

**LABORATORY SERVICES FOR
DIALYSIS PATIENTS IN FLORIDA**

A Report to the Florida Legislature

February 1, 2000



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LABORATORY SERVICES FOR DIALYSIS PATIENTS IN FLORIDA

A Report to the Florida Legislature

The 1999 Florida Legislature requested that the Agency for Health Care Administration (AHCA) investigate the relationship between dialysis centers, the centers' medical directors, and the laboratories that serve dialysis patients. This report is the result of that investigation.

Background

Kidneys perform a very important function in human beings, as they are responsible for filtering waste products from the bloodstream. If the kidneys fail — or can no longer perform the filtering process — excessive accumulation of these waste products in the blood leads quickly to death.

In such instances of kidney failure, often referred to as End Stage Renal Disease or ESRD, kidney dialysis is a lifesaving treatment. The dialysis process provides an artificial means of filtering waste products from the blood. There are two primary methods by which dialysis is performed. The most common is *hemodialysis* where the patient's blood is routed through a machine that filters the blood.

The other common method is called *peritoneal dialysis*. This form of dialysis uses the lining of the abdomen — or peritoneum — as the filtering membrane. Dialyzing fluid is introduced into the abdominal cavity, allowed to stay there for one or two hours and removed.

Patients are most commonly dialyzed three times per week, with each session lasting several hours. Dialysis, however, is not a cure for ESRD. Dialysis is most effective as a way of keeping patients alive until they can receive a kidney transplant.

A History of ESRD in Florida

ESRD in Florida

Congress established the Medicare End Stage Renal Disease Program in 1972 to help meet the medical needs of individuals with ESRD. This legislation extended Medicare coverage to virtually all individuals with ESRD who require dialysis or transplantation to sustain life. Today, Medicare pays for an overwhelming majority of ESRD services (including laboratory). Medicaid, prior to 1999 is estimated to account for less than two percent of ESRD payments.

Every Medicare-eligible individual who is diagnosed with ESRD qualifies for Medicare benefits. This does not happen immediately, as Medicare has an exclusion period (of anywhere from 90 days to two and a half years depending on the patient's previous insurance status) before the program pays for dialysis. During the exclusion period, the patient's existing private health insurance program pays for the service. Some individuals with no work record in the U.S. (e.g. immigrants or housewives) never paid into the Medicare system and are not eligible for benefits.

Consolidation in ESRD

Following Medicare's decision to begin coverage for ESRD, dialysis centers began to proliferate in the U.S. and Florida. For many years, typical dialysis centers in Florida were affiliated with a hospital or had been created by a nephrologist for the treatment of his or her patients.

In the past five or six years, this began to change. Rapid advances in medical procedures and technology in renal disease began to offer patients an improved quality of life. This new technology forced dialysis centers to devote larger amounts of money to equipment. At the same time, Medicare has not raised payments for ESRD services in an attempt to reign in program costs. These changes have generally meant that centers' costs were going up while their income was going down.

This development is part of an overall trend in the medical industry during this decade. The economics of this atmosphere emphasized the need for streamlining operations and increasing patient volume. These pressures led to rapid consolidation in the ESRD industry. By 1999 three large national and multinational health care corporations have come to own a majority of the 274 ESRD centers in Florida. It should be noted that this figure comes from the HCFA-chartered network of dialysis centers and includes all types of dialysis facilities including free-standing private centers, hospitals and federally-owned centers.

More than 60 percent of the dialysis centers in Florida are owned by one of the three largest national health care corporations (or "chains"). Fresenius Medical Care North America — a subsidiary of a large German multinational corporation — is the leader with 72 centers in Florida (26.3 percent). The second largest player in the market — Gambro Healthcare with 62 centers (22.6 percent) — is part of a large Swedish multinational. The only domestically owned player

is Total Renal Care in third with 35 centers (12.8 percent). Table 1 shows these companies' state and national market share.

Company	Centers in Florida	Percent of Florida Market	Percent of National Market
Fresenius Medical Care	72	26.3%	23.6%
Gambro	62	22.6%	13.6%
Total Renal Care	35	12.8%	14.6%
Other (public, private & corporate)	99	36.1%	n/a

Source: Network 7

Laboratory Testing and ESRD

Dialysis changes the chemical makeup of the patient's blood. Because of this, and to attempt to track the effectiveness of the dialysis, laboratory testing of the blood is an essential component of the dialysis process. In order to run smoothly, the dialyzing patients and their physicians must seek laboratory testing services that are not only high quality, but performed and returned quickly.

Medicare recognizes this fact in that ESRD is the only disease category for which payment of certain laboratory testing is included in its composite rate. This means that Medicare acknowledges ESRD patients need certain tests to be performed on a regular basis, and so pays for them ahead of time. Physicians are free to order tests other than those covered in the composite rate, but those must be ordered independently and are subject to "local medical review" scrutiny by the Medicare carrier.

There are, however, often relatively few ESRD patients in any one place at any one time. Moreover, the reporting required by Medicare and by state-of-the-art medical techniques requires sophisticated software that is not necessary in other areas of health care. Therefore, in any one community there are rarely enough ESRD patients for local labs to economically justify the capital outlay required to upgrade their computer hardware and software.

Medicare's rules for billing for dialysis lab services are more complex than in typical lab services. Medicare charges the labs with billing according to these rules. These rules govern when a patient might have a particular test in relation to other tests that have been performed within set time frames. The lab must track this information. If a lab is billed incorrectly, the lab is held responsible for repaying the fee to Medicare.

As with dialysis centers, these pressures, along with flat-lined Medicare payments for testing, have led to significant consolidation in the ESRD testing industry. In order to increase the number of ESRD patients they served, several labs invested in the new equipment and software and began marketing themselves nationally. Nationwide courier services and FAX/computer reporting allowed centers in Florida to send their lab samples to California and receive customized reports in less than 48 hours. Conversely, this also allowed centers from all over the US to send their lab samples to dialysis labs located in Florida.

The relatively small numbers of ESRD patients nationally serves to limit the number of national reference ESRD laboratories. This attendant consolidation in the industry has led to fewer and fewer labs providing a full spectrum of services to dialysis centers. While most centers utilize local community laboratories such as LabCorp or their local hospital for emergency or HMO testing, they almost universally use a limited number of national reference labs for a large majority of their testing.

ESRD Reference Laboratories in Florida

It is estimated that there are currently 10 to 15 reference labs that exclusively serve ESRD patients nationally. Of these, only five seem to command significant market share. Of these five, three are located in Florida. These labs take referral work from across the nation in addition to their own communities.

Most of the larger labs are owned by vertically integrated health care corporations that own a large number of dialysis centers in the U.S. (and Florida). These corporations also often own companies that manufacture dialysis material and supplies.

The three dialysis reference labs in Florida are:

Laboratory	Affiliation	Location
Total Renal Laboratories, Inc.	Total Renal Care, Inc.	DeLand
Gambro Healthcare Laboratory Service	Gambro Healthcare	Fort Lauderdale
ESRD Laboratory	Independent	Fort Lauderdale

LabCorp and ESRD Lab Testing

Nearly every center responding to a survey conducted by the Agency for Health Care Administration reported that they use the nation's largest reference laboratory — LabCorp — for some dialysis lab testing. The testing volume referred to LabCorp was universally small — averaging around five percent of a center's total test volume. LabCorp was used by all but one of the responding centers because they were often required to send tests there for their patients covered by HMOs.

HMOs typically sign a national or regional contract with a large reference lab such as LabCorp to provide all testing services for the HMO's patients. When an enrollee of one of these HMOs develops ESRD, the HMO continues to expect the testing to be performed at its contracted lab.

LabCorp was the first-choice lab for only one reporting facility. For that reason, LabCorp is not included in the following analysis.

The Process of this Study

As mentioned previously, the 1999 Florida Legislature requested that the Agency for Health Care Administration (AHCA) investigate the relationship between dialysis centers, the centers' medical directors, and the laboratories that serve dialysis patients. The Legislature requested the following six separate pieces of information:

1. An analysis of the past and present utilization rates of clinical lab services for dialysis patients,
2. Document the financial arrangements among dialysis centers and among centers and medical directors,
3. Document any business relationships and affiliations with clinical labs,
4. The extent of self referral of dialysis patients to clinical labs,
5. Quality and responsiveness of clinical lab services for dialysis patients, and
6. The average annual revenue for dialysis patients for clinical lab services in the past ten years.

Much of the information in this report was obtained through a survey of all 274 dialysis centers in Florida. This survey asked the centers to document such things as their relationship with their medical director, and their relationship with their clinical lab. Of the 274 centers, AHCA received completed surveys from 191 (nearly 70 percent). The three major Florida reference labs for ESRD patients were also surveyed.

In addition to these surveys, AHCA staff interviewed a number of representatives of organizations involved with ESRD laboratory services. All facility and lab data included in this study were self-reported.

In addition to the report itself, several appendices have been provided to summarize additional salient data provided by the Florida Dialysis Center Survey.

Data Requested By The Legislature

1. An analysis of the past and present utilization rates of clinical lab services for dialysis patients

Two of the three labs — Total Renal Labs and ESRD Labs — responded to AHCA's survey of laboratory utilization. Gambro's lab indicated its desire to participate in the survey, but their data had not been received in time for the publication of this report.

In addition to the lack of responses, the utilization data that was submitted did not produce information that could be compared between labs. The problem with the data is that each lab organizes its information systems differently. ESRD tracks its testing volume by the number of tests billed. TRL, on the other hand, tracks volume by tests performed.

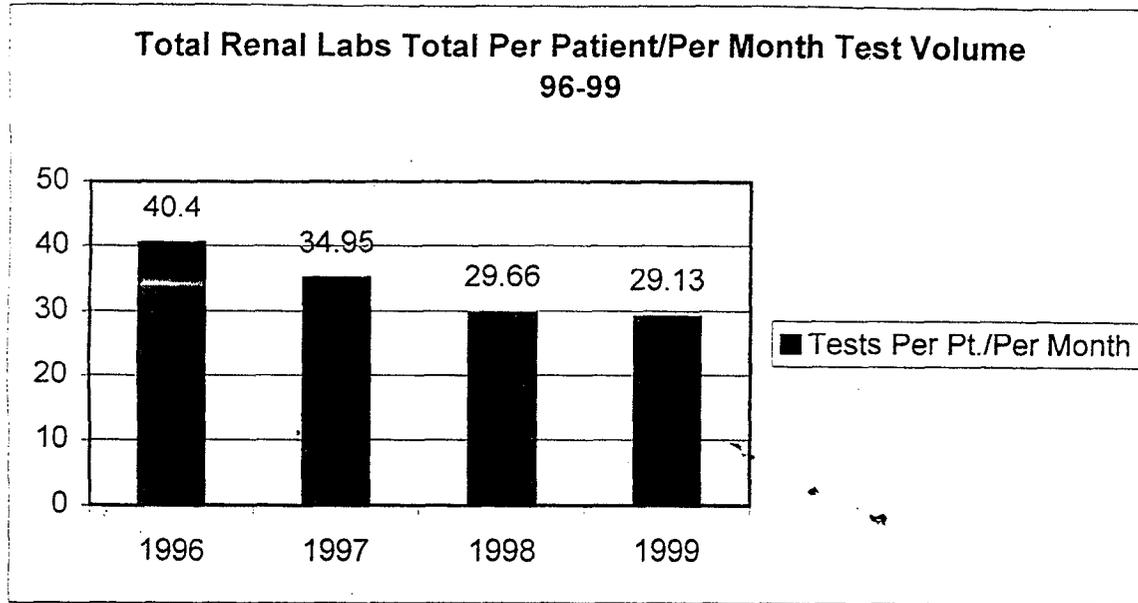
This is a problem because a large number of tests that are performed are not billed. The "composite" tests are paid for by the dialysis facility, not billed to insurance. Billing figures will therefore contain an artificially reduced level of testing volume.

This problem extends to comparisons of the utilization of certain high-volume tests such as calcium levels. The calcium level test is included in the composite rate the first time it is performed in a month, and any additional calcium tests during the month are billed to an insurance carrier. The testing volume for individual tests is therefore also subject to artificially reduced volumes under billing numbers.

It should be noted that TRL was especially helpful in providing its test utilization numbers.

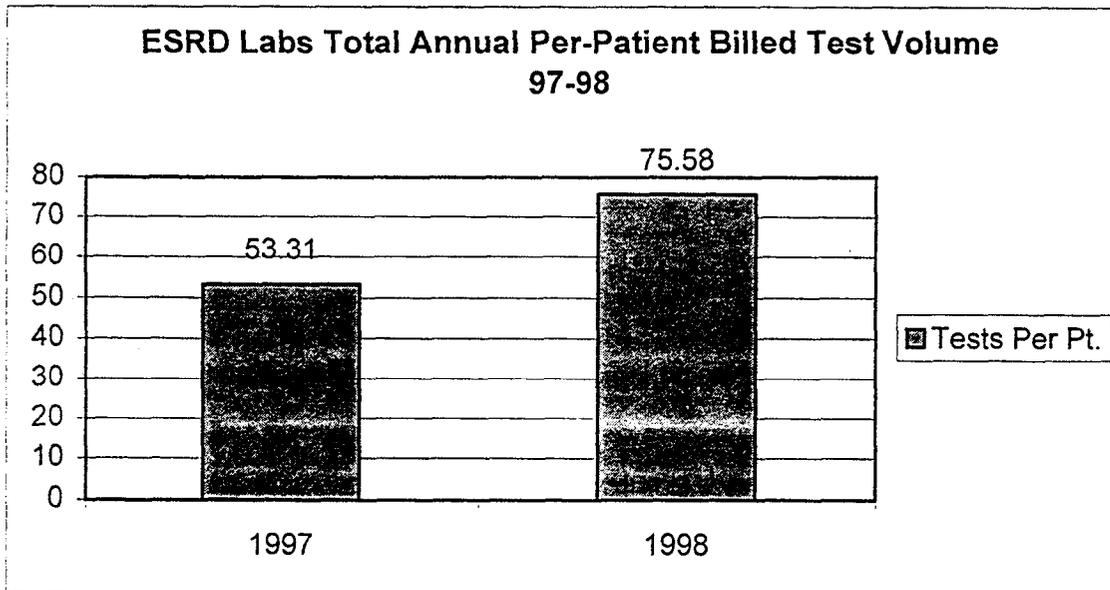
In the absence of comparable data, Figures 1 and 2 detail the utilization rates reported by TRL and ESRD Labs respectively.

Figure 1



Source: Total Renal Labs 1999

Figure 2



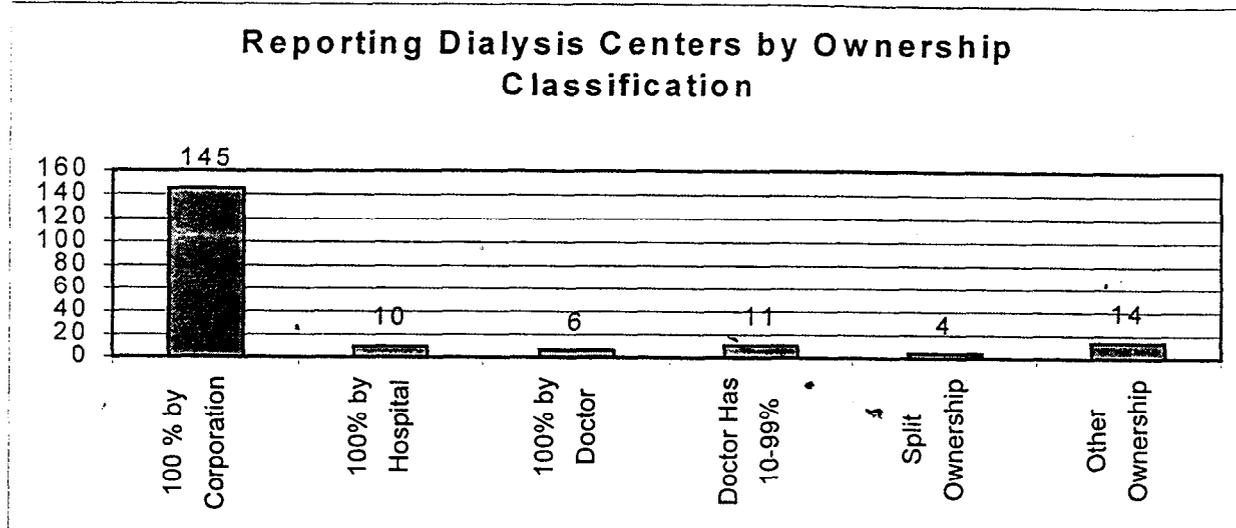
Source: ESRD Labs 1999

2. Document the financial arrangements among dialysis centers and among centers and medical directors

The majority of the dialysis centers in Florida are affiliated with large chains. Beyond that, there are several small groups of affiliated centers, often not-for-profit facilities. The rest are largely physician-owned independent centers. Fresenius, Gambro, and TRC are the only ownership

groups large enough to be tracked by Network 7 — the HCFA-chartered association of ESRD facilities.

Figure 3



Source: 1999 AHCA Dialysis Center Survey

The three largest chains of dialysis facilities operating in Florida are owned by a corporation that is a subsidiary of a larger corporation that has vertically integrated by owning other companies that make ESRD supplies and ESRD laboratories.

Medicare requires that centers employ a physician (nephrologist) to serve as medical director of the facility. The medical director is most often charged with performing administrative tasks relating to the center's clinical activities. These arrangements are almost universally contractual arrangements. Medicare dictates the method and manner – but not the compensation level - of financial arrangements in these contracts. For example, it is illegal for medical directors' compensation arrangements to be tied to patient volume. This would be a violation of federal anti-kickback laws. In a few instances the medical director owns the building in which the center is located and leases it to the center.

While it is not particularly uncommon for the medical director of a center to have some limited ownership interest, only four centers (2.1 percent of respondents to the AHCA survey) indicated that the medical director was the outright owner of the facility.

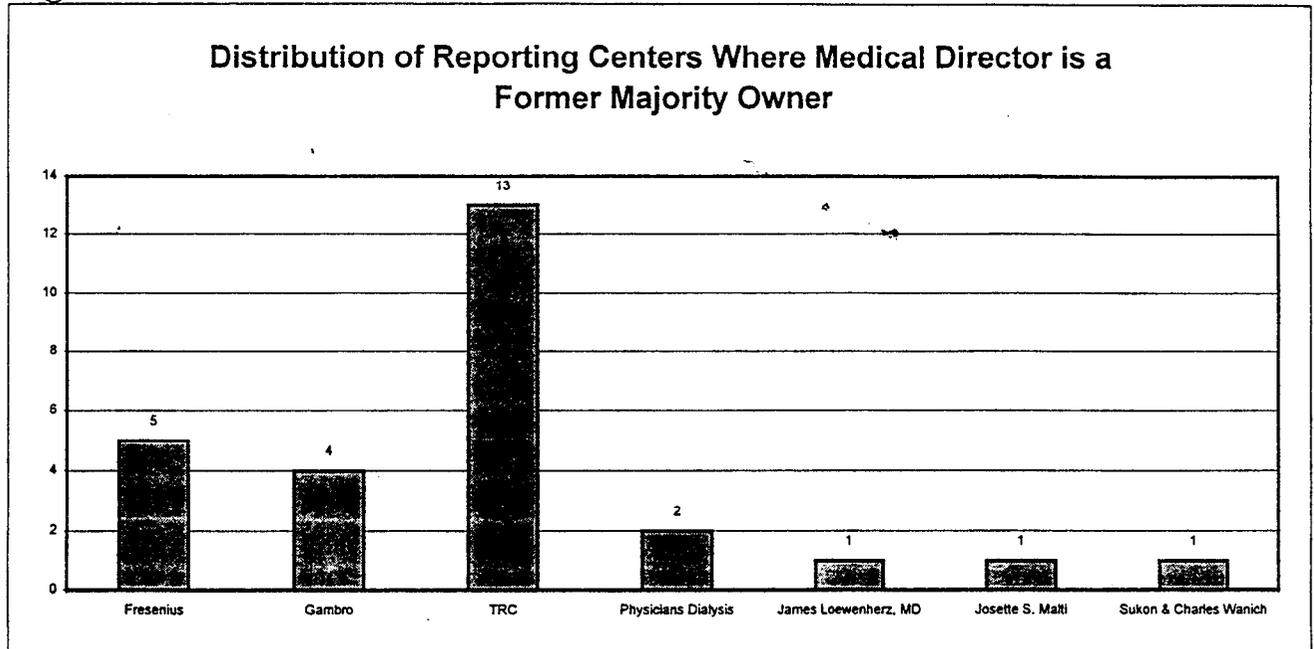
It is not unusual for the medical director to be a former majority owner. In such cases the medical director's relationship with the center is characterized by the fact that the doctor most probably sold the center to the current owner. This type of arrangement is most common in relatively small centers (as measured by the number of doctors on staff). Twenty-four centers (12.6 percent of respondents) with between three and ten physicians indicated that their medical director was a former majority owner.

In contrast only three (1.6 percent of respondents) centers with more than ten physicians and only two (1.0 percent of respondents) centers with 20 or more physicians reported that their

medical director was a former majority owner. No centers with one or two physicians reported such an arrangement.

In total, only 27 centers (14.1 percent of respondents) reported such an arrangement. Of these centers, a major chain currently owns 22 — or 81.5 percent of centers reporting such arrangements. Figure 4 shows the distribution by current owner of centers where the medical director is a former majority owner.

Figure 4



Source: 1999 AHCA Dialysis Center Survey

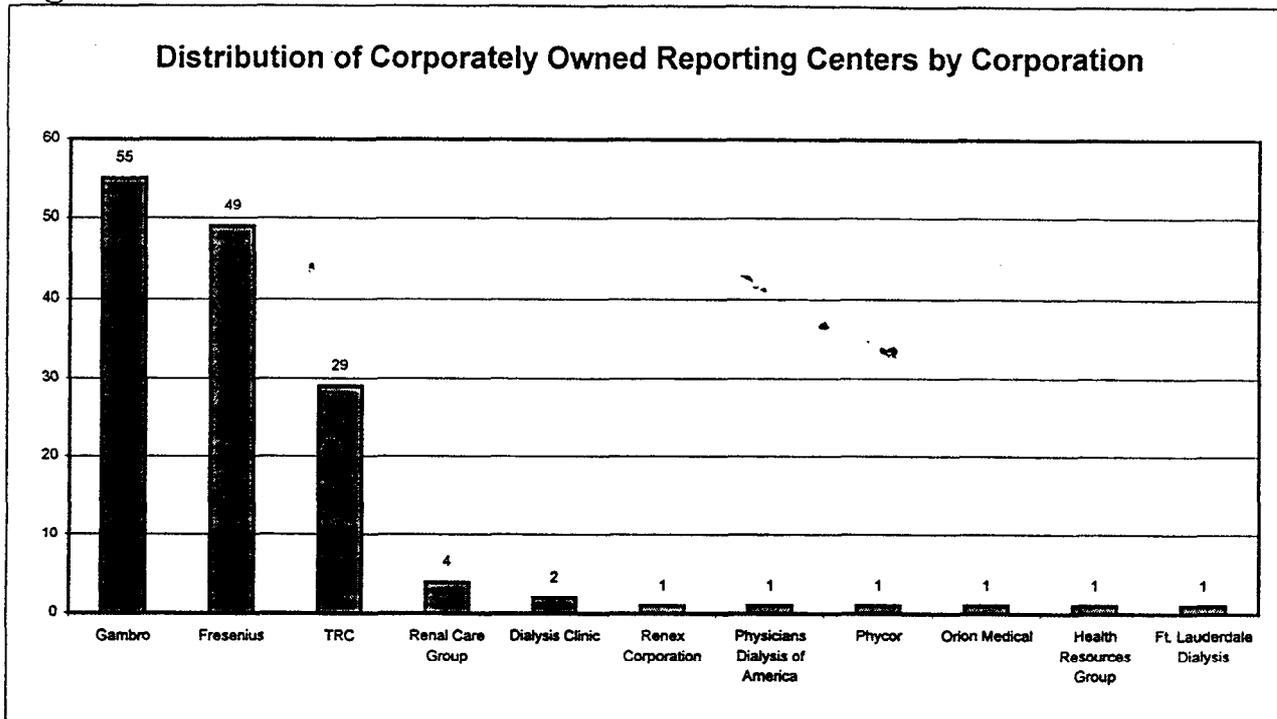
3. Document any business relationships and affiliations with clinical labs.

According to Network 7 (the HCFA-chartered network), Fresenius Medical Care owns 72 centers in Florida. Spectra Renal Management owns labs in Fremont, California and Rockleigh, New Jersey that are used by all 49 reporting Fresenius facilities for their reference lab work. The facilities and the lab are owned by companies that are in turn owned by the same company. The Spectra lab in California is the largest provider of services to independent ESRD facilities nationally. Figure 3 details the distribution of Florida dialysis centers by ownership type.

Gambro Healthcare owns 62 centers in Florida. Gambro Healthcare Laboratory Service owns a lab in Fort Lauderdale that is used by all 55 reporting Gambro facilities for their reference lab work. The facilities and the lab are owned by companies that are in turn owned by the same company.

Total Renal Care owns 35 centers in Florida. Total Renal Laboratories owns a lab in DeLand that is used by all 29 reporting Total Renal Care facilities for their reference lab work. The facilities and the lab are owned by companies who are in turn owned by the same company. Figure 5 details the distribution of corporately owned reporting centers.

Figure 5



Source: 1999 AHCA Dialysis Center Survey

In all, 138 of the 145 (92.5 percent) corporately owned centers reported the use of a lab that was owned by the same company as owned the facility.

Few independent facilities indicated a non-service oriented financial relationship with a clinical lab. Independents are free to initiate relationships with any of the reference laboratories that will accept them. The nature of these few relationships is unclear and could be subject to a misunderstanding of the question where the existence of a contract was construed to be a financial relationship.

Most hospital-based centers use their in house laboratories. Hospitals can use their labs because the dialysis provided in the inpatient setting is usually episodic in nature and not subject to the reporting required in the outpatient setting.

4. The extent of self referral of dialysis patients to clinical labs

Dialysis centers — in and of themselves — are not legally allowed to order testing on patients; even those covered by the composite rate. Under Medicare rules a physician must explicitly order each test performed on a dialysis patient. Consequently, it is possible for a physician to

order testing from a laboratory different from the one with which the center has a standing relationship.

The dialysis industry in Florida — as it currently exists — therefore does not provide for “self-referral” as is it contemplated in the Patient Self Referral Act of 1992. The 1992 law prohibited physicians from referring patients to certain types of facilities if they had ownership interest in the facility. No practicing physicians have significant ownership interest (outside of stock) in the laboratories most typically used for ESRD testing.

If however, one were to define “self-referral” more broadly, it could be argued that chain dialysis centers’ use of labs that are owned by the same company that owns them constitutes self-referral. This type of self-referral is widely practiced in Florida’s dialysis industry. Every chain-owned dialysis center utilizes a lab owned by their parent company. Therefore, we would expect to discover with additional data - such as medical director contracts – that this occurs in some instances where there was - or is - a financial “relationship” with the physician. Table 2 shows chain dialysis center choices of clinical labs in Florida. Table 3 shows the clinical lab choices of non-affiliated centers.

Table 2: Labs Selected by Reporting Chain-Owned Dialysis Centers in Florida

Center Owner	Number of Centers Reporting	Lab Used	Percentage
Fresenius	55	Spectra (Fresenius)	100%
Gambro	49	Gambro Labs	100%
Total Renal Care	29	Total Renal Labs (TRC)	100%

Source: 1999 AHCA Dialysis Center Survey

Table 3: Lab Choices of Reporting Independent Dialysis Facilities in Florida

Laboratory	Number of Reporting Independent Centers Using Lab	Percentage of Independents
Fresenius	11	24.4%
Gambro	2	4.4%
Total Renal Care	10	22.2%
ESRD Laboratory	5	11.1%
LabCorp	1	2.2%
Other	16	35.5%

Source: 1999 AHCA Dialysis Center Survey

5. Quality and responsiveness of clinical lab services for dialysis patients

The three “niche” laboratories that serve Floridians with ESRD offer specialized services to their patients. These services include extensive databases on individual patients and customized reporting. Given the nature of caring for patients with ESRD, lab tests often need to be viewed in the context of other lab results from previous weeks or months. Most hospital and community labs do not provide this level of result tracking and reporting as a matter of course. There is a general consensus that these niche labs provide a “value added” service to ESRD clinics and patients that enhance patient care.

In interviews with representatives of the three ESRD specialty laboratories, there was unanimity in the belief that dialysis patients in Florida receive high quality service from all three labs. While each lab felt it offered something unique, they felt that overall quality was not an issue.

The Agency for Health Care Administration is the licensing body for all clinical laboratories in Florida. AHCA is therefore charged by statute with developing and upholding quality standards for these laboratories. These laboratories are surveyed bi-annually and are visited regularly by AHCA’s clinical staff.

All three labs in Florida that primarily serve ESRD patients currently have licenses in good standing with AHCA. This directly indicates that the quality of testing in these labs is at least good enough to ensure the continued well-being of the patients served. Table 4 indicates the last on-site survey and results for each of the three in-state ESRD reference labs. None of the three dialysis reference labs in Florida have restrictions on their licenses due to quality concerns.

Lab	Last On-Site Survey	Current License Standing
Gambro	October 29, 1997	Unencumbered
Total Renal Care	June 11, 1997	Unencumbered
ESRD Laboratory	November 17, 1997	Unencumbered

Source: AHCA 1999

None of the centers surveyed indicated problems with responsiveness of their regular labs. Given that nephrologists are free to change laboratories at any time – regardless of the centers’ lab contracts – chronic unresponsiveness in such a competitive environment would likely result in a lab’s ultimate failure.

6. The average annual revenue for dialysis patients for clinical lab services in the past 10 years

Very few – if any – lab tests are performed outside of a fee schedule that dictates what a lab will be paid for the test. Therefore only the number of tests performed impact a lab's revenue from one period to the next. Two labs with the same utilization patterns could therefore expect to realize very similar revenue streams.

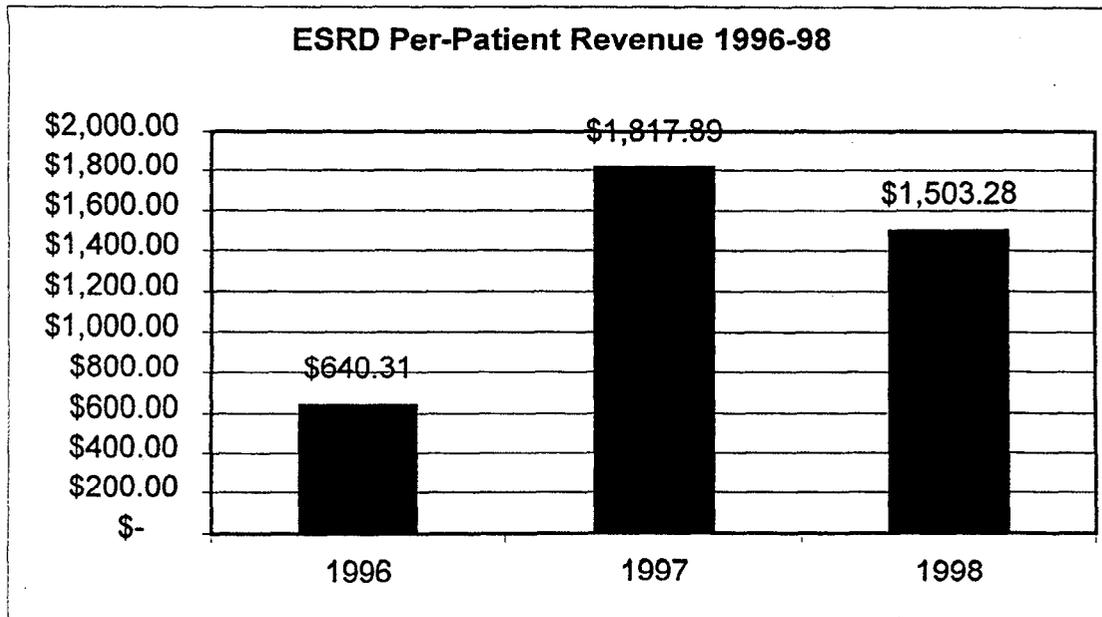
Publicly traded, for-profit companies own two of the three labs: TRL and Gambro Labs. Such companies consider information regarding their pricing structures to be their most proprietary data. While Gambro has **declined to provide any information regarding their testing revenue**, TRL has indicated that they believe the release of **per-patient revenue data would be tantamount to disclosing their pricing structure**. TRL believes this could potentially damage their competitive position.

TRL also indicated their concerns that the Securities and Exchange Commission (SEC) would frown on the release of this information, as it could provide information that could lead to collusive activities on the part of the labs. That is, the SEC might be concerned that the release of such information could allow competitor labs to know their pricing structure and as such potentially raise (or lower) their prices to bring them in line with their competitors.

ESRD Laboratory, however, did provide revenue information for 1996 through 1998. Those figures are provided in Figure 6.

Please note that all three of the ESRD reference labs have only existed in their current form since 1996. Therefore, getting ten years of data would not be feasible.

Figure 6



Source: ESRD 1999

Discussion

Consolidation and Vertical Integration

The consolidation discussed earlier has driven individual segments of the ESRD industry to become affiliated with a few large corporations. Reimbursement limits and increasing costs have driven these companies to vertically integrate through the purchase of one or more of their major suppliers. Hence, corporations have purchased not only the centers, but also the companies that manufacture dialysis supplies and the labs that do the testing.

Vertical integration has been the hallmark of the U.S. health care industry in the 1990s. Hospitals are buying doctors' practices and ambulatory surgical centers. Large clinics are purchasing hospitals. HMOs are buying durable medical equipment suppliers, clinical labs and doctors' practices. The ESRD sector is a reflection of this industry-wide trend.

Vertically integrated corporations can lower their costs — and increase their profitability — through greater economies of scale and greater control over their cost structure. This can ideally lead to lower costs to health care consumers and enhanced quality.

On the other hand, vertical integration can lead to excessive market power for the company. In some cases — such as the health care industry — if a vertically integrated company wishes to increase income in one of its businesses it could conceivably have one of its other businesses increase orders from the company in question.

The above referenced situation is understood by all of the major health care payors — especially Medicare. These payors have instituted rules to remove the profitability from such activities through large fines or criminal prosecution.

Once an entity, or an industry, has been identified as prone to these types of behavior they are typically subjected to corporate integrity agreement with the local Medicare carrier. Under such agreements, virtually all of the claims filed from the entity in question are subjected to review.

Sometimes an entire industry is identified as having a high incidence of fraud and abuse. In such cases Medicare focuses its attention on the industry through enhanced auditing and computer screens. The home health industry was a recent target of such focus.

Medicare Anti-Fraud Activities

In July of 1996, Medicare released Unrestricted Medicare Fraud Alert 9610: *Billing for Laboratory Tests Covered Under the ESRD Composite Rate* alerting its carriers to the potential for labs to bill for tests covered in the composite rate. Such billing is considered double billing and constitutes fraud. Additionally, Medicare's fraud task force Operation Restore Trust has been focusing on fraud in the dialysis services industry.

On January 19 of this year, Fresenius Medical Care agreed to settle an ongoing fraud investigation for \$486 million. This fine is the largest in Medicare history. The investigation centers on the activities of National Medical Care, which merged with Fresenius in 1996. Although most of the alleged fraud took place prior to the merger, Fresenius has agreed to what the Department of Health and Human Services calls “the most comprehensive corporate integrity agreement ever imposed.”

Medicare cited Gambro Healthcare in October 1999 for \$18.8 million in overpayments for laboratory testing occurring from January of 1996 through May of 1998. No fraud has been alleged, but Gambro voluntarily stopped submitting claims to Medicare for 13 months. The Medicare investigation is continuing.

The Attorney General for the State of Michigan filed suit in September against Gambro Healthcare of Michigan and Gambro Healthcare Patient Services, Inc. saying they “entered into agreements with health care providers to limit any new competitors from entering the market” and then raised prices in those markets.

Total Renal Laboratories, Inc. has been suspended from billing Medicare for laboratory services pending the resolution of a carrier investigation into the lab’s billing practices. The carrier has alleged that 99.3 percent of the lab’s billings over the time in question were inappropriate. TRL is appealing this determination.

It should be noted, however, that seven of the largest national chain community labs have also been indicted and fined by HCFA for the fraudulent overutilization of lab tests. SmithKline Beecham alone paid out more than \$325 million in fines to Medicare. SmithKline also no longer accepts any dialysis testing.

It is apparent that Medicare and HHS are being aggressive in their efforts to police the dialysis testing industry. This enhanced level of scrutiny serves to limit the opportunities for entities to profitably engage in illegal activities. Florida Medicare carrier staff stated their belief that fraud and abuse was a legitimate concern in the utilization of kidney dialysis lab testing, but felt that any specific scheme to do so would be identified quickly by the carrier.

GAO and Dialysis Laboratories

In September of 1997, the General Accounting Office (GAO) published a report entitled *Widely Varying Lab Test Rates Suggest Need for Greater HCFA Scrutiny*. The study found wide disparities between the testing levels of different labs, from a high of 224 tests per patient per year in one lab to nine tests per patient per year in another (with an average of 56 tests). The GAO recommended that HCFA “profile physicians ordering laboratory tests for dialysis patients” and that the individual carriers should then “scrutinize ordering physicians who order too many or too few tests.”

It is important to note that the GAO did not conclude that there were too many tests being done overall, just that the variability was too great. The main concern was for quality of care — not economics.

Managed Care and Renal Dialysis

Medicare is currently pilot-testing capitated managed care plans for patients with ESRD. If the test is successful, Medicare will support congressional action to allow ESRD patients in Medicare Managed Care Plans — which is now forbidden. Florida is one of the states participating in the pilot project. Additionally, the privately insured dialysis patients, much as the population at large, are increasingly likely to be covered by managed care plans.

These managed care plans typically have their own agreements with laboratories that supersede the center's lab agreements. As discussed in a preceding section, the Dialysis Center Survey respondents indicated that generally HMO-mandated labs, usually large chain-owned community labs such as Lab Corp or Qwest, performed five to ten percent of their lab testing.

It is apparent that Lab Corp and Qwest are already doing some dialysis lab testing and stand ready to perform more should the need arise. Lab Corp has stated that they have the capacity to handle any additional testing that might be required should dialysis chains be required to divest themselves of their labs.

If managed care expands in Medicare ESRD, as it is anticipated to do, the large chains that own laboratories will have a diminishing ability to dictate who does their lab testing.

Conclusions & Recommendations

The data collected on specific areas of interest to the legislature point to the following conclusions on the individual area:

An analysis of the past and present utilization rates of clinical lab services for dialysis patients
This was one of the primary areas where a lack of consistent data precludes a definitive analysis of the subject. Two principal problems played into this issue; the lack of data and the lack of comparable data among collected data sets. Compulsory data submission and an independent audit of utilization rates would likely be the only method of insuring a consistent measure of these rates.

Document the financial arrangements among dialysis centers and among centers and medical directors

Florida's dialysis industry is dominated by three large national health care corporations. These providers own large numbers of dialysis centers that are centrally managed. Only four centers reported that they were owned by their medical director. A minority (approximately 15 percent) of responding centers of any ownership type reported that their medical director was a former majority owner. A minority (slightly less than 13 percent) of responding "chain" centers reported that their medical director was a former majority owner.

Document any business relationships and affiliations with clinical labs

Nearly all centers had signed business agreements with the clinical lab(s) they were using. All “chain” centers utilized a lab owned by the same corporation. 51 percent of the non-corporate centers used corporate labs. 5 percent of respondents used ESRD Labs. 38 percent of responding centers used LabCorp or some other lab.

Only two centers indicated non service-oriented, non-ownership relationships with a clinical lab. The nature of these relationships is unclear.

The extent of self-referral of dialysis patients to clinical labs

Using the definition of “self-referral” most directly contemplated by the Patient Self Referral Act of 1992 – that is the referral of a patient by their physician to a facility in which the physician is an owner – there is no known self-referral occurring in the dialysis lab industry as no practicing Florida physicians are majority owners in the companies that own the lab.

Under the expanded definition of self-referral to include the utilization by dialysis centers of labs owned by the same company that owns the center, self-referral is practiced in all “chain” centers. Due to some managed care contracts, however, the amount of all chain lab work being sent to chain labs approximates 95 percent.

Quality and responsiveness of clinical lab services for dialysis patients

The quality and responsiveness of lab services for dialysis patients is at least satisfactory to state standards. All participants in the study indicated satisfaction with lab quality and responsiveness.

The average annual revenue for dialysis patients for clinical lab services in the past ten years

This was the other primary area where a lack of data precludes a definitive analysis of the subject. Compulsory data submission and an independent audit of financial records would likely be the only method of insuring a consistent measure of these rates.

Recommendations

The Florida Legislature directed the Agency for Health Care Administration to study several issues that would assist the legislature in general - and the health care committees in particular — to determine if the corporate ownership of both dialysis clinics and clinical laboratories should be more definitively addressed.

While the Agency has had the opportunity to review the accounts of Medicare fraud and abuse reported in other states, the Agency was unable to directly comment on two of the fundamental issue areas requested by the legislature:

1. The issue of lab test utilization could not be ascertained as neither Fresenius nor Gambro, the two major players in the Florida dialysis market, chose to respond to the request for information citing proprietary issues. Without the cooperation of the mentioned companies, the Agency would be required to commit investigative resources that the legislature did not provide in order to secure reliable data.

2. Additional investigative resources might also allow the Agency to provide more complete information regarding clinical laboratory revenue and other financial arrangements between the clinics and the labs.

Ultimately, AHCA cannot adequately respond to the legislatures request without additional time and resources. The Agency recommends that the Legislature give the Agency broad subpoena power and the direction to work with the Attorney General's Medicaid Fraud Control Unit as well as the Insurance Commissioner's office.

AHCA additionally recommends that funding be provided so that the study can be performed through one of the state's public universities or a private consultant. AHCA estimates the cost for such a university-led study to approximate \$230,000.

Appendix A

General Data on Florida Kidney Dialysis Facilities

Number of Centers Reporting:

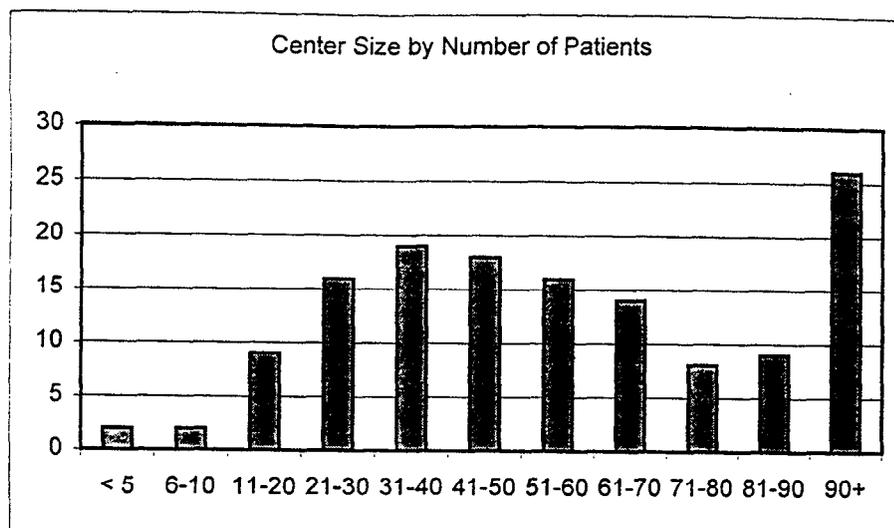
191 (70%) Florida dialysis centers responded to the AHCA survey.

Florida Dialysis Centers by Number of Patients:

Number of Patients	Frequency	Percent	Valid Percent	Cumulative Percent
< 5	2	1	1.4	1.4
6-10	2	1	1.4	2.9
11-20	9	4.7	6.5	9.4
21-30	16	8.4	11.5	20.9
31-40	19	9.9	13.7	34.5
41-50	18	9.4	12.9	47.5
51-60	16	8.4	11.5	59
61-70	14	7.3	10.1	69.1
71-80	8	4.2	5.8	74.8
81-90	9	4.7	6.5	81.3
90+	26	13.6	18.7	100
Total	139	72.8	100	

Source: AHCA 1999

Figure A-1



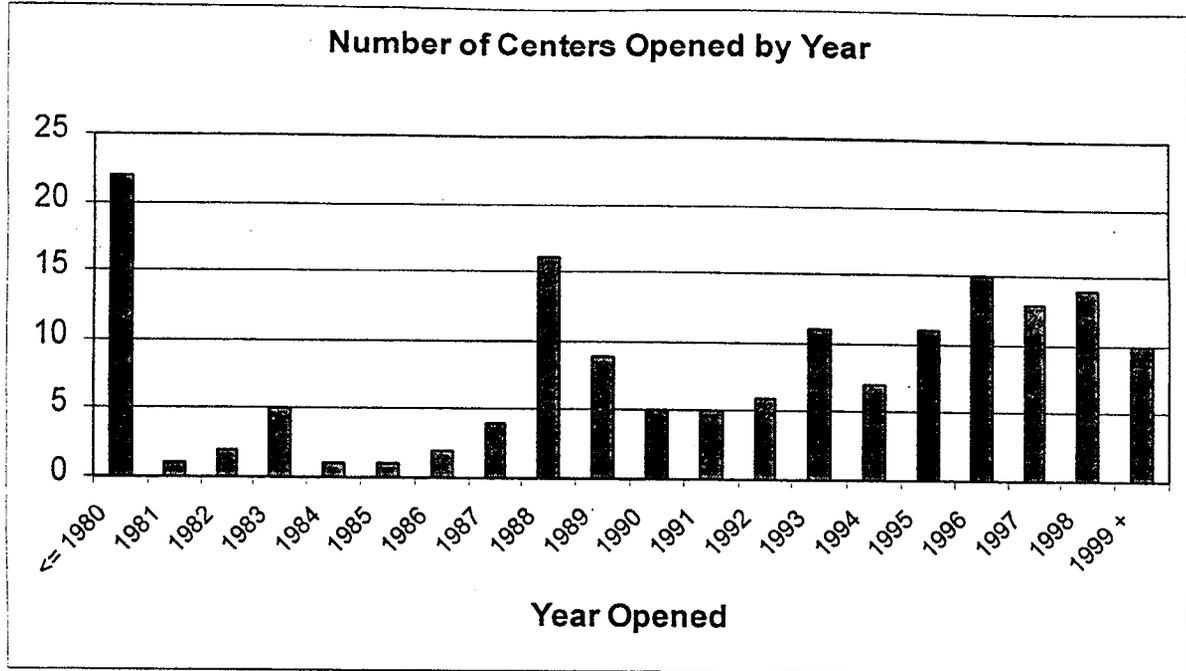
Source: AHCA 1999

Florida Dialysis Centers by Date Opened:

Year Opened	Frequency	Percent	Valid Percent	Cum Percent
<= 1980	22	11.5	13.8	13.8
1981	1	0.5	0.6	14.4
1982	2	1	1.3	15.6
1983	5	2.6	3.1	18.8
1984	1	0.5	0.6	19.4
1985	1	0.5	0.6	20
1986	2	1	1.3	21.3
1987	4	2.1	2.5	23.8
1988	16	8.4	10	33.8
1989	9	4.7	5.6	39.4
1990	5	2.6	3.1	42.5
1991	5	2.6	3.1	45.6
1992	6	3.1	3.8	49.4
1993	11	5.8	6.9	56.3
1994	7	3.7	4.4	60.6
1995	11	5.8	6.9	67.5
1996	15	7.9	9.4	76.9
1997	13	6.8	8.1	85
1998	14	7.3	8.8	93.8
1999 +	10	5.2	6.3	100
Total	160	83.8	100	

Source: AHCA 1999

Figure A-2



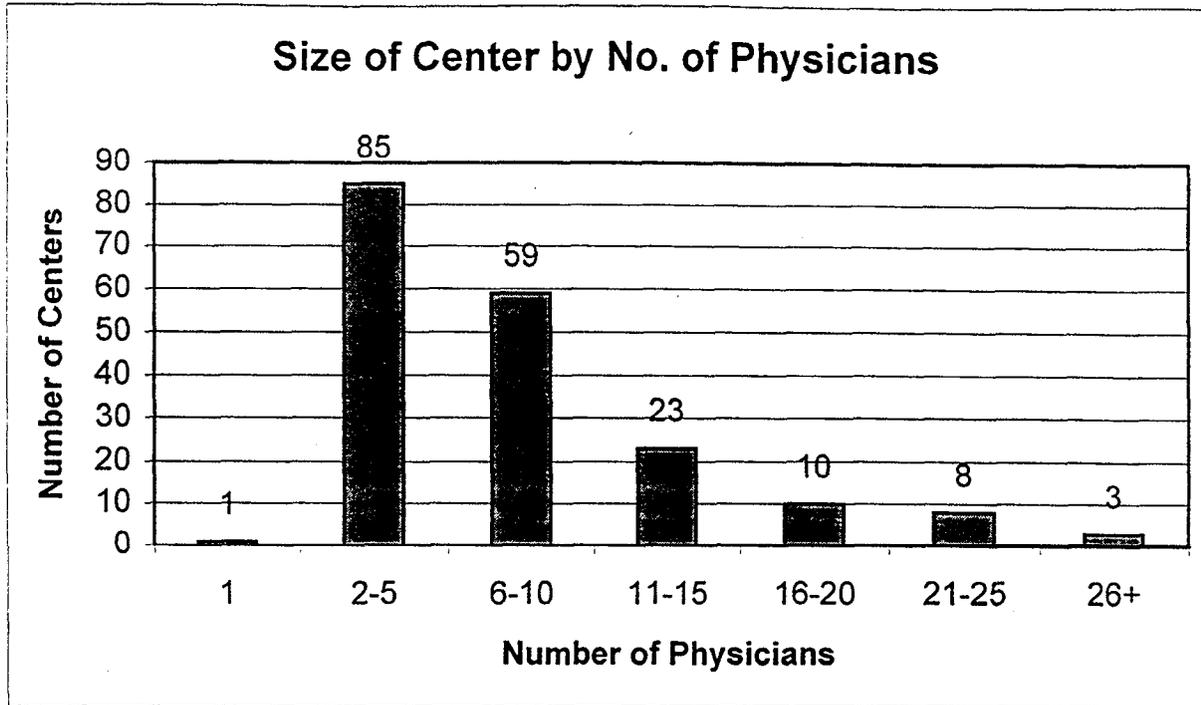
Source: AHCA 1999

Florida Dialysis Centers by Number of Doctors:

Group Size	Frequency	Percent	Valid Percent	Cumulative Percent
1	1	0.5	0.5	0.5
2-5	85	44.5	45.0	45.5
6-10	59	30.9	31.2	76.7
11-15	23	12.0	12.2	88.9
16-20	10	5.2	5.3	94.2
21-25	8	4.2	4.2	98.4
26+	3	1.6	1.6	100.0
Valid Total	189	99.0	100.0	
Missing	2	1.0		
Total	191	100		

Source: AHCA 1999

Figure A-3



Source: AHCA 1999

Appendix B

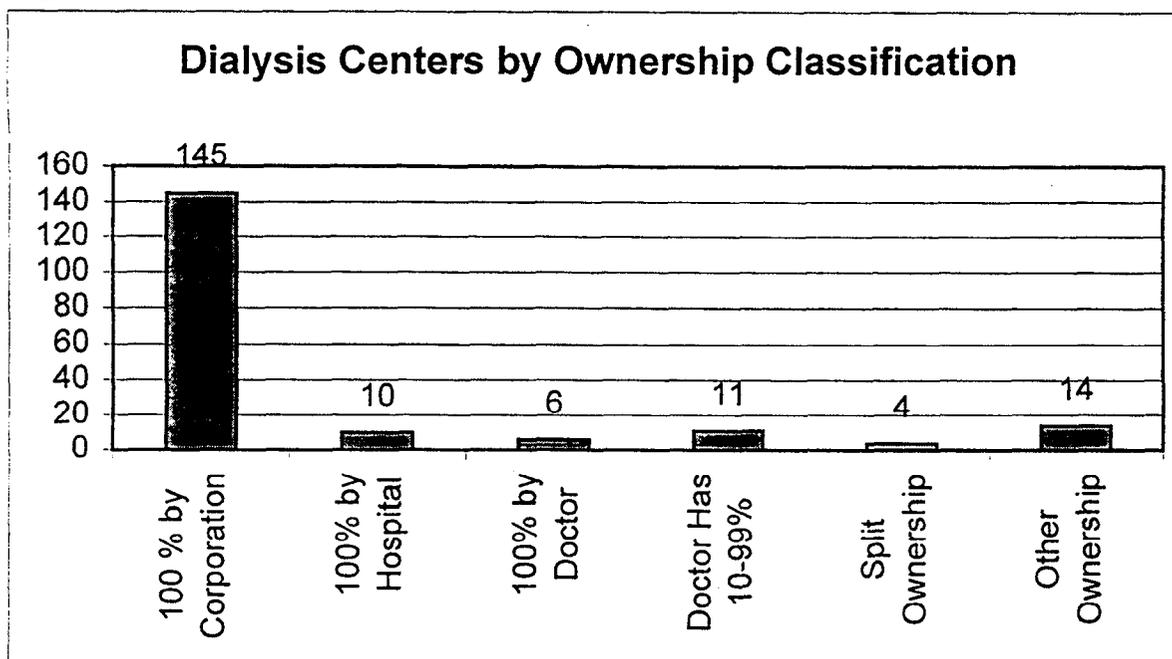
Corporate Involvement in Florida Dialysis Centers

Florida Dialysis Centers By Type of Ownership:

Owner %	Frequency	Percent	Valid Percent	Cumulative Percent
100 % by Corporation	145	75.9	75.9	76.4
100% by Hospital	10	5.2	5.2	81.7
100% by Doctor	6	3.1	3.1	84.8
Doctor Has 10-99%	11	5.8	5.8	90.6
Split Ownership	4	2.1	2.1	92.7
Other Ownership	14	7.3	7.3	100
Total	191	100	100	

Source: AHCA 1999

Figure B-1



Source: AHCA 1999

Figure B-2

Ownership of Corporately-Owned Centers	
Gambro Healthcare	55
Fresenius Medical Care	49
Total Renal Care	29
Renal Care Group, Inc.	4
Dialysis Clinic, Inc	2
Renex Corporation	1
Physicians Dialysis of America Holdings of Florida	1
Phycor	1
Orion Medical Enterprises	1
Health Resources Group	1
Ft. Lauderdale Dialysis Facility Corp.	1

Source: AHCA 1999

Chain Purchases of Florida Dialysis Centers:

Dialysis Center	Year	#	Percent of Reporting Centers
Fresenius			
Fresenius Medical Care	1986	2	1.0%
Fresenius Medical Care	1989	8	4.2%
Fresenius Medical Care	1990	1	0.5%
Fresenius Medical Care	1992	1	0.5%
Fresenius Medical Care	1993	2	1.0%
Fresenius Medical Care	1994	1	0.5%
Fresenius Total		15	7.9%
Gambro			
Gambro Healthcare		13	6.8%
Gambro Healthcare	1992	1	0.5%
Gambro Healthcare	1995	5	2.6%
Gambro Healthcare	1996	6	3.1%
Gambro Healthcare	1997	3	1.6%
Gambro Healthcare	1998	2	1.0%
Gambro Total		30	15.7%

Dialysis Center	Year	#	Percent of Reporting Centers
TRC			
Total Renal Care	1995	10	5.2%
Total Renal Care	1996	3	1.6%
Total Renal Care	1997	2	1.0%
Total Renal Care	1998	8	4.2%
Total Renal Care	1999	4	2.1%
TRC Total		27	14.1%
Other			
St. Augustine Dialysis Facility Corporation	—	1	0.5%
The Marital Estate of Albert Dreiling	—	1	0.5%
Physicians Dialysis of America Holdings of Florida	1998	2	1.0%
Allan Ira Jacob, MD/PDA Holdings, Inc.	1989	1	0.5%
Total		5	2.6%

Source: AHCA 1999

Appendix C

Extent of Center Medical Director Financial Relationship with Corporate Facility

The Legislature expressed interest in understanding the extent to which physicians serving as medical directors of dialysis facilities are also acting as an owner of the facility. It is also informative to look at the number of physicians currently serving as medical directors of dialysis facilities who were former owners who sold their facility to a corporation.

Centers Where Medical Director is Currently an Owner – By Number of Staff Physicians:

Very Small Centers (1 or 2 doctors on staff):

Number of centers with 1 or 2 docs where medical director is owner: 0 (0.0%)

Number of centers with 1 or 2 docs where medical director is a former majority owner: 2 (1.0%)

Number of centers with 1 or 2 docs where medical director is a former majority owner that is currently owned by a corporation: 2 (1.0%)

Centers With 1 or 2 Docs Where Medical Director Is A Former Majority Owner

Center Owner	Number of Centers
Total Renal Care	2

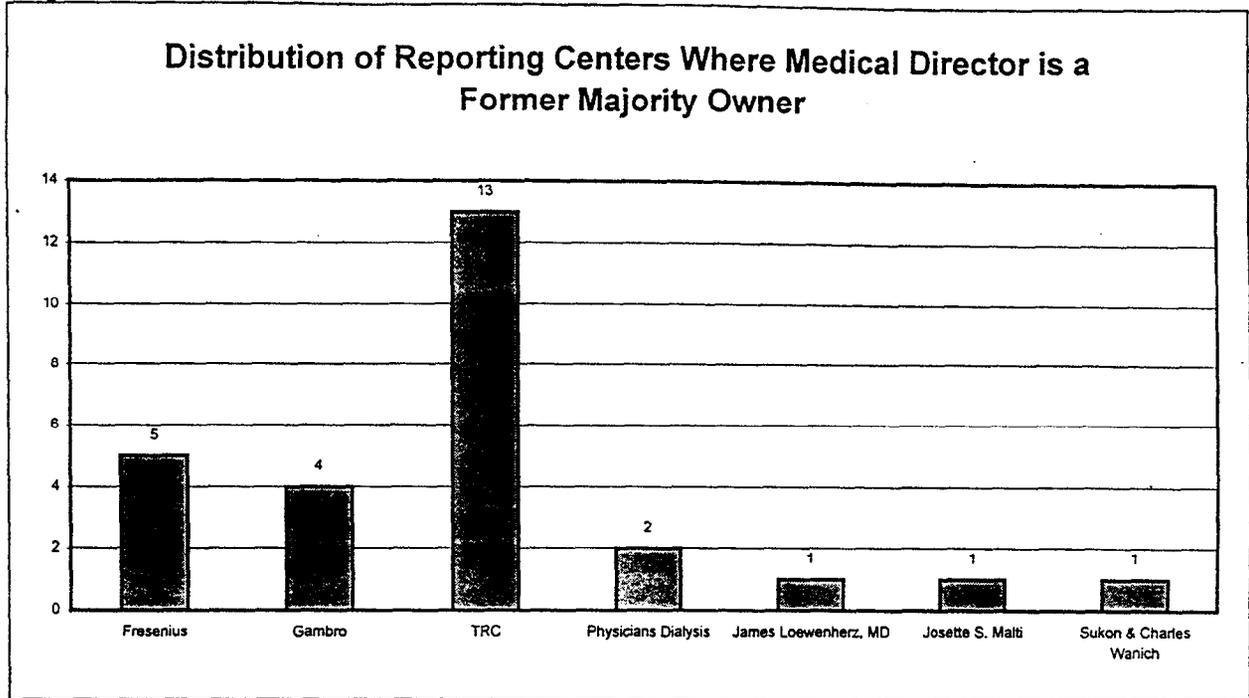
Small Centers (3 or more doctors on staff):

Number of centers with three or more docs where medical director is owner: 4 (2.1%)

Number of centers with three or more docs where medical director is a former majority owner: 27 (14.1%)

Number of centers with three or more docs where medical director is a former majority owner that is currently owned by a corporation: 22 (11.5%)

Figure C-1



Source: AHCA 1999

Medium-Sized Centers (10 or more doctors on staff):

Number of centers with ten or more docs where medical director is owner: 0 (0.0%)

Number of centers with ten or more docs where medical director is a former majority owner: 3 (1.6%)

Number of centers with ten or more docs where medical director is a former majority owner that is currently owned by a corporation: 2 (1.0%)

Centers With Twenty Or More Docs Where Medical Director Is A Former Majority Owner

Center Owner	Number of Centers
Josette S. Malti	1
Fresenius Medical Care	1
Gambro Healthcare	1

Large Centers (20 or more doctors on staff):

Number of centers with twenty or more docs where medical director is owner: 0 (0.0%)

Number of centers with twenty or more docs where medical director is a former majority owner: 2 (1.0%)

Number of centers with twenty or more docs where medical director is a former majority owner that is currently owned by a corporation: 1 (0.5%)

Centers With Twenty Or More Docs Where Medical Director Is A Former Majority Owner

Center Owner	Number of Centers
Josette S. Malti	1
Gambro Healthcare	1

Extent of Medical Director Control of Lab Test Ordering

The Legislature expressed interest in dialysis centers' medical directors and their relationship with the owner of the center and their relationship with the lab used by the center. Integral to that question is the extent to which these medical directors were reported by the facilities to control the standing lab orders.

General Centers:

Number of Centers where medical director is part owner (50% or less) and is responsible for standing orders: 15/16 (93.8%)

Number of Centers where medical director is part owner (50% or less) and is responsible for standing orders: 0/1 (0.0%)

Average size - in number of physicians - of centers where doctors are responsible for standing orders: 7.79

Corporate/Non-Corporate Centers:

Number of corporate centers where the medical director is a former majority owner and is responsible for standing orders: 9/145 (6.2%)

Number of non-corporate centers where the medical director is responsible for standing orders: 22/45 (48.9%)

Number of corporate centers where the medical director is responsible for standing orders: 64/145 (44.1%)

Current Labs Used by Florida Dialysis Facilities

The Legislature expressed interest in dialysis centers' choice of laboratories. While it would appear that corporately owned (TRC, Gambro, Fresenius) centers have little choice about which lab they use, non-corporate centers do exercise individual prerogative in selecting a lab. The choices made by these "independent" centers is therefore of interest.

Lab Choices of Independent Centers:

Number of non-corporate centers using corporate labs (TRL, Spectra, or Gambro): 23/45 (10, 11, and 2 respectively) or 51.1%.

- ◆ Number of non-corporate centers using ESRD Labs: 5/45 (11.1%)
- ◆ Number of non-corporate centers using LabCorp: 1/45 (2.2%)
- ◆ Number of non-corporate centers using other labs: 16/45 (35.5%)

Non-Corporate Centers' Choices of Non-Corporate Labs	
All Children's Hospital	1
Dade County Public Health Trust	1
Florida Hospital Medical Center Lab	1
Health First Holmes Regional Medical Center	3
Jackson Memorial Hospital	1
LabCorp	1
Memorial Regional Hospital - Lab. Dept.	1
Methodist Medical Center	1
Miami Children's Hospital Clinical Laboratory	1
St. Luke's Hospital	1
St. Mary's Medical Center	1
Tampa General Hospital	1
U.S. Government	1
West Palm Beach VA Hospital	1

Previous Lab Utilized by Florida Dialysis Facilities

Another aspect of the lab choice question is the type of lab that corporate centers chose before a large lab-owning chain purchased them.

Previous Lab:

Number of corporate centers that list ESRD as their former lab: 3

Number of non- corporate centers that list ESRD as their current lab and a corporate lab as their previous lab: 0

Number of non-corporate centers that list a corporate lab as their current lab, that also list LabCorp/Quest/Smith-Kline Beecham as their former lab: 0

Appendix G

Extent of Self Referral to Labs

Number of corporate facilities using a lab owned by the same company: 138/145 (95.2%)

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