U.S. Department of Health and Human Services
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KICC News

A quarterly newsletter by the National Kidney Disease Education Program | Issue #6 | Spring/Summer 2008

CMS Updates Conditions for Coverage for ESRD Facilities

In April 2008, the Centers for Medicare and Medicaid Services (CMS) released the final rule on the Conditions for Coverage (CFC) for End-Stage Renal Disease (ESRD) facilities, laying out the criteria a facility must meet to be certified to provide dialysis services to Medicare beneficiaries. The rule reflects the first update of the CFC since they were originally published in 1976 and finalizes the proposals originally publicized in February 2005.

The rule focuses on the importance of patient rights, patient safety, and the patient's participation in the development of his or her own plan of care. Each facility is required to develop a quality assessment and performance improvement program that would track the facility's performance in patient health outcomes. This regulation also reduces the detailed and burdensome requirements that dialysis facilities had to meet previously and provides flexibility for facilities to use their resources to meet the needs of individual patients and achieve better outcomes of care.

Facilities will have 180 days from the date of publication to comply with most of the new requirements. *For more information, please visit www.cms.hhs.gov/CFCsAndCoPs/13_ESRD.asp or contact Ms. Teresa Casey at Mary.Casey@cms.hhs.gov, Lynn Riley at lynn.riley@cms.hhs.gov, or Lauren Oviatt at lauren.oviatt@cms.hhs.gov.*

CDC Identifies Topics and Data Sources for Surveillance Project

The Centers for Disease Control and Prevention (CDC) is developing a national surveillance system for chronic kidney disease (CKD) based on existing national and regional data sources. Because this is a resource intensive project, CDC is implementing it in phases. The phases are as follows: identify and prioritize topics and measures relevant to CKD surveillance; evaluate each data source/topic-measure-indicator combination; plan for integration of all the data source to form a functional national surveillance system; assess the feasibility of integration of all the data sources, including the USRDS and the diabetes surveillance system; pilot test; and disseminate a final report and recommendations.

CDC has completed the first two phases. They have identified the following six topics relevant to CKD surveillance: burden of CKD, awareness of CKD, burden of risk factors for CKD, health consequences in CKD patients, CKD processes and quality of care, and health system capacity for CKD. CDC has also evaluated each data source against the desirable characteristics, which include sensitivity, stability, and ability, to represent the U.S. population to assess the project's utility.

CDC is now working on transferring the information they have collected to a website. CDC will also be conducting a pilot test of the integration of data and data sources, developing a web-based report, and drafting a brief CKD fact sheet for the public. *For more information, please visit www.cdc.gov/diabetes/projects/kidney.htm or contact Dr. Desmond Williams at desmond.williams@cdc.hhs.gov.*

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HRSA Works to Improve Organ Donation Processes

The Health Resources and Services Administration (HRSA) Organ Donation and Transplantation Breakthrough Collaboratives have helped to increase organ donation over 20% in recent years, but 60,000 potential kidney recipients are still waiting—about 4,000 of whom die waiting annually.

Possible kidney allocation improvements are under study by HRSA's contractor, the Organ Procurement Transplantation Network (OPTN). Chances for young adults to get transplanted are decreasing with the present waiting time-based system. A new allocation process using the "net benefit" likely for each patient (balancing time on dialysis with likelihood of long term success) is under consideration.

Although not common, transmission of infection or neoplasm from the donor is a devastating complication. HRSA and the Food and Drug Administration (FDA) have been working with the OPTN to increase management of these instances and to conduct studies to inform policy-making.

HRSA has advised the OPTN to consider oversight and policy issues for living donation. In addition to extending donor follow-up, HRSA has supported NIH studies on the risks of being a living donor. OPTN is also working to optimize the process of a multiple switch option for living kidney donation for donors who are incompatible with their intended recipient. *For more information, please visit www.organdonor.gov or contact Dr. Jim Burdick at JBurdick@hrsa.gov.*

Drug Dosing in the Post-Creatinine Standardization Environment

The Laboratory Working Group of the National Kidney Disease Education Program (NKDEP) has established a subcommittee to write recommendations for clinicians about estimating kidney function for drug-dosing purposes in the post-creatinine standardization environment. Over the next couple of years clinical laboratories will implement methods of creatinine measurement with calibration traceable to the IDMS reference system. IDMS-traceable calibration produces creatinine values that are 10% to 20% lower. Although there is a revised MDRD estimating equation for use with IDMS-traceable methods, no IDMS-traceable version exists for the Cockcroft-Gault equation—the traditional method of estimating kidney function for drug dosing purposes. This has created some concern among pharmacists and clinicians, particularly when dosing drugs with a narrow therapeutic index. This multi-disciplinary group of experts includes representatives from the FDA and is chaired by Dr. Lesley Stevens. *For more information, contact Dr. Andrew Narva at Andrew.Narva@niddk.nih.gov.*

FDA and NKF Host Conference to Review Proteinuria Data

The FDA and The National Kidney Foundation (NKF) co-sponsored a conference to review data on proteinuria as a surrogate outcome in CKD in May 2008. Presented during the conference were data that resulted from observational and interventional trials in diabetic and non-diabetic kidney diseases. Also discussed were measurement and assay issues, as well as definitions of albuminuria. NKDEP will let *KICC News* readers know when the summary of the discussions and conclusions is released.

NKDEP National Kidney Disease Education Program

NIDDK National Institute of Diabetes and Digestive and Kidney Diseases

Please send your story ideas for future issues of *KICC News* to Eileen Newman at eileen.newman@nih.gov.