entered into a Memorandum of Understanding defining each agency or organization's role in developing, establishing, and enforcing standards or guidelines for responders' respiratory protective devices. NIST has initiated Interagency Agreements with NIOSH and SBCCOM to aid in the development of appropriate protection standards or guidelines. NIOSH has the lead in developing standards or guidelines to test, evaluate, and approve respirators.

NIOSH, SBCCOM, and NIST have hosted public meetings on April 17 and 18, 2001; June 18 and 19, 2002; October 16 and 17, 2002; and April 29, 2003, presenting their progress in assessing respiratory protection needs of responders to CBRN incidents. The methods or models for developing hazard and exposure estimates, and the status in evaluating test methods and performance standards that may be applicable as future CBRN respirator standards or guidelines were discussed at these meetings.

The Quality Assurance/Administrative update module had been under development prior to the introduction of the CBRN topics and has been previously presented in an open format, the last of which were public meetings held on August 8, 2000, in Washington, DC, and on August 16, 2000, in San Francisco, California. More recent developments have necessitated revisions that will be highlighted at this meeting.

FOR FURTHER INFORMATION CONTACT: Event Management, P.O. Box 880, 3610 Collins Ferry Road, Morgantown, WV 26507, Telephone 304–285–4750, Fax 304–285–4459, E-mail *confserv@netl.doe.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 29, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–13969 Filed 6–3–03; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5003–N]

RIN 0938–ZA39

Medicare Program; Demonstration: End-Stage Renal Disease—Disease Management

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice informs interested parties of an opportunity to apply for a waiver allowing them to participate in the End-Stage Renal Disease (ESRD) Disease Management Demonstration. We are planning a demonstration that will increase the opportunity for Medicare beneficiaries with ESRD to receive integrated disease management services and to test the effectiveness of paying for services received by these beneficiaries in a new way. The demonstration aims to test the effectiveness of disease management models to increase quality of care for ESRD patients while ensuring that this care is provided more effectively and efficiently. The demonstration features two distinct payment options: (1) Capitation, and (2) a fee-for-service bundled payment option. Organizations participating under the capitation payment option will be responsible for providing all Medicare covered services for beneficiaries who choose to participate in the demonstration. We plan to use risk-adjusted ESRD capitation rates being developed for use in the demonstration. A similar system of payment rates for ESRD is planned for the M+C program in 2005.

Organizations participating under the fee-for-service bundled payment model will provide disease management services and dialysis services. They will receive payment for an expanded set of dialysis services, which includes items additional to those included under the current composite rate for outpatient dialysis services. Organizations under this option will be required through disease management to coordinate non-ESRD services, but will not have to provide or contract for these services directly.

Organizations under both capitation and fee-for-service bundled payment models will be subject to a reconciliation around the risk-adjusted ESRD payment rate. Organizations under the capitation model will be able to propose risk-sharing arrangements, which would allow them to share any losses or gains with us. Applicants under the fee-for-service bundled payment model will share 50 percent/50 percent on gains and losses (or a similar arrangement to assure budget neutrality). The maximum amount of the incurred gain or loss for the applicant under the fee-for-service bundled payment model will be the amount of the additional payment for the expanded set of dialysis services.

A competitive application process will be used to select organizations to participate in this demonstration. The demonstration is planned for 4 years.

DATES: Applications will be considered timely if we receive them on or before September 2, 2003.

ADDRESSES: Mail applications to: Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Research, Development, and Information, Division of Demonstration Programs, Attn: Sid Mazumdar, Mail Stop: C4–17–27, 7500 Security Boulevard, Baltimore, Maryland 21244. Applications must be typed for clarity and should not exceed 40 double-spaced pages, exclusive of the executive summary, resumes, forms, and documentation supporting the cost proposal. Because of staffing and resource limitations, we cannot accept applications by facsimile (FAX) transmission. Applications postmarked after the closing date, or postmarked on or before the closing date but not received in time for panel review, will be considered late applications.

FOR FURTHER INFORMATION CONTACT: Sid Mazumdar, CMS Project Officer, at (410) 786–6673, or *smazumdar@cms.hhs.gov.*

Eligible Organizations

Potentially qualified applicants are companies experienced with providing services to ESRD patients. The demonstration will be especially appropriate for dialysis providers and disease management organizations. It will also be open to Medicare+Choice organizations and integrated health care systems.

SUPPLEMENTARY INFORMATION:

I. Background

A. Problem

Many Medicare+Choice organizations and private insurers have realized the importance of the effective coordination of care for persons with chronic conditions. The quality and cost of the care generally can be improved through better integration of the delivery system. The Medicare program is evaluating payment methods to create incentives to improve the quality of care, encourage

the coordination of services, and control costs.

Beneficiaries with (ESRD) are the only group eligible for benefits under Medicare Parts A and B who are prohibited from enrolling in M+C organizations, although a beneficiary who develops ESRD after enrolling in an M+C plan may remain enrolled.

Medicare coverage of individuals with ESRD was initiated in 1972 with the goal of providing life-saving treatment to patients with chronic renal failure. Over 30 years, the number of individuals with ESRD covered by the Medicare program has grown far beyond its expected size and budget, from 7,000 patients in the first year to more than 350,000 in 2001. The ESRD population is currently growing at 7 percent per year and has doubled in the past decade.

In recent years, the ESRD population has accounted for an increasing proportion of Medicare outlays. Between 1992 and 2001, Medicare spending for outpatient dialysis services furnished by freestanding facilities increased by about 10 percent per year. Intravenous medications have also increased Medicare spending for ESRD. Spending for injectible drugs increased from $1.3 billion in 1998 to $2.3 billion in 2001. In 2001, Medicare expenditures for ESRD amounted to $15 billion. The total Medicare cost for the ESRD program is projected to more than double in the next 10 years.

B. Approaches and Demonstration Project

This demonstration follows an earlier ESRD managed care demonstration. In 1993, the Congress required the Secretary to conduct an ESRD Managed Care Demonstration Project. As a result of this mandate, section 13567(b) of the Omnibus Budget Reconciliation Act (OBRA) 1993, Pub. L. 103–66, we implemented a demonstration that allowed ESRD patients to enroll in managed care settings. Participating managed care organizations were to be responsible for the total medical care of ESRD enrollees as well as provide specific case management functions and additional benefits of utility to the ESRD population.

Responding to our solicitation, three organizations joined the demonstration; Kaiser Permanente in southern California, Health Options Incorporated in Florida, and Xantus Corporation in Tennessee. Kaiser Permanente and Health Options Incorporated remained in the demonstration. Xantus discontinued demonstration operations in March 2000. The organizations that remained were a health maintenance organization (HMO) and an HMO subsidiary, both with separate M+C contracts.

The CMS-sponsored evaluation for the project shows the demonstration approach to be operationally feasible and the quality of care was maintained or improved. Overall, the patients who were enrolled in the demonstration reported high satisfaction, improved quality of life, and positive clinical outcomes. The executive summary of this report is available at *http://cms.hhs.gov/researchers/reports/2002/execsum.pdf.*

We plan the new demonstration to foster more types of integrated care for Medicare beneficiaries with ESRD. We seek to test innovative approaches to integrating the chronic care management services for patients with ESRD with other acute care services. Responding to published research on the effectiveness of disease management methods in treating ESRD patients, the demonstration aims to test the effectiveness of disease management models to increase quality of care for ESRD patients while ensuring that this care is provided more effectively and efficiently. Disease management techniques are intended to improve patient care and save money by coordinating interventions and educating patients about managing ESRD and its comorbid conditions.

National organizations have defined approaches to disease management, in order to improve patient outcomes while containing health care costs. Disease management programs tend to target persons whose primary health problem is a specific disease, along with comorbid conditions. Interventions tend to be highly structured and emphasize the use of standard protocols and adherence to clinical guidelines.

Common features to disease management include:

- Identification of patients and matching the intervention with the need.
- Use of evidence-based practice guidelines.
- Services designed to enhance patient self-management and treatment plan adherence, including education and behavior modification programs.

Additional features essential for disease management of ESRD include:

- A central role for the nephrologist.
- Management of the many comorbid conditions of ESRD.
- Care managers with specialized knowledge of diet, medications, total health status, and personal needs of ESRD patients.
- Integrated administrative and financial arrangements among providers of services to ESRD beneficiaries.

The new demonstration includes three delivery models and two payment models, or options. The delivery models are: (1) Managed care, (2) models similar to the approach taken under the Program for All-Inclusive Care for the Elderly (PACE-type) under sections 1894 and 1934 of the Social Security Act, and (3) fee-for-service. The two payment options are (1) capitation and (2) fee-for-service bundled payment. The capitation payment option applies to both managed care and PACE-type delivery models. The fee-for-service bundled payment delivery option would apply only to the fee-for-service model. The delivery and payment models have different implementation methods that are discussed in this solicitation. For each model, the organization will take responsibility for operations such as enrollment (capitation payment model), disease management, care coordination, and financial management.

An additional component to the demonstration payment method, for both managed care and fee-for-service is an incentive payment for quality. Under the demonstration, we will reserve five percent of the payment, either capitation or bundled payment, to be available for quality incentive payments. Capitation payments would be set at 95 percent of the risk-adjusted ESRD payment rate. Ninety-five percent of the additional payment for an expanded bundle will be paid for the fee-for-service option.

For both models, goals for a demonstration organization would be to implement clinical protocols for common clinical events, as well as for objectives as anemia management and diabetes management, and for quality of care in areas such as dialysis treatment modality, consideration for transplantation, post-transplantation follow-up, management of vascular access, prevention of peritoneal catheter exit site infections, and monitoring of dialysis adequacy. A site would coordinate inpatient, outpatient, and home-based services, ensuring continuity of care for multiple chronic care problems and comorbidities, in particular, cardiovascular disease, hypertension, and diabetes.

II. Capitation Payment Model (Managed Care and PACE-Type Delivery Models)

Under the capitation payment model, organizations serving ESRD patients would receive a risk-adjusted ESRD capitation payment in order to test the effectiveness of disease management models in increasing quality of care for

ESRD patients while containing costs. Organizations participating under capitation arrangements would be responsible for managing the care of ESRD patients and providing all Medicare covered services for enrolled beneficiaries. Participating organizations may propose to cover additional services that are not currently covered by Medicare. The following are examples of these additional services:

- Transportation.
- Nutritional services.
- Dental services.
- Prescription drugs (full or limited).
- Preventive care aimed at comorbidities.
- Home care services.
- Exercise programs.
- Education on disease.
- Counseling (including spiritual).
- Diabetes management.
- Cardiovascular management.

Beneficiaries would agree, as a condition of participation in the demonstration, to receive services through the participating organization. Organizations responding must demonstrate capability to identify beneficiaries for the demonstration, and they must be licensed to bear risk. Organizations would be required to meet M+C conditions regarding access and availability of care.

A. Managed Care Model

The managed care delivery model may be attractive to organizations such as large dialysis providers and entities that currently offer M+C plans. The optimal approach for these organizations would consider arrangements with hospitals and other providers to service the entire range of health care needs for ESRD patients, including transplantation. These companies would coordinate referrals for the comorbidities of ESRD patients and therefore should be able to manage treatments to improve quality and reduce costs compared to fee-for-service. Care coordination has the potential to enhance the continuity of patient care, improve clinical outcomes, and improve patient satisfaction. Managed care organizations would contract with disease management entities or directly provide disease management to all participating beneficiaries.

Studies have reported the growth over the past decade of for-profit dialysis facilities and chains of dialysis facilities under common ownership. According to a recent report, the five largest dialysis corporations provide services to more than 70 percent of all dialysis patients in the U.S. (Source: United States Renal Data System). The capitation payment model will provide an incentive for these companies to combine their services with those of other healthcare providers to create efficient systems for the care of ESRD patients. The demonstration also will capitalize on the clinical, financial, and organizational expertise of independent dialysis companies. Other companies, including single-or multi-site disease management companies, have shown potential for cost savings through clinical and organizational innovations. Networks that coordinate the entire range of patients' care will enhance the continuity of care for illnesses and conditions that impact ESRD patients. Since ESRD patients will choose whether to participate or remain in fee-for-service, companies already serving patients on a fee-for-service basis that participate in the managed care model of this demonstration will be required to continue these fee-for-service arrangements for patients who do not choose to participate in the demonstration. However, it is expected that many, if not all, will enroll.

B. PACE-Type Model

The PACE program provides for managed care services for very frail community dwelling elderly, most of who are dually eligible for Medicare and Medicaid. The PACE-type model is a variation of the managed care model described above, although with greater emphasis on patient care coordination. For the purposes of this project, the PACE-type model would be a delivery option, receiving no additional payment beyond the risk-adjusted ESRD rates. In the PACE-type model, the provider would ensure that all services, including those provided by contracted providers, would be controlled by an interdisciplinary team composed of professional and para-professional staff (for example, physicians, nurse practitioners, registered nurses, licensed practical nurses, occupational therapists, physical therapists, dietitians, day health center supervisors, recreation therapists, social workers, health workers, and drivers). The team would have responsibility for assessing participant needs, formulating care plans, directly delivering services, managing the care provided by contracted providers, and providing ongoing monitoring of treatment outcomes. Constant monitoring effectively would disclose potential needs for care plan adjustments. The team also would have the responsibility for maintaining high quality of care while simultaneously controlling program costs.

Organizations providing dialysis as well as other health care services exclusively to ESRD patients may base their delivery system on a variation of the PACE-type model emphasizing disease management protocols and multidisciplinary team management at one central site. Flexibility would be allowed in designing service delivery provisions, to be negotiated during the period before implementation. Organizations proposing the PACE-type model will not be required to only include dual eligible ESRD beneficiaries.

C. Eligibility Requirements

For the capitation model, an applicant organization must have at least preliminary arrangements with other organizations to assure the integrated provision of all Medicare-covered services. We expect organizations to select geographic areas where they will make arrangements with hospitals and other providers to service the entire range of Medicare covered health care needs of ESRD patients. All services should be geographically accessible to all ESRD patients in a service area (for example, within one hour or 50 miles of a patient's residence). However, special transportation arrangements may be needed to make transplant services available. Applications should include discussion of proximity of service providers, including hours of availability and other aspects of access. Maps would be useful. We encourage programs to allow a wide choice of modalities, while recognizing that for certain qualified applicants this choice is necessarily limited to in-center dialysis only.

All persons eligible for the Medicare ESRD benefit and in the service area would have the opportunity to participate on a voluntary basis except for patients who become eligible for the Medicare hospice benefit prior to enrolling in the demonstration. Demonstration sites could exclude patients according to particular criteria, including those under 18 years old, if justified. The demonstration organization would make clear that patient participation is entirely voluntary and that the ESRD beneficiary who chooses not to do so remains entitled to all Medicare-covered services.

Information provided by the provider to beneficiaries would include the network of providers who have contracted with the demonstration organization, including dialysis facilities, hospitals, and transplant surgeons, and that receiving services

through this network is a condition of participation in the demonstration.

D. Payment

For the managed care and PACE-type models, we plan to use risk-adjusted ESRD capitation payment rates being developed for the demonstration. These rates are part of the development of the ''selected significant conditions'' model for M+C risk adjustment. A similar set of payment rates for ESRD is planned for the M+C program in 2005. This risk adjuster will factor a greater number of comorbidities into the payment. The capitation payment method would depend on an organization's ability to submit data for relevant diagnoses recorded during hospital inpatient stays, hospital outpatient visits and physician visits. For the proposed new payment methodology for M+C ESRD, see *http://www.cms.hhs.gov/healthplans/rates/2004/45day-section-b.asp.* The actual ESRD risk-adjusted payment rates for 2004 will be available on our Web site in the near future.

The methodology will pay separate payment rates for dialysis, transplant, and post-transplant modalities. The organization would submit monthly data indicating the modality status for enrollees. The developmental phase for the demonstration would offer a period when CMS and organizations would be able to work together to establish the operational requirements of specific payment options. There will be no phase-in of the risk adjusted ESRD rates for the demonstration—payment will begin with one hundred percent, or full, risk adjustment. The actual payment amount will be reduced by five percent, which will be available later depending on performance on quality measures.

III. Fee-for-Service Bundled Payment Model

This delivery and payment model is appropriate for organizations such as disease management companies, dialysis facilities, and integrated health systems that will conduct disease management for ESRD patients and provide dialysis services under a new bundled payment methodology. Organizations will be expected to coordinate all services utilized by patients receiving dialysis through the organization. They will not be responsible for providing services other than disease management and dialysis services, and Medicare will process and pay all claims on a fee-for-service basis.

However, the organizations will be partially at risk for expenses incurred by Medicare for patients who receive dialysis services through the organization. Annually, we will conduct a reconciliation, wherein patients' total Medicare costs will be compared to what their risk-adjusted payment amounts would be. (See Financial Risk, below.) For the purposes of the reconciliation, organizations will be accountable for a patient's Medicare expenses until a patient either begins to receive dialysis services in another dialysis facility or in a nursing home, that is, the patient's care is no longer managed by the organization. (As an example, if a patient receiving services in a demonstration dialysis facility is admitted to a hospital and then returns to the facility for dialysis, the Medicare cost for the hospital stay will be counted as part of the demonstration organization's expenses.) Under this payment option, the maximum amount of incurred gain or loss for the organization will be equivalent to the total amount of the add-on payment for the expanded bundle.

The organization would identify distinct facilities that will participate in the demonstration. To minimize favorable selection, all, or nearly all, patients treated within the set of facilities that are included in the demonstration would be paid for under the bundled rate. The beneficiaries would be informed that the organization is participating in a new payment and disease management project. The organization would make special arrangements for those patients who choose to opt out of the demonstration. An acceptable arrangement would involve placing a patient who chooses to opt out in another facility, while ensuring that location and transportation arrangements are convenient for the patient. If this condition is not met, we would make arrangements for these people to continue in the facility under a separate payment from the demonstration. In addition, we would not include dialysis patients in the demonstration who are members of M+C plans.

The demonstration payment for the bundle is constructed as an add-on to the otherwise applicable specific composite rate payment for each geographic area, as listed in the CMS Program Memorandum for February 1, 2001 (Transmittal A–01–19). The expanded bundle add-on includes payment for several classes of drugs: Erythropoietin, Levocarnitine, phosphate binders, iron supplements, and Vitamin D analogs; necessary laboratory tests; and radiology. (See appendix I for a full list of items under the bundled payment.) Applicants for this option will have the choice of also including vascular access services in the expanded bundle add-on. Nearly all routine dialysis services are included in the bundle. Other items and services will be separately billable outside the bundle. Organizations will not be able to bill separately for items in the bundle.

The Medicare add-on payment for the expanded bundle not including vascular access services is $71.63 per session. The add-on payment for the bundle including vascular access services is $86.63. (These numbers include a one percent deduction for Medicare savings.) These payments do not include any potential co-payments and were calculated on Medicare claims data from July 2000 through December 2001, and will be used exclusively for this demonstration. We will update the payment for the expanded bundle to reflect changes in Medicare payment levels.

The add-on bundle rates include payment for disease management services. Organizations must provide a detailed description of the disease management services they will provide, including information on their proposed interventions, the type and number of patients to whom each intervention is targeted, and the frequency with which such interventions are expected. Applicants should also describe how these services will increase quality and reduce costs.

In accordance with the withhold for quality, five percent will be subtracted from the bundled payment rate. As described below, the five percent will be available later depending on performance on quality measures.

In rare circumstances when patients use other dialysis facilities, the organization will be responsible for reimbursing the facility at Medicare fee-for-service payment levels. It will have received the bundled payment on behalf of the beneficiary who is temporarily absent from the geographic area. Applicants should consider in their proposals what constitutes a temporary absence. The organization will continue to provide disease management services and coordinate other Medicare services while the patient is away.

Applicants proposing the fee-for-service option with the bundled dialysis payment should be aware that the implementation period will be at least six months, because of significant bill-paying systems changes. We will update the payment for the expanded bundle on an annual basis to reflect changes in Medicare payment levels. Facilities will be able to participate under this option for patients receiving home dialysis services under Method I. Demonstration payments will not be made for Method II home dialysis patients.

IV. Supplemental Coverage

The demonstration will be open to ESRD beneficiaries for whom Medicare is either primary or secondary payer. In the case of demonstration participants for whom another payer is primary, the demonstration organization must submit valid bills with the primary payer to collect the appropriate payment amount as specified by the demonstration's payment rules.

To make the demonstration financially viable, participating organizations may collect cost-sharing in the form of premiums, deductibles, and co-payments to beneficiaries in lieu of the cost-sharing amounts for which beneficiaries are responsible under the ordinary fee-for-service payment rules. To be financially attractive to beneficiaries, these should have actuarial values that are lower than current Medicare fee-for-service cost-sharing.

A beneficiary participating in the demonstration may choose to retain his or her Medigap policy. Participating organizations should clearly explain to beneficiaries the advantages of retaining and risks of discontinuing their Medigap coverage. Under the fee-for-service bundled payment option, participating organizations will be able to bill any supplemental insurance plan that the enrolled beneficiary holds for cost-sharing purposes. If a secondary payer is Medicaid or a group health plan, that payer may pay some or all of a beneficiary's monthly premium for enrollment.

Under the demonstration, an organization receiving a fully capitated payment may pursue the possibility of billing existing Medigap policies held by a beneficiary participating in the demonstration, or bill Medicaid, for the amount of cost-sharing that otherwise would be paid under Medicare fee-for-service. The demonstration organizations may attempt to make such arrangements with Medigap plans, State Medicaid agencies, and State insurance regulators.

Beneficiaries participating in the capitation demonstration will have the option of terminating supplementary coverage. In these cases, the selected demonstration organizations must work with the beneficiaries to ensure that either their policy is maintained at the end of the demonstration, or that beneficiaries understand that if they drop supplemental coverage, enrollment in their supplemental plans is not guaranteed at the end of the demonstration. It will be incumbent on the demonstration organizations to provide proper notice to potentially participating beneficiaries about their Medigap rights if the individual's participation in the demonstration ceases. Specifically, the demonstration organization should be explicit in its marketing information to beneficiaries about the scope of rights that accrue to patients under age 65 in the particular State.[1]

If the beneficiary intends to cancel a Medigap policy and if the arrangements with the supplemental insurer do not guarantee that the beneficiary has the same coverage at the end of the demonstration, it must be clear that the beneficiary chooses to participate in the demonstration with full knowledge of this possibility. Providers and beneficiaries are advised that the demonstration is time-limited, and that dropping a Medigap policy presents a significant risk. We will ensure that demonstration organizations communicate the advisability of maintaining Medigap coverage to potential participants.

When demonstration awards are made, the Terms and Conditions will require that the awardee submit for our approval a Phasedown Plan explaining how demonstration participants are to be assisted in converting back to previous insurance coverage and fee-for-service care at the conclusion of the demonstration, as well as during the project. This requirement will apply to organizations under both capitation and fee-for-service bundled payment models.

[1] Generally, an individual who voluntarily disenrolls from a managed care demonstration will not have guaranteed issue rights. If an individual is enrolled in a managed care demonstration and enrollment ceases under circumstances set forth in section 1851(e)(4) of the Act (for example, the demonstration is terminated), the individual will have the right to buy certain Medigap plans on a guaranteed issue basis (generally Plans A, B, C or F). This right generally will not accrue to an individual who wishes to voluntarily disenroll from the managed care demonstration. It also generally will not apply if an individual is enrolled in the fee-for-service model of the demonstration, since the statutory provision in section 1882(s)(3)(B)(iii) of the Act provides guaranteed issue rights to individuals in a managed care organization.

If an individual drops a Medigap policy to enroll in the ESRD managed care demonstration and it is the first time the individual has enrolled in Medicare managed care, that individual has a 12-month trial period. The individual may disenroll from the demonstration within the first 12 months and purchase his or her former Medigap policy, if it is still available from the same issuer. If the former policy is not available, the individual can buy Medigap Plans A, B, C, or F. Individuals who join the demonstration upon first becoming eligible for Medicare Part A at age 65 would not have ''trial period'' rights.

It is important to note that Federal law does not require a Medigap open enrollment period for beneficiaries under age 65, so Medigap insurers do not have to sell policies to this population. State law governs what Medigap choices are available to Medicare beneficiaries under age 65. Currently, twenty-two States have laws that provide Medigap rights to beneficiaries under 65. The Medigap plans available to the under-65 population vary by State.

V. Financial Risk

A. Risk-Bearing Requirements

We will work with organizations that have requested capitation payment in the pre-implementation period to assure they meet the risk-bearing requirements under their State. We will consider the individual circumstances of the provider in relation to State law and the demonstration project, but we cannot exempt organizations from State law. Organizations will be required to meet all of the State's insurance requirements to the extent applicable. There is no risk-bearing licensure requirement for the fee-for-service model.

B. Risk Sharing

Organizations may propose risk-sharing arrangements under either the capitation or fee-for-service bundled payment options. If risk sharing is included for the capitation option, a year-end reconciliation will be conducted to compare an actual Medical-Loss-Ratio (MLR) to a target Medical-Loss-Ratio. Any differences, either gains or losses, would be shared on a symmetrical basis by the organization and us. As part of the proposal, organizations should submit a projected revenue and expense statement showing calendar year 2004 estimated per member per month Medicare revenue and member premium; benefit expenses (hospital inpatient, hospital outpatient, dialysis, professional, other Medicare services, and non-Medicare services); and administrative expenses. The statement should show any co-payment credits for the various services and reflect payment from Medicaid or supplemental insurers. A target MLR will result from the ratio of benefit expenses to revenues. One year after the end of each operational year, the organization should send a certified actual revenue and expense report to determine the actual MLR.

If risk sharing is proposed, there should be three calculations of projected savings/losses—optimistic or best case assumptions, expected or normal assumptions, and pessimistic or worst-case assumptions. Budget neutrality should be assessed for each situation. The risk-sharing proposal must include a 2 percent full-risk corridor above and below the targeted Medical-Loss-Ratio. In addition, prior to awards, we will work with applicants to determine whether the proposed Medical-Loss-Ratio is set at a level where the risk-

sharing arrangement is projected to be budget neutral under expected or normal assumptions. If risk sharing is proposed for the capitation model, we will share risk only on medical benefit expenses. Administrative expenses must be reasonable and consistent with prior practices. Applicants can propose the percentages of risk sharing and risk corridors, but these must be symmetrical, for example, 50 percent organization/50 percent CMS beyond the 2 percent full risk corridor; 40 percent organization/60 percent CMS beyond the 2 percent full risk corridor on gains and losses. Seventy-five percent is the most we will share on gains or losses.

For the fee-for-service option, a CMS reconciliation will be conducted to compare total Medicare payments made on behalf of patients receiving dialysis and disease management services to total risk-adjusted ESRD payments that would have been received under the capitation payment model (minus the dollar amount of the one percent subtracted from the payment for the expanded bundle). It is expected that through efficiencies generated by disease management and a bundled dialysis payment, organizations will break even or achieve overall savings. Similar to the capitation model, there will be a 2 percent full-risk corridor above and below the targeted payment amount. Organizations will share with CMS 50 percent/50 percent on gains and losses resulting from the reconciliation beyond the full-risk corridor on gains and losses (or a similar arrangement to assure budget neutrality). The maximum amount of incurred gain or loss will be equivalent to the amount of the add-on payment for the expanded bundle. For the purposes of the reconciliation, organizations will be responsible for a patient's Medicare expenses until a patient either begins to receive dialysis services in another dialysis facility or in a nursing home. A 12-month period will be allowed for claim lag.

Similar to the capitation model, fee-for-service applicants should outline calculations of budget neutrality under optimistic or best-case assumptions, expected or normal assumptions, and pessimistic or worst-case assumptions.

VI. Legislative Authority

Depending on the model chosen by the applicant and approved by us, the demonstration project and the waivers granted to permit it would be authorized by one of two statutory provisions, or by both such provisions. The original ESRD managed care demonstration described above was, as noted, conducted in accordance with specific Congressional authority for such a demonstration in the context of ''Social HMO'' or ''SHMO'' demonstration projects. The managed care model demonstrations, as well as those we are referring to as ''PACE-type'', would be authorized under this broad authority. These types of demonstration models would also be authorized by the authority in section 402 of the Social Security Amendments of 1967, 42 U.S.C. section 1395b-1, which permits demonstrations, testing ''changes in methods of payment'' and the waiver of rules relating to payment, as well as the coverage of services not otherwise covered by Medicare. In the case of a fee-for-service demonstration model, this latter authority would authorize the demonstration.

A. SHMO Authority

Section 2355 of the Deficit Reduction Act of 1984 (Pub. L. 98–369) required the Secretary to approve applications to carry out SHMO demonstrations to provide for the integration of health and social services under the direct financial management of a provider of services. Up to four additional projects were mandated by section 4207(b)(4) of the Omnibus Budget Reconciliation Act (OBRA) of 1990, Pub. L. 101–508. (This authority, as amended, is referred to as SHMO II.) In accordance with the previous demonstration, we are interpreting the term ''project'' to refer to the overall demonstration project, and that a significant number of organizations can participate in the proposed demonstration.

Section 13567(b)(2)(B) of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) mandated that these demonstration waivers be extended through the end of 1997 and required at least one of the four new projects: ''to demonstrate * * * the effectiveness and feasibility of innovative approaches to refining, targeting and financing methodologies and benefit design, including the effectiveness and feasibility of integrating acute and chronic care management for patients with end-stage renal disease through expanded community care case management services.''

The Congress subsequently mandated that these demonstrations be extended. Section 631 of the Medicare, Medicaid and SCHIP Benefits Improvement Act of 2000 (BIPA) mandated an extension through August of 2003. While under current statute, a mandate that the demonstrations continue would expire on that date; we believe that to the extent a demonstration is otherwise permitted under the SHMO authority, it can be conducted under this authority subsequent to this date.

The Congress in Section 4207(b) of the Omnibus Budget Reconciliation Act of 1990 provided authority to waive ''any requirements of titles XVIII or XIX of the Social Security Act that, if imposed, would prohibit such project from being conducted.''

B. Section 402 Authority

Section 402(a)(1)(A) of the Social Security Amendments of 1967, 42 U.S.C. section 1395b–1(a)(1)(A), authorizes the Secretary to develop and engage in demonstrations ''* * * to determine whether, and if so which, changes in the method of payment or reimbursement * * * for health care and services under health programs established by the Social Security Act * * * would have the effect of increasing efficiency and economy of health services under such programs through the creation of additional incentives to these ends without adversely affecting the quality of such services * * *.'' Section 402(a)(1)(B), 42 U.S.C § 1395b–1(a)(1)(B) authorizes a demonstration to determine whether covering services not otherwise covered by Medicare (in this case, disease management services) would result in more economical provisions of Medicare covered services.

Under section 402(b) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1(b)), the Secretary may waive requirements in title XVIII that relate to reimbursement or payment. This authority will allow payment on a capitation basis rather than under the Medicare fee-for-service rules, and would allow fee-for-service/bundled payment and risk sharing around a traditional fee-for-service payment system. Section 402(a)(2), 42 U.S.C. § 1395b–1(a)(2), authorizes Medicare trust funds to cover the costs of the additional services under section 402(a)(1)(B).

VII. Quality Assurance and Improvement

A. Quality Indicators

Under the demonstration, we would link financial incentives to improvements in quality outcome indicators. Five percent of the capitation or expanded bundle payment rates will be reserved for incentive payments related to quality improvement activities.

For determining the incentive payment, we will use indicators profiled in the ESRD Clinical Performance Measures (CPM) Project. Indicators for the incentive payment will include adequacy of dialysis, anemia

management, serum albumin, bone disease, and vascular access.

Organizations will be able to earn all or part of the five percent withheld for quality. For each of the five measures, an organization will earn one half of one percent for achieving either of the improvement or the threshold targets outlined below. Appropriate targets will be used for patients receiving peritoneal dialysis. For each measure, the amount of incentive would be weighted according to the proportion of hemodialysis to peritoneal dialysis patients.

The demonstration will require further indicators for the evaluation of disease management efforts. Although not representing factors in the calculation of the financial incentive, organizations will be monitored for quality indicators measuring potential outcomes of disease management. Indicators of particular interest include blood pressure control, comprehensive diabetes care, adult immunizations, measures of successful transplantation or referrals for transplant evaluation, quality of life (QoL or CAHPS surveys), patient safety, psychiatric evaluation, referral and follow-up, and the percentage of referrals with consult and discharge summaries. The evaluation of the demonstration will assess all available measures of quality of care in the context of the demonstration. In addition, the demonstration will require at its initiation an updated Form CMS–2728 (that is, ESRD Medical Evidence Report Medicare Entitlement and/or Patient Registration) to be submitted for each patient. The 2728 will be used as a baseline for patient demographics, clinical lab values, and co-morbid conditions. This baseline data will be used along with the CPM Data to monitor patient enrollment so that selection bias is minimized. They will also be used for patient care monitoring to ensure that patients receive at least the same level of medically necessary services and medications as determined by the patient's phyisican as they received, prior to enrollment.

B. Incentive Payment for Quality

There will be two kinds of quality outcome targets—targets for an organization's improvement over time and those that measure an organization against a predetermined threshold level that takes into account nationwide performance for a quality indicator.

Improvement targets would be set using a methodology that bases the target on improvements in the ''quality deficit''. The quality deficit would be defined as 100 percent minus the organization's actual rate for assigned beneficiaries in the previous year. Improvement targets would be set at 10 percent over the deficit from 100 percent. Threshold targets would be set at 20 percent above the nationwide percent deficit from 100 percent.

Improvement Target = [Percent of patients in previous year meeting quality indicator + (10 percent * (100 percent − Percent of patients in previous year meeting quality indicator))]

Threshold Target = [Nationwide percent of patients meeting quality indicator + (20 percent * (100 percent − Nationwide percent of patients meeting quality indicator))]

The targets would be re-evaluated annually. Each measure would be worth an equal proportion of the total five percent reserved for quality improvement. Allowing organizations to earn incentive payments by meeting/exceeding either predefined thresholds or improvement targets would require bigger improvements for low performers than high performers and would take into account that it may be more difficult to improve on already high performance.

Example

(Quality Indicator: Adequacy of Hemodialysis, Percent of patients receiving hemodialysis with KT/V ≥ 1.2. Nationwide Percent: 86 percent, Source: 2001 Annual Report on ESRD Clinical Performance Measures Project)

For Organization A, 80 percent of hemodialysis patients in the previous year had a Kt/V ≥ 1.2.

• The organization's improvement target would be 82 percent [80 percent + (10 percent * (100 − 80))].

If 82 percent of the organization's hemodialysis patients have a Kt/V ≥ 1.2 in the operational year, the organization would earn half of the incentive payment for this quality indicator for meeting the improvement target.

• The nationwide percent of patients with Kt/V ≥ 1.2 is 86 percent; therefore, the threshold target is 88.8 percent [86 percent + (20 percent * (100 − 86))].

If 89 percent of the organization's hemodialysis patients have a Kt/V ≥ 1.2 in the operational year, then the organization would earn half of the incentive payment for this quality indicator for meeting the threshold target.

C. Clinical Quality Data Collection

For quality data assurance, we would use the Clinical Performance Measures Project data system, which is administered by the Quality Measurement and Health Assessment Group, Center for Beneficiary Choices, CMS. The CPM Project would provide data within 9 to 12 months for all five measures discussed above. By way of contrast, data using claims are less complete and take longer to obtain. Currently, CPM data are collected annually over a three-month time frame. For the demonstration, we intend to collect these data quarterly to examine trends more closely. Although the current CPM project only reports these indicators for a small percentage of dialysis patients, this demonstration would require a 100 percent reported sample. A CMS pilot project under development for electronic submission of clinical ESRD data may be ready within the next year. If feasible, we would require demonstration sites to utilize this system. The developmental period will be used to verify the details of reporting for individual sites, for example, how values will be established for patients with multiple observations in a quarter.

D. Quality Improvement

An optimal organization would include an approach to improving and ensuring quality of care for Medicare ESRD patients. Quality of care strategies would be beneficial if they are patient-centered and focus on outcomes of care and could be measured and monitored. The quality improvement program would include the following features:

• Written quality improvement policies and procedures
• Written patient education program
• A standing quality improvement committee
• Patient grievance and appeal systems
• Provider credentialing system

VIII. Budget Neutrality

This demonstration must be budget neutral. This means that the expected costs that are incurred to Medicare for each site under the demonstration can be no more than the expected costs were the demonstration not to occur. Before awards are made, our actuaries will review and approve documentation to support budget neutrality calculations.

IX. Evaluation and Reporting Requirements

We plan to award a separate contract to evaluate the ESRD demonstration. Awardees for the demonstration would agree to cooperate with our evaluation contractor, including participation in periodic site visits and providing information necessary to conduct the evaluation. The specific requirements for sites related to the evaluation of the demonstration would be finalized once

an evaluation contract has been awarded.

In addition, awardees under the fee-for-service bundled payment option will be required to provide line item billing for all non-composite expanded bundle services. For both capitation and fee-for-service bundled payment options, ability to submit data under the CPM project will be beneficial.

X. Submission of Applications

A. Purpose

This notice solicits applications for demonstration projects that increase the opportunity for Medicare beneficiaries with ESRD to receive integrated care management. The demonstration aims to test the effectiveness of disease management models to increase quality of care for ESRD patients while ensuring that this care is provided more effectively and efficiently.

Participating organizations will be able to solicit participation in the demonstration by patients whom they currently treat in the fee-for-service system as well as new patients. Organizations under both capitation and fee-for-service bundled payment models will be subject to a reconciliation around the risk-adjusted ESRD rates. (For the fee-for-service bundled payment option, one percent of the amount of the add-on to the bundled payment will be subtracted from this target.) Organizations under the capitation model will be able to propose symmetrical risk sharing arrangements around a two percent corridor, which would allow them to share any losses or gains with us. Applicants under the fee-for-service bundled payment model will share around a two percent corridor with CMS 50 percent/50 percent on gains and losses. The maximum amount of incurred gain or loss will be equivalent to the amount of the add-on payment for the expanded bundle. An incentive payment for quality is also included in the demonstration. The demonstration is planned for four years.

B. Submission of Applications

Each applicant organization is to submit one application regardless of the number of proposed demonstration sites. The application is to be coordinated and submitted by a component of the organization that currently treats or organizes the treatment of ESRD patients. If applicable, variations related to proposed sites should be outlined in the application text or supplemental materials.

We are seeking innovative proposals from qualified organizations that can test whether care of Medicare beneficiaries with ESRD can be more efficiently and effectively provided using models involving disease management, and whether clinical outcomes can be improved with a cost that is budget neutral to the Medicare program.

Interested organizations are able to use the capitation and fee-for-service bundled payment models outlined in this solicitation. Organizations in the demonstration will adopt one of the managed care, PACE-type or fee-for-service bundled payment delivery models. For the capitation models, the entire range of medical needs of ESRD patients must be addressed through a network of contracted or affiliated providers.

In order to be considered for review by the technical review panel, applicants must submit their applications in the standard format outlined in our Medicare Waiver Demonstration Application. Applications not received in this format will not be considered. The Medicare Waiver Demonstration Application may be accessed at the following Internet address: *http://www.cms.hhs.gov/healthplans/research.* The application outlines all application requirements including the format and content requirements.

Queries for the narrative portion of the application should be submitted in writing by mail, fax, or e-mail to: Sid Mazumdar, 7500 Security Boulevard, C4–17–27, Baltimore, MD 21244–1850: FAX: 410 786–1048, E-mail: *smazumdar@cms.hhs.gov,* or *ESRDDEMO@cms.hhs.gov.*

Applications should be sent to: Sid Mazumdar, Project Officer, Division of Demonstration Programs, Centers for Medicare & Medicaid Services, C4–17–27, 7500 Security Boulevard, Baltimore, MD 21244–1850.

C. Evaluation Process and Criteria

If the application meets the basic eligibility requirements (that is, responds to all components of the solicitation), it will be referred to a technical review panel for evaluation and scoring. Panels of experts from the government or private sector will conduct an independent review. The panelists' comments and evaluations will be transcribed into a summary statement that will serve as the basis for award decisions. The panelists' evaluations will contain numerical ratings based on the rating criteria specified in this section, the ranking of all applications, and a written assessment of each application. In addition, we will conduct a financial analysis of the recommended proposals and evaluate the proposed projects to assure that they are budget neutral.

The evaluation criteria and weights are described below. These criteria are intended to identify specific information that will be useful for evaluating the application for the ESRD Disease Management Demonstration and how the applicant will be evaluated on that information in accordance with the Medicare Demonstration Waiver Application referenced above.

1. Purpose of Project/Statement of Problem (10 points)

The applicant will be evaluated on how it defines the purpose of the ESRD demonstration project, that is, the specific goals and objectives to be achieved, and how taking part in the demonstration will lead to these goals. A successful applicant should include an explanation of its ability to manage care, access, additional benefits, and costs for ESRD patients. A successful application would also include specific indicators that could be used to measure these goals and, if possible, appropriate comparison groups.

2. Technical Approach (40 points)

(a) *Organizational Structure and Service Delivery Capacity.* Organizations may consist of single or multiple sites, and the central component may be an organization other than a dialysis company (for example, an organization specializing in disease management). If the central component of the demonstration organization is a disease management or other kind of organization, it would have established relationships with facilities that provide dialysis services.

(b) *Description of Sites Specific to the Demonstration.* Applicants will be evaluated on their operational structure. In addition, an applicant will be evaluated on its explanation of how its organizational components will coordinate to provide medical treatment and disease management to ESRD patients. It will also be evaluated on the experience and background of its component parts in serving ESRD patients.

An applicant organization may propose to operate the demonstration at more than one site. The applicant will identify which of the three delivery options—managed care, PACE-type, or fee-for-service bundled payment options it chooses for the demonstration, as well as explain the nature of any affiliations with providers, persons, and organizations. An applicant for the capitation option will also be evaluated

on how it will provide non-ESRD medical services to its population.

Applicants will be evaluated on their infrastructure to carry out the selected delivery model. This may include:

- Facilities.
- Equipment.
- Appropriate information and financial services.
- Ability to handle claims to pay providers (for the managed care and PACE-type models).
- Composition of the multidisciplinary team and how the team will function (for the PACE-type model).
- Any special arrangements that may be needed to make transplant services available.

Applicants under all three delivery options—managed care, PACE-type and the fee-for-service bundled payment—should identify the dialysis facilities where services will be provided, and how patients receiving services in those facilities will receive information about the demonstration project, including information on the advantages of retaining and risks of discontinuing Medigap coverage. It is expected that the bundled payment will be for all patients at the facility. In the event that a patient does not want to receive services at the facility, the applicant organization should identify other dialysis facilities conveniently located and with openings so as to allow a patient to receive services. If such a facility is not located within a reasonable distance, the applicant organization should state how it will accommodate patients who do not wish to participate. Applicants should also address what arrangements it will make for traveling patients who receive care in other facilities.

Whether an applicant proposes to serve a disadvantaged population or area will be an important consideration as to whether it is selected for the demonstration. Applications will be evaluated on how they propose to reach out to minorities or other disadvantaged individuals. A demographic profile of the service area, including estimated numbers of ESRD patients by age, sex, race and ethnicity, treatment status/modality and poverty status, along with any relevant socioeconomic or transportation issues, will be considered in determining the demonstration site's potential for assisting a disadvantaged population or area.

(c) *Disease Management Features.* Applicants will be evaluated on their disease management program, including their understanding of the role of the nephrologist in the care of the ESRD patient and the role of the care manager in providing or coordinating services beyond the dialysis facility. In addition, applicants will be evaluated on:

- The proposed disease management services and how they will increase quality and reduce costs.
- The proposed roles of the physician, case managers, and other appropriate staff such as advanced practice nurses, in planning for and coordinating the care of ESRD patients.
- The schedule of visits with the nephrologist and frequency of dialysis.
- The methods of training to ensure a team of care managers with specialized knowledge of diet and medications, as well as other personal needs of ESRD patients.
- How multidisciplinary teams will be used to serve ESRD patients, including the composition of these teams and proposed activities.
- The development and use of protocols to guide case managers' activities.
- If applicable, accreditation specific to disease management by a national organization.

(d) *Service Package*

Under the capitation option, all Medicare-covered services are to be provided. If a demonstration organization participates in a State Medicaid program, then it must work with that State program to meet its requirements. Applicants will be evaluated on their experience with the special clinical, service, and social support needs of the ESRD population and any measures they plan to take to enhance these measures in the demonstration. Applicants will be evaluated on their ability to offer patients a wide choice of treatment modalities, although it is recognized that certain providers may be limited in offering this choice.

3. Financial and Organizational Capability (35 points)

(a) *Ability to Bear Risk.* Applicants must be in compliance with State laws and regulations. Any activities undertaken by an organization under the capitation payment model cannot place the organization in conflict with State requirements on financial risk-bearing. If applicable, applicants will be evaluated on their ability to meet risk-bearing requirements.

(b) *Ability to Meet Enrollment Projections.* Applications will also be evaluated on how many beneficiaries are expected to be treated each year at each site. Under the capitation options, the applicant will be evaluated on its marketing strategy, including its plans to enroll both current and new patients to the demonstration. In addition, the applicant will be evaluated on how it explains how beneficiaries will be informed about supplemental insurance (Medigap) policies and protections. The applicant may restrict eligibility of enrollees by age or other criteria, as long as it gives an acceptable justification.

(c) *Staffing.* Applicants will be evaluated on demonstrated expertise among key personnel, including the following:

- Clinical knowledge and experience, including nephrology.
- Managed care and disease management expertise.
- Financial management expertise.

(d) *Financial and Organizational Provisions.* Applicants will be evaluated on the attractiveness to beneficiaries of Medicare cost-sharing arrangements under the demonstration.

Applicants choosing either the capitation payment or fee-for-service bundled payment options will be evaluated on their projection for attaining budget neutrality for the Medicare program. Applicants for the fee-for-service bundled payment option should include the expanded bundle payment as a medical expense, and project budget neutrality by comparing the payment to costs savings from the disease management intervention on an annual basis. Applicants should justify their proposed cost savings by projections of reduced utilization, references to disease management literature, and the organization's experience. An applicant for the fee-for-service bundled payment option should estimate the amount of ESRD and non-ESRD Medicare claims for its patient population.

If proposing risk sharing for the capitation option, an applicant will be evaluated on the quality of their projected revenue and expense statements, as well as on their analysis of budget neutrality. An applicant for the capitation option will be evaluated on the appropriateness of its Medical Loss Ratio.

(e) *Ability to Implement.* The applicant's organization will be evaluated on the basis of its ability to effectively develop and implement this demonstration project (including evidence of approval by governing boards), commitment of funds to planning and development, and formation of multi-disciplinary and cross-component task forces. The demonstration allows organizations to shift from treating patients in fee-for-service to treating them in managed care. Applicants choosing the managed care or PACE-type delivery option must explain how this change in service delivery will be completed, including

articles of incorporation and protocols for patients. The applicant should state how these elements will impact care, as well as service integration, utilization, access and availability.

Also, the applicant will be judged on its experience in conducting projects of similar clinical scope and organizational complexity as that proposed for the demonstration.

(f) *Information Systems and Management Plan.* Applicant organizations will be evaluated on whether they have sufficient management and clinical information systems and reporting mechanisms to implement the demonstration, including the ability and commitment to provide individual health status (for example, the Health Outcomes Survey) and utilization data. In addition, the applicant should delineate the information that will be collected to support this demonstration, for example, the CMS 2728 (both for new patients and existing patients pending demonstration entry), line item costs for prescribed medications, labs, radiology and other services, all comorbid conditions, patient demographics and facility characteristics.

4. Capability for Quality Assessment and Improvement (15 points)

Under the demonstration, we will link financial incentives to improvements in quality outcome indicators.

Knowledge and participation in our ESRD Clinical Performance Measures Project will be beneficial.

Applicants will also be evaluated on their quality improvement system, including the following:

- Written quality improvement policies and procedures.
- A standing quality improvement committee.
- Patient grievance and appeal systems.
- Provider credentialing system.
- Organizational modification methodology for applicants planning to shift from fee-for-service to the managed care model.

An organization's application will be evaluated on how it will measure improvements in health outcomes attributable to its disease management interventions.

XI. Final Awards

From among the most highly qualified applicants, the final selection of projects for the demonstration will be made by the Administrator and will take into consideration a number of factors, including operational feasibility, budget neutrality, geographic location, and program priorities (such as testing a variety of approaches for delivering services, targeting beneficiaries, and payment). We reserve the right to determine the scope of the project, which includes limiting the number of awards and beneficiaries covered under the demonstration. In evaluating applications, we rely on our past experience with successful and unsuccessful demonstrations. We expect to make the awards in 2003.

XII. Collection of Information Requirements

The application and instructions associated with this solicitation are approved under OMB control number 0938–0880, with a current expiration date of 05/31/03. We have requested a three year extension of the application. Pending OMB approval, this current application is valid through the interim period. The form and instructions can be obtained from the CMS web site referenced elsewhere in this notice.

Appendix I: Services Included in the Expanded Dialysis Bundle

A. Drugs

EPO (Erythropoietin, Epoetin Alpha) HCPCS Codes Q9920–Q9940 Aranesp (J0880)
Iron (J1750, J1755, J1760, J1770, J1780, J2915, J2916)
Vitamin D (J0630, J0635, J0636, J2500, J1270)
Levocarnitine (J1955)
Phosphate Binders (J0610)

B. Labs/Radiology

Laboratory HCPCS Codes (208 codes)

73120 X-Ray Exam Hand
75710 Artery X-Rays Arm/Leg
75716 Artery X-Rays Arms/Legs
75774 Artery X-Ray, Each Vessel
75893 Venous Sampling by Catheter
75964 Repair Artery Blockage; Each
76070 CT Scan, Bone Density Study
76075 Dual Energy X-Ray Study
76092 Mammogram, Screening
76778 Echo Exam Kidney Transplant
78070 Parathyroid Nuclear Imaging
78351 Bone Mineral Dual Photon
80048 Basic Metabolic Panel
80051 Electrolyte Panel
80053 Comp Metabolic Panel
80061 Lipid Panel
80069 Renal Function Panel
80074 Acute Hepatitis Panel
80076 Hepatic Function Panel
80156 Assay Carbamazepine
80162 Assay for Digoxin
80185 Assay for Phenytoin
80186 Assay for Phenytoin, Free
80197 Assay for Tacrolimus
80198 Assay for Theophylline
80202 Assay for Vancomycin
80410 Calcitonin Stimulation Panel
81000 Urinalysis, Nonauto, W/Scope
81001 Urinalysis, Auto, W/Scope
81002 Urinalysis, Nonauto W/O Scop
81003 Urinalysis, Auto, W/O Scope
81005 Urinalysis
81007 Urine Screen for Bacteria
81015 Microscopic Exam Urine
82009 Test for Acetone/Ketones
82010 Acetone Assay
82017 Acylcarnitines, Quant
82040 Assay Serum Albumin
82042 Assay Urine Albumin
82108 Assay, Aluminum
82232 Beta–2 Protein
82247 Bilirubin Total
82248 Bilirubin Direct
82270 Test Feces Blood
82306 Assay Vitamin D
82307 Assay Vitamin D
82308 Assay Calcitonin
82310 Assay Calcium
82330 Assay Calcium
82374 Assay Blood Carbon Dioxide
82379 Assay Carnitine
82435 Assay Blood Chloride
82465 Assay Serum Cholesterol
82550 Assay CK (CPK)
82565 Assay Creatinine
82570 Assay Urine Creatinine
82575 Creatinine Clearance Test
82607 Vitamin B–12
82728 Assay Ferritin
82746 Blood Folic Acid Serum
82747 Folic Acid, RBC
82800 Blood PH
82803 Blood Gases: PH, PO2, PCO2
82805 Blood Gases W/O2 Saturation
82810 Blood Gases, O2 Sat Only
82945 Glucose Other Fluid
82947 Assay Quantitative, Glucose
82948 Reagent Strip/Blood Glucose
82950 Glucose Test
82977 Assay GGT
83036 Glycated Hemoglobin Test
83540 Assay Iron
83550 Iron Binding Test
83718 Blood Lipoprotein Assay
83735 Assay Magnesium
83937 Assay Osteocalcin
83970 Assay Parathormone
83986 Assay Body Fluid Acidity
84075 Assay Alkaline Phosphatase
84100 Assay Phosphorus
84105 Assay Urine Phosphorus
84132 Assay Serum Potassium
84133 Assay Urine Potassium
84134 Assay Prealbumin
84155 Assay Protein
84160 Assay Serum Protein
84295 Assay Serum Sodium
84315 Body Fluid Specific Gravity
84443 Assay Thyroid Stim Hormone
84450 Transferase (AST) (SGOT)
84460 Alanine Amino (ALT) (SGPT)
84466 Transferrin
84478 Assay Triglycerides
84520 Assay Urea Nitrogen
84540 Assay Urine Urea-N
84545 Urea-N Clearance Test
84630 Assay Zinc
85002 Bleeding Time Test
85004 Automated Diff WBC Count
85007 Differential WBC Count
85008 Nondifferential WBC Count
85009 Differential WBC Count
85013 Hematocrit
85014 Hematocrit
85018 Hemoglobin
85021 Automated Hemogram
85022 Automated Hemogram
85025 Automated Hemogram
85027 Automated Hemogram
85032 Manual Cell Count, Each

85041 Red Blood Cell (RBC) Count
85044 Reticulocyte Count
85045 Reticulocyte Count
85046 Reticyte, HGB Concentrate
85048 White Blood Cell (WBC) Count
85049 Automated Platelet Count
85345 Coagulation Time
85347 Coagulation Time
85348 Coagulation Time
85520 Heparin Assay
85595 Platelet Count, Automated
85610 Prothrombin Time
85611 Prothrombin Test
85651 RBC SED Rate, Nonauto
85652 RBC SED Rate, Auto
85730 Thromboplastin Time, Partial
85732 Thromboplastin Time, Partial
86140 C-Reactive Protein
86317 Immunoassay, Infectious Agen
86590 Streptokinase, Antibody
86644 CMV Antibody
86645 CMV Antibody, IGM
86687 HTLV–I
86688 HTLV–II
86689 HTLV/HIV Confirmatory Test
86692 Hepatitis, Delta Agent
86701 HIV–1
86702 HIV–2
86703 HIV–1/HIV–2, Single Assay
86704 HEP B Core AB Test
86705 HEP B Core AB Test
86706 HEP B Surface AB Test
86707 HEP BE AB Test
86708 HEP A AB Test
86709 HEP A AB Test
86803 HEP C AB Test
86804 HEP C AB Test Confirm
86812 HLA Typing, A, B, /C
86813 HLA Typing, A, B, /C
86816 HLA Typing, DR/DQ
86817 HLA Typing, DR/DQ
86900 Blood Typing, ABO
86901 Blood Typing, RH (D)
86903 Blood Typing, Antigen Screen
86904 Blood Typing, Patient Serum
86905 Blood Typing, RBC Antigens
86906 Blood Typing, Rh Phenotype
87040 Blood Culture Bacteria
87070 Culture Specimen, Bacteria
87071 Culture Bact
87072 Culture Specimen By Kit
87073 Culture Bact
87075 Culture Specimen, Bacteria
87076 Bacteria Identification
87077 Culture Bact
87081 Bacteria Culture Screen
87084 Culture Specimen By Kit
87086 Urine Culture, Colony Count
87088 Urine Bacteria Culture
87147 Culture Typing, Serologic
87163 Culture, Any Source, Add'l ID Reqd
87181 Antibiotic Sensitivity, Each
87184 Antibiotic Sensitivity, Each
87185 Enzyme Detection
87186 Antibiotic Sensitivity, MIC
87187 Antibiotic Sensitivity, MBC
87188 Antibiotic Sensitivity, Each
87190 TB Antibiotic Sensitivity
87197 Bactericidal Level, Serum
87205 Smear/Stain, Interpret
87271 CMV, DFA
87340 HEP B Surface AG, EIA
87341 HEP B HBSAG Neutral AG, EIA
87350 HEP B AG, EIA
87380 HEP Delta AG, EIA
87390 HIV–1 AG, EIA
87391 HIV–2 AG, EIA
87515 HEP B, DNA, Direct
87516 HEP B, DNA, AMP
87517 HEP B, DNA, Quant
87520 HEP C, RNA, Direct
87521 HEP C, RNA, AMP
87522 HEP C, RNA, Quant
87525 HEP G, DNA, DIRECT
87526 HEP G, DNA, AMP
87527 HEP G, DNA, Quant
89050 Body Fluid Cell Count
89051 Body Fluid Cell Count
93000 Electrocardiogram Complete
93005 Electrocardiogram Tracing
93010 Electrocardiogram Report
93040 Rhythm ECG w/Report
93041 Rhythm ECG Tracing
93042 Rhythm ECG Report
93307 Echo Exam Heart
93308 Echo Exam Heart
G0001 Drawing Blood for Specimen
G0202 Screening Mammography, Digital

C.Vascular Access

Vascular Access HCPCS Codes (122 Codes)

00350 Anes-Major Vessels Neck; Nos
00532 Anes-Access Cent Venous Circ
01784 Anesthesia-AV Fistula
01844 ANES–VASC Shunt, Shunt Revis
35180 Repair Blood Vessel Lesion
35190 Repair Blood Vessel Lesion
35206 Repair Blood Vessel Lesion
35226 Repair Blood Vessel Lesion
35236 Repair Blood Vessel Lesion
35256 Repair Blood Vessel Lesion
35450 Repair Arterial Blockage
35451 Repair Arterial Blockage
35452 Repair Arterial Blockage
35453 Repair Arterial Blockage
35454 Repair Arterial Blockage
35455 Repair Arterial Blockage
35456 Repair Arterial Blockage
35457 Repair Arterial Blockage
35458 Repair Arterial Blockage
35459 Repair Arterial Blockage
35460 Repair Venous Blockage
35470 Repair Arterial Blockage
35471 Repair Arterial Blockage
35472 Repair Arterial Blockage
35473 Repair Arterial Blockage
35474 Repair Arterial Blockage
35475 Repair Arterial Blockage
35476 Repair Venous Blockage
35860 Explore Limb Vessels
35875 Remove Clot In Graft
35876 Remove Clot In Graft
35900 Excision Of Infected Graft—Extremity
35903 Excise Graft Extremity
35910 Excision Of Infected Graft—Extremity
36000 Place Needle In Vein
36005 Injection, Venography
36011 Place Catheter In Vein
36140 Establish Access To Artery
36145 Artery To Vein Shunt
36215 Place Catheter In Artery
36216 Place Catheter In Artery
36217 Place Catheter In Artery
36245 Place Catheter In Artery
36246 Place Catheter In Artery
36247 Place Catheter In Artery
36400 Drawing Blood
36406 Drawing Blood
36410 Drawing Blood
36420 Establish Access To Vein
36425 Establish Access To Vein
36488 Insert Catheter Vein
36489 Insert Catheter Vein
36490 Insert Catheter Vein
36491 Insert Catheter Vein
36493 Reposition CVC
36533 Insert Access Port
36534 Revise Access Port
36535 Remove Access Port
36550 Declot Vascular Device
36800 Insert Cannula
36810 Insert Cannula
36815 Insert Cannula
36819 AV Fusion By Basilic Vein
36820 AV Anastomosis-Perm Access
36821 Artery-Vein Fusion
36825 Artery-Vein Graft
36830 Artery-Vein Graft
36831 AV Fistula Excision
36832 AV Fistula Revision
36833 AV Fistula
36834 Repair A–V Aneurysm
36835 Artery To Vein Shunt
36860 Ext Cannula Declotting
36861 Cannula Declotting
36870 Thrombectomy
37190 Repair A–V Aneurysm
37201 Transcatheter Therapy Infuse
37205 Transcatheter Stent
37206 Transcatheter Stent Add-On
37207 Transcatheter Stent
37208 Transcatheter Stent Add-On
37209 Exchange Arterial Catheter
37607 Ligate Fistula
49420 Insert Abdominal Drain
49421 Insert Abdominal Drain
49422 Remove Perm Cannula/Catheter
71010 Chest X-Ray
71015 Chest X-Ray
71020 Chest X-Ray
71021 Chest X-Ray
71022 Chest X-Ray
71030 Chest X-Ray
71035 Chest X-Ray
75790 Visualize A–V Shunt
75820 Vein X-Ray Arm/Leg
75822 Vein X-Ray Arms/Legs
75860 Vein X-Ray Neck
75894 X-Rays Transcatheter Therapy
75896 X-Rays Transcatheter Therapy
75898 Follow-Up Angiogram
75900 Arterial Catheter Exchange
75901 Mechanical Removal Of Pericath Obstructive Material
75902 Mechanical Removal Of Intraluminal Obstructive Material
75960 Transcatheter Intro Stent
75961 Retrieve Broken Catheter
75962 Repair Arterial Blockage
75978 Repair Venous Blockage
76080 X-Ray Exam Fistula
76942 Echo Guide For Biopsy
76960 Echo Guidance Radiotherapy
93900 Duplex Scan Of Hemodialysis Access
93922 Extremity Study
93923 Extremity Study
93925 Lower Extremity Study
93926 Lower Extremity Study
93930 Upper Extremity Study
93931 Upper Extremity Study
93965 Extremity Study
93970 Extremity Study
93971 Extremity Study
A4300 Cath Impl Vasc Access Portal
M0900 Excision Without Graft

Authority: Section 402 of the Social Security Act Amendments of 1967 (42 U.S.C. 1395b1).

(Catalog of Federal Domestic Assistance Program No. 93.779, Health Care Financing Research, Demonstrations and Evaluations)

Dated: May 10, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–13829 Filed 5–29–03; 12:09 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Grants for Policy-Oriented Rural Health Services Research; Grant Announcement Number HRSA–03–091

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Office of Rural Health Policy (ORHP) announces that approximately $900,000 in Fiscal Year (FY) 2003 funds are available for competitive grants for policy-oriented rural health services research. Individual research projects that address rural health services will be funded under this announcement. This program is authorized by Section 301 of the Public Health Service Act. Eligibility is open to public, private, and non-profit—including faith-based and community-based—organizations. Further information is provided in the Eligibility Requirements section. Grant awards will be limited to $150,000 per grantee. It is anticipated that six (6) awards will be made. The project period is twelve months.

APPLICATION DEADLINES: Applications must be received by 4 p.m. Eastern Time on July 7, 2003. Completed applications must be sent to HRSA Grants Application Center (GAC), 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879.

Applications shall be considered as meeting the deadline if they are either (1) received on or before the deadline date; or (2) postmarked on or before the deadline date and received in time for orderly processing. Applicants must obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service in lieu of a postmark. Private metered postmarks are not acceptable as proof of timely mailing. Late applications will not be reviewed. Applicants will receive a confirmation of receipt notice from the HRSA Grants Application Center.

The standard application form and general instructions for completing applications (Form PHS 398) have been approved by the Office of Management and Budget. To receive an application kit, contact the HRSA Grants Application Center toll-free at 1–877–477–2123 or write them at HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879. To order an application kit for this program, you must identify the program citing the following program name, catalogue of federal domestic assistance number, and announcement number: Grant Program for Policy-Oriented Rural Health Services Research, Catalogue Of Federal Domestic Assistance Number: 93.155, Grant Announcement Number: HRSA–03–091.

On-line grant application: Applicants should note that HRSA anticipates accepting grant applications online in the last quarter of the Fiscal Year (July through September). Please refer to the HRSA grants schedule at *http://www.hrsa.gov/grants.htm* for more information.

Letter of intent: In order to allow the ORHP to plan for the objective review process, applicants are requested to notify the ORHP in writing of their intent to apply. This notification is not binding, but serves to inform the ORHP of anticipated numbers of applications that may be submitted. Do not fax notification. Notification is requested no later than June 11, 2003. The address for notification is: Emily Costich, Policy-Oriented Rural Health Services Research Program, Office of Rural Health Policy, Health Resources and Services Administration, Room 9A–55, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Information or technical assistance regarding business, budget, or financial issues should be directed to the Division of Grants Management Operations, Health Resources and Services Administration, 5600 Fishers Lane, Room 7–89, Rockville, Maryland 20857, 301–443–2280. Specific contacts are:

Janice M. Gordon, Grants Management Officer, Division of Grants Management Operations, Telephone: 301–443–2385, E-mail: *jgordon@hrsa.gov.*

Darren S. Buckner, Grants Management Specialist, Division of Grants Management Operations, Telephone: 301–443–1913, E-mail: *dbuckner@hrsa.gov.*

Requests for technical or programmatic information on this announcement should be directed to Emily Costich, Office of Rural Health Policy, Room 9A–55, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–0502, E-mail: *ecostich@hrsa.gov.*

SUPPLEMENTARY INFORMATION: Policy-oriented rural health services research is useful because it informs policy-makers concerned with rural health issues and it enhances knowledge about rural health and rural health services. In addition, rural health services research addresses critical concerns facing rural communities in their quest to secure adequate, affordable, high quality health services. Research findings are useful to inform a wide audience of national, state, and local decision-makers about rural health issues. Research findings have been instrumental in bridging gaps between policy and program needs.

Research Priorities: These grants are designed to provide support both for entities established in the rural health services research field as well as those entering this field. These grants are also intended to advance specific areas of rural health services research in which a limited amount of research exists. To determine what specific rural health services research is in progress in the areas of applicant interest, query the Database for Rural Health Research in Progress at: *http://www.rural-health.org.* This grant program will support individual research projects and excludes clinical/biomedical research and the expenditure of funds for delivery of services.

Research Areas

Applications are sought for the research areas specified below, either singly or in combination. These areas are not listed in any priority order. Applications falling outside these research areas may be returned at the discretion of the Office of Rural Health Policy as being non-responsive.

(1) Mental Health
(2) Substance Abuse
(3) Oral Health
(4) American Indian/Alaska Native/Native Hawai'ian Health Issues
(5) Integration of Native and Non-Native Health Care
(6) Special Populations—Children, Women, Homeless, Elderly
(7) Chronic Disease (*e.g.*, Asthma and Diabetes)
(8) Bioterrorism Preparedness
(9) Frontier Issues
(10) Medicaid
(11) S–CHIP
(12) End of Life Care
(13) Continuum of Care
(14) Public Health Issues