public Need shall contain all data and information required by the Department. These data and information shall be submitted in a prescribed format. All applications shall be prepared in triplicate: two (2) copies to be submitted to the Department; one (1) copy to be submitted to the appropriate Health Systems Agency. 5.03.

5.02. General Data and Information Content - The applicant must:

- (1) Present quantitative data and qualitative information to demonstrate a public need for the proposed project exists in the area to be served;
- (2) Provide data and information concerning the services to be offered;
- (3) Considering five (5) year population projections, set forth data and information showing the anticipated demand for the proposed service(s);
- (4) Identify by presentation of substantive data the requirements of the proposed project for both professional and non-professional staff and the means by which same shall be obtained;
- (5) Provide comparative data to show the relationship between the current cost to consumers and the cost upon project completion;
- (6) Considering geographic barriers and time/miles travelled, present evidence that the project will contribute to improved accessibility and distribution of health services in the health service area;
- (7) Set forth data and information as to why there is not less costly, more efficient or more appropriate alternatives to such services and describe alternatives that the applicant has studied and found not practicable. This should include a discussion of alternatives to new construction;
- (8) Present data and information to show that funds will be available to complete and support the proposed project;
- (9) Disclose the names and addresses of all directors and owners or persons having a financial interest of 5% or more in the medical care facility;
- (10) Disclose the names and addresses of the operator(s) of the medical care facility, if other than the owner, and a copy of any agreement or contract between the owner and operator.

5.03 Required Assurances - The applicant shall give assurance that:

- (1) The work on the proposed project will be initiated within the period of time set forth in the Certificate of Public Need; and,
- (2) Completion of the proposed project will be pursued with reasonable diligence; and,
- (3) The proposed project will be constructed, operated and maintained in full compliance with all applicable local, State and Federal laws, rules, regulations, and ordinances.

SECTION 6.00

STANDARD REVIEW PROCESS

- 6.01. Pre-Consultation - Each Health Systems Agency and the Bureau of Resources Development in the Department shall provide advice and assistance to potential applicants concerning community health resources needs upon request. Such advice and assistance shall be advisory only and shall not be a commitment on behalf of the Health Systems Agency, the Statewide Health Coordinating Council or the Commissioner.
- 6.02. Obtaining Application Forms - Application forms shall be available from the Commissioner upon written request. The request shall identify the owner, the type of project for which forms are requested, and the proposed scope (size) and location of the proposed project.
- 6.03. Review for Completeness - The applicant shall be notified by the Department within fifteen (15) days following receipt of the application that the application is complete as submitted, or that additional information is required to complete the application before the application can be accepted. No application shall be reviewed until it has been determined by the Department to be complete. All applications completed on or before the tenth (10th) day of the month shall be accepted by the Department on the tenth (10th) day of that month. Applications completed subsequent to the tenth (10th) day of the month shall be accepted on the tenth (10th) day of the month following completion.
- 6.04. Ninety Day Review Cycle - The review of an application for Certificate of Public Need shall be accomplished within ninety (90) days of acceptance of a completed application.
- 6.05. Consideration of Applications - Insofar as practical, in consideration of the time limits involved as set forth in these Rules and Regulations, all applications for the same or similar projects in the same medical service area shall be reviewed concurrently by reviewing agencies.
- 6.06. Review of Complete Application
- 6.06.01. Review Cycle - At the close of work on the tenth (10th) day of each month, the Department shall prepare letters of notification of acceptance of completed applications and send such letters to project sponsors. The letter of notification shall contain a schedule indicating: (a) the date by which the appropriate Health Systems Agency review shall be completed, which date shall not exceed sixty (60) days from the date the application was accepted as complete; (b) the date by which the Statewide Health Coordinating Council review and recommendation shall be completed, which date shall not exceed eighty (80) days from the date the application was accepted as complete; and (c) the date by which the Commissioner shall render his determination. Unless agreed to by the applicant, the review schedule shall not be extended.

- 6.06.02. Health Systems Agency Required Notifications - Upon notification by the Department of acceptance of a completed application, the appropriate Health Systems Agency shall notify the applicant of the Health Systems Agency's review schedule and also notify health care providers and specifically identifiable consumer groups who may be affected by the proposed project directly by mail. Such notification shall include: (a) the date and location of the public hearing on the application, which shall be conducted in the county or city wherein a project is proposed; (b) the date, time and place the final recommendation of the Health Systems Agency shall be made. The Health Systems Agency shall also give notice of the public hearing in a newspaper of general circulation in such county or city at least nine (9) days prior to such public hearing.
- 6.07. Participation by Affected Persons - Any person affected by a proposed project under review may submit opinions, data and other information in writing directly to the appropriate Health Systems Agency, the Statewide Health Coordinating Council, and the Commissioner at appropriate times for consideration prior to their final action.
- 6.08. Amendment to an Application - The applicant shall have the right to amend an application at any time during the review and recommendations of the appropriate Health Systems Agency. Any amendment to an application subsequent to a Health Systems Agency recommendation shall constitute a new application.
- 6.09. Withdrawal of an Application - The applicant shall have the right to withdraw an application from consideration at any time, without prejudice.
- 6.10. Action on an Application
- 6.10.01. Commissioner's Responsibility - Decisions as to approval or disapproval of applications for Certificates of Public Need shall be rendered by the Commissioner.
- 6.10.02. Notification Process-Extension of Review Time - The Commissioner shall make an initial determination to approve or disapprove an application for a Certificate of Public Need and make known the reasons for the determination by letter to the applicant within ninety (90) days of notification of formal acceptance of a completed application, provided no extension of time for consideration has been agreed to by the applicant. A copy of the Commissioner's letter shall also be provided to the Health Systems Agency.

SECTION 7.00

ADMINISTRATIVE REVIEW PROCESS

- 7.01. Purpose - The purpose of the administrative review process shall be to permit appropriate consideration and response to those projects which would create minimal impact on the scope, quality or costs for health services provided by a health facility, or to permit required responsiveness in meeting emergency situations.
- 7.02. Applicability - The administrative review procedure may be applicable to: (a) a capital expenditure of a medical care facility in excess of \$150,000 which does not change bed capacity or replace the existing beds, or does not substantially change the services offered by the facility; or (b) a capital expenditure of less than \$150,000 which does change bed capacity or replace existing beds or substantially changes the services offered by the facility; or (c) a capital expenditure in excess of \$150,000 involving an emergency situation recognized as such by the Commissioner.
- 7.03. Application - Requests for administrative review shall be made by submission of appropriate data and information in a form prescribed by the Commissioner, to the Commissioner, with a copy to the appropriate Health Systems Agency.
- 7.04. Process - The Health Systems Agency shall, within thirty (30) days of receipt of a copy of the request for Administrative Review and following the public hearing conducted in accordance with Section 6.06.02(b) of these regulations, notify the Commissioner of its recommendation with respect to the project for which an administrative review has been requested. Failure of the Health Systems Agency to notify the Commissioner within the thirty (30) days allowed for such notification shall constitute a recommendation of approval by such Health Systems Agency. If such Health Systems Agency recommendation is unfavorable, the Commissioner shall so notify the applicant and require that a formal application be submitted pursuant to Section 6.00 of these Rules and Regulations.
- 7.05. Action on Application - The Commissioner shall determine and notify the applicant within thirty-five (35) days following receipt of the request whether a Certificate of Public Need may be issued on the basis of this information or whether a formal application for a Certificate of Public Need is required.

SECTION 8.00

DURATION/EXTENSION/REVOCATION OF CERTIFICATES

- 8.01. Duration - A Certificate of Public Need shall be valid for a period of twelve months and shall not be transferrable under any circumstances. Such certificates may be renewed, by the Commissioner, for two additional six month periods not to exceed two years from the date of issuance by which time the project shall be under construction. Extension beyond two years may be granted by the Board provided the owner can demonstrate that additional periods of time are reasonably necessary to initiate construction of the project.

8.02. Extension by Commissioner

- 8.02.01. Basis for Extension - An extension of a Certificate of Public Need during the two years following the date of issuance may be obtained from the Commissioner by submission of satisfactory evidence of progress (#8.03) being made toward the project's completion for which the Certificate of Public Need was issued.
- 8.02.02. Requests for Extension - Requests for extension shall be submitted in writing with a copy to the appropriate Health Systems Agency, at least thirty (30) days prior to the expiration date of the Certificate. Appropriate forms for extension shall be sent to the applicant by the Department sixty (60) days prior to the expiration date.
- 8.02.03. Health Systems Agency Review - Any request for an extension of a Certificate of Public Need shall be reviewed by the appropriate Health Systems Agency within twenty (20) days of receipt, the recommendations on the request by that Agency shall be forwarded to the Commissioner. Failure of the Health Systems Agency to notify the Commissioner within the time frame prescribed shall constitute a recommendation of approval by such Health Systems Agency.
- 8.02.04. Notification of Decision - Extension of Certificate of Public Need by the Commissioner shall be made in the form of a letter from the Commissioner and shall become part of the official project file.

8.03. Demonstration of Progress - Within any extension period in which a Certificate of Public Need is in force, the applicant shall provide satisfactory evidence of progress toward the implementation of the project, in accordance with the following times:

A. Twelve months following issuance:

(1) Proof of ownership or control of site; (2) documentation that the site meets all zoning and land use requirements; (3) documentation that architectural planning has been initiated; and (4) for equipment and new services projects: copies of purchase orders or lease agreements; (5) submission of preliminary architectural drawings and working drawings to appropriate State reviewing agencies and State Fire Marshall; and (6) documentation that construction financing has been completed or will be completed within two (2) months.

B. Eighteen months following issuance:

(1) Documentation that all required financing is completed; (2) initiation of preconstruction site work; and (3) advertisement of construction bids or selection of construction contractor.

C. Twenty-four months following issuance:

- (1) Documentation of awarded construction contract; and (2) initiation of construction.

8.04. Extension by Board

- 8.04.01. Basis for Extension - An extension of a Certificate of Public Need beyond the two (2) years following the date of issuance may be obtained from the Board, when the Board, in its sole discretion finds substantial and continuing progress toward the development of the project has been made. In making its determination, the Board shall consider whether: (a) delays in development of the project have been caused by events beyond the control of the owner; (b) substantial delays in development of the project may not be attributed to the owner; and (c) a reasonable time-table for completion of the project can be assured by the owner.
- 8.04.02. Requests for Extension - A request for extension by the Board shall be submitted to the Department in writing with a copy to the appropriate Health Systems Agency at least thirty (30) days prior to the expiration date of the Certificate. A format for requesting an extension by the Board shall be provided to the owner by the Department sixty (60) days prior to the expiration date of the Certificate.
- 8.04.03. Health Systems Agency Review - Any request for an extension of a Certificate of Public Need beyond two years from the date of issuance shall be reviewed by the appropriate Health Systems Agency within twenty (20) days of receipt and comments on the request by that agency shall be forwarded to the Board before decision. Failure of the Health Systems Agency to notify the Board within the time frame prescribed shall constitute a recommendation of approval by such Health Systems Agency.
- 8.04.04. Notification of Decision - An extension of a Certificate of Public Need by the Board shall be made in the form of a letter from the Commissioner and shall become part of the official project file.

8.05. Revocation

- 8.05.01. Lack of Progress - Failure of any project to meet the progress requirements stated in 98.03 shall be cause for certificate revocation, unless the Commissioner determines sufficient justification exists to permit variance, considering factors enumerated in 98.04.01.
- 8.05.02. Significant Unapproved Changes - Any significant change in the approved project, as defined in 52.24 for which the Commissioner has not granted prior written approval, shall be cause for revocation.

- 8.05.03. Failure to Initiate Construction - Failure to initiate construction of the project within two years following the date of issuance of the Certificate of Public Need shall be cause for revocation, unless due to extenuating circumstances, the Board, in its sole discretion, extends the Certificate upon written request of the applicant.
- 8.05.04. Misrepresentation - Upon determination that an applicant has knowingly misrepresented or knowingly withheld relevant data or information prior to the issuance of a Certificate of Public Need, the Commissioner shall revoke said Certificate.
- 8.05.05. Non-Compliance with Assurances - Failure to have complied with the assurances given pursuant to §5.03 of these Regulations shall be cause for revocation.
- 8.06. Reapplication - An applicant, having had its Certificate of Public Need revoked by the Commissioner, may, without prejudice or preference, re-apply, in accordance with these Rules and Regulations.

SECTION 9.00

EXEMPTIONS

- 9.01. Eligibility - Any person, formally committed and lawfully obligated to develop a medical care facility project, as defined herein, on or before December 31, 1972, shall be determined to be exempt from having to obtain a Certificate of Public Need.
- 9.02. Determination by Commissioner - The determination of whether such medical care facility project is exempt, and the extent to which such exemption shall apply, shall be made by the Commissioner, based upon satisfactory evidence and documentation submitted by the owner or proposed owner of such project to demonstrate that:
 - (1) A formal plan delineating the scope and extent of such project existed on or before December 31, 1972;
 - (2) The owner of such project was formally committed to develop such project on or before December 31, 1972, and remains legally committed to such project; and,
 - (3) The owner of such project expended or irreversibly committed \$100,000 or more toward such project on or before December 31, 1972.

SECTION 10.00

ADMINISTRATIVE HEARINGS AND APPEALS

10.01. Reconsideration of Initial Determination

- 10.01.01. Applicant Initiation - Any applicant whose application for a Certificate of Public Need has been disapproved by the Commissioner may, within thirty (30) days of the decision, request in writing, an informal fact-finding consultation conference before the Commissioner.
- 10.01.02. Health Systems Agency Initiation - In the event the Commissioner's initial determination is contrary to the recommendation of the Health Systems Agency, the Health Systems Agency may request in writing within thirty (30) days of the decision an informal fact-finding consultation conference.
- 10.01.03. Notifications and Suspensions - Upon receipt of a request for a fact-finding consultation conference, the Department shall notify the applicant, Health Systems Agency and competing applicant and suspend the Certificate(s) of Public Need in question.
- 10.01.04. Establishing Time, Date, Place - Within seven (7) days of a request for an informal fact-finding consultation conference, the Commissioner shall set a date and place for the conference which shall be within thirty (30) days of receipt of the request.
- 10.01.05. Notification of Decision - Not later than thirty (30) days following the conference the Commissioner shall affirm or vacate the initial determination and shall notify all parties of the action in writing.

10.02. Formal Evidentiary Hearing

- 10.02.01. Applicant Initiation - Any applicant whose application for a Certificate of Public Need has been disapproved by the Commissioner following the informal fact-finding consultation conference may, within thirty (30) days following the decision, request in writing a formal evidentiary hearing before the Commissioner.
- 10.02.02. Health Systems Agency Initiation - In the event that the Commissioner's decision following the informal fact-finding consultation conference is contrary to the recommendation of the Health Systems Agency, the Health Systems Agency may request in writing, within thirty (30) days of the decision, a formal evidentiary hearing before the Commissioner.

- 10.02.03. Notifications and Suspensions - Upon receipt of a request for a formal evidentiary hearing, the Department shall notify the applicant, Health Systems Agency and competing applicant and suspend the Certificate(s) of Public Need in question.
- 10.02.04. Establishing Time, Date, Place - Within seven (7) days following receipt of a request for a formal evidentiary hearing the Commissioner shall set a time, date and place for a formal hearing which shall be within thirty (30) days of receipt of the request.
- 10.02.05. Notification of Decision - Not later than sixty (60) days following completion of the hearing record, the Commissioner shall provide written notification of a request for a formal evidentiary hearing, setting forth his final decision and the reasons therefor.

10.03. Formal Independent Hearing

- 10.03.01. Applicant/Health Systems Agency Initiation - Any applicant whose application for a Certificate of Public Need has been disapproved or any Health Systems Agency whose recommendation was contrary to a final decision of the formal evidentiary hearing may, within thirty (30) days request in writing, a formal hearing proceeding before an independent hearing examiner. The hearing examiner shall be appointed by the Governor from an agency of State government other than the Department.
- 10.03.02. Notifications and Suspensions - Upon receipt of a request for a formal independent hearing, the Department shall notify the applicant, Health Systems Agency and competing applicant and suspend the Certificate(s) of Public Need in question.
- 10.03.03. Establishing Time, Date, Place - Within thirty (30) days following receipt of a request for a formal independent hearing, the Department, in consultation with the appointed hearing examiner, shall set a time, date and place for the formal independent hearing.
- 10.03.04. Limitations of Review - The review of the hearing examiner shall be limited to a determination of whether there was substantial procedural compliance and whether the Commissioner exceeded his discretion in evaluating the evidence presented.

- 10.03.05. Required Consideration - The hearing examiner shall take due account of the presumption of official regularity, the experience and specialized competence of the Commissioner, and the purposes of the Virginia Medical Care Facilities Certificate of Public Need Law.
- 10.03.06. Authority of Hearing Examiner - The hearing examiner shall be empowered to affirm or vacate the decision of the Commissioner and remand the matter to the Commissioner for such further proceedings as are appropriate.
- 10.03.07. Notification of Decision - The hearing examiner shall notify the applicant, Health Systems Agency and competing applicant of the decision and the reasons therefor in writing within thirty (30) days following completion of the hearing record.

10.04. Court Review

- 10.04.01. Appeal to Circuit Court - Any applicant aggrieved by the final decision of the Hearing Examiner may, within thirty (30) days after receipt of notice of the Hearing Examiner's decision, obtain a Circuit Court review in accordance with Section 32-211.9, Code of Virginia (1950), as amended.
- 10.04.02. Appeal to Supreme Court - The applicant may appeal the decision of the Circuit Court in the same manner as appeals are taken and as provided by law.

SECTION 11.00

SANCTIONS

- 11.01. Violation of Virginia Medical Care Facilities Certificate of Public Need Law - Any person, partnership, firm, company, trust, association corporation, or other legal entity, which commences, constructs or undertakes construction of a medical care facility project without having obtained a Certificate of Public Need or during the pendency of an order of suspension, shall be guilty of a misdemeanor and upon conviction, shall be punished by a fine of not less than fifty dollars (\$50) nor more than one thousand dollars (\$1,000).
- 11.02. Violation of Rules and Regulations - Any person who shall violate, disobey, refuse, omit, or neglect to comply with any of these Rules and Regulations shall be subject to the provisions of Section 32-6.4 of the Code of Virginia (1950), as amended.
- 11.03. Injunctive Relief - Any court of record having chancery jurisdiction in the county or city where a proposed project is under construction or is intended to be constructed, located, or undertaken shall have jurisdiction to enjoin, on petition of the Commissioner, the Board or the Attorney General, any project which is constructed, undertaken, or commenced without the required Certificate of Public Need as referred to herein.

SECTION 12.00

SEVERABILITY CLAUSE

- 12.01. If any clause, sentence, paragraph, subdivision, section or part of these Rules and Regulations, shall be adjudged by any court of competent jurisdiction to be invalid, the judgement shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, subdivision, section or part thereof directly involved in the controversy in which the judgement shall have been rendered.

JULY 1, 1978 AMENDMENTS TO RULES AND REGULATIONS FOR
IMPLEMENTATION OF VIRGINIA MEDICAL CARE FACILITIES
CERTIFICATE OF PUBLIC NEED LAW

- (1) In Section 2.17 following the word "organization," add the words "home health agencies" to the definition of "Medical Care Facilities."

2.17 "Medical Care Facilities:" Any institution, place, building or agency whether or not licensed or required to be licensed by the State Board of Health or the State Mental Health and Mental Retardation Board, by or in which facilities are maintained, furnished, conducted, operated, or offered for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition, whether medical or surgical, of two or more non-related mentally or physically sick or injured persons, or for the care of two or more non-related persons requiring or receiving medical, surgical or nursing attention or services as acute, chronic, convalescent, aged, physically disabled, or crippled, including, but not limited to a general hospital, sanatorium, sanatorium, nursing home, intermediate care facility, extended care facility, health maintenance organization, home health agency, mental hospitals, mental retardation facility and any other related institution and facility, whether operated for profit or nonprofit, and whether privately owned or operated or owned or operated by a local governmental unit or which is the recipient of reimbursements from third party health insurance programs or prepaid medical services plans. The term shall also include intermediate care facilities established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts. This term shall not include a physician's office; provided, however, the term "physician's office" shall not include independent laboratories or specialized centers or clinics developed for the provision of outpatient or ambulatory surgery, renal dialysis therapy, radiation therapy, computerized tomography (CT) scanning, or other medical or surgical treatments requiring the utilization of equipment not usually associated with the provision of primary health services, the cost of which exceeds two hundred thousand dollars (\$200,000) per unit of equipment. The term "medical care facility" shall not include a first aid station for emergency medical or emergency surgical treatment.

- (2) Following Section 4.14, add a new subsection, 4.15, stating additional factors that the Commissioner must consider in determining public need.

4.15 The area, population, topography, highway facilities and availability of such services in the particular part of the health service area in which the facility is proposed.

RULES AND REGULATIONS

(u)

economically feasible." This standard was developed by the Department in this context.

A number of sources support a minimum unit size of 20 pediatric beds, including planning agencies in California, Massachusetts, Ohio, Pennsylvania, and Wisconsin. Consolidation of pediatric care in units of at least 20 beds in urbanized areas will promote the concentration of nursing and support staff with special pediatric knowledge and skills, the increased training of staff, and the provision of special treatment and other ancillary facilities which meet the special needs of children. (A pediatric inpatient unit is a specific section, ward, wing, hospital or unit devoted primarily to the care of medical and surgical patients usually less than 18 years old, not including special care for infants.)

The criteria of 30 minutes travel time reflects interest in ensuring that children remain close to their homes, family and friends. Frequent visits to hospitalized children are highly desirable and can be an aid to improvement and recovery. The American Academy of Pediatrics has recommended to its State Chapters that child health plans should provide that primary care for children should be available within 30 minutes. This access standard is consistent with those of many local and State planning agencies such as those in Massachusetts, New York, Pennsylvania, and Wisconsin.

§ 121.206 Pediatric inpatient services—occupancy rates.

(a) *Standard.* Pediatric units should maintain average annual occupancy rates related to the number of pediatric beds (exclusive of neonatal special care units) in the facility. For a facility with 20-39 pediatric beds, the average annual occupancy rate should be at least 65 percent; for a facility with 40-79 pediatric beds, the rate should be at least 70 percent; for facilities with 80 or more pediatric beds, the rate should be at least 75 percent.

(b) *Discussion.* Variable occupancy rates are designed to reflect the need for smaller units to maintain the capacity to accommodate normal day-to-day fluctuations in admissions and to set aside pediatric beds for particular ages and types of cases. Such scheduling problems are less severe in pediatric units of a greater capacity. Moreover, large units are able to sustain higher occupancy rates because they are frequently associated with regional centers which serve patients needing types of care that can be scheduled on a more flexible basis. It is not intended, of course, to encourage unnecessary admissions or stays to achieve these levels. This standard is identical to that recommended by the American Academy of Pediatrics.

§ 121.207 Open heart surgery.

(a) *Standard.* (1) There should be a minimum of 200 open heart procedures performed annually, within three years after initiation, in any institution in which open heart surgery is performed for adults.

(2) There should be a minimum of 100 pediatric heart operations annually, within three years after initiation, in any institution in which pediatric open heart surgery is performed, of which at least 75 should be open heart surgery.

(3) There should be no additional open heart units initiated unless each existing unit in the health service area(s) is operating and is expected to continue to operate at a minimum of 350 open heart surgery cases per year in adult services or 130 pediatric open heart cases in pediatric services.

(b) *Discussion.* Open heart surgery for congenital and acquired heart and coronary artery disease represents a marked advance in patient care. Highly specialized open heart procedures require very costly, highly specialized manpower and facility resources. Thus, every effort should be made to limit duplication and unnecessary resources related to the performance of open heart procedures, while maintaining high quality care. Minimum case loads are essential to maintain and strengthen skills. (Open heart surgery procedures are defined as procedures which use a heart-lung by-pass machine to perform the functions of circulation during surgery.)

A minimum of 200 adult open heart surgery procedures should be performed annually within an institution to maintain quality of patient care and make most efficient use of resources. This standard is based on recommendations of the Inter-Society Commission on Heart Disease Resources. In order to prevent duplication of costly resources which are not fully utilized, the opening of new units should be contingent upon existing units operating, and continuing to operate, at a level of at least 350 procedures per year. The 350 level assumes an average of 7 operations a week, a schedule that in the Department's judgement is feasible in most institutions providing these services. In units that provide services to children, lower targets are indicated because of the special needs involved. The established level for pediatric units is consistent with the recommendation of the Pediatric Cardiology Section of the American Academy of Pediatrics. In determining the utilization target of 130 pediatric open heart cases, the Department used the same ratio as for adult units. In the case of units that provide services to both adults and children, at least 200 open heart procedures should be performed, including 75 for children. In some areas, open heart surgical teams,

including surgeons and specialized technologists, are utilizing more than one institution. For these institutions, the guidelines may be applied to the combined number of open heart procedures performed by the surgical team where and adjustment is justifiable in line with Section 121.6(B) and promotes more cost effective use of available facilities and support personnel. In such cases, in order to maintain quality care a minimum of 75 open heart procedures in any institution is advisable, which is consistent with recommendations of the American College of Surgeons. Data collection and quality assessment and control activities should be part of all open heart surgery programs.

§ 121.208 Cardiac catheterization.

(a) *Standard.* (1) There should be a minimum of 300 cardiac catheterizations, of which at least 200 should be intracardiac or coronary artery catheterizations, performed annually in any adult cardiac catheterization unit within three years after initiation.

(2) There should be a minimum of 150 pediatric cardiac catheterizations performed annually in any unit performing pediatric cardiac catheterizations within three years after initiation.

(3) There should be no new cardiac catheterization unit opened in any facility not performing open heart surgery.

(4) There should be no additional adult cardiac catheterization unit opened unless the number of studies per year in each existing unit in the health service area(s) is greater than 500 and no additional pediatric unit opened unless the number of studies per year in each existing unit is greater than 250.

(b) *Discussion.* The modern cardiac catheterization unit requires a highly skilled staff and expensive equipment. Safety and efficacy of laboratory performance requires a case load of adequate size to maintain the skill and efficiency of the staff. In addition, the underutilized unit represents a less efficient use of an expensive resource and frequently reflects unnecessary duplication. Based on recommendations from the Inter-Society Commission on Heart Disease Resources, the Department believes that a minimum level of 300 catheterizations per year is indicated to achieve economic use of resources. Several State health planning agencies, such as New Jersey, suggested a higher minimum level and the Department will be considering whether a higher level should be established in the future. The Department has also determined the existing units should be performing more than 500 cardiac catheterizations or 250 pediatric cardiac catheterizations before a new unit is opened. The 500 level is

STATE BOARD OF HEALTH
COMMONWEALTH OF VIRGINIA



1979

STATE MEDICAL FACILITIES PLAN

6. OPEN HEART SURGERY FACILITIES

6.1 Introduction and Definition

Open heart surgery procedures are defined as procedures which use a heart-lung by-pass machine to perform the functions of circulation during surgery.¹ (Cardiac surgery procedures that do not require the use of a by-pass pump are designated closed heart procedures). An open heart surgery unit is defined as an operating room equipped to provide for open heart surgery procedures.

6.2 Current Status

There were 5 facilities reporting the performance of open heart surgery in the State during 1978. Table 6-1 below summarizes information describing the existence and use of open heart surgery facilities in the

TABLE 6-1

INVENTORY AND UTILIZATION DATA FOR
OPEN HEART SURGERY FACILITIES
(1978 LICENSURE SURVEY DATA)

<u>HSA</u>	<u>PD</u>	<u>Institution</u>	<u>City</u>	<u># of Open Heart Procedures</u>		<u># of Units</u>	<u>Cardiac Cath. Lab</u>
				<u>Adult</u>	<u>Ped</u>		
I	10	Univ. of Va.	Charlottesville	281	45	2 ^a	yes
II	8	Fairfax Hospital	Falls Church	260	0	1	yes
IV	15	Richmond Veterans	Richmond	136	0	1	yes
IV	15	M.C.V.	Richmond	700	80	2	yes
V	20	Norfolk General	Norfolk	278	43	1	yes
VI	--	Holston Valley Hosp.	Kingsport, TN	will begin Aug/Sept 79		1	yes

^aAt the University of Virginia one of the operating rooms is used almost entirely for cardiac surgery. The second room is equipped in order to allow management of emergency cases requiring open heart surgery when the other room is in use but the second room also serves for the performance of all of the thoracic and vascular surgery.

Sources: 1978 Annual Survey of Medical and Nursing Facilities and Health Systems Plans

¹Federal Register, vol. 43 & 60, March 28, 1978--National Guidelines

1 applicable and the last one says -- let me get the wording
2 right here -- ". . . agency action which encompasses
3 matters subject by law to a trial de novo in any court."
4

5 Our position is, whether or not
6 Riverside was entitled to a certificate in the first
7 place is a subject of a trial de novo, which is what
8 we have here, a motion for declaratory judgment.

9 In summary, it's very simple.

10 There was never any case decided here, never any
11 regulation adopted. It was simply an expression of
12 an opinion. If the position of the Commonwealth is
13 supported today, it seems to me it means nothing less
14 than a ruling by the Court it was the intention of the
15 Legislature to confer upon Dr. Kenley the authority
16 which has always been vested in courts, to make judicial
17 determinations or adjudications in a declaratory judgment
18 action. He can simply, in response to a telephone call
19 from some hospital or other health provider, say, "No,
20 you're not going to do that. You have to apply for a
21 Certificate of Need," and according to the Commonwealth,
22 that's a case decision and unless you follow the pro-
23 cedure set forth here with the attendant time limitations,
24 you have no access to any judicial relief. I say simply
25 that was not the intention of the Legislature.

1 It was not intended to vest Dr. Kenley with the
2 authority to render declaratory judgments which are
3 legally binding on people in situations where all he
4 has done --

5 THE COURT: What did he do? Just
6 write his --

7 MR. DOWDING: They just contacted
8 him some way and he wrote the letter which is attached,
9 which says that in his opinion, he concludes -- it's
10 there with the file -- I don't know whether I'm mis-
11 quoting -- that in one area of heart surgery, the
12 hospital can go on, but in the area of open heart
13 surgery, the hospital has got to apply for a Certificate
14 of Need.

15 THE COURT: And they applied?

16 MR. DOWDING: Yes, sir. And that's
17 going on now. After looking back and re-evaluating the
18 situation, we conclude we should never have applied
19 for the certificate in the first place. That's why
20 we filed this motion for declaratory judgment in an effort
21 to obtain by this Court, after hearing the very limited
22 evidence as to what the situation was with the open
23 heart surgery program at that particular time -- our
24 position is going to be that we were not required to
25

1 apply for a certificate, that Dr. Kenley's opinion was
2 erroneous and that our program at that time was, although
3 not an active program, was still a viable, ongoing program
4 which we could simply start up again without going through
5 the certificate process.

6 But this procedure has to do with
7 situations where there has been a hearing, evidence
8 has been presented in some form, a formal order, as
9 referred to in these rules, has been entered by the
10 Commissioner. Otherwise, you've got a situation where
11 Dr. Kenley has the right to make an adjudication, a
12 declaratory judgment, if you please, and the only
13 remedy a party would have would be to go through this
14 proceeding.

15 THE COURT: No hearing?

16 MR. DOWDING: No hearing and no
17 order. The only thing that was ever filed, to my
18 knowledge, was this letter. Whether there were some
19 conferences -- I'm sure there probably were, hospital
20 personnel and Dr. Kenley. I don't even know whether
21 it was personally or over the telephone, to be frank
22 with Your Honor. Certainly the sending of a letter
23 does not constitute entry of a final order.

24 MR. ADAMS: It's attached to Dr.
25

1 Kenley's affidavit, Judge.

2 THE COURT: And is this the letter,
3 sir, that you contend is a decision, a case decision?

4 MR. ADAMS: Yes, sir.

5 MR. DOWDING: I think I have finished.

6 MR. ADAMS: Judge, I think his
7 argument is basically answered by the York Street Inn
8 case, which I attached to my brief. Of course, it's
9 a fairly recent case from the Supreme Court. In that
10 case, there apparently, again, was a letter or some
11 very informal communication from a state agency, saying
12 that a bar could not use this backgammon type of decor
13 as a table in the bar, and I think it's clear from
14 Justice Poff's opinion that the Court unanimously
15 construed that to be a "case decision" and I think once
16 that is realized, then --

17 THE COURT: Well, you're setting
18 this Commissioner of Health up as a czar. He's a court
19 unto himself. All he's got to do is answer a letter and
20 that's a ruling.

21 MR. ADAMS: Judge, I think if you
22 just look at other aspects of government, for example,
23 you can make an inquiry of the Commissioner of Internal
24 Revenue and get a ruling from him and that's perfectly
25

1 acceptable. If you don't like that, you can appeal
2 to a court in a timely fashion. We're not making the
3 Health Commissioner a czar, but at the same time, when
4 a facility approaches him in a formal nature, as they
5 did in this particular case, and he takes the time out
6 with his staff to look at all the information that's
7 provided him and to engage in whatever types of consulta-
8 tions are necessary with the facility and then renders
9 a decision, then it seems to me, when you look at the
10 General Assembly's intention in the Administrative
11 Process Act, which is intended to supplement laws
12 where they just don't provide for this type thing, then
13 it seems to me clear it was incumbent upon the hospital
14 to tell him, "No, we disagree with your opinion." Instead,
15 they made application, which, to my mind, means at that
16 time, they agreed with his decision and acceded to his
17 view of the law. Had they disagreed, they should have
18 in some fashion said, "No. We disagree with you." They
19 didn't do that. Only two years later they try to blow
20 life into that action. So I don't think anybody can
21 fairly accuse the Health Commissioner of doing anything
22 unfair to the facility.

23 THE COURT: I didn't do that.

24 MR. ADAMS: I understand that, sir.
25

1 All I'm saying, the General Assembly put the Administrative
2 Process Act in for a purpose. If we permit this
3 particular declaratory judgment to go forward --

4 THE COURT: Was there a hearing or
5 anything on this?

6 MR. ADAMS: Judge, I don't believe
7 there was any hearing in a formal courtroom type --

8 THE COURT: Was there any order
9 entered?

10 MR. ADAMS: I believe his letter
11 was an order.

12 THE COURT: I disagree with that.
13 I can't enter an order by writing a letter. I don't
14 know why the Health Commissioner can.

15 MR. ADAMS: I believe if you will
16 look at the York Street Inn case, you'll see that's all
17 they have is a letter.

18 THE COURT: I looked at that case.

19 MR. ADAMS: Yes, sir.

20 THE COURT: I'm going to overrule
21 the demurrer. I think they have a right to proceed
22 to determine whether or not they had to apply for a
23 Certificate of Need in the first place. I don't believe
24 the Commissioner has authority just to answer an inquiry
25

1 and that becomes full force and effect of the law. I
2 just don't believe that's right. If that's what the
3 statute says, seems like to me that statute is
4 unconstitutional. Anyway, I overrule it.

5 MR. ADAMS: Very well, Judge. I
6 wish you would reconsider, because I think you're
7 making a mistake.

8 THE COURT: I don't think I made a
9 mistake. I think I'm right.

10 MR. ADAMS: While we're here, if
11 I could raise one other issue before I get back on the
12 road, I filed some discovery back in June. I didn't
13 push on it.

14 MR. DOWDING: I can assure you it
15 will be answered in the immediate future. Really, I
16 probably should have called you. I simply told the
17 hospital, "Take your time getting the information
18 necessary to answer these interrogatories," because, you
19 know, as a matter of fact, I got the interrogatories
20 before I got the demurrer, so I said, "Well, maybe the
21 cart is ahead of the horse." But anyway, in any event,
22 if you would like an order, I'll be glad to endorse
23 an order. We'll file the answers within a few weeks
24 or three weeks.
25

1
2 GERALD R. BRINK, after being first
3 duly sworn, testified in behalf of the Plaintiff, as
4 follows:

5 DIRECT EXAMINATION

6 BY MR. DOWDING:

7 Q What is your name?

8 A Gerald R. Brink.

9 Q And what is your position with
10 Riverside Hospital?

11 A Executive Vice President.

12 Q And that places you where in the
13 order of seniority or command in the administrative setup
14 in the hospital?

15 A Administrator of the hospital.

16 Q How long have you been employed
17 by the hospital?

18 A Approximately fifteen and a half
19 years.

20 Q And tell us, quickly, which positions
21 you have held during that period of time.

22 A I began as Administrator Resident
23 and Assistant Administrator and Associate Administrator
24 and now Executive Vice President.

25 Q All right. Now, Mr. Brink, at my

1 request, have you researched the available documents
2 and other material at the hospital so that you can give
3 the Court sort of a chronological history of the
4 Department of Cardiology at Riverside, with particular
5 reference to the surgical program?

6 A Yes, sir.

7 Q All right. When was the department
8 first established?

9 A It was September of '71, when our
10 first Director of Cardiology arrived at the hospital.

11 Q And that was who?

12 A Dr. Morgan.

13 Q Is he still there?

14 A Yes, sir.

15 Q And, basically, what was the object
16 of the program at that time?

17 A The object of the cardiology program
18 was to establish or bring in a cardiologist to supervise
19 our Cardiology Department and to begin the development
20 of the open heart surgery program.

21 Q And you speak of the "open heart
22 surgery program." Can you tell the Court generally
23 what type of surgery you're referring to?

24 A Well, again, I'm a lay person, but
25

1 we were referring to, at that time, the open heart
2 surgery program included everything, in our minds,
3 that had to do with any kind of cardiovascular surgery
4 including opening the heart and assisting with the pump.
5

6 Q All right. Now, can you tell us
7 when the first surgical procedure in which a pump was
8 actually used was performed at Riverside?

9 A February 2, 1973.

10 Q And by whom was that surgery
11 performed?

12 A The major physician was Dr. Bosher.

13 Q I believe he's a surgeon from the
14 Medical College of Virginia?

15 A Yes, sir.

16 Q And generally speaking, what are
17 the necessary components for the team to perform this
18 particular type surgery? And by the way, unless I
19 specify differently, I'm speaking of procedures in
20 which the pump is actually turned on and used on the
21 patient.

22 A Of course, there's a surgeon,
23 who's the most critical part; and usually there's an
24 assistant surgeon, or there was when we were doing it;
25 the anesthesiologist; the pump technicians; the nurses

1 or the surgical staff, nurses or technicians; and
2 other ancillary personnel, such as the lab technicians
3 and such, which had to do the blood work and chemistry,
4 which they needed instantly.

5 Q Now, over what period of time were
6 these procedures performed?

7 A I'm assuming you're meaning in
8 years?

9 Q Yes. You said the first was
10 February 2, 1973. When was the last?

11 A Last performed was September 3,
12 1976, when we actually used the pump.

13 Q All right. Now, during that period
14 of time, do you know how many of these procedures were
15 performed?

16 A No. Offhand, I don't have that
17 number with me.

18 Q All right. But in any event, what
19 personnel were used other than Riverside personnel?

20 A Well, what we tried to do when
21 we built the program, we did not want to have the
22 cost, we wanted to be cost effective, so as we started
23 it, we worked out with Dr. Bosher that he would bring
24 his people down, which included the pump technicians and
25

1 anesthesiologists, to assist us with establishing a
2 program. So we didn't have to have these expensive
3 people on right at the beginning of the program.
4 The idea there was that we would establish the program,
5 that it would become very functional and we would, as
6 time passed, we would hire our own technicians, pump
7 technicians, and have our own anesthesiologists
8 perform the program. So we were relying, during that
9 period of time, basically on his team. In the process
10 of that, we did hire our own pump technicians and
11 train them and have them perform those procedures.

12 Q Before we get to that, were some
13 of the procedures performed by doctors on the staff
14 at Riverside?

15 A Yes.

16 Q Both in association with Dr. Boshier
17 and without him being there?

18 A Yes. Dr. Boshier was actually
19 brought in with association with the Winfrey, Graham
20 and Umstott group. They did as many and they did, also,
21 during that period of time, perform some surgery on
22 their own.

23 Q That is, Dr. Boshier would not be
24 there, but his pump technicians and anesthesiologist --
25

1 A Nurse and anesthesiologists.

2 Q Nurse and anesthesiologists were
3 there. All right. Now, what was the situation subsequent
4 to September of 1976? You said the last procedure was
5 done then. Can you explain to the Court what took
6 place from that point on, as far as this type procedure
7 was concerned?

8 A Well, even during that period of
9 time, we were recruiting people for our own staff so it
10 could be a self reliant program. As I said before,
11 we did recruit a pump technician and that part of the
12 program was stable.

13 Q While we're on that subject, can
14 you give us the dates that the pump technician was
15 employed at Riverside?

16 A Yes, I can. It was November 11 of
17 1974.

18 Q Until when?

19 A He was there for three years.
20 Coincidentally, he left on November 11, 1977. To go
21 on with the sequence, September 3, 1976, the reason
22 we suspended the program at that time is because Dr.
23 Bosher's anesthesia coverage was no longer available
24 and we had not been successful at that time in obtaining
25

1 enough anesthesiologists to be able to cover the program
2 full time and, therefore, it was the decision of the
3 Surgical Executive Committee, the Executive Committee
4 of the hospital staff and the hospital administration
5 to suspend the program until we could assure that we
6 would have the proper time and provide the proper quality
7 of that program. At no time were we under the under-
8 standing that there was any kind of Certificate of Need
9 regulation that would hold us from opening the program
10 back up again.

11 Q All right. Now, the anesthesia
12 problem, you say that the MCV anesthesia was no longer
13 available?

14 A Yes.

15 Q Were there anesthesiologists on
16 the staff of Riverside in September of '76, who were
17 qualified and competent to do the anesthesia work in
18 connection with this type procedure?

19 A Yes, sir. Two of the anesthesiologists
20 were qualified at that time to provide anesthesia with
21 the pump. However, they were used on a routine daily
22 schedule and time allotment. We would have had to
23 sacrifice a lot of the other programs in order to
24 pull them out to do the open heart surgery. That's why
25

1 it was decided to suspend, you know, the routine provision
2 of that procedure at that time.

3 Q All right. Now, the next basic
4 period of time would be from September of 1976 until
5 December of 1977, that being the date of Dr. Kenley's
6 letter. Were there patients at Riverside who were
7 referred by their attending cardiologists for this
8 type of surgery?

9 A Yes, sir, there were, and we have
10 submitted a list, and I think it's in the evidence there,
11 of the number of cases that were available, but at
12 that time were referred on to probably MCV at that time
13 to perform the cases.

14 Q And the statistics as to the number
15 of patients who were referred during this period of
16 approximately fifteen months is in the documents which
17 have been submitted?

18 A Yes.

19 Q Now, during that same period of
20 time, at least from September of '76 until, I believe
21 you said November 11, '77, when the pump technician
22 resigned --

23 A Yes.

24 Q Was he on duty full time, on the
25

1 payroll full time?

2 A He was on duty full time and he
3 was on call as the pump technician in case we ever
4 needed him.

5 Q And as far as the other equipment
6 and facilities that were needed to perform this type
7 surgery, were they present at the hospital?

8 A Present and fully operational, yes.

9 Q All right. And can you describe,
10 just in summary fashion for the Court, the physical
11 facilities and equipment required that are present
12 there?

13 A We have a room in the surgery
14 which was designed for open heart surgery. At that
15 time, it was one of our older rooms. We added four
16 surgical suites in 1972-73 and at that time, we
17 renovated one of the surgical rooms to be specifically
18 for open heart surgery. There was an additional pump
19 room to handle all the equipment monitoring necessary.
20 At the same time, or not at the same time, but a few
21 years later, because of the volume of open heart
22 catheterizations, which are the principal determinant
23 of open heart surgery, we applied for and received a
24 certificate which included the construction of our
25

1 heart catheterization lab and, which, our statistics
2 and reason for the heart cath lab was because of open
3 heart surgery.

4 Q And the physical expansion of the
5 plant at Riverside to construct the catheterization
6 laboratory required a Certificate of Need?

7 A Yes.

8 Q And that was received and a copy
9 of that has been submitted with the documents. Now,
10 perhaps, for the record, would you tell us, just
11 basically, what the lab is, what function it performs
12 and to what extent it was utilized during this period?

13 A The cath lab?

14 Q Yes.

15 A I could tell you a little bit about
16 that. A cardiologist or physician could go into
17 detail more, but --

18 Q Just basically what its function is.

19 A Its function is for the cardiologist
20 to determine, again, through the X-ray and catheterization
21 procedure, whether or not a patient is in need of open
22 heart surgery.

23 Q And is that lab in use full time or
24 was it in use during these periods of time that we're
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1 on a standby basis?

2 A Yes, sir. There were. I believe
3 the statistics on that are also submitted, and I think
4 at that time, it was between that period of time there
5 were six pericardiectomies performed in which they
6 required a pump assistant to be on the standby.

7 Q During those procedures, was the
8 pump technician available?

9 A The pump technician was available
10 and there at that time, yes, sir.

11 Q Was an anesthesiologist present?

12 A Plus the anesthesiologist.

13 Q And to the best of your knowledge,
14 was there anything in the way of equipment, personnel
15 or otherwise that was not present when these procedures
16 were done, that would have been necessary had it
17 become necessary to use the pump?

18 A No. The physicians had specified
19 at that time that they were performed in the open heart
20 surgery room and everything was available in case they
21 needed to be set up on the pump.

22 Q Now, can you describe for the Court,
23 Mr. Brink, what other activity was going on at the
24 hospital, what other efforts were being made during
25

1 this period of time in connection with -- when I
2 say "program," I am, again, still talking about the
3 procedures requiring the pump to actually be used --
4 as far as recruitment or otherwise?

5 A Well, we were constantly recruiting
6 for one or two more anesthesiologists and we specified
7 these anesthesiologists, if they came to Riverside,
8 had to be open heart pump trained, and during that
9 process, we did attract an anesthesiologist that, at
10 that time, was Dr. Allmond, and I think he arrived,
11 his privileges were approved on May 26 of '77. So
12 we were able to accomplish having the anesthesia at
13 that time and we had the pump technician and then we
14 began again the planning stages of pulling together
15 and assuring that this program was a high quality and
16 operational program until we received the correspondence,
17 which was referred to earlier, from HSA. Our first
18 correspondence, we thought was just a routine correspondence
19 because we knew that the HSA did not have, at that time,
20 the authority to close down programs, and so we answered
21 it as quickly as possible. When we discovered that it
22 was becoming a question of whether or not we could
23 open up the program, then I think a lot of wheels started
24 turning and things became very serious because that was
25

1 the first time we were aware that somebody was going
2 to tell us that we couldn't continue our program.

3 Q And was your first notice of this
4 Dr. Kenley's letter to Mr. Boynton, dated December 27,
5 with a copy to you and a copy to Mr. St. Clair?

6 A That was the first official --
7 that was the first notice we had from Dr. Kenley, yes.

8 Q For the record, who is Mr. St.
9 Clair?

10 A Mr. St. Clair is the President
11 of the corporation.

12 Q And he formerly occupied the
13 position of Administrator?

14 A Of Administrator, yes.

15 Q And this came to your attention,
16 this letter?

17 A Yes.

18 Q And your interpretation of it was
19 what?

20 A Well, my interpretation, at that
21 time, was, since Dr. Kenley is the final voice in
22 the Certificate of Need process, was, my gosh, we better
23 abide by it. He said it was, you know, a finding and
24 we certainly were disappointed.
25

1 Q And thereafter, there was
2 additional correspondence, etc., which has been
3 submitted, which I'm sure you're familiar with. And
4 the purpose of that was what?

5 A The purpose of that correspondence
6 was basically to appeal to him and say that we did have
7 an ongoing program and we didn't feel it fit under
8 any twelve month restriction, because we didn't know
9 of any twelve month restriction at that time. I would
10 say if we knew there was a twelve month restriction,
11 we would have been performing open heart surgery. We
12 would have convinced Dr. Bosher and we would have
13 hired -- we would have gone out and continued the
14 program somehow if we would have known there would
15 have been a restriction to reopen.

16 Q My next question was, had you
17 ever heard of any twelve month restriction of any kind
18 prior to receiving a copy of that letter?

19 A Not in the State statutes, no, sir.
20 BY THE COURT:

21 Q Question was, did you know of any
22 restriction? The question, sir, was, did you know of
23 any twelve months restriction?

24 A I haven't reviewed them, so I'm not
25

1 sure of the dates and I read a lot of things since
2 then, but the federal statute did mention something
3 about twelve months, but I don't know exactly when
4 that was. I don't know if it's prior or after or
5 what.

6 BY MR. DOWDING:

7 Q Of course, Dr. Kenley doesn't have
8 anything to do with enforcement of federal statutes?

9 A No, sir. We deal, Dr. Kenley
10 deals with the State statutes.

11 Q Now, the hospital did eventually
12 apply for a Certificate of Need?

13 A Yes, sir. We were told we had
14 to and we do want the program, so we applied for a
15 Certificate of Need.

16 Q And incidentally, Mr. Brink, when
17 you received a copy of Dr. Kenley's letter of December
18 27, did you undertake to investigate the legal
19 technicalities of it or anything of that nature?

20 A Well, we knew that it wasn't in
21 the regulations. We looked at the regulations and
22 it wasn't there and this is what we appealed to Dr.
23 Kenley on, the fact it wasn't in the regulations and
24 shouldn't be enforceable to us.
25

1 Q And that is reflected in the later
2 c orrespondence?

3 A Yes, it is.

4 Q But in any event, you received
5 subsequent correspondence from him, reaffirming his
6 position?

7 A That we had to apply for a
8 Certificate of Need.

9 Q And you went ahead and applied.
10 All right. Just a moment.

11 BY THE COURT:

12 Q I'm not quite clear as to what's
13 happened to this application. What happened to the
14 application?

15 A The application for Certificate of
16 Need was denied by Dr. Kenley and we since appealed it
17 and went through the first informal hearing, are in
18 the stages of determining whether or not it should go
19 to -- correct me if I'm wrong -- but to the formal
20 hearing stage, which could take a decent period of time.

21
22 MR. DOWDING: There is a rather
23 involved appeal procedure connected with
24 that. I might say, in response to Your
25

1 Honor's comment, we feel that -- our position
2 is that we should never have had to apply
3 for the Certificate of Need.

4 THE COURT: I understand your position.
5 I'm just wondering what happened to it.
6 What is it? In some administrative appeal?

7 MR. DOWDING: Yes, sir. As I under-
8 stand it, the hospital and the Health
9 Department have agreed to hold in abeyance
10 the next stage of the administrative appeal
11 process pending the outcome of this suit.

12
13 BY MR. DOWDING:

14 Q Is that your understanding?

15 A Yes.

16 Q One other point, Mr. Brink. As
17 far as the recruitment of personnel is concerned on
18 your staff, now, what is the situation as far as surgeons
19 are concerned? Do you still have Drs. Winfrey and
20 Umstott and Graham on your staff?

21 A And Dr. Calhoun.

22 Q Who is Dr. Calhoun and what is his
23 specialty?

24 A Dr. Calhoun joined the group of
25

1 Hop Graham and Charlie Umstott. Hop Graham is a fully
2 trained open heart surgeon. He came to Riverside --

3 Q But I mean -- you said "Graham."
4 You mean Calhoun?

5 A I'm sorry. Calhoun. He's fully
6 trained. He came to Riverside Hospital to perform open
7 heart surgery and at this time hasn't been allowed to
8 do that because of the problem that we're in here today.
9 We, in turn, have three anesthesiologists who are pump
10 trained and we have an application for another one
11 who wants to come to Riverside if we have an open heart
12 surgery program at this time.

13
14 MR. DOWDING: All right, sir. I
15 think that's all I want to ask you at this
16 time. Answer Mr. Adams, please.

17
18 CROSS EXAMINATION

19 BY MR. ADAMS:

20 Q Mr. Brink, just one point for clarifi-
21 cation. There were actually two communications, weren't
22 there, from Dr. Kenley? One was dated December 27,
23 1977, which was a letter from Dr. Kenley to Mr. Boynton,
24 that you got a copy of?
25

1 A Right.

2 Q And then you or the hospital
3 apparently solicited Dr. Kenley's opinion again
4 sometime in 1978 and he then sent a letter to the
5 hospital, dated November 28, 1978, indicating that he
6 felt you had to apply for a Certificate of Need; is
7 that not correct?

8 A I don't have that right in front
9 of me.

10
11 THE COURT: November 21st, wasn't it?

12 MR. ADAMS: November 21st. Excuse
13 me, Your Honor. You've got hold of the
14 facts better than I do.

15
16 A I believe that's true. I don't
17 have it in front of me.

18 BY MR. ADAMS:

19 Q I'll show you this letter, which
20 I will represent to the Court is an accurate copy of
21 what's been introduced into evidence.

22 A Yes.

23 Q So there have been two communica-
24 tions from the Health Commissioner, one in late '77 and
25

1 one in late '78. Am I correct in understanding, Mr.
2 Brink, you have testified the last time the hospital
3 used the open heart machine was in September of '76; is
4 that correct?

5 A The last time we actually attached
6 it to the patient, yes.

7 Q From September of '76, that last
8 time you used the machine, to the present, have you
9 actually offered to the public or to the medical
10 community open heart surgery?

11 A Yes. We held out that we offered
12 the open heart surgery program between that time.

13 Q When did you do that?

14 A I don't remember offhand. It's in
15 the files, I know that.

16 Q Can you give an approximation?

17 A year? A month?

18 A I believe it's probably in October,
19 September of this last year. It was before the change
20 in regulations was being proposed and the Norfolk General
21 Hospital was going ahead with doing surgery and we were
22 debating whether or not we should actually do surgery
23 or just hold out to the public that we're still offering
24 the program.
25

1 Q So we're talking about sometime
2 in 1979, you offered to the public open heart surgery;
3 is that correct?

4 A If that date is correct, we did do
5 that, yes, before that period of time, and we could
6 have performed it at that time.

7 Q How did you offer it to the public?

8 A I believe we offered it through an
9 advertisement in the paper.

10 Q At any time prior to that offering
11 or that advertisement, did you make any other kind of
12 offer to either the public or the medical community
13 that you were performing open heart surgery?

14 A We did not make any formal public
15 advertisement prior to that.

16 Q Mr. Brink, isn't it really true
17 that you, at that time, as well as the entire medical
18 community in this area, as well as in Richmond and
19 Norfolk, knew that you were not performing open heart
20 surgery, that you had, in fact, discontinued the program?
21

22 MR. DOWDING: Perhaps -- excuse me.

23 Go ahead, Mr. Brink.
24
25

1 A We knew we had not performed it and
2 attached the machine since 1976 except for the pericardi-
3 ectomies, but we were still capable of doing it and
4 the only reason we didn't perform it is because we didn't
5 want to fall under the restrictions or be legally
6 involved with the Commissioner of Health from the stand-
7 point of whatever restrictions of law they put on us or
8 penalties for performing it without a Certificate of
9 Need, because we were told we needed a Certificate
10 of Need. So I wasn't going to jeopardize myself or
11 my career, basically, and jump in and perform that when
12 the Commissioner has told me I shouldn't, but we were
13 prepared to do it and we still offered the program
14 although we were under restrictions.

15 BY MR. ADAMS:

16 Q Mr. Brink, are you familiar with
17 the national guidelines concerning heart surgery?

18 A I have not reviewed them recently.

19 Q But you know they do exist?

20 A Yes.

21 Q Do you know, by any chance, how
22 the federal government would define open heart surgery?

23 A At this time or at that time?

24 Q Well, let's try both times.
25

1 A At this time, I know that they
2 define it as pump assisted cases. At that time, I
3 was not aware that that definition was -- that the
4 federal government had that definition in the regulations.

5 Q But do you know that they did or
6 did not? You're saying you just don't know?

7 A I just don't know whether they had
8 that in their definition or not.

9 Q Could you explain for me again why,
10 from the period, from September of 1976 to the present,
11 you have not performed open heart surgery, using the
12 machine?

13 A From September until November, when
14 we got the first -- or I'll say December, when we were
15 told by the Commissioner not to do it, we were preparing
16 ourselves to perform it again as we recruited the
17 anesthesiologist and had the proper people available
18 to do it. After that time, we did not perform it, because
19 we were under what we thought was the correct determina-
20 tion of the Commissioner that we had to have a Certificate
21 of Need and, therefore, we would not perform it until
22 we had such.

23 Q In other words, what you're saying
24 is, you were in the business of open heart surgery, but
25

1 you weren't? Is that what you're telling me?

2 A We were in the business of open
3 heart surgery, but the Commissioner did not allow us
4 to perform it. We're very capable of performing it.

5 Q Did the Commissioner attempt to
6 take any type of formal action to prohibit you?

7 A Not other than the fact he told
8 me that we had to have a Certificate of Need and that
9 means if I don't have a Certificate of Need, then
10 I have to deal with what you all can do to me under
11 that law if I go ahead and do it.

12
13 MR. DOWDING: You're referring to
14 the criminal penalties, etc.?

15 THE WITNESS: Yes.

16
17 BY MR. ADAMS:

18 Q Mr. Brink, in order to do open
19 heart surgery, do you have to have a cath lab?

20 A No, you do not have to have a cath
21 lab to do them.

22 BY THE COURT:

23 Q As I understand it, a cath lab,
24 that's very important in determining whether or not
25

1 open heart surgery is necessary?

2 A Absolutely. I'm sure the doctors
3 could answer that better than I can. But I mean if
4 you ask a rhetorical question, do you absolutely have
5 to have one to do it, no. It's certainly recommended
6 it be part of the program.

7 BY MR. ADAMS:

8 Q Mr. Brink, isn't it true you can
9 even have a free-standing or -- excuse me -- free-standing
10 cath lab without even having open heart surgery whatso-
11 ever?

12 A Yes, you can. It may not be very
13 successful.

14 BY THE COURT:

15 Q Let me ask you this. Do you
16 know of any hospital that has an open heart surgery
17 program that does not have a cath lab?

18 A I do not know of any, no.

19
20 MR. ADAMS: Thank you, Mr. Brink.

21
22 REDIRECT EXAMINATION

23 BY MR. DOWDING:

24 Q Mr. Brink, the question was asked
25

1 about the definition, federal definition of open
2 heart surgery and I hand you a document, ask you if
3 you can identify that?

4 A Yes, I can. It's a copy of the
5 Federal Register, Volume 43, No. 60.

6 Q What was the date of publication
7 of that?

8 A March 28, 1978.

9 Q To your knowledge, is that
10 the first definition of open heart surgery that
11 appeared in any federal publication or guidelines or
12 rules?

13 A To my knowledge, this is where it
14 was first defined.

15
16 MR. DOWDING: All right, sir. We
17 would like to offer this, if the Court
18 please.

19 MR. ADAMS: No objection, Your Honor.

20 THE COURT: Well, let me see what
21 it says. Where does it appear in there?

22 MR. DOWDING: It's underlined, Your
23 Honor, underlined part, Your Honor. It
24 was underlined when we copied it, so we
25

1 couldn't undo that, not that it makes any
2 difference.

3
4 (Photocopy of one page of
5 Rules and Regulations, Federal Register
6 Volume 43, No. 60, dated March 28, 1978,
7 was received in evidence as Plaintiff's
8 Exhibit No. 7.)

9
10 MR. DOWDING: Sir, I have no further
11 questions of Mr. Brink. Does the Court
12 have any questions?

13 THE COURT: No.

14 MR. ADAMS: No, sir.

15 THE COURT: Thank you, sir.

16
17 (Witness stood aside)

18
19
20 DR. WALTER H. GRAHAM, after being
21 first duly sworn, testified in behalf of the Plaintiff,
22 as follows:

23 DIRECT EXAMINATION

24 BY MR. DOWDING:

25 Q What is your name, sir?

1 A Walter H. Graham.

2 Q And what is your profession?

3 A I am a thoracic and cardiovascular
4 surgeon.

5 Q And when were you licensed to
6 practice medicine?

7 A In the year 1960, when I graduated
8 from medical school.

9 Q Are you on the staff at Riverside
10 Hospital?

11 A Yes, I am.

12 Q When did you join the staff?

13 A In July of 1969.

14 Q Now, I don't want to go into a whole
15 lot of detail, but -- on your educational background,
16 but I assume you graduated from medical school and
17 performed the necessary intern and residency requirements
18 in your specialty fields; is that correct?

19 A That's correct.

20 Q Are you board certified in any
21 specialties?

22 A I am board certified by the American
23 College of General Surgery and Thoracic and Cardiovascular
24 Surgery, both.
25

1 Q And the specialty field of
2 cardiovascular surgery, generally, what type surgical
3 procedures does it encompass?

4 A Cardiovascular surgery includes
5 surgery on the heart, the vessels, the great vessels
6 and peripheral vessels.

7 Q All right. Now, Dr. Graham, I'm
8 going to refer to some surgical procedures. I may
9 refer to them as "open heart" procedures or by some
10 other term, but you will understand, won't you, I
11 am referring to heart surgery procedures which involve
12 the actual use of what has been referred to as the
13 "pump"?

14 A Yes, sir.

15 Q All right. Now, it's in evidence
16 that the first of these procedures was performed in
17 February of 1973 and that the last one was performed
18 on September 6 of 1976. Now, during that period of
19 time, could you describe for the Court to what
20 extent you, personally, participated in those procedures?
21

22 A As a member of the cardiac surgical
23 team, I was involved in most of the procedures at that
24 time, I would say, some as a surgeon and some as the
25 assistant surgeon with Dr. Bosher in the capacity of a

1 consultant, from Richmond.

2 Q Now, as I understand it, during all
3 of those procedures, the pump technicians and the nurse
4 who handled the anesthesia came from MCV; is that
5 correct?

6 A That's correct.

7 Q That is, until the pump technician
8 was employed by Riverside in 1974?

9 A Even when Riverside hired their
10 own, the pump technicians, the ones from Medical College
11 of Virginia and ones from McGuire Hospital still came
12 down to assist in some of the cases.

13 Q Did Drs. Winfrey and Umstott also
14 participate in some of these procedures?

15 A That's correct.

16 Q And did you and the other physicians
17 perform some of these procedures without Dr. Bosher
18 being present?

19 A Yes, we did.

20 Q Do you know how many were performed
21 during that period of time?

22 A If my memory serves me correctly,
23 I think we performed somewhere between 80 and 85 pump
24 assisted procedures where the pump was actually used.
25

1 Q Now, I want to talk for just a
2 moment about the period of time from September of
3 1976 up until December of 1977. It's already in the
4 evidence that during that period of time, no surgical
5 procedures were performed at Riverside where the
6 pump was actually used on the patient. Is that your
7 understanding?

8 A That's correct. The pump was not
9 actually hooked up to the patient during that period
10 of time.

11 Q All right. Now, there has also
12 been evidence that during this period of time,
13 there were six procedures known as pericardiectomies?

14 A That's correct.

15 Q What is the nature of that procedure?

16 A Pericardiectomy involves removal
17 of the sac around the heart. Sometimes becomes constricted
18 so it cannot beat forcibly. When doing this, it's easy
19 to enter the heart, the heart muscles, enter the coronary
20 arteries and injure one of these vessels. It's for
21 that reason these procedures are most commonly performed
22 in conjunction with a pump standby, if you will, where
23 the patient can go on cardiopulmonary by-pass should
24 some inadvertent problem occur.
25

1 BY THE COURT:

2 Q Slip of the knife?

3 A Slip of the knife, which is easy
4 to do with the inflammation.

5 BY MR. DOWDING:

6 Q And I may lead you a little bit.
7 During this period of time, did you, personally,
8 perform four of these procedures?

9 A Yes, sir. I think I did.

10 Q And in these procedures that you,
11 personally, performed, was the pump on a standby basis
12 as you have described?

13 A It was on standby and available to
14 us and our perfusionist was available to us and we saw
15 to it he was not tied up doing other procedures, so he
16 was readily available.

17 Q Would you have performed these
18 four procedures if the pump had not been available on
19 a standby basis?

20 A No, sir. I would not have.

21 BY THE COURT:

22 Q When were those procedures performed?

23 A In the year 1977.

24 MR. DOWDING: I think that's all I
25

1 want to ask you, doctor. Would you answer
2 Mr. Adams' questions?
3

4 CROSS EXAMINATION
5

6 BY MR. ADAMS:

7 Q Dr. Graham, I believe you testified
8 that most commonly when people are doing pericardiectomies,
9 you would have a heart-lung machine primed and ready to
10 go; is that correct?

11 A That's the most accepted way of
12 performing, yes, sir.

13 Q Are you basing your testimony upon
14 medical practice in Riverside Hospital or in the State
15 of Virginia? How far does your --

16 A I guess it's a national opinion,
17 although some of the procedures are performed where
18 they do not have cardiopulmonary by-pass.

19 Q So in other words, it's not really
20 necessary to have the pump to do a pericardiectomy?

21 A I think it depends on the individual
22 judgment of the operating surgeon and individual case
23 in question. I would hesitate to do certain pericardi-
24 ectomies without it, whereas there are some related to
25 heart failure, malignancy, renal failure, this sort of thing,

1 where the pericardium is not constricted to the heart,
2 that we might do and have done.

3
4 THE COURT: Depends on whether you
5 are the cutter or the cuttee.

6 MR. ADAMS: Might depend on who
7 the cutter is.

8
9 BY MR. ADAMS:

10 Q Dr. Graham, how long does it take --
11 let's assume you're doing one of these operations and
12 something goes sour; how long would it take you to
13 hook a patient up to the heart-lung machine?

14 A Now, we don't have a perfusionist,
15 but when we had a perfusionist, probably would have
16 taken us 10 to 15 minutes.

17 Q What is a perfusionist?

18 A A pump technician who runs the pump.

19 Q Can you just briefly tell us
20 what is involved in hooking a person up to the
21 machine?

22 A In lay terms, the heart-lung machine
23 serves the function of the heart and lungs of the
24 patient, oxygenates the blood and pumps it throughout the
25

1 body. There are basically two lines to hook up to the
2 patient: one arterial line, which usually goes in the
3 aorta or one of the vessels; and venous line goes
4 into the heart or one of the atrial chambers or one
5 of the peripheral veins. You hook the two lines to the
6 patient and the pump takes over the functions.

7 Q Does that just work on the
8 heart or do you have to go to other parts of the body?

9 A You can do it by just working
10 on the heart. Years ago they did it to other parts
11 of the body.

12 Q Dr. Graham, could you tell us
13 what your definition of an open heart surgery program is?

14 A That depends on whether you are
15 speaking about today or before. Historically, when
16 I first started in cardiac surgery, open heart surgery,
17 to me, meant opening the heart to close a defect in
18 the heart, to insert a heart valve or something of
19 this nature. In 1969 and 1970, that began to change
20 with coronary by-pass surgery, where we began to graft
21 into the coronary arteries without opening into any
22 chamber of the heart, and that's what we're talking
23 about and that's what the majority of open heart surgery
24 involves in this country today. I prefer to call it
25

1 cardiac surgical procedures with pump assist or pump
2 standby and define it in that particular manner. But
3 open heart surgery, as we thought of it, was any
4 cardiac surgical procedure where we had the perfusion
5 available whether we used it or not. At this time, I
6 think my definition would be modified as guided by the
7 federal guidelines, etc.

8 Q In other words, if I understand
9 you correctly, today, your definition would be you're
10 actually using the pump on patients?

11 A I would still define it as pump
12 assist procedures because there are other procedures
13 on aorta, etc., trauma cases, ruptures, where you
14 may not use the pump but readily have it in the room
15 either to perfuse the patient or sometimes collect
16 blood to perfuse back into the patient without the pump
17 totally supporting it. There are procedures where the
18 pump does not take over the complete -- doesn't
19 oxygenate the blood, just pumps it. There are varied
20 ways of using a perfusion apparatus.

21 Q But in any event, in your current
22 definition, you, at least to some extent, would use
23 the pump; is that correct?

24 A Or have it available.
25

1 Q In 1976, what would your definition
2 have been?

3 A My definition of open heart surgery
4 at that time included any procedure done on the heart.

5 Q Any type of cardio-thoracic surgery;
6 is that correct?

7 A Cardio-thoracic surgery, yes.

8 Q Is that what most other doctors
9 would have said?

10 A I think in general, that's a true
11 statement, because the American Society of Thoracic
12 Surgery and other thoracic surgical societies have
13 undertaken and made definitions. This is what defines
14 just what open heart surgery involves. But at that
15 time, there were no guidelines, federally or otherwise,
16 I'm aware of.

17 Q Dr. Graham, why today, when we look
18 at the national guidelines and even look at the State's
19 definition, which references the use of the pump, why
20 have all of these definitions, which have gone through
21 some kind of public scrutiny before being promulgated,
22 why, now, are we restricting ourselves to the use of
23 the pump?
24

25 MR. DOWDING: That may assume something

1 period September '76 to December '77, just so the
2 record is clear, they were the pericardiectomies
3 performed with the pump on standby?
4

5 A That's correct.

6 Q Were there other pericardiectomies
7 performed where the pump was not on standby?

8 A We've done some since then where
9 we didn't have a perfusionist available, but they
10 were different type pericardiectomies.

11 Q Just for the record, what is the
12 difference? What type pericardiectomies would you
13 feel free to do without a pump standby?

14 A Where it's done mainly for patients
15 with renal failure or heart failure or tumor patients,
16 where the pericardium is not adherent to the heart such
17 as with a constricted pericardium, and the cardiologists
18 are pretty accurate in diagnosing this beforehand, so
19 we know pretty well what we're dealing with.

20
21 MR. DOWDING: All right, sir.

22
23 RECROSS EXAMINATION

24 BY MR. ADAMS:

25 Q Since 1977, have you all performed

1 one of these procedures where you have had the machine
2 on standby?

3 A Not since our perfusionist left.

4 Q When did the perfusionist leave?

5 A I believe Mr. Brink gave the date.
6
7 I think it was somewhere in --

8
9 MR. DOWDING: November 7 or 11.

10 THE COURT: Armistice Day 1977.

11 MR. ADAMS: I have no further questions.

12
13 (Witness excused)

14
15 MR. DOWDING: If Your Honor please,
16 that concludes the evidence on behalf of the
17 Plaintiff in this case. I wonder if we
18 could have a five minute recess?

19 THE COURT: Yes, sir.

20
21 (Brief recess)

22
23 MR. ADAMS: Your Honor, we have no
24 evidence to put on. We are prepared for
25 final argument.

1
2 THE COURT: I don't believe that's --

3 MR. ADAMS: It's what other cardiac
4 surgeons say in other cases. I would suggest, if you're
5 curious about it, we go ahead and submit the letter
6 from Dr. Kenley.

7 THE COURT: Doesn't have anything
8 to do with it. I just couldn't understand why they didn't
9 want them to have it to start with.

10 The question is, I think, as has
11 been put by Mr. Dowding correctly, is whether or not,
12 when they were denied, when they were ruled that they
13 could not perform any further surgery which requires
14 the use of the machine unless and until they got the
15 Certificate of Need from the State or from whomever
16 they get it, whether or not that was a lawful ruling
17 so as to prevent the hospital from operating using these
18 procedures. Now, the fact that the hospital elected
19 not to go forward in view of the position of the
20 Commissioner, I don't think is controlling, as you argue,
21 because they were, I think in good faith, trying to,
22 from what I understand, trying to work this thing out
23 so nobody would run into any problems with anybody that
24 couldn't be solved, because the general feeling, I'm sure,
25

1 by the lay people was that when one of the State
2 officials makes a ruling or alleged ruling, that they
3 have to abide by it. And you say, "Why didn't they
4 come running down here?" Well, I don't know.

5 Probably, had I been in that position, I would have
6 proceeded and let the State come running down here to
7 see whether it was, but everybody views things
8 differently, I suppose.

9 I have sat here and listened to
10 this evidence. From the medical evidence I have
11 heard, these people were performing open heart surgery
12 under the definition as it existed in 1976, 1977, 1978,
13 until that federal thing came out, which really doesn't
14 change it at all. They said they had their heart
15 machine on standby, had the operators on standby,
16 were ready to hook it up if it had to be, the Commissioner
17 notwithstanding, and I don't see where they had to make
18 any change, substantial change in their routine. Seems
19 like to me they were proceeding with open heart surgery
20 right along and I think that the Commissioner's ruling
21 that they were not was arbitrary. It wasn't based on
22 any statute or you would have cited it, not based on
23 any rule or you would have cited it. He knew, perhaps,
24 somebody was going to say something about twelve months
25

1 and so he threw that out before it became effective.

2 We have run into this before, where they undertake to
3 operate on a rule, skin a rabbit before they catch him.

4 * I just think the Commissioner's ruling was invalid, void
5 ab initio, and the fact the hospital has waited all
6 these years, trying to work this thing out without
7 really going forward, they should not be penalized for
8 that. I see no reason in the world why they have to
9 have a Certificate of Need. They were complying with
10 the law in 1976 and 1977 and the Commissioner had no
11 right to strip them of that privilege and the fact he
12 did undertake to strip them, now he can't say, "Well,
13 even though what I did was wrong in 1977, still they
14 haven't done it and twelve months have gone by, four
15 years have gone by and, therefore, they cannot now do
16 it under the regulations," and I so rule. *

17
18 All right, folks. Always nice to
19 have you all in my court.

20 * * *