

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 physician 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