

THE CERTIFICATE OF NEED PROCESS: END STAGE RENAL DISEASE

Background

The Department of Health determines Public Need for End Stage Renal Disease (ESRD) stations through a PHHPC Ad Hoc Committee recommended methodology from 2008 that uses ESRD patient data to project the number of stations needed in each county. The planning year is five years from the latest available patient data and is currently 2021. This methodology for the projection of ESRD stations is neither mentioned in nor excluded by regulation 709.4 End Stage Renal Dialysis which addresses public need in broad, non-numeric terms. Only twelve states still require CON for ESRD. Of those, only Vermont borders New York.

Problem

Until recently, projected public need for ESRD stations was comfortably outpacing CON applications for additional stations. The language of the Ad Hoc Committee's recommendations could even be interpreted to imply that this was the intended effect. The Committee's written report did not anticipate nor include any practical guidance as to how the Department should handle potential disapprovals or competitive review scenarios, which is where the Department finds itself today.

As of October 2017, there are 10 projects proposing construction of 231 stations on hold due to the Department's calculated need for stations being insufficient to support a recommendation for approval (all in a competitive review status). These numbers are based on an updated projection using the most recent patient data from April 2016 and using the highest projected value within a 95% percent confidence interval. In many of these instances, applicants have put forth compelling arguments in support of additional ESRD stations based on local factors specific to the proposed service area, however, the Department's current policies and procedures do not allow for consideration of these local factors in forming its recommendation of need.

Recommended Solution:

Continue to utilize the current need methodology in regulation and the projected public need calculation that the Ad Hoc Committee of PHHPC recommended, but incorporate into the Department's policies and procedures a process for consideration of local factors presented by applicants, which may include but not be limited to the following:

- documented evidence of the unduplicated number of ESRD patients on waiting lists;
- the location of the proposed facility and documented unreasonable travel times for treatment;
- specialty services such as home peritoneal dialysis training offered by the applicant but not offered at surrounding facilities;
- extent to which the application addresses medically underserved populations;
- patient migration patterns;
- the applicant's quality of care metrics;
- quality complaints or low CMS ratings for area facilities;
- recommendations from the local health systems;
- the extent to which the applicant's policies and procedures include efforts to coordinate with other local healthcare providers in the care of its ESRD patients;
- whether the proposed stations would provide improvements or innovations in the delivery of health services and serve to promote quality assurance and cost effectiveness;
- DSRIP participation or other affiliations.

Attachment 1: Regulation 709.4 End stage renal dialysis service.

Effective Date 12/28/1994

709.4 End stage renal dialysis service.

(a) This methodology will be utilized in the evaluation of certificate of need applications involving the construction or establishment of new or replacement dialysis stations used in the treatment of End Stage Renal Disease. It is the intent of the State Hospital Review and Planning Council that this methodology, when used in conjunction with the planning standards and criteria set forth in section 709.1 of this Part, become a statement of basic principles and planning/decision making tools for guiding and directing the development of dialysis stations for End Stage Renal Disease services throughout the state.

Additionally, it is intended that the methodology will provide the health systems agencies and potential applicants with sufficient flexibility to consider the unique characteristics of their respective areas in determining need. The goals and objectives of the methodology expressed herein are expected to ensure that an adequate supply of dialysis stations is available to provide access to care to all those in need of in-facility dialysis.

(b) The factors to be considered in determining the public need for dialysis stations shall include, but not be limited to, the following:

(1) evidence that the proposed dialysis services capacity proposed will be utilized sufficiently to be financially feasible as demonstrated by a five-year analysis of projected costs and revenues associated with the program;

(2) evidence that the proposed service or additional capacity will enhance access to services by patients including members of medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services (for example, low-income persons, racial and ethnic minorities, women, and handicapped persons), and/or appropriate rural populations;

(3) evidence that the facility's hours of operation and admission policies will promote the availability of services which are acceptable to those in need of such services, in particular, operational hours that permit individuals in dialysis to continue employment.

(4) the facility's willingness and ability safely to serve dialysis patients; and

(5) when an existing provider proposes to add twelve or more stations, evidence, derived from analysis of factors including but not necessarily limited to both existing patient referral and use patterns and projected referral and use patterns which would result from addition of the proposed stations, indicating that approval of such stations will not jeopardize the quality of service provided at or the financial viability of other existing dialysis facilities or services within the applicant's planning area. However, a finding that the proposed facility would jeopardize the financial viability of such existing facilities will not, of itself, require a recommendation of disapproval of the application.

(c) Public need for a proposed facility or station shall be deemed to exist when review and consideration of evidence concerning each of the five factors set forth in subdivision (b) of this section results in an affirmative finding.

**CERTIFICATE OF NEED METHODOLOGY as
APPLIED to CHRONIC RENAL DIALYSIS
FACILITIES**

REPORT TO THE PLANNING COMMITTEE

**NEW YORK STATE DEPARTMENT OF HEALTH
STATE HOSPITAL REVIEW AND PLANNING COUNCIL
PLANNING COMMITTEE**

May 22, 2008

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Final Report of the Dialysis Workgroup

Introduction

The Dialysis Workgroup (Workgroup) was convened in November 2006 to review the methodology used to determine the need for chronic dialysis station and to develop a report for presentation to the New York State Department of Health's (Department or DOH) State Hospital Review and Planning Council (SHRPC). The Workgroup was chaired by practicing nephrologist, Renee Garrick, MD. Members of the Workgroup included Sr. Pauline Brecanier, Marc Korn, Anthony Lechich, MD, and Michael Sloma. The Workgroup met, holding public hearings and soliciting testimony from the public, providers, and all other interested parties, in November and March 2006, January, May, and September 2007.

Specifically, the Workgroup was charged with reviewing the current methodology used to approve Article 28 End Stage Renal Disease (ESRD) chronic dialysis stations and to determine if the Certificate of Need (CON) process is hindering access to care. The Workgroup was asked to evaluate several related questions, including

- A. How to mitigate barriers to care including but not limited to geographical boundaries and travel times used in the methodology; transportation to and from dialysis treatment especially as it relates to para-transit systems; number of shifts per day per machine; incidence vs. prevalence; staffing (nursing & training of technicians) and impact of shifts.
- B. How the Department should respond to multiple requests to establish chronic dialysis stations in any one geographic area.
- C. The impact that the aging of the dialysis population has on the availability of access to dialysis care, with special attention focused on dialysis access for patients residing in residential health care facilities

The recommendations can be found in each section of this report. In general, the recommendations can be classified as impacting the federal or the state program and pertaining to the CON process or quality of care. The chart below indicates what type and program will be most impacted by the recommendations made.

	Recommendation Number	
	Federal	State
CON Program		1-4-16
Quality of Care	6-12-13	2-9-11-13
Both	5	3-7-8-14-15

Data

Data used in this report came from many sources.

- The Department maintains data on each licensed Article 28 facility in the State. The data maintained regarding ESRD facilities was used and includes name, number of stations, type of facility, ownership, etc for each. Additionally, data from the Institutional Cost Reports (ICR) was used.
- Data was requested from each currently licensed facility. A questionnaire was developed that specifically focused on the current distribution of dialysis facilities; the hours of operation and the number of shifts currently operating in each facility; the RN, and technical staff to patient ratio. (Attachment 1).

- Information from the End-Stage Renal Disease Network (IPRO ESRD Network of New York, Inc.) was used as reported in their Annual Reports. USRDS provided the Department with the number of residents in each zip code who received dialysis in 2004.
- All meetings were open to the public. At these meetings, dialysis providers, patients, and other health care providers gave input regarding the impact that transportation has on access to dialysis care, the effects of reimbursement on delivery, the role of nursing homes in providing care, as well as all other topics discussed.

Overview of End Stage Renal Disease Services in New York State

CONs Received by DOH

The Department acknowledges CONs when they are complete and ready for review. From January 1, 2003 through August 2007, there were 108 CONs acknowledged by the Department for chronic dialysis services; 73 were Administrative Reviews¹ and 35 were Full Reviews². No CONs for chronic dialysis were denied during this time period. There were 11 CONs that were withdrawn by the applicant. The Department does not track the reason for withdrawal, however for those CONs acknowledged 1/1/2003 through 9/30/2007 their current status is:

Status	2003	2004	2005	2006	2007	Total
Under Review (Pending)	1	2	1	3	12	19
Contingent Approval Letter Sent		2	2	7		11
Final Approval Letter(s) Prepared			1	2		3
Must Request Permission to Start Construction	1	1	2	3	1	8
Permission to Start Construction Granted	1	3	1	2		7
Under Construction		1	3	3		7
Told To Contact Area Office	1	1	2	2		6
Project Complete	10	18	6	1	0	35
Hearing Requested			1			1
Withdrawn	2	4	3	2		11
Total	16	32	22	25	13	108

The Department is striving to contact providers whose CONs have not progressed to completion.

Patients

The total number of patients treated as outpatients for chronic renal dialysis in New York for the period 2001-2005³ was:

- 2001 – 20,973
- 2002 – 21,438
- 2003 – 22,040
- 2004 – 22,372
- 2005 – 22,714

The above number of patients can include out-of-state residents as well as New Yorkers.

¹ Administrative Review is done when an existing provider request to add stations, change location or ownership, or add an extension clinic.

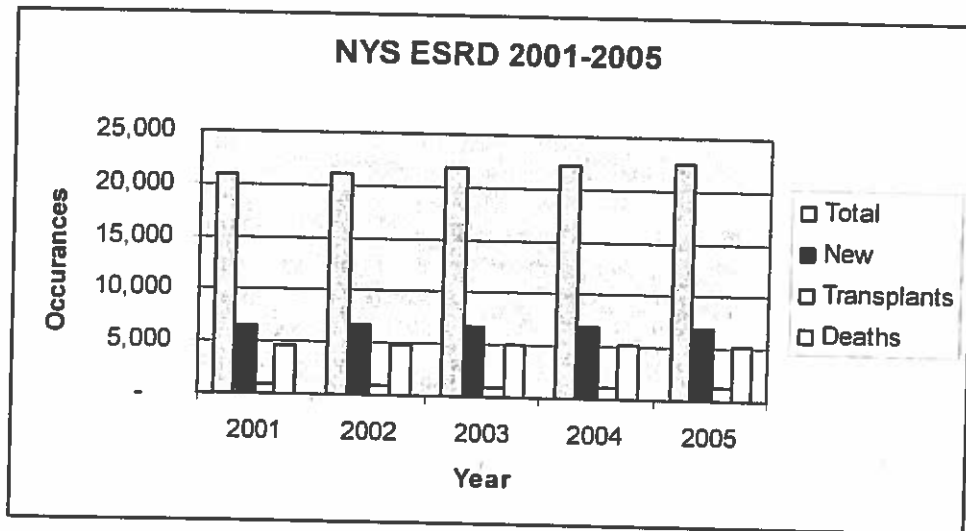
² Full Reviews are for establishment of a new operator, when a competitive situation exists, or for any other reason the Commissioner deems necessary.

³ IPRO ESRD Network of New York

In 2005, the IPRO End Stage Renal Disease Network of New York, Inc. reported that, on December 31, 2005, there were 22,510 New Yorkers living with ESRD. In 2005, it was also reported that there were

- 1231 transplants performed
- 6,935 newly diagnosed residents
- 5,169 ESRD deaths

The chart below shows the general trends for incidence (the number of new cases) and prevalence, (the number of people requiring dialysis) for 2001-2005. The specifics are shown in Attachment 2.



During 2001-2005, there was a 6% increase in the incidence and an 8% increase in the prevalence of dialysis patients. Deaths also increased by 9%. Overall there was an 8.3% increase in the number of patients treated in New York 2001-2005.

Types of Facilities

The federal government approves and licenses End Stage Renal Disease facilities. The Centers for Medicare & Medicaid Services defines four types of ESRD facilities:

1. Renal Transplantation Center

A hospital unit which is approved to furnish, directly, transplantation and other medical and surgical specialty services required for the care of ESRD transplant patients; including inpatient dialysis furnished directly or under an arrangement with an ESRD provider. A renal transplantation center may also be a renal dialysis center.

15 of these types of facility are currently operating in New York State. These facilities are not subject to chronic dialysis station need methodology.

2. Renal Dialysis Center

A renal dialysis center is a hospital unit that is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement and

outpatient dialysis). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

59 of these types of facilities are currently operating in New York State. These facilities are called 'hospital based' facilities in New York State.

3. Renal Dialysis Facility

A renal dialysis facility is a unit that is approved to furnish dialysis service(s) directly to ESRD patients.

172 of these types of facilities are currently operating in New York State. These facilities are called 'Free Standing' in New York State.

4. Self Dialysis Unit

A self-dialysis unit is a unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and which furnishes self-dialysis services.

At the present time, there is one self dialysis unit, a DTC extension clinic, operating in New York State.

The Department categorizes facilities by whether they are Hospital Based (Renal Dialysis Center) or Free Standing (Renal Dialysis Facility). Free Standing facilities are a subset of Diagnostic and Treatment Centers. Both types of facilities, Hospital Based and Free Standing, can, and do, have extension clinics.

Currently facilities are one of eight types of business entities: In the last legislative session, a bill was passed allowing publicly traded corporations to directly own and operate chronic dialysis facilities in the State (effective January 2008). The impact of this change in regulation is not yet known

- Proprietary Corporations
- Proprietary LLC
- Proprietary LLP
- Public Corporations
- Public County
- Public Municipality
- Public State
- Voluntary Corporations

Of all the facilities, a small number, treat only pediatric patients.

Statewide Distribution of Stations

Not all Counties, or other designated planning regions, currently have a chronic dialysis facility within their border (Attachment 3). There are 13 rural Counties without facilities. In 2004, 366 New Yorkers lived in these Counties and had to obtain their dialysis services in other than their County of residence. In 2005 it is estimated that 3,357 New Yorkers were not treated in the County in which they reside (Attachment 7).

The lack of facilities in an area negatively impacts a patient's ability to obtain treatment. In rural areas this is particularly difficult because of compounding issues of the lack of reliable year round transportation.

Other New York State Initiatives

Preventing kidney disease and its progression to ESRD has the potential to improve quality of life for countless individuals and to save millions of health care dollars by avoiding the need for dialysis and hospitalization. It is estimated that as many as 1.2 million New York State residents have chronic kidney disease. In March 2007, Governor Spitzer announced plans to establish a New York State Chronic Kidney Disease Detection, Control and Prevention Task Force. This task force will work to increase healthcare provider and public awareness of the steps that can be taken to prevent the development of kidney disease and its progression to kidney failure.

Current Methodology

The State currently employs a methodology that primarily considers the number of treatments that each dialysis treatment station can provide annually, the number of patients treated, expected increase/decrease in incidence and prevalence, transportation, staffing, etc. The need mythology is not only formula driven but responds to the regulations (Attachment 10).

A treatment shift is between 3.5 and hour hours each. It is estimated that each hospital based facility can provide 499 treatments per year per station and that each free standing dialysis treatment station can provide 702 treatments per year. These treatments translate to 3.2 patients per station per year a hospital based unit and 4.5 patients per year for each station in a free standing unit. These numbers are based upon the following calculation:

Free Standing: $2.5 \text{ shifts per day} \times 6 \text{ days per week} \times 52 \text{ weeks} \times 90\% = 702 \text{ dialysis procedures per station per year} / 156 \text{ treatments per year} = 4.5 \text{ patients per station per year}$

Hospital Based: $2.0 \text{ shifts per day} \times 6 \text{ days/week} \times 52 \text{ weeks} \times 80\% = 499 \text{ dialysis procedures per station per year} / 156 \text{ treatments per year} = 3.2 \text{ patients per station per year}$

Hospital based and free standing facilities target different patients. Hospital Based facilities generally treat sicker patients who are unable to be treated in free standing facilities. Hospital based facilities must provide backup for free standing facilities when a patient's condition warrants additional care, in times of disaster, etc. Federal regulations require that each free standing facility have an agreement with a hospital to provide services, an affiliation agreement or an arrangement to provide inpatient care and other hospital services for their patients. In short, hospital based units provide the fail safe for the delivery of treatment in New York State.

Using this methodology, the 4,097 operational and the 561 approved not yet operational stations; the number of patients that could be treated for a full year is 20,077. There are currently an additional 282 stations for which the Department has received CONs, if we include these stations; the State has the total capacity to treat 21,327 patients for one full year.

Based upon the data noted above, statewide, utilization of chronic dialysis stations was 104% (using all approved stations) or 118% (operating stations only) in 2005. These utilization percentages indicate a current need for chronic dialysis stations statewide without consideration for increases in need.

Attachment 4 shows 2005 utilization by County based upon current Department methodology. It also shows utilization based upon three (3) shifts per day (936 treatments per station per year).

Using a methodology that prescribes three (3) shifts per day per station (for both hospital based and free standing stations), we find that, for 2005, the utilization for all approved stations would have been 74% while for only operational stations; the utilization would have been 85% statewide. Although these calculations do not take regional population differences into account they indicate that across the State, based on a three shift model, there would be sufficient current and near-future capacity statewide. This again suggests that the methodology of CON calculation which calls for 2 or 2.5 shifts per day (depending on the facility type) is not itself is not a barrier to access across the State

Barriers to Care

The Workgroup identified impediments faced by patients in obtaining services and impediments faced by providers in delivering care.

Reimbursement

Most ESRD patients qualify for Medicare within 30 months of the start of treatment. Dialysis treatments performed in a Medicare approved facility are reimbursed on a per treatment rate called the "composite rate". Medicare pays 80% of the composite rate, with the patient responsible for the remaining 20%. Medicare's composite rate includes labor, supplies and routine lab tests. Providers can bill separately for certain medications administered during the dialysis treatment (i.e. EPO, Iron), non-routine lab tests, Hepatitis B vaccines, etc. Upstate, Medicare reimburses providers about \$240 per treatment (total reimbursement calculated at \$300 per treatment) and downstate (as well as those facilities classified as being upstate), the reimbursement rate is about \$290 (total reimbursement calculated at \$362.50 per treatment). These reimbursement rates reflect a January 2005 1.6% increase to the composite rate.

While the payments to units are fixed, the expenses are not. Thus, staffing costs, supplies, equipment and facility purchase and maintenance costs, water cost, electric and fuel cost (to generate dialysis grade water) are not fixed. Together this means that the margins for profit are very small. This is especially true for dialysis units who service small numbers of patients and for units that care for patients whose comorbidities are such that a high patient to staff ratio is required to achieve optimal patient care. These low profit margins do not encourage providers to enter the dialysis arena

Payor Types

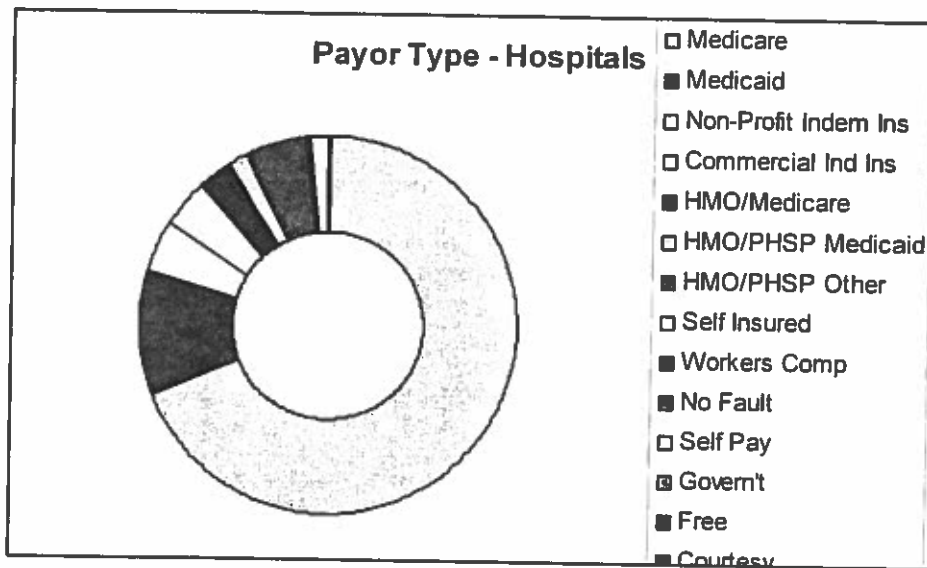
Providers are required to submit Institutional Cost Reports (ICR) to the Department annually. ICR data are reported based upon operating certificate number. Thus, if a provider has extension clinics, the number of visits/treatments reported will reflect the primary and all secondary sites for that provider. Accordingly, if a provider has facilities in more than one County, that data will be reported together. Attachment 5 and Attachment 6 show Payor by County (note caveat above).

Among the data reported are the number of treatments/visits and the payment source. The table below shows reported 2005 data. Please note that these data have not completed the auditing process and thus should be used only for estimation purposes.

60 hospital based providers reported. For those 60, Medicare was responsible for 68.9% followed by Medicaid with 10.5%. Free care was 0.1% and self pay was 1.6%. Most facilities reported providing no free care with only three hospitals reporting having provided a total of 483 free care visits:

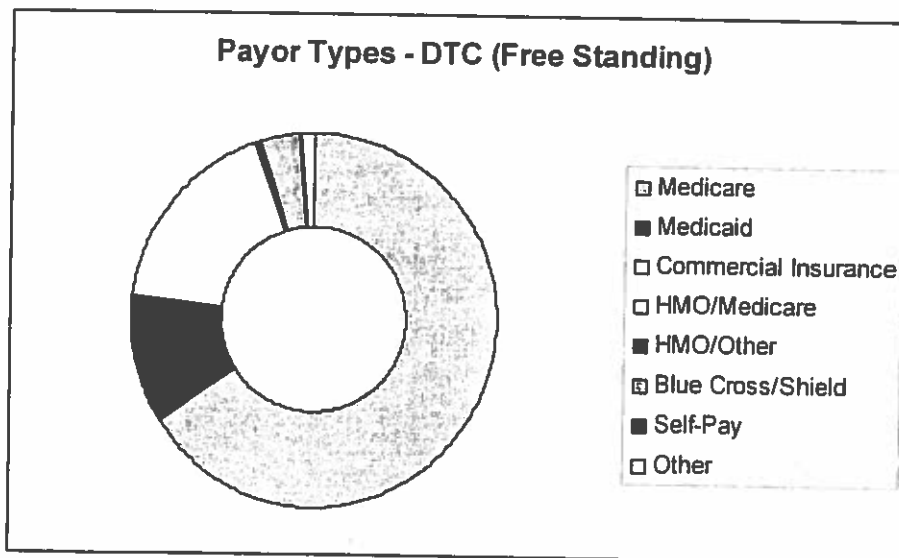
Facility	Number of Free Care Visits
Woman's Christian Association	1
City Hospital Center At Elmhurst	61
Kings County Hospital Center	421

The following chart represents the hospital payors by type.



Six free standing DTCs did not file 2005 ICR data, thus the chart below reflects data for 63 providers. While the greatest share was paid by Medicare (65.9%), insurance companies, including Blue Cross, Blue Shield and commercial companies, were the next highest payors with 23.1%. Free care was the same as that for Hospitals at 0.1%. For free standing facilities, this 0.1% represented 2,359 treatments.

The chart depicting DTC/Free Standing payors is shown below.



Transportation

Transportation issues were, by far, the most often expressed barrier to access to care.

Federal guidelines state that a patient preferably should not have to travel more than one hour to obtain treatment (adjusted for weather). Though an adequate guide line, this parameter cannot be applied directly; for example, it can take more than one hour to travel ten miles in Nassau County and it can take more than one hour to travel 20 miles during snow season in Cattaraugus County.

Some of the most common issues expressed with transportation are:

- Chronic dialysis patients are often too ill to avail themselves of public transportation.
- In many counties the county provided Paratransit groupa will not cross county lines. Therefore patients who rely on Paratransit may be transported to a facility within their County but farther from their home,
- The only transportation Medicare will provide is transportation by ambulance for those patients who meet strict medical criteria; most dialysis patients do not qualify for this.
- Medicaid covers the use of ambulettes, but we found that though they can, many ambulette companies will not cross County lines. Thus Medicaid patients might have to go to facilities fater from their home to which they can obtain transportation.
- All transportation in rural areas is problematic. There is often no public transportation available to the patients. Patients must rely on themselves, family or friends.
- Traffic congestion is a problem in urban areas. Patients often arrive late for their appointments and thus, if they are able to be treated at all, cause delays and cancellations in that day's schedule for other patients.
- Patients in Residential Health Care Facilities are transported to facilities three times weekly. This can be difficult for patients and if patients require transportation by ambulance the costs quite high costs. It has been estimated that an ambulance trip averages \$309.⁴ Thus, the Medicare cost of transporting one nursing home patient to and from dialysis treatment is estimated at \$96,400 annually.

Financial

How a patient pays their 20% share of the cost of treatment can be a barrier to care.

ESRD patients with no insurance often go to the Emergency Department of a local hospital where they are admitted and provided treatment. The burden of illness in these patients is often greater because they often have limited access to routine dialysis care. Instead they seek intermittent treatments, often only when quite ill, through hospital emergency rooms. Because of their degree of illness the cost of treatment is usually greater and less successful than that of the typical chronic dialysis patient. Though these patients tend to live in the larger urban areas, rural areas also see their share of people who do not qualify for Medicare coverage.

Patients enrolled in Managed Care programs have the responsibility of paying co-pay for services provided. Discussions with providers and patients indicate that those co-payments are sometimes very high and limit a patient's ability to cover these costs and to maintain their homes, cover other expenses, etc. Physicians from several regions in the State have expressed concern regarding this issue. Insurance companies are known to have \$30+ copay per treatment. For a dialysis patient, this equals \$390 per month for this copay alone. In 2004, the National Kidney Foundation notified CMS that they were opposed to ESRD patients in managed care programs.

⁴ Data from CMS

Staffing

The questionnaire sent to facilities (Attachment 1) requested data pertaining to the number of RNs, LPNs and Patient Care Technicians on staff per shift. The summary of these responses is presented below.

At least one professional (registered nurse or medical doctor) must be in a facility when patients are receiving treatment. Additionally because of the complexity of the care it is mandated that dialysis nurses must have several months training with ESRD patients. The general shortage of trained dialysis RNs was reported as a serious impediment to access by every user group.

Staffing has an impact on facilities and the number of shifts per day they offer. Though all areas are affected this is especially true in rural areas. For example, CONs have been submitted and approved for additional stations in order to accommodate more patients per shift rather than by extending the hours of unit operation. Thus one nurse can oversee 24 stations during one shift rather than requiring 2 RNs by operating the unit for two shifts of 12 patients each.

The federal government sets standards for staffing levels and qualifications for licensed professionals in ESRD facilities and the New York State Education Department is responsible for licensing professionals. Per NYS Education regulations patient assessment can and should be done only by an RN. Both the initiation and termination of treatment requires an assessment, thus requires an RN. Should any problems occur during treatment, such as responding to alarms, an RN must assess the patient and act accordingly. In addition, many patients have at least three associated co-morbid conditions and many have cognitive impairments. Thus the RNs caring for these patients require highly specific training and special skills.

The issues of staffing cost and availability have necessitated that other levels of care givers, LPNs and patient care technicians, participate in the care of dialysis patients. The responsibilities and assignments of these individuals are governed by the Department of Education. Given the important roll that these individuals can have in the care of dialysis patients it is important that these other professionals have clear evidence of proper training and ongoing review to ensure current competency.

Not all of the 232 facilities to which questionnaires were sent, responded. Data was adjusted to be able to compare facilities and numbers were rounded to facilitate this process. Thus the picture we are presenting is an adequate representative sample on which we can draw conclusions. See Attachment 8 for the detail responses. The table below shows the highest and lowest ratios reported.

Facility Type	Number of Facilities Reporting	RN Lowest Ratio to Patients	RN Highest ratio to Patients	Number of Facilities Reporting	LPN Lowest Ratio to Patients	LPN Highest ratio to Patients	Number of Facilities Reporting	PCT Lowest Ratio to Patients	PCT Highest ratio to Patients
DTC	43	1:25	1:1	38	1:30	1:1	43	1:12	1:1
DTC-EC	43	1:21	1:1	31	1:30	1:1	42	1:10	1:1
HOSP	25	1:12	1:1	16	1:11	1:1	13	1:12	1:2
HOSP-EC	32	1:15	1:1	25	1:24	1:1	24	1:24	1:1

Registered Nurses (RN)

144 facilities (62%) of facilities responded with data regarding the number of RNs per shift.

Licensed Practical Nurses (LPN)

111 facilities provided the highest and lowest number of LPNs per shift.

Patient Care Technicians (PCT)

122 facilities provided the highest and lowest number of PCTs per shift.

Shifts per Day

145 facilities reported this data to the Department via the questionnaire. Number of shifts per day reported is as follows:

- 1 shift – 1 facility
- 1.5 shifts – 1 facility
- 2 shifts – 25 facilities
- 2.5 shifts 12 facilities
- 3 shifts - 58 facilities
- 3.5 shifts - 15 facilities
- 4 shifts 33 facilities

84.6% of all Hospital Based facilities are operating more shifts per day than Department methodology suggests and 72.3% of Free Standing facilities exceed Department methodology.

Shifts Per Day	Hospital Based	Free Standing	All
1	0.0%	0.8%	0.7%
1.5	0.0%	0.8%	0.7%
2	15.4%	16.8%	16.6%
2.5	3.8%	9.2%	8.3%
3	50.0%	38.7%	40.7%
3.5	7.7%	10.9%	10.3%
4	23.1%	22.7%	22.8%

Attachment 9 shows maps with indications of shifts per day.

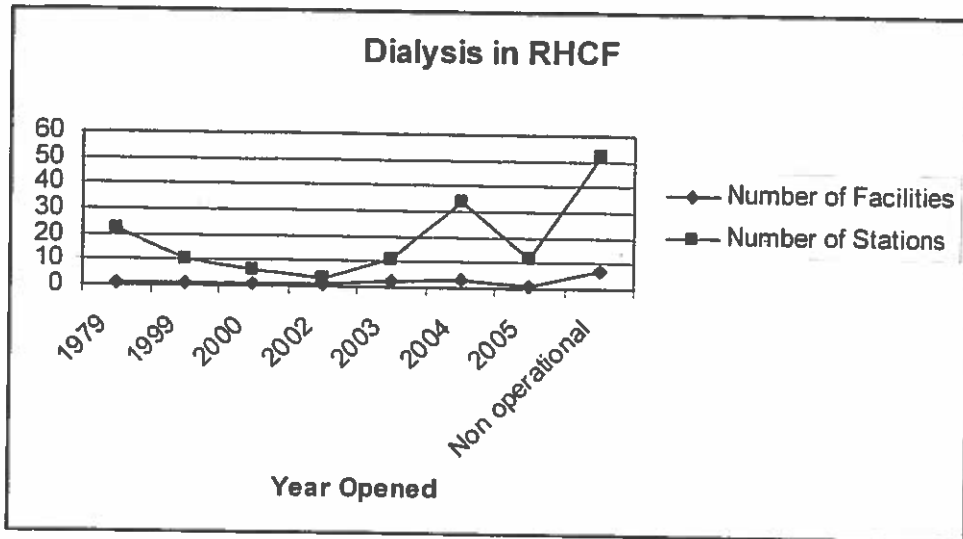
The Department, the ESRD Industry, and IPRO ESRD Network of NY all have expressed concerns that four shifts a day is not ideal. A major concern is that almost one quarter of New York State facilities are operating in this red zone

Dialysis and the Elderly

The elderly present a unique set of issues.

Residents of of RHCF who require dialysis must either receive the treatments in the RHCF facility or be transported to an established dialysis unit. These trips can be both expensive for the RHCF especially if an ambulance is required for transport) and exhausting and disruptive for the patient.

In 1979 the first dialysis facilities located in a RHCF was established. There is now eleven facilities that are physically located in Residential Health Care Facilities. They are the same as any other DTC ESRD facility in that they have to accept patients from both the RHCF and from the general public according to New York State regulations. These eleven facilities have a total of 106 free standing stations.



There are an additional six facilities that are approved but not yet operational which will provide 44 additional stations. These 17 facilities are located in the following Counties:

- Bronx – 2
- Columbia - 2
- Kings – 3
- Nassau – 4
- New York – 2
- Oneida – 1
- Queens - 1
- Richmond – 1
- Suffolk - 1

There are CONs currently under review for three facilities in RHCfs with a combined 24 stations.

The available data support this belief in as much as at least 53% of all new ESRD patients from 2001-2005 were people 65years or older. The Department estimates that, based upon 2005, the State's elderly population will increase by 16% in 2015 and 22% by 2020. Based on current evidence regarding incidence and prevalence rates, it is likely that the new incident patients will live longer than prior groups. This is clearly a desirable outcome from a patient care perspective and one that will add to the need for new stations. Additionally in that the elderly are the fastest growing group needing dialysis patients, the transition of the baby boomers into the elderly demographics will substantially add to the need for new stations.

Another issue raised to the Workgroup regarded the general provision of dialysis services for residents of RHCfs. The issue relates to the current health care proxy law in place in New York State which requires that, for patients who lack capacity, the appointed proxy must have clear and convincing evidence of the patient's wishes in order to direct their care. Many scenarios were reviewed and discussed. Three commonly occurring examples, described below, were considered by the work group. The later recommendations stem from consideration of these examples.

- dialysis treatments may be initiated in an acute care setting for a patient with capacity who has chosen not to name a health care proxy. In such cases, the ultimate patient outcome and long term quality of life is unknown and if the patient subsequently loses capacity, absent a court order, it may be necessary to continue the treatments following placement in a RHCF
- a similar patient may have a proxy, but have failed to provide the proxy with clear evidence regarding his or her wishes as related to dialysis treatments

- a resident of a RHCF who is unable to give consent may come to require dialysis services and, absent a health care proxy with clear prior knowledge of the patient's wishes, it may be necessary to obtain direction from a court in order to know how to legally proceed.

CONCLUSIONS AND RECOMMENDATIONS

From the available data, the Workgroup finds that the current need calculations are not limiting access to care. Rather, the data gathered by the Workgroup (Attachment 4) demonstrate that in both rural and urban areas, three and, in some areas, four shifts a day are routinely being performed. These numbers EXCEED the current levels suggested by the need methodology calculations now in place. In addition, the data provided (detailed data for Attachment 4), demonstrated that, in some cases, facilities providing less than 3 shifts per day are in geographic proximity to facilities providing over 3 shifts per day.

Thus, these data suggest that the current need methodology is not preventing the creation of new units and, as such, the need methodology is not, in itself, preventing access to care. Rather, in both urban and rural parts of the State, other factors appear to be potentially affecting the creation of new and expansion of existing dialysis facilities. Identified factors include:

- financial considerations largely related to the reimbursement methodology in place for the provision of dialysis services
- staffing considerations
- transportation concerns
- issues potentially related to patient choice
- issues relating to access to care for those dialysis patients that are aging and physically debilitated.

The Recommendations below focus on each of these areas:

CON Need Methodology

With regard to the current CON calculation of need methodology, as noted, the current standards are NOT limiting the ability of providers to open new units. Rather, as the data demonstrate, in many areas of the State more patients are being dialyzed per station than advocated by the current methodology, and were applications for new stations received, under the current need methodology, these applications would be approved.

Most of the comments obtained by the Workgroup, including those of the ESRD IPRO Network and the State dialysis survey teams, suggested with few exceptions that three shifts a day on each station should be used as the upper end target, and that facilities operating at this capacity be considered "full." The Workgroup noted that exceptions to this would include those geographical areas where staffing and population considerations reasonably prevent expansion, facilities that cater to employed patients (who choose to receive dialysis after work), and patients whose transportation limitations necessitate late evening dialysis.

The Workgroup also noted that there are a few highly specialized units that cater to pediatric populations and these units should be altogether excluded from the CON need calculations when determining the need for dialysis expansion.

Recommendations:

1. The workgroup suggests that the calculation of need methodology should be reviewed at least biannually and should be based on analysis of the previous five years cumulative patient numbers for each geographic region. (Data are available from the United States Renal Data System [USRDS] database as provided by the ESRD network contracted

through CMS). As discussed later, most available public forms of transportation do not cross County lines, and this fact should be considered when evaluating specific geographic regions.

2. Units routinely operating more than 3 shifts of patients per station should be given an opportunity to work with the State to demonstrate their special circumstances and, as applicable, given an opportunity to provide expansion plans. Such plans could include the addition of home dialysis and peritoneal dialysis services. In areas without units where need exists and in areas where units have not expanded and there is a demonstrable need as determined by the current CON methodology the State may consider initiating a RFP process to help address the needs of the region.
3. The Workgroup agreed that efforts to "balance" unit enrollment from the vantage point of the State would be extremely complex and may actually serve to limit patient choice. There are a myriad of reasons that units in the same geographic area may be underutilized as compared to other nearby facilities. The Workgroup does not endorse achieving a balanced regional occupancy by shifting patients among the available facilities.
4. The Workgroup recognizes that the Department may be required to simultaneously review more than one CON from the same geographic area. These applications typically have different groups of owners/investors and providers, and to some extent may represent "competing" applications. Depending on the application, the flow of patients into and out of a unit can also be influenced by the unit's investors or owners. As discussed above, the Workgroup does not support achieving a regional balance by "moving" patients from an over-utilized facility to an under-utilized facility. At the same time, the workgroup recognizes the State's need to responsibly marshal health care resources, especially in a field such as dialysis where highly specialized staff is at a premium (see later).

The Workgroup recommends that, in such cases, the applicants be urged to work collaboratively to best serve the needs of the community. If both applicants are qualified, and if expansion is supported by the CON needs methodology, then consideration should be given to phasing in the stations over time, with the phase-in based on the number of "new starting patients" in the units. Patients who are transferred from one unit to the other should not be considered as "new start" patients but as transfer patients. This approach will allow regional station needs to be met, and should minimize financial harm and staffing disruptions that can be engendered by excess capacity.

Financial Factors

Certain financial factors also exist that may limit expansion. As noted on Attachments 5 and 6 the majority of dialysis services are reimbursed by Medicare and Medicaid. Third-party insurance coverage is more prevalent in freestanding dialysis treatment centers than in hospital-based facilities. Several units submitted data to the Workgroup suggesting that particular managed care plans have required patients to pay a "co-pay" for each dialysis treatment. In some areas of the State this is more prevalent than in others. Regardless of the geography, this requirement represents approximately 144 co-pays for dialysis services each year, and can pose an extreme financial hardship for the patients and their families.

The initial CON calculations and descriptions detailed earlier denote that the Need calculations for hospital-based units anticipate that these units reserve extra empty stations to accommodate the "surge capacity" that may accompany any emergency condition. In addition, hospital based units *tend* to care for patients who are more ill and who require more intensive staffing ratios than those required by the patients of a typical freestanding facility.

Recommendations:

5. The Workgroup appreciates that most of the financial issues related to dialysis reimbursement are outside the purview of the State. However the Workgroup recommends that the appropriate regulatory group take the necessary steps to prevent per-treatment co-pay from being charged.
6. Several stakeholders commented that all aspects of staffing (Nursing, Dietician, Social Services and patient technicians), are directly influenced by patient acuity and co-morbidities. The workgroup supports the suggestion that State and Federal dialysis reimbursement methodologies be re-evaluated to accommodate this distinctly high risk population.

The Workgroup suggests that it would be feasible for reimbursement methodologies to be "weighted" for a patients' co-morbidity index (as attested to and verified on the CMS 2728 Dialysis enrollment filing). In turn, a facilities' reimbursement and staffing model could be adjusted to match their co-morbidity and acuity ranking. There are several potential benefits of such a modeling approach. Expert user groups, such the Renal Physicians Association (RPA), American Society of Nephrology, and the Renal Administrators Association among others, may be asked to help devise this type of scaled reimbursement system.

7. The Workgroup suggests that, when facilities are being surveyed, the classification of the unit (Hospital based, Renal Dialysis Center, "Free Standing" Renal Dialysis Facility, and extension clinics of Dialysis Centers and Facilities) be carefully clarified. The Workgroup is not suggesting a change in nomenclature, but rather is supporting that the classification be verified as surveyed.
8. The Workgroup also recommends that the number of stations and location of facilities with isolation capability in each geographic area be tracked. There is currently no requirement that units provide isolation stations, and, therefore, the regional allocation of stations may be skewed and the overall number of isolation stations may not be in line with regional needs. This is an important parameter that could be addressed through the CON process.
9. Whether a facility supports and provides home and peritoneal dialysis should also be tracked by the Department. Research has shown that these treatment modalities tend to improve a patients health.

Staffing

Staffing considerations exist which may limit facility creation and expansion, and thereby impede access to care. Multiples stakeholders identified the availability of dialysis nurses as one of the most pressing concerns of the dialysis community.

Recommendations:

10. The Workgroup suggests that the State continues to seek solutions to the widespread nursing shortage that has affected many sectors of the nursing profession. Payback grants, reduced tuition, "signing bonuses," and similar remedies may help encourage talented individuals to remain as primary nursing caregivers. The data in Attachments 4 and 8 suggest that elements of the nursing shortage exist statewide.
11. The current CMS requirements for participation set professional staffing at one professional during treatment hours. This professional is most often an RN. The Workgroup suggests that this staffing requirement be re-evaluated, especially in light of the chronic co-morbidities and aging of the dialysis population. The RN ratio should be

based on numbers of concurrent occupied stations (for example, one RN for every 10 occupied stations). Achieving this goal is predicated on the availability of dialysis RNs.

12. It is recommended that the State seek a process to recognize the roll of Patient Care Technicians and to standardize their education, training and continued evidence of competency as it pertains to the care of dialysis patients. The Workgroup recommends that consideration be given to a certification process for Patient Care Technicians to ensure uniformity of training and education.

Elderly and Dialysis Services

Access to dialysis services by people who reside in resident healthcare facilities also represents a barrier to care. Research indicates, and several stakeholders presented evidence indicating, that dialysis services are becoming increasingly common in the elderly age group. Many of these individuals reside in long-term residential care facilities. For the RHCF resident as well as for all elderly, transportation to and from dialysis can represent a major obstacle for many of the residents of an RHCF and an extraordinary expense for all.

Recommendation:

13. The Department should work with IPRO ESRD Network of New York to identify chronic dialysis patients who reside in a RHCF. Patients age 65 and older represent the fastest growing segment of the dialysis population and accurate data regarding the growth of this patient group is critical
14. If the apparent growth of the elderly population is substantiated, then regulatory alterations should be considered to allow Article 28 RHC facilities to open chronic dialysis units that are specifically designed for their own residents and are not open to the public at large. Such RHCF units would be required to be licensed by the federal government and comply with all other existing chronic dialysis facility codes and regulations, including the provision of dialysis specific social work and dietary services.
15. The workgroup identified several complex social, legal, and medical issues regarding the topic of consent for long term dialysis services for patients without capacity and without a health care proxy. In conjunction with the current law, the Workgroup strongly endorses the need for health care providers and facilities to help explain the benefit of having a named health care proxy who is knowledgeable about the wishes of the patient. Given the scope and complexity of the issues involved, the Workgroup believes that this important, multifaceted issue might be best addressed by a special committee of the New York State Task Force of Life and the Law.

Transportation

Transportation issues also pose a barrier to dialysis access. Though the issues differ in rural, suburban and in urban counties, some problems occur in all area of New York. As indicated in Attachments 5 and 6, most dialysis services are paid for by Medicare. However, Medicare does not cover transportation to or from the dialysis facility except for the sickliest thus ambulance transportation to and from dialysis is not routinely medically justifiable. If existing at all, public transportation is not always a feasible alternative to patients due to their weakened state immediately following treatment. Transportation by Ambulette is reimbursed in New York State by Medicaid. However, this service is not reimbursed by Medicare.

This constellation of regulations presents a substantial barrier for many poor, elderly and infirmed dialysis recipients.

Recommendation:

16. The Workgroup recommends that the State and Federal government work together to alleviate this barrier to dialysis. One possibility is that Medicare could provide vouchers to dialysis patients to allow them to receive transportation via the State's Medicaid ambulette system. Physicians and social workers could together certify patient need based on predetermined medical criteria.

Attachment 1 – Questionnaire to all ESRD Providers

Facility Name
Facility Address
Facility Phone
County:
PFI
Type
Name of Respondent
Title of Respondent
Date
Surveyor

1. Number of licensed chronic operational stations (do not include any correctional facility stations) _____
2. Number of operational chronic dialysis stations currently in use (do not include any correctional facility stations) _____
3. Hours of Operation for patient treatment
____ AM ____ PM Mon - Wed - Fri
____ AM ____ PM Tues - Thurs - Sat
4. Number of patient shifts per day: _____
5. Average hours/duration of treatment: _____
6. Do you provide care to pediatric and adult patients?
Adults _____ Pediatric _____
7. Registered Nurse to patient ratio highest ratio during day: _____
8. Registered Nurse to patient ratio lowest ratio during day: _____
9. LPN to patient ratio highest ratio during day: _____
10. LPN Nurse to patient ratio lowest ratio during day: _____
11. Tech to patient: ratio best ratio during day: _____
12. Tech to patient: ratio lowest ratio during day: _____
13. Number of Isolation Stations: _____
14. Number of isolation patients treated in 2005: _____
15. Do you have both beds and chairs in your facility? If so, number of beds in routine use:

16. Number of in center patients treated 2005: _____
17. Number of new to dialysis in center treated patients 2005: _____
18. Number of new via transfer in center treated dialysis patients 2005: _____
19. Number of discharges (death/transplant/relocations) in 2005: _____
20. Number of transients treated in 2005: _____
21. Estimated number of home hemo patients treated 2005 _____
22. Estimated number of PD patients treated 2005 _____
23. Do you routinely have a wait list? Yes No _____
24. Average number of patients on wait list: _____
New patients _____ Relocating Patients _____
25. Accept Nursing Home patients? Yes No If yes, number of hemodialysis patients in 2005: _____
26. Accept bed bound Nursing Home patients? Yes No _____
27. Do you go to on site in to a Nursing Home to dialyze patient? If yes, number of patients treated in 2005: _____
28. If facility located in a nursing home, number of non resident patients treated 2005: _____
29. Do you have a home training program? If so how many patients (pts dialyzed at their home, not in a nursing home) were in the program in 2005: _____

Attachment 2 – Incidence and Prevalence 2001-2005

Incidence						
	2001	2002	2003	2004	2005	% Change 2001-2005
Age 0 to 64	2,990	3,134	3,018	3,098	3,291	10%
Age 65 to 84	3,105	3,091	3,248	3,255	3,075	-1%
Age 85 +	435	425	455	525	569	31%
Age 65+	3,540	3,516	3,703	3,780	3,644	3%
Total	10,070	12,168	12,427	12,662	12,584	6%

Prevalence						
	2001	2002	2003	2004	2005	% Change 2001-2005
Age 0 to 64	11,553	11,688	11,961	11,997	12,149	5%
Age 65 to 84	8,371	8,605	8,985	9,169	9,179	10%
Age 85 +	879	865	965	1,049	1,182	34%
Age 65+	9,250	9,470	9,950	10,218	10,361	12%
Total	20,803	21,158	21,911	22,215	22,510	8%

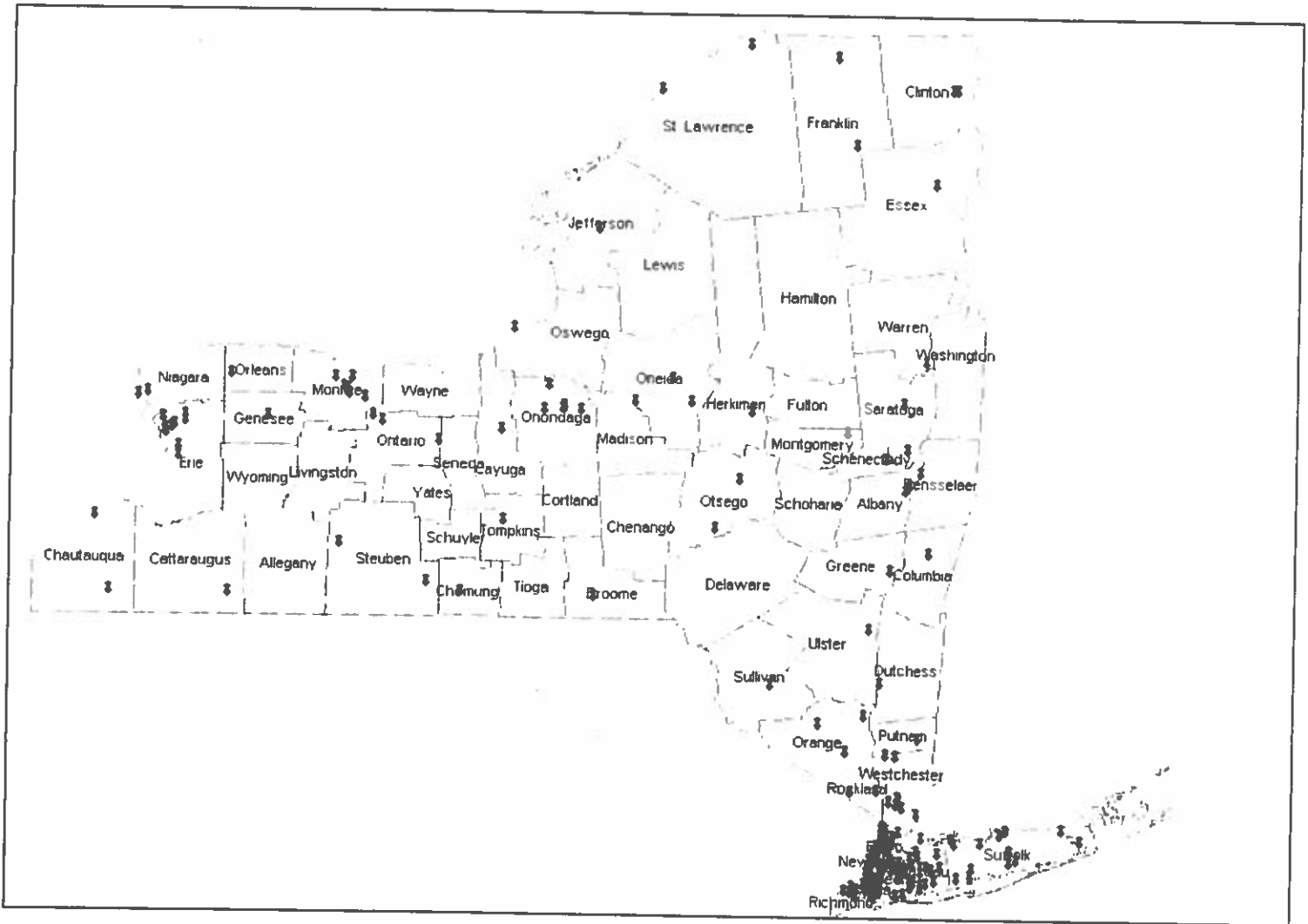
The percentage of people on dialysis was slightly higher in the five year period 2001-2005 than the percentage of new patients. This is interpreted to mean that people were generally receiving treatment for a longer period of time. We must also consider the number of patients who ceased treatment during this period. These are shown below.

Deaths					
2001	2002	2003	2004	2005	% Change 2001-2005
4,741	4,802	5,109	5,203	5,169	9%

Attachment 3 - Location of Facilities

Counties with No Dialysis Facilities

- Allegany • Fulton • Schoharie • Tioga • Wyoming
- Chenango • Hamilton • Schuyler • Washington • Yates
- Delaware • Lewis • Seneca • Wayne •



Attachment 4 - Utilization Rates Current Methodology versus 3 Shifts per Day

County	Approved Stations	DOH Methodology Utilization	3 Shifts/Day Methodology Utilization	County	Approved Stations	DOH Methodology Utilization	3 Shifts/Day Methodology Utilization
Albany	54	109%	82%	New York	508	126%	89%
Bronx	502	93%	68%	Niagara	24	132%	99%
Broome	63	85%	57%	Oneida	53	124%	75%
Cattaraugus	13	149%	79%	Onondaga	123	110%	83%
Cayuga	13	82%	62%	Ontario	37	144%	97%
Chautauqua	28	148%	79%	Orange	57	111%	79%
Chemung	20	120%	88%	Orleans	10	76%	57%
Clinton	26	57%	42%	Oswego	13	85%	64%
Columbia	27	50%	38%	Otsego	26	106%	69%
Cortland	10	0%	0%	Putnam	17	84%	63%
Dutchess	24	146%	110%	Queens	570	110%	80%
Erie	198	107%	76%	Rensselaer	17	115%	86%
Essex	6	67%	50%	Richmond	122	97%	71%
Franklin	18	111%	59%	Rockland	41	135%	85%
Genesee	16	89%	67%	Saratoga	38	81%	61%
Greene	24	48%	36%	Schenectady	24	121%	91%
Herkimer	6	89%	67%	St Lawrence	34	21%	12%
Jefferson	42	54%	41%	Steuben	19	112%	73%
Kings	650	108%	79%	Suffolk	265	97%	69%
Livingston	12	n/a	n/a	Sullivan	14	121%	90%
Madison	8	89%	67%	Tompkins	7	124%	93%
Monroe	144	159%	102%	Ulster	34	74%	55%
Montgomery	16	103%	77%	Warren	21	106%	79%
Nassau	393	92%	68%	Westchester	283	80%	59%

Attachment 5 - DTC (Free Standing) Treatments/Visits by Payor⁵

County	Total Procedures	Medicare	Medicaid	HMO/ Medicare	HMO/ Other	Insurance	Self Pay	Other
Albany	50,137	77.6%	3.4%	0.0%	0.0%	18.7%	0.4%	0.0%
Bronx	464,963	61.6%	12.9%	0.0%	0.0%	21.0%	0.0%	4.5%
Dutchess	25,118	63.7%	7.9%	0.0%	0.0%	28.4%	0.0%	0.0%
Erie	111,010	63.3%	3.2%	2.1%	4.7%	26.8%	0.0%	0.0%
Greene	16,736	80.9%	2.7%	0.0%	0.0%	16.4%	0.0%	0.0%
Kings	356,251	64.9%	15.0%	0.0%	0.0%	19.8%	0.2%	0.0%
Monroe	67,408	59.6%	7.5%	0.0%	0.0%	32.9%	0.1%	0.0%
Nassau	82,217	70.8%	4.5%	0.0%	0.0%	24.4%	0.3%	0.0%
New York	256,605	70.4%	13.3%	0.0%	1.0%	15.2%	0.2%	0.0%
Onondaga	74,033	70.6%	5.3%	0.0%	0.0%	21.4%	0.0%	0.0%
Ontario	11,956	58.2%	2.0%	12.7%	4.9%	22.2%	0.0%	0.0%
Orange	18,100	69.2%	6.8%	0.0%	0.0%	24.0%	0.0%	0.0%
Queens	175,835	57.1%	21.1%	0.0%	0.0%	21.6%	0.2%	0.0%
Richmond	59,727	58.9%	6.2%	0.0%	0.0%	34.9%	0.0%	0.0%
Rockland	13,751	79.0%	5.2%	0.0%	0.0%	15.8%	0.0%	0.0%
Saratoga	52,017	77.1%	1.9%	0.0%	0.0%	16.8%	0.0%	4.2%
Schenectady	20,129	74.7%	3.4%	0.0%	0.0%	22.0%	0.0%	0.0%
Suffolk	35,773	67.5%	5.2%	0.0%	0.0%	27.3%	0.0%	0.0%
Tompkins	7,485	80.0%	4.1%	0.0%	0.0%	15.8%	0.0%	0.0%
Westchester	132,108	75.8%	6.5%	0.0%	0.0%	17.8%	0.0%	0.0%
Total	2,031,359	65.9%	11.0%	0.2%	0.4%	21.3%	0.1%	1.1

⁵ Assumption: Location of the majority of facilities and extension facilities used as the County.

Attachment 6 - Hospital Based Treatments/Visits by Payor⁶

County	Visits Reported	Medicare	Medicaid	Insurance	HMO/ Medicare	HMO/ PHSP Medicaid	HMO/ PHSP Other	Self Insured	Wrks Comp	No Fault	Self Pay	Govem't	Free	Courtesy
Bronx	39,206	61.9%	19.4%	8.2%	0.4%	0.1%	6.2%	0.4%	0.0%	0.0%	3.3%	0.0%	0.0%	0.0%
Broome	25,574	89.3%	2.5%	6.0%	0.0%	0.0%	1.9%	0.0%	0.0%	0.0%	0.2%	0.0%	0.0%	0.0%
Cattaraugus	8,566	75.4%	3.6%	6.9%	3.5%	3.0%	5.8%	0.0%	0.0%	0.0%	0.2%	1.7%	0.0%	0.0%
Chautauqua	18,949	78.4%	3.2%	4.9%	6.0%	2.8%	3.2%	0.0%	0.0%	0.0%	0.1%	1.3%	0.0%	0.0%
Chemung	15,686	89.8%	1.5%	8.3%	0.0%	0.0%	0.0%	0.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Clinton	11,314	83.0%	3.1%	13.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.3%	0.0%	0.0%	0.0%	0.0%
Dutchess	17,006	86.0%	4.0%	10.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Erie	17,858	64.9%	12.1%	6.6%	6.7%	5.1%	4.5%	0.0%	0.0%	0.0%	0.0%	0.1%	0.0%	0.0%
Franklin	10,410	82.3%	6.6%	11.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Kings	46,050	52.7%	24.2%	3.3%	4.6%	2.0%	5.7%	0.0%	0.0%	0.0%	6.5%	0.0%	0.9%	0.0%
Monroe	77,143	60.3%	7.1%	1.7%	18.3%	1.3%	8.4%	2.5%	0.2%	0.0%	0.3%	0.0%	0.0%	0.0%
Nassau	93,673	64.3%	12.0%	11.9%	2.1%	1.0%	4.8%	0.3%	0.0%	0.1%	3.4%	0.1%	0.0%	0.1%
New York	81,774	46.5%	31.7%	3.3%	1.5%	6.3%	4.8%	1.8%	0.0%	0.0%	4.0%	0.0%	0.0%	0.0%
Oneida	45,174	80.8%	3.5%	6.6%	0.0%	0.0%	9.1%	0.0%	0.0%	0.0%	0.1%	0.0%	0.0%	0.0%
Onondaga	45,660	85.8%	1.4%	12.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Ontario	10,924	73.7%	2.2%	7.5%	7.3%	0.0%	7.9%	0.0%	0.0%	0.0%	0.1%	1.3%	0.0%	0.0%
Orange	17,417	78.9%	6.5%	8.4%	0.5%	0.8%	3.6%	0.0%	1.0%	0.0%	0.2%	0.2%	0.0%	0.0%
Orleans	14,256	66.6%	3.8%	9.1%	0.0%	0.0%	20.4%	0.0%	0.0%	0.0%	0.1%	0.0%	0.0%	0.0%
Otsego	15,704	68.4%	5.8%	12.5%	0.5%	0.5%	7.3%	3.3%	0.0%	0.0%	0.6%	1.2%	0.0%	0.0%
Putnam	7,300	80.5%	0.0%	10.4%	0.0%	0.0%	3.9%	0.0%	0.0%	0.0%	5.1%	0.0%	0.0%	0.0%
Queens	43,518	49.0%	19.4%	15.1%	1.2%	4.6%	7.5%	0.0%	0.0%	0.0%	3.2%	0.0%	0.1%	0.0%
Rockland	25,042	72.2%	8.9%	9.8%	3.3%	0.4%	4.9%	0.0%	0.0%	0.0%	0.3%	0.0%	0.0%	0.0%
St Lawrence	28,308	88.4%	2.4%	8.7%	0.0%	0.0%	0.2%	0.0%	0.0%	0.0%	0.3%	0.0%	0.0%	0.0%
Steuben	7,768	77.6%	4.4%	11.6%	3.3%	1.1%	2.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Suffolk	115,684	75.3%	5.2%	15.3%	1.6%	0.4%	1.8%	0.0%	0.1%	0.0%	0.3%	0.0%	0.0%	0.0%
Warren	15,220	78.4%	1.0%	0.6%	0.0%	0.0%	20.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Westchester	5,051	70.7%	12.1%	6.0%	4.2%	0.0%	6.7%	0.0%	0.0%	0.0%	0.4%	0.0%	0.0%	0.0%
Total	860,235	68.9%	10.5%	8.8%	3.1%	1.5%	4.9%	0.5%	0.1%	0.0%	1.6%	0.1%	0.1%	0.0%

⁶ Assumption: Location of the majority of facilities and extension facilities used as the County.

Attachment 7 - 2005 County Residency and Treatment Comparison

The Department only has 2004 data regarding the number of residents receiving dialysis. To estimate the number of residents in 2005, a factor of a 3% increase was applied to 2004 data as reflected below.

County	2005 Calculated Residents	2005 Patients Treated in County	Residents Not Treated in Home County	County	2005 Calculated Residents	2005 Patients Treated in County	Residents Not Treated in Home County
Albany	323	265	58	Niagara	244	143	101
Allegany	24	0	24	Oneida	245	238	7
Bronx	2,612	2,040	572	Onondaga	583	611	-28
Broome	198	215	-17	Ontario	103	216	-113
Cattaraugus	92	62	30	Orange	321	270	51
Cayuga	77	48	29	Orleans	40	34	6
Chautauqua	167	133	34	Oswego	102	50	52
Chemung	116	105	11	Otsego	53	107	-54
Chenango	55	0	55	Putnam	68	64	4
Clinton	78	65	13	Queens	3,151	2,739	412
Columbia	70	61	9	Rensselaer	155	88	67
Cortland	40	0	40	Richmond	567	523	44
Delaware	49	0	49	Rockland	251	208	43
Dutchess	228	158	70	Saratoga	138	139	-1
Erie	995	904	91	Schenectady	146	131	15
Essex	34	18	16	Schoharie	10	0	10
Franklin	83	64	19	Schuyler	10	0	10
Fulton	43	0	43	Seneca	22	0	22
Genesee	57	64	-7	St Lawrence	103	25	78
Greene	53	52	1	Steuben	88	83	5
Hamilton	5	0	5	Suffolk	1,418	1,096	322
Herkimer	64	24	40	Sullivan	90	76	14
Jefferson	89	103	-14	Tioga	44	0	44
Kings	4,230	3,082	1,148	Tompkins	30	39	-9
Lewis	19	0	19	Ulster	168	113	55
Livingston	58	0	58	Warren	59	100	-41
Madison	61	32	29	Washington	58	0	58
Monroe	963	878	85	Wayne	95	0	95
Montgomery	67	74	-7	Westchester	1,088	1,009	79
Nassau	1,571	1,592	-21	Wyoming	24	0	24
New York	2,196	2,707	-511	Yates	14	0	14
Sub-Total	14,717	12,746	1,971	Sub-Total	9,488	8,102	1386

Statewide:

- Total 2005 Calculated Residents = 24,205
- Total 2005 Patients Treated in County = 20,848
- Total Residents Not Treated in Home County = 3,357

Attachment 8 - Staffing

Includes all facilities regardless of response

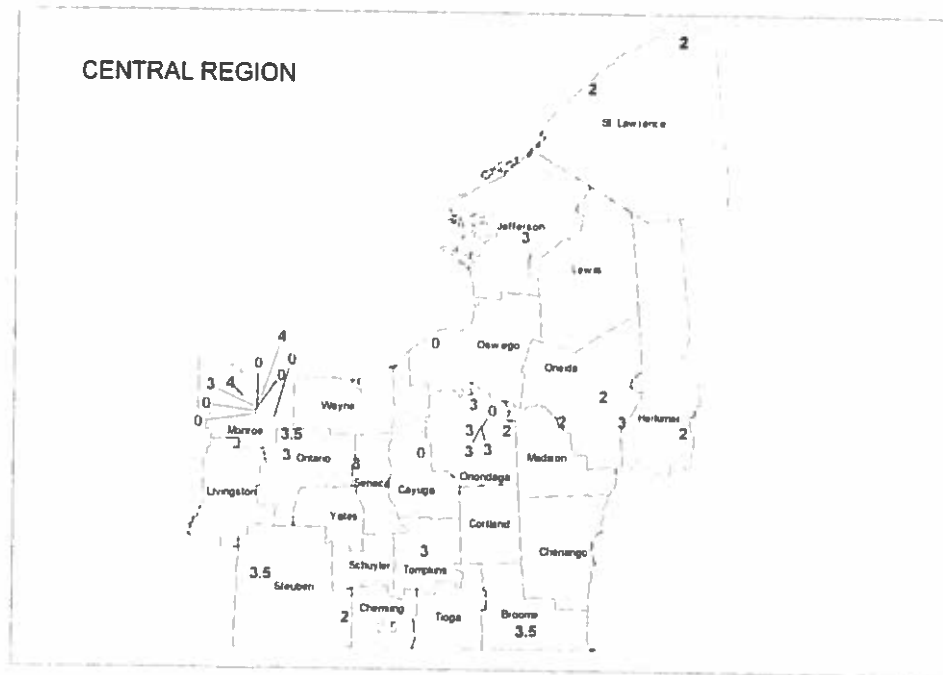
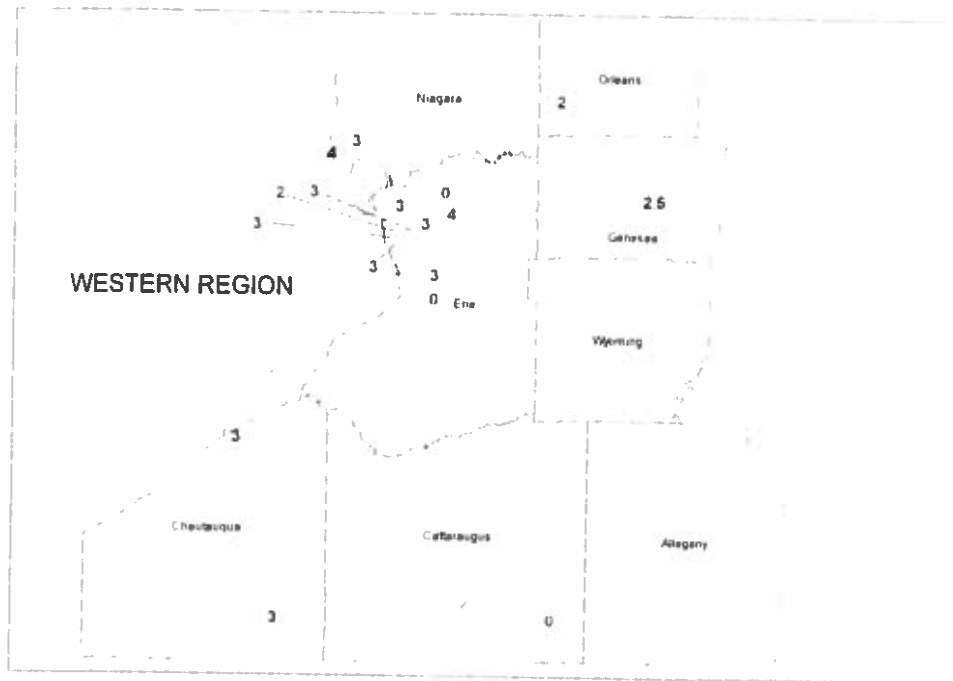
County	Type of Facility	RN Lowest Ratio to Patients	RN Highest Ratio to Patients	LPN Lowest Ratio to Patients	LPN Highest Ratio to Patients	PCT Lowest Ratio to Patients	PCT Highest Ratio to Patients	County	Type of Facility	RN Lowest Ratio to Patients	RN Highest Ratio to Patients	LPN Lowest Ratio to Patients	LPN Highest Ratio to Patients	PCT Lowest Ratio to Patients	PCT Highest Ratio to Patients
Albany	DTC	1:24	1:8	1:24	1:12	1:6	1:3	New York	DTC						
Albany	DTC							New York	DTC						
Bronx	DTC	1:2	1:1	1:2	1:1	1:3	1:2	New York	DTC-EC	1:8	1:6	1:10	1:10	1:4	1:4
Bronx	DTC	1:8	1:7	1:8	1:7	1:4	1:3	New York	HOSP	1:3	1:1			1:5	1:7
Bronx	DTC	1:8	1:8	1:30	1:30	1:6	1:6	New York	HOSP	1:4	1:2			1:4	1:2
Bronx	DTC	1:12	1:12	1:6	1:6	1:3	1:3	New York	HOSP	1:4	1:3	1:1	1:1		
Bronx	DTC							New York	HOSP						
Bronx	DTC-EC	1:3	1:3					New York	HOSP						
Bronx	DTC-EC	1:6	1:4					New York	HOSP						
Bronx	DTC-EC	1:6	1:4	1:4	1:3	1:4	1:3	New York	HOSP						
Bronx	DTC-EC	1:6	1:10	1:20	1:20	1:5	1:4	New York	HOSP						
Bronx	DTC-EC	1:8	1:8	1:8	1:8	1:4	1:4	New York	HOSP						
Bronx	DTC-EC	1:12	1:6	1:12		1:3	1:4	New York	HOSP						
Bronx	DTC-EC	1:12	1:12	1:9	1:9	1:4	1:4	New York	HOSP						
Bronx	DTC-EC	1:13	1:8	1:25	1:25	1:5	1:6	New York	HOSP-EC	1:4	1:2			1:4	1:3
Bronx	DTC-EC							New York	HOSP-EC	1:8	1:6	1:24	1:24	1:6	1:8
Bronx	DTC-EC							New York	HOSP-EC	1:12	1:4			1:4	1:4
Bronx	HOSP	1:3	1:3			1:4	1:4	New York	HOSP-EC	1:12	1:6			1:5	1:4
Bronx	HOSP	1:3	1:2					Niagara	DTC	1:15	1:8	1:15	1:8	1:5	1:8
Bronx	HOSP							Niagara	DTC-EC	1:9	1:5	1:9	1:9	1:9	1:5
Bronx	HOSP							Oneida	HOSP	1:3	1:4	1:4	1:3		
Bronx	HOSP-EC							Oneida	HOSP-EC	1:4	1:4	1:4	1:4		
Broome	HOSP	1:9	1:6	1:6	1:3	1:3	1:3	Onondaga	DTC	1:3	1:3	1:3	1:3	1:3	1:3
Broome	HOSP-EC	1:8	1:7			1:4	1:3	Onondaga	DTC						
Cattaraugus	HOSP							Onondaga	HOSP-EC	1:10	1:3	1:4	1:3	1:4	1:3
								Onondaga	HOSP-EC	1:11	1:3	1:3	1:2	1:3	1:2

County	Type of Facility	RN Lowest Ratio to Patients	RN Highest Ratio to Patients	LPN Lowest Ratio to Patients	LPN Highest Ratio to Patients	PCT Lowest Ratio to Patients	PCT Highest Ratio to Patients	County	Type of Facility	RN Lowest Ratio to Patients	RN Highest Ratio to Patients	LPN Lowest Ratio to Patients	LPN Highest Ratio to Patients	PCT Lowest Ratio to Patients	PCT Highest Ratio to Patients
Cayuga	DTC-EC							Onondaga	HOSP-EC	1:12	1:3	1:3	1:3	1:3	1:3
Chautauqua	HOSP	1:4	1:3	1:7	1:7			Onondaga	HOSP-EC	1:15	1:3	1:3	1:3	1:3	1:3
Chautauqua	HOSP	1:8	1:3	1:5	1:2			Ontario	DTC	1:8	1:3			1:4	1:2
Chemung	HOSP							Ontario	DTC-EC	1:12	1:12	1:12	1:12	1:4	1:4
Clinton	HOSP	1:2	1:1					Ontario	HOSP	1:6	1:3	1:3	1:3		
Clinton	HOSP-EC	1:4	1:4	1:4	1:4	1:13	1:12	Orange	DTC						
Columbia	DTC	1:6	1:4	1:6	1:4	1:6	1:4	Orange	HOSP-EC	1:6	1:3	1:3	1:3	1:10	1:5
Dutchess	DTC	1:12	1:3	1:4	1:1	1:4	1:2	Orange	HOSP-EC						
Erie	DTC	1:3	1:1	1:3	1:1	1:4	1:1	Orleans	HOSP-EC	1:5	1:2	1:4	1:3	1:4	1:3
Erie	DTC	1:12	1:12	1:4	1:4	1:4	1:4	Oswego	DTC-EC						
Erie	DTC	1:12	1:6	1:12	1:6	1:4	1:12	Otsego	HOSP	1:6	1:4	1:6	1:5	1:12	1:4
Erie	DTC	1:14	1:14	1:14	1:7	1:5	1:7	Otsego	HOSP-EC	1:4	1:2	1:4	1:3	1:12	1:6
Erie	DTC	1:25	1:8	1:8	1:4	1:4	1:4	Putnam	DTC	1:16	1:8	1:16	1:8	1:4	1:4
Erie	DTC-EC	1:3	1:1	1:3	1:1	1:3	1:1	Queens	DTC						
Erie	DTC-EC							Queens	DTC	1:3	1:2	1:3	1:2	1:4	1:3
Erie	DTC-EC							Queens	DTC	1:6	1:6			1:3	1:3
Erie	HOSP	1:3	1:3	1:3	1:3	1:3	1:3	Queens	DTC	1:8	1:8	1:8	1:8	1:4	1:4
Erie	HOSP	1:7	1:5	1:11	1:7	1:11	1:7	Queens	DTC			1:9	1:4	1:4	1:3
Essex	HOSP-EC	1:6	1:4	1:6	1:4	1:6	1:4	Queens	DTC						
Franklin	HOSP	1:2	1:4	1:3	1:2	1:7	1:3	Queens	DTC						
Franklin	HOSP							Queens	DTC						
Genesee	HOSP-EC	1:12	1:4	1:6	1:3	1:3	1:3	Queens	DTC						
Greene	DTC-EC	1:10	1:3			1:3	1:5	Queens	DTC-EC	1:3	1:3	1:3	1:3	1:3	1:3
Herkimer	HOSP-EC	1:4	1:4	1:4	1:4			Queens	DTC-EC	1:3	1:1			1:3	1:2
Jefferson	DTC	1:3	1:3	1:3	1:3			Queens	DTC-EC	1:3	1:1	1:3	1:1	1:4	1:2
Kings	DTC	1:3	1:2	1:3	1:2	1:4	1:3	Queens	DTC-EC	1:3	1:1	1:3	1:1	1:4	1:2
Kings	DTC	1:4	1:2	1:1	1:1	1:8	1:5	Queens	DTC-EC	1:8	1:5	1:12	1:12	1:4	1:4
Kings	DTC	1:6	1:4			1:5	1:4	Queens	DTC-EC	1:11	1:7			1:4	1:4
Kings	DTC	1:12	1:6	1:12	1:12	1:3	1:2	Queens	DTC-EC	1:12	1:5	1:12	1:12	1:3	1:4
Kings	DTC	1:12	1:9			1:4	1:3	Queens	DTC-EC						
Kings	DTC	1:14	1:7			1:4	1:3	Queens	HOSP						

County	Type of Facility	RN Lowest Ratio to Patients	RN Highest Ratio to Patients	LPN Lowest Ratio to Patients	LPN Highest Ratio to Patients	PCT Lowest Ratio to Patients	PCT Highest Ratio to Patients	County	Type of Facility	RN Lowest Ratio to Patients	RN Highest Ratio to Patients	LPN Lowest Ratio to Patients	LPN Highest Ratio to Patients	PCT Lowest Ratio to Patients	PCT Highest Ratio to Patients
Kings	DTC	1:15	1:10	1:30	1:15	1:4	1:3	Queens	HOSP						
Kings	DTC							Queens	HOSP						
Kings	DTC							Queens	HOSP						
Kings	DTC							Queens	HOSP						
Kings	DTC							Queens	HOSP-EC	1:3	1:3			1:3	1:3
Kings	DTC							Queens	HOSP-EC	1:12	1:6			1:6	1:3
Kings	DTC							Rensselaer	DTC						
Kings	DTC-EC	1:4	1:3	1:4	1:3	1:4	1:3	Richmond	DTC	1:5	1:4	1:15	1:10	1:3	1:4
Kings	DTC-EC	1:4	1:2	1:2	1:1	1:9	1:6	Richmond	DTC	1:11	1:9	1:11	1:9	1:4	1:2
Kings	DTC-EC	1:6	1:4			1:4	1:3	Richmond	DTC	1:12	1:8	1:23	1:12	1:6	1:8
Kings	DTC-EC	1:7	1:5			1:4	1:2	Richmond	DTC-EC	1:4	1:2			1:4	
Kings	DTC-EC	1:10	1:5	1:30	1:30	1:4	1:2	Richmond	DTC-EC	1:8	1:3	1:8	1:3	1:3	1:2
Kings	DTC-EC	1:16	1:8	1:16	1:16	1:4	1:4	Richmond	HOSP						
Kings	DTC-EC	1:18	1:4	1:20	1:15	1:4	1:3	Rockland	DTC						
Kings	DTC-EC							Rockland	HOSP						
Kings	DTC-EC							Saratoga	DTC-EC	1:9	1:6	1:9	1:9	1:5	1:9
Kings	HOSP							Saratoga	DTC-EC						
Kings	HOSP							Schenectady	DTC						
Kings	HOSP							St Lawrence	HOSP	1:8	1:8	1:3	1:2	1:8	1:8
Kings	HOSP							St Lawrence	HOSP-EC	1:4	1:1	1:4	1:1		
Kings	HOSP							Steuben	HOSP	1:4	1:3	1:4	1:3		
Kings	HOSP							Steuben	HOSP-EC	1:3	1:2	1:2	1:1	1:1	1:1
Kings	HOSP							Suffolk	DTC	1:9	1:2	1:18	1:6	1:5	1:4
Kings	HOSP-EC							Suffolk	DTC	1:12	1:6	1:24	1:12	1:3	1:3
Kings	HOSP-EC							Suffolk	DTC						
Madison	HOSP-EC	1:4	1:4	1:4	1:4			Suffolk	DTC-EC	1:10	1:5			1:5	1:3
Monroe	DTC							Suffolk	HOSP	1:3	1:2			1:3	1:6
Monroe	DTC							Suffolk	HOSP	1:6	1:4			1:3	1:6
Monroe	DTC-EC							Suffolk	HOSP						
Monroe	DTC-EC							Suffolk	HOSP						
Monroe	DTC-EC							Suffolk	HOSP						

County	Type of Facility	RN Lowest Ratio to Patients	RN Highest Ratio to Patients	LPN Lowest Ratio to Patients	LPN Highest Ratio to Patients	PCT Lowest Ratio to Patients	PCT Highest Ratio to Patients	County	Type of Facility	RN Lowest Ratio to Patients	RN Highest Ratio to Patients	LPN Lowest Ratio to Patients	LPN Highest Ratio to Patients	PCT Lowest Ratio to Patients	PCT Highest Ratio to Patients
Monroe	HOSP	1:4	1:2	1:4	1:2			Suffolk	HOSP-EC	1:4	1:3	1:1		1:3	1:2
Monroe	HOSP	1:4	1:1	1:4	1:1			Suffolk	HOSP-EC	1:8	1:4	1:16	1:8	1:16	1:3
Monroe	HOSP	1:12	1:12	1:8	1:4	1:8	1:4	Suffolk	HOSP-EC	1:12	1:6	1:12	1:6	1:8	1:4
Montgomery	DTC-EC							Suffolk	HOSP-EC						
Nassau	DTC	1:3	1:2	1:3	1:2	1:4	1:2	Sullivan	DTC-EC	1:7	1:4			1:7	1:4
Nassau	DTC	1:4	1:1	1:4	1:1	1:5	1:3	Tompkins	DTC	1:7	1:2	1:7		1:4	1:7
Nassau	DTC	1:12	1:6	1:12	1:12	1:4	1:3	Ulster	HOSP-EC	1:5	1:5	1:7	1:5	1:15	1:5
Nassau	DTC-EC	1:4	1:1			1:6	1:4	Warren	HOSP-EC	1:8	1:3	1:8	1:4	1:24	1:15
Nassau	DTC-EC	1:15	1:6	1:18		1:4	1:5	Westchester	DTC	1:6	1:3	1:20		1:5	1:10
Nassau	DTC-EC	1:17	1:9	1:17	1:9	1:3	1:4	Westchester	DTC	1:6	1:5			1:6	1:5
Nassau	DTC-EC	1:18	1:6	1:18	1:18	1:4	1:4	Westchester	DTC	1:12	1:8	1:3	1:2	1:3	1:2
Nassau	DTC-EC	1:19	1:6	1:19		1:4	1:4	Westchester	DTC	1:12	1:10	1:10	1:9	1:4	1:3
Nassau	DTC-EC	1:21	1:10	1:7	1:6	1:5	1:10	Westchester	DTC						
Nassau	DTC-EC							Westchester	DTC						
Nassau	HOSP	1:2	1:2					Westchester	DTC-EC	1:3	1:2				
Nassau	HOSP	1:4	1:4	1:4	1:4	1:6	1:6	Westchester	DTC-EC	1:4	1:3	1:5	1:3	1:3	1:3
Nassau	HOSP-EC	1:3	1:3			1:3	1:3	Westchester	DTC-EC	1:5	1:2	1:14	1:14	1:7	1:7
Nassau	HOSP-EC	1:3	1:3	1:3	1:3			Westchester	DTC-EC	1:10	1:6	1:19	1:5	1:5	1:3
Nassau	HOSP-EC	1:6	1:3	1:6	1:3			Westchester	DTC-EC	1:12	1:6	1:4	1:3	1:4	1:3
Nassau	HOSP-EC	1:12	1:6	1:4	1:4			Westchester	HOSP	1:3	1:1				
Nassau	HOSP-EC	1:15	1:15	1:4	1:3			Westchester	HOSP						
New York															
New York	DTC	1:4	1:2	1:1	1:1	1:5	1:3								
New York	DTC	1:8	1:8	1:8	1:8	1:4	1:4								
New York	DTC	1:9	1:6	1:4	1:3	1:4	1:3								
New York	DTC														
New York	DTC														
New York	DTC														
New York	DTC														
New York	DTC														

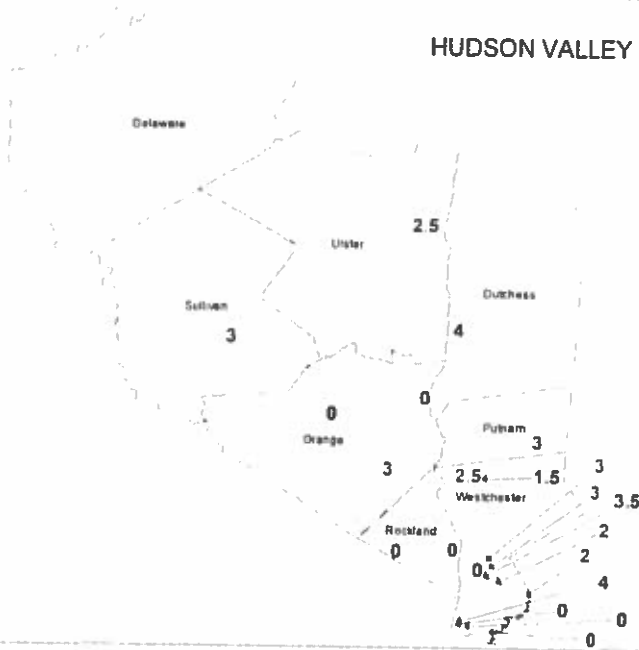
Attachment 9 – Shifts per Day Maps



NORTHERN REGION



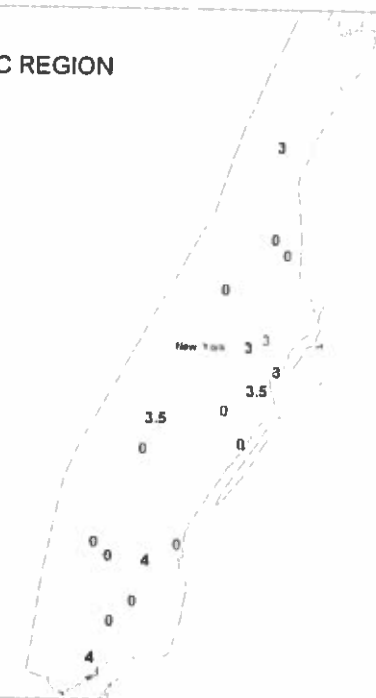
HUDSON VALLEY REGION

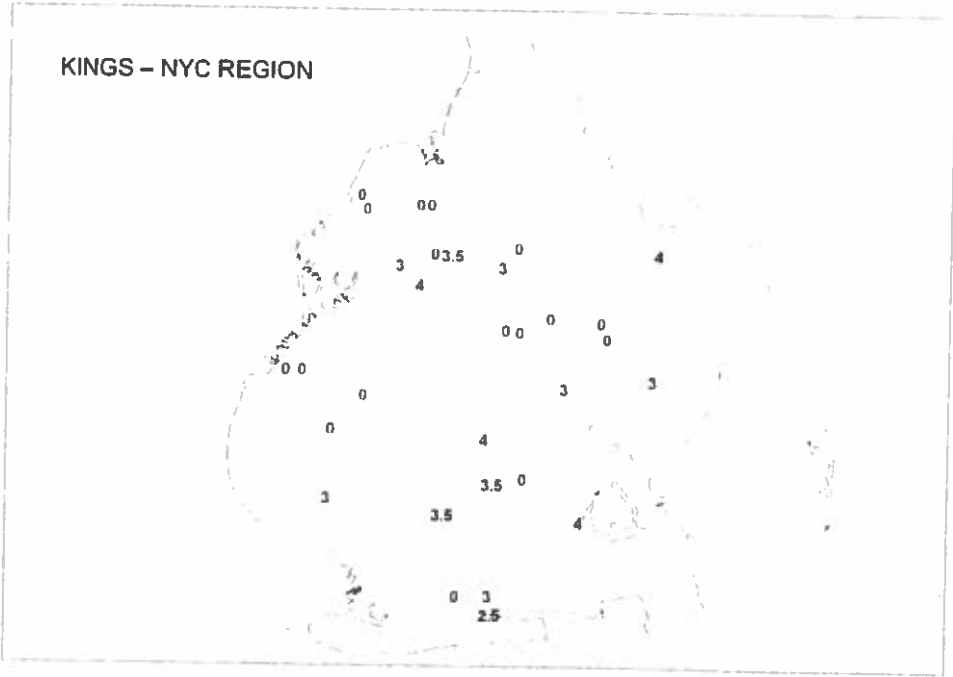
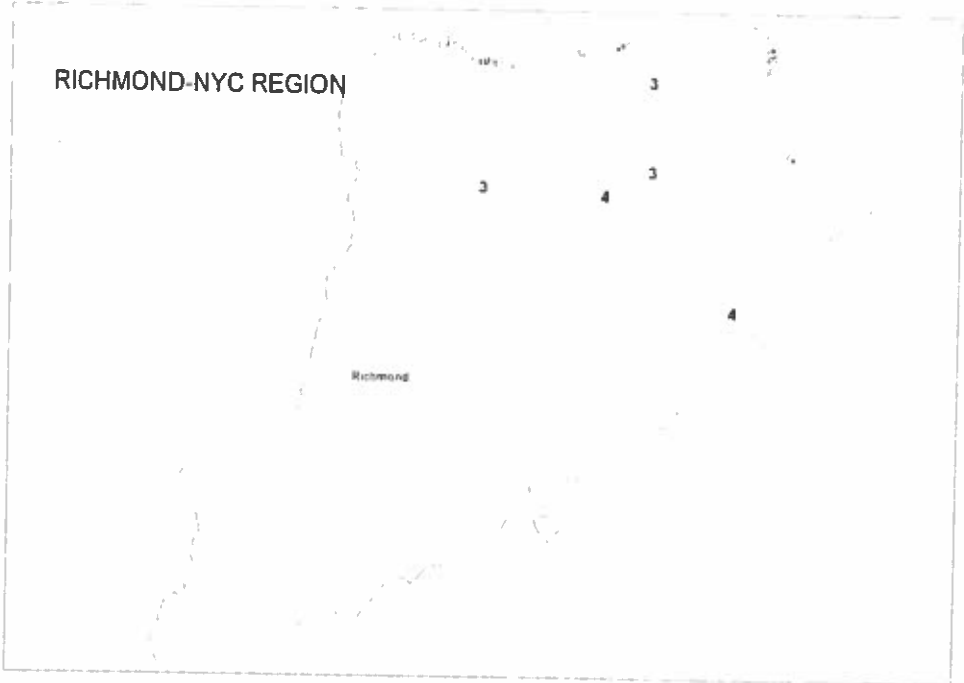


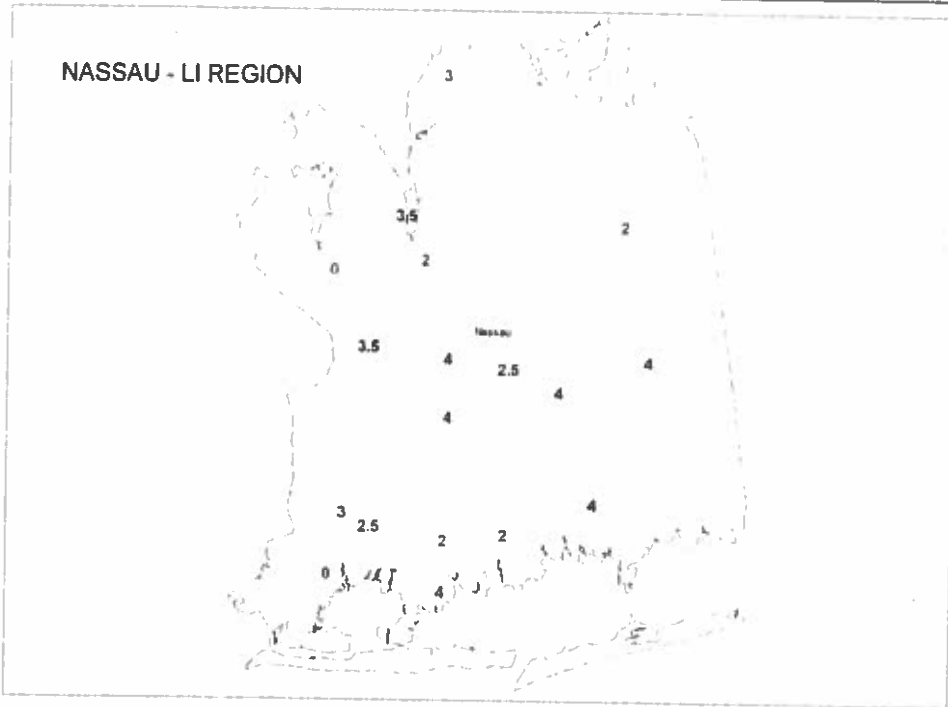
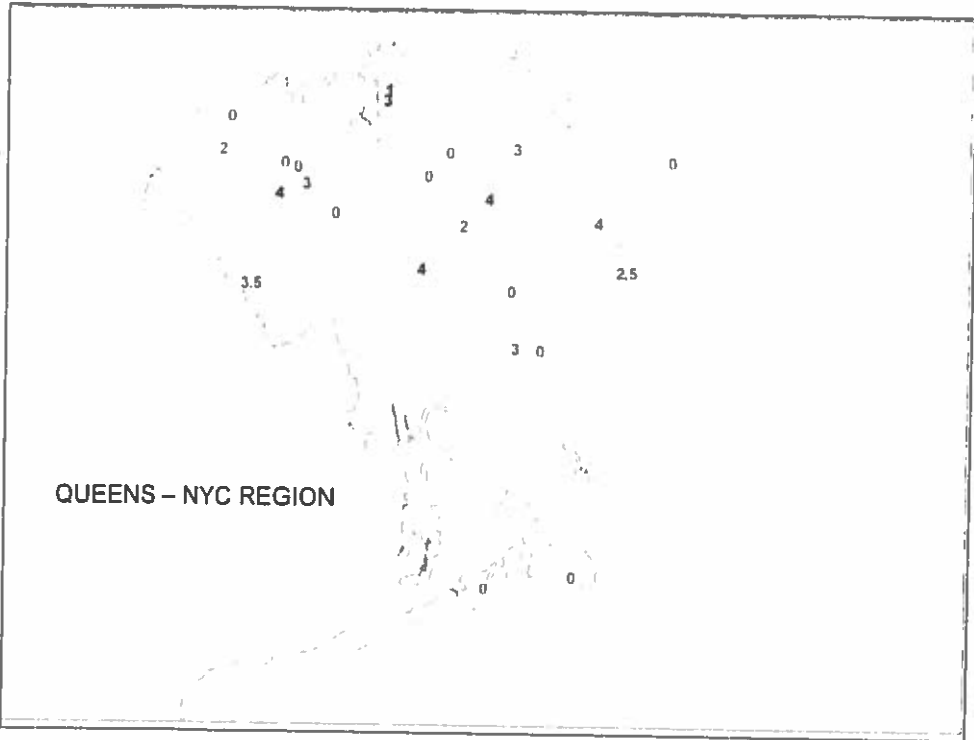
BRONX-NYC REGION



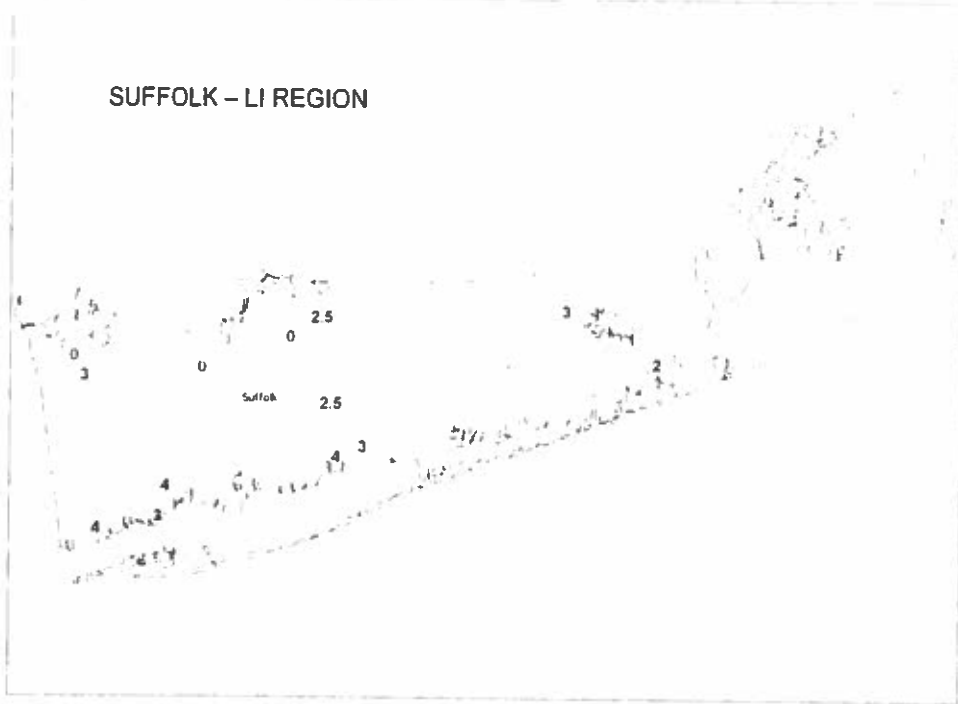
NEW YORK - NYC REGION







SUFFOLK - LI REGION



Attachment 10 – Public Need Regulations

Effective Date: 12/28/94

Title: Section 709.4 - End stage renal dialysis service

709.4 End stage renal dialysis service. (a) This methodology will be utilized in the evaluation of certificate of need applications involving the construction or establishment of new or replacement dialysis stations used in the treatment of End Stage Renal Disease. It is the intent of the State Hospital Review and Planning Council that this methodology, when used in conjunction with the planning standards and criteria set forth in section 709.1 of this Part, become a statement of basic principles and planning/decision making tools for guiding and directing the development of dialysis stations for End Stage Renal Disease services throughout the state. Additionally, it is intended that the methodology will provide the health systems agencies and potential applicants with sufficient flexibility to consider the unique characteristics of their respective areas in determining need. The goals and objectives of the methodology expressed herein are expected to ensure that an adequate supply of dialysis stations are available to provide access to care to all those in need of in-facility dialysis.

(b) The factors to be considered in determining the public need for dialysis stations shall include, but not be limited to, the following:

(1) evidence that the proposed dialysis services capacity proposed will be utilized sufficiently to be financially feasible as demonstrated by a five year analysis of projected costs and revenues associated with the program;

(2) evidence that the proposed service or additional capacity will enhance access to services by patients including members of medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services (for example, low-income persons, racial and ethnic minorities, women, and handicapped persons), and/or appropriate rural populations;

(3) evidence that the facility's hours of operation and admission policies will promote the availability of services which are acceptable to those in need of such services, in particular, operational hours that permit individuals in dialysis to continue employment.

(4) the facility's willingness and ability safely to serve dialysis patients; and

(5) when an existing provider proposes to add twelve or more stations, evidence, derived from analysis of factors including but not necessarily limited to both existing patient referral and use patterns and projected referral and use patterns which would result from addition of the proposed stations, indicating that approval of such stations will not jeopardize the quality of service provided at or the financial viability of other existing dialysis facilities or services within the applicant's planning area. However, a finding that the proposed facility would jeopardize the financial viability of such existing facilities will not, of itself, require a recommendation of disapproval of the application.

(c) Public need for a proposed facility or station shall be deemed to exist when review and consideration of evidence concerning each of the five factors set forth in subdivision (b) of this section results in an affirmative finding.