

# **Design, Development, and Implementation of an Improved Medicare Outpatient End Stage Renal Disease Prospective Payment System**

## **Database Report**

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## ***I. Background***

This document is a review of the data that are available to the Centers for Medicare and Medicaid Services (HCFA) to broaden and improve the current outpatient prospective payment system (PPS) for Medicare ESRD beneficiaries. Several recent government initiatives have motivated an examination of the current ESRD PPS. The system, known as the composite rate, has not been revised substantially since inception, despite several changes that have taken place in the delivery of ESRD therapy since that time. HCFA issued a Request For Proposals (RFP) on August 1, 2000 for the initial phase of an evaluation of the feasibility of substantially expanding the bundle of services that are included in the PPS, with planned follow-up phases for implementation of the expansion. The contract for the HCFA project was awarded to the University of Michigan. Subsequent to the RFP, the Benefits Improvement and Protection Act of 2000 (BIPA) was enacted. Section 422c of BIPA requires an expansion of the coverage of the ESRD prospective payment system. This document has been prepared by the University of Michigan under contract with HCFA, as an assessment the information that is needed, the data that are available, and the utility of available databases for meeting those information needs. In order to clearly state the problem, we include here an extract from the original RFP.

The current system has aspects of both a PPS and fee for service reimbursement. The current unit of payment, the composite rate per dialysis treatment, is intended to cover the renal related services and supplies routinely provided to Medicare beneficiaries. But providers also can bill Medicare for other dialysis related services in addition to receiving the composite rate. As part of outpatient ESRD payment reform, HCFA is planning to develop an ESRD PPS in which all renal related services, tests, drugs, and supplies ultimately are bundled into a fixed reliable payment rate. The first phase of this research will assess the feasibility of using currently available HCFA databases and other sources to proceed with the development of a bundled ESRD PPS. Subsequent phases of this contract will determine the need for any additional data, explore the sufficiency and testing of that data, evaluate the need to create and test an assessment instrument, and create an ESRD data file for further analysis. These data subsequently will be examined to test their feasibility for the construction of facility specific measures of case mix, which may predict differences in appropriate consumption in the context of a bundled Medicare outpatient ESRD PPS

## ***II. Introduction***

In the broadest terms, the objective for a revised dialysis payment system is to promote the delivery of high quality, dialysis-related services in an economically efficient manner. Accomplishing this objective requires a careful analysis of the workings and shortcomings of the existing payment system, an analysis of how well existing data are able to inform decisions about the costs incurred by an efficient provider delivering high quality services, and analyses of the relationships between dialysis modality, case mix, and costs. These analyses will be required to devise a system that ensures access to quality care for more complex patients and ensures equitable reimbursement to those facilities who serve them. Broadening the bundle of services included in the composite rate can simplify the billing process and can remove incentives for excessive use of separately billable services. However, broadening the bundle necessitates increased attention to quality assurance measures to ensure that the expanded PPS does not result in an inappropriate reduction in the use of some services that were formerly billed separately (e.g. EPO). Further, case mix adjustments may have to be developed. Even if the cost of services included in the existing composite rate does not vary substantially with case mix factors, the services in a broader bundle might exhibit significant, predictable variations. Finally, a broader bundle makes facility revenues more predictable but also places facilities at risk for the costs of providing a wider array of services. If these risks are substantial (particularly for small, independent facilities who cannot spread the risk of unusually costly “outliers” over many cases), a mechanism for incorporating such outlier cases in an expanded PPS might be warranted.

Data Needs. In the development of a proposal for a prospective payment system for ESRD-related services, several types of data are likely to be necessary or at least highly useful. To understand the types of data most essential, it is important to consider carefully the uses to which the data will be put. There are at least four distinct processes requiring data analysis: (1) development of the original PPS system; (2) regular (such as annual) maintenance and updating of the system; (3) regular reporting of the quality and appropriateness of patient care; (4) occasional special studies, perhaps leading to system refinement. We describe the nature of each of these processes briefly.

## ***III. Development of an expanded PPS system***

Several crucial issues must be addressed in order to expand the current PPS system to include more services in a fair and effective manner.

1. Identification of the products to be included in the bundle. For example, Section 422(c) of BIPA requires that a more comprehensive composite rate include drugs that are "routinely used" such as EPO and other drugs. Outpatient vascular access services and procedures may also be included in the basic product.
2. Definitions of the products to be included in the PPS may also depend on other factors:
  - a. Definition of standard adjustments to the payment schedule. Adjustments for patient severity (case mix adjustment) can help to protect individual providers from the financial risk associated with a heterogeneous patient population, and can help protect patients for whom care is more costly than average from discrimination. Definition of such adjustments requires determination of the distribution of expenditures of various categories across different types of ESRD patients.

- b. Determining possible differentials for different dialysis modalities (peritoneal dialysis, hemodialysis, home hemodialysis) and non-traditional schedules (daily hemodialysis) may be necessary in order to assure the potential for patients and their physician to make the most appropriate care choices given the patients' individual needs and preferences.
  - c. Are there categories of providers, defined by geography or other relevant characteristics, in which the costs of providing the basic product are significantly higher or lower than the mean? If so, should these cost differences be reflected in a payment differential? Answers to these questions require information regarding cost variability by type of provider, standardizing for product. A wage index or other input price adjustments could also conceptually fall into the definition of standard adjustments.
3. The potential for substitution of different services outside of the PPS system for services that are intended to be part of the PPS will be important for some services. For example, the provision of vascular access is a necessary component of dialysis, but this service is currently typically provided through a combination of inpatient and outpatient services. Changes in billing procedures and practice patterns resulting from a new PPS will require observation and measurement for future policy considerations.
4. A method should be determined to identify outliers, or patients whose condition is so atypical that their medical treatment would cost much more than the planned payment structure.
5. Determination of base payment rate for the typical producer. Setting a regulated price is optimally based on knowledge of the relevant cost of the efficient producer. Information on the costs, or at least on the payments made to providers, is necessary for the basic product.
6. Determination of the unit of payment for each patient. Several alternatives are under consideration, including per dialysis session, per week, or per month.
7. Determination of how to manage the payment for patients who move among providers.

#### ***IV. Regular Maintenance of the PPS***

HCFA will consider a regular (such as annual) update of the system to reflect changes in the determinants of cost and quality. Section 422b of BIPA requires adjustment for market basket inflation and changes in market, productivity, new technologies, and margin of profit. For example, wage inflation might justify a general increase in the basic price. Or, cost-reducing productivity improvements might justify a reduction in price. Data necessary for regular maintenance might include rates of change in input prices and changes in staffing ratios. Although changes in medical technology are not predictable, a system for review of such changes will also be needed to allow for modifications in the PPS.

#### ***V. Regular Reporting of the Quality and Appropriateness of Patient Care***

The institution of a new payment system establishes a new set of incentives for providers. Some of these changes in incentives are expected, understood, and often desired. But even the best-designed

payment systems can stimulate unexpected provider responses, some of which could lead to reductions in the quantity or quality of care. We are particularly interested in provider responses that might harm patient care. Hence, a system of data collection must be established that permits monitoring of patient care quality and access.

## ***VI. Special Studies***

Either in response to the incentives in the new system or because of changes in the technology of ESRD care, providers may change their production processes. Such changes might warrant occasional modifications to the payment system. In addition to regular updates accounting for routine factors such as changes in input prices, a special update might be important in the first few years following implementation of the revised PPS because practice patterns may change in ways that cannot be fully foreseen. For example, an updated payment system might make an assumption about proportion and characteristics of patients switched to subcutaneous EPO administration in response to adding EPO to the bundle. However, the actual prevalence of subcutaneous administration will not be known with certainty until after the payment system is implemented. Another example is that payment for a product that includes vascular access procedures might motivate physicians affiliated with dialysis units to inappropriately hospitalize patients needing vascular access more frequently. Such a process change can have expenditure-increasing implications, and an adjustment to the system may be warranted. Or, there might be a quality-enhancing but cost-increasing technological development. Failure to adjust the payment system to reflect the higher costs will retard the diffusion of this technology or force offsetting compromises in other aspects of patient care. The nature of these studies is unpredictable. Hence, some of the data necessary to carry them out will have to be identified when the need for the special study becomes apparent. Occasional special studies might result in changes in the definitions of the products, changes in the basic price, or changes in categories of producers meriting payment adjustment.

## ***VII. PPS Data Sources***

There are many sources of information that can be used to develop an expanded outpatient ESRD PPS. Each of these data sources can be useful for meeting the needs listed above in section 2. We have divided the possible PPS data sources into three groups. This first group consists of primary, recurring, government data sources. These sources generally collect data about entire populations rather than about samples. The second group consists of broader data systems that link and integrate data from multiple sources in the first group. These broader data systems will be the most effective way to access most of the sources in the first group. The third group consists of special studies. These typically collect data about a sample of patients, are of limited duration, and may not be sponsored by the government.

## A. Databases

### 1. HCFA STANDARD ANALYTICAL FILES (SAFS) FOR INSTITUTIONAL CLAIMS

#### i. Scope

The SAFs for institutional claims (inpatient hospitals, outpatient facilities, skilled nursing facilities, hospices, and home health agencies) are a near universe of patient claim level data. The database is updated quarterly and HCFA estimates that the SAFs are at least 98% complete when the database is closed annually. There are Medicare beneficiaries for whom there are no claims, however. For example, beneficiaries enrolled in a Medicare Health Maintenance Organizations (HMOs) will not have claims during the period of enrollment. The outpatient SAF will be the primary source for information about the current payments received by dialysis facilities for treatment of ESRD patients.

#### ii. Years available

The Health Care Financing Administration (HCFA) institutional SAFs started with 1989 claims data. The institutional SAFs are updated quarterly with an annual closure of the database in July of the following year. Prior to 1989, a 20% subset of national Medicare institutional claims were collected as part of the MEDPAR system. The SAFs are available on line at HCFA using the HCFA Decision Support Access Facility (DSAF). The DSAF is a mainframe CLIST (a file containing a list of basic computer commands) that runs a program, which allows menu driven access to the actual data files which are stored near line in cartridges (stored in a robot which mounts the cartridges on demand).

#### iii. Number of observations

In 1999 for example, there were 12,239,392 inpatient claims of which 598,587 (4.9%) were for ESRD patients, 107,018,890 outpatient claims of which 5,472,423 (5.1%) were for ESRD patients, 3,154,837 skilled nursing facility (SNF) claims of which 98,393 (3.1%) were for ESRD patients, 1,274,572 hospice claims of which 12,658 (1.0%) were for ESRD patients, and 9,786,788 home health agency claims of which 314,120 (3.2%) were for ESRD patients.

#### iv. Key variables for cost determination

There are various payment and charge variables in the SAFs which would be useful for cost determination. There are two payment variables, the total payment amount, and the primary payer paid amount, which could help determine total payments for Medicare secondary payer patients if these data are reliably entered. There is also a total charge variable. The provider number can be used for allotting payments and charges to facilities. One of the types of record trailers for the claims is a Claim Revenue Center Group. The Claim Revenue Center Group contains a revenue center code identifying the type of center and a charge amount for the services provided in that center which will be useful for breaking down the components of the total charge amount.

| Variable name   | SAS variable name* |
|---|--------------------|
| Claim Payment Amount  | PMT_AMT            |
| National Claims History (NCH) Primary Payer Claim Paid Amount | PRPAYAMT           |
| Claim Total Charge Amount                                     | TOT_CHRG           |
| Provider Number   | PROVIDER           |
| Revenue Center Code   | REV_CNTR           |
| Revenue Center Total Charge Amount                            | REV_CHRG           |

\* The SAS system is an integrated system of software providing complete control over data access, management, analysis, and presentation.

#### v. Key variables for case mix evaluation

In addition to demographic variables such as date of birth, sex, and race, the main portion of the SAF records contains other variables that are possibly useful for case mix adjusting. For example, the principal diagnosis and the E diagnosis (E codes identify the external cause of injuries, poisonings, or other adverse affects) will be useful for case mix adjusting. Three of the trailers: the Claim Diagnosis Group containing diagnoses (occurring up to 10 times); the Claim Procedure Group containing procedures (occurring up to 6 times); and the Claim Revenue Center Group containing the variables revenue centers, the HCFA Common Procedure Coding System (HCPCS) procedure code, initial modifier, second modifier, and unit counts (occurring up to 58 times) will be relevant for case mix adjusting.

| Variable name   | SAS variable name |
|---|-------------------|
| Beneficiary Birth Date  | BENE_DOB          |
| Beneficiary Sex Identification Code                             | SEX               |
| Beneficiary Race Code   | RACE              |
| Claim Principal Diagnosis Code                                  | PDGNS_CD          |
| Claim Diagnosis E Code  | DGNS_E            |
| Claim Diagnosis Code  | DGNS_CD           |
| Claim Procedure Code  | PRCDR_CD          |
| Revenue Center Code   | REV_CNTR          |
| Revenue Center HCFA Common Procedure Coding System (HCPCS) Code | HCPCS_CD          |
| Revenue Center HCPCS Initial Modifier Code                      | MDFR_CD1          |
| Revenue Center HCPCS Second Modifier Code                       | MDFR_CD2          |
| Revenue Center Unit Count                                       | REV_UNIT          |

#### vi. Ability to link to other data sources

All of the SAF files contain the Medicare Beneficiary Claim Account Number (SAS: CAN, either the Social Security Administration Social Security Number (SSN) or the Railroad Retirement Board Identification numbers (RRB)) and a Beneficiary Identification Code (SAS: BIC). Together the two codes form the Healthcare Identification Code (HIC = CAN + BIC), which can be used to link SAF records with other healthcare databases. Because beneficiaries occasionally change HICs, crosswalk files obtained from the ESRD Program Medical Management and Information System (PMMIS)/Renal Beneficiary and Utilization System (REBUS) (PMMIS/REBUS) IDEN data and/or from the Medicare Enrollment Database (EDB) must be obtained to perform a proper linkage.

#### vii. Collection form

The institutional claims are primarily filed electronically. A paper copy of the patient billing form, HCFA UB-92, appears in Appendix 1. The data are collected by HCFA Carriers, edited and forwarded to the HCFA Common Working File sites, further edited and forwarded to HCFA.

## **2. HCFA STANDARD ANALYTICAL FILE (SAF) FOR PHYSICIAN/SUPPLIER CLAIMS**

### **i. Scope**

The Physician/Supplier SAF is a near universe of Medicare patient physician/supplier claims. These files differ from the institutional claim SAFs for ESRD payment evaluation purposes in that they contain physician specific payments for services that may be covered under an outpatient ESRD PPS. The database is updated annually. HCFA estimates that the physician/supplier SAF is 98% complete at the time of annual closure.

### **ii. Years available**

The Physician/Supplier SAF started with the 1991 claims data. Prior to 1991 HCFA only maintained a 5% sample of physician/supplier claims. The physician/supplier SAF is updated annually with data becoming available in August of the following year.

### **iii. Number of observations**

To obtain physician/supplier claims data, a “finder” file is built and submitted to HCFA. HCFA staff members add the data request and the finder file to a batch of jobs to be run against the physician/supplier database monthly. In 1999, the finder file of ESRD patients yielded 23,376,898 physician/supplier claims for ESRD patients. The size of the complete physician/supplier database for all Medicare patients is not available on output documents. A reasonable estimate would assume that claims for ESRD patients are about 5% of the total claims and would yield an annual database of approximately 470 million claims.

### **iv. Key variables for cost determination**

On the main portion of the physician/supplier claims there are the following variables: payments, primary payer payments, submitted charges, and allowed charges, which could be used for cost determination. On the Carrier Line Item Record trailer the following variables: UPINs, provider specialties, type of service codes, payments, deductibles, primary payer payments, submitted charges, and allowed charges which could be used for cost determination.

| <b>Variable names</b>                      | <b>SAS variable names</b> |
|--|---------------------------|
| Claim Payment Amount                       | PMT_AMT                   |
| Carrier Claim Primary Payer Paid Amount    | PRPAYAMT                  |
| NCH Carrier Claim Submitted Charge Amount  | SBMT_CHRG                 |
| NCH Carrier Claim Allowed Charge Amount    | ALOWCHRG                  |
| Carrier Line Performing UPIN Number        | PRF_UPIN                  |
| Line HCFA Provider Specialty Code          | HCFASPCL                  |
| Line HCFA Type Service Code                | TYPSRVCB                  |
| Line NCH Payment Amount                    | LINEPMT                   |
| Line Beneficiary Part B Deductible Amount  | LDEDAMT                   |
| Line Beneficiary Primary Payer Paid Amount | LPRPDAMT                  |
| Line Submitted Charge Amount               | LSBMTCHG                  |
| Line Allowed Charge Amount                 | LALOWCHG                  |

## v. Key variables for case mix evaluation

On the main portion of the physician/supplier records, the following demographic variables possibly useful for case mix analysis and adjustment are found: birth dates, sex, and race. Also on the main section of the SAF records, principal diagnoses will be useful for case mix adjusting. Two of the trailers: the Carrier Claim Diagnosis Record containing the diagnoses occurring up to four times and the Carrier Line Item Record containing the variables: UPINs, provider specialties, type of service, HCPCS codes, and modifiers could be useful for case mix adjustment.

| Variable names                      | SAS variable names |
|-------------------------------------|--------------------|
| Beneficiary Birth Date              | BENE_DOB           |
| Beneficiary Sex Identification Code | SEX                |
| Beneficiary Race C                  | RACE               |
| Claim Principal Diagnosis Code      | PDGNS_CD           |
| Claim Diagnosis Code                | DGNS_CD            |
| Carrier Performing UPIN Number      | PRF_UPIN           |
| Line HCFA Provider Specialty Code   | HCFASPCL           |
| Line HCFA Type Service Code         | TYPSRVCB           |
| Line HCPCS Code                     | HCPCS_CD           |
| Line HCPCS Initial Modifier Code    | MDFR_CD1           |
| Line HCPCS Second Modifier Code     | MDFR_CD2           |

## vi. Ability to link to other data sources

The physician/supplier SAF contains the Medicare Beneficiary Claim Account Number CAN, either the Social Security Administration SSN or the RRB identification number and a BIC. Together the two codes form the HIC, which can be used to link SAF records with other healthcare databases. Because beneficiaries occasionally change HICs, crosswalk files obtained from the PMMIS/REBUS IDEN data and/or from the EDB must be obtained to perform a proper linkage.

## vii. Collection form

Physician/supplier data are submitted on the form HCFA 1500 which appears in Appendix 1. The data are collected by HCFA Regional Carriers and HCFA Durable Medical Equipment Regional Carriers (DMERC), edited and forwarded to the HCFA Common Working File sites, further edited, and forwarded to HCFA.

## 3. HCFA 2728, CHRONIC ESRD MEDICAL EVIDENCE FORM DATABASE

### i. Scope

The Medical Evidence Database in the PMMIS/REBUS system is a nearly universal patient level historical database that is used to establish or re-establish the medical eligibility of the patient for Medicare ESRD benefits. The database is updated daily.

### ii. Years Available

The collection of Medical Evidence data began in 1977 but it was not until 1982 that the submission of the Medical Evidence form became mandatory. Data are updated daily.

### **iii. Number of observations**

As of February 22, 2001 there were 1,134,711 records in the Medical Evidence Database. Approximately 80,000 records are added yearly corresponding to incident ESRD patients and to transplant failure patients returning to ESRD status. Old records are not removed at death.

### **iv. Key variables for case mix evaluation**

The Medical Evidence database contains information about insurance coverage at onset of ESRD, a field capturing the primary cause of ESRD (over 100 categories), and fields capturing the following comorbidities: congestive heart failure, ischemic heart disease, myocardial infarction, cardiac arrest, cardiac dysrhythmia, pericarditis, cerebrovascular disease, peripheral vascular disease, hypertension, diabetes, diabetes on insulin, chronic obstructive pulmonary disease, tobacco use, alcohol dependence, drug dependence, HIV positive, and AIDS. Various laboratory values are also coded: hematocrit, hemoglobin, serum albumin, creatinine, urea clearance, and the BUN, all of which are indicators of the patient's health status.

### **v. Ability to link to other data sources**

The Medical Evidence database contains the Medicare Beneficiary CAN and a BIC. Together the two codes form the Healthcare Identification Code (HIC), which can be used to link Medical Evidence records with other healthcare databases. Some care is needed with such a linkage, however as Medical Evidence records for patients not already eligible for Medicare benefits are coded with a BIC of ZZ. The BIC ZZ is not a standard Medicare BIC and for patients with such a BIC (and often for those with a BIC of T) patient matching has to be done on the basis of other identifiers (e.g., surname, first name, SSN, birth date, sex)

### **vi. Collection form**

Medical Evidence data are collected on the form HCFA 2728 which appears in Appendix 1. The data are collected by the HCFA ESRD Networks and forwarded to HCFA.

## **4. HCFA ANNUAL FACILITY SURVEY**

### **i. Scope**

The HCFA Annual Facility Survey (AFS) is a near universe of facility level data collected annually from free-standing and hospital related dialysis facilities.

### **ii. Years collected**

The HCFA Annual Facility Survey has been collected annually since 1980. With the addition of non-Medicare certified Veteran's Administration facilities in 1992, the survey is completed by more than 99% of existing dialysis facilities.

### **iii. Number of observations**

In the 1998 Facility Survey, 3,648 facilities completed the survey and in 1999, 3,881 facilities completed the survey. The number of facilities has been increasing each year since the inception of the survey.

### **iv. Key variables for cost determination**

The provider address is part of the survey and the data fields: city, SSA county code, Federal Information Processing Standard (FIPS) county code, and zip code may be useful for determining

urbanality as part of potential price adjusters. The survey also provides counts by modality of treatment (hemodialysis, peritoneal dialysis) at the beginning and end of the survey period which can be used to validate counts determined from claims data. Similarly, data fields describe organs harvested, organs obtained, organs transplanted, and patients transplanted all of which may be relevant to cost determination. The survey contains the field, total stations, which might be utilized to determine cost effectiveness.

#### **v. Ability to link to other data sources**

The AFS does contain the Medicare provider number so that this database may be linked to other databases at the provider of care level.

#### **vi. Collection form**

The AFS is collected on the form HCFA 2744 which can be found in Appendix 1. The data are collected by the HCFA ESRD Networks and forwarded to HCFA.

### **5. CENTER FOR DISEASE CONTROL (CDC): NATIONAL SURVEILLANCE OF DIALYSIS-ASSOCIATED DISEASES IN THE UNITED STATES**

#### **i. Scope**

The CDC National Surveillance of Dialysis-Associated Diseases is a facility level database with a 90% response rate.

#### **ii. Years available**

The Centers for Disease Control and Prevention (CDC) has been conducting surveillance of hemodialysis-associated hepatitis since the early 1970s. In an effort to obtain a higher response rate, and thus more complete information, CDC initiated a cooperative program with the Health Care Financing Administration (HCFA) in 1976 that provided for a questionnaire from CDC to be included in HCFA's annual facility survey. Since collaboration with HCFA was begun, the CDC survey has been performed for calendar years 1976, 1980, 1982 to 1997, and 1999.

#### **iii. Number of observations**

Ninety percent of the completed 1999 AFS forms yields approximately 3,500 facilities completing the CDC survey.

#### **iv. Key variables for case mix evaluation**

In addition to variables addressing the occurrence of hemodialysis-associated hepatitis, other hemodialysis-associated diseases and practices not related to hepatitis have been included over the years. The CDC questionnaire is continually updated to collect data about hemodialysis practices and hemodialysis-associated diseases of current interest and importance. The on-going information about the presence of hemodialysis associated diseases may be useful for determining facility level comorbidity information for potential case mix adjustment.

#### **v. Ability to link to other databases**

The CDC survey has the Medicare provider number as an identifier of the provider of services and, therefore can be linked at the facility level with other databases.

**vi. Collection Form**

The collection form for this data is CDC 53.7, National Surveillance of Dialysis Associated Diseases (see Appendix I). The data are collected by the HCFA ESRD Networks together with the HCFA AFS and are forwarded to the CDC.

**6. MEDICARE COST REPORTS****i. Scope**

The Medicare Cost Reports are a nearly universal provider level database. All renal facilities that are certified by Medicare (free-standing or hospital based) are required to submit annually a detailed cost report containing a breakdown of costs.

**ii. Years available**

The Medicare Cost Reports for free-standing and hospital-based renal facilities have been collected for many years. Currently available on the HCFA web site are databases for the years 1994-99.

**iii. Number of observations**

There is one observation per facility per quarter and there were approximately 3,900 facilities reporting cost information in the last available cost report.

**iv. Key variables for cost determination**

There are 2 separate databases for Medicare Cost Reports, one for hospital based facilities and one for free-standing facilities. In both databases, however, total costs, FTE costs, erythropoietin (EPO) costs, other drug costs, and other institutional costs can be determined. These databases could be useful for providing overall cost values.

**v. Ability to link to other databases**

The Medicare Cost Reports database contains the Medicare provider number so that this database may be linked to other databases at the care provider level.

**vi. Collection form**

Two forms are used for the collection of Medicare Cost Reports. The independent renal facility (free-standing) form is HCFA 265-94 and the Hospital-based renal facility form is HCFA 2552-96 from which the renal minimum data set is generated from Worksheets S-2 and S-5 and Worksheets I 1-5. These data collection forms are included in Appendix 1. The data for hospital-based facilities and for free-standing facilities are generated in the facilities and forwarded directly to HCFA.

**7. MEDICARE ENROLLMENT DATABASE (EDB)****i. Scope**

The Medical Enrollment Database (EDB) is a universe of Medicare eligible patients. The EDB contains not only all currently eligible patients but also all historically eligible patients. The database is updated daily.

## ii. Years available

The EDB contains patients dating back to 1972. In particular, it contains Medicare ESRD patients from 1973, the first year that ESRD was a Medicare covered illness.

## iii. Number of observations

The ESRD subset of the EDB contains approximately 1.5 million patients as of February 22, 2001.

## iv. Key variables for cost determination

Four of the relations in the EDB are relevant to cost determination primarily by helping determine periods of eligibility and types of eligibility. The four relations are, 1) the patient identification relation from which the HICs, the birth dates, and the death dates are relevant variables 2) the primary payer relation from which the entitlement start dates and entitlement end dates are relevant (any entry here means that Medicare is a secondary payer) 3) the group health organization relation from which the entitlement start dates and end dates are relevant and, 4) the ESRD relation from which the entitlement start dates, end dates, sources, and termination reasons are relevant.

| Variable name                                    | SAS variable name |
|--|-------------------|
| Healthcare identification Code                   | HIC               |
| Birth Date                                       | BENE_DOB          |
| Death Date                                       | BENE_DOD          |
| Primary Payer Entitlement Start Dates            | PPBEG             |
| Primary Payer Entitlement End Date               | PPEND             |
| Group Health Organization Entitlement Start Date | GHOBEG            |
| Group Health Organization Entitlement End Date   | GHOEND            |
| ESRD Entitlement Start Date                      | ESRBEG            |
| ESRD Entitlement End Date                        | ESREND            |
| ESRD Entitlement Source Code                     | ESRSSC            |
| ESRD Entitlement Termination Reason              | ESRTRC            |

## v. Ability to link to other databases

In addition to the current HIC, the EDB contains a relation listing all HICs ever associated with each beneficiary and thus can be linked on the patient level with other databases. The list of HICs must be used to link data to other databases where the history of HICs is not present.

## vi. Collection Forms

There is no Medicare collection form for the EDB. The Medicare Enrollment Database is directly generated from the Social Security Enrollment Database with which it interacts daily to update eligibility fields and other information about status changes.

## **8. ONLINE SURVEY CERTIFICATION AND REPORTING SYSTEM (OSCAR)**

### **i. Scope**

OSCAR is a database that contains data from surveys of every institutional health care provider in the United States that is certified to provide services under either Medicare or Medicaid (or both). Seventy-five percent of active ESRD facilities were surveyed in the last five years, twenty percent in the last year.

### **ii. Years available**

The OSCAR began in October 1991 and was based on data from MMACS (Medicare/Medicaid Automated Certification System), which was discontinued in March 1990. Each facility's record contains information only from its most recent four surveys.

### **iii. Number of observations**

There were 16,886 records in the OSCAR on December 8, 2000. Each record contains up to 3,326 data items for each provider.

### **iv. Key variables for cost determination**

For ESRD facilities the OSCAR reports the types of services provided (e.g., hemodialysis, peritoneal dialysis, home training hemodialysis, home training peritoneal dialysis, home support peritoneal dialysis), the number of stations (total, hemodialysis, hemo training), the number of patients at a given time (each shift, each day for a week), the number of patients by treatment modality (total dialysis, hemodialysis, peritoneal dialysis, home patients), the number of staff members (registered nurses, licensed practical nurses, social workers, dieticians, technicians), and deficiencies (written policies/procedures re: hemodialyzer reuse, hours for dialysis scheduled for patient convenience, water for dialysis analyzed periodically, bacteriology of the dialysate). These data are potentially useful in checking the reliability of overlapping items on the Medicare cost reports and HCFA and CDC facility surveys, and as a source of information on quality deficiencies identified by state surveyors, which can be useful in the ongoing monitoring of care under the revised PPS.

### **v. Ability to link to other databases**

The OSCAR contains the Medicare provider number so that this database may be linked to other databases at the provider of care level.

### **vi. Collection form**

The OSCAR data are collected using a forms package that contains the Survey Report Form (SRF), the Medicare/Medicaid Certification and Transmittal Form (HCFA-1539) and Medicare/Medicaid applications for certification. Originally the complete forms package was sent online to central office update systems from the HCFA regional offices where the source document files were maintained. Currently State agencies survey facilities and key survey information into the system using modems from microcomputers located at State agency sites.

## **9. DEATH NOTIFICATION DATABASE**

### **i. Scope**

The Death Notification Database is a patient level set of data that is nearly universal on the subset of Medicare patients who have died. This database is updated daily.

**ii. Years available**

PMMIS began collection of the death notification forms in 1977.

**iii. Number of observations**

As of February 22, 2001 there were 765,048 death notification records in the Death Notification database. The Death Notification database is updated daily and is constantly growing. In the earlier years of this database, Death Notification forms were not universally completed for all patients.

**iv. Key variables for cost determination**

The death date, obtained from the Death Notification database or from the EDB, could be used for right censoring time series cost determination analyses.

**v. Key variables for case mix evaluation**

The cause of death from the Death Notification may prove useful for determining comorbid conditions for case mix adjustment.

**vi. Ability to link to other databases**

The Death Notification database contains the Medicare Beneficiary CAN and a BIC. Together the two codes form the Healthcare Identification Code (HIC), which can be used to link Death Notification records with other healthcare databases. Some care is needed with such a linkage, however as the HIC is not always present on this database and patient matching has to be done on the basis of other identifiers (e.g., surname, first name, SSN, birth date, sex). The Social Security Death Master File can be linked to these data in this way.

**vii. Collection forms**

The Death Notification database is based on data received on form HCFA 2746-U3 (see Appendix 1). The Death Notification forms are collected by the HCFA ESRD Networks and forwarded to HCFA.

**10. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN) TRANSPLANT DATA****i. Scope**

The Scientific Registry of Transplant Recipients (SRTR) database is a patient level set of data for the ongoing evaluation of the scientific and clinical status of solid organ transplantation in the United States. This database is updated monthly with data collected by the OPTN. The SRTR is administered by University Renal Research and Education Association (URREA), a not for profit health research foundation, in collaboration with the Kidney Epidemiology and Cost Center (KECC) at the University of Michigan. Kidney transplants account for approximately 64% of all transplants.

**ii. Years available**

The United Network for Organ Sharing (UNOS) began the collection of solid organ transplant data in 1988.

**iii. Number of observations**

As of May, 2001 there were waiting list records in the SRTR for 453,500 transplant candidacies. The database also includes clinical data from 267,122 transplants and 1,092,457 transplant followup records. The database is constantly growing.

#### iv. Key variables for cost determination

The transplant date, and the date of graft failure for kidney patients obtained from the SRTR database may be useful for determining cut-off points for cost determination (i.e. for right censoring time series cost determination analyses).

#### v. Key variables for case mix evaluation

There are comorbid conditions and laboratory test data collected prior to and during waitlisting. Some additional comorbid and laboratory data are collected at the time of transplant and for transplant followup reports, which could be pertinent in the event of a return to dialysis.

#### vi. Ability to link to other databases

Patient matching must to be done on the basis of identifiers such as surname, first name, SSN, birth date, and sex in order to link this data with other databases. Much of this work has already been done by the University of Michigan KECC to link the SRTR data with HCFA ESRD data. The resulting linked records will then have a Healthcare Identification Code (HIC) where available.

#### vii. Collection forms

The SRTR data is collected with the UNet (Service Mark not an acronym) on-line system by the OPTN.

## B. Data Systems

### 1. ESRD PROGRAM MEDICAL MANAGEMENT AND INFORMATION SYSTEM (PMMIS)/RENAL BENEFICIARY AND UTILIZATION SYSTEM (REBUS) (PMMIS/REBUS)

#### i. Databases

The following table describes the databases which comprise the PMMIS/REBUS data system.

| Database                   | Years available   | Description  | Data Source   |
|----------------------------|---|--|---|
| Patient Master File (IDEN) | 1977-present  | Basic patient identification, demographic, and eligibility data  | EDB, Networks   |
| Medical Evidence (ME)      | 1977-present extensively revised 1981   | Patient identification, demographic, and cause of ESRD data plus date of first dialysis  | HCFA Form 2728 ESRD Medicare Entitlement and/or Patient Registration  |
| Death Notification (DN)    | 1977-present extensively revised 1990   | Patient identification, place, date and cause of death (1 primary and up to 4 secondary, renal replacement therapy discontinued and reasons why, transplant, functional, dialysis after transplant                                   | HCFA ESRD Death Notification Form 2746  |
| Transplant Event Data      | 1977-present form revised 1982, parallel collection by HCFA and UNOS* 1987-1993 | Transplant date, donor characteristics, recipient characteristics  | ESRD Transplant Information, form HCFA-2745; Numerous UNOS/PHS/HCFA forms replaced by UNET system – OPTN Network level.   |
| Transplant Follow-up Data  | 1977-present revised like transplant event data                                 | Patient status, graft status, patient location, immunosuppressive utilization, death dates, cause of death, cause of graft failure collected at discharge, 6 months post transplant, each year post transplant, and at graft failure | HCFA ESRD Transplant Follow-up Form; UNOS/PHS/HCFA Recipient Follow-up forms replaced by UNET system – OPTN Network level |
| Dialysis Summary           | 1977-present  | Patient identification, quarterly summary of dialysis bills (includes a summary of   | Common Working Files  |

|                 |              |   |                      |
|-----------------|--------------|---|----------------------|
| (QDIAL)         |              | sessions and EPO and dialysis charges after circa 1995 but not of total charges or payments)                    |                      |
| Inpatient Stays | 1977-present | Patient identification, up to 5 diagnoses, up to 3 procedures, DRG, and EPO charge (no total charge or payment) | Common Working Files |

## ii. Enhancements to input databases

On the IDEN database records, PMMIS/REBUS includes information about the most recent dialysis provider, date of last dialysis session, dialysis type, information about the first and last administration of EPO, identification of the first dialysis treatment date, and the cause of ESRD. PMMIS/REBUS verifies modality, provider and setting and also tries to catch and remove duplicate entries (caused mainly when a patient who previously had an “XX” or “T” BIC becomes Medicare eligible and receives a ‘real’ HIC and BIC).

On the Medical Evidence database, PMMIS/REBUS runs a test algorithm to verify eligibility for Medicare and certain dates and adds the results of the test. Also, a certification date is added.

On the Death Notification database, PMMIS/REBUS runs a set of edits and indicates the result in a variable.

## 2. KIDNEY EPIDEMIOLOGY AND COST CENTER (KECC) ESRD DATABASE

### i. Databases

The following table describes the databases which comprise the KECC data system.

| Database                           | Years available | Description   | Data Source   |
|------------------------------------|-----------------|---|---|
| Institutional Medicare Claims      | 1989-present    | All claims data from inpatient hospitals, Skilled Nursing Facilities (SNFs), Outpatient facilities (hospital-based and free-standing), Hospices, and Home Health Agencies. The database contains total charges, total payments, dialysis sessions and charges, EPO administrations, doses and charges, DRG (inpatient only) | HCFA Standard Analytical Files (SAFs)<br>REBUS/PMMIS Dialysis Summary and Inpatient Stays |
| Institutional Medicare Details     | 1989-present    | Key variables to link to the relevant Claim, a code value which can be a claim condition code, a diagnostic code, an ICD-9 procedure code, a revenue center code, a discharge status code or a claim value code corresponding to trailer records in the HCFA SAF  | HCFA Standard Analytical Files (SAFs)<br>REBUS/PMMIS Dialysis Summary and Inpatient Stays |
| Physician/Supplier Medicare Claims | 1991-present    | Line items containing diagnoses, HCFA Common Procedure Coding System (HCPCS) codes, Service code, type of service code, place of service code, submitted charge, allowed charge, and payment, provider Universal Physician Identification Number (UPIN), provider specialty code, and primary payer code                    | HCFA Physician/Supplier SAFs  |
| Patients                           | 1977-present    | PMMIS/REBUS patient demographics, unique patient id, date of first ESRD service computed  | HCFA Patient Master File (IDEN), Medical Evidence,  |

|                          |              |  |   |
|--------------------------|--------------|--|---|
|                          |              | based on PMMIS/REBUS Medical Evidence database, Medicare dialysis claims, and kidney transplant dates, death date and causes of death from PMMIS/REBUS Death Notification database   | inpatient SAF, outpatient SAF, UNOS transplant files  |
| Medical Evidence         | 1977-present | Same as PMMIS/REBUS with unique patient id   | HCFA Medical Evidence (ME)  |
| Facility                 | 1980-present | Derived from HCFA Annual Facility Survey with added unique facility ID   | HCFA Annual Facility Survey   |
| Residence                | 1989-present | A residence history (up to 50 occurrences) for ESRD patients   | Derived from HCFA EDB   |
| Inpatient Hospital Stays | 1989-present | Contains from and through dates, DRG, dialysis sessions, up to 10 diagnoses, up to 10 procedures, and the current ESRD treatment modality.   | Derived from the inpatient SAF and the KECC Treatment History database.                                       |
| Treatment History        | 1989-present | The treatment history is a record of time periods in one modality of treatment with one provider. In addition to the overall history, periods following a 60-day rule are also maintained, i.e., less than 60 days on a modality in one provider are not treated as a separate period. | Derived from Patients, Medicare Claims (SAFs), PMMIS/REBUS Quarterly Dialysis and PMMIS/REBUS Inpatient Stays |
| Transplant               | 1977-present | Patient Demographic and clinical transplant details  | UNOS OPTN Scientific Registry of Transplant Recipient Files (SRTR)  |
| Transplant Follow-up     | 1977-present |  | SRTR Follow-up Files  |
| Transplant Wait list     | 1995-present |  | SRTR Waitlist Files   |

## ii. Enhancements to input database

The primary addition to the HCFA data from which the KECC databases are derived is a unique patient identifier. A unique patient identifier is assigned and is used across all of the data sources, allowing the various sources to be treated as a single integrated database. Patient IDs are assigned to each data record by matching the patient identifiers on that record to a central table of patients. This process eliminates a substantial number of duplicate patient records.

A date of first ESRD service is computed for each patient based on the Medical Evidence Form, Medicare dialysis claims, and kidney transplant dates. This date is used as the start of ESRD for each patient. This process also determines whether there is enough data for this patient to establish that they really have ESRD.

For kidney transplants, the database computes transplant failure dates based on the Medical Evidence Forms indicating a return to dialysis, a resumption of Medicare dialysis claims, the occurrence of a subsequent transplant, or a Transplant Follow-up record indicating a graft failure.

## **3. STANDARD INFORMATION MANAGEMENT SYSTEM (SIMS)**

### i. Databases

SIMS is a data entry and management system being developed by the HCFA ESRD Networks. The following table describes the databases that are planned for inclusion in SIMS.

|                        |    |   |
|------------------------|----|---|
| Patient Event Tracking | NA | Patient identification, demographics, eligibility, provider, modality with a history of changes |
|------------------------|----|---|

|                                 |    |  |
|---------------------------------|----|--|
| Medical Evidence                | NA | Data entry of HCFA 2728  |
| Death Notification              | NA | Data entry of HCFA 2746  |
| Facility Information            | NA | Data for partial generation of HCFA 2744, patient counts per facility to be generated from Patient Event Tracking database |
| Beneficiary grievances/contacts | NA | NA   |
| Quality Improvement Projects    | NA | NA   |

## ii. Enhancements to input database

When completed SIMS will allow data entry of ESRD data at the facility level with common fields, common editing, and common acceptable ranges of values that should greatly enhance the quality of the data. Currently Medical Evidence and Death Notification Forms are being transmitted by SIMS to HCFA.

When available, patient event tracking across facilities and networks will be of prime importance to determining the facility responsible for each patient at any given point of time. The key advantage of the SIMS system is the availability of variables from currently disparate sources including variables for case mix adjustment, and quality/practice pattern monitoring (see HCFA-2728 for specific variables). The SIMS is intended to centralize and standardize collection of data from several sources and to provide continuously updated data.

## **4. UNITED STATES RENAL DATA SYSTEM COORDINATING CENTER (USRDS CC) DATABASE**

### i. Databases

The following table describes the databases which comprise the USRDS CC data system which is maintained by the Minneapolis Medical Research Foundation (MMRF).

| Database                           | Years available | Description  | Data Source                            |
|------------------------------------|-----------------|--|--|
| Institutional Medicare Claims      | 1989-present    | All claims data from inpatient hospitals, Skilled Nursing Facilities (SNFs), Outpatient facilities (hospital-based and free-standing), Hospices, and Home Health Agencies. The database contains total charges, total payments, dialysis sessions and charges, EPO administrations, doses and charges, DRG (inpatient only), | HCFA Standard Analytical Files (SAFs). |
| Physician/Supplier Medicare Claims | 1991-present    | Line items containing diagnoses, HCFA Common Procedure Coding System (HCPCS) codes, Service code, type of service code, place of service code, submitted charge, allowed charge, and payment, provider Universal Physician Identification Number (UPIN), provider specialty code, and primary payer code.                    | HCFA Physician/Supplier SAFs           |
| Patient Roster                     | 1977-present    | PMMIS/REBUS patient demographics, unique patient id  | HCFA Patient Master File (IDEN)        |
| Medical Evidence                   | 1977-           | Same as PMMIS/REBUS with unique patient id   | HCFA Medical Evidence                  |

|                          |              |  |   |
|--------------------------|--------------|--|---|
|                          | present      |  | (ME)  |
| Facility                 | 1980-present | Derived from HCFA Annual Facility Survey with added unique facility ID   | HCFA Annual Facility Survey   |
| Residence                | 1989-present | A residence history (up to 50 occurrences) for ESRD patients   | Derived from HCFA EDB   |
| Inpatient Hospital Stays | 1989-present | Contains from and through dates, DRG, dialysis sessions, up to 10 diagnoses, up to 10 procedures, and the current ESRD treatment modality.   | Derived from the inpatient SAF and the Treatment History database.  |
| Treatment History        | 1989-present | The treatment history is a record of time periods in one modality of treatment with one provider. In addition to the overall history, periods following a 60-day rule are also maintained, i.e., less than 60 days on a modality in one provider are not treated as a separate period. | Derived from Patients, Medicare Claims (SAFs), PMMIS/REBUS Quarterly Dialysis and PMMIS/REBUS Inpatient Stays |
| Transplant               |              | Patient Demographic and clinical transplant details  | UNOS OPTN Recipient Files   |
| Transplant Followup      |              |  | UNOS OPTN Followup Files  |
| Transplant Wait list     |              |  | UNOS OPTN Waitlist Files  |

## ii. Variables calculated and added to input database

The current USRDS database for 2000 has made use of a graphical information system (GIS) to enhance the geographical presentation of ESRD data.

## C. Special Studies

### 1. DIALYSIS MORTALITY AND MORBIDITY STUDY (DMMS)

#### i. Sample

The USRDS Dialysis Morbidity and Mortality Study (DMMS) is an observational study in which demographic, comorbidity, laboratory, treatment, socioeconomic, and insurance data were collected for a large random sample of U.S. dialysis patients, using the patient's dialysis records. The study included 4 phases ("waves") of data collection on over 20,000 randomly selected dialysis patients over a 3-year period. Almost all Medicare certified dialysis facilities participated in one of the four waves. Pediatric dialysis facilities (defined as those having 30% or more pediatric patients) were excluded from participation in the DMMS as they had just been included in a separate Pediatric Growth and Development Study.

A sample of dialysis units (N=550) was randomly selected for Wave I of the DMMS from the Master List of Medicare Approved Dialysis Facilities as of December 31, 1993. This Master List exists as part of the annual Medicare Survey of Dialysis Facilities. The sample of patients selected for Wave I of the DMMS was selected from a national census of hemodialysis patients as of December 31, 1993. This census of hemodialysis patients (Medicare and non-Medicare) was provided by the 18 ESRD Networks. Patients were excluded if they were less than 15 years of age, in training for any self care treatment, or receiving Continuous Ambulatory Peritoneal Dialysis (CAPD), home hemodialysis or other dialysis on 12/31/93. From the 550 selected facilities, a total of 6300 in-center hemodialysis patients were selected for inclusion in the study (to achieve a sample size goal of 6000 patients, assuming a 95 percent response rate) in the following manner: To increase the number of incident (new) patients included, all hemodialysis patients starting therapy in December of 1993 were included

(N=1100 expected). The remaining 5200 patients were randomly selected from the remaining eligible patients receiving hemodialysis on December 31, 1993 at the selected facilities. Approximately one in five patients were selected from each facility to obtain the desired sample size. Of these, it was expected that approximately 25 percent would have started hemodialysis in 1993 (also labeled “incident”) and the remainder would have started in prior years (labeled “prevalent”). The “core” set of data questions was administered to all patients in the sample. Patients identified as incident in 1993 (all patients starting hemodialysis in December 1993 in addition to a random sample of patients starting ESRD treatment in the remaining months of 1993 and on hemodialysis on December 31, 1993) were included in the “non-core” study of vascular access. A random selection of one half of the overall sample of 6300 patients was drawn for the nutrition and anemia studies.

A sample of U.S. dialysis units was randomly selected for each of Waves 2, 3, and 4 of the DMMS. The dialysis units included in Waves 2, 3 and 4 are each a random selection of 25 percent of the dialysis units in the United States listed on the Master List of Medicare Approved Dialysis Facilities as of December 31, 1993 and not already included in Wave 1. The Master List exists as part of the annual ESRD Facility Survey.

Wave 2 of the DMMS is a prospective study of incident hemodialysis and peritoneal dialysis patients (Medicare and non-Medicare) who initiated ESRD therapy in 1996. Since Wave 2 included a sample of patients starting dialysis in 1996/97, the dialysis units for this Wave were a random selection of 25 percent of the dialysis units listed on the December 1993 Master List in addition to all new dialysis units opening after January 1, 1994. For the purposes of this study, the definition of an incident patient is one who is receiving regular in-center hemodialysis or any type of peritoneal dialysis treatments for chronic renal failure at least once weekly for the first time. This does not include patients receiving intermittent dialysis treatments for fluid overload or heart failure. Modality type was identified on day 60 of ESRD. Patients treated with peritoneal dialysis or hemodialysis on this date (day 60) were eligible. The modality assignment for patients on HD but training for PD on day 60 was deferred 10 days. Patients were excluded if they were on another form of therapy e.g. home hemodialysis, if they had a previous transplant, or if they were less than 18 years of age. The study start date was considered the date that the modality type was defined (about day 60 of ESRD). To obtain comparable numbers of PD and HD patients within the sample, PD patients were oversampled. All eligible incident PD patients were included whereas only twenty percent of all corresponding HD patients were included, selecting only those whose social security number ended with “2” or “9”.

From among the randomly selected dialysis units for Waves 3 and 4, the sample of patients selected for Waves 3 and 4 of the DMMS was selected from a national census of hemodialysis patients as of December 31, 1993. The 18 ESRD Networks provided this census of hemodialysis patients (Medicare and non-Medicare). For all Waves, patients were excluded if they were less than 15 years of age, if they were on home hemodialysis, or if they had a previous transplant. For Waves 3 and 4, patients were also excluded if they were in training for any self-care treatment or if they were on peritoneal dialysis. For Wave 2, patients on peritoneal dialysis were included. Modality assignment for Wave 2 was defined on day 60 of ESRD. The modality assignment for patients on HD but who were training for PD on day 60 was deferred 10 days.

## ii. Years

The year for which information was requested for Waves 1, 3, and 4 is 1994. Wave 2 describes events occurring in 1996-1997.

### **iii. Key variables for case mix evaluation**

The core component of the DMMS contains information on comorbid conditions present in 1994 and practice patterns, both of which will be useful for case mix adjusting and for checking the sensitivity of case mix adjusting. The DMMS may be used as a source of comorbidities that are collected after the onset of ESRD. Comorbidities for this nationally representative sample can be linked to claims data to develop benchmark cost models and determine how sensitive these models are to the exclusion of comorbidities that would be difficult to reliably measure on a national basis. Also, the prevalence of comorbidities in DMMS could be compared to other sources such as the HCFA 2728 and claims records. Among the comorbid conditions captured are smoking status, prior diagnosis of congestive heart disease, coronary artery disease, angina, myocardial infarction, cardiac arrest, cerebrovascular accident, transient ischemic attacks, peripheral vascular disease, absent foot pulses, claudication, congestive heart failure, pericarditis, diabetes, lung disease, neoplasm (together with site), bilateral amputee, cardiomegaly by X-ray, left ventricle hypertrophy by EKG or echocardiogram, and AIDS. Also captured are prior treatments such as bypass surgery, coronary angioplasty, coronary angiography (with status), amputation due to peripheral vascular disease, limb amputation (other cause), and insulin therapy. Among the therapies captured are whether parenteral iron was administered, the route of administration, the date of first administration, the dose, the number of administrations per week; whether EPO was administered, units of EPO per administration, units of EPO per week, EPO administration start date post ESRD, most recent hematocrit prior to administration, and whether EPO was administered prior to ESRD onset.

### **iv. Linkability**

The collection form for the DMMS Waves, 1, 3, and 4 contained social security numbers (SSNs), and Medicare HICs, name, and sex obtained from the December 31, 1993 Network censuses, as well as space for correction by the facility. Wave 2 contained space for the facility to enter name, sex, SSN, HIC, and birth date. Given this information we were able to link more than 90% of the DMMS data with the KECC database; the non-linked patients are predominantly not eligible for Medicare.

### **v. Collection form and method**

The data collection forms for the various waves of the DMMS and for the various special studies that accompanied each wave appear in Appendix 1. The DMMS forms were filled out in the dialysis facility by facility staff. A validation study was performed by network staff who validated a subset of the data collected on the core form.

## **2. DIALYSIS OUTCOMES AND PRACTICE PATTERNS STUDY (DOPPS)**

### **i. Sample**

The Dialysis Outcomes and Practice Patterns Study (DOPPS) is a prospective, longitudinal, observational study of hemodialysis patients and facilities in seven countries with large populations of dialysis patients: France, Germany, Italy, Japan, Spain, the United Kingdom, and the United States. The goal of the study is to determine which practice patterns are associated with the best patient outcomes, with adjustment for a wide range of patient case-mix characteristics. The primary outcomes of interest are mortality, hospitalization, quality of life, and vascular access events. The facility sample from the seven countries consists of 327 hemodialysis centers in which 24,392 patients were treated

when the study began. A random sample of 10,332 patients has been selected thus far for more detailed longitudinal data collection. Departing patients are replaced during the study. A study coordinator at each dialysis facility collects baseline and longitudinal patient data. Patients are asked to complete a questionnaire that addresses quality of life on a yearly basis. The medical director and nurse manager in each facility complete a practice pattern questionnaire. The study was initiated sequentially in the United States, then Europe, and finally Japan, between 1996 and 1999 and is currently ongoing in all countries.

The countries were selected on the basis of geographic diversity, variation in practices and outcomes, and relatively large numbers of ESRD patients. The basic study design and study instruments are shared across all countries with minor local modifications as necessary.

Facility Sample. In the United States, a stratified random sample of chronic hemodialysis facilities was selected to achieve variation in practice patterns and outcomes. The initial sampling frame consisted of a random subsample of a listing of dialysis facilities published by the Health Care Financing Administration (HCFA). For each dialysis facility, a measure of mortality was estimated using the adjusted mortality ratio (AMR) for the year 1996, based on publicly available measures of crude mortality, mean age and percent of diabetic patients in each facility. The AMR estimates the standardized mortality ratio (SMR), which is the ratio of observed to expected deaths in a facility where expected deaths are based on the age, race, sex, and diabetic status of each patient treated in the center. The AMR is based on average rather than individual patient characteristics. A simple random sample of 97 dialysis facilities was initially selected without regard to the AMR. In order to augment the representation of facilities with extremes in outcomes (and potentially in practice patterns), a purposive sample of 31 facilities were drawn from the upper tail and 33 from the lower tail of the AMR distribution. A representative description of US dialysis facilities can be obtained using the random sample or the overall sample weighted by the probability of facility selection.

In Europe, the sample is composed of 20 dialysis centers from each of the five participating countries for a total of 100 facilities. Facilities were sampled from all dialysis facilities in each country, obtained from national sources with the assistance of the country investigators. Within each country, the sample was proportionately stratified by geographic region and facility type in order to assure that the facilities were representative. As the number of geographic regions generally exceeded the sample size, sample stratification was achieved by setting a maximum quota for each region. The facility type strata were determined by the conventions used in each country (e.g. center vs. satellite centers). In Japan, 66 dialysis facilities were enrolled from a national list of hemodialysis facilities. The sample was stratified by geographic region (prefecture) and facility type.

Facilities treating fewer than 20 chronic hemodialysis patients in the US and fewer than 25 elsewhere were excluded for reasons of study efficiency (the minimum size was increased for Europe and Japan because fewer facilities were enrolled than in the US). This restriction led to the exclusion of fewer than 5% of all hemodialysis patients in each country. Facilities treating less than the threshold number of patients after recruitment (because the patient count declined after facility enrollment) were retained in the study.

Patient Sample. At the start of the project, the study coordinator in each participating facility listed the census of prevalent in-center hemodialysis patients greater than 17 years of age. This census listing includes basic patient information such as age, race, sex, and the cause of ESRD. At regular intervals of approximately every four months, the census is updated to indicate all new and departed patients

since the last census update. The date and reason for each departure are entered on the census form. Within each participating facility, the census listing was used to select a random sample of 20 to 40 patients, varying according to the size of the facility. Detailed longitudinal data collection is performed for this representative sample of patients. Departed patients are replaced approximately every four months, using random selection from the patients entering the dialysis facility during the interval.

Data Collection. A study coordinator in each participating dialysis center performs data collection. In addition, specific questionnaires are completed by sampled patients, the medical director, and the nurse manager of each participating facility. The cumulative census form provides basic data about all hemodialysis patients treated in each facility (see above). The study coordinator completes a detailed medical questionnaire for each patient selected for the sample. Medical questionnaire information is largely abstracted from the medical record, supplemented by personal knowledge of the patients. The medical questionnaire addresses a variety of areas including ESRD history, medical and psychosocial history, dialysis prescription, laboratory data, and prescribed medications at the time of study enrollment. The study coordinator completes an interval summary approximately every four months for each sampled patient. The interval summary updates laboratory data, dialysis prescription, medication use and the interval occurrence of hospitalizations, outpatient events and medical interventions, vascular access events, and departures. Patients are asked to complete a questionnaire that includes the Kidney Disease Quality of Life survey (KDQOL™) and modules concerning pre-ESRD care, economic aspects of ESRD, employment and rehabilitation. Patients repeat the KDQOL™ survey each year.

Facility practice patterns are measured by comprehensive questionnaires that are completed by the medical director and the nurse manager (or designee) at each dialysis center. These surveys address a wide range of practice and management issues including dialysis prescription, water quality, dialyzer re-use practices, staffing patterns, nutrition, vascular access, and health maintenance and are repeated at yearly intervals. In addition, the summary of patient-specific treatments at the facility level provides valuable information about practice patterns.

The same data collection instruments are used in each country, with minor modifications as appropriate (i.e. incorporation of local terminology, deletion of answer choices known to be unavailable). The questionnaires were translated from American English to French, German, Italian, Japanese, Spanish, and Queen's English. In each country, the translated questionnaires were reviewed for meaning and context by nephrologists and pre-tested in dialysis centers not selected for the study.

## **ii. Years**

DOPPS data collection began in 1996 and is continuing.

## **iii. Key variables for case mix evaluation**

DOPPS can provide an extensive list of comorbidities (see the list under DMMS) which are collected longitudinally. With DOPPS the development of comorbidities in a dialysis population can be traced. This provides a unique opportunity for testing case mix methodologies.

## **iv. Linkability**

Of course, only the patients from dialysis centers in the United States can be linked with Medicare databases and since DOPPS has non-Medicare patients enrolled, those patients will not link. The Social Security Number is collected by DOPPS and can be matched against the EDB to obtain HICs

for those DOPPS patients who are also eligible for Medicare. Nearly 90% of DOPPS United States patients can be linked with Medicare data.

#### **v. Collection forms**

The various data collection forms used in the United States for DOPPS appear in Appendix 1.

### **3. HCFA MANAGED CARE DEMONSTRATION (DEMO)**

#### **i. Sample**

The HCFA Managed Care Demonstration seeks to test the notion that managed care can raise the health status of beneficiaries while reducing out-of-pocket costs and overall program costs. The incentive is to provide high quality care such that high cost, acute health episodes are averted. For example, approximately 38% of ESRD program costs are for hospitalizations, and in theory, many of these can be prevented through high delivered dose of dialysis, better care of vascular access, and other “best practices.”

The Medicare ESRD Demonstration project was begun at three sites across the country: Health Options, Inc. (HOI), a subsidiary of Blue Cross/Blue Shield of Florida, based in Miami; Southern California Kaiser Permanente Medical Group (KP), based in Los Angeles; and Xantus Health Care Corporation, based in Nashville, Tennessee. Each program developed its own unique structure, though similarities exist. The demonstration was initiated in September, 1996 and the sites began enrolling patients in 1997.

Managed Care (MC) can be described as a system in which a single, legally-entitled entity accepts the financial and clinical responsibility for the coordination and funding of a broad spectrum of medical care for a group of patients. An important part of this MC concept is that the legal entity agrees to accept a prospective fixed price per patient for a given time period. MC can be contrasted to fee-for-service (FFS) in which the payment structures are to reimburse providers for each medical service on an individual patient basis. The system in place in the United States for End Stage Renal Disease (ESRD) patients is primarily FFS, although the composite rate represents a prospective pricing structure for outpatient routine dialysis services; applied on a per treatment basis. Medicare is the primary insurer for over 90 percent of the ESRD patients in the U.S. regardless of their age. MC is a major alternative for the FFS system and is a central part of health care reform proposals, both conceptually and practically. Currently Federal law, which governs Medicare, does not permit ESRD patients to join Medicare MC plans, although patients who are in a Medicare Risk MC plan at the time they develop ESRD are eligible to elect to continue MC coverage.

In an attempt to better understand the potential benefits and limitations of MC to provide services for patients with ESRD, the US Congress legislated that a demonstration (Demo) be conducted to test the feasibility and appropriateness of treating ESRD patients under MC plans. In 1996, HCFA made three separate awards to health maintenance organizations to conduct a demonstration of insuring ESRD patients who were otherwise eligible for Medicare primary insurance. These MC organizations selected for the Demo were allowed considerable flexibility in the design and implementation of their insurance plans.

Of the three health plans originally chosen to conduct the Demo, only two have survived into the current period, namely Health Options Inc. (HOI) of Southern Florida and Kaiser Permanente (KP) of Southern California. These Demo plans offer two distinct models of care. The Florida site has primarily fee-for-service (FFS) contracts with the majority of their providers, with the exception of the capitation arrangements made with primary care nephrologists and select specialists. The KP Demo plan is a closed-practice plan for specialist and inpatient care, with the majority of outpatient dialysis services provided under FFS provider contracts (although over the course of the Demo, KP has been internalizing more of their dialysis care). Both plans offer outpatient medications included in their formulary at no cost to patients and medical care with no patient coinsurance obligations. Coinsurance and copayments were waived as part of the “extra benefits” offered, over and above the benefits offered in the standard Medicare Risk HMO, which were intended to equal the additional 5 percent of the Average Annual Per Capita Cost (AAPCC) that the health plans were reimbursed for conducting the Demonstration. In contrast, standard FFS Medicare does not generally cover outpatient medications and typically has a 20 percent patient coinsurance obligation for nearly all medical services.

Existing adult chronic renal failure patients (including hemodialysis (HD) and peritoneal dialysis as well as functioning kidney transplant patients) for whom Medicare was the primary insurer and who were resident in the two geographic areas, were initially recruited by the two Demo sites indirectly through marketing materials mailed by HCFA. Subsequently, the Demo sites were also given opportunities to market directly to ESRD patients and staff at local dialysis facilities. Patients who were already enrolled in the KP Medicare Risk HMO plan were listed and randomized by HCFA and given the opportunity to join the Demo on a two-for-one basis (i.e., for every two new enrollees, KP could enroll one of their existing MC patients into the Demo plan). These KP patients are referred to as “rollover” patients or KP RO. Enrollment commenced in February and June 1998 for the CA and FL Demo sites respectively. Active recruitment and intake was continuous for at least 12 months at both sites, with “passive” enrollment continuing until the end of the three-year Demonstration period.

## **ii. Comparison samples**

Nationally Representative DOPPS Patients. Demo HD patients are compared to a nationally representative sample of US in-center adult HD patients from the Dialysis Outcomes and Practice Patterns Study (DOPPS). Because DOPPS patients are representative of the entire U.S. and thus include only a few dialysis facilities that are located within the Demo service areas, for the focused geographic comparisons, we broadened our selection of DOPPS patients to include those residing anywhere within CA or FL. Some analyses compare Demo patients to the entire US DOPPS sample and are adjusted for geographic region of the US in these instances.

Approximately 82 percent of DOPPS patients have Medicare primary FFS insurance. Among these patients, a small number (about 5 percent) are covered by Medicare Risk HMO plans. The remaining 18 percent are insured by private health plans (of which, about 30% are managed care plans) or state Medicaid. These patients are most likely in the midst of the coordination period prior to their becoming eligible for Medicare primary coverage.

Matched Geographic Comparison Patients. In addition to the DOPPS, matched samples of FFS and non-Demo MC (NDMC) (i.e., Medicare Risk HMO) patients were also randomly selected from Demo service area dialysis facilities for comparison to the Demo patients. The FFS and NDMC patients were matched to the Demo patients according to their distributions of age, race, and time since onset of ESRD.

Managed Care Kaiser Rollover Patients. Patients who were “rollovers,” i.e., those already covered by the Kaiser MC plan who were randomly selected to “roll over” into the Demo plan, need to be treated separately and are denoted as KP RO. Because these patients were found to differ from those enrolling in the Demo program and from FFS, these patients will be separated from the new KP Demo enrollees. A comparison of these KP RO patients to the selected matched sample of NDMC patients may be of interest to see whether differences exist between the two MC groups.

CA and FL Medicare FFS Patients. All ESRD patients residing in California and Florida who were on hemodialysis on December 1, 1998 and had Medicare as their primary insurer were identified using the Medicare Enrollment Database. Claims data from the HCFA Standard Analysis Files were queried for these patients to be used in the analysis of cost and utilization.

### **iii. Years**

The Demo collected data in 1997-98.

### **iv. Key variables for cost determination**

The Demonstration allows comparison of managed care costs compared to fee for service costs among several groups of Medicare patients. The specific variables are the variables of relevance in the HCFA SAFs.

### **v. Key variables for case mix evaluation**

The Demo used the same set of comorbid conditions that are collected for DOPPS patients.

### **vi. Linkability**

In general the Demo patients can be linked to other Medicare data but, of course, there will be no claims data for these patients during their enrollment period. The Demo did find claims for the year prior to enrollment for the majority of the Demo patients (some had been previously enrolled in the KP MC plan).

### **vii. Collection forms**

See Appendix 1.

## **4. FRESENIUS MEDICAL CARE DATABASE**

### **i. Scope**

The Fresenius database includes clinical indicators and cost elements for the approximately 1,000 ESRD facilities in the Fresenius chain. Initial discussions with Fresenius management indicate a willingness to share relevant data with us for this project. A separate report is planned to summarize data that are available from the Fresenius database.

**ii. Years available**

Undetermined.

**iii. Number of observations**

This database includes about 25% of all dialysis patients.

**iv. Key variables for cost determination**

Data from this study are likely to be available to HCFA and may be useful in occasional special studies. Data may include cost report summaries and billing information.

**v. Ability to link to other databases**

Patient data in this database will need to be kept confidential. These data may be available but the ability to link to other databases is not yet clear.

**vi. Collection Forms**

The data collection forms for this study are not available.

**5. HEMODIALYSIS STUDY****i. Scope**

The Hemodialysis Study, directed by Tom Greene Ph.D. of the Cleveland Clinic Foundation, is a multicenter randomized clinical trial of hemodialysis prescriptions for patients with end stage renal disease that includes participants from over 65 dialysis facilities associated with 15 clinical centers in the United States.

**ii. Years available**

The Hemodialysis Study has been collecting data since 1994. Formal randomization of patients began in 1995. The study is scheduled to end in the fall of 2001.

**iii. Number of observations**

This study uses a recruitment-with-replacement design to maintain a sample size of 900 patients. In all 1517 patients have been enrolled as of July 1, 1999.

**iv. Key variables for cost determination**

Data from this study are available to HCFA and may be useful in occasional special studies.

**v. Ability to link to other databases**

Participants in this study were assigned randomized clinical treatment for study purposes. These data are available but cannot be linked to other databases.

**vi. Collection Forms**

The data collection forms for this study are not available.

## ***VIII. Developing the primary analytical database***

Much of the data needed to inform the determination of payment rates for a revised PPS and to determine whether case mix adjustments are warranted is at the level of the individual patient. The primary patient file will track the treating facility, dialysis modality, claims and comorbidities for all Medicare eligible ESRD patients. This will involve identifying the patients, their periods of Medicare Primary Payer status, assigning patients to a particular treating facility at each point in time, and then accruing claims and comorbidity history to these identified patients and eligibility periods. These patient data can be linked, as needed, with a variety of data that are available at the facility level, including aggregate costs from the Medicare Cost Reports, annual facility surveys (HCFA and CDC), and regulatory data from OSCAR. Links can also be made for patients in the samples of facilities included in special studies such as DMMS, DOPPS, the Managed Care Demonstration, and the HEMO Trial. The cost reports and claims records are the most important sources of cost and change information.

## ***IX. Potential uses and limitations of each database***

### **1. HCFA Standard Analytical Files (SAFs)**

The SAFs provide the only means of detailing Medicare spending on renal-related care for all eligible ESRD patients. The Outpatient SAF will be the primary source for information about the current payments received by dialysis facilities for treatment of ESRD patients. The physician/supplier SAF could also be used to determine the extent to which certain services that might be covered under an expanded PPS are currently billed by physician/supplier providers rather than by the dialysis facility. The Outpatient SAF claims filed under non-dialysis revenue centers but providing services identified as renal-related will also be used for the same purpose. Overall, these files will allow the characterization of Medicare payments by patient, by modality, by unit of time, and by specific service or type of service.

In addition to payments and charges which will be used for cost determination, the SAF claims also contain diagnostic codes (ICD-9-CM) and procedure codes, which can be used to track comorbidities and treatment patterns. These will be useful for cost determination and for case mix adjustment.

Analyses will have to recognize several limitations of the SAFs. First and foremost, the SAFs reflect charges for services and Medicare payments. Ideally, we would have data on the cost to facilities of providing services rather than charges and payments. Thus, using claims data as a basis for determining the cost of services requires an assumption that the amounts paid by Medicare provide a reasonable reflection of the costs experienced by an efficient provider delivering the service or that charges can be adjusted to costs based on cost report ratio of cost to charges for ancillary type services. A further limitation of the claims files are that often no Medicare claims are generated when Medicare is not the primary payer for the beneficiary and no Medicare claims are generated for HMO beneficiaries. An additional weakness of institutional SAF claims is that the payment is the payment for the entire claim. The Medicare SAFs contain line items containing HCPCS codes for procedures performed, revenue center codes indicating the relevant revenue center, and diagnoses associated with the performed procedures. They only contain a charge associated with the procedures not a payment. Payments are only the aggregate amount paid for the entire claim (typically a month of services). Individual components covered by the current composite rate are not separately reported on outpatient

dialysis claims, so for items currently included we can only observe the number of dialysis treatments and the allowable payment rate. Due to the current payment limit of 3 weekly sessions, the claims files will not be very useful in determining the differential cost of non-traditional schedules such as dailyhemodialysis. Finally, the infrequent updates (quarterly) and the lack of a completely closed database at any given point in time need to be considered. If direct access were available to the National Claims History (NCH, the common working files), this weakness could be cured by continuously updating a claims database. Table 1 from "Reliability and Validity in Hospital Case Mix Measurement", (Pettengill and Vertrees, HCFA Review, Vol. 4:2, 1982) gives an approach as to how hospital costs and billed charges can be combined to yield cost per discharge.

The paid claims data are central to the development of a PPS. Product definition and the determination of which services to include in the basic product will be determined by examining paid claims. Determination of outliers to differentiate payment levels will be determined by examining certain cases within the paid claims. Some equivalent of the claims data will be needed to monitor performance after a prospective payment system is developed. Maintenance of the PPS demands some equivalent of the current claims data so that appropriate adjustments can be made to the PPS as practice patterns and technology change. Similarly some equivalent of the claims will be needed for quality control. The claim equivalent collection should at the least collect diagnoses and procedures performed. For monitoring and refinement purposes, consideration needs to be given to the issue of which components of an expanded bundle (e.g., EPO) need to be specifically reported on the claims and subject to audit. Such reporting requirements would compromise one potential benefit of an expanded bundle (less paperwork for the facility to file and HCFA to process). However, a major weakness of the existing bundle is the difficulty of monitoring the types and quantities of services that go into the billable unit of a dialysis treatment, and hence the difficulty of determining the true cost of dialysis.

## 2. HCFA 2728, Chronic ESRD Medical Evidence Form Database

This form is the only universal source of information about the cause of ESRD. The Medical Evidence database will also provide information about comorbidities at ESRD onset affecting the course of the ESRD. Such data will help determine if differential levels of payment should be based on some type of case mix adjustments.

The primary weaknesses are a lack of completeness in many of the forms and the fact that the comorbidities are only available at the start of ESRD. Reporting of comorbidities does not affect the primary purpose of the form, which is to establish Medicare eligibility on the basis of chronic renal failure. Thus, we would expect comorbid conditions to be underreported, and underreporting has in fact been verified by comparisons to the DMMS. Further, the completeness of reporting may vary systematically by physician or region. Because completion of this form is required only at the onset of ESRD, there is no follow-up reporting of newly developed comorbidities or of cured, former comorbidities. Further verification against the DMMS, comorbidities reported in the claims files, or data from dialysis firms would be useful.

## 3. HCFA Annual Facility Survey

The AFS can be used together with cost reports in the development of the PPS to determine if any facility specific differences should be determinants of payment differentials. An example of this is the urban adjustment in the inpatient hospital PPS.

The primary weakness of the HCFA AFS is that its accuracy depends on complete reporting by each facility and full reporting by all facilities. Unfortunately neither of these processes has been validated.

#### 4. CDC: National Surveillance of Dialysis-Associated Diseases in the United States, 1999

These facility level data may be useful in the development stage as well as in the ongoing maintenance of the PPS. In particular, they provide a national means of tracking the diffusion of various technologies and practices, provided the surveys are kept sufficiently up-to-date by including any important, new technologies and practices early in their diffusion process.

#### 5. Medicare Cost Reports

The Medicare cost reports will be important in the development and maintenance of the PPS particularly in the determination of Medicare allowable costs and the cost impact of the PPS. These data may provide some verification that, on aggregate, the assumption that Medicare payments approximate costs is not egregiously wrong. The reports also provide certain statistical data such as staffing patterns and number of dialysis stations as well as on costs. The cost reports should allow the development of a cost to charge ratio which might be useful in estimating costs for line items where only the charge is recorded. They also potentially permit the estimation of statistical cost functions to assess the aggregate impact of dialysis modality mix, comorbidities, and practice patterns on Medicare allowable costs (see Dor, Held, and Pauly, 1992, and Hirth, Held, Orzol, and Dor, 1999).

The primary weakness of the cost reports is that very different formats are used for free-standing dialysis facilities as opposed to hospital-based facilities. The categories, particularly revenue center categories, in the two formats are sufficiently distinct that they really cannot be collapsed and compared on very many categories. Further, since the reports are not used to set payments to individual facilities, the level of auditing is not high. However, studies using cost report data have been able to explain nearly 90 percent of cost variation across facilities, which would not be likely if the data contained many large, non-random reporting errors.

#### 6. Medicare Enrollment Database (EDB)

The EDB will help to define Medicare secondary payer periods and the HMO membership periods. This will be crucial to the development and maintenance of a PPS because failure to exclude such periods from the cost analysis would generate a downward bias on the estimates.

The weakness of the EDB, if any, is the mode of access to the data. Access can be obtained only through the EDB Workbench. The EDB Workbench is a mainframe clist (list of commands) that operates a set of programs that allow menu-driven access to the EDB data. There are only a small, finite number of ways in which the data can be accessed through the Workbench, e.g., the most common way to access EDB information is by providing a finder file for the Workbench to use to select EDB patient records.

## 7. OSCAR

These data are potentially useful in checking the reliability of overlapping items on the Medicare Cost Reports and HCFA and CDC facility surveys, and as a source of information on quality deficiencies identified by state surveyors. This can be useful in the ongoing monitoring of care under the revised PPS. The primary weaknesses are that facilities are not surveyed every year and that although the data elements are uniform nationally, the survey process varies by state.

## 8. Death notification database

These data will be used to end the patient's eligibility period.

\* \* \*

The following data sets are available for samples of patients and facilities rather than for the universe of patients or facilities. Their potential uses are therefore limited, but they are likely to play a significant role in supporting specific parts of the analyses underlying the expanded PPS. These potential uses and limitations will only be briefly described here.

## 9. DMMS

The DMMS can serve as a "gold standard" for the reporting of comorbidities to which other sources (claims, HCFA 2728) can be compared. Case mix adjustment models can be built using DMMS data linked to claims, allowing the comparison of the performance of models based on a broad set of measures to models based on more limited sets of measures that could feasibly be collected and implemented on a universal basis. Similarly, comparisons could be made to alternative patient groupings intended to capture variations in the cost of care.

Multivariate cost models will use various sets of candidate case mix adjusters to determine the relationships between these variables and costs at the patient and facility levels. Detailed comorbidities available from sources such as DMMS or DOPPS will allow benchmark models to be estimated for a sample of patients. These models can then be restricted to case mix measures that are universally available and verifiable (and, hence, are feasible candidates for inclusion in a case mix adjustment system). Comparisons of these more limited, but feasible, adjustments to the benchmark models will allow us to determine how well a feasible case mix adjustment system is likely to perform relative to a more sophisticated system. Should this performance be poor, recommendations for collection and auditing of additional case mix adjustment data could follow. These analyses should be performed for each major dialysis modality.

## 10. DOPPS

DOPPS could be put to similar uses as DMMS, but it also has the further advantages of having data collected for a longer period of time. In addition, the sampling strategy oversampled units with well above average or well below average standardized mortality rates (SMRs), allowing a comparison of costs and practice patterns among facilities experiencing very different clinical outcomes.

## 11. Managed Care Demonstration

The Managed Care Demonstration Project will provide some insight on the difficulties of collecting information similar to claims when claims are not required for reimbursement. The Project also provides some insight on the difference between Fee-for-Service and managed care patient management and costs.

## 12. HEMO Trial

Data from the HEMO Trial can be used to establish the cost differential associated with higher dialysis dose and high flux membranes. Should these interventions prove to be clinically beneficial, HCFA may want to ensure that payments are sufficient to make their use economically feasible.

### ***X. Preliminary work in identifying eligibility periods and costs***

For the purpose of this Database Report, we will briefly discuss several preliminary data analyses we have completed. Presentation of final estimates and recommendations for further data collection are beyond the scope of this report. This section serves only to illustrate the types of analyses of existing data that could be undertaken to inform the construction of a revised PPS and determine what gaps exist in these databases.

The cost estimates that are possible using existing data available to HCFA rely heavily on the Medicare claims SAFs. Costs can be identified on a per dialysis session basis (for HD, or dialysis session equivalent for PD) or per unit of time. We anticipate that cost measures per unit time, which could always be converted to a per treatment basis by dividing by the average number of treatments in the time interval, will be more useful.

Estimating costs per unit of time requires an assignment of the patient to a specific dialysis facility for a specific period of time. Thus, the ability to make unambiguous, continuous, and non-overlapping assignments needs to be explored.

An analysis of all dialysis patients from 1995-2000 revealed that about 25 percent of patients had at least one period of overlapping service dates on outpatient dialysis claims from multiple providers. In such cases, assignment of payments to providers would be difficult in a system based on a per unit of time payment. A summary of the types of overlaps that occurred, and their frequencies is included as Appendix 2.

Once the eligible patients, their at-risk periods, and their assignment to providers have been established, cost estimation can begin. Most of the costs potentially included under an expanded PPS for renal-related outpatient care will appear as outpatient institutional claims with dialysis revenue center codes. However, some may appear in the physician/supplier files or may even appear without any specific indication of dialysis-relatedness. In preliminary work, we have identified total charges by HCPCS code in 1999 for dialysis revenue centers and from physician/supplier claims. A summary of the top 100 codes by total charges is included as an Appendix. Note that only a fraction of EPO costs are accounted for in our preliminary analyses as most of these costs need to be captured from the dialysis revenue center line items rather than from the claims details that we have examined.

We have also mapped carrier-specific codes to the carriers that use them for outpatient dialysis, physician/supplier and durable medical equipment claims. The difficulty with these carrier-defined codes is the lack of a description field on the SAFs. HCFA has obtained descriptions of these codes to allow them to be identified and categorized.

## ***XI. Conclusion***

This document describes the available data sources for the development and implementation of a revised PPS for outpatient, renal-related care and discusses how these data sources might be used in this process and our initial assessment of their limitations. Our initial review of the available databases indicates that despite some significant challenges, using primarily existing data as the basis for a new bundled PPS for renal-related care is likely to be feasible. The data are not always ideal, but these databases are likely to have error rates similar to those of the databases used to successfully develop HCFA's other prospective payment systems. The existing composite rate masks details of services that are provided under the composite payments. Analyses of the individual claims and cost reports must be combined to yield total cost models. It is important to note that any PPS should remain open to revision or updating as its imperfections become apparent.

The final report of Phase I will include a variety of analyses necessary to make a final determination as to whether or not these databases can provide an adequate empirical basis for a revised payment system. Specific analyses aimed at establishing payment rates, case mix and other adjustments, and updating and monitoring processes will be proposed for Phase II. In areas where the existing data have substantial limitations, primary data collections may also be proposed.