REPORT OF THE
JOINT COMMISSION ON HEALTH CARE

RENAL DIALYSIS/MAMMOGRAPHY STUDY PURSUANT TO HJR 556 AND HJR 642

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

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Preface

House Joint Resolution No. 556 of the 1999 General Assembly Session directs the Joint Commission on Health Care (JCHC) to examine the adequacy of state oversight of freestanding renal dialysis facilities. As part of this review, JCHC is also directed to study (i) the advisability of licensure of dialysis technicians, (ii) needed changes, if any, to state law and regulations; and (iii) other issues as appropriate.

House Joint Resolution No. 642, also of the 1999 General Assembly Session, directs JCHC to study the feasibility of regulating mammography equipment, facilities, and services in Virginia. As part of the study, JCHC is directed to (1) review the requirements of the federal Mammography Quality Standards Act to determine the obligations, rights, and responsibilities of states in accrediting, certifying, inspecting, and monitoring mammography facilities, including reviewing and enforcing qualifications for competent staff; (ii) review the arrangements between the U.S. Food and Drug Administration and the Virginia Department of Health's Bureau of Radiological Health for the inspection of mammography facilities; (iii) estimate the costs of accrediting and certifying such facilities for the state; (iv) determine the feasibility and appropriateness of an interagency approach to enforce federal quality control requirements at the state level; and (v) recommend ways which would enable the Commonwealth to ensure quality among mammography facilities and the medical personnel who work in them.

Based on our research and analysis during this review, we concluded the following concerning renal dialysis services:

- dialysis facilities rely extensively on unlicensed personnel for patient care,
- dialysis facilities are regulated by HCFA but federal regulations do not contain any qualification requirements for dialysis technicians,
- dialysis technicians receive training from their employers based on a national core curriculum, but there is considerable variation in the length of training programs,
- national certification of dialysis technicians is available but few dialysis technicians employed in Virginia are certified,
- dialysis facilities in Virginia compare favorably with facilities in neighboring states in terms of outcome indicators,
- the Virginia Department of Health inspects dialysis facilities for HCFA and has received relatively few complaints concerning dialysis facilities,

- Virginia nursing regulations prohibit the administration of medications by unlicensed personnel unless explicitly authorized by the Virginia Drug Control Act,
- certain types of medications are, in practice, routinely administered by unlicensed personnel as part of dialysis treatment, and
- unlike Virginia, 16 other states have enacted statutes and/or regulations governing dialysis services.

Based on our research and analysis during this review, we concluded the following concerning mammography services:

- federal statutes and regulations prescribe certification, accreditation, and quality of care standards for mammography,
- the U.S. Food and Drug Administration (FDA) is the certifying body for all mammography facilities,
- the Bureau of Radiological Health (BRH) within the Virginia Department of Health conducts an annual certification inspection for the U.S. Food and Drug Administration – about 60 percent of Virginia facilities have no inspection deficiencies,
- the American College of Radiology is the accreditation body for Virginia facilities pursuant to a contract with the FDA,
- states are authorized by federal regulations to apply to the FDA to become accreditation bodies, but only four states have done so,
- the FDA believes that state accreditation bodies are effective and comparable to the ACR,
- the BRH would like to become an accreditation body as it believes facilities would benefit through improved service and decreased cost,
- it appears feasible for Virginia to implement and administer an accreditation program, but it would be difficult for BRH to convince facilities that its program is comparable to that of the ACR, and
- the FDA is currently drafting proposed regulations that would authorize states to apply to become certifying bodies for mammography services.

A number of policy options were offered for consideration by the Joint Commission on Health Care regarding the issues discussed in this report. These policy options are listed on pages 65-66.

Our review process on this topic included an initial staff briefing, which comprises the body of this report. This was followed by a public comment period during which time interested parties forwarded written comments to us regarding the report. The public comments (attached at Appendix B) provide additional insight into the various issues covered in this report.

On behalf of the Joint Commission on Health Care and its staff, I would like to thank the Virginia Department of Health, the Virginia Renal Association, and the American College of Radiology for their cooperation and assistance during this study.

Patrick W. Finnerty
Executive Director

December, 1999

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Authority for the Study

House Joint Resolution No. 556 of the 1999 General Assembly Session directs the Joint Commission on Health Care (JCHC) to examine the adequacy of state oversight of freestanding renal dialysis facilities. As part of this review, JCHC is also directed to study (i) the advisability of licensure of dialysis technicians, (ii) needed changes, if any, to state law and regulations; and (iii) other issues as appropriate.

House Joint Resolution No. 642, also of the 1999 General Assembly Session, directs JCHC to study the feasibility of regulating mammography equipment, facilities, and services in Virginia. As part of the study, JCHC is directed to (1) review the requirements of the federal Mammography Quality Standards Act to determine the obligations, rights, and responsibilities of states in accrediting, certifying, inspecting, and monitoring mammography facilities, including reviewing and enforcing qualifications for competent staff; (ii) review the arrangements between the U.S. Food and Drug Administration and the Virginia Department of Health's Bureau of Radiological Health for the inspection of mammography facilities; (iii) estimate the costs of accrediting and certifying such facilities for the state; (iv) determine the feasibility and appropriateness of an interagency approach to enforce federal quality control requirements at the state level; and (v) recommend ways which would enable the Commonwealth to ensure quality among mammography facilities and the medical personnel who work in them.

Issue Brief Outline

This issue brief presents the results of JCHC's staff reviews as directed by both HJR 556 and HJR 642. Both study resolutions, found in Appendix A, focus on the regulation of specific health care services within the Commonwealth. This issue brief is divided into six sections. This section discussed the authority for the study. The second section provides a general overview of renal disease and dialysis services. The third section discusses oversight and regulation of dialysis facilities and services. The fourth section provides a general overview of mammography services and federal regulations. The fifth section discusses the extent of state involvement in the regulation of mammography services. The sixth section discusses policy options.

II.
Overview of Renal Disease and Dialysis Services

Renal Disease Affects the Proper Functioning of Human Kidneys

Kidneys perform many functions which are essential for human survival. Kidneys remove toxic waste products from the human body, maintain the acid/base balance in the body, aid proper regulation of the body's electrolyte balance; maintain the body's fluid balance by regulating the amount of salt and water that is removed from urine, and also release hormones which help to control blood pressure. When the kidneys fail, waste products and excess fluids build up in the body to toxic levels, and circulate in the blood.

Diabetes and hypertension are the leading causes of renal failure, accounting for approximately 68 percent of all cases in Virginia. Nationally, the incidence of renal disease during 1998 was 318 new cases diagnosed per one million population. Virginia's incidence rate during the same time period was slightly greater, at 341 cases per one million population.

Dialysis is a Process That Removes Unwanted Wastes and Fluid From the Bloodstream

There are two general modes of dialysis treatment: hemodialysis and peritoneal dialysis, both of which can be performed at a dialysis facility or at a patient's home. In hemodialysis, blood is sent from the patient's body through a dialysis machine that filters out body waste before returning the blood to the patient. In peritoneal dialysis, the blood is filtered within the patient's abdominal cavity before leaving the patient's body.

Hemodialysis is the method of dialysis most frequently prescribed by physicians. In order to clean the blood with hemodialysis, it is first necessary to gain access to the bloodstream. A permanent access site, or entry into the circulatory system, is created using a minor surgical operation.

Hemodialysis utilizes several different types of devices. A dialyzer is needed to allow the patient's blood to come into contact with the cleansing dialysate. The dialyzer is a semi-permeable membrane which allows some harmful substances, such as urine, to be removed from the bloodstream while allowing other valuable substances, such as red blood cells, proteins, and hormones, to remain in the bloodstream. Dialysate, a

mixture of treated water and chemicals, removes wastes and fluid and adds needed substances to the blood. A delivery system is needed to constantly supply fresh dialysate and remove used dialysate. Modern high-tech delivery systems include a blood pump, ultrafiltration pump, dialysate conductivity monitor, and several alarms and pressure gauges.

A hemodialysis treatment is usually performed three times a week, usually for two to four hours at a time. Because waste products are removed from the body only three times a week, hemodialysis patients must follow a strict diet and limit their fluid intake.

Most dialyzers are reprocessed – meaning that they are cleansed and disinfected to be used again by the same patient – instead of being discarded after a single use. Water is used in dialysis to prepare dialysate and to flush out dialyzers during reprocessing. If dialysis water contains impurities such as bacteria, mud, metals, sediment, or chemicals, these impurities may enter the patient's bloodstream through the dialyzer membrane and cause disease or injury. Because dialysis uses large amounts of water, even tiny amounts of contaminants can be dangerous for patients.

Peritoneal dialysis is a type of dialysis that uses the patient's own peritoneum, which is the lining of the abdominal wall, to filter out wastes and excess water. Under this type of dialysis, a catheter is surgically inserted into the abdomen. The peritoneum becomes the semi-permeable membrane between the dialysate and the patient's waste-filled blood supply. Only about ten percent of dialysis patients in Virginia were treated using peritoneal dialysis during 1998.

The Number of Dialysis Patients In Virginia is Increasing

There were 7,025 dialysis patients in Virginia as of December 31, 1998. This represented an approximate 7 percent increase from 1997. The number of dialysis patients in Virginia has been increasing over time. From 1992 through 1997, the number of Virginia dialysis patients per one million population increased from 904 to 1,239. There are 108 free-standing dialysis facilities in Virginia.

There are several likely contributing factors underlying this increase. Patients who were not considered good candidates for dialysis 25 years ago, primarily those age 65 or older or those with diabetes or hypertension, are now routinely placed on dialysis. Such individuals are also living longer as the result of improved medical treatment. Unfortunately, improved longevity of such individuals can be accompanied by the onset of renal disease. In addition, dialysis patients as

a group are living longer. According to the United States Renal Data System, there has been a progressive improvement in first-year survival among dialysis patients since 1985. Finally, a lack of a sufficient number of kidneys for all individuals who desire a transplant tends to keep individuals with renal failure on dialysis as opposed to enabling them to become transplant recipients.

Medicare is the Primary Payment Source for Dialysis Services

The Social Security Amendments of 1972 extended Medicare coverage to individuals with end-stage renal disease (ESRD) who require dialysis or a kidney transplant to maintain life. There is no minimum age for eligibility under the renal disease provision. In Virginia during 1998, 87 percent of dialysis patients were covered through the Medicare program. An additional four percent had enrollment applications pending with Medicare. Only nine percent of the dialysis patients in Virginia during 1998 were not covered by Medicare. Nationally, Medicare accounted for approximately 75 percent of all dialysis expenditures during 1997.

Under the Medicare ESRD program, dialysis facilities receive a fixed amount of reimbursement per patient treatment session. The per treatment amount varies somewhat depending on the geographic region within which the facility is located. In Virginia, the amount of per patient reimbursement ranges from approximately $117 to $133. Facilities in the Northern Virginia area tend to be at the higher end of the reimbursement range. However, Medicare actually reimburses the facility for only 80 percent of the per patient treatment amount. The remaining 20 percent must come from any supplemental coverage, such as commercial insurance or Medicaid, that the patient may have. This reimbursement amount, referred to as the composite rate, is intended to cover most routine dialysis treatment expenditures. However, facilities may bill Medicare separately for certain medications and other dialysis-related items such as electrocardiograms and blood transfusions.

Since the Medicare ESRD program began in 1974, there has been only a single increase – of $1 in 1991 – in the composite rate. There has not been any inflation adjustment in the composite rate. During interviews with JCHC staff, dialysis providers consistently stated that the industry is under increasing fiscal stress and that, due to the lack of any inflation adjustment in 25 years, facilities are effectively receiving less reimbursement today than in prior years. The Medicare Payment Advisory Commission, in a June 1999 report to Congress, examined concerns about the effect of Medicare's payment and coverage policies on the quality of care. According to the commission, the U.S. Secretary of

Health and Human Services should examine the feasibility of a multi-tiered composite rate that would allow for different payments based on the frequency and duration of prescribed dialysis.

The Dialysis Industry Is Consolidating in an Attempt to Achieve Sufficient Economies of Scale Given Limited Reimbursement

Partly in response to the lack of increased Medicare reimbursement, a noticeable trend in the industry has been the acquisition of independent dialysis facilities by large national and international chain organizations. As of December 1998, 62 percent of the dialysis units in Virginia were owned by three large national chains, which serve 63 percent of the state's dialysis patients. Nine smaller regional chains, by comparison, accounted for only 17 percent of the dialysis units and 18 percent of the patients. Non-chain facilities account for 21 percent of the units and 19 percent of the patients. The vast majority of dialysis facilities in Virginia are operated on a for-profit, as opposed to not-for-profit, basis.

Dialysis Facilities Rely Extensively on Unlicensed Personnel In Order to Provide Needed Services

Dialysis facilities employ several different types of personnel. These include registered nurses, licensed practical nurses, social workers, dietitians, and a variety of different types of dialysis technicians. Among these various types of personnel, only dialysis technicians are not currently required to be licensed by the State of Virginia. During interviews with JCHC staff, several providers commented on the fact that, given the low level of Medicare reimbursement, the industry has grown to rely increasingly on unlicensed dialysis technicians, who are typically paid less than licensed personnel, in order to provide direct patient care. Dialysis technicians comprised 30 percent of the total staff, and 35 percent of the direct patient care staff in facilities which responded to a JCHC staff survey. However, providers stated that unlicensed does not mean unqualified, and explained that many dialysis technicians have considerable experience, are highly qualified, and function as leaders within their respective facilities.

Dialysis technicians perform a number of different types of functions within the industry. These include providing direct patient care, re-processing dialyzers, and maintaining the dialysis machines and water treatment systems. General types of direct patient care activities that are typically provided by dialysis technicians include setting up the dialysis machine, initiating dialysis by inserting the needle into the patient's vascular access and by administering several types of medications that are routinely used during dialysis, monitoring the patient during the

treatment, and finally terminating dialysis and cleaning the machine in preparation for the next patient.

There does appear to be variation within the industry in terms of the extent to which these activities are performed by the same, or different, dialysis technicians. Some dialysis facilities utilize a greater division of labor than do others. For example, some dialysis facilities have patient care technicians, as well as equipment technicians who maintain equipment such as water treatment systems, and re-use technicians who re-process dialyzers. However, some other facilities utilize a greater degree of cross-training of their technicians so that they tend to perform patient care as well as some equipment functions.

The standard practice within the industry is for all activities performed by dialysis technicians to be performed under the direct supervision of a registered nurse. Based on data obtained from JCHC's staff survey of the dialysis facilities in Virginia, it appears that registered nurses, and licensed practical nurses, continue to be present in dialysis facilities in significant numbers in comparison to unlicensed personnel. On average, per facility, there appear to be more licensed staff than unlicensed staff, but also more dialysis technicians than registered nurses. (Figure 1).

Figure 1

Direct Patient Care Staff Employed by Renal Dialysis Facilities in Virginia

	RNs	LPNs	Dietitian	Social Worker	Unlicensed Technicians
Median Number of Staff	4	2	1	1	5
Average Number of Staff	5	4	1	1	6

Note: Survey responses were received from 54 facilities, or 47 percent of all facilities surveyed.

Source: JCHC staff analysis of data obtained from JCHC staff survey of renal dialysis facilities located in Virginia.

Based on JCHC staff interviews with managers of several dialysis facilities, it appears that the standard industry practice for direct patient care staffing ratios is 1 staff for every four patients. For example, a 1997 national survey conducted by the U.S. Centers for Disease Control estimated, the median patient to staff ratio to be 4 to 1. Based on JCHC's facility survey, the patient to direct care staff ratio among the survey respondents is approximately 3.5 to 1 (Figure 2).

Figure 2

Direct Patient Care Staffing Ratios in Virginia Renal Dialysis Facilities

	First Shift	Second Shift	Third Shift
Median Number of Patients Per Staff Member	3.5	3.3	3.3
Average Number of Patients Per Staff Member	3.4	3.4	3.4
Range of Patients Per Staff Member	2 - 4	2 - 8	2 - 4

Note: Survey responses were received from 54 facilities, or 47 percent of all facilities surveyed. Only 1 facility reported a patient to direct care staff ratio of 8 to 1.

Source: JCHC staff analysis of data obtained from JCHC staff survey of renal dialysis facilities located in Virginia.

A National Core Curriculum Has Been Developed by the Industry to Guide the Education and Training of Dialysis Nurses and Technicians

In 1992 the pharmaceutical company Amgen, Inc. commissioned the development and publication of the Core Curriculum for the Dialysis Technician. The core curriculum was prepared under the auspices of an advisory board comprised of physicians, nurses, and technicians. The core curriculum was developed in response to educational and training challenges that had arisen within the dialysis community over the course of many years. For example, it was believed in 1992 that dialysis

technology was neither formalized nor standardized, and that the definition, role, and scope of practice of a dialysis technician remained the subject of debate. Furthermore, increasingly sophisticated dialysis technology and an increasing patient population were believed to be adding to the industry's educational and training burden.

There are seven modules to the core curriculum. The first three cover the basic principles of both hemodialysis and peritoneal dialysis. The remaining modules cover specifics of hemodialysis only, since the majority of technicians are more involved in this modality. The curriculum is designed to be flexible so that individual facilities may adapt it in accordance with their unique needs and circumstances and different types of equipment and technology. Flexibility was also required in recognition of the fact that the definition and scope of practice for the dialysis technician are extremely variable from state to state and from facility to facility.

There Appears to Be Some Variation Among Dialysis Facilities in Virginia In Terms of How Dialysis Technician Training Programs Are Actually Administered

All of the facilities who responded to the JCHC staff survey reported that they have an educational and training program for their unlicensed technicians. JCHC staff reviewed documentation describing the orientation and training of dialysis technicians at three different dialysis providers: a large national chain facility, a regional chain facility, and an independent, freestanding facility. Based on this review, it appeared that these three providers have developed official training programs and curricula that are based, at least in part, upon the national core curriculum. However, some individuals interviewed by JCHC staff as well as some survey respondents made comments which appear to be premised on the belief that there is, in practice at some facilities, a lack of standardized education and training for dialysis technicians. For example:

> A standardized test could be developed, administered by the RN nurse manager at the unit, and sent off for grading.
>
> * * *
>
> Education and training of unlicensed technicians should be standardized.
>
> * * *
>
> I would like to see a nationwide, standardized orientation program and competency testing program for dialysis technicians.

Technicians should be required to participate in classroom and clinical education and then tested for competency.

* * *

Technicians are taught a procedure, but have no knowledge of the theory behind it.

The standard practice among dialysis facilities in Virginia is to train dialysis technicians using a combination of classroom instruction and actual hands-on clinical experience. However, among respondents to the JCHC survey, the implementation of training varies somewhat in terms of the duration of programs. As is summarized in Figure 3, the number of reported hours of required classroom instruction, clinical experience and continuing education vary.

Figure 3

Duration of Educational and Training Programs for Dialysis Technicians at Virginia Renal Dialysis Facilities

	Number of Hours of Classroom Instruction	Number of Hours of Clinical Experience	Number of Hours of Required Annual Continuing Education
Median	80	240	10
Average	78	274	9
Range	0 – 240	64 – 720	0 - 30

Note: Survey responses were received from 54 facilities, or 47 percent of all facilities surveyed. Only three facilities reporting not requiring any hours of formal classroom training.

Source: JCHC staff analysis of data obtained from JCHC staff survey of renal dialysis facilities located in Virginia.

While most of the survey respondents reported that passage of a written competency examination was required as a condition of employment, nine facilities reported that they did not have such a

requirement. Among those facilities that do require passage of a written competency examination, most facilities required a minimum passing score of 80 percent. However, the range of minimum passing scores ranged from 75 to 90 percent.

Given that the core curriculum is designed and intended to be flexible, a certain amount of variation in training protocols is to be expected. Variation in training practices may also reflect the qualifications of individuals that the facilities are able to hire as technicians. It appears that, as a matter of industry practice, facilities prefer to hire individuals with some type of medical and/or patient care background. One facility reported that its policy is only to hire technicians who are certified as emergency medical technicians or paramedics. Of course, facilities in Virginia may not always be actually able to hire such individuals.

Outcome Indicators Have Been Developed by the Dialysis Industry in Collaboration with the U.S. Health Care Financing Administration

In 1994, HCFA developed the ESRD Health Care Quality Improvement Program, with input from the renal community. The program includes the ESRD Core Indicators Project, which is HCFA's first nationwide, population-based study to assess and identify opportunities to improve the care of dialysis patients. The study is based on a random-sample of in-center hemodialysis patients, and a separate random sample of peritoneal dialysis patients, who were at least 18 years of age. According to the 1998 Annual Report of the ESRD Core Indicators Project, there are four core indicators:

- adequacy of dialysis – measured in terms of the amount of urea that is removed from the blood during dialysis;
- anemia management – measured by hematocrit and hemoglobin values;
- serum albumin – as an indicator for assessing mortality risk; and
- blood pressure values – for the peritoneal dialysis sample only.

Figure 4 summarizes the values of the national core indicators as reported by HCFA. These data provide a "snapshot" view of dialysis outcomes as measured over just a short time period, in this case October to December 1997. Since the ESRD core indicators project was first implemented, performance in relation to each of these core indicators has been improving. In addition, the National Kidney Foundation has

subsequently developed clinical practice guidelines as part of its own dialysis outcomes quality initiative.

Figure 4

National Outcome Indicators for Dialysis Services – ESRD Core Indicators Project (October – December 1997)

General Indicator	Specific Measure	Percentage of U.S. Dialysis Patients In Compliance with Core Indicator
Adequacy of Dialysis	Mean Urea Reduction Ratio $\geq$ 65 percent	72%
Adequacy of Dialysis	Mean Kt/V $\geq$ 1.2	78%
Anemia Management	Mean hematocrit value > 30%	79%
Serum Albumin	Mean serum albumin value $\geq$ 3.2 (BCG method)	83%
Serum Albumin	Mean serum albumin value $\geq$ 3.5 (BCP method)	83%
Blood Pressure Control	Mean systolic blood pressure > 150	77%
Blood Pressure Control	Mean diastolic blood pressure > 90	84%

Note: Serum albumin is an indicator for assessing mortality risk

Source: JCHC staff analysis of data published in 1998 Annual Report ESRD Core Indicators Project (U.S. Health Care Financing Administration, December 1998).

The core indicator data presented by HCFA is analyzed by network rather than by individual state. There are 18 ESRD network organizations throughout the United States that are under contract with HCFA to perform quality assurance activities. With just four exceptions, each network contains more than one state. Virginia is part of network 5 along with Maryland, West Virginia, and the District of Columbia. Florida, Illinois, New York and Texas each comprise their own network. Therefore, data sufficient to support an extensive state-by-state comparison of dialysis outcomes was not available to JCHC staff.

It is possible to compare performance outcomes across the various networks. Network 5 has rather consistently been at the low end of the outcome indicator spectrum, below the national average, in terms of adequacy of dialysis. On the other hand, network 5's performance has been better in relation to the national average in terms of anemia management and serum albumin. Nevertheless, such an approach does not permit identification of those states which are most responsible for a network's relatively high or low performance. It is possible to compare Virginia to the other states within Network 5 in terms of some key outcome indicators. As is illustrated in Figure 5, Virginia compares favorably within Network 5.

Obviously, there is a range of measured performance outcomes among dialysis facilities within any state, including Virginia. Based on data collected from JCHC survey respondents, the percentage of adult, in-center hemodialysis patients with urea reduction ratios $\geq$ 65 percent ranged from 100% to 58%. Similarly, the percentage of hemodialysis patients with hematrocrit values $\geq$ 30 percent ranged from 100% to 48%. Patient compliance with prescribed treatment regimen may be one possible contributing factor to the wide range of self-reported outcome measures.

Figure 5

Comparison of Virginia to Other States in ESRD Network 5 on Selected Dialysis Outcome Indicators

	Virginia	Maryland	West Virginia	District of Columbia
Patients with mean urea reduction ratio≥65%	82.4%	74.6%	82.3%	75.0%
Patients with mean Hematocrit ≥ 31%	75.1%	74.7%	65.1%	70.5%
Patient Mortality Rate	17.6%	19.4%	22.6%	15.6%

Notes: Urea reduction ratio data is for 4th quarter 1998, Hematocrit data is for 4th quarter 1997, and mortality rate data is for 1997. Increasing urea reduction ratios, increasing hematocrit values, and decreasing mortality rates are indicative of improving outcomes.

Source: Mid-Atlantic Renal Coalition.

III.
Regulation of Renal Dialysis Services

Renal Dialysis Facilities Are Regulated by HCFA Pursuant to Medicare Conditions of Participation

Title 42 of the U.S. Code of Federal Regulations, at §405.2100 et seq., contain the federal regulations governing renal dialysis facilities which participate in the Medicare Program. The regulations contain a number of different conditions that facilities must comply with. Each condition, in turn, contains several different standards that must be satisfied. The regulatory conditions of participation pertain to:

- minimum utilization rates,
- furnishing data and administration for ESRD program administration,
- participation in network activities,
- compliance with federal, state, and local laws and regulations,
- governing body and management,
- patient long-term program and patient care plan,
- patients' rights and responsibilities,
- medical records,
- physical environment,
- reuse of hemodialyzers and other dialysis equipment,
- facility director,
- facility staff, and
- minimal service requirements.

Figure 6 summarizes the types of regulatory standards that apply to several of the Medicare conditions of participation.

The federal regulations require dialysis facilities to have the following types of staff: chief executive officer, medical director, supervisor of nursing services, dietitian, and social worker. The regulations define the qualifications for each type of position. However, the federal regulations contain no provisions concerning the use or qualifications of dialysis technicians.

According to the regulations, properly trained personnel must be present in sufficient numbers to meet patient needs, including those arising from medical and non-medical emergencies. The regulations further mandate that each facility must employ at least one full time licensed, registered nurse with at least six months of dialysis experience to be responsible for nursing services. Whenever patients are undergoing

dialysis, one currently licensed health professional (e.g. a physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care must be on duty to oversee patient care. In terms of the appropriate patient/staff ratio, the regulations state that "an adequate number" of personnel must be present such that it is appropriate for the level of care being provided, and such that it meets the needs of patients.

Figure 6

Types of Regulatory Standards for Selected Medicare Conditions of Participation for ESRD Facilities

Condition	Standards
Compliance with federal, state, and local laws and regulations	facility licensure, licensure or registration of personnel, and conformity with other laws
Governing body and management	disclosure of ownership, operational objectives, chief executive officer, personnel policies and procedures, use of outside resources, patient care policies, medical supervision and emergency coverage, and medical staff
Patient's rights and responsibilities	informed patients, participation in planning, respect and dignity, confidentiality, and grievance mechanism
Physical environment	building and equipment, favorable environment for patients, contamination prevention, and emergency preparedness
Facility staff	registered nurse, on-duty personnel, and self-care dialysis training personnel
Minimal service requirements	outpatient dialysis services, laboratory services, social services, dietetic services, and self-dialysis support services

Source: JCHC staff analysis of 42 CFR §405.2100 et seq.

The Virginia Department of Health Performs Medicare-Certification Inspections Pursuant to a Contract With HCFA

In Virginia, HCFA contracts with the Virginia Department of Health (VDH) for performance of Medicare certification survey inspections. Staff from the VDH Center for Quality Health Care Services and Consumer Protection, Division of Acute Care Services, conduct the facility inspections. Each inspection contains interviews conducted with a sample of facility patients, as well as with facility staff. The inspections are performed utilizing interpretive guidelines, prepared by HCFA, pertaining to the federal regulations. VDH currently is completing a three-year cycle during which it has inspected all ESRD facilities in the state. VDH anticipates that it will continue with the three-year inspection cycle for ESRD facilities over the course of the next three years. According to dialysis facilities who responded to the JCHC staff survey, 58 percent reported that they would like the Medicare inspection to occur at least every two years.

Over the past three years, about 35 percent of ESRD facilities in Virginia have been cited for deficiencies as a result of Medicare certification inspections. VDH performed 88 inspections from October 1996 through June 1999. Among these facilities, 31 of these were cited for deficiencies. Conversely, approximately two-thirds of facilities have been found to have no deficiencies pursuant to the federal regulations. According to VDH management, all deficiencies are considered to constitute at least some potential for harm to dialysis patients. Figure 7 summarizes the types of deficiencies that Virginia dialysis facilities have been cited for by VDH inspectors.

VDH has received relatively few complaints from dialysis patients. From September 1995 through April 1999, a total of 27 complaints were received. All of these complaints were investigated by VDH staff. Only five of the complaints contained allegations that were substantiated based on VDH's subsequent investigation. However, of those five, only three resulted in a finding that the facility was out of compliance with regulatory standards. These were as follows:

- patient care technicians were not properly trained in cannulation of the grafts or in handling of biohazardous waste, there was contamination of the water delivery system, and the facility was not clean;

- facility failed to dispose of biohazardous waste in a safe manner resulting in a waste disposal company receiving a needle stick; and

- four patients experienced a cardiac arrest due to mix-up of medications.

Figure 7

Types of ESRD Facility Deficiencies Cited by Virginia Department of Health During Medicare Certification Inspections (October 1996 – June 1999)

Type of Deficiencies	Number of Instances
Environmental and Cleanliness	29
Non-Compliance with Proper Water Testing	9
Patient Care Documentation	7
Other/Miscellaneous	13

Source: Virginia Department of Health.

In each of these three cases, an acceptable plan of correction was required to be submitted to VDH. A re-inspection was conducted at each facility to assure effective implementation of the plan of correction.

HCFA Has Established A Regional Network Structure to Promote Quality Assurance in Renal Dialysis Facilities

Quality improvement in the ESRD program is the primary responsibility of the ESRD network organizations. Originally authorized by federal legislation in 1978, there are 18 ESRD network organizations under contract to HCFA. These organizations serve as liaisons between the federal government and providers of ESRD services. Other responsibilities of network organizations include the collection of data to administer the national ESRD program, and provision of technical assistance to providers and patients.

As previously mentioned, Virginia is part of network 5, along with the District of Columbia, Maryland, and West Virginia. Network 5 is administered by Mid-Atlantic Renal Coalition (MARC). MARC is a non-profit organization governed by a Board of Directors. A medical review board directs MARC's quality measurement, management, and monitoring initiatives. The medical review board identifies network-wide and facility-specific opportunities for improvement through the routine monitoring and analysis of data. Recent efforts have focused on improving the adequacy of dialysis. Under this effort, facility specific reports have been developed which show how that facility compares to other facilities in the network, and within the individual state. MARC also issues an annual report which presents a wide range of information pertaining to dialysis services and outcomes within the network. A copy of the annual report is sent to the Virginia Department of Health.

MARC seeks patient input into program activities through a patient advisory committee and by recruiting patient coordinators in each dialysis facility. There is patient representation on the medical review board and several other committees. Each network administers a patient grievance process. During 1998, MARC received and processed 10 formal written grievances. MARC was unable to provide JCHC staff with information concerning how many of those grievances, if any, involved Virginia facilities. During 1998, MARC distributed grievance forms and brochures to 15 additional patients who either resolved their concerns at the facility level, or who decided not to file a grievance. Concerns from 16 additional patients were resolved by patient education, MARC communication with the facility or regional personnel, referral to a State Medicare survey agency, or patient transfer to another facility.

There Are Additional Sources of National Oversight for Renal Dialysis Facilities

JCHC staff received numerous comments from various individuals stating their opinion that renal dialysis facilities are already highly-regulated health-care providers. Other regulatory agencies which were cited as focusing on the renal dialysis industry were the U.S. Centers for Disease Control (CDC), for infection control purposes, and the U.S. Occupational Safety and Health Administration (OSHA). OSHA requirements include those pertaining to blood borne pathogens, and respiratory protection.

The CDC annually surveys dialysis facilities in order to perform surveillance concerning dialysis-associated diseases. The national surveillance project was initiated in the early 1970's because of a high incidence of hepatitis B virus among hemodialysis patients and staff at that

time. Since that time, incidence rates of hepatitis B have decreased. In 1994, five outbreaks of hepatitis B infection among hemodialysis patients were reported in three states: California, Nebraska, and Texas.

Dialysis facilities must comply with infection control precautionary guidelines, including those for HIV, hepatitis B, and tuberculosis, established by CDC. Dialysis unit precautions are more stringent than standard precautions that apply to other types of health care faciities. For example, standard precautions require the use of gloves only when touching blood, body fluids, secretions, excretions, or contaminated items. In contrast, dialysis unit precautions require glove use whenever patients or hemodialysis equipment is touched.

Virginia Statutes and Regulations Concerning Delegation of Nursing Tasks to Unlicensed Personnel Are Applicable to Renal Dialysis Facilities

Section 54.1-3000 of the *Code of Virginia* defines the practice of nursing. As defined by the *Code of Virginia*, "registered professional nursing" means the performance for compensation of any nursing acts in the:

- observation, care, and counsel of individuals who are ill, injured, or experiencing changes in normal health processes or in the maintenance of health;
- supervision and teaching of those who are or will be involved in nursing care;
- delegation of selected nursing tasks to appropriately trained unlicensed persons as determined by the Board of Nursing; or
- administration of medications and treatments as prescribed by any person authorized by law to prescribe such medication and treatment.

In January 1999, as required by House Bill 1055 passed by the 1998 General Assembly, the Board of Nursing promulgated emergency regulations concerning the delegation of nursing tasks by registered nurses to unlicensed personnel. The regulations established several criteria for determining which types of nursing tasks could be delegated. According to the regulations, delegation of nursing tasks and procedures shall occur only in accordance with a plan for delegation adopted by the entity responsible for client care. The delegation plan is required to provide "identification of the educational and training requirements for unlicensed persons and documentation of their competencies." Delegation shall be made only if several criteria are met. These criteria include:

- in the judgement of the delegating nurse, the task or procedure can be properly and safely performed by the unlicensed person and the delegation does not jeopardize the health, safety and welfare of the client; and
- the delegating nurse retains responsibility and accountability for nursing care of the client, including nursing assessment, planning, evaluation, documentation, and supervision.

According to the regulations, the delegating nurse shall determine the method and frequency of supervision of unlicensed staff to whom tasks have been delegated based on factors including, but not limited to:

- the stability and condition of the client;
- the experience and competency of the unlicensed person;
- the nature of the tasks or procedures being delegated; and
- the proximity and availability of the registered nurse to the unlicensed person when the nursing tasks will be performed.

Delegation of tasks that violat these provisions is grounds for disciplinary action by the Board of Nursing.

In Virginia, the standard industry practice is for unlicensed technicians to work under the direct supervision of a registered nurse. However, according to results of the JCHC staff survey, 31 percent of the respondents reported that they do not have a registered nurse on duty at all times, during all shifts, when the facility is open and providing dialysis treatment. According to these 16 facilities, a licensed practical nurse is on duty at all times, including those times when a registered nurse is not present. According to HCFA's interpretive guidelines to the Medicare certification regulations, "if state law requires a registered nurse or physician to administer emergency intravenous medications, then such a person must be present during dialysis treatments."

The emergency regulations promulgated by the Board of Nursing in January 1999 specify five types of nursing tasks which may not be delegated to any unlicensed person. These include:

- activities which involve nursing assessment, problem identification, and outcome evaluation which require independent nursing judgment;
- counseling or teaching except for activities related to promoting independence in personal care and daily living;
- coordination and management of care involving collaboration, consultation, and referral;
- emergency and non-emergency triage; and

- administration of medications except as specifically permitted by §54.1-3000 et seq. of the *Code of Virginia* (the Virginia Drug Control Act).

Several Types of Medications Are Routinely Used During Dialysis

Three types of medications are routinely used during hemodialysis. These are heparin, saline and lidocaine. Heparin is an anti-clotting medication that allows blood to flow freely through the dialysis machine. Lidocaine is frequently used as a local anesthetic during the initiation of dialysis. Saline is a solution used to prime the intravenous tubing prior to the initiation of dialysis. According to information collected from the JCHC staff survey, these medications are typically administered by unlicensed dialysis technicians, pursuant to medical treatment protocols established by the governing body of each facility. Only five of the 54 survey respondents reported that their unlicensed dialysis technicians do not administer any medications. Four of the 54 respondents reported that their unlicensed technicians also administer mannitol, which is given to expand blood volume, if too much fluid is removed or if fluid is removed so quickly that the patient has low blood pressure. Administration of these various types of medications is included as part of the national core curriculum for dialysis technicians.

Virginia Statutes Concerning The Types of Health Care Practitioners Who May Administer Medications Are Applicable to Renal Dialysis Facilities

Section 54.1-3408 of the *Code of Virginia* contains provisions concerning the administration of drugs by health care practitioners. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, a licensed nurse practitioner, a licensed physician assistant, or a TPA-certified optometrist is authorized by §54.1-3408 to "prescribe, dispense or administer controlled substances in good faith for medicinal or therapeutic purposes" within the course of professional practice. These practitioners may further cause drugs to be administered by a "nurse, physician assistant, or intern" under their direction and supervision.

Section 54.1-3408 of the *Code of Virginia* defines several exceptions to the general provision that only specific medical practitioners may administer drugs to patients. These exceptions include:

- other persons who have been properly trained and who administer drugs only under the control and supervision of the prescriber or a pharmacist, but only to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the

Board of Health or psychiatric hospitals licensed by the State Mental Health, Mental Retardation, and Substance Abuse Services Board;

- emergency medical services personnel who have been certified and authorized to administer such drugs pursuant to Board of Health regulations governing emergency medical services and who are acting within the scope of such certification;

- certified respiratory therapy practitioners may administer inhalation controlled substances;

- registered nurses and licensed practical nurses may be authorized by a prescriber to possess (1) epinephrine for administration in treatment of emergency medical conditions and (2) heparin and sterile normal saline to use for the maintenance of intravenous access lines;

- an employee of a school board, who is trained in the administration of insulin and glucagon, may assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes, pursuant to a written order or standing protocol issued by a prescriber, but only when licensed personnel are not present to administer the medication; and

- licensed pharmacists, registered nurses, or licensed practical nurses under the immediate and direct supervision of a registered nurse, may administer immunization vaccines to adults, pursuant to a protocol approved by the Board of Nursing.

Section 54.1-3408 of the *Code of Virginia* states further that its provisions "shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing, and who administers such drugs in accordance with a physician's instructions", but only when such drugs would normally be self-administered by:

- a resident of a facility licensed or certified by the State Mental Health, Mental Retardation, and Substance Abuse Services Board;
- a resident of any adult care residence which is licensed by the Department of Social Services;
- a resident of the Virginia Rehabilitation Center for the Blind and Visually Impaired;

- a resident of a facility approved by the Board of Juvenile Justice for the placement of children in need of services;
- a program participant of an adult day-care center licensed by the Department of Social Services; or
- a resident of any facility authorized or operated by a state or local government whose primary purpose is not to provide health care services.

None of the previously described statutory provisions concerning the administration of medications explicitly authorize unlicensed dialysis technicians to administer medications. However, other sections of the *Code of Virginia* that govern the practice of medicine and other healing arts also contain certain provisions concerning the types of individuals who may legally administer drugs. These provisions may also potentially apply to dialysis technicians. Section 54.1-2901 of the *Code of Virginia* states that the provisions of the chapter shall not prevent:

- "Any...other technical personnel who have been properly trained from rendering care or services within the scope of their usual professional activities which shall include the taking of blood, the giving of intravenous infusions and intravenous injections, and the insertion of tubes when performed under the orders of a person licensed to practice medicine"; and

- "Any practitioner licensed or certified by the Board [of Medicine] from delegating to personnel in his personal employ and supervised by him, such activities or functions as are nondiscretionary and do not require the exercise of professional judgement for their performance and which are usually or customarily delegated to such persons by practitioners of the healing arts...."

In all likelihood, the provisions of 54.1-2901 are those that dialysis facilities in Virginia are relying upon to authorize the administration of medications by dialysis technicians. However, given the stricter requirements of the Virginia Drug Control Act, and Board of Nursing regulations, the General Assembly may wish to clarify the provisions of the Code of Virginia concerning the conditions under which unlicensed dialysis technicians may administer medications.

The Renal Dialysis Industry Has Previously Examined Issues Pertaining to Training, Utilization, and Supervision of Unlicensed Dialysis Technicians

During the late 1980's and early 1990's both the Mid-Atlantic Renal Coalition and the National Kidney Foundation Dialysis Technician Task Force examined issues pertaining to the use of dialysis technicians within the industry. MARC established a subcommittee of its medical review board to address the use of dialysis technicians in Network 5. Based on its review, the MARC medical review board subcommittee issued the following recommendations:

- The use of dialysis patient care technicians, in a controlled environment, is appropriate.

- It is considered appropriate for patient care technicians to perform a specific set of routine dialysis activities, performed according to carefully designed protocols approved by the facility's governing body. These include the administration of heparin, normal saline, subcutaneous lidocaine, mannitol, hypertonic saline, and glucose.

- Training should be conducted internally by the facilities following a formal, written protocol approved by the facility's governing body.

- Certification and examination should be conducted internally by facilities following a formal, written protocol approved by the facility's governing body, and administered by a registered nurse trained in dialysis. The training protocol and certification process should include standards for completion and performance.

- Supervision by a registered nurse is preferred. However, this would impose significant economic and operational hardships on dialysis facilities in some areas, particularly rural areas where there is a significant nursing shortage. Supervision by a licensed practical nurse, who has undergone a qualification program for training and supervision in administration of medications, is therefore appropriate.

The subcommittee's final report was subsequently adopted by the MARC medical review board and the MARC board of directors.

The National Kidney Foundation dialysis technician task force reviewed job descriptions for dialysis technicians, as well as standards for training and possible mechanisms for certification. Based on its review, the task force developed its own position description for a dialysis patient care technician, as well as a training curriculum. According to the task

force, a review of state nurse practice statutes indicated that no legal barriers existed to the articulation of a role description for dialysis technicians based on existing practice patterns. However, according to the task force, a "notable exception is the administration of medications." The task force reported that the National Kidney Foundation "does not take exception to the administration of routine medications by dialysis technicians, but understands that local law may prohibit some activities." The dialysis technician position description developed by the task force included the administration of routine medications.

Only a Relatively Small Number of States Have Enacted Statutes and Promulgated Regulations Pertaining Specifically to Renal Dialysis Facilities

Most states do not require ESRD facilities to be licensed, nor do they regulate the qualifications, use or practice of dialysis technicians. The majority of states, including Virginia, rely on HCFA and its contractors (i.e., the Medicare ESRD survey inspection agencies and the ESRD network organizations) for quality assurance and patient protection within renal dialysis facilities. Only 16 states have enacted statutes to regulate ESRD facilities. These states are: Alabama, Arizona, California, Colorado, Connecticut, Kentucky, Maine, Massachusetts, Montana, Nevada, New Hampshire, Ohio, Oregon, Rhode Island, South Carolina, and Texas.

Thirteen of these states require that the facilities be licensed by the states, and impose various licensure provisions upon the facilities. Three of these states – California, New Mexico, and Oregon - do not require that the facilities be licensed, but do require that the dialysis technicians be certified as a condition of employment. These three states typically require that dialysis training and testing programs be approved by the state, that technicians receive a specified amount of annual continuing education, and that certification may be obtained from a nationally-recognized testing organization.

There is considerable variation in terms of the specific regulatory provisions that these states have enacted. For example, some states (i.e. Texas and South Carolina) have promulgated extensive regulations that replicate, in large part, the existing Medicare conditions of participation. However, some states have enacted regulations that do not appear in the Medicare regulations. For example, some states require that there be a registered nurse on duty in the facility at all times when dialysis treatment is being performed (i.e. Alabama, Connecticut, South Carolina). Other states have enacted minimum staff ratios (i.e. South Carolina and Texas). Some states have enacted statutes and regulations which specify the

conditions under which unlicensed dialysis technicians may administer medications (i.e. California, Nevada, New Mexico, Oregon, and Texas).

The Renal Dialysis Industry in Virginia Would Likely Oppose Any Additional Regulation of Facilities or Technicians

During JCHC staff interviews conducted during the study, numerous comments were made by representatives of the dialysis industry concerning their belief that no additional regulation by the state is warranted. Issues concerning fiscal stress on the industry due to low Medicare reimbursement, the extent of facility-based education and training programs, and the highly-regulated nature of the industry at present, were the common reasons provided as a justification for this opinion.

JCHC staff sought to obtain additional input from the industry through the facility survey. Due to the relatively low survey response rate, it is not possible to make inferences concerning all dialysis facilities in Virginia. However, among those 47 percent of facilities that responded to the survey, a majority of respondents indicated that some type of state licensure requirement for facilities is advisable (Figure 8). This finding is somewhat contradictory to interview comments that JCHC staff received from a small number of facility managers. It is possible that some types of staff within a facility, such as nurses, may have different views on the advisability of licensure than do other types of staff, such as administrators. For example, many of the facility responses to the JCHC survey that agreed that facility licensure is advisable were completed by supervising nurses rather than by the facility administrator to whom the survey was actually mailed by JCHC staff.

Figure 8 also illustrates that a majority of survey respondents do not believe that state licensure of dialysis technicians is advisable. Several respondents cited the likelihood of increased labor costs for facilities if technicians are required to be licensed. There was, however, more agreement among the survey respondents concerning the advisability of some type of mandatory certification requirement, short of actual licensures, for dialysis technicians.

Figure 8
Dialysis Industry Perspective on Advisability of Additional State Oversight or Regulation

JCHC Survey Statement	Percent of Survey Respondents Agreeing with Statement	Percent of Survey Respondents Disagreeing with Statement
State Licensure of Dialysis Facilities is Advisable	62%	38%
State Licensure of Dialysis Technicians is Advisable	36%	63%
Mandatory Certification of Dialysis Technicians is Advisable	46%	54%

Source: JCHC staff analysis of data collected from JCHC staff survey of dialysis facilities.

The Virginia Board of Health Professions Has Criteria for Determining Whether and At What Level Health Care Occupations Should Be Regulated

Criteria for determining whether and at what level health care occupations should be regulated were initially established by the Board of Health Professions (BHP) in 1983. The criteria were subsequently revised in 1991. In 1992, policies and procedures based on the revised criteria were adopted by the Board of Health Professions. The seven criteria are listed in Figure 9.

The BHP can decide, pursuant to its own authority, to study a particular health profession in order to determine if regulation is needed. In so doing, BHP would apply these criteria in order to assess the need for regulation. Alternatively, the General Assembly could direct the BHP to study the need for regulation of a particular health profession. According to BHP staff, the BHP has not examined the need for regulation of dialysis technicians. It was beyond the scope of this study to systematically apply the Board of Health Professions' criteria to the practice of unlicensed technicians within the renal dialysis industry in Virginia.

Figure 9
Virginia Board of Health Professions' Criteria for Evaluating the Need for Professional Regulation

Criterion	Description
Risk for Harm to the Consumer	The unregulated practice of the health occupation will harm or endanger the public health, safety, or welfare. The harm is recognizable and not remote or dependent on tenuous argument. The harm results from (a) practices inherent in the occupation, (b) characteristics of the clients served, (c) the setting or supervisory arrangements for the delivery of the health services, or (d) from any combination of these factors
Specialized Skills and Training	The practice of the health occupation requires specialized education and training, and the public needs to have benefit by assurance of initial and continuing occupational competence.
Autonomous Practice	The functions and responsibilities of the practitioner require independent judgment and the members of the occupational group practice autonomously.
Scope of Practice	The scope of practice is distinguishable from other licensed, certified, and registered occupations, in spite of possible overlapping of professional duties, methods of examination, instrumentation, or therapeutic modalities.
Economic Impact	The economic costs to the public of regulating the occupational group are justified. These costs result from restriction of the supply of practitioners, and the cost of operation of regulatory boards and agencies.
Alternatives to Regulation	There are no alternatives to State regulation of the occupation which adequately protect the public. Inspections and injunctions, disclosure requirements, and the strengthening of consumer protection laws and regulations are examples of methods of addressing the risk for public harm that do not require regulation of the profession or occupation.
Least Restrictive Regulation	When it is determined that State regulation of the occupation or profession is necessary, the least restrictive level of occupational regulation consistent with public protection will be recommended to the Governor, the General Assembly, and the Director of the Department of Health Professions.

Source: Virginia Board of Health Professions.

Advisability of State Regulation and Oversight of Renal Dialysis Facilities

The level and extent of policies, procedures and mechanisms that are currently in place through the Medicare program to regulate renal dialysis facilities appear to be reasonable. Industry regulators interviewed by JCHC staff stated their belief that the renal dialysis community is doing a good job of monitoring and policing itself within the existing federal regulatory structure. The empirical data that was available to JCHC staff is not suggestive of an urgent need for further regulation of the industry at this time. As has been previously discussed, dialysis outcome indicators for Virginia facilities appear to be favorable, most dialysis facilities have not been cited for deficiencies through the Medicare inspection process, and there have been relatively few complaints filed against facilities. In all likelihood, state licensure requirements for dialysis facilities would necessitate provision of additional resources to the Virginia Department of Health in order to administer the requirements.

On the other hand, more than 60 percent of the respondents to the JCHC staff survey agreed that state licensure of facilities is advisable. A key issue in considering the need for state licensure requirements is how often dialysis facilities need to be inspected by an outside entity in order to provide adequate assurance of quality care and patient protection. There does appear to be some support within the industry for more frequent inspections. A majority of the respondents to the JCHC survey indicated that they would prefer to receive a Medicare certification inspection at least every other year, while the current practice is to inspect the facilities every three years. The State of Texas has used its facility licensure program as a means of providing biennial inspections. Given that there will always be some facilities whose performance is relatively poor compared to the rest of the industry, the extent to which patients in those facilities are adequately protected under the existing regulatory structure is a valid public policy issue.

Advisability of State Licensure of Dialysis Technicians

Renal dialysis facilities rely extensively on the use of unlicensed dialysis technicians for the performance of many dialysis-related tasks, including the administration of certain prescribed medications. JCHC staff estimate that there are approximately 600 to 700 dialysis technicians employed in Virginia. Nearly two-thirds of the JCHC survey respondents believe that state licensure requirements for dialysis technicians are not advisable. A primary reason for this position appears to be concerns that licensure will increase labor costs for an industry that is already experiencing fiscal pressures.

Another means of increasing the amount of oversight of dialysis technicians, short of an actual licensure requirement, is a requirement for certification. There is also one nationally-recognized certifying body for dialysis technicians – the Board of Nephrology Examiners, Inc. (BONENT), which has been incorporated as an independent testing body since 1974. In order to take the BONENT examination, a dialysis technician must have at least one year of dialysis experience, and a high school diploma or equivalent. A primary goal of the BONENT program is to identify safe, competent practitioners in nephrology technology.

At the current time, it appears that extremely few dialysis technicians in Virginia are certified by BONENT. However, nearly half of the respondents to the JCHC staff survey expressed support for some type of mandatory certification requirement for dialysis technicians. In addition, the Virginia chapter of the National Association of Nephrology Technicians/Technologists is very supportive of certification. Nevertheless, a majority of the JCHC survey respondents did not believe that mandatory certification requirements for technicians are advisable. Some respondents pointed out that some dialysis patients are trained to perform hemodialysis at home with a partner, neither of whom are certified. Therefore, according to this view, why do technicians need to be certified?

The issue of dialysis technician certification requirements is being examined in other states, and may warrant further consideration in Virginia by the General Assembly. In Ohio, the issue has been developing for five years, and legislation is currently pending in the Ohio legislature. This issue could potentially benefit from additional study by the Board of Health Professions.

IV.
Overview of Mammography Services and Regulation

Mammography is an X-Ray Procedure Used to Detect Breast Cancer

Mammography is the most effective technique for the early detection of breast cancer. Mammography involves the use of specially-designed radiographic, or x-ray, equipment. The practice of mammography can be divided into two broad categories, screening and diagnostic. Screening involves examination of women who do not display any symptoms of breast cancer, in an attempt to detect cancer before a lesion is palpable. Diagnostic mammography is performed on women who, by virtue of symptoms or physical findings, are considered to have a substantial likelihood of already having breast cancer. There is a sub-category of diagnostic mammography called stereotactic mammography. This is used to assist physicians in guiding a biopsy needle to the site of the cancerous lesion. There are approximately 10,000 mammography facilities in the United States, 229 of which are located in Virginia.

Using mammography, small tumors and breast abnormalities can be detected up to two years before they would be found using a physical examination. In 1996, according to the Virginia Cancer Registry, there were more than 13,000 cases of breast cancer in Virginia, making it the single most prevalent type of cancer among state residents. It has been estimated that approximately 1,000 women in Virginia will die from breast cancer during 1999. Nationally, breast cancer is second only to lung cancer in the number of female cancer-related deaths. The American Cancer Society and the American Medical Association both recommend that women 40 years of age and older have an annual mammogram. The earlier that breast cancer is detected, the greater the likelihood of successful treatment and patient survival.

Although mammography can be very useful in detecting early-stage cancer, it is one of the most technically challenging radiological procedures. This is because mammograms are among the most difficult radiographic images to read, and ensuring the quality of the mammographic image is difficult. The effectiveness of mammography as a cancer detection technique is directly related to the quality of mammography procedures. A mammogram that is incorrectly interpreted as showing an abnormality could cause a woman to go through unnecessary, uncomfortable, and costly follow-up procedures, such as a biopsy. In addition, women would be subject to understandably high levels of stress due to the fear of having cancer. Conversely, a mammogram that is read as normal when an abnormality is actually

present could result in missed diagnosis and delayed treatment, which could subsequently result in the need for more costly treatments or even death.

The Practice of Mammography Was the Subject of Several National Reviews During the 1980s and Early 1990s

There were a number of developments within the radiation control and radiological professions pertaining to mammography beginning in the early 1980's. A 1980 report by the National Council on Radiation Protection and Measurements (NCRPM) reached several conclusions, including that, although the usefulness of mammography in symptomatic patients was well documented, the examination itself should be presumed to carry some risk of carcinogenesis. A 1986 report by NCRPM reached a number of conclusions, including:

- diagnostic mammography of symptomatic women should always be performed when indicated, utilizing recommended equipment and techniques and well-trained, knowledgeable personnel;
- mammographic equipment should be chosen to provide acceptable image quality at typical average radiation dose values; and
- image quality should be maintained by a quality assurance program involving specified periodic measurements and readjustment of all aspects of the imaging/viewing system.

In 1986 the U.S. Food and Drug Administration (FDA), in collaboration with the states, evaluated the radiation exposures of mammography machines used by radiological facilities. The study also included an evaluation of image quality. The results showed an overall decrease in radiation exposure from the previous decade, although there were a significant number of procedures being performed using equipment not specifically designed for mammography. In addition, the image quality scores were significantly low, raising concerns as to whether cancers were remaining undetected.

A 1990 U.S. General Accounting Office study found that many mammography providers lacked adequate quality assurance programs. In 1991, the U.S. Health Care Financing Administration (HCFA) established a certification program for Medicare providers through its Medicare screening mammography program. In 1992, hearings held by the U.S. Senate Committee on Labor and Human Resources revealed a wide range of problems with mammography services in the United States.

The Federal Mammography Quality Standards Act Governs the Practice of Mammography

In 1992, the U.S. Congress enacted the Mammography Quality Standards Act (MQSA). This federal statute became effective on October 1, 1994, and applies to all mammography facilities in the U.S. with the exception of those operated by the U.S. Department of Veterans Affairs. The goal of the legislation was to assure that mammography is safe and reliable, and thus will allow detection of breast cancer at its earliest, most treatable stages. The MQSA contains a number of requirements, including that:

- the FDA establish quality standards for mammography equipment, personnel, and practices;
- all mammography facilities be accredited by an FDA-approved accrediting body (either a nonprofit organization or a state agency) and obtain a certificate from the FDA in order to legally provide mammography services after October 1, 1994; and
- all mammography facilities be evaluated annually by a certified medical physicist and be inspected annually by FDA-approved inspectors.

The MQSA also provides a right of appeal for mammography facilities who are denied certification, and requires the U.S. Secretary of Health and Human Services to annually evaluate the performance of each accrediting body and report its findings to Congress. The MQSA authorizes sanctions for facilities that fail to comply with its provisions. Sanctions which may be imposed include directed plans of correction, monetary penalties, as well as suspension and revocation of the MQSA certificate. In certain circumstances, the U.S. Secretary of Health and Human Services may suspend a certificate before holding a hearing. If a facility's certificate is revoked, no person who owned or operated the facility at the time of the sanctioned act may own or operate a mammography facility for two years. The U.S. Secretary of Health and Human Services is also authorized to file suit in federal court in order to enforce the provisions of the MQSA. The MQSA provides for the right of sanctioned facilities to seek judicial review of the sanctions, through the federal appellate courts.

The MQSA was reauthorized by Congress in 1998. The reauthorization legislation granted the FDA some additional authority to regulate mammography. Among the provisions of the reauthorizing legislation were those:

- requiring that a report describing the mammogram results, in terms easily understood by a lay person, be sent directly to each patient;

- authorizing the U.S. Secretary of Health and Human Services, if it is determined that the quality of mammography performed by a facility is so inconsistent with quality standards as to present a significant health risk, to require such facility to notify patients and their referring physicians of the deficiencies presenting such risk, the potential harm resulting, and appropriate remedial measures;

- requiring that mammograms be maintained by a facility with the patient's medical records for at least five years, or for at least ten years if no subsequent mammograms of the patient are performed by the facility; and

- requiring that a facility release original mammograms, not copies, when a patient requests the films.

The current congressional authorization for the MQSA expires in 2002.

The FDA Has Promulgated Regulations Pursuant to the MQSA

Several different type of mammography personnel must comply with the requirements of the MQSA:

- Physicians who interpret mammographic images,
- Radiologic technologists who perform mammographic procedures, and
- Medical physicists who survey mammography equipment and oversee the equipment-related quality assurance practices of the facility.

Following the enactment of the MQSA, the FDA issued interim regulations that established requirements for accrediting bodies and quality standards and certification requirements for mammography facilities. These interim regulations became effective in February 1994. The FDA published the MQSA final regulations in October 1997, which became effective on April 28, 1999. There are two major sections to the regulations: (1) accreditation, and (2) quality standards and certification.

The federal regulations, summarized in Figure 10, contain quality standards pertaining to the following areas:

- personnel,
- equipment,
- medical records and mammography reports,
- quality assurance – general,
- quality assurance – equipment,
- quality assurance – mammography quality outcomes audit,

- mammographic procedures and techniques for mammography of patients with breast implants,
- consumer complaint mechanism,
- clinical image quality, and
- additional mammography review and patient notification.

Figure 10

Minimum Quality Standards For Mammography – Summary of Selected Provisions

Standard	Summary of Requirements
Personnel	Defines the initial qualifications (in terms of certification and licensure, and formal training and medical education in mammography) and continuing experience and education for interpreting physicians, radiologic technologists, and medical physicists.
Equipment	All radiographic equipment used for mammography shall be specifically designed for mammography. There are technical requirements pertaining to motion of the tube-image receptor assembly, image receptor sizes, beam limitation and light fields, magnification, focal spot selection, compression, technique factor selection and display, automatic exposure control, x-ray film, intensifying screens, film processing solutions, lighting, and film making devices.
Medical Records and Mammography Reports	Defines contents and terminology, communication of mammography results to the patient and to health care providers, facility recordkeeping, and mammographic image identification.
Quality Assurance – General	Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services. Defines the quality assurance responsibilities of the lead interpreting physician, interpreting physicians, medical physicist, and quality control technologist. Requires maintenance of quality assurance records.

Figure 10 (continued)

Minimum Quality Standards For Mammography – Summary of Selected Provisions

Standard	Summary of Requirements
Quality Assurance - Equipment	Each facility must perform a variety of equipment tests. Depending on the test, they are performed on either a daily, weekly, quarterly, semi-annual, or annual basis. Every day, the film processor shall be tested to ensure that it is properly adjusted and maintained. Weekly tests include an image quality evaluation including an FDA-approved phantom. Semi-annual tests include those for darkroom fog, screen-film contact, and compression device performance. Annual tests include those for automatic exposure control performance, kilovoltage peak accuracy and reproducibility, and focal spot condition.
Quality Assurance – Mammography Medical Outcomes Audit	Each facility shall follow-up on positive mammography assessments and shall collect and review outcome data in order to correlate pathology results with the interpreting physician's findings. This is designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms. Audit analyses shall be performed at least annually.
Consumer Complaint Mechanism	Each facility shall have a documented system for collecting and resolving complaints. A record of each serious complaint shall be retained for at least three years. Consumers must be instructed on how to address serious complaints to the accreditation body. Unresolved serious complaints must be reported by the facility to the accreditation body.
Clinical Image Quality	Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

Source: JCHC staff analysis of Quality Mammography Standards, Final Rule (Federal Register, October 28, 1997).

In June 1997, the FDA published a direct final rule that amended the mammography regulations to include a new reporting requirement that each facility send all patients a summary of the mammography report written in lay terms within 30 days of the mammographic examination. In the case of "suspicious" or "highly suggestive of malignancy" results, the facilities are required to send patients a summary of the mammography report as soon as possible.

Federal Regulations Concerning Accreditation of Mammography Facilities

The purpose of accreditation is to ensure that all mammography facilities are adequately and consistently evaluated for compliance with national quality standards. The federal MQSA regulations provide accrediting bodies with several types of responsibilities. The accreditation review consists of two general processes: (1) evaluation of facility documentation, including that pertaining to personnel qualifications, education, training, as well as a mammography equipment evaluation performed by a medical physicist; and (2) an examination of mammographic images.

The accreditation body is required to review clinical images from each facility accredited by the body at least once every three years. Clinical images are actual mammographic films taken by facility staff. The accreditation body is required to use the following attributes for all clinical image reviews:

- positioning – sufficient breast tissue shall be imaged to ensure that cancers are not likely to be missed because of inadequate positioning;
- compression – shall be applied in a manner that minimizes the potential obscuring effect of the overlying breast tissue;
- exposure level – shall be adequate to visualize breast structures;
- contrast - shall permit differentiation of subtle tissue density differences;
- sharpness - margins of normal breast structures shall be distinct and not blurred;
- noise –noise in the image shall not obscure breast structures or suggest the appearance of structures not actually present;
- artifacts – artifacts due to lint, processing, scratches, and other factors external to the breast shall not obscure breast structures or suggest the appearance of structures not actually present; and
- examination identification – each image shall be identified using specified information.

According to the regulations, all clinical images that are submitted must be those that the facility's interpreting physician interpreted as negative or benign.

The accreditation body is also required to review "phantom" images as part of the accreditation review process. A phantom is an FDA-approved plastic block that contains 16 embedded objects of varying size and type. The phantom is intended to serve as a model of a female breast that contains various types of abnormalities. A phantom image test is used to assess the ability of a mammography facility to produce high quality images by radiographing the plastic block to determine how many of the embedded test objects can be detected in the resultant image. An accreditation body is required to use a system for scoring phantom images that has been approved by the FDA.

Accreditation bodies are also required to conduct on-site visits and random clinical image reviews of a sample of facilities to monitor their compliance with established standards. Each accreditation body is required to annually visit at least five percent of the facilities it accredits. However, a minimum of five facilities shall be visited, and visits to no more than 50 facilities are required. At least 50 percent of the facilities visited shall be randomly selected. Other facilities visited shall be selected based on problems identified through state or FDA inspections, serious complaints received from consumers or others, a previous history of noncompliance, or any other information in the possession of the accreditation body, inspectors, or the FDA. Accreditation bodies are also required to conduct annual clinical image reviews of randomly selected images for at least three percent of the facilities that it accredits.

The MQSA is Generally Credited with Helping to Promote Improvements Within the Practice of Mammography

The initial impact of the MQSA program on mammography quality was evaluated by the U.S. General Accounting Office (GAO) in 1995. GAO concluded that there had been quality improvements, and attributed the improvement to two factors. First, all mammography facilities had to meet a single uniform set of national standards that were substantially the same as those advocated by the American College of Radiology (ACR). Second, 35 percent of the facilities that underwent a first review of accreditation by the ACR between October 1994 and August 1995 failed, but over 85 percent of those facilities subsequently received accreditation after improving the quality of their performance. According to GAO, this represented a major improvement in the quality of mammography nationwide.

In 1997, another GAO report compared MQSA inspection results in fiscal years 1995 – 1997. The report concluded that overall MQSA had a positive effect on the quality of mammography services, and had not affected consumer access to mammography services. The 1997 GAO report noted that the percentage of facilities with significant deficiencies in meeting the interim MQSA regulations declined from 23 percent in FY 1995 to 13 percent in FY 1997. GAO also found that the percentage of facilities with acceptable phantom image tests had remained at 98 percent since 1995, compared to the 89 percent level found in 1992 during a pre-MQSA national survey of mammography facilities.

Administration of the MQSA Accreditation and Certification Program in Virginia Involves the FDA, the American College of Radiology, and the Virginia Bureau of Radiological Health

In Virginia, as in every other state, the FDA is ultimately responsible for the proper implementation and administration of all the MQSA requirements. This entails certifying all U.S. mammography facilities that have received accreditation by an approved accreditation body; training and certifying federal and state inspectors, inspecting all mammography facilities annually, overseeing facility efforts to correct deficiencies, and educating mammography facilities and the public about quality mammography. In Virginia, the FDA is the "certifying body", which means that it is the entity that actually issues the formal certificate to facilities which demonstrate compliance with all of the MQSA accreditation and certification requirements. The FDA can also respond to consumer complaints and initiate enforcement actions.

Most of the FDA-certified MQSA facility inspectors are state personnel, typically employees of state health departments, working under contract with FDA. Currently, 47 states have MQSA inspection contracts with the FDA. In Virginia, the FDA has contracted with the Virginia Bureau of Radiological Health, which is part of the Virginia Department of Health, to perform the annual MQSA certification inspection for each of the 229 mammography facilities located in Virginia. Annual MQSA certification inspections were implemented in October 1995.

In Virginia, as in 45 of the other 49 states, the American College of Radiology is the sole "accreditation body", which means that it is the only entity that has been authorized by the FDA to accredit mammography facilities. Pursuant to the MQSA, a facility must be re-accredited every three years.

The American College of Radiology Has Been The Primary Accrediting Body for Mammography Facilities In Virginia and Across the United States Since 1987

The ACR, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The ACR is a non-profit professional society whose primary purposes are to advance the science of radiology, improve service to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education. The ACR is the country's oldest and largest accrediting body for mammography. The mammography accreditation program was initially developed in 1987 by the ACR task force on breast cancer.

Originally, the ACR accreditation program was purely voluntary. The FDA used the ACR accreditation process as its model in drafting the accreditation requirements contained in the MQSA. In March 1994, following the enactment of the MQSA and the mandatory accreditation requirement, the ACR was approved by the FDA as an accrediting body. Currently, the ACR accredits over 95 percent of the approximately 10,000 mammography facilities in the United States. As the accreditation body, the ACR can respond to and investigate complaints against facilities. The ACR received only three complaints against Virginia facilities from August 1996 through August 1999.

Pursuant to the ACR accreditation program, each facility must complete an entry application to provide basic facility, equipment, and personnel information. If the facility satisfies the initial accreditation evaluation criteria, the ACR notifies the FDA that the facility has submitted an application package and in turn the FDA issues the facility a six-month provisional certificate. A full application is then sent to the facility which requests information concerning various MQSA requirements, including the qualifications of personnel. Image quality and radiation dose evaluations are conducted based on review of phantom images and clinical images. Processor quality control documentation must also be submitted. When all stages of the evaluation are completed, a final report that includes specific assessments and recommendations is issued. Those facilities that successfully meet all criteria are awarded a three-year accreditation.

The ACR sends an annual update package to each accredited facility for completion in order to verify that they maintain consistent quality during the three-year accreditation period. As part of this verification process, facilities are required to submit quality control documentation, a medical physicist's survey report for each mammography unit, and an

update of their application data, identifying changes in personnel and equipment. Additional validation through on-site surveys and random film checks may also be performed by ACR at any time during the accreditation cycle (Figure 11).

The Virginia Bureau of Radiological Health Conducts the Annual MQSA Facility Certification Inspection for the FDA

The Virginia Bureau of Radiological Health (BRH) is part of the Virginia Department of Health's Office of Epidemiology, Division of Health Hazards Control. The BRH contains a number of program units. These include X-ray registration and inspection, radioactive materials licensing and inspection, environmental radiation, emergency response, and indoor radon. A key operating objective of the BRH is to protect the public from unnecessary exposure to radiation.

Figure 11

On-Site Visits to Mammography Facilities Performed by the American College of Radiology (1996 – 1999)

Type of On-Site Visit	Number Performed in United States	Number Performed in Virginia
Targeted, Interventional On-Site Visits	66	2
Randomly Selected On-Site Surveys	137	2
Randomly Selected and Targeted Clinical Image Reviews	1,246	22

Source: American College of Radiology.

Once a facility receives accreditation, the FDA issues the facility a full certificate and the BRH has one year to complete an inspection. The state inspector will contact the facility to schedule an on-site inspection. The facility is notified at least five days prior to the start of the inspection. The MQSA inspection covers the following areas:

- equipment performance, including phantom image quality and radiation dose;

- radiologic technologist and medical physicist quality assurance/quality control tests and tasks;
- medical audit and outcome analysis records;
- medical records (mammography reports); and
- personnel qualification records.

The BRH is not involved in the resolution of complaints made against a facility.

The BRH utilizes two FTEs to perform the MQSA inspections. This workload is actually spread among one radiation safety supervisor and five radiation safety specialists. Regional inspectors are used by BRH to minimize travel and lodging costs. In Virginia, the MQSA certification inspection takes, on average, about six hours to complete. If there are items of noncompliance, the facility is required to address those deficiencies and, depending upon the severity of the non-compliance, may have to submit a plan of corrective action to the FDA and the state inspector. Each of these BRH staff have received MQSA inspector training from the FDA, and are FDA-certified. These individuals must also receive continuing education and training in order to maintain their status as FDA-certified MQSA inspectors. Pursuant to the contract with BRH, the FDA has provided test equipment for each of the inspectors and a laptop computer for uploading inspection data to the FDA. The same test equipment is also used for state inspections of other x-ray equipment.

The FDA contract with Virginia for federal fiscal year 1999 provides $119,464 for inspections and $9,378 for training. The FDA reimburses the states for the cost of the annual inspections under the contract. The cost to the facility for the annual MQSA certification inspection is $1,549 per facility and $204 for each additional mammography unit. If the items of non-compliance are severe, then a follow-up inspection may be necessary. The fee for a follow-up inspection is $878. These funds are paid by the facility to the FDA, which in turn uses the revenue to reimburse the states for performing the facility inspections.

Most Virginia Mammography Facilities Are Found to Have No Deficiencies During MQSA Certification Inspections

MQSA certification inspections can result in a facility being cited for three different levels of deficiencies. Level one deficiencies are considered to be the most serious, followed by level two, with level three deficiencies

considered the least serious. Examples of level one deficiencies include a failure of the facility to adhere to the various types of personnel qualification standards, particularly those requiring licensure and certification. Examples of level two deficiencies include failure to comply with continuing education requirements, inadequate phantom image scores, and inadequate quality control documentation. Level three deficiencies include a failure of the facility to display its MQSA certificate, as well as various film processing deficiencies.

Figure 12

Deficiencies Cited During MQSA Certification Inspections of Virginia Mammography Facilities (Percentage of Each Type of Deficiency Cited)

Deficiency Level(s)	Federal Fiscal Year 1999 (Year-to-Date)	Federal Fiscal Year 1998
1 and 2, Only	1%	0%
1 and 3, Only	0%	0%
2 and 3, Only	9%	13%
1,2, and 3	0%	1%
1 Only	0%	0%
2 Only	10%	15%
3 Only	19%	11%
No Noncompliance	61%	59%

Note: All figures do not total to 100 percent due to rounding.
Source: JCHC staff analysis of U.S. Food and Drug Administration data.

According to data provided by the FDA, about 60 percent of Virginia facilities were found to have no deficiencies during inspections conducted from 10/1/97 – 9/30/98. (Figure 12). Of the 39 percent of facilities cited for deficiencies, virtually all of the deficiencies cited were for level two or three. In addition, there were far fewer level one deficiencies in Virginia than in the U.S. as a whole. During inspections conducted

since October 1, 1998, that trend is continuing. During inspections conducted thus far in federal fiscal year 1999, 61 percent of Virginia facilities have no deficiencies. According to FDA data, Virginia's inspection deficiency statistics, including the percentage of facilities with zero deficiencies, are comparable to the facility data for the United States as a whole.

V.
State Involvement in Mammography Regulation

The *Code of Virginia* Contains Provisions Governing the Control of Radiation, Including That Used in the Healing Arts

Section 32.1-277 et seq. of the *Code of Virginia* authorizes the State Board of Health to "establish a program to promote the orderly regulation of radiation within the Commonwealth...and to facilitate intergovernmental cooperation with respect to use and regulation of sources of radiation to the end that duplication of regulation may be minimized." The State Board of Health is also authorized by statute to "establish a program to permit maximum utilization of sources of radiation consistent with the public health and safety." Section 32.1-277 of the *Code of Virginia* requires the State Board of Health to "require registration, inspection and certification of all diagnostic and therapeutic x-ray machines used in the healing arts." The State Health Commissioner is authorized to impound, pursuant to §32.1-238 of the *Code of Virginia*, sources of radiation in the possession of any person "who is not equipped to observe or fails to observe" provisions of Virginia law or VDH regulations.

Section 32.1-233 of the *Code of Virginia* establishes a Radiation Advisory Board (RAB) to be appointed by the Governor. The statutory responsibilities of the RAB are to:

- review and evaluate policies and programs of the Commonwealth relating to ionizing radiation; and
- make recommendations to the Commissioner and Board of Health...and furnish such technical advice as may be required, on matters relating to the development, utilization, and regulation of sources of ionizing radiation.

The Virginia Department of Health Promulgated Radiation Protection Regulations in 1988

Pursuant to its statutory authority, the VDH has promulgated regulations concerning radiation protection. These regulations, which include equipment performance criteria, are not specific to mammography. However, certain of the regulatory provisions are applicable to the practice of mammography. These include, primarily, the requirement that every owner or operator of an X-ray machine shall have the machine certified and inspected by the VDH. In practice, for

mammography equipment, the MQSA certification inspection satisfies Virginia's state regulatory requirement for certification and inspection of X-ray equipment. However, mammography facilities must still pay an annual $15 state registration fee, which applies to all types of general purpose x-ray machines pursuant to VDH regulations.

According to BRH management, the State's radiation protection regulations are dated and in need of substantial revision. BRH staff spent approximately two years drafting proposed revisions to the regulations. In the Spring of 1999, the draft revisions prepared by BRH staff underwent internal review by VDH management. Subsequently, a decision was made by VDH management to re-start the process of drafting revisions to the radiation protection regulations. At the present time, the regulations promulgated in 1988 are still in effect.

Federal Regulations Authorize States to Apply to the FDA to Become Accrediting Bodies for Mammography Services

State agencies wishing to be designated as accreditation bodies for mammography services by the FDA are required to undergo an extensive application process. As part of the application, state agencies must provide a detailed description of the accreditation standards the applicant will require facilities to meet, and substantiate their equivalence to the quality standards contained in the MQSA. Applicants must also provide a detailed description of the accreditation review and decisionmaking process that will be used, including the following:

- procedures for performing clinical image reviews, random clinical image reviews and additional mammography reviews;
- procedures for performing phantom image review;
- procedures for assessing mammography equipment evaluations and surveys;
- procedures for initiating and performing onsite visits to facilities;
- procedures for assessing facility personnel qualifications;
- copies of the accreditation application forms, guidelines, instructions and other materials the applicant will send to facilities during the accreditation process, including an accreditation history form that requires each facility to provide a complete history of prior accreditation activities;

- policies and procedures for notifying facilities of deficiencies;
- procedures for monitoring corrections of deficiencies by facilities;
- policies and procedures for suspending or revoking a facility's accreditation;
- policies and procedures that will ensure processing of accreditation applications and renewals within a timeframe approved by FDA;
- description of the applicant's appeals process for facilities contesting adverse accreditation status decisions;
- education, experience, and training requirements for the applicant's professional staff, including reviewers of clinical or phantom images;
- description of the applicant's electronic data management and analysis system, and the applicant's ability to provide electronic data in a format compatible with FDA data systems;
- resource analysis that demonstrates that the applicant's staffing, funding, and other resources are adequate to perform the required accreditation activities;
- fee schedules with supporting cost data;
- statement of policies and procedures established to avoid conflicts of interest;
- statement of policies and procedures established to protect confidential information;
- description of the applicant's consumer complaint mechanism; and
- any other information as may be required by the FDA.

Only Four States Have Been Certified As Accreditation Bodies By FDA

Mammography facilities in Virginia, as is the case in the vast majorityof the states, are accredited by the ACR. Only four states – Arkansas, California, Iowa, and Texas – have been designated as accreditation bodies by the FDA. In these four states, mammography

facilities have the option of seeking accreditation from the ACR, or from the state agency. Pursuant to the MQSA, a state cannot mandate that a mammography facility in its state only seek accreditation from the state agency. The specific state agencies which have been designated as accreditation bodies are:

- Arkansas Department of Health – Division of Radiation Control and Emergency Management;
- California Department of Health Services – Radiologic Health Branch;
- Iowa Department of Public Health – Bureau of Radiological Health; and
- Texas Department of Health – Bureau of Radiation Control.

The FDA Believes That The Four States' Accreditation Bodies Are Functioning Effectively, and In a Manner Comparable to the ACR, And Are Upholding MQSA Quality Standards

The MQSA requires the FDA to annually evaluate the performance of all accreditation bodies, and to report the results of its evaluation to Congress. The evaluation is required to include a determination of whether there are major deficiencies in an accreditation body's performance that, if not corrected, would warrant withdrawal of FDA-approval. According to the FDA, the four state agencies already approved as accreditation bodies are all performing very well in their roles.

The most recently available FDA evaluation report to Congress is for the time period June 1, 1996 – May 31, 1997. According to the report, "all accreditation bodies are meeting the legal requirements established under the MQSA." The report concluded that:

- all accreditation bodies had adequate professional staffing levels and staff members all had proper qualifications;

- all accreditation bodies had instituted policies and procedures to ensure that applications are fully and properly processed within a six month time period;

- there were no significant differences in average phantom image scores;

- outcomes for overall phantom image acceptability were consistent and appropriate among selected accreditation body phantom image reviewers;

- all of the accreditation bodies' clinical image review programs were of high quality;

- clinical image review quality control activities which promote consistency among the various reviewers were in place at all of the accreditation bodies; and

- overall compliance levels among facilities were comparable, suggesting comparable performance among accreditation bodies.

FDA's most recent evaluation report, for the time period June 1, 1997 through May 31, 1998, is still in draft form and the subject of internal review at FDA. Therefore, this more recent report was not available for use by JCHC staff. However, according to a JCHC staff interview with an FDA official, FDA continues to be highly satisfied overall with the performance of the state accreditation bodies.

There Are Some Differences Among The Various Accreditation Programs

An FDA official told JCHC staff that there is a "difference in styles" between the ACR accreditation review process and those utilized by the states. The strengths of the ACR process were described as including the use of national experts to conduct the clinical and phantom image reviews. The state programs were described as "much more hands on, and able to guide facilities through the process." According to the FDA official, staff from the state accreditation bodies know the mammography facilities, and have hands-on experience, which "makes a difference."

One of the primary differences between the ACR's accreditation review process and those of some of the other states is the number of times that a facility is allowed to submit mammographic images for review prior to "failing" the accreditation process. If a facility's initial submission to the ACR is determined to be deficient, ACR allows one additional submission. If that submission is also determined to be deficient, the facility is considered to have "failed" accreditation. Some of the other accreditation bodies allow a greater number of submissions than does ACR prior to failing a facility (Figure 13). According to the FDA, the higher number of allowed submissions in Arkansas and Iowa is due primarily to the fact that those states, through the use of their own clinical image review panels, are able to complete the image review process more quickly than is ACR.

- Another distinction among the state accreditation bodies is whether or not the state has decided to contract with the ACR for the review of clinical and phantom images. ACR utilizes national panels of 90 radiologists and 34 medical physicists to review clinical images and phantom images, respectively. Each member

Figure 13
Number of Permitted Submissions of Mammographic Images By Accreditation Bodies

Accreditation Body	Number of Submissions	Explanation of Accreditation Provisions
American College of Radiology	2	Following failure, a facility may be allowed to resume mammography by being "reinstated". This requires the facility to submit a corrective action plan to ACR. If the corrective action plan is approved, the facility is reinstated and may re-apply for accreditation.
Arkansas	3	A corrective action plan is required after a third failure. Upon submission of corrective action plan, facility may re-apply for accreditation
California	3	Preceptorship training program required for facilities that fail accreditation a third time
Iowa	3	Corrective action plans are required after a second failure. Significant corrective actions, such as new staff or new equipment, are required after a third failure. Facilities that fail a fourth time are denied re-application without major corrective action, such as a new radiologist and/or a new mammographic unit.
Texas	3	After each denial, the facility must submit a corrective action plan for approval. With each denial, the corrective action plan becomes more extensive. After the third denial, the facility is required to put all of their mammography personnel through a preceptorship training program and have an on-site visit by accreditation body staff.

Source: JCHC staff interviews, and analysis of data provided by the five accreditation bodies.

of the panel receives additional training from the ACR. California and Texas contract with the ACR for clinical and phantom image reviews, and therefore utilize the ACR review panels. Arkansas and Iowa, in contrast, have elected to establish their own image review panels:

- Arkansas has its own clinical image review panel of six radiologists who serve on a voluntary basis. The state also has its own three-person phantom image review panel of FDA-certified MQSA inspectors who have appropriate training in phantom image review.
- Iowa has its own clinical image review panel of six board-certified radiologists with active mammography practices in Iowa. These reviewers participate in an initial training and annual radiological in-services. Iowa's phantom image review panel consists of three MQSA-trained mammography inspectors, and one board-certified medical physicist.

The FDA Assesses Accreditation Pass and Fail Rates As Part of Its Evaluation Report to Congress

From June 1, 1996 through May 31, 1997, according to the FDA's most recently available report to Congress, the accreditation pass rate of mammography facilities varied from 81 percent to 100 percent at the conclusion of the six-month accreditation cycle. Accreditation pass rates for the various accreditation bodies were as follows:

- California – 81 percent,
- American College of Radiology – 98 percent,
- Arkansas – 100 percent, and
- Iowa – 100 percent.

These accreditation pass rates represent the percentage of facilities that have been accredited upon the expiration of the maximum number of mammographic image submissions that each state allows. So, for example, 100 percent of the facilities that applied to Iowa passed by their third submission.

According to the FDA, there was a difference between the ACR and the state accreditation bodies regarding the reasons for failing the accreditation process. "Because of the interactive relationship between the States and their facilities, the State accreditation bodies require and verify that all deficiencies for phantom image scores are corrected prior to submission of clinical images. Consequently, the only reason for failure with a State accreditation body is suboptimal clinical images. By comparison, according to the FDA, "approximately 15 percent of failures

under the ACR accreditation process are for reasons other than clinical image review."

The accreditation pass rate reported by FDA is different in concept from the percentage of facilities who are deemed to be deficient based on the review of their initial submission. According to ACR, 30 percent of its facilities are currently determined to be deficient based on their initial submission. According to staff of the other accreditation bodies, their initial deficiency rates are lower than ACR's:

- California – 21%,
- Iowa – 5%, and
- Arkansas – 2%.

The fact that initial deficiency rates are higher than the actual accreditation failure rate reflects the fact that most facilities adequately correct any deficiencies prior to making a second submission.

The Virginia Bureau of Radiological Health Favors an Approach Under Which Virginia Would Apply to the FDA to Become An Accreditation Body, Thereby Streamlining the Regulatory Structure

According to BRH staff, while the MQSA has improved the quality of mammography services in the United States, the regulatory process is cumbersome. Furthermore, in the opinion of BRH staff, a lack of coordination among the FDA, the ACR, and the BRH provides opportunities for noncompliance. However, only one such actual incident of non-compliance has been cited by BRH staff:

> *A mammography facility in Virginia, which used a mobile unit to provide services, applied to the ACR for accreditation, was issued a provisional certificate, and subsequently failed the clinical image review. The facility informed the ACR that it was discontinuing mammography services. Subsequently, however, the facility submitted another package to ACR to perform mammography, and another provisional certificate was issued. The facility again failed the clinical image review, and ACR instructed the facility to return the provisional certificate. The facility did not return the certificate. The BRH never inspected the facility, since it was always in provisional status, and MQSA inspections are not performed on machines while they are in provisional status.*
>
> *Following an inquiry by a local hospital concerning the mobile facility, BRH notified the FDA, which sent an enforcement team to the facility. The FDA requested assistance from BRH to impound the mammography equipment, provide a clinical review of the facility's images, and provide for*

patient notification. BRH determined that no state regulation had been violated, and consequently there was no basis for impounding the machine. BRH also notified FDA that it had no mechanism to perform clinical image reviews. A private inspector under contract to BRH had completed the state inspection of the equipment three months prior, and had failed to question the facility's statement that it was initiating a package for provisional status to the ACR.

According to BRH management, this facility took advantage of its provisional status in order to continue to provide mammography services even though it was not certified. The FDA does not follow-up on facilities terminating mammography services while in provisional status, to ensure that provisional certificates are returned. However, BRH management also acknowledged that its private inspector had not provided adequate services, and should have recognized the situation when the state inspection was performed. Furthermore, according to BRH management, its inability to impound the machines reflects the fact that the state's radiation protection regulations are dated, and need to be revised in order to link state x-ray equipment registration and certification requirements to federal mammography certification requirements. In this case, the owner and operator of the facility did plead guilty pursuant to an enforcement action iinitiated by FDA.

BRH management and staff are of the opinion that it would be advantageous for the Virginia Department of Health, through the Bureau of Radiological Health to seek accreditation body status from the FDA. BRH management and staff have described several advantages that they believe would result from accreditation body status. In general, BRH strongly believes that it can administer an accreditation review process that is comparable to that of the ACR, while providing a better level of overall service to mammography facilities in the state, at a lower cost to facilities than is currently charged by the ACR. One of the primary reasons that BRH believes this to be true is that, since its staff currently perform annual MQSA inspections on all Virginia facilities, it is more familiar with the personnel, operations, practices, and equipment in these facilities than ACR could realistically expect to be.

According to BRH, a simplified regulatory structure would provide facilities with "one-stop shopping" concerning questions that facilities have concerning MQSA. In other words, facilities would have to deal in practice with only one entity for MQSA purposes than the current two. During interviews with JCHC staff, BRH management acknowledged that accreditation body status would increase its workload, but is of the opinion that mammography facilities in Virginia would benefit as a result. Officials from the other state accreditation bodies expressed the general

opinion the practice of mammography in their states has been further improved as a result of the state's involvement in accreditation.

The Commonwealth's Radiation Advisory Board has previously discussed the feasibility of Virginia becoming an accreditation body. The RAB established a committee to examine the issue. In 1997, work began on a draft report but it was never completed.

The four state accreditation bodies have provided several different explanations of what their motivations were to seek accreditation body status from the FDA:

- The Arkansas General Assembly passed a law in 1989 requiring mammography facilities be accredited through the Arkansas Department of Health (ADH). The fact that the ADH already had a viable accreditation program tailored after the voluntary ACR program, and that Arkansas mammography facilities were already familiar with ADH policies and procedures, was the primary considerations in seeking accreditation body status.

- Iowa considered the level and quality of service that they could provide to facilities, compared to that provided by the ACR, to be its primary motivation in seeking accreditation body status.

- Texas was mandated by the 1997 state legislature to apply for accreditation body status. The legislation was a result of mammography facilities indicating their preference for a state-operated accreditation body. The Texas department of health believed that mammography facilities would benefit from "one-stop shopping" that would result from a reduced number of regulatory bodies. Texas also determined that it could charge a lower accreditation fee than the ACR.

- California had an existing state certification program for mammography equipment, and viewed accreditation body status as an extension of its regulatory function.

At the request of JCHC staff, BRH staff prepared a cost estimate for a Virginia-based mammography accreditation program. According to its estimate, BRH staff believes that it can administer a mammography accreditation program at a lower per facility fee than is currently charged by ACR. Within approximately three to five years of obtaining accreditation body status, BRH management estimates that it will be able to administer a program for as much as fifty percent less than what ACR currently charges facilities. Over the shorter term, however, the BRH accreditation fee would not be able to be quite so low. Over the first one to

three years after obtaining accreditation body status, BRH staff recommend that accreditation fees be set at no more than 90 percent of what ACR currently charges facilities.

Over the long-term, BRH staff estimates that one additional full-time equivalent (FTE) staff position would be needed in order to effectively administer an accreditation program. However, BRH staff believes that this additional position could be fully funded from accreditation fee revenue. Over the short term, due to the expectation that only a small number of facilities would initially seek accreditation from the state, less than one additional FTE would be required. However, a minimal amount of additional state resources, probably less than $50,000 per year, would be required during the initial start-up of the program.

The BRH staff estimate is based on three key assumptions. First, that 50 percent of mammography facilities in Virginia would elect, over a period of approximately three to five years, to seek accreditation from BRH rather than from the ACR. According to the FDA, the trend among the state accreditation bodies has been a gradual increase in the number of accredited facilities. Second, that the BRH would contract with the ACR for performance of clinical and phantom image reviews. Third, that the costs of administering the program would be fully funded by accreditation fee revenue paid by mammography facilities. The estimate is also based on data that BRH collected from the other four states which showed that, on average, staff spent an average of 2.6 hours reviewing facility accreditation applications, for the first machine, and an additional half-hour for every additional machine. Figure 14 provides comparative data concerning accreditation body fee structures, and the percentage of facilities that each accredits.

The Radiological Profession is Likely to Oppose An Initiative by the Bureau of Radiological Health to Becoming an Accreditation Body

There is likely to be a significant amount of opposition within the radiological profession concerning the feasibility and advisability of BRH becoming an accrediting body. While JCHC staff did not conduct a formal survey of a large number of radiologic professionals, there does appear to be a considerable amount of professional skepticism that the state could effectively implement an accreditation program that upholds the same standards in the same manner as does ACR. ACR is viewed by many, perhaps most, radiologists in Virginia as the preeminent mammography accreditation body. ACR staff expressed the opinion that mammography facilities would prefer to maintain their association with ACR due to its national expertise and perspective. In addition, ACR staff stated their

Figure 14
State Mammography Accreditation Bodies –
Selected Characteristics

	Fees	Percentage of Facilities Accredited
ACR	$900 for first machine, $800 for each additional machine. $375 if facility reapplies after first deficiency. $500 if facility re-applies after second deficiency.	95 percent of facilities in U.S.
California	No actual accreditation fee, since legislature did not enact enabling legislation for accreditation program and fee schedule. Annual State mammography equipment certification fee is $208 for ACR-certified facilities, and $412 for California-certified facilities.	53 percent of facilities in state
Arkansas	$700 for first unit, $500 for each additional unit. This fee includes the initial reviews of images. $100 for any additional image review that is required	56 percent of facilities in state
Iowa	$200 per unit for clinical image review. State charges an additional $200 for annual randomly-selected clinical review. This is done pursuant to state regulations, not MQSA requirements and therefore the state does not consider this to be an accreditation fee.	86 percent of facilities in the state
Texas	$720 for first unit, $345 for each additional unit (includes initial image reviews) $220 for any additional required clinical image reviews, and $110 for any additional required phantom image reviews.	0 currently. Program was approved by FDA in April 1999. Four percent of facilities in the state have submitted applications.

Source: JCHC staff interviews, and analysis of data provided by the five accreditation bodies.

belief that it would be difficult for Virginia to carry out all the activities necessary to start-up a mammography accreditation program.

Several radiologists interviewed by JCHC staff generally agreed with the assessment provided by ACR staff:

> We are comfortable with ACR, as it provides a national standard of quality. Clinical image review is very important. I am not sure where Virginia will turn to for clinical image review services if they do not use the ACR.
>
> * * *
>
> We consider ACR to be the gold standard. Some of their processes are tedious at times, and extensive, but we understand that. I would be concerned about the expertise of the state in assuming that role. I do not think they have the resources to keep the process as pure as does ACR. What you want to do is create a mirror-image of the ACR, not more strict or less strict. Then the only difference becomes cost and degree of responsiveness. The cost of accreditation grows continually and that is a concern. It would be really hard to decide to apply to the state program while it was in a start-up phase. In a medical malpractice case, I would rather have the full weight of the ACR behind me than a new organization.
>
> * * *
>
> It is feasible for Virginia to establish and administer an accreditation program. They could do it. But they could not do it as good as ACR. In reality, I don't think we have in Virginia the scope of expertise to do as good a job in clinical image review as ACR does. In reality, ACR does a pretty good job.
>
> * * *
>
> It is hard to believe that the state could do a better job than the ACR.
>
> * * *
>
> I think the current process works well. I am biased against any efforts to change it.

A few other radiologists interviewed by JCHC staff were more critical of ACR:

I get the sense that ACR is too busy. For the volume of work they handle, the feel they are doing a very good job. The cost is a lot but what really gets me is that if they do not like your images, and you have to re-submit, they charge you a lot. I have seen obvious mistakes in their clinical image reviews. The responsiveness of ACR to my questions depends on who and when you call, and also depends on the nature of the question. I think they treat different people differently.

* * *

The ACR process is too expensive and too cumbersome, particularly the on-site review. The ACR has made this into a real money making thing for themselves. The State would perform more expeditiously and more economically, and in a manner comparable to the ACR.

JCHC staff also interviewed some medical physicists and radiologic technologists concerning their perspective on the accreditation process. A range of opinions were expressed concerning the current accreditation process in Virginia, but generally appeared to favor a streamlining of the regulatory process, and perhaps a greater role for the state.

I think Virginia would do a great job as an accreditation body, but there are other considerations. Our patients are very educated, and want us to be accredited by the ACR. I also don't know what insurance companies and managed care companies would think about facilities that were accredited by an entity other than the ACR. As ACR has gotten busier, it has impacted some of their time frames. When I have a question, I call the Bureau of Radiological Health. I am confident of their answer. I do think that Virginia would administer an accreditation review process that is cheaper and faster than ACR.

***

The cost of the ACR process is too high. ACR is just overwhelmed. As long as the standards were the same or better than ACR's, I would have no problem with the state serving as the accreditation body. But the radiologists would be harder to convince.

***

ACR is overwhelmed by the sheer number of facilities that they are accrediting. ACR has been inconsistent in terms of answering questions. By comparison, the Bureau of Radiological Health always seems to have the right answer. I think that Virginia could perform this process quicker than the ACR. I do admire the ACR for putting the accreditation program together, but I think the consistency of having one regulatory body would be helpful.

***

I would like to see the number of regulatory bodies that facilities have to deal with reduced. I strongly support the state becoming an accreditation body, in order to get everything together under one umbrella.

***

There is over regulation. The BRH and the ACR both require the same general type of information, but in somewhat different formats. It would be nice if the process were more streamlined. BRH staff have been extremely helpful, and are actually with us in our facilities. We never really see anyone from ACR.

FDA Is Currently Drafting Proposed MQSA Regulations That Would Authorize States to Apply to FDA to Become Certifying Bodies

An FDA demonstration project is currently underway in Illinois and Iowa, wherein these two states have been permitted by the FDA to serve as the certifying bodies for mammography services. As such, these states are responsible for all certification, inspection and enforcement activities pursuant to the MQSA. This includes responsibility for issuing the MQSA certificate to the facilities. One of the implications of this is that the states must fund their own inspection programs, rather than receiving contract payments from the FDA. Iowa is actually charging a far lower certification fee than is currently charged by the FDA. Iowa's charge is $850 for the first unit, and $300 for each additional unit. FDA's charge, by comparison, is $1,549 for the first unit and $204 for each additional unit. An Illinois official interviewed by JCHC staff stated the primary benefit of becoming a certifying body is to be able to bring facilities with problems into compliance with the MQSA much faster than FDA is able to.

The FDA is currently in the process of drafting proposed regulations that would authorize all states to apply to the FDA to become certifying bodies. FDA's current schedule anticipates that the proposed regulations will be completed by July 2000. ACR staff expressed the opinion to JCHC staff that certifying body status for Virginia would be more consistent with

state's traditional regulatory and enforcement role than would accreditation body status. BRH management is of the opinion that certifying body status would require a greater amount of additional resources, particularly to support enforcement actions, than would accreditation body status.

Feasibility and Appropriateness of Changes to the Regulatory Structure in Virginia

Mammography is a heavily-regulated health care service. Among the relevant public policy questions for Virginia are whether certain types of changes to the current regulatory structure are both feasible and advisable, and to what extent the Virginia Department of Health should be involved in the regulation of mammography. Currently, there are two routes available for VDH to pursue if it wishes to play a more active role in the regulation of mammography services. The first is to apply to the FDA to become an accreditation body. If BRH is approved as an accreditation body, mammography facilities in Virginia would have the option of seeking accreditation either from ACR or BRH. The second route is to promulgate state radiation protection regulations that are specific to mammography. The VDH does not currently have the opportunity to apply to the FDA to become a certifying body. As was previously mentioned, the FDA is currently drafting proposed regulations that would allow states to do so.

In theory, the VDH could probably prepare and submit an application to the FDA to become an accreditation body at any time under the scope of its existing authority. However, in practice, enabling legislation and appropriate state regulations would be needed in order for BRH to establish an accreditation fee schedule, and actually collect the fees from facilities. Currently, the only fee that VDH is authorized to collect from mammography facilities is the $15 annual registration fee assessed against all types of x-ray equipment.

Whether the promulgation of any VDH regulations specific to mammography should occur in isolation, or as part of an overall revision to the state's radiation protection regulations is a valid question. The prior efforts of the VDH have been directed toward a comprehensive revision of all the regulations. Consequently, it is reasonable to expect that future efforts will also be, and probably should remain, comprehensive in scope. Revised regulations could be drafted to include provisions which appropriately integrate MQSA requirements, and which give VDH the authority to impound mammography equipment that is not MQSA-certified.

If the experience of four other states can be considered a valid basis for comparison, it appears feasible for BRH to obtain accreditation body status and to implement and administer a mammography accreditation program. This would likely require some additional, but relatively minimal, state resources during the initial start-up of the program. However, according to the BRH, the program would prove advantageous to mammography facilities over the long term.

Initially, it should be expected that relatively few facilities would seek accreditation from the state. But, if the experience of other states is any guide, the percentage should approach 50 percent – whereupon BRH estimates it could administer the program, on a fully-cost recoverable basis, at a far lower cost to facilities than that currently charged by ACR. This assumes that BRH would contract with ACR for the clinical and phantom image review. It should be noted that ACR is planning to implement a new accreditation process under which a facility may apply for accreditation for all of the different radiographic services that it provides, not just for mammography, by means of a single application. When this program is implemented, it could serve to negate any cost savings that the state may be able to offer facilities. The ACR hopes to offer this program by the year 2000.

While establishment of an accreditation program may be feasible, it would not necessarily be easy for the VDH or BRH. One of the biggest challenges would be that of convincing facilities that it is competent to accredit facilities and that there is no difference in the accreditation process compared to that used by ACR.

In terms of the advisability and appropriateness of such a move, JCHC have received arguments on both sides. There does not appear to be any widespread, grassroots support on the part of mammographers for a second accrediting body. On the other hand, JCHC staff did receive several comments which suggest concerns regarding the adequacy of the current regulatory structure. Moreover, BRH staff appear to believe quite strongly that a greater level of state involvement in the regulation of mammography would be in the best interest of the facilities in the state.

VI.
Policy Options

The following policy options are offered for the Joint Commission on Health Care regarding the renal dialysis and mammography topics discussed in this issue brief. It is noted that, for the most part, these policy options are not mutually exclusive. The Joint Commission on Health Care may choose to pursue two or more of these options.

Policy Options – Renal Dialysis

Option I: **Take no action.**

Option II: **Introduce legislation to amend the *Code of Virginia* to clarify and specify the types of patient care activities that may be provided by unlicensed dialysis technicians, as well as the types of medications that they may administer. The legislation should address §§54.1-3000 et seq. (the Virginia Nurse Practice Act), 54.1-3408 (the Virginia Drug Control Act), and 54.1-2901.**

Option III: **Introduce legislation establishing mandatory certification requirements for dialysis technicians. This legislation could be drafted to require certification from a nationally-recognized certifying body within a specified number of years.**

Option IV: **Introduce a joint resolution requesting the Virginia Board of Health Professions, with technical assistance from the Board of Medicine, the Board of Nursing, and the Board of Pharmacy to study the need for state regulation of dialysis technicians. The study should identify any needed revisions to provisions of the *Code of Virginia*, including the Virginia Nurse Practice Act and the Virginia Drug Control Act.**

Policy Options – Mammography

Option I: Take no action.

Option II: Introduce legislation to amend §32.1-229 of the Code of Virginia directing the State Board of Health to (1) promulgate regulations for the accreditation and certification of mammography equipment, facilities, and services, (2) authorizing the State Board of Health to seek approval from the U.S. Food and Drug Administration to establish a mammography accreditation program, and (3) authorizing the State Board of Health to establish an accreditation fee schedule for mammography equipment, facilities, and services. *(Note: accompanying budget amendments for 1 full-time equivalent staff position, and $50,000 in additional resources during an initial three-year start-up period, would be needed with this option.)*

Option III: Introduce a joint resolution requesting the Commonwealth Radiation Advisory Board, with technical assistance from the Bureau of Radiological Health, the American College of Radiology, the Medical College of Virginia, the University of Virginia, and Eastern Virginia Medical School, to complete its study of the feasibility and advisability of Virginia becoming an accreditation body and a certifying body for mammography services.

APPENDIX A

HOUSE JOINT RESOLUTION NO. 556

Directing the Joint Commission on Health Care, with the assistance of the State Department of Health, to examine the adequacy of state oversight of freestanding renal dialysis facilities.

Agreed to by the House of Delegates, February 7, 1999
Agreed to by the Senate, February 18, 1999

WHEREAS, renal dialysis is an important part of care for persons with chronic kidney disease; and

WHEREAS, the Joint Commission on Health Care has previously reviewed the adequacy of state oversight of other types of health care facilities; and

WHEREAS, the State Department of Health is the primary state regulator of health care facilities; and

WHEREAS, outpatient renal dialysis services provided within hospitals is currently regulated by the State Department of Health under regulations promulgated by the State Board of Health; and

WHEREAS, renal dialysis services are offered in a variety of settings; and

WHEREAS, consumer concern has been expressed regarding the adequacy of state oversight of freestanding renal dialysis facilities; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Joint Commission on Health Care, with the assistance of the State Department of Health, be directed to examine (i) the adequacy of current state oversight of freestanding renal dialysis facilities; (ii) needed changes, if any, to state law and regulations; (iii) the advisability of licensure of dialysis technicians; and (iv)
other issues as appropriate.

All agencies of the Commonwealth shall cooperate fully with the Joint Commission and its staff during this study, upon request.

The Joint Commission shall report its findings and recommendations to the Governor and the 2000 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents

HOUSE JOINT RESOLUTION NO. 642

Directing the Joint Commission on Health Care to study the feasibility of regulating mammography equipment, facilities, and services in Virginia.

Agreed to by the House of Delegates, February 23, 1999
Agreed to by the Senate, February 18, 1999

WHEREAS, following skin cancer, breast cancer is the most common cancer among women, and is the leading cause of cancer death among women between ages 40 and 55; and

WHEREAS, one out of every 28 women dies from breast cancer in the United States; and

WHEREAS, several techniques have been developed to provide screening and early diagnosis of breast cancer, and among such screening techniques, mammography has resulted in the early detection of breast cancer; and

WHEREAS, in 1992 the Congress of the United States enacted the Mammography Quality Standards Act (MQSA) to establish standards for the certification and inspection of mammography facilities to maximize the effectiveness of this important breast cancer screening technique; and

WHEREAS, the MQSA established standards for equipment and medical personnel who perform, read, and interpret mammogram images; and

WHEREAS, however, questions linger about the accreditation and certification of mammography facilities and equipment, and the qualifications of medical personnel who work in such facilities and perform mammography services; and

WHEREAS, under the MQSA states are permitted to review the accreditation and certification credentials of mammography facilities, and the U.S. Federal Food and Drug Administration has contracted with the State Health Department's Bureau of Radiological Health to perform inspections of mammography facilities in the Commonwealth; and

WHEREAS, concern has been raised about unaccredited and uncertified mammography facilities, and poorly qualified staff conducting mammograms, such conditions which jeopardize the lives of many women; and

WHEREAS, recently legislation has been introduced to reauthorize and strengthen the inspection, accreditation, and certification of facilities, and the qualifications of medical personnel who provide mammogram services and interpretations of images; and

WHEREAS, consideration should be given to establishing the Commonwealth as the accrediting agency, expanding its responsibilities to monitor and inspect mammography facilities, and availing itself to rights and privileges granted states under the Reauthorization of the Mammography Quality Standards Act to ensure that only accredited and certified mammography facilities and qualified medical personnel perform mammography services in Virginia; now,
therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Joint Commission on Health Care be directed to study the feasibility of regulating mammography equipment, facilities, and services in Virginia. During the course of its study, the Joint Commission shall review the requirements of the Mammography Quality Standards Act and the provisions of the reauthorization of the Act to determine specifically the obligation, rights, and responsibilities of states in accrediting, certifying, inspecting, and monitoring mammography facilities, including reviewing and enforcing the qualifications for competent staff. The Joint Commission shall review the arrangements between the U.S. Federal Food and Drug Administration and the State Health Department's Bureau of Radiological Health for the inspection of mammography facilities; estimate the costs of accrediting and certifying such facilities to the state; determine the feasibility and appropriateness of an interagency approach to enforce federal quality control requirements at the state level; and recommend ways which would enable the Commonwealth to ensure quality among mammography facilities and the medical personnel who work in them.

Technical assistance shall be provided to the Joint Commission by the State Health Department's Bureau of Radiological Services, the Radiation Advisory Board, the Board of Medicine, the Office of the Attorney General, the Medical College of Virginia at Virginia Commonwealth University, the American College of Radiology, and the Medical Center at the University of Virginia. The Joint Commission shall confer with the U.S. Food and Drug Administration and such other federal agencies during the study, as may be appropriate.

All agencies of the Commonwealth shall provide assistance to the Joint Commission, upon request.

The Joint Commission shall complete its work in time to submit its findings and recommendations to the Governor and the 2000 Session of the

General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

APPENDIX B

JOINT COMMISSION ON HEALTH CARE

SUMMARY OF PUBLIC COMMENTS: RENAL DIALYSIS STUDY (HJR 556)

Individuals/Organizations Submitting Comments

A total of 64 organizations and individuals submitted comments in response to the HJR 556 report on renal dialysis.

- Janell K. Almquist, R.N.
- Continental Dialysis Center of Springfield-Fairfax
- Crystal Springs Dialysis – June Patterson, Director of Nurses
- Crystal Springs Dialysis – Patricia Rappold, Area Inservice Coordinator
- Fresenius Medical Care – Gary J. Booth, Regional Manager
- Fresenius Medical Care – Deborah A. Harvey, Vice President of Operations
- Jefferson Nephrology Ltd.
- National Renal Administrators Association
- Total Renal Care, Inc.
- Virginia Beach Dialysis Center, Inc.
- Virginia Hospital and Healthcare Association
- Virginia Renal Association
- Responses from 49 Health Care Providers (two different form letters)

Policy Options Included in the HJR 556 Issue Brief

Option I: Take no action.

Option II: Introduce legislation to amend the *Code of Virginia* to clarify and specify the types of patient care activities that may be provided by

unlicensed dialysis technicians, as well as the types of medications that they may administer. The legislation should address §§54.1-3000 et seq. (the Virginia Nurse Practice Act), 54.1-3408 (the Virginia Drug Control Act), and 54.1-2901.

Option III: Introduce legislation establishing mandatory certification requirements for dialysis technicians. This legislation could be drafted to require certification from a nationally-recognized certifying body within a specified number of years.

Option IV: Introduce a joint resolution requesting the Virginia Board of Health Professions, with technical assistance from the Board of Medicine, the Board of Nursing, and the Board of Pharmacy to study the need for state regulation of dialysis technicians. The study should identify any needed revisions to provisions of the *Code of Virginia*, including the Virginia Nurse Practice Act and the Virginia Drug Control Act.

Overall Summary of Comments

Fifty-eight of the 64 commenters supported Option II (although four of those commenters supported only part of the Option). Two commenters supported Option I while one commenter supported Option III.

Summary of Individual Comments

Janell K. Almquist, R.N.

Janell K. Almquist, R.N. commented in support of Option III.

Continental Dialysis Center of Springfield-Fairfax

Becca Beyer, Facility Administrator commented in support of Option II.

Crystal Springs Dialysis – June Patterson, Director of Nurses

June Patterson, Director of Nurses for Crystal Springs Dialysis, indicated opposition to Options I, II, and IV noting that dialysis technicians "may perform different realms of duties even within one organization....It is up to each organization to clearly specify and train their dialysis technicians using the general guidelines developed by NKF, ANNA, MARC, etc. State licensure would be an additional duplicative and costly process, both to the state and to the facilities." Ms. Patterson noted support for the portion of Option II that focuses on the types of medications that dialysis technicians are allowed to administer "since this has been an area of interpretative rather than concrete instruction."

Crystal Springs Dialysis – Patricia Rappold, Area Inservice Coordinator

Patricia Rappold, Area Inservice Coordinator for Crystal Springs Dialysis, proposed either revising Option II or considering another Option. Ms. Rappold recommended a revision that "would specify the medications that patient care technicians could administer with proper training and documentation of training." In support of this revision, Ms. Rappold noted that given proper training "patient care technicians should be allowed to give medications as Heparin, Xylocaine, and Saline under the supervision of a licensed staff member. If patient care technicians are not allowed to administer these mentioned medications, the quality and continuity of patient care may be affected. Proper training is the key to dialysis medication administration. Routine administration of these medications on a daily basis maintains their efficiency of administering them."

Fresenius Medical Care – Gary J. Booth, Regional Manager

Gary J. Booth, Regional Manager for Fresenius Medical Care commented in general support of Option II. Mr. Booth specifically proposed "an additional exemption to the State Pharmacy Act to exempt patient care technicians from the Act as long as they; (1) have been fully trained on the administration of the medication; (2) the medication is integral and routine in the performance of their duties; (3) have a written physician's order or protocol to follow and (4) given under the supervision of a licensed nurse."

Fresenius Medical Care – Deborah A. Harvey, Vice President of Operations

Deborah A. Harvey, Vice President of Operations for Fresenius Medical care commented in support of the latter part of Option II that involves legislation to address specific sections of the *Code of Virginia*. Ms. Harvey indicated "support that action be taken to clarify and amend, as necessary, the Board of Pharmacy regulations to specifically address dialysis technicians, the scope of their training...and, as such, their recognized ability to administer heparin and saline which are more treatment related than patient related." Ms. Harvey noted opposition to Options I, III, and IV.

Jefferson Nephrology Ltd.

Frederic B. Westervelt, M.D., F.A.C.P. stated his "request that the Boards [of Medicine, of Pharmacy, and of Nursing] and the Commission, withhold enforcement of the present prohibition [regarding the administering of medication by patient care technicians] until option 2...can be pursued and appropriate legislation to amend the Code of Virginia may be enacted." Dr. Westervelt indicated the following: "I appreciate the Boards, and share with them the need to operate within the law. They must be made aware that the current use of PCTs is not flouting the law, for we truly believe that we have been operating in proper fashion, safely and professionally. Some of the PCTs in practice have 20 or more years of outstanding service, with a superb record of performance."

National Renal Administrators Association

Shelley Clark, Area Administrator, Southwest Virginia Facilities for NRAA, commented in support of a revision of Option I and in opposition of Options II through IV as "duplicative and costly options for both the State of Virginia and the Dialysis Providers." Ms. Clark noted that all dialysis facilities are required to follow federal regulations but that there are differences in state regulations and it would be appropriate for Virginia to address some state-level issues. Ms. Clark specifically states that "Virginia Legislation should address correcting the Drug Control Act to specify administration of heparin, normal saline, subcutaneous lidocaine, mannitol, hypertonic saline and glucose."

Total Renal Care, Inc.

Stanley Lindenfield, Senior Vice President and Chief Medical Officer, commented in support of Option II. The reasons cited for this support included: "i) to resolve the current conflict in Virginia law; ii) to allow the current standard of practice in Virginia and nationwide, which recognizes the unique care provided to dialysis patients, to continue, as supported by professional organizations, such as the End Stage Renal Disease (ESRD) Network 5 (which serves Virginia) and the American Nephrology Nurses Association (ANNA); and iii) to address the shortage of licensed and/or registered nurses available to dialysis providers."

In explaining the conflict in Virginia law, Dr. Lindenfield states that the Medical Practice Act (*Code of Virginia* , Chapter 29, Article 1, Section 54.1-2901) has historically been interpreted "to allow unlicensed patient care dialysis technicians to perform certain care tasks [such as administering] intravenous infusions such as saline, heparin, and intradermal Lidocaine, within the scope of their usual professional activities." However, under the Virginia Drug Control Act (*Code of Virginia*, Section 54.1-3408) "which is currently being enforced as the controlling statute, only registered nurses or LPNs are allowed to administer such intravenous infusions." Dr. Lindenfield indicates that this conflict between the two statutes needs to be resolved quickly because the conflict "has placed the Medicare certification of outpatient dialysis facilities in jeopardy"

and without Medicare certification a number of facilities will have to cease operating.

Virginia Beach Dialysis Center, Inc.

Linda S. Beisch, Director of Nursing, commented on her opposition to changes being proposed regarding the role of patient care technicians. Ms. Beisch stated that the industry standard has been to allow patient care technicians to administer specified medications as directed by policies determined by the facility's medical director. She indicated that not allowing patient care technicians "to give normal saline would pose an unneeded hazard to the patient."

Virginia Hospital and Healthcare Association

Susan C. Ward, Vice President of VHHA, indicated support for the "current level of regulation of renal dialysis services. These programs are currently heavily and apparently effectively regulated under existing federal and state law....As suggested in Option II, it may be useful to consider clarifying current state nursing regulation and the Drug Control Act to ensure that renal dialysis technicians are authorized to continue their current practice of administering medications."

Virginia Renal Association

Ann S. Tennett, Past President of VRA, commented in support of a revision of Option II. "Legislation may be introduced to amend the Virginia Code Drug Control Act 54.1-3408 to clarify the types of medications patient care technicians may administer. Training in dialysis procedures and policies should be done by the individual dialysis unit with testing done by the dialysis center. To require licensure or certification of patient care technicians could jeopardize the home dialysis program as well as place hardship (both financial and regulatory) on all dialysis centers in the Commonwealth."

Responses from 49 Health Care Providers

Forty-nine providers (the vast majority of whom were employees of one national chain of dialysis centers with a presence in Virginia) sent in letters in support of Option II.

JOINT COMMISSION ON HEALTH CARE

SUMMARY OF PUBLIC COMMENTS: MAMMOGRAPHY STUDY (HJR 642)

Individuals/Organizations Submitting Comments

A total of five organizations and individuals submitted comments in response to the HJR 642 report on mammography.

- American College of Radiology
- Physics Associates
- Virginia Chapter American College of Radiology
- Virginia Department of Health
- Virginia Hospital and Healthcare Association

Policy Options Included in the HJR 642 Issue Brief

Policy Options - Mammography

Option I: **Take no action.**

Option II: **Introduce legislation to amend §32.1-229 of the Code of Virginia directing the State Board of Health to (1) promulgate regulations for the accreditation and certification of mammography equipment, facilities, and services, (2) authorizing the State Board of Health to seek approval from the U.S. Food and Drug Administration to establish a mammography accreditation program, and (3) authorizing the State Board of Health to establish an**

accreditation fee schedule for mammography equipment, facilities, and services. ***(Note: accompanying budget amendments for 1 full-time equivalent staff position, and $50,000 in additional resources during an initial three-year start-up period, would be needed with this option.)***

Option III: Introduce a joint resolution requesting the Commonwealth Radiation Advisory Board, with technical assistance from the Bureau of Radiological Health, the American College of Radiology, the Medical College of Virginia, the University of Virginia, and Eastern Virginia Medical School, to complete its study of the feasibility and advisability of Virginia becoming an accreditation body and a certifying body for mammography services.

Overall Summary of Comments

Option I was supported by the American College of Radiology, the Virginia Chapter of the American College of Radiology, and the Virginia Hospital and Healthcare Association. Dr. Anthony of Physics Associates strongly supported Option II. The Virginia Department of Health did not indicate clear support for any of the Options.

Summary of Individual Comments

American College of Radiology

Charles K. Showalter, Director, Federal Programs, commented in support of Option I with Option III as an alternative "with the focus on becoming a certifying agency and bringing the regulatory authority within the state." Mr. Showalter made additional comments to the report including the following: "The focus of the study seemed to be on the possibility that the Virginia BRH might become an Accreditation Body. I would suggest that a better focus might have been to explore the possibility of becoming a Certifying Agency once FDA promulgates regulations...This would bring the

regulatory authority to Virginia, whereas becoming an AB would not do so. It might also result in more savings for Virginia facilities if the State could perform the required annual inspections for a lesser fee than is charged by the FDA."

Physics Associates

Lee S. Anthony, Ph.D, stated he strongly supports Option II. Dr. Anthony added that he "would further strongly support Virginia's becoming a Credentialing Body as soon as feasible....(1) We have exceptionally well qualified personnel in the Virginia Bureau of Radiological Health to carry out this program and (2) We can carry out these duties in a more responsive and cost effective manner."

Virginia Chapter American College of Radiology

Spencer B. Gay, President commented on behalf of the Virginia Chapter of ACR in support of Option I. Dr. Gay stated that "the Chapter knows of no evidence that efficiency justifications would warrant designation of the Bureau of Radiological Health by the FDA as an accreditation and certification body, despite the Bureau's current inspection obligations under MQSA. In fact, the FDA has acknowledged that while states that are both accreditation bodies and inspection agencies may be able to combine some functions, 'it is important that all facilities meet the same accreditation and inspection requirements, The agency believes it is unlikely that any requirements pertaining to accreditation bodies or facility standards can be eliminated entirely in states with dual status.'"

Virginia Department of Health

E. Anne Peterson, Acting State Health Commissioner did not specifically support any of the Options. Dr. Peterson noted that under Option I, "Since FDA would ultimately remain responsible for the proper implementation and administration of all the MQSA requirements, VDH would not need to expand its current program of inspection of the facilities by increasing the staffing level and funding for certification, accreditation, and inspection." Regarding the adoption of Option II, Dr. Peterson reported the following: "The

only advantage under this option would be that the state would regulate the mammography facilities instead of the FDA and the fees charged by the VDH would potentially be lower than those charged by FDA. Nonetheless, the state would have to invest seed money to establish the program, hire and train new staff, initiate legislative proposals to amend the *Code of Virginia*, revise the regulations through the Administrative Process Act to become a regulatory authority, impose and collect fees from the facilities, establish penalties for violations, and take remedial and other legal actions against violators." Option III was reported to offer no "particular advantage since the Radiation Advisory Board would essentially duplicate the efforts in preparing a study similar to that submitted by the JCHC staff."

Virginia Hospital and Healthcare Association

Susan C. Ward, Vice President commented in support of Option I.

JOINT COMMISSION ON HEALTH CARE

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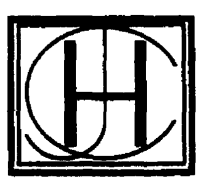

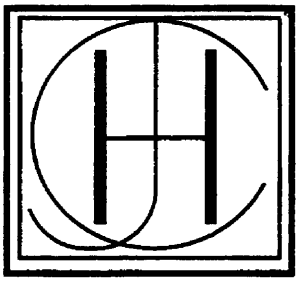

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