National Kidney Disease Education Program (NKDEP)
National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), National Institute of Health (NIH)

Kidney Interagency Coordinating Committee (KICC) Meeting
September 9, 2011, Natcher Conference Center

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I. Welcome and Introductions

Andrew Narva, MD, FACP

Dr. Narva welcomed committee members and thanked them for their participation.

The committee was created in 1987 by Congress. The goal of the committee is to encourage cooperation, communication, and collaboration among all Federal agencies involved in kidney research and other kidney-related activities.

The focus of the fall 2011 meeting is the role of federal agencies in improving quality of care. The absence of evidence to support many guideline recommendations complicates efforts to promote improved care. The cost of pharmacological interventions can further complicate treatment decisions.

II. ERSD Quality Incentive Program

Kimberly Smith, MD, MS

As a result of the Affordable Care Act, there has been an increased emphasis on quality within the Department of Health and Human Services (HHS). These efforts are guided by the National Strategy for Quality Improvement in Health Care (National Quality Strategy). The National Quality Strategy is designed to promote patient-centered, quality health care.

Goals of National Quality Strategy

- **Better Care**
  Improve the overall quality, by making health care more patient-centered, reliable, accessible, and safe.
- **Healthy People and Communities**
  Improve the health of the U.S. population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher-quality care.
- **Affordable Care**
  Reduce the cost of quality health care for individuals, families, employers, and government.

The Centers for Medicare & Medicaid Service's (CMS) Office of Clinical Standards and Quality (OCSQ) provides leadership and coordination for the development and implementation of a cohesive approach to measuring and promoting quality. It identifies and encourages best practices and techniques in quality improvement.

A recent initiative of the OCSQ is the ESRD Quality Incentive Program (QIP), the first in a series of CMS programs that mark a significant change in how Medicare reimburses providers and facilities for patient care. CMS developed the ESRD QIP to be the nation's first pay-for-performance (also known as "value-based purchasing") program as mandated by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Along with the ESRD QIP, MIPPA also created a new payment system to replace a payment system in effect since 1983. The "composite rate" under the old system included some drugs, laboratory tests, and supplies. Over time, the expenditures for separately billable drugs (e.g., erythropoeisis-stimulating agents [ESAs], vitamin D analogues) have increased substantially. They now constitute 40 percent of total Medicare spending for outpatient dialysis.

Beginning in 2012, dialysis facilities across the country will be paid for renal dialysis services based on the quality of care—not just the quantity of the services provided. For the ESRD QIP, CMS is identifying measures and setting standards with the ultimate goal of improving patient outcomes and providing incentives for providers and facilities to incorporate quality, value, and efficiency in delivering care. As part of the program, CMS will:

- Assess the quality of dialysis care through measures and performance standards;
- Starting January 1, 2012, apply payment reductions of up to 2 percent for providers that do not meet these standards; and
- Publicly report facility performance (e.g., results on the CMS website, certificate posted in each facility).

For payment year 2012, the following measures were used:

- Anemia management – percent of patients whose hemoglobin level is less than 10 g/dL and percent of patients whose hemoglobin level is greater than 12 g/dL.
- Dialysis adequacy – percent of patients with urea reduction ratio (URR) of at least 65 percent.

Data from 2010 claims will be used to assess these measures. The measures will be individually scored, with the scores being combined into a total performance score. The total performance score will be used to determine the payment deduction, starting January 1, 2012.

QIP Statutory Requirements

- Measures on anemia management that reflect the labeling approved by the FDA for such management
- Measures on dialysis adequacy
- To the extent feasible, measures of patient satisfaction
- Suggests measures of iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula)
- Measures must be endorsed by a consensus body, such as the National Quality Forum (NQF), unless feasible and practical measures do not exist for the topic area

On July 1, 2011, CMS proposed changes to the program for payment years 2013 and 2014. For payment year 2013, CMS proposed to retire the measure of hemoglobin less than 10 g/dL but proposed to keep the remainder of the program the same. Data from 2011 claims will be used to assess the remaining measures. For payment year 2014, several additional measures were proposed which are designed to recognize both achievement and improvement. Under the proposal, ninety (90) percent of the performance score would be based on five "clinical" measures:

- Hemoglobin >12 g/dL;
- URR replaced with Kt/V;
- Vascular access type (catheter and fistula measures);
- Vascular access infection (claims-based); and
- Standardized hospitalization ratio – admissions (SHR).

An additional three "reporting" measures would comprise 10 percent of the performance score:

- CDC National Healthcare Safety Network (NHSN) Dialysis Events;

- In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey; and
- Mineral metabolism monitoring (measurement of serum calcium and phosphorus).

The process of developing performance measures for ESRD is made more difficult due to the lack of evidence on the effectiveness of various treatments. An example is the modifications to the FDA approved labeling for erythropoiesis-stimulating agents (ESAs) in June 2011.

The ESA labels now warn:

- In controlled trials with chronic kidney disease (CKD) patients, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target a hemoglobin level of greater than 11 g/dL.
- No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks.

ESA labels now recommend:

- For patients with CKD, consider starting ESA treatment when the hemoglobin level is less than 10 g/dL. This advice does not define how far below 10 g/dL is appropriate for an individual to initiate. This advice also does not recommend that the goal is to achieve a hemoglobin of 10 g/dL or a hemoglobin above 10 g/dL. Individualize dosing and use the lowest dose of ESA sufficient to reduce the need for red blood cell transfusions. Adjust dosing as appropriate.

This labeling change and a reassessment of the clinical evidence for anemia management in ESRD resulted in the proposal to retire the hemoglobin <10 g/dL measure from the ESRD QIP measure set. CMS published the proposed rule for payment years 2013 and 2014 in the Federal Register in July 2011. Public comment on the proposed rule closed on August 30, 2011 and the final rule is expected to be published November 1, 2011.

III. CMS End-Stage Renal Disease (ESRD) Measure Development

Shari Ling, MD

There are various reasons for using performance measures. The measures can serve as a mechanism for driving improvement by providing feedback to providers. They can also provide information that allows the public to be knowledgeable consumers of care. In addition, through the use of incentives they can promote improvement. They can also be a force for driving overall system transformation and policy decisions.

In developing effective measures, it is important to identify areas where the use of measures can make a difference so that measurement drives change. The Centers for Medicare and Medicaid Services (CMS) and the National Quality Forum (NQF) have established four desirable attributes for measures.

> **Importance** – including health and financial importance, potential for improvement and variability of performance, and clinical evidence to support the measure
>
> **Scientific Acceptability** – the measure is valid and reproducible

Usability – meaningfulness

Feasibility – can be implemented for a reasonable cost, is logistically feasible, and does not constitute an undue burden to providers

There are different types of measures. The two most commonly used are process and outcome measures. Process measures look at whether the appropriate processes are used to deliver the care. These types of measures are often favored by the health care community because they are within the control of the organization or clinician. Process measures are not usually risk adjusted. Instead they rely on the use of exclusions and the stratification of results by patient characteristics. Outcomes measure the end result and can be influenced by many factors, including patient factors. For this reason, they require risk adjustment.

There are also composite measures, which are usually created to look at how well a more comprehensive set of related processes of care are delivered and provide more insight into the quality of care delivered for a particular health condition. Combining measures can make it easier for users to quickly interpret the information.

A critical aspect of measure development is identifying appropriate data sources. Currently, claims data are being used to assess most measures, which does not allow for proper measurement. Implementation of CROWNWeb, the CMS electronic health record (EHR) system, will improve measurement.

The process CMS uses to develop measures is designed to allow input from stakeholders at each step. A contractor conducts research (e.g., environmental scan, stakeholder survey, etc.) and develops the measures with input from a technical expert panel. The potential measures are then tested, refined, and released for public comment. Based on the comments received, the measures are refined and final measures developed. Some CMS measures are submitted to the NQF, an independent body, for endorsement. The NQF panels only considers measures as they are submitted, they cannot modify the measures.

The Affordable Care Act (ACA) includes many requirements related to quality reporting and public reporting. CMS is working to implement these requirements through the implementation of CROWNWeb and programs such as the Physician Quality Reporting System (PQRS), which creates a financial incentive for eligible professionals to satisfactorily report data on certain quality measures for Medicare Part B services paid under the physician fee schedule. Measures selected for PQRS are specific to specialties and address clinical and program gaps. They are designed for use in multiple settings by a variety of eligible professionals.

Throughout the measurement development process, there is ample opportunity for involvement across federal agencies. CMS is already collaborating with the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), and the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE).

IV. Agency Updates

- AHRQ: Dr. Chang reported that the screening and monitoring for CKD report will be out in the next few months. A portion of this report was used for the task force's screening recommendations, which will be released for in 2012. There may be a public comment period on these recommendations. There is also an upcoming report on biomarkers for management of anemia in pre-dialysis and dialysis patients. This is coming out for public comment later this year.
- Centers for Disease Control and Prevention: Dr. Williams reported that CDC has received funding for the CKD surveillance website for the next 5 years.

V. Adjournment

Dr. Narva closed the meeting, thanking participants for their participation.