

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