



Indian Health Service

**Division of Diabetes  
Treatment and Prevention**

# **Guide to the Development of Reservation-Based Dialysis Services**

**Indian Health Service**

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## **Purpose of this Manual**

American Indian and Alaska Native people (AI/AN) experience relatively high rates of End-Stage Renal Disease (ESRD), severe kidney disease which requires renal replacement therapy (dialysis or transplantation) to sustain life. This manual is meant to serve as a reference for Tribes and communities who are interested in improving access to dialysis services.

There are multiple models for providing reservation-based dialysis. This document describes the process of assessing need and developing a scope of work for a Tribe to become a dialysis provider or to obtain services from an outside contractor. This manual is not a final resource. Detailed discussion of many issues is intentionally omitted. A complete discussion of all issues would require a document hundreds of pages in length. However, this document will move the medical and administrative leadership well along the path of understanding the complexity of renal replacement therapy and assist in developing a fully integrated dialysis program.

## **Background, Overview and Introduction**

### Demographics

Approximately 5.2 million people identified themselves as AI/AN alone or in combination with one or more other races in the 2010 U.S. census. This includes members of 560 federally recognized Tribes. In addition:

- Approximately 38% live on rural reservations.
- Twenty two percent (22%) live near reservations.
- The median age is 28 years vs. 36 years for the U.S. overall.
- Thirty two percent (32%) live below the poverty level vs. 13% of the U.S. overall.

### The Burden of Diabetes Mellitus

Diabetes mellitus type 2 (DM2) and its complications have a higher prevalence in the AI/AN population than the U.S. overall. Note just a few statistics:

- The prevalence (percent of patients at a given point in time) of diagnosed diabetes among AI/AN people ages 20-44, 45-64, and over 65 years in FY 2012 was 5.1%, 22.7% and 35.0% respectively.
- In AI/AN people, 15.9% of adults aged 20 years and older had diagnosed diabetes in 2012, compared to 7.6% of non-Hispanic whites.
- Among AI/AN adults, in FY 2012 the rate of diagnosed diabetes varied by region from 6.0% among Alaska Natives to 24.1% among American Indians in southern Arizona.
- From 2006 to 2012, the prevalence of diagnosed diabetes in AI/AN adults increased 4.6% (15.2% to 15.9%). This increase was driven primarily by those aged 65+, who had a 6.7% increase (32.8% to 35.0%).

The increase in prevalence in AI/AN adults is likely due to obesity and other risk factors, greater awareness and testing, increased longevity in those diagnosed at younger ages, and improved reporting of medical data.

Diabetes is associated with a range of complications including cardiovascular disease and kidney disease. Diabetes mellitus often leads to progressive loss of kidney function. Chronic kidney disease (CKD) is diagnosed when kidney function decreases by one half or when protein appears in the urine. Kidney failure is diagnosed when kidney function falls below 15% of normal. When a person with kidney failure is treated with dialysis or transplantation, that person

has End Stage Renal Disease (ESRD). Diabetes is the most common cause of kidney failure in both AI/AN and non-AI/AN people.

### The Burden of End Stage Renal Disease (ESRD)

AI/AN people experience higher rates of ESRD than whites in the U.S. Data from the United States Renal Data System (USRDS), show that, at the end of 2011, 8437 AI/AN were being treated for ESRD, reflecting a prevalence rate twice that of white Americans. In addition:

- During the 10-year period from 1988-1997, the number of AI/AN people with ESRD tripled, with much slower increases during the past decade.
- More than two-thirds (69%) of AI/AN people who initiated treatment for ESRD in 2007-2011 had ESRD as a complication of DM2, compared to 46% of whites and 44% of African Americans.
- The incidence (new patients starting during a specified period of time, usually one calendar year) of ESRD due to DM2 among AI/AN people during 2011 (298/million) was more than twice the rate in white people (122/million).
- The incidence among AI/AN women was higher (317/million) than in AI/AN men (221/million).
- Consistent with the earlier onset of DM2 among AI/AN people, the mean age for initiation of dialysis for AI/AN is 56.6 years, eight years younger than for whites.

### Treatment of ESRD

Treatment options for kidney failure include conservative management (no dialysis), hemodialysis (HD), peritoneal dialysis (PD), and kidney transplantation. These treatment modalities are described in detail later in this document.

The Indian Health Service (IHS) provides health services to approximately 2 million AI/AN people, with an annual budget of \$3.1 billion. These services may be provided directly, through Tribally contracted and operated programs, or through health care services contracted from private providers. Although IHS has extensive primary care and diabetes treatment programs, it does not provide dialysis services directly. (See below)

For many Tribes, the burden of ESRD has become a major health and economic problem. Significant efforts have gone into establishing dialysis services on reservations or in communities near reservations. The first on-reservation dialysis unit was established at Shiprock, NM in 1979. At the end of 2012, there were over 30 dialysis units serving predominately AI/AN patients on or near reservations.

### Barriers to caring for AI/AN with ESRD

Although reservation-based dialysis units have improved the access of patients to renal replacement therapy (dialysis therapy, specifically), barriers to optimal care remain. These include:

- Rural and isolated settings where travel to facilities is made difficult by distance, weather, and road conditions. A survey of AI/AN dialysis patients in AZ and NM showed that 56% traveled more than an hour each way for their dialysis treatments.
- High rates of poverty, with its attendant problems of transportation, family support, availability of support resources and awareness of medical therapies.
- Difficulty in recruiting and retaining staff in outlying areas to support a dialysis program.

- Language, education and cultural differences—a survey of AI/AN dialysis patients living in AZ and NM, showed that 80% live on a reservation, 31% have no more than an elementary school education, and 73% do not speak English in the home.
- High percentage of patients with diabetes and associated complications: The burden of co-morbid conditions complicates the medical therapy of these patients. Retinopathy which may result in blindness (30%), amputations, heart disease, peripheral vascular disease which may result in amputation (44%), neuropathy, and liver disease (10%) are common.

### Survival on Dialysis

Despite socio-economic barriers and high rates of co-morbid disease, survival among AI/AN ESRD patients is *better* than among white patients. The USRDS reports a mortality rate for prevalent dialysis patients in 2011 of 204.9/1000 patient years for whites and 155.2/1000 patient years for AI/AN. Survival among AI dialysis patients in ESRD Network 15 appears to be better than USRDS rates overall. Virtually all of the reservation-based facilities in Network 15 have standardized mortality ratios (SMR) of less than 0.7 ( $\leq 1.0$  expected), which is remarkable because the nutritional status as determined by serum albumin (considered a predictor of mortality) is lower (worse) than the Network mean for all patients.

The reasons for these survival differences have not been determined. Interestingly, recent data show that better survival is associated with higher blood quantum.

### **Finances**

The Medicare End Stage Renal Disease Program was established in 1972. It is the only program that provides Medicare coverage to all persons, regardless of age, with a specific disease process: kidney failure. Medicare reimburses 80% of the capitated cost (see definition below) of dialysis treatments, transplant, and other health care. The remaining 20% is paid by private insurance, Medicaid programs, or by the IHS Purchased/Referred Care (PRC) program (formerly known as Contract Health Service), for eligible patients. The capitated payment rate paid to dialysis providers per treatment includes equipment, supplies, medications, and personnel. Physicians (nephrologists) receive separate reimbursement for their medical services. A third form of payment is through private insurance. If a patient has private insurance, even if they are eligible for Medicare, the private carrier must pay for the first 33 months of dialysis or until transplantation, whichever comes first.

Because the vast majority of IHS beneficiaries are eligible for Medicare or Medicaid and/or have private insurance, IHS pays less than 20% of the cost of dialysis care provided to PRC eligible ESRD patients (transportation not included). Although IHS pays only a small portion of the cost of care, IHS and the local Tribe can control the scope and quality of dialysis services provided by private dialysis units through a competitive contracting process. In order to represent the interests of ESRD patients in the local community, IHS and Tribal health leaders should understand the “business of dialysis.”

For additional information, visit the CMS website: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/index.html>

## **ESRD Prospective Payment System (PPS) Overview**

### ESRD Prospective Payment System (PPS) Base Rate

ESRD Prospective Payment System (ESRD PPS) – Section 153(b) of Pub. L. 110-275, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), amended section 1881(b) of the Social Security Act to require the implementation of an ESRD bundled payment system effective January 1, 2011. Under MIPPA, the ESRD PPS replaced the previous basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD-related items and services. The ESRD PPS provides a case-mix adjusted single payment to ESRD facilities for renal dialysis services provided in an ESRD facility or in a beneficiary's home.

Renal dialysis services are all items and services used to furnish outpatient maintenance dialysis in the ESRD facility or in a patient's home. They include but are not limited to:

- All items and services included under the composite rate as of December 31, 2010;
- ESRD-related erythropoiesis stimulating agents (ESAs) and their oral or other forms of administration;
- ESRD-related injectable drugs and biologicals and their oral or other forms of administration;
- ESRD-related oral or other forms of non-injectable drugs and biologicals;
- ESRD-related diagnostic laboratory tests;
- Home and self-dialysis training; and
- All supplies, equipment, and support services necessary for the effective performance of a patient's dialysis furnished in the ESRD facility or in a patient's home.

### Per Treatment Basis

Under the ESRD PPS, payment is made on a per treatment basis. The ESRD PPS base rate is the per treatment unit of payment that applies to both adult and pediatric patients. ESRD facilities furnishing dialysis treatments in-facility are paid for up to three treatments per week, unless there is medical justification for more than three weekly treatments. ESRD facilities treating patients at home regardless of modality may not receive payment for more than three hemodialysis (HD) equivalent treatments per week. ESRD facilities furnishing dialysis in-facility or in a patient's home are paid for a maximum of 13 treatments during a 30 day month and 14 treatments during a 31 day month unless there is medical justification for additional treatments.

### Market Basket Update

CMS updates, on an annual basis, the ESRD PPS base rate by the ESRD bundled market basket percentage increase factor minus a productivity adjustment factor.

### ESRD PPS Case-Mix Adjustments

The ESRD PPS includes patient-level adjustments (also known as the case-mix adjustments), facility-level adjustments, and training adjustments, as well as an outlier payment. Under the ESRD PPS, the beneficiary co-insurance amount is 20% of the total ESRD PPS payment, after the deductible.

### Patient-level case-mix Adjustments

The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients to account for case-mix variability. The adult case-mix adjusters include variables (age, body surface area (BSA), and low body mass index (BMI)) that have been part of the basic case-mix adjusted composite rate payment system. In addition, the ESRD PPS includes adult case-mix adjustments for six co-morbidity categories (three acute and three chronic) as well as the onset of renal dialysis. Pediatric patient-level adjusters consist of combinations of two age categories and two dialysis modalities.

### Onset of Dialysis Adjustments

An ESRD facility may only receive the onset of dialysis adjustment for adult Medicare ESRD beneficiaries. The onset period is defined as the initial 120 days of outpatient maintenance dialysis, which is designated by the first date regular chronic dialysis began as reported on the CMS Form 2728. The onset of dialysis adjustment factor is a multiplier used in the calculation of the ESRD PPS per treatment payment amount for dialysis furnished in either an ESRD facility or home setting.

### Facility-level Adjustments

There are two facility-level adjustments in the ESRD PPS. The first adjustment accounts for ESRD facilities furnishing a low-volume of dialysis treatments. The second adjustment reflects urban and rural differences in area wage levels using an area wage index developed from Core Based Statistical Areas (CBSAs).

### Training Add-on

The training add-on payment is computed by using the national average hourly wage for nurses from the Bureau of Labor Statistics. The payment accounts for nursing time for each training treatment that is furnished and is adjusted by the geographic area wage index. The training add-on payment applies to both peritoneal dialysis and hemodialysis training treatments. This amount will be added to the ESRD PPS payment each time a training treatment is provided by the Medicare certified training ESRD facility.

### Outlier Policy

The ESRD PPS provides additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable. Outlier payments are based on a comparison of the predicted Medicare allowable payment (MAP) per treatment to actual incurred expenditure per treatment for services which were or would have been considered separately billable prior to the implementation of the ESRD PPS. ESRD outlier services include:

- ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;
- ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;
- Medical or surgical supplies used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and
- Renal dialysis services that were or would have been, prior to January 1, 2011, separately billable under Part D.

- Implementation of ESRD-related oral-only drugs (i.e. oral drugs that do not have an injectable equivalent) has been delayed until January 1, 2024.

The list of ESRD-related outlier services may be found on the CMS website:  
[http://www.cms.gov/ESRDPayment/30\\_Outlier\\_Services.asp#TopOfPage](http://www.cms.gov/ESRDPayment/30_Outlier_Services.asp#TopOfPage)

### Consolidated Billing

The ESRD PPS implemented consolidated billing requirements for limited ESRD-related Part B items and services. Certain ESRD-related laboratory services, limited drugs and biologicals, equipment, and supplies are subject to consolidated billing and no longer separately payable when provided to ESRD beneficiaries by providers other than the ESRD facility.

The list of drugs and biologicals used for the ESRD PPS consolidated billing may be viewed on the CMS website:  
[http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated\\_Billing.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html)

Note that this list is not all-inclusive and any ESRD-related item or service is paid to the ESRD facility under the ESRD PPS.

### Legislative Citations

Section 153(a) Public Law 110-275, the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)(14)(A)(i) Subject to subparagraph (E), for services furnished on or after January 1, 2011, the Secretary shall implement a payment system under which a single payment is made under this title to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment (including a payment adjustment under paragraph (12)(B)(ii)) and for such services and items furnished pursuant to paragraph (4).

## **Establishing On-Reservation Dialysis**

The first step in determining how ESRD services can best be provided to a community is to perform an assessment of the need for such services. The options of services to be provided and providers of those services are numerous. There are options for the kinds of delivery of care (hemodialysis and peritoneal dialysis and the location thereof) and there are options for just how to provide that care: i.e., which contractor will actually provide the care.

Strategies for providing dialysis services in remote areas include reservation-based dialysis facilities, offering the following services, in part or fully:

- In-Center Hemodialysis
  - This modality and those mentioned below includes all services, enumerated in the attachments, but including staff and patient education, social services, nutritional services, etc.
- Chronic Ambulatory Peritoneal Dialysis (CAPD)
- Continuous Cycler Peritoneal Dialysis (CCPD)
- Home Hemodialysis
- Satellite of a larger facility

While the vast majority of IHS beneficiaries are covered by Medicare and/or Medicaid, IHS, like the Veterans Administration, was not included as a provider under the Medicare ESRD Program. Recent legislation has made it possible for IHS to provide dialysis services but the agency lacks the infrastructure or technical resources to do so in a cost-efficient manner. By contracting with outside providers, IHS is able to maintain control of the scope and quality of care, while paying only a small portion of the cost (20% for patients with Medicare only). However, a Tribe may choose to provide all of the services noted below. Either is an option.

Providing dialysis services is a complex process. When starting a new facility it is crucial to meet all regulatory requirements. Setting up a new facility correctly is no small task. Proper start-up procedures are important to preventing injury to patients and staff; developing a good relationship with the patients, professionals, and the community; preventing rework; and cost containment. While each facility is unique due to geographical location, population served, size, number of patients, staffing, scheduling, etc., there are procedures that are common to all dialysis facilities.

### “Needs” Assessment

Before beginning the search for a dialysis provider, or deciding to be an independent provider, the Tribe must assess the need for dialysis services. Based on that assessment, the decision to move forward will be Tribal and based on local priorities. Some factors to consider are:

- Current number of ESRD patients in service area and projected growth in area ESRD population.
- Distance to the nearest dialysis facilities for current dialysis patients.
- Availability of transportation and transportation problems due to weather, roads, condition of vehicles, etc.
- Potential for expanding home dialysis services (peritoneal dialysis and home hemodialysis).
- Quality of life difference by providing local service.
- Funding available to support non-self-supporting units.
- Other community health needs, given finite health allocated funds.

In addition to assessing need, the Tribe must also be able to provide the following resources to support the infrastructure:

- Availability of land to construct a new facility or land with an existing structure that could be modified to adequately house the facility to meet current needs, as well as expansion to meet future needs.
- Adequate water supply in both quantity and quality.
- Availability of qualified professional, technical, and administrative staff in or near the community.
- Availability of emergency medical services (EMS) in the community.

### Possibilities for Contracting or Providing Dialysis Services

There are a range of options for providing dialysis services locally with three typical general approaches:

Example #1: The Tribe would do a complete “turn-key” operation, including:

- Building a building
- Completing the finish out according to regulatory guidelines

- Negotiating contracts and purchasing all water and dialysis equipment
- Negotiating contracts and purchasing all disposables, pharmaceuticals, etc.
- Developing and implementing all policies and procedures according to established state, county, and federal guidelines
- Developing personnel guidelines, hiring and maintaining all staff
- Developing billing procedures
- Developing accounting procedures
- Developing required governmental reporting, governing and auditing procedures

Example #2: The Tribe could enter into a management agreement. One possible *hybrid* could be:

- Developing or providing a building for lease hold improvements by a dialysis provider company.
- Having the dialysis company provide a turn key management agreement, including all of the aforementioned services.

Example #3: The Tribe could enter into a joint venture with a dialysis provider:

- Real estate, costs of providing the services, and oversight of the facility would be jointly owned.
- Management would be provided by an established dialysis provider, but the profitability, if any, would be shared.

There are other possibilities, but most are a variation on one of these three examples.

### Contract Negotiation

There are three phases associated with entering into an agreement with a third party to assist in providing dialysis services:

- Have an exact and explicit understanding of the services to be provided. These should be precisely delineated and provided in a Request for Proposal (RFP).
- Understand the comparative process in assessing various responses to the RFP. This is a complicated process, often comparing “apples to oranges” and requiring a detailed understanding of the nuances of dialysis industry contracting. This process should be performed by personnel intimately familiar with the dialysis provider industry.
- Negotiate the final contract with the provider of choice.

When contract negotiations begin with a potential provider, one problem that has been encountered is failure of the providers to understand IHS and IHS and the Tribe’s failure to understand the providers. Clear communication regarding expectations on both sides will help smooth the negotiation process and help avoid misunderstandings.

### Contracts & Agreements

The Tribes control access to the patients for dialysis providers. They therefore may use the contracting process to define care expectations and parameters. Whether the Tribe decides to provide the dialysis services or contract for these services, there are several outside contracts and agreements that will have to be written and signed. Some are required by federal regulation and others are for services not provided by or available through the dialysis facility.

Once the Tribe has assessed the need for reservation-based dialysis and the scope of work has been defined, a Request for Proposals (RFP) may go out to competing entities. There are large corporations (chains) and smaller, independent corporations. The large chains are fewer than they used to be, now only being Fresenius Medical Care (FMC), DaVita, and Dialysis Clinic, Inc. (DCI). Proposers are aware of the rapid growth of ESRD in the AI/AN community. Dialysis is a business and Proposers are highly competitive, and will compete for the opportunity to provide services on reservations. However, the small percentage of patients with private insurance (which provide the greatest profits to the corporations) makes some of the providers leery of responding competitively for Tribal contracts.

To demonstrate the complexity of contracting, please note, the number of contracts required, to simply open a dialysis facility (not fully inclusive). All of these should be included and/or expected in an RFP or addressed by a provider in response to a RFP:

- Medical Director Contract – The Federal Register requires a contract between a qualified physician and the dialysis facility.
- Dietitian and Social Worker Contract – If the dietitian and social worker are not employees of the facility, contracts for their services are required.
- ESRD Network Contract – The facility must maintain a current agreement of participation with the ESRD Network in their area.
- Acute Dialysis Contract – Each facility must have an agreement for “acute” or in-patient services for their patients when they are hospitalized, so they will continue to receive their dialysis treatments.
- Back-up Dialysis Contract – A contract for back-up dialysis is required for emergencies and disasters. This is an agreement with another dialysis provider, to dialyze patients in the event treatment is not possible in their home facilities due to fire, flood, hurricane, tornado, power outage, etc.
- Home Dialysis HD & PD Contract – If the facility does not have the capabilities of providing home hemodialysis or peritoneal dialysis training and follow-up, this modality must be offered through contract with another facility.
- Transplant Contract – Each dialysis facility must have an agreement with a transplant program affiliated with a donor program, to provide transplant work-up and surgery.
- Laboratory & Blood Bank Contract – Laboratory and blood bank services must be provided through contract.
- Tribal-Dialysis Provider Contract – If the Tribe contracts with an outside provider for dialysis services, a contract must be signed with IHS for the provider to receive CHS funds.

#### Other Contracts & Agreements

##### Insurance and HMO Contracts

Patient transportation

Equipment and supplies

Pharmaceuticals

Clinic and office equipment maintenance

Telephone, pager, cell phone, alarm system

Disposable and hazardous waste

In addition to items specified by separate contracts, the following items should be components of an RFP:

- Credentialing of licensed staff

- Experience in ESRD management in the AI/AN population
- Frequency of physician, dietitian and social worker visits
- “Open unit policy” (permitting privileges to any qualified physician to whom a patient is referred, not just corporation-affiliated physicians)
- Patient-to-direct care staff ratio specification
- Staff training, education, and certification, including Basic Life Support (BLS), Advanced Cardiac Life Support (ACLS), Automated External Defibrillator (AED).
- HIPPA compliant access of IHS and Tribal health personnel to unit to ensure continuity of primary care
- Reimbursement agreement
- Pre-dialysis care clinics with early orientation
- Amenities and availability of language translators
- Quality Management program

See Attachment 1 for items which, at minimum, should be included in a “start-up” check list.

### **Assessing the Quality of Dialysis Services**

The Medicare ESRD program includes a rigorous quality improvement component in which all dialysis facilities must participate. The ESRD Networks, described below, monitor quality of care and implement efforts to improve care.

The ESRD amendments to the Social Security Act of 1972 provided for the establishment of Networks to assist the Centers for Medicare and Medicaid to monitor the quality of care delivered to dialysis patients by providers of dialysis services and transplantation, quality of life, and outcomes monitoring. Each of the 18 Networks is responsible for their assigned geographic areas. Each Network office is staffed by an Executive Director, Quality Improvement and Data Management Staff, and Patient Services Staff, plus a group of volunteers, including the Medical Review Board, Patient Advisory Committee, Grievance Committee, and the Network Council.

Each Network produces an Annual Report which includes Demographics, Standardized Mortality Ratios (SMR), Standardized Hospitalization Ratios (SHR), Standardized Transplant Ratios (STR), results of National and Network core and key indicator monitoring, and special projects and studies. This data comes from each facility reporting to the Network in a standardized manner.

See Attachment 2 for a listing of regional Networks.

Additional, further quality oversight is provided through CMS contracts with state survey agencies, usually the state health departments. These agencies routinely survey dialysis facilities for compliance with national and state rules and regulations.

The delivery of dialysis is highly regulated to advocate for the patient by helping to ensure the safe delivery of care. The following is a list of regulatory agencies, standards, and guidelines that influence the care of dialysis patients:

- Federal Register (ESRD Facility Survey Report & Addendum)
- American National Standard (ANSI/AAMI) for Hemodialysis
- AAMI/CMS Standard for Reuse of Hemodialyzers
- OSHA/NIOSH - Formaldehyde & HAZCOM
- CDC - HBV, HCV, HIV, Standard Precautions
- ESRD Network Standards of Patient Care

- CMS Clinical Performance Measures
- JCAHO Standards
- K/DOQI and KDIGO Guidelines
- ANNA Standards of Clinical Practice for Nephrology Nursing
- Renal Physician's Association Standards
- Standards of Practice: Renal Social Workers
- Standards of Practice: Renal Nutritionists (CRN)
- Local & State Standards
- “Conditions for Coverage of Suppliers of ESRD Services” from the *Federal Register*,
- “Interpretive Guidelines ESRD Facilities”, and “End Stage Renal Disease Facility Report” (Form HCFA-3427) and
- End Stage Renal Disease Facility Report Addendum (Form HCFA-3427A) may be found in the Appendix.

A significant component of assessing dialysis providers should include a close and detailed assessment of their overall quality program, including:

- How data is generated.
- How data is reported.
- Whether all disciplines are reported.
- Whether all conditions and regulatory requirements are met.
- Any infractions and disciplinary actions in other contractual relationships have occurred, are outstanding, and including resolutions.

## **Case Studies**

Examples of successful efforts by several Tribes may help illustrate the issues discussed above.

### Case Study #1: Ft. Peck Sioux and Assiniboine Facility

The Ft. Peck Tribal Dialysis Unit in Poplar, MT on the Ft. Peck Reservation has provided chronic hemodialysis to individuals with End Stage Renal Disease (ESRD) since 1988. The facility is a certified, licensed, freestanding unit, which is Tribally owned and operated by the Sioux and Assiniboine Tribes.

Prior to hemodialysis services being offered in Poplar, MT, patients with ESRD had to travel to Minot, ND for treatment. This was a 400-mile round trip for the patients three times a week. The physical and emotional toll on these individuals prompted health care officials, the Tribal Council, and the Indian Health Service to look at options for providing dialysis locally.

In 1988, a six station chronic hemodialysis facility was opened in Poplar, MT, located in the Verne E. Gibbs Indian Health Center. This was a collaborative project between the Sioux and Assiniboine Tribes, Indian Health Service, and Frances Mahon Deaconess Hospital in Glasgow, MT.

Construction of a new 10-station dialysis facility was completed in 1999 with state of the art hemodialysis equipment and water treatment system. Nine stations are utilized every Monday, Wednesday, and Friday and will accommodate up to 27 patients when all three shifts are filled. Additional shifts can be added to accommodate expansion by opening Tuesday, Thursday, and Saturday if the need should arise. Reimbursement for chronic hemodialysis services is primarily Medicare, Medicaid, and private insurance.

In 1995, the Tribes and Indian Health Service implemented the Kidney Health Protocol to identify Native American diabetic patients with early kidney disease. The objective of the protocol was to delay or halt the progression of kidney disease and to enable kidney patients to have an active role in the management of their health. To date, over 300 individuals have been referred to the kidney specialist.

Currently over 70% of the patients undergoing chronic hemodialysis at the Ft. Peck Tribal Dialysis Unit has Type 2 Diabetes as the cause of ESRD. Newly diagnosed diabetics in the Ft. Peck Service Unit have continued to increase with nearly 1000 individuals identified with type 2 diabetes during a recent fiscal year.

The general health status of patients starting hemodialysis has improved since 1995, due to early referrals to kidney specialists (nephrologists). Treating complications of ESRD such as anemia, malnutrition, bone disease and high blood pressure has helped significantly to ease the financial burden on the Tribes and Indian Health Service. The primary referral to the nephrologist is the individual with diabetic nephropathy due to type 2 diabetes. Other causes of ESRD are hypertension, glomerulonephritis and IGA Nephropathy.

Disease management strategies to slow progression of kidney damage are focused on good blood sugar and blood pressure control. This is a collaborative effort by the Diabetes Program and the renal team and conducted during the patient's clinic appointment with the nephrologist. As the patient's kidney disease advances, management of uremic complications is addressed. Currently, 25 patients undergo dialysis three times a week averaging four hours per treatment. The dialysis unit employs staff consisting of six Registered Nurses and two technicians for daily operation. Other members of the patient care team include the Medical Director from Bismarck, ND, a Registered Dietitian, and a Social Worker, all of whom are contracted by the Dialysis Unit.

Overall, the Ft. Peck Dialysis project has been a successful collaborative effort of the Tribes, the community, and the Indian Health Service.

Other facilities providing chronic hemodialysis service in the area include:

- Williston, ND, which is 67 miles east of Poplar. This unit is a six-station satellite program of St. Alexis Hospital in Bismarck, ND
- Havre, MT, is 232 miles west of Poplar. This is a three-station hospital based satellite program of Benefis Hospital in Great Falls, MT.

### Case Study #2: Zuni, NM

Prior to 1986, there was no hemodialysis services offered in Zuni, NM. Patients with ESRD had to travel to Gallup, NM for treatment. This was a 75 mile round trip for the patients three times a week. The physical and emotional toll on these individuals prompted health care officials, the Tribal Council, and the Indian Health Service to look at options for providing dialysis locally.

The Zuni Dialysis Unit serving the Zuni reservation in Zuni, NM has provided chronic hemodialysis to individuals with End Stage Renal Disease (ESRD) since 1986. It started as a 6 station unit in the Zuni IHS Hospital Service Unit. In March 1988, a new 7 station facility serving 23 patients was built on land leased from the Zuni Tribe by Rehoboth-McKinley Christian Health Care Services (RMCHCS), in Gallup, NM. The facility was expanded twice, from 7 to 10 stations, and then again to 14 stations. In June 2003 a new 25 station facility with state of the art equipment and water treatment was completed, which currently serves 118 patients. In addition to hemodialysis, they also offer home peritoneal dialysis for their patients. The facility is a certified, licensed, freestanding unit owned and operated under contract by RMCHCS.

Reimbursement for chronic hemodialysis services is primarily Medicare, Medicaid, and private insurance.

The primary cause of renal failure among the Zuni population is type 2 diabetes. Currently over 98% of the patients undergoing chronic hemodialysis at the Zuni Dialysis Unit have type 2 diabetes as the primary cause of ESRD. Newly diagnosed diabetics in the Zuni Service Unit have continued to increase.

With the high incidence of type 2 diabetes, the Tribe and community started a primary prevention program, the Diabetes Fitness Series.

### **Conclusion**

This document provides an introduction to some of the important issues in providing reservation based dialysis services. Communities considering developing new dialysis facilities should consider working with an independent dialysis business consultant who can advise on the feasibility and long term viability of a new facility.

**Attachment 1**  
**1. Facility Start-up Checklist**

**Facility Name:**

**Projected opening date:**

ITEM	Person Responsible	Date Started	Target Date	Date Completed
<b>Plans &amp; Blueprints Complete</b>				
<b>Permits applied for</b>				
<b>Certificate of Need Filed</b>				
<b>Licenses Applied For</b>				
<b>Other:</b>				
<b>Other:</b>				
<b>REGULATORY</b>				
<b>Medicare Provider #</b>				
<b>Medicaid Provider #</b>				
<b>State Renal Program #</b>				
<b>CMS Transfer of Ownership Form Completed</b>				
<b>Certificate of Occupancy</b>				
<b>Other:</b>				
<b>Other:</b>				
<b>TAXES</b>				
<b>Payroll Tax Withholding #</b>				
<b>State Tax ID #</b>				
<b>Sales &amp; Use Tax</b>				
<b>Franchise Tax</b>				
<b>Application for Exemption:</b>				
<b>Property Tax-City</b>				
<b>Property Tax-County</b>				
<b>Real Property</b>				
<b>Personal Property</b>				
<b>Other:</b>				
<b>Other:</b>				
<b>REGISTRATION</b>				
<b>Secretary of State</b>				
<b>State Board of Equalization</b>				
<b>Attorney General</b>				

ITEM	Person Responsible	Date Started	Target Date	Date Completed
<b>Franchise Tax Board</b>				
<b>Other:</b>				
<b>Other:</b>				
<b>STAFF HIRING &amp; TRAINING</b>				
<b>Administrator</b>				
<b>Nurse Manager</b>				
<b>Dietitian</b>				
<b>Social Worker</b>				
<b>RN/LPNs</b>				
<b>Chief BioMed Technician</b>				
<b>Patient Care Technician</b>				
<b>Reprocessing Technician</b>				
<b>Bookkeeper (AP &amp; AR)</b>				
<b>Other:</b>				
<b>Other:</b>				
<b>SYSTEMS CHECKLIST</b>				
<b>Computer System</b>				
<b>General Ledger System</b>				
<b>Business Staff Trained</b>				
<b>MIS System</b>				
<b>MIS Training</b>				
<b>Medicare Survey Checklist</b>				
<b>Other:</b>				
<b>Other:</b>				

ITEM	Person Responsible	Date Started	Target Date	Date Completed
<b>POLICIES &amp; PROCEDURES</b>				
<b>Personnel P&amp;P</b>				
<b>Clinical P&amp;P</b>				
<b>Dialyzer Reprocessing P&amp;P</b>				
<b>Equipment Maintenance P&amp;P</b>				
<b>Other:</b>				
<b>Other:</b>				
<b>EQUIPMENT</b>				
<b>Water Treatment Equipment</b>				
<b>Reuse Equipment</b>				
<b>Dialysis Machines</b>				
<b>Dialysis Chairs</b>				
<b>Scale</b>				
<b>Blood Pressure Equipment</b>				
<b>Emergency Cart/AED</b>				
<b>Office Furniture</b>				
<b>WATER TREATMENT</b>				
<b>Product Water Analysis</b>				
<b>Water Cultures</b>				
<b>PLANT MAINTENANCE</b>				
<b>Water Utilities Applied For</b>				
<b>Electric Utilities Applied For</b>				
<b>Gas Utilities Applied For</b>				
<b>Telephone</b>				
<b>Security System</b>				
<b>Hazardous Waste Removal</b>				
<b>Trash Removal</b>				
<b>Housekeeping</b>				
<b>Grounds Maintenance</b>				
<b>Laundry</b>				
<b>Other:</b>				
<b>Other:</b>				
<b>CONTRACTS/AGREEMENTS</b>				
<b>Medical Director/ Nephrologist</b>				
<b>Dietitian</b>				
<b>Social Worker</b>				
<b>Insurance</b>				
<b>HMO/Insurance Contracts</b>				
<b>Telephone/Pager/Cell Phone</b>				
<b>Alarm System</b>				
<b>Clinic Equipment</b>				
<b>Clinic Furniture</b>				
<b>Clinic Supplies</b>				
<b>Office Equipment</b>				
<b>Office Furniture</b>				
<b>Office Supplies</b>				

ITEM	Person Responsible	Date Started	Target Date	Date Completed
<b>ESRD Network Participation</b>				
<b>Transplant Program</b>				
<b>PD/Home Dialysis</b>				
<b>Acute Dialysis</b>				
<b>Back-up Dialysis</b>				
<b>Laboratory</b>				
<b>Blood Bank</b>				
<b>Med. Record Consultant</b>				
<b>Med. Record Storage</b>				
<b>Patient transportation</b>				
<b>IHS</b>				
<b>Other:</b>				
<b>Other:</b>				
<b>Other:</b>				

**Attachment 2**  
**2. ESRD Network Offices and Directors**

NETWORK 1 (CT, ME, MA, NH, RI, VT)  
DANIELLE DALEY, MBA  
IPRO ESRD Network of New England  
30 Hazel Terrace, Woodbridge, CT 06525  
Phone: (203) 387-9332 • Fax: (203) 389-9902  
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NETWORK 2 (NY)  
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IPRO ESRD Network of New York  
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11042  
Phone: (516) 209-5619 • Fax: (516) 326-8929  
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NETWORK 3 (NJ, PR, VI)  
CHRISTOPHER BROWN  
Quality Insights Renal Network 3  
Cranbury Gates Office Park  
109 South Main Street, Suite 21, Cranbury, NJ  
08512  
Phone: (609) 490-0310 • Fax: (609) 490-0835  
E-mail: [chrisbrown@nw3.esrd.net](mailto:chrisbrown@nw3.esrd.net)

NETWORK 4 (DE, PA)  
SHANE B. PERRY  
The Renal Network, Inc.: ESRD Network 4  
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15222  
Phone: (412) 325-2250 • Fax: (412) 325-1811  
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NETWORK 5 (DC, MD, VA, WV)  
NANCY C. ARMISTEAD, MPA  
Mid-Atlantic Renal Coalition  
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Phone: (804) 320-0004 • Fax: (804) 320-5918  
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NETWORK 6 (GA, NC, SC)  
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27609  
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E-mail: [jkrisher@nw6.esrd.net](mailto:jkrisher@nw6.esrd.net)

NETWORK 7 (FL)  
MARTHA HANTHORN, MSW, LCSW  
FMQAI: The Florida ESRD Network  
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NETWORK 8 (AL, MS, TN)  
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NETWORK 9 (IN, KY, OH)  
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8291/2120  
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NETWORK 11 (MI, MN, ND, SD, WI)  
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Renal Network of the Upper Midwest, Inc.  
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NETWORK 12 (IA, KS, MO, NE)  
KATRINA M. DINKEL, MA  
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ESRD Network of Texas, Inc.  
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NETWORK 15 (AZ, CO, NV, NM, UT, WY)  
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NETWORK 17 (AS, GU, HI, MP, N. CA)  
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NETWORK 18 (S. CA)  
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FMQAI: ESRD Network 18  
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Angeles, CA 90028  
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**Attachment 3**  
**3. Model Contract Scope of Work**

PART I - SECTION B - SUPPLIES OR SERVICES AND PRICES

**B-1**     **INTRODUCTION**

The Indian Health Service (IHS) has instituted a policy (See Attachment J-3), Federal Register dated June 30, 1986 to contract for health services for Indian beneficiaries only with those hospitals, physicians and other health care providers which agree to accept, as payment in full, reimbursement at rates no higher than the Medicare allowable rates.

This contract is a non-personal health care services, as defined in FAR 37.101, under which the Contractor is an independent Contractor.

**B-2**     **THE FOLLOWING ARE SCHEDULES BY LOCATIONS**

**BID SCHEDULE A: XXX LOCATION.**

The Contractor shall provide ESRD health care services as defined in the "Scope of Work" to IHS beneficiaries residing within the XXX Service Unit.

**A-1-a.**    **Reimbursement to the Contractor for ESRD Services will be according to the Medicare reimbursement methodology.**

**A-1-b.**    **Reimbursement to the Contractor for a new patient awaiting Medicare eligibility will be according to Medicare reimbursement methodology.**

**A-1-c.**    **Reimbursement to the Contractor for ACUTE INPATIENT BEDSIDE DIALYSIS IS: \$350.00 per patient. This rate is inclusive of all necessary personnel, equipment, and supplies required to provide ESRD services, with the exception of Epogen (EPO) treatments, which shall be reimbursed at the Medicare rate.**

**A-1-d.**    **Reimbursement to the Contractor for an ACUTE PATIENT DIALYZED AT THE CONTRACTOR'S DIALYSIS UNIT will be according to the Medicare reimbursement methodology and the Epogen (EPO) will be reimbursed at the Medicare rate.**

PART I - SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

**C-1.**     **PURPOSE OF CONTRACT:**

This contract is for the provision of outpatient End Stage Renal Disease (ESRD) services, for eligible Native American Indians and Alaskan Natives who are IHS, Contract Health Service (CHS) beneficiaries in accordance with the Code of Federal Regulations (CFR), Title 42, Part 36. Services must be requested or referred by a designated IHS Contracting Officer or the authorized representatives of the

Contracting Officer, whose name(s), organization component and dollar limitation per order shall be furnished to the provider by the designated IHS Contracting Officer.

The ESRD provider hereinafter referred to as the "Contractor", shall provide health care services to those IHS patients who are referred by the IHS, here-in after referred to as the "Government" as set forth in this contract.

**C-2. SCOPE OF WORK**

- A. The Contractor shall provide ESRD services, which includes In Center Hemodialysis, Continuous Ambulatory Peritoneal Dialysis (CAPD), and Continuous Cycling Peritoneal Dialysis (CCPD), Home Dialysis training, and other necessary services considered a routine part of ESRD health care. These services shall be provided in accordance with Health Care Financing Administration (HCFA) standards.
- B. The Contractor shall provide all necessary personnel, supplies, drugs, equipment, laboratory, facilities, water treatment system, waste disposal, malpractice insurance and other items and expertise necessary for or incident to provide such services. Scheduling of and costs of all necessary maintenance and repairs shall be the responsibility of the Contractor.
- C. The Contractor shall have the capability to provide outpatient dialysis treatments to IHS/CHS beneficiaries residing within the boundaries of the following medical facilities: XXX Health Care Facility,
- D. The Contractor's facility must be located within a 5 mile radius of the medical facilities in XXX. These Dialysis Units shall be a contractor-owned freestanding units which shall be located off Government premises; Medicare and Medicaid certified and shall maintain such certification throughout the term of this contract. Failure to maintain certification will be cause for immediate termination of this contract.
- E. The Contractor's facilities shall be "open" to all qualified physicians. No physician to whom a patient is referred will be denied clinical privileges. There shall be no undue delay in granting these privileges.
- F. The referring medical staff will be the primary care providers of all other medical care other than ESRD conditions.
- G. All hospitalizations and surgical procedures are to be referred to the nearest IHS hospital capable of providing the necessary care. The referring medical facilities' Clinical Director will be the local contact and coordinator of referrals, patient emergency transportation, treatment and consultation.
- H. *The Contractor shall submit complete copies of patient care conferences to the appropriate Service Unit Dialysis Liaison on a prompt and regular basis.*
- I. The Contractor shall provide a long-term program with broad long-range plans for providing a particular kind of treatment within a specified setting based on the needs and resources of the patient. The Contractor shall

demonstrate the selection of the most suitable treatment modality (dialysis or transplantation) based on medical, nutritional and social evaluation of the patient. A copy of this plan shall be provided to the appropriate *Service Unit Dialysis Liaison* for inclusion in the patient's medical record.

- J. The Contractor shall have a plan to improve access to renal transplantation and home dialysis.
- K. *The Contractor's Medical Director, for each dialysis unit, shall be a Nephrologist. The Contractor shall require the patient's attending nephrologist to be physically present in the dialysis unit at least once a week to see the patient(s). The Contractor shall ensure continuity of care through collaboration between the attending physician(s) and the referring medical staff.*
- L. The Contractor shall provide staff, follow-up and support for outpatient hemodialysis, CAPD and CCPD.
- M. The Contractor shall provide patient amenities (i.e. television, reading materials, etc.) for hemodialysis patients.

C-3. **ESRD SUPPLIES**

The Contractor shall supply the following items: temporary vascular access lines, alcohol wipes, sterile gauze, and other supplies normally associated with ESRD treatment.

C-4. **DRUGS**

The Contractor shall provide all necessary drugs which are considered a routine part of ESRD health care services and any additional drugs which are reimbursable under the ESRD program.

C-5. **LABORATORY**

The Contractor shall be responsible for all necessary laboratory tests which are considered a routine part of ESRD health care services.

C-6. **HOUSING:** Housing may be made available to the Contractor for living quarters at Government rental rates applicable at the time of occupancy and adjusted annually. Lease arrangements can be made between the Service Unit and the Contractor for Government housing if needed and as available.

C-7. **QUALITY IMPROVEMENT:**

- A. The Contractor shall have a Quality Improvement (QI) Plan which is integrated with the appropriate Service Unit QI Plan. Two (2) focused studies per year, one (1) of which will be an assessment of patient satisfaction. *The Contractor shall coordinate these efforts with each Service Unit Dialysis Liaison.*
- B. Bi-annual reports of QI activities and an annual evaluation of the QI and monitoring results will be given to the Contracting Officer's Representative (COR) on the following dates: April 15th and October 15th.

- C. The Contractor's patient grievance procedure shall be consistent with ESRD Network XXX Standards.
- D. **DIALYSIS WATER QUALITY:** The Contractor shall perform monthly biological and chemical tests in accordance with the standards set forth by the Association for the Advancement of Medical Instrumentation, JCAHO and American National Standards Institute Inc.
- E. The Contractor shall share all dialysis unit specific data provided to the facility by Network XXX with the appropriate Service Unit Dialysis Liaison.

**C-8. CLIENT BACKGROUND**

Many of the patients receiving dialysis treatment under this contract may only speak a native language and/or reside on an Indian Reservation. Therefore, the Contractor shall insure that a competent XXX interpreter shall be available in the dialysis unit whenever a XXX speaking patient is receiving treatment.

**C-9. REVIEW RIGHTS**

The Contractor shall allow full access to the dialysis unit and patients' records shall be available to the COR or designee, including IHS Environmental Health Officers, IHS Medical Officers, and representatives of Tribal Health Boards.

**C-10. QUALIFICATIONS**

- A. **FACILITY:** The Contractor's dialysis unit shall be State and Medicare Certified and shall maintain such certification during the life of this contract.
- B. **STAFF:**
  - 1. The Contractor's staff must be certified and licensed as appropriate to provide ESRD health care services.
  - 2. The Contractor's professional staff shall be state licensed and/or board certified by the appropriate medical/professional board.
  - 3. The Contractor's RN's shall be trained and certified in Advanced Cardiac Life Support (ACLS).
  - 4. The ratio of the Contractor's direct patient care staff to patients shall not exceed 1:4.
  - 5. Continuing medical education for the contractor's staff shall occur at least monthly.
  - 6. The Contractor shall provide reports of patient load ratios for nutritionists and social workers.

**PART I - SECTION D PACKAGING AND MARKING - Not Applicable**

**PART I - SECTION E INSPECTION AND ACCEPTANCE**

**E-1. INSPECTION**

The Contracting Officer or designee is authorized to review by on-site or through review of records or through any other reasonable manner the quality of care rendered under this contract. The Contractor shall furnish medical records including a narrative summary when requested by the Contracting Officer or designee. Adequate records should be maintained to reflect accuracy with respect to claims submission as well as for quality and appropriateness of care. All records of medical and surgical services, supplies and business records shall be subject to review by the Contracting Officer or designee.

**E-2. ACCEPTANCE**

Payment will be denied by the Fiscal Intermediary (FI) when such care does not support the charges or if the service is not deemed medically necessary or appropriate. Such determination may be made by the Government, PSRO, Utilization Review Committee, or the FI, whichever is appropriate. Claims will also be denied where the patient was not eligible for services under this contract or the service provided was outside the scope of this contract. In the event the FI denies a claim, the Contractor shall have the right to request review by the Government, depending upon the nature of the denial. The FI shall not be liable for any claims denied.

**PART I - SECTION F - DELIVERIES OR PERFORMANCE**

**F-1. PERIOD OF PERFORMANCE**

- A. Performance period of this contract shall begin on \_\_\_\_\_ and shall not extend beyond the completion date of \_\_\_\_\_, unless the period is changed by written modification to the contract.
- B. If the Government exercises its options pursuant to FAR 52.217-9 Option to Extend the Term of the Contract, the period of performance will be extended in accordance with the following schedule.

**YEAR**

**OPTION PERIOD**

- First Year Option
- Second Year Option
- Third Year Option
- Fourth Year Option

**F-2. CLINICAL REPORTING AND SPECIAL COMMUNICATIONS**

- A. Disclosure of Clinical Information. Where the Indian Health Service is carrying out its duties with respect to conservation of the health of the Indians, the relationship of the service to the Indian shall be regarded as that of physician to patient so that restrictions generally applicable to the release of clinical information by the dialysis unit will not be applicable to the release of such information to the IHS.

- B. **Clinical data reports for the records of each patient shall be maintained in compliance with Joint Commission on Accreditation of Healthcare Organizations or Medicare Certification.**

**F-3. REQUIRED REPORTS**

**Deliverables as required in Section C, Work Statement, and Section G, Contract Administration Data, shall be submitted in accordance with the instructions given in those sections.**

- A. *The Contractor shall submit, to the appropriate Service Unit Dialysis Liaison (SUDL), a duplicate of monthly workload record sent to the ESRD Network. **This information shall include new and established patients, by name, third party eligibility, and treatment modality.** The SUDL will perform a bi-annual review on transplant and home dialysis rates.*
- B. **The Contractor shall make available copies of all surveys made by the state, federal, and ESRD Network to the SUDL. This includes unit-specific data related to morbidity and mortality.**