

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 400, 405, 410, 412, 413, 414, 488, and 494

[CMS-3818-P]

RIN 0938-AG82

Medicare Program; Conditions for Coverage for End Stage Renal Disease Facilities

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the requirements that end stage renal disease (ESRD) dialysis facilities must meet to be certified under the Medicare program. The revised requirements focus on the patient and the results of the care provided to the patient, establish performance expectations for facilities, encourage patients to participate in their care plan and treatment, eliminate many procedural requirements from the current conditions for coverage, and preserve strong process measures when necessary to promote patient well being and continuous quality improvement. These changes are necessary to reflect the advances in dialysis technology and standard care practices since the requirements were last revised in their entirety in 1976.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 5, 2005.

ADDRESSES: In commenting, please refer to file code CMS-3818-P. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission.

You may submit comments in one of three ways (no duplicates, please):

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Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3818-P, PO Box 8012, Baltimore, MD 21244-8012.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

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For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Robert Miller (410) 786-6797, Teresa Casey (410) 786-7215, and Rachael Weinstein (410) 786-6775 (Conditions for Coverage and Quality Standards). Jan Tarantino, (410) 786-0905 (Survey and Certification).

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-3818-P and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its

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Acronyms

- AKF American Kidney Fund
- AAMI Association for the Advancement of Medical Instrumentation
- ANNA American Nephrology Nurses Association
- AHRQ Agency for Healthcare Research and Quality
- AED Automatic external defibrillator
- AIA American Institute of Architects
- ANSI American National Standards Institute
- BBA Balanced Budget Act of 1997
- BONENT Board of Nephrology Nursing Examiners Nursing and Technology
- BUN Blood urea nitrogen
- CAHPS Consumer Assessment of Health Plans Survey
- CBC Center for Beneficiary Choices
- CDC Centers for Disease Control and Prevention
- CHI Consolidated Health Informatics
- CEO Chief executive officer
- CLIA Clinical Laboratory Improvement Amendments
- CMS Centers for Medicare and Medicaid Services
- CPG Clinical practice guidelines
- CPM Clinical performance measures
- CPR Cardiopulmonary resuscitation
- CROWN Consolidated Renal Operations in a Web-enabled Network
- DHHS Department of Health and Human Services
- DME Durable medical equipment
- DOQI Disease Outcomes Quality Initiative

- DSN Dialysis Surveillance Network
- EMS Emergency medical system
- ESRD End stage renal disease
- FDA Food and Drug Administration
- HHA Home health agency
- HIPAA Health Insurance Portability and Accountability Act of 1996
- ICH In-center hemodialysis
- IOM Institute of Medicine
- IT Information technology
- LSC Life Safety Code
- MedPAC Medicare Payment Advisory Commission
- MSW Master's degree social worker
- NANT National Association of Nephrology Technicians
- NF Nursing facility
- NFPA National Fire Protection Association
- NIH National Institutes of Health
- NISTA National Institute of Standards and Technology Act
- NKF National Kidney Foundation
- NKF-K/DOQI National Kidney Foundation's Kidney Disease Outcomes Quality Initiatives
- NNCC Nephrology Nursing Certification Commission
- NNCO National Nephrology Certification Organization
- NQF National Quality Forum
- NTTAA National Technology Transfer and Advancement Act of 1995
- OBRA 1990 Omnibus Reconciliation Act 1990
- OIG Office of the Inspector General
- OMB Office of Management and Budget
- QAPI Quality assessment and performance improvement
- RPA Renal Physicians Association
- RRG Rapid response group
- SNF Skilled nursing facility
- VISION Vital Information System to Improve Outcomes in Nephrology
- URR Urea reduction rate
- USRDS United States Renal Data System

I. Introduction and the Provision of Reference Materials

A. Introduction

The Centers for Medicare and Medicaid Services (CMS) is committed to modernizing the existing regulations that are based on largely procedural standards. One of our key initiatives is to revise many of the health and safety conditions to focus on the patient's experience with care in the delivery setting, patient outcomes of care, and the elimination of unnecessary procedural requirements.

In concert with the Administration's regulatory reform initiative, we believe that new ESRD regulations should—

- Be founded on evidence;
- Be patient-centered;
- Promote outcomes desired for Medicaid and Medicare beneficiaries as well as others served by participating ESRD suppliers of services;
- Establish a framework for the collection and reporting of consensus-driven performance standards;

- Set clear expectations for dialysis facility accountability; and
- Stimulate improvements in processes, outcomes of care, and beneficiary satisfaction.

In addition, the new ESRD conditions for coverage must comport with our national performance measurement strategy, which consists of three principles: (1) Performance measures should be consumer and purchaser-driven; (2) performance measures should be in general, commonly-used terms, and their associated collection tools should be generally available at little or no cost to dialysis facilities; and (3) the content and collection of data and performance measures derived from that data should be standardized.

B. Provision of Informational and Review Aids

In our development of the proposed rule, we have included references to a number of reports, articles, and other documents in the preamble. To indicate the source of this information, we have provided a brief parenthetical acknowledgement at the end of referenced statement and have provided a full citation for the reference in the bibliography (*see* section of VIII.C. of this preamble). Other informational and review aids incorporated in this proposed rule include—

- A table of contents;
- A list of acronyms;
- A chart listing the new provisions (*see* section VIII.A. of this preamble); and
- A crosswalk of the existing requirements to the proposed requirements (*see* section VIII.B. of this preamble).

II. Background

A. History

ESRD is a kidney impairment that is irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life. Dialysis is the process of cleaning the blood artificially with special equipment when the kidneys have failed.

Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603) originally extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation. The ESRD program became effective July 1, 1973, and initially operated under interim regulations published in the **Federal Register** on June 29, 1973 (38 FR 17210). In the July 1, 1975 **Federal Register** (40 FR 27782), we published a proposed rule that revised sections of the regulations relating to:

- The Medicare conditions for coverage for suppliers of ESRD services;
- Certification procedures;
- Establishment of minimal utilization rates;
- Designation of ESRD network areas;
- Establishment of Network Coordination Councils; and
- The provision of a Medical Review Board.

A comment period lasting 60 days followed and comments were carefully considered. On June 3, 1976 the final rule was published in the **Federal Register** (41 FR 22501). Subsequently, the ESRD Amendments of 1978 (Pub. L. 95–292), amended title XVIII of the Social Security Act (the Act) by adding section 1881. Sections 1881(b)(1) and 1881(f)(7) of the Act further authorize the Secretary to prescribe health and safety requirements (known as conditions for coverage) that a facility providing dialysis and transplantation services to dialysis patients must meet to qualify for Medicare reimbursement. In addition, section 1881(c) of the Act establishes ESRD network areas and network organizations to assure that dialysis patients are provided appropriate care.

B. Existing ESRD Regulations

The requirements from section 1881(b), (c), and (f)(7) are implemented in regulations at 42 CFR 405, subpart U, Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services.

The existing regulations describe the health and safety requirements that dialysis facilities and renal transplantation centers must meet to furnish care to Medicare beneficiaries. The regulations in subpart U also include the provision that dialysis facilities be organized into Network areas and describe the role that Networks play in the ESRD program.

The purpose of the existing conditions for coverage (also known as conditions) is to protect dialysis patients' health and safety and to ensure that quality care is furnished to all patients in Medicare-approved dialysis and kidney transplantation facilities. To determine if a facility meets these conditions, the State survey agency performs on-site surveys of the facility. If a survey indicates that a facility is in compliance with the conditions, and all other Federal requirements are met, we then certify the facility as qualifying for Medicare payment. Medicare payment for outpatient maintenance dialysis and kidney transplantation is limited to facilities meeting these conditions.

Our decision to propose major changes to the existing conditions is

based on several considerations. As discussed above, revising the ESRD requirements is part of our effort to modernize regulations and move toward a patient outcome-based system that focuses on quality assessment and performance improvement. We believe that revising the conditions for coverage will encourage improvement in outcomes of care for beneficiaries. Secondly, the existing ESRD conditions were originally adopted in 1976 and although some amendments have been made they have not been comprehensively revised since that time. The existing requirements for dialysis facilities emphasize the policies and procedures that must be in place to support good patient care, and they focus on a facility's capacity to furnish quality care, rather than on the actual provision of quality care to patients and the outcomes of that care. Third, we wish to incorporate the most recent medical and scientific guidelines and recommendations for dialysis facilities from the Centers for Disease Control and Prevention (CDC), the Association for the Advancement of Medical Instrumentation (AAMI), and recognize current practice guidelines and standards of practice such as the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (NKF-K/DOQI) clinical practice guidelines (CPGs).

The existing ESRD conditions do not require the facility to operate a patient-centered, outcome-oriented quality assessment and performance improvement program. Moreover, changes have taken place in the delivery of services to dialysis patients, and these advances are not reflected in the existing requirements. Thus, we have concluded that significant revisions to the conditions for coverage for ESRD facilities are essential. The proposed changes reflect improvements in standard care practices, the use of more advanced technology and equipment, and, most notably, a framework to incorporate performance measures viewed by the scientific and medical community to be related to the quality of care provided to dialysis patients.

C. Overview

Since 1994, we have received comments from the renal community at large and we have used the contributions provided by the community in developing the revised conditions contained in this proposed rule. Several renal organizations have offered recommendations regarding the conditions for coverage during the bimonthly public 2001 and 2002 CMS meetings on ESRD topics. Notices of

these were announced on the CMS Web site (<http://www.cms.hhs.gov/opendoor/schedule.asp>). We believe that many in the community support the overall shift in the proposed conditions from an emphasis on process-oriented requirements to a more patient-centered, outcome-oriented approach. Further, we believe that virtually all members of the community support a quality assessment and performance improvement requirement and the development of a comprehensive data set that will contain information on the characteristics of ESRD facilities, its patient population, as well as outcome measures of patient care.

The fundamental principles that guided us during this collaborative effort to develop new conditions were as follows:

- Ensure that patients' rights and physical safety are protected.
- Stress continuous quality assessment and performance improvement, incorporating, to the greatest extent possible, outcome-oriented, data-driven measures. Thus, the new conditions would invest a major expectation for performance in a requirement that each facility participate in its own quality assessment and performance improvement program. This allows the facility flexibility to create its own self-tailored program of continuous quality improvement. Facilities could be flexible and creative in their approach to patient care and delivery of services as they use their own information to assess and improve patient services, outcomes, and satisfaction.
- Facilitate flexibility in how dialysis facilities meet our performance requirements;
- Eliminate unnecessary administrative policies. Process-oriented standards are only included where we believe they are essential to protect patient health and safety;
- Focus on the continuous, interdisciplinary, integrated care system that a dialysis patient experiences, centered around patient assessment, care planning, service delivery, and quality assessment and performance improvement; and
- Stress patient satisfaction and ongoing patient involvement in the development of the care plan and treatment.
- Finally, in order for the ESRD facility conditions to move from a process and structure orientation toward a more patient-centered, outcome-oriented approach, individual patient and facility specific outcome measures must be identified and evaluated or in the absence of existing measures, they

must be developed and validated with community input to ensure they are clinically meaningful and reflect current scientific knowledge.

D. The Establishment of Central Requirements

We are proposing new conditions for coverage for ESRD facilities that revise or eliminate many of the existing requirements and establish critical central requirements. The central requirements of the proposed rule are grouped into three broad categories: (1) Patient safety; (2) patient care (which includes quality assessment and performance improvement); and (3) administration. Subpart A contains general provisions, for example, statutory authority, definitions, and requirements for compliance with Federal, State and local laws and regulations. Subparts B (patient safety) and C (patient care) of the proposed conditions for coverage would focus the facility's efforts on the actual care delivered to the patients, the performance of the dialysis facility, and the impact of the treatment furnished by the dialysis facility on the health status of its patients.

In Subpart B (patient safety), we are proposing to retain and strengthen some process-oriented patient safety provisions that we believe remain highly predictive of ensuring desired outcomes and preventing harmful outcomes. Accordingly, the patient safety requirements incorporate current CDC infection control procedures, retain and update our incorporation by reference of the AAMI standards and guidelines for water quality and dialyzer reuse practices, and incorporate by reference applicable current Life Safety Code (LSC) provisions.

Subpart C (patient care) includes: (1) Requirements that emphasize a dialysis facility's fundamental responsibility to respect and promote the rights of each patient (patient rights); (2) the critical nature of a comprehensive assessment in determining appropriate treatments and achieving desired health outcomes (patient assessment); (3) the interdisciplinary team approach of providing dialysis services to patients and the process by which the interdisciplinary team will achieve effective patient health outcomes (patient plan of care); (4) the quality assessment and performance improvement program which would charge each dialysis facility with the responsibility for carrying out a performance improvement program of its own design to affect continuing improvement in quality outcomes and patient satisfaction; and (5) the

consolidation of the various aspects of home dialysis care into a single condition (care at home).

Subpart D (administration) covers the operation of the dialysis facility in a patient outcome-oriented environment, including: (1) Minimum personnel qualifications; (2) the role of the medical director; (3) the facility's relationship with its servicing ESRD network; (4) medical recordkeeping; and (5) minimum operating responsibilities of the facility, including data collection and reporting requirements (governance).

We recognize that there are some who believe that regulations—particularly those that directly affect the health and safety of patients—should be very prescriptive in their detail to ensure that providers do not engage in practices that threaten patient health and safety. Therefore, we invite public comment on this fundamental shift in our regulatory approach, especially in terms of: (1) How we could improve on this approach; (2) what additional requirements could be removed or added to provide greater flexibility; and (3) which existing and new requirements are critical to patient care and safety.

E. Development of Outcome-Based Performance Quality Measures

Sections 1881(b)(5)(B) through (D) of the Act provide authority for us to obtain the data we need from ESRD suppliers. In accordance with these goals, we envision an information system that protects patients' privacy in compliance with the new privacy protections afforded by the Department's health information privacy regulations at 45 CFR Parts 160 and 164. These regulations were developed under the authority of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The data could be accessed by us as well as dialysis patients, the public, dialysis facilities, State survey agencies, ESRD networks, researchers, policy makers, renal physicians, and other professionals providing care to dialysis patients (where permitted by the privacy regulations). This system would provide information to meet the needs of the entire renal community, particularly the patients, to make better choices about care, and to help dialysis providers identify opportunities for continuous improvement in patient care processes.

This proposal is in keeping with our strategic plan to help patients and the public become better informed about the health care services they need and receive so they can make better health

care choices and participate more fully in their care. The availability of information will permit patients to become more active and effective participants in their own care and in their facility's quality improvement process.

1. Dialysis Facility Compare

One of the first steps to make information more available to the public is the CMS Dialysis Facility Compare website at: <http://www.Medicare.gov/Dialysis/Home.asp>. Dialysis Facility Compare contains various dialysis facility characteristics and specific quality measures including the percentage of in-center hemodialysis patients with a urea reduction rate (URR) (a measure of the adequacy of dialysis) equal to or greater than 65, the percentage of patients treated with Epogen who have hematocrits of 33 percent or greater (reflecting adequately managed anemia), and patient data categories on every dialysis facility approved to participate in the Medicare program.

2. Dialysis Facility Data Reporting Requirements

Sections 1881(b)(5)(B) through (D) of the Act require ESRD suppliers to furnish all necessary information to CMS, the ESRD networks, and State survey agencies. Moreover, existing regulations at § 405.2133 require that each ESRD facility furnish data and information in a manner and frequency specified by the Secretary. This proposed regulation would continue to require facilities to provide data and other information, but in electronic format, including clinical performance measures (CPM) data, necessary for the administration of the ESRD program.

3. Facility Specific Reports

In 1996, CMS first distributed facility-specific reports to Networks and facilities. These reports were compiled by the University of Michigan, using data from the CMS forms used for patient eligibility and patient death purposes; the CMS claims forms; the certification forms; and facility-specific data on infection control practices collected by the CDC.

The initial reports presented comparative data on patient characteristics, patient outcomes, and facility practice patterns. A common CMS database and common data formulations were used to create these reports. Each year since 1996, these reports have been distributed to ESRD Networks and ESRD facilities. The reports have formed a basis for implementing and understanding

quality improvement activities. The data that form the basis for these facility-specific reports are used to report patient outcomes and to develop additional reports.

CMS has expanded the Facility Specific Reports to include a broader array of information, including facility-specific reports for the use of State survey agencies, state-specific reports, and region-specific reports. The facility-specific reports have been improved by the expansion of facility practice pattern information, explanatory text with each report, table and graph modifications, and the inclusion of additional risk-adjusters in the calculations of the standardized mortality ratio.

4. The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF-K/DOQI) Clinical Practice Guidelines

In March 1995, the National Kidney Foundation (NKF) initiated the National Kidney Foundation-Dialysis Outcomes Quality Initiative (NKF-DOQI), the first comprehensive effort in nephrology designed to provide evidence-based guidance to clinical care in nephrology. Development of the NKF-DOQI clinical practice guidelines involved a 2-year effort in which independent interdisciplinary workgroups reviewed the available body of scientific literature on hemodialysis and peritoneal dialysis adequacy, vascular access, and anemia. Each workgroup was composed of renal experts from diverse clinical disciplines and renal patients. The workgroups were tasked with developing and promulgating clinical practice guidelines for the treatments of patients with ESRD. Four principles guided the project's decision-making: (1) Use of a high level of scientific and methodological rigor in the guideline development process; (2) commitment to an interdisciplinary approach; (3) independence of the workgroups; and (4) openness of the guideline development process. To that end, the workgroups developed draft guidelines with supporting rationales that included the evidentiary basis for the recommendations.

Draft guidelines were subject to an unprecedented three-stage review process: (1) An advisory council, comprised of 25 experts, provided comments on the initial draft of the guidelines; (2) a variety of organizations (that is, ESRD networks, professional and patient associations, dialysis providers, government agencies, product manufacturers, and managed care groups) were invited by NKF to review and comment on a revised draft of the guidelines; and (3) a final draft of

the guidelines was made available for public review by all interested individuals or parties.

Four sets of DOQI clinical practice guidelines were published by the NKF in 1997, including recommended practices for management of anemia, adequacy of hemodialysis, adequacy of peritoneal dialysis, and vascular access. In 2000, the scope of DOQI expanded to encompass the spectrum of chronic kidney disease prior to the need for dialysis services. To reflect this expansion, DOQI became K/DOQI. A total of 114 chronic kidney disease clinical practice guidelines were developed by the workgroups and reviewed by numerous professionals and patients. The NKF has published Bone Metabolism and Disease in Chronic Kidney Disease clinical practice guidelines and Hypertension and Antihypertensive Agents in Chronic Kidney Disease as well as Managing Dyslipidemias guidelines. The latest set of clinical practice guidelines being developed under the K/DOQI umbrella are the CPGs for Cardiovascular Disease in Dialysis patients.

5. CMS ESRD Clinical Performance Measures Project

In 1999, we merged our ongoing ESRD Core Indicators Project, a quality improvement project, originally started in 1994, into a new ESRD Clinical Performance Measures Project (ESRD CPM Project). The ESRD CPM Project is an ongoing effort between us, the ESRD networks, and dialysis facilities to collect performance measures on a representative sample of dialysis patients in the areas of adequacy of dialysis, anemia management, nutrition (that is, serum albumin), and more recently, vascular access (DHHS/CMS/CBC, pp. 1–104). The ESRD CPM Project was developed to implement section 4558(b) of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33). This provision required the Secretary to develop and implement a method to measure and report on the quality of renal dialysis services provided under Medicare no later than January 1, 2000.

The goal of the CPM Project was to identify NKF DOQI guidelines that were suitable for the agency's quality improvement initiatives and to meet the BBA requirement. The ultimate purpose of the project is to assist suppliers of ESRD services in improving the care provided to ESRD patients.

In 1998, we contracted with PRO-West (now named Qualis Health), a Seattle-based private nonprofit healthcare quality improvement organization, to facilitate the process of developing dialysis clinical

performance measures (CPMs) based on the NKF's DOQI (now K/DOQI) guidelines.

The process included several components. The first was to develop a mechanism to assure appropriate participation from the community in order to facilitate the acceptability and utility of the CPMs. The second was to prioritize the NKF DOQI guidelines based on the strength of the evidence supporting the guidelines, the feasibility of developing performance measures, and the significance of the areas addressed to the quality of care delivered to dialysis patients. The third was to identify a limited set of CPMs that could be used to support quality improvement activities as well as assist us in assessing nationally the quality of care delivered to Medicare beneficiaries. The fourth was to develop sampling and data specifications for the CPMs to facilitate measurement. Finally, we requested the development of data collection and analysis strategies to be used to augment the existing national performance measurement system.

The CPM Project was conducted in collaboration with a broad range of stakeholders in the community. In order to facilitate this involvement, participation was solicited through contacts with professional and voluntary associations, presentations at national meetings, and invitations to individuals identified through a variety of sources.

Four expert groups were convened to address each of the topic areas covered by the NKF DOQI guidelines: (1) Hemodialysis adequacy; (2) peritoneal dialysis adequacy; (3) vascular access; and (4) anemia management. The NKF DOQI guidelines were ranked via a survey of renal experts for their suitability as candidates for development of CPMs. All 114 NKF DOQI guidelines were included on a survey tool developed by CMS that was distributed to the rapid response group (RRG) and other expert consultants. Suitability of guidelines was based on clinical importance, feasibility of measurement, and the respondent's assessment of the strength of the evidence supporting the guideline.

We accepted 36 proposed guidelines for further evaluation and the 4 expert groups developed specific review criteria, algorithms, and CPMs selected through the prioritization process described above. The CPM development process was a modification of a methodology described by the Agency for Healthcare Research and Quality (AHRQ) (formerly the Agency for Health Care Policy and Research (AHCPR)). Candidate guidelines that did not have

a strong evidence basis were eliminated from further consideration. Sixteen CPMs were developed based on 22 of 36 candidate NKF DOQI clinical practice guidelines.

Data collection instruments were subsequently developed and submitted to us for field testing. Three data collection tools were developed and pilot tested. The first instrument was intended to collect data for the hemodialysis adequacy, anemia management, and vascular access CPMs from hemodialysis patient records. The second instrument was designed to collect adequacy and anemia management data for peritoneal dialysis patients. The third instrument focused on information about facility policies, procedures, and practices related to selected hemodialysis adequacy CPMs. In the summer of 1999, after field-testing, the CPMs were applied to a sample of 8,853 randomly selected adult hemodialysis patients and 1,650 randomly selected adult peritoneal dialysis patients.

In summary, the NKF DOQI process resulted in a broad set of guidelines amenable to prioritization based on strength of evidence, clinical importance and feasibility. The current NKF K/DOQI guidelines are widely accepted among the renal community and increase the likelihood that future CPMs can be developed and supported by a broad cross-section of stakeholders, including clinical practitioners, industry representatives, professional associations, and others interested in assessment and improvement of the care provided to dialysis patients.

We have been working closely with the ESRD networks and information technology contractors to develop the Vital Information System to Improve Outcomes in Nephrology (VISION) database. VISION is a patient-specific, facility-based, outcome-oriented information system that will enable dialysis facilities to electronically collect and report both demographic and clinical data that can be profiled to assist efforts to improve outcomes of care. VISION will capture, among other things, data from the CMS ESRD CPM Project. VISION will be designed so that Consolidated Health Informatics (CHI) standards will be met.

The CHI establishes health messaging and vocabulary standards that enable data sharing across all Federal systems. Implementation of the CHI standards is prospective (that is, applicable to new systems and systems undergoing major upgrades). Current plans are to upgrade the ESRD Information System within the next 2 to 3 years. Since the CHI standards are prospectively applied, the

CHI standards will be incorporated when we upgrade the ESRD information system.

Following the upgrade to the ESRD information system, ESRD facilities will be required to submit data using the new information technology (IT) system. They can accomplish submission of data that is consistent with the CHI standards by either modifying their internal systems or by using mapping tools that are provided by the National Library of Medicine (NLM) at no cost. The CHI standards are posted on the *egov.gov* Web site located at http://www.whitehouse.gov/omb/egov/glob/health_informatics.htm.

6. CPM Data Reporting

ESRD CPM Project data have been collected for 1999, 2000, 2001, and 2002 and published in annual reports. The 2001 ESRD CPM report can be found on the Internet at <http://www.cms.gov/esrd/1.asp>. The data for each year include a random sample, stratified by ESRD network, of adult in-center hemodialysis patients and a random peritoneal dialysis patient sample of 5 percent of adult peritoneal dialysis patients in the nation. The sample size of adult in-center hemodialysis patients was selected to allow us to be 95 percent confident that Network-specific estimates for selected clinical measures are accurate within plus or minus 5 percent. The sample also included a 30 percent "over sample" for in-center hemodialysis patients and a 10 percent "over sample" for peritoneal dialysis patients to compensate for anticipated nonresponse rates. In 2002, the in-center hemodialysis sample included 8,863 patients and the peritoneal dialysis sample included 1,451 patients. Also, a 5 percent national sample of hemodialysis facilities was drawn, consisting over 200 hemodialysis facilities.

Three data collection tools were used, an in-center hemodialysis form (Form CMS-820), a peritoneal dialysis form (Form CMS-821), and a hemodialysis facility-specific form.

We believe that the ESRD CPM Project is an effective tool to facilitate ESRD quality improvement, and this project has successfully tracked positive improvements in patient outcomes of care in several areas. The 2001 Annual Report for the ESRD CPM Project contains additional Outcomes Comparison Tools (for hemodialysis and peritoneal dialysis). Outcomes Comparison Tools are practical quality improvement instruments that can be used by ESRD facilities to benchmark their performance outcomes against rates at the ESRD network's level

(hemodialysis only) and the nation. Therefore, we are proposing in the Governance condition for coverage (§ 494.180(h)), that all ESRD facilities collect and provide us with ESRD CPM Project data electronically. This proposal applies only to the current CPMs and is discussed in more detail later in this preamble. We will carefully evaluate any revisions to the CPMs as well as any future CPMs, developed in accordance with the National Technology Transfer and Advancement Act of 1995 process (described in the next section of this preamble) for possible inclusion as electronic reporting requirements. The Secretary will provide notice and an opportunity for comment in the **Federal Register** before the CPMs are updated or new measures are adopted.

7. Updating Existing ESRD Patient-Specific Performance Measures and Developing Future ESRD Facility Performance Standards

We would like to propose ESRD performance standards that dialysis facilities would be required to meet as well as propose a method to recognize updates in existing consensus-based patient-specific performance measures. We are proposing to adopt a framework that will utilize existing Federal legislation and operational guidelines. The National Technology Transfer and Advancement Act of 1995 (NTTAA) Pub. L. 104–113 and OMB Circular A–119 specify circumstances in which Federal agencies should use technical standards developed by voluntary consensus bodies. The phrase “technical standards” is defined in the NTTAA at section 12(d)(4) as “performance-based or design-specific technical specifications and related management systems practices.”

The NTTAA has been implemented by, among other things, the provisions of the Office of Management and Budget (OMB) Circular No. A–119 (63 FR 8546, February 19, 1998). OMB Circular No. A–119 was published to: (1) Revise and clarify policies on Federal use and development of voluntary consensus standards; (2) set policy for conformity assessment activities; and (3) improve the clarity and effectiveness of the previously published (October 20, 1993) circular. By implementing the policies in this circular, we intend to reduce to a minimum our reliance on government-specific standards.

Definitions of terms and phrases within the circular are designed for very broad application, but are meant to be applicable to any specific and appropriate subject matter, including health care performance measures.

The circular defines a “performance standard” as a standard that states requirements in terms of required results with criteria for verifying compliance but without stating the methods for achieving required results. “Voluntary consensus standards” are defined as standards developed or adopted by voluntary consensus standards bodies, both domestic and international. “Voluntary consensus standards bodies” are organizations that plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures. One example of a voluntary consensus standards body is the National Forum for Health Care Quality Measurement and Reporting, also known as the National Quality Forum (NQF), which is currently engaged in various projects such as standardizing measures of hospital quality and developing diabetes mellitus treatment performance measures.

The expected products of a voluntary consensus body would include the measures or indicators and standards, as well as explanatory text and other supporting documentation, such as guidelines for reporting the indicators. A voluntary consensus body would make a draft product available for general public review during the development of the measures. When the performance standards are complete, we would evaluate them and then promulgate the standards following the requirements of the Administrative Procedures Act.

We are not advocating the NQF as the voluntary consensus body that is most appropriate to develop ESRD performance standards. We have only provided an illustration of the manner in which performance standards are being developed. Other organizations, for example, the NKF–K/DOQI, also function in a manner consistent with voluntary consensus bodies. Once ESRD facility performance measures are developed by a voluntary consensus body, the Secretary would evaluate those facility performance measures and adopt those that meet our needs for the effective administration of the ESRD program after notice and comment rulemaking required by the Administrative Procedures Act.

We will also reference the NTTAA later in this preamble under our discussion of the Governance condition for coverage (*see* § 494.180(h)).

F. Summary of the Contents of the Proposed Rule

We are proposing to revise both the content and the organization of the existing regulations. The ESRD Network

conditions for coverage will remain in part 405, subpart U. Through a separate proposed rule regarding conditions of participation for transplant hospitals, we are proposing to move the renal transplant center conditions to part 482. The ESRD conditions for coverage (health and safety provisions for dialysis facilities) would be moved from existing 42 CFR part 405, subpart U, to a new 42 CFR part 494, where they would follow regulations establishing standards for other Medicare providers, such as the conditions of participation for hospitals (42 CFR part 482), long-term care facilities (42 CFR part 483), and home health agencies (42 CFR part 484). The termination of Medicare coverage and alternative sanctions conditions at § 405.2180 through § 405.2184 will be recodified to § 488.604 through § 488.610. Since many of the existing ESRD conditions would be revised, consolidated with other conditions, or deleted, we also propose to completely renumber and reorganize the requirements. The format for the dialysis facility conditions for coverage represents a dramatic change from the organization of the existing regulations, which contain nearly 20 conditions addressing organizational structure, utilization rate requirements, and other process-intensive requirements. The proposed regulations are divided into four subparts: general provisions, patient safety, patient care, and administration.

The proposed organization of Part 494 is as follows:

Subpart A—General Provisions

- § 494.1 Basis and scope.
- § 494.10 Definitions.
- § 494.20 Compliance with Federal, State, and local laws and regulations.

Subpart B—Patient Safety

- § 494.30 Condition: Infection control.
- § 494.40 Condition: Water quality.
- § 494.50 Condition: Reuse of hemodialyzers and other dialysis supplies.
- § 494.60 Condition: Physical environment.

Subpart C—Patient Care

- § 494.70 Condition: Patient rights.
- § 494.80 Condition: Patient assessment.
- § 494.90 Condition: Patient plan of care.
- § 494.100 Condition: Care at home.
- § 494.110 Condition: Quality assessment and performance improvement.
- § 494.120 Condition: Special purpose renal dialysis facilities.
- § 494.130 Condition: Laboratory services.

Subpart D—Administration

- § 494.140 Condition: Personnel qualifications.
- § 494.150 Condition: Responsibilities of the medical director.
- § 494.160 Condition: Relationship with ESRD network.

§ 494.170 Condition: Medical recordkeeping.

§ 494.180 Condition: Governance.

The following provides a detailed discussion of each new requirement and a discussion of the existing ESRD requirements that have been revised or deleted in this proposed rule.

III. Provisions of Proposed Part 494 Subpart A (General Provisions)

A. Basis and Scope (Proposed § 494.1)

[If you choose to comment on issues in this section please include the caption "Basis" at the beginning of your comment.]

Proposed § 494.1, identifies the statutory authority for the regulations. Proposed § 494.1 also states that provisions of part 494 serve as the basis for survey activities for determining whether a dialysis facility meets the conditions for coverage under the Medicare program. We note that the organizational format of the proposed conditions permits the elimination of almost all of the material in existing § 405.2100, Scope of subpart, which consists largely of a description of the contents of the existing ESRD conditions for coverage.

B. Definitions (Proposed § 494.10)

[If you choose to comment on issues in this section please include the caption "Definitions" at the beginning of your comment.]

Under proposed § 494.10, we set forth definitions for terms used in the ESRD conditions. Existing § 405.2102 provides a list of 32 definitions. We are proposing to eliminate the definitions of several terms for which we believe the meaning is self-evident, as well as terms that are not used in the revised conditions. We do not believe it is appropriate to have substantive requirements contained in those definitions. Thus, we would move definitions that contain qualification requirements to the appropriate conditions in the proposed rule. We have proposed to retain the definition of "furnishes on the premises" and add it to proposed § 494.180 (Governance). We are proposing a modification of the definition of "home dialysis" to recognize the assisting role that a family member/caregiver may play. We have previously received questions about whether the definition of "home" includes institutional settings such as nursing facilities (NFs) and skilled nursing facilities (SNFs). Please refer to section V.D. of this preamble in which we discuss the unique needs of the NF/SNF dialysis patient and the overall issue. We are soliciting comment on whether the definition of "home" for

"home dialysis" should also include these institutional settings.

We propose to include the following definitions in § 494.10:

- *Dialysis facility* means an entity that provides (1) outpatient maintenance dialysis services; or (2) home dialysis training and support services; or (3) both. A dialysis facility may be an independent or hospital-based unit (as described in § 413.174(b) and (c) of this chapter), or a self-care dialysis unit, which furnishes only self-dialysis services.
- *Discharge* means the termination of patient care services by a dialysis facility.
- *Furnishes directly* means the ESRD facility provides the service through its own staff and employees or through individuals who are under contract with the facility to furnish these services personally for the facility. We note that furnishes directly does not apply to companies providing services under contract or arrangement.
- *Home dialysis* means outpatient dialysis performed at home by an ESRD patient (or caregiver) if the individual performing such dialysis has completed the course of training required in § 494.100(a) of this part.
- *Interdisciplinary team* (as required in § 494.80 (Patient assessment)) means the group of persons responsible for providing patient care to each dialysis patient.
- *Self-dialysis* means dialysis performed with little or no professional assistance by an ESRD patient (or caregiver) if the individual performing such dialysis has completed an appropriate course of training as required in § 494.100(a) (Care at Home).
- *Transfer* means a temporary or permanent move of a patient from one dialysis facility to another that requires the transmission of the patient's medical record information to the facility receiving the patient.

C. Compliance With Federal, State, and Local Laws and Regulations (Proposed § 494.20)

[If you choose to comment on issues in this section please include the caption "Compliance with Laws and Regulations" at the beginning of your comment.]

Existing § 405.2135 requires that a dialysis facility be in compliance with applicable Federal laws and that a dialysis facility be licensed or approved as meeting applicable standards by the agency of the State or locality responsible for approval. Section 405.2135 further requires a facility to comply with all relevant laws (for example, laws relating to licensure of

staff) and requires conformity with other laws (for example, fire safety, equipment maintenance).

We propose to retain the requirement that dialysis facilities must be in compliance with applicable Federal, State, and local laws and regulations pertaining to fire safety, equipment, and any other relevant health and safety issues. We are also proposing that dialysis facilities must be in compliance with the appropriate Federal, State, and local laws and regulations regarding drug and medical device usage. An example of meeting applicable Federal regulations is that the dialysis facility must use FDA-approved/cleared medical devices and adhere to the devices' labelling instructions. We have added these examples because drugs and medical devices are major components of dialysis facilities and compliance with existing laws and regulations in this area is important in ensuring patient safety.

We may find a facility to be in violation of these conditions for coverage if the facility is found out of compliance with any Federal, State, and local law or regulation pertaining to health and safety requirements.

IV. Provisions of Proposed Part 494 Subpart B (Patient Safety)

A. Infection Control (Proposed § 494.30)

[If you choose to comment on issues in this section please include the caption "Infection Control" at the beginning of your comment.]

Patients with ESRD have impaired immunological systems and are more at risk of developing serious infections than similarly situated non-ESRD patients. During hemodialysis therapy, there is a potential for patients to be exposed to a variety of microbial pathogens (including blood-borne pathogens) if proper procedures are not meticulously followed. Likewise, peritoneal dialysis patients are at risk of contamination leading to peritonitis if proper procedures are not followed. This proposed rule stipulates that the dialysis facility must provide and monitor conditions to ensure a sanitary environment that prevents the transmission of infectious agents.

The existing standards relating to infection control are contained in § 405.2140(b)(1) and (c). Section 405.2140(b)(1) requires written procedures for controlling hepatitis and other infections. It further specifies that the procedures include surveillance and reporting of infections, housekeeping, handling of waste and contaminants, and sterilization and disinfection. Section 405.2140(c) requires the facility

to employ appropriate techniques to prevent cross-contamination between the unit and adjacent hospital or public areas.

We believe infection control is vital to the health and safety of dialysis patients and others; and therefore, we propose to establish infection control as a separate condition for coverage (§ 494.30). The proposed infection control requirement states that each dialysis facility must provide and monitor a sanitary environment that prevents and controls the transmission of infectious agents, within and between the unit and any adjacent hospital, or other public areas. The proposed requirement sets forth the basic guidelines or procedures that facilities must follow to prevent and control infections.

Proposed § 494.30(a)(1) requires that the facility demonstrate that it follows standard infection control precautions, including the "Recommended Infection Control Practices for Hemodialysis Units At a Glance" with the exception of screening for Hepatitis C as explained below. The "At a Glance" section is in the publication, "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients" developed by the Centers for Disease Control and Prevention (CDC) (DHHS/CDC, 20–21). We propose to incorporate these guidelines to prevent and control cross contamination and the spread of infectious agents. These CDC infection control recommendations specific to the hemodialysis setting were developed in consultation with other Federal agencies and specialists and are based on available knowledge regarding transmission of infectious agents.

Recommended Infection Control Practices for Hemodialysis Units at a Glance

Infection Control Precautions for All Patients

- Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station; remove gloves and wash hands between each patient or station.

- Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before taken to a common clean area or used on another patient.

—Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient.

—Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.

- When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.

- Do not use common medication carts to deliver medications to patients. Do not carry medication vials, syringes, alcohol swabs or supplies in pockets. If trays are used to deliver medications to

individual patients, they must be cleaned between patients.

- Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.

- Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines pressure monitors. Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed routinely between patients.

- Clean and disinfect the dialysis station (chairs, beds, tables, machines, etc.) between patients.

—Give special attention to cleaning control panels on the dialysis machines and other surfaces that are frequently touched and potentially contaminated with patients' blood.

—Discard all fluid and clean and disinfect all surfaces and containers associated with the prime waste (including buckets attached to the machines).

- For dialyzers and blood tubing that will be reprocessed, cap dialyzer ports and clamp tubing. Place all used dialyzers and tubing in leak-proof containers for transport from station to reprocessing or disposal area.

SCHEDULE FOR ROUTINE TESTING FOR HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) INFECTIONS

Patient status	On admission	Monthly	Semi-annual	Annual
All patients	HBsAg*, Anti-HBc (total)* Anti-HBs*, Anti-HCV, ALT†			
HBV susceptible, including non-responders to vaccine		HBsAg		
Anti-HBs positive(>10 mIU/mL), anti-HBc negative				Anti-HBs
Anti-HBs and anti-HBc positive		No additional HBV testing needed		
Anti-HCV negative		ALT	Anti-HCV	

Hepatitis B Vaccination

- Vaccinate all susceptible patients against hepatitis B.

- Test for anti-HBs 1–2 months after last dose.

—If anti-HBs is <10 mIU/mL, consider patient susceptible, revaccinate with

an additional three doses, and retest for anti-HBs.

—If anti-HBs is >10 mIU/mL, consider immune, and retest annually.

—Give booster dose of vaccine if anti-HBs declines to <10 mIU/mL and continue to retest annually.

Management of HBsAg-Positive Patients

- Follow infection control practices for hemodialysis units for all patients.

- Dialyze HBsAg-positive patients in a separate room using separate machines, equipment, instruments, and supplies.

- Staff members caring for HBsAg-positive patients should not care for HBV susceptible patients at the same time (e.g., during the same shift or during patient change-over).

We are proposing an exception to the CDC recommendation for monthly and semiannual screening for all hemodialysis patients for hepatitis C. Patients with clinical indicators or risk factors for hepatitis C should receive diagnostic testing as deemed necessary by the attending physician. Medicare covers diagnostic testing for hepatitis C on a case-by-case basis, but does not cover blanket hepatitis C screening at this time. According to the CDC, transmission of hepatitis C can be prevented by strict adherence to infection control precautions recommended for all hemodialysis patients.

The "At a Glance" page highlights the crucial CDC recommendations that serve as the minimum acceptable infection control practices. This document reproduced above is currently available on the CDC Web site at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm>.

There is substantial evidence that the CDC guidelines work in preventing the transmission of bloodborne infections. Recommendations for the control of hepatitis B in hemodialysis centers were first published in 1977 and within 3 years there was a sharp reduction in incidence of hepatitis B infection among both patients and staff members in hemodialysis centers (Alter, pp. 860–865).

The entire CDC RR05 report contains recommendations for infection control precautions in greater detail than the "At a Glance" highlights. We considered proposing that the entire CDC RR05 document be incorporated by reference. However, we want to be less prescriptive and burdensome in our requirements while protecting patient safety. Dialysis facilities are encouraged to utilize the more comprehensive document when developing their infection control programs. For example, the CDC infection control precautions for all patients identify procedures for cleaning up a blood spill; and detail information on glove use, protective gear, and handwashing. The CDC has issued additional guidance regarding hand hygiene and environmental infection control in the October 25, 2002 and June 6, 2003 issues of the Morbidity and Mortality Weekly Report that dialysis facilities may want to reference in their infection control policies (DHHS/CDC, pp. 1–45 and DHHS/CDC, pp. 1–44, respectively).

Existing § 405.2140(b)(1) requires that written policies and procedures must be in effect for preventing and controlling hepatitis and other infections. There is no current requirement in the conditions for coverage addressing patient isolation. However, many facilities have adopted the 1977 CDC guidelines that recommend use of a separate dialysis area, preferably a separate isolation room, for dialyzing hepatitis B surface antigen positive patients. Newly opened hemodialysis units would be required to have isolation rooms for hepatitis B positive patients as described in the "At a Glance" section. For existing units in which a separate room is not possible, there would be required to be a separate area removed from the mainstream of activity that also allows for dedicated staff and dedicated dialysis machines. When the facility determines that a patient is infectious (from admission or at least annual testing) the guidelines state that the facility would be required to isolate the infected patient from susceptible patients to prevent the transmission of the disease. We propose to require at § 494.30(a)(2) that a facility implement and maintain patient isolation procedures that prevent and control the spread of infectious agents and communicable diseases.

We also propose at § 494.30(a)(3) that facilities implement appropriate procedures for the handling, storage, and disposal of waste, and for disinfection. Appropriate waste storage and disposal procedures are important not only for the control of infections within the units, but also for the welfare of the unit staff and the community. Since local policies vary, we do not believe it is appropriate to specify the minimum requirements for waste storage and disposal. Rather, facilities should continue to operate in accordance with applicable local laws and accepted public health procedures. We also propose to require that facilities implement protocols for cleaning and disinfection because we believe that adequate disinfection of surfaces, medical devices, and equipment is an important part of a facility's efforts to control and prevent cross-contamination. We propose to add a requirement for the implementation and maintenance of procedures regarding cleaning of surfaces and devices potentially contaminated with blood to prevent patients from coming into contact with a blood-borne pathogen. The CDC RR05 recommendations and dialysis equipment manufacturers' instructions provide valuable

information on procedures a facility may adopt to meet this requirement.

We considered proposing to include the American Institute of Architects (AIA) Guidelines for Design and Construction of Hospitals and Health Care Facilities, which outline building requirements pertinent to dialysis facilities. The AIA standards provide guidance to facilities regarding unit design and parts of the guidance relate to infection control. While we believe it is desirable for new units to follow AIA standards, and many States have adopted these as minimum standards, we recognize it may be overly burdensome to require existing dialysis units to adhere to these standards.

We also considered including in the proposed rule the Healthcare Infection Control Practices Advisory Committee's (HICPAC) guidelines entitled "Hand Hygiene in Healthcare Settings" and "Guideline for Preventing Intravascular Device-Related Infections." We are inviting comments on whether we should require new dialysis facilities to adhere to AIA design standards or HICPAC guidelines.

We propose requirements for oversight of facility infection control in § 494.30(b). The facility must implement and monitor biohazard and infection control policies and activities within the dialysis unit. Any infection control policies adopted by the facility are only effective when put into action. We propose that facilities must designate a registered nurse as the infection control or safety officer who maintains current infection control information, and reports to the facility's chief executive officer or administrator and quality improvement committee. The infection control nurse must maintain current infection control information including the most current CDC guidelines for the proper techniques in the use of vials and ampules containing medication. For example, facilities should not pool vials of any medications. An outbreak of *Serratia liquefaciens* from contamination of erythropoietin at a hemodialysis center serves as a reminder of the importance of the proper handling of medications in protecting the dialysis patient. (Grohskopf, pp. 1491–1497.)

The infection control or safety officer is also responsible for making recommendations regarding infection control training and improvements. The designation of an infection control officer provides a structure for infection control, encourages the maintenance of up-to-date information, and increases accountability for infection control.

We propose to maintain the essence of the existing requirement for surveillance and reporting of the incidence of

infection (§ 405.2140(b)(1)). The facility must analyze and document the incidence of infections to identify trends and establish baseline information on infection incidence as proposed in § 494.30(c). By conducting a trend analysis of infections, the facility will be able to identify opportunities for improvement to prevent or eliminate the spread of infection or communicable disease between patients. By tracking the number and types of infections, the facility can identify areas that require improvement, indicate areas that have improved, define measures to improve outcomes, review implementation of improvement measures, and determine the success of the improvement measures implemented.

In August 1999, the CDC initiated the CDC Dialysis Surveillance Network (DSN), a voluntary national surveillance system monitoring bloodstream and vascular infections by individual hemodialysis centers. The purposes of the DSN are to provide a method for individual hemodialysis centers to record and track rates of vascular access infections, other bacterial infections, and intravenous antimicrobial starts, and to provide rates for comparisons among various dialysis centers. The infection control or safety officer should look toward the CDC surveillance system as a resource. Information on the DSN may be found on the following Web site: <http://www.cdc.gov/ncidod/hip/Dialysis/dsn.htm>.

The existing standard governing infection control (§ 405.2140(b)(1)) contains a requirement governing reuse of dialyzers which states that when dialysis supplies are reused, records are maintained that can be used to determine whether established procedures covering the rinsing, cleaning, disinfection, preparation, and storage of reused items conform to the requirements for reuse. This standard is redundant with the reuse requirements included in the AAMI guidelines that are incorporated by reference in both the existing and proposed regulations. Therefore, we are proposing to delete the requirement in § 405.2140(b).

Existing § 405.2140(c) requires that written patient care policies specify the functions of facility personnel and self-dialysis patients with respect to contamination prevention. We are proposing to delete the "written policy" requirement because it is process-oriented and a paperwork burden.

As noted above, the existing conditions for coverage require policies for surveillance and reporting of infections at § 405.2140(b)(1). In this proposed rule, reporting requirements

for communicable diseases are listed at § 494.30(d). The facility must maintain a current list of the communicable diseases that must be reported according to Federal, State, and local requirements, and have a procedure for reporting these communicable diseases, which allows the facility to accurately report incidences of communicable diseases. These requirements are in concert with the present standard operating practices in dialysis facilities.

B. Water Quality (Proposed § 494.40)

[If you choose to comment on issues in this section please include the caption "Water Quality" at the beginning of your comment.]

Water quality is of vital importance to a dialysis facility and to the patient. Because we believe water quality is an essential health and safety issue for ESRD patients, we are proposing a condition for coverage for water quality in this proposed rule.

The hemodialysis patient's blood has the potential to be exposed to toxic contaminants present in water. Some chemical contaminants are not normally harmful when present in small amounts in usual physiological fluids. However, since hemodialysis patients are exposed to the large volume of water that is used to make dialysate, chemical contaminants can be dangerous to them. If water supplies are biologically or chemically contaminated, the patient may experience infection or other adverse consequences. Limits on bacterial growth in water and dialysate are necessary to prevent high bacterial counts associated with pyrogenic reactions (fevers, chills, nausea).

The patient's exposure to contaminated water can be through water mixed with dialysate, water mixed with reprocessing germicides, or water used to flush out dialyzers. Contamination of the water system with organic and inorganic chemicals, bacteria, and endotoxins can result in adverse patient reactions, such as hemolysis, bacteremia, pyrogenic reactions, or death. Exposure to some contaminants such as aluminum can cause chronic health problems, while exposure to other contaminants such as fluoride can be fatal. Therefore, a dialysis facility must monitor the quality of the water used in treatments, as well as monitor the equipment used in water treatment.

In the September 18, 1995 **Federal Register** (60 FR 48039), we published a final rule that incorporated by reference the 1992 AAMI standard for water quality and the AAMI recommended guidelines for monitoring purity of water as published in the

"Hemodialysis Systems," ANSI/AAMI RD5: 1992, sections 3.2.1, 3.2.2, and Appendix B, sections B1–B5 (American National Standards Institute 1992). Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally. AAMI standards and guidelines undergo a regular 5-year review process that allows updates and revisions. These consensus recommendations are intended to help ensure patient safety.

The AAMI guidelines referenced in the existing conditions for coverage have been replaced by more recent AAMI guidelines, and therefore, we are proposing to incorporate new AAMI references. The ANSI/AAMI RD5: 1992 document has been replaced by "Concentrates for Hemodialysis" ANSI/AAMI RD61: 2000, "Water Treatment Equipment for Hemodialysis Applications" ANSI/AAMI RD62: 2001, and "Dialysate for Hemodialysis" ANSI/AAMI RD 52:2004. These publications update the information on monitoring of water quality currently incorporated by reference in § 405.2140(a)(5) and provide additional recommended practices.

We are proposing to incorporate by reference the following revised AAMI water quality standards, published in "Water Treatment Equipment for Hemodialysis Applications," 4.2.1 and 5.2.1, Water Bacteriology; 4.2.2 and 5.2.2, Maximum Level of Chemical Contaminants; and 4.3, Water Treatment Equipment requirements (American National Standards Institute, 2001). The updated water purity standards, section 4.2.1, now include bacteria and endotoxin action levels that identify the concentration at which steps (such as system disinfection and retesting) should be taken to reduce the levels to an acceptable range. Facilities must take corrective action when these action levels are met or exceeded.

The AAMI list of contaminants for which water must be tested has been expanded to include antimony, beryllium, and thallium. These chemicals were added based on changes in the United States Environmental Protection Agency Safe Drinking Water Act 1996 (Pub. L. 104–182). AAMI's rationale for testing water for these contaminants may be found in the appendix of the ANSI/AAMI RD62: 2001 document at A.4.2.2 (American National Standards Institute, 2001).

We have also included the updated AAMI requirements for water treatment equipment. This inclusion provides clarity by defining the minimum

standards for water treatment equipment needed to protect patient safety. Proper hemodialysis is dependent on the quality of the dialysate. A water system consisting of the proper components and maintained in accordance with the manufacturers' instructions, can be expected to produce dialysate that meets the AAMI standards and produces acceptable patient outcomes. The minimum safety requirements are specified in the AAMI standards referenced in proposed § 494.40(a)(1)(iii) for each component of the water treatment system (that is, deionization, reverse osmosis, monitors, sediment filters, carbon absorption media, automatically regenerated water softeners, storage tanks, piping systems; and when used, ultrafilters, ultraviolet irradiators, hot water disinfection systems, ozone disinfection systems, and tempering valves). A water treatment system consisting of the proper equipment components as identified by AAMI (and the Food and Drug Administration (FDA)) is standard practice in dialysis facilities.

We are proposing state of the art water purity monitoring guidelines outlined in ANSI/AAMI RD52: 2004 "Dialysate for Hemodialyzers" section 7.2.1 document. Proposed § 494.40(a)(2) incorporates by reference the section that specifies the frequency of water purity testing to insure meeting the AAMI limits specified in § 494.40(a)(1)(i) and (ii) as follows:

- Bacteria and bacterial endotoxin levels of water must be measured—
 - ++ In established systems at least monthly;
 - ++ In newly-installed systems at least weekly until an established pattern of compliance can be demonstrated.
- At least monthly in samples drawn from—
 - ++ The first and last outlets of the water distribution loop;
 - ++ Where water enters the dialyzer reprocessing equipment;
 - ++ Outlet of the water storage tanks, if used;
 - ++ Concentrate or from the bicarbonate concentrate mixing tank.
- Bacteria levels must be measured at least monthly from a sample of two or more dialysis machines, this sampling must ensure that all machines are tested at least once a year.
- Chemical analysis of water purity must be done at least once a year and when—
 - ++ The system is installed;
 - ++ Membranes are replaced if using a reverse osmosis system;
 - ++ Seasonal variations in source water suggest worsening water quality; and

++ Reverse osmosis rejection rates, which are monitored daily using continuous-reading monitors that measure product water conductivity, fall below 90 percent.

Ultrapure dialysate has received attention in the clinical literature and the working draft AAMI standards "Dialysate for Hemodialysis" RD52 contains guidelines pertaining to ultrapure dialysate. We are not proposing a requirement for ultrapure dialysate at this time but we do invite comment on this topic. We also welcome comment on the requirements for the frequency of water purity testing.

In addition, we are proposing further evidence-based requirements consistent with AAMI guidelines within the proposed water quality condition. The existing conditions for coverage do not address requirements for the water treatment equipment, although the interpretive guidelines for § 405.2140(a)(5)(ii) do advise that water treatment systems must include a carbon tank and either a reverse osmosis or deionization system (DHHS/CMS, 1995). We are proposing that the water treatment system must include a reverse osmosis or deionization component that conforms to the referenced water treatment equipment for hemodialysis applications AAMI guidelines 4.3.5 and 4.3.6. This is in keeping with current standards of practice, which are widely adhered to by dialysis facilities. The reverse osmosis process serves to remove dissolved salts, bacteria, viruses, pyrogens, and organic molecules. Deionization serves to remove ions. A reverse osmosis system along with pretreatment is used in the vast majority of all dialysis centers and this requirement should not present an additional burden to hemodialysis centers.

A consequence of patient exposure to high levels of chloramine via dialysis is hemolytic anemia, which may be life-threatening. The 1992 AAMI guidelines specified at least once daily testing of purified water for chlorine/chloramine levels. It is now widely recognized that testing before each shift of hemodialysis sessions, which is the current standard in many dialysis units, provides greater patient safety. Therefore, we are proposing at § 494.40(c)(2) to require chlorine/chloramine testing of water samples that must be taken from the exit port of the initial chlorine/chloramine removal component (or carbon tank) prior to each patient shift or every 4 hours, whichever is shorter, during operation of the water system, unless the facility ensures on a daily basis that the source water is chlorine/chloramine free by way of testing. In addition,

proposed § 494.40(c)(2)(i) would require subsequent testing from the backup component (or second carbon tank) if the test shows greater than 0.50 parts per million (ppm) for free chlorine or 0.10 ppm for chloramine. Due to the dangers of chlorine/chloramine exposure, each water purification system must provide for the adequate removal of chlorine/chloramine and this is standard operating practice in hemodialysis facilities. In conformity with the referenced AAMI guidelines at 4.3.9, carbon tanks used for the removal of chlorine/chloramine must contain granulated activated carbon and provide adequate empty bed contact time to be effective. A backup component or second carbon tank must be in place for failure of the first line component for chlorine/chloramine removal (or first carbon tank), in order to protect patients during a hemodialysis session.

Dialysis facilities would be required to follow the applicable FDA recommendations in "Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis" that 2 carbon tanks be installed in series with empty bed contact time of 10 minutes (DHHS/FDA, 1997). The second carbon tank provides the backup safety measure. Some dialysis facilities have three or four carbon tanks that provide even more assurance there will not be chloramine breakthrough. We invite comment as to whether our proposed conditions for coverage that include expanded water equipment requirements are still too minimal. In addition, we are requesting comments on whether the current AAMI guidance regarding carbon tanks is adequate to address all potential health and safety problems associated with chlorine, chloramines, and unannounced variations in source water. Specifically, we seek comments regarding where there is sufficient evidence to require Medicare-participating dialysis facilities to maintain at least two carbon tanks (that is, primary and backup) as part of their water treatment system, regardless of the current composition of its source water.

We are proposing in § 494.40(e) to require active surveillance of hemodialysis patient reactions during and following dialysis, particularly when there are adverse reactions that might be associated with a problem with the water purification system. The facility must take steps to protect patient safety and obtain the appropriate blood and dialysate cultures. Evaluation of the water purification system must be undertaken as well as any necessary corrective action (§ 494.40(d)).

If chlorine/chloramine levels in treated water from the last backup component (or carbon tank) are above the AAMI standards as required in proposed § 494.40(a)(1)(ii), dialysis treatments must be immediately stopped to protect patients from exposure to chlorine/chloramine as proposed in § 494.40(c)(2)(ii). The medical director, who is ultimately responsible for water quality, must be notified immediately and corrective action taken. A corrective action plan is also required (see § 494.40(d)) whenever any of the water purity action levels or standards, including but not limited to, chemical, microbial, and endotoxin, are detected.

We propose to add a requirement, consistent with in the AAMI document RD52:2004, that specifies that once mixed, bicarbonate concentrate must be used within the time specified by the manufacturer of the concentrate and may not be mixed with fresh concentrate. The holding of the bicarbonate concentrate presents the risk of bacterial growth and should be avoided.

We considered addressing water quality for home dialysis patients in this condition, but we decided instead to include a requirement that the facility monitor water used by its home dialysis patients to ensure that the water meets the AAMI standards under the proposed “care at home” condition for coverage (§ 494.100). Addressing all home dialysis issues under a single condition simplifies the organization of the regulations and eliminates the need for readers to refer to separate sections for the requirements for home dialysis services.

C. Reuse of Hemodialyzers and Bloodlines (Proposed § 494.50)

Section 1881(f)(7) of the Act requires the Secretary to establish protocols for reuse of hemodialyzers for those facilities that voluntarily elect to reuse the filters. The Act further states that dialysis facilities that fail to follow the reuse protocol will be subject to denial of participation in the Medicare program and denial of payment for dialysis treatment not furnished in compliance with the reuse protocol.

In hemodialysis the patient's blood is cleansed of impurities when it passes through the filter (hemodialyzer) of a hemodialysis machine. There are various techniques that allow some of these filters to be reused under certain conditions. Reuse involves cleaning, disinfecting, and preparing such hemodialysis devices for subsequent use for the same patient. Although the potential exists for adverse patient

outcomes from reuse, reprocessing and reuse of dialyzers are safe when proper techniques are utilized.

The existing regulation at § 405.2150 requires ESRD facilities reusing hemodialyzers to meet the guidelines and standards adopted by AAMI and issued in July 1993, as “Reuse of Hemodialyzers” (American National Standards Institute, 1993). We are proposing to retain this requirement in the proposed rule but to incorporate by reference the newly revised version and associated amendment (ANSI/AAMI RD47: 2002 and ANSI/AAMI RD47: 2002/A1: 2003) which replaces the 1993 version. This document received final AAMI approval on November 7, 2002.

Some in the renal community believe that we should not incorporate the CDC guideline that prohibits reuse for hepatitis B patients. They believe there is no documentation that reuse contributes to the spread of hepatitis or that it negatively affects the patient with hepatitis. In addition, they indicated that this prohibition is costly to facilities because a new dialyzer must be used for each session.

Hepatitis B is a highly contagious and potentially damaging illness, especially for a dialysis patient. Thus, the CDC has for many years recommended extreme caution and isolation for those patients who are Hepatitis B positive. Many physicians, nurses and other professionals involved in the dialysis field have similarly supported the position of extreme caution in treating the hepatitis B positive patient. The 2001 CDC guidelines advise against the reprocessing of dialyzers used for patients who have Hepatitis B because of the risk to facility staff. The hepatitis virus is relatively stable in the environment and has been shown to remain viable for several days on surfaces (via blood spills). While there may be no appreciable evidence to demonstrate that reuse would increase the spread of hepatitis B, there is not conclusive evidence that reuse in this population is safe. At this time we propose to maintain the CDC guidelines prohibiting reuse for hepatitis B patients to minimize the incidence of this mode of transmission.

We are also proposing at § 494.50(b)(2) that the hemodialyzer manufacturer recommendations be followed, or if an alternate method for reprocessing hemodialyzers is used, that the facility have documented evidence that the method is safe and effective. According to FDA guidance, hemodialyzer labeling should reflect the clinical use of a hemodialyzer, and whether it is intended for single or multiple usage (DHHS/FDA, 1995).

Only hemodialyzers and bloodlines labeled for multiple use may be reused. In addition, manufacturers of reusable hemodialyzers are required to provide adequate instructions for safe and effective reuse in accordance with 21 CFR 801.5. If the facility chooses to use an alternate method for reprocessing hemodialyzers there must be sufficient scientific evidence that the method is safe and effective. This flexibility is provided to allow for the use of newer and improved technologies that are proven safe in scientific studies which may become available in the future. The FDA approved label recommendations for the proper use of the device must be adhered to by dialysis facilities.

Existing § 405.2150(a)(2) states that to prevent any risk of dialyzer membrane leaks due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. We have received informal suggestions that we alter the current language because many facilities use bleach as part of the reuse process to flush and clean blood deposits before the actual germicide soaking process is initiated. However, for purposes of reuse, we consider bleach to be a cleansing agent, not a germicide. The requirement to discard dialyzers treated with a different germicide does not apply to bleaching. Nonetheless, since the language appears to be confusing to some, we are proposing to clarify the provision in proposed § 494.50(b)(3) by inserting the phrase “other than bleach.”

Some in the renal community and on the AAMI RD47 workgroup stated that discarding dialyzers exposed to a second germicide was expensive and unnecessary if air pressure leak test results indicated the dialyzer was still effective. However, we are proposing to retain the requirement in existing § 405.2150 that if a dialyzer is exposed to a second germicide it must be discarded because we are concerned that exposure to different germicides may cause membrane leaks. While we recognize that it may be considered wasteful by some to discard dialyzers with test values that indicate they are still effective, we believe this is a necessary safety measure. We do not have sufficient evidence that clearly supports the safety of using multiple germicides on hemodialyzers. We welcome comment on the issue of multiple germicide use in reused hemodialyzers.

Existing § 405.2150(a)(3) requires that facilities take appropriate blood cultures at the time a patient has a febrile response and discontinue reuse of

hemodialyzers in the case of pyrogenic reactions, bacteremia, or unexplained reactions possibly associated with ineffective reprocessing, until the entire reprocessing system is evaluated. We have been advised that a single febrile response in one patient can be the consequence of many different etiologies not related to reuse, including an infected access, a current infection, or contamination of the water purification system. Members of the renal community suggested that a febrile reaction in a single patient is rarely attributed to dialyzer reuse. Facilities do not believe it is necessary to terminate reuse or order blood cultures when a febrile reaction occurs in only a single patient. It was suggested that a facility need only respond through aggressive evaluation of its water purification system, dialysis concentrates, and reuse system when the surveillance of febrile events reveals a cluster of febrile patients. Based on this evaluation, the facility can make an appropriate clinical decision concerning termination of reuse. As a result, we are proposing in § 494.50(c) to revise the regulations to state that a facility need only obtain blood and dialysate cultures and evaluate its reprocessing and water purification systems in response to an adverse reaction when clinically indicated. If the evaluation indicates that the facility should discontinue reuse, we expect facilities to have established contingency plans, suspend the reuse of hemodialyzers until the problem has been corrected, and report the adverse outcomes to the FDA and other agencies as required by Federal, State or local laws and regulations.

Existing § 405.2150(c) lists 4 requirements applicable to a facility that reuses bloodlines. Facilities must: (1) Limit the reuse of bloodlines to the same patient; (2) not reuse bloodlines labeled for "single use only"; (3) reuse only bloodlines for which the manufacturer's protocol for reuse has been accepted by the FDA in accordance with the premarket notification (see section 510(k) of the Food, Drug, and Cosmetic Act and 21 CFR 876.5860 of the regulations); and (4) follow the FDA-accepted manufacturer's protocol for reuse of that bloodline. We propose to maintain the first requirement to limit the reuse of bloodlines to the same patient because the risk of transmitting blood-borne pathogens is so high, and reusing for the same patient limits the risk of cross-contamination. We also propose to maintain the third and fourth requirements, that is, a facility may reuse only bloodlines for which the manufacturer's protocol for reuse has

been accepted by the FDA; and that the facility must follow the FDA-accepted manufacturer's protocol for reuse of the bloodline. With these requirements, the facility must follow any specific instructions listed by the FDA, as well as any guidelines by the manufacturer that may not be discussed in the FDA regulations. We are proposing to delete the second existing requirement that facilities not reuse bloodlines labeled for "single use only" because it is redundant with the existing third and fourth requirements. Since the FDA would not recommend reuse on bloodlines labeled "single use only," there is no need to maintain the requirement.

D. Physical Environment (Proposed § 494.60)

[If you choose to comment on issues in this section please include the caption "Physical Environment" at the beginning of your comment.]

The existing physical environment condition (§ 405.2140) stipulates that the physical environment in which dialysis services are furnished afford a functional, sanitary, safe, and comfortable setting for patients, staff, and the public. The existing regulation consists of four separate standards concerning building and equipment, favorable environment for patients, contamination prevention, and emergency preparedness. We propose to refine the physical environment section to include only those elements that relate directly to the physical surroundings of the dialysis facility and to relocate the remaining elements to other sections in the proposed rule that relate more closely to those subject areas.

The existing building and equipment requirements in § 405.2140(a), include fire safety procedures, equipment maintenance, facility maintenance, and water treatment. Based on the experience and suggestions of our surveyors, we propose to establish separate standards for the building itself in proposed § 494.60(a) and equipment in proposed § 494.60(b). We propose to maintain the existing requirement (described in § 405.2140(a)) that the building in which dialysis services are furnished be constructed and maintained to ensure the safety of patients, the staff, and the public. The dialysis facility should be free from hazards that may bring harm to the patients, the staff, and the public.

The existing language of § 405.2140(a)(2) stipulates that all electrical and other equipment used in the facility be maintained free of defects that could present a potential hazard to

patients or personnel and that there is a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility. We propose at § 494.60(b) to maintain the essence of this requirement but to clarify that all equipment is maintained in accordance with the manufacturer's recommendations. Based on their experience with the equipment, we believe manufacturers have the most knowledge about routine maintenance and recommended repair.

Existing § 405.2140(b) requires each facility to maintain a favorable environment for patients; and the facility must be maintained and equipped to provide a functional, sanitary, and comfortable environment with an adequate amount of well-lighted space for the services provided. The existing language in this standard combines several different concepts, including sanitary environment and infection control, and we propose to address each subject in separate sections of the regulation. As a result, we are proposing at § 494.60(c) to include only those standards regarding the safety and comfort of each patient.

Since the proposed conditions are outcome-oriented, we believe that we do not need to specify all the process requirements that a facility must meet to provide a dialysis environment in which the patient can receive quality care. Each facility can develop its own strategies and techniques as long as the space for treating each patient is sufficient to provide needed care and services, prevent cross-contamination, and accommodate medically needed emergency equipment and staff. Existing § 405.2140(b) also requires the facility to provide a well-lit space. We propose to delete this requirement because it is too subjective to be meaningful, and we believe this detail is better left to the judgment of the facility staff.

We expect the dialysis facility to provide patients with a comfortable environment. Existing § 405.2140(b)(4) requires that heating and ventilation systems be capable of maintaining adequate and comfortable temperatures. We recognize that not all patients are comfortable at the same temperature; and therefore, proposed § 494.60(c)(2) specifies that the facility maintain a temperature that is comfortable for the majority of patients. The dialysis facility must make reasonable accommodations for patients who are not comfortable at the temperature setting determined by the majority of patients. The facility has the option of allowing patients to bring a blanket to dialysis or providing freshly laundered blankets to the patients. Infection control procedures must be

adhered to in either case. Often patients need a warm environment because of lowered body temperature during the dialysis process, and therefore, facilities should look to patients rather than staff to ascertain comfortable building temperatures.

In the emergency preparedness standard (proposed § 494.60(d)), we have proposed requirements that we believe are fundamental for a dialysis facility to prepare effectively for emergency situations. These requirements include: (1) Procedures for medical and non-medical emergencies; (2) staff and patient training; (3) facility emergency equipment; and (4) periodic evaluation of emergency plans. Existing § 405.2140(d) requires the facility to have written policies and procedures that specifically define the handling of emergencies that may threaten the health and safety of patients. The existing regulations also stipulate that facility staff should be trained for any emergency or disaster, as part of their employment orientation.

We propose to clarify at § 494.60(d) that each dialysis facility must implement emergency preparedness procedures to manage potential medical and nonmedical emergencies that are likely to threaten the health or safety of facility patients, the staff, and the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. The facility will need to identify which hazards are most likely to effect their facility, evaluate how to minimize risks, and plan how to best protect patients in the event of an emergency, using an emergency management approach. We do not expect individual facilities to develop emergency plans for natural disasters that typically do not affect their geographic location. For example, facilities located in the Southeast would not typically need to develop emergency procedures for earthquakes. Facilities located in the central plains States, on the other hand, would need to be prepared for tornadoes. All facilities must plan for fire, care related emergencies, equipment and power failures, and interruption of the water supply, because these emergencies may occur regardless of a facility's geographic location.

In addition to having emergency procedures, a facility will need to plan ahead so that necessary information and tools are available to staff and patients. For example, a facility would need to have current patient telephone numbers, addresses, and transportation

information available before an emergency happens rather than scrambling to update this kind of information during an emergency. As a resource in their movement toward an emergency management approach, dialysis facilities may want to use the ESRD facility emergency preparedness guidelines available from the ESRD Networks.

We propose to maintain the existing requirement that a facility train each staff member on the actions required for different medical and nonmedical emergencies. The existing conditions for coverage require that emergency preparedness procedures be reviewed and tested at least annually and revised as necessary. Also, all personnel must be knowledgeable and trained in their respective roles in emergency situations. We are proposing that staff training must be evaluated at least annually and that staff must demonstrate knowledge of emergency procedures. This requirement is designed to ensure the safety and security of both the patients and the staff. We propose also to require that the facility provide periodic training to patients and staff. Patients routinely treated in dialysis units are at risk for medical emergencies. As a result, standard medical practice dictates that the facility must have trained personnel, drugs, and emergency equipment available to adequately support patients until an Emergency Medical System (EMS) unit responds to the facility.

We are proposing at § 494.60(d)(1)(ii) that staff must maintain current cardiopulmonary resuscitation (CPR) certification. This is the standard practice in United States dialysis facilities. We have not prescribed the type or number of staff who must maintain CPR certification but at a minimum, the patient care staff must maintain current CPR certification. In this instance, patient care staff are staff who routinely provide direct medical care to patients in the dialysis unit.

We would maintain the standard in the existing regulation (§ 405.2140(d)(5)) that the facility provides appropriate training to patients, so that they know the facility's emergency procedures, since they may need to take steps to protect themselves during an emergency. Dialysis patients need to be informed on what to do, where to go, whom to contact from home, and how to disconnect themselves from dialysis equipment if an emergency occurs.

The existing text in § 405.2140(d)(3) requires that the facility have available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and

equipment. We propose to maintain this requirement, but we want to eliminate the confusion regarding the meaning of "fully equipped." We propose to define the minimum emergency equipment that must be on the premises and immediately available as "oxygen, airways, suction, artificial resuscitator ventilation bag, defibrillator, and emergency drugs." We propose to specifically require defibrillators. Automated external defibrillators (AEDs), in particular, have been shown to save lives in a variety of settings, most notably aboard airlines and in airports. One Seattle study (*Arch Intern Med.* 2001;161:1509–1512 available at <http://www.ARCHINTERNMED.com>) identified dialysis centers as having a relatively high incidence of cardiac arrest (≥ 0.746 per practice annually). In the 9 dialysis facilities studied there were 47 cardiac arrests over a 7-year period. Approximately 56 percent, or 26 patients, had ventricular fibrillation and may have benefited from use of an AED. The authors of this study presented their findings to the nine dialysis centers and all nine agreed to equip their centers with AEDs and to train their staff in the use of AEDs.

The key to saving a life is getting the defibrillator on the patient as soon as possible. The AED allows dialysis facility staff to defibrillate a patient without requiring the immediate presence of a physician. According to the American College of Emergency Physicians (www.acep.org/1,2891,0.html), when a person suffers a sudden cardiac arrest, the chance of survival decreases by 7 to 10 percent for each minute that passes without defibrillation. The very real potential for saved lives supports the financial investment in an AED. The cost of an AED is approximately \$2,000 to \$3,000. Some units have already voluntarily purchased AEDs. Very small units (for example, units with two hemodialysis stations) may find the purchase of an AED to be a heavy financial burden. We are soliciting comments on whether small, predominantly rural dialysis facilities should receive special consideration and possibly an exemption from the defibrillator requirement. We propose that the dialysis nursing staff must be trained on the proper use of emergency equipment and emergency drugs. Staff could be trained on the use of an AED in conjunction with the CPR training. Having the right equipment at the time of an emergency is only useful when staff is well versed in how to effectively use it. In addition, the facility must have

a plan to obtain EMS assistance when needed.

We are proposing to require a defibrillator without specifying an AED due to the fact that some dialysis units already have access to a defibrillator. Hospital-based dialysis units, in particular, may have immediate physician availability built into the hospital-wide cardiac resuscitation plan. This reduces the financial burden of the proposed defibrillator requirement.

We are proposing to maintain the requirement that facilities conduct reviews of their emergency and disaster plans to ensure that facilities appropriately respond to the situations and needs that may arise from a variety of emergencies, medical and nonmedical. We are proposing in § 494.60(d)(3)(ii) that facilities review their emergency and disaster plans at least annually. Drill and emergency episodes often reveal a weakness or flaw in the design of the emergency plan. An annual update will allow such flaws or potential problems to be identified and corrected.

Existing § 405.2140(b)(3) specifies that the facility have a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made. We propose to delete this requirement because we believe this is not a physical environment issue. It is important that patients are appropriately monitored during the dialysis session. However, monitoring is most effectively done through interaction between the patients and the staff in the dialysis area and not from a monitoring station.

We believe that existing § 405.2140(b)(5) is another process-oriented requirement, and we propose to delete this requirement. This requirement states that facilities using central batch processing must make arrangements to meet the needs of patients with special dialysis solutions. The Patient plan of care condition, proposed § 494.90, would require the dialysis facility to implement the care plan and make arrangements to meet the individual requirements of each patient regardless of whether those needs are related to special dialysis solutions or other medically necessary supplies or equipment.

The existing emergency preparedness standard (§ 405.2140(d)) enumerates the facility physical emergency management procedures but provides minimal standards for the procedures that must be followed during a fire. We propose to strengthen the section governing fire safety to provide greater

detail regarding the appropriate procedures that must be followed.

We are proposing at § 494.60(e) to adopt the 2000 edition of the National Fire Protection Association's (NFPA) Life Safety Code (LSC). The LSC is a compilation of fire safety requirements for new and existing buildings and is updated and published every 3 years by the NFPA, a private, non-profit organization dedicated to reducing loss of life due to fire.

The Medicare and Medicaid conditions of participation have historically incorporated by reference these requirements along with Secretarial waiver authority. The statutory basis for incorporating NFPA's LSC for ESRD facilities falls under the Secretary's general rulemaking authority.

The 2000 edition of the LSC is divided into several occupancy chapters including a business chapter, educational chapters, ambulatory health care occupancy chapters, and health care occupancy chapters. The business occupancy chapter pertains to clinics and offices. The educational occupancy chapters pertain to schools and day care centers. The health care occupancy chapters pertain to inpatient health care facilities (for example, hospitals, nursing homes). Finally, the ambulatory health care occupancy chapters pertain to facilities that provide outpatient medical treatment that may render the patient temporarily incapable of self-preservation (for example, critical access hospitals, dialysis centers).

The *NFPA LSC Handbook* specifically designates Chapter 20 and Chapter 21 for outpatient dialysis services. We propose to adopt, as recommended by the NFPA LSC, Chapter 20 (that is, new ambulatory health care occupancy buildings) and Chapter 21 (that is, existing ambulatory health care occupancy buildings) of the 2000 edition of the LSC for all outpatient dialysis facilities regardless of size.

The LSC classifies dialysis facilities as ambulatory health care occupancies because the treatment is not a routine medical visit to a doctor's office but rather a procedure that may hinder the patient from self-preservation in the event of an emergency or fire. Incapability of self-preservation might be the result of the use of general anesthesia or a treatment such as dialysis. Dialysis patients are not as mobile as a person working or visiting an office building or health clinic but more mobile than patients being treated in an inpatient health care facility, such as a hospital or nursing home. Chapters 20 and 21 give a level of safety from fire that is greater than the typical business

occupancy but less than a health care occupancy such as a hospital or nursing home.

Under our proposal, an outpatient dialysis facility would comply with the business occupancy provisions in Chapters 38 (that is, the new business occupancies) and 39 (that is, existing business occupancies) with the additional provisions contained within Chapters 20 and 21. Where there may be a conflict between the business occupancy chapter and the ambulatory health care occupancy chapter, the more stringent requirements would apply (LSC sections 20.1.1.1.2 and 21.1.1.1.2). The requirements of Chapters 20 and 21 are described below.

Chapter 20.1.2.1 and Chapter 21.1.2.1 require 1-hour fire separation between different occupancies or tenants in a multi-tenant building. We believe most dialysis facilities currently meet this requirement because most State building codes already require this provision.

Chapters 20.2.4 and 21.2.4 require that there be at least two emergency exits. Emergency lighting is required by Chapters 20.2.9.1 and 21.2.9.1 to ensure that the center is lighted and that egress paths are illuminated to allow movement during an emergency.

Chapters 20.2.9.2 and 21.2.9.2 require an essential electrical system. This provision does not apply to dialysis facilities because dialysis equipment is not life-support equipment under the Life Safety Code.

Chapters 20.3.4.4 and 21.3.4.4 require the fire alarm system to provide automatic notification of a fire to emergency forces. This is of great importance for the protection of patients. Any delay in the notification of fire and rescue personnel could adversely impact the health and safety of patients and expose them to a fire, smoke, or toxic gases created by the fire.

Chapters 20.3.7 and 21.3.7 pertain to smoke compartmentation, otherwise known as subdivision of building space. Section 3.7 of Chapters 20 and 21 apply to any dialysis facility that is larger than 5,000 square feet (or 10,000 square feet for facilities with sprinklers). We believe most dialysis facilities will fall within the exceptions outlined in this provision. If a dialysis facility is smaller than 5,000 square feet and protected by an approved, supervised sprinkler system, then section 3.7 of Chapters 20 and 21 do not apply.

Section 7 of Chapters 20 and 21 specify procedures to assist outpatient dialysis facilities in providing fire safety. Section 7.1 of Chapters 20 and 21 propose evacuation plans and fire exit drills and require staff to practice the

procedures outlined in the dialysis facilities written emergency plans. Section 7.1 of Chapters 20 and 21 are appropriate for outpatient dialysis facilities because there is a possibility a dialysis patient could lose blood or suffer unnecessary risks if the patient were removed from the dialysis machine during a fire drill. We believe that requiring a dialysis facility to stop dialysis treatment and evacuate all dialysis patients during a fire drill is an unnecessary procedure that could jeopardize the dialysis patient's health and safety. Annex A, Explanatory Material to the 2000 NFPA LSC provides guidance for conducting fire drills when it is inexpedient and impractical to move patients during a fire drill. Many health care occupancies conduct fire drills by choosing the location of the simulated emergency in advance; practicing the movement of simulated patients or empty wheelchairs to adjacent safe areas, and ensuring that staff have the efficiency, knowledge, and response capability to implement the facility's fire emergency plan. Surveyors may determine whether this standard was met by checking a dialysis facility's records and interviewing staff to verify that the emergency and fire drills were conducted not less than once in each 3-month period and that staff are very familiar with the procedures.

Section 7.1.1 in Chapters 20 and 21 also require that the dialysis facility prominently post its emergency plan. We expect the plan to include continuity of essential building operations in the event of an emergency. Electrical, water, fire protection, ventilation, and communications systems are some, but not all, areas a dialysis facility should consider in its disaster plan. A good reference, but not a requirement for developing an emergency plan for a dialysis facility, is the NFPA 99—Standard for Health Care Facilities, Chapter 11, Health Care Emergency Preparedness (NFPA, November 2001). Our intent in proposing the posting requirement is to ensure patients, staff and the public have the proper information to quickly evacuate in the event of an emergency.

The remaining provisions in section 7 of Chapters 20 and 21 include requirements for the procedures in case of fire (20.7.2 and 21.7.2); maintenance of exits (20.7.3 and 21.7.3); smoking regulations (20.7.4 and 21.7.4); furnishings, beddings, decorations (20.7.5 and 21.7.5); maintenance and testing of life safety-related equipment (20.7.6 and 21.7.6); portable space heating devices (20.7.7 and 21.7.7); and

construction, repair and improvement operation (20.7.9 and 21.7.9).

We recognize that for some dialysis facilities it would be extremely burdensome to adhere strictly to all of the LSC requirements. For example, older dialysis facilities or facilities leasing space in an office building may not be able to add sprinkler systems. We are proposing to retain our existing authority to waive specific provisions of the LSC on a case-by-case basis, further reducing the exposure to additional cost and burden for facilities with unique situations that can justify the application of waivers which we determine will not endanger the health and safety of patients. We propose that a waiver may be granted for a specific LSC requirement if: (1) We determine that the waiver would not adversely affect the patient/staff health and safety; and (2) we determine that it would impose an unreasonable hardship on the facility to meet a specific LSC requirement. A provider may request a waiver from its State Agency. The State Agency will review the request and make a recommendation to the appropriate CMS Regional Office. The CMS Regional Office will review the waiver request and the State Agency's recommendation and make a final decision on the waiver request. A waiver cannot be granted if patient safety is compromised in any way.

A State may also request that a State fire and safety code, imposed by State law, be applicable to all dialysis facilities rather than the LSC proposed in this rule. The State must submit the request to its CMS Regional Office and the Regional Office will forward the State's request to CMS Central office for a final determination.

V. Proposed Part 494 Subpart C (Patient Care)

A. Patients' Rights (§ 494.70)

[If you choose to comment on issues in this section please include the caption "Patients' Rights" at the beginning of your comment.]

The existing patients' rights condition, § 405.2138, requires that the facility's governing body adopt written patients' rights policies that are administered by the facility's chief executive officer (CEO). Sections 405.2138(a)(1) through (5) state that patients must be informed regarding the following: (1) Their rights and responsibilities; (2) services available at the facility and charges not covered; (3) their medical condition (by a physician); (4) the facility's reuse policies; and (5) their suitability for transplantation or home dialysis.

Sections 405.2138(b)(1) and (2) afford patients the right to participate in planning their medical treatment; require that a patient may be transferred or discharged for only medical reasons or for the patient's or other patient's welfare or nonpayment of fees; and require that patients must be given advance notice to ensure an orderly transfer or discharge. Section 405.2138(c) states that patients must be treated with respect and dignity; § 405.2138(d) protects patient confidentiality of personal and medical records; and § 405.2138(e) states patients must be advised, encouraged, and assisted in exercising their rights to bring grievances (through a representative, if desired) without fear of discrimination or reprisal.

We are proposing to revise the provisions of this condition to include a number of changes, in keeping with our goals to reduce the Federal regulatory burden on dialysis facilities, eliminate unnecessary procedural requirements, and revise the conditions for coverage to be more outcome-oriented while protecting the basic rights of ESRD patients.

First, we are proposing at § 494.70 that the facility must inform patients (or their representatives) of their rights and responsibilities when they begin their treatment at the facility, and must also protect and provide for the exercise of those rights. We believe it is important to take steps to ensure that patients are fully and promptly informed of their rights. The existing regulatory language permits a facility an unspecified period of time to complete this activity. However, we believe that all dialysis patients must be informed of their rights and responsibilities when they begin their treatment, which is the standard practice in dialysis facilities, so they may exercise them from the beginning of their relationship with the facility.

Existing § 405.2138 provides a list of numerous persons to whom these written patient rights policies must be "made available." The list includes patients and guardians, next of kin, sponsoring agencies, representative payees, and the public. Essentially, the facility must provide the list of patient rights to anyone who asks to see them. Rather than specifying a list of people to whom the patients' rights policies must be made available, we are proposing at § 494.70 that facilities inform the patients (or their representatives), and at § 494.70(c) that facilities post a copy of the patients' rights in a prominent location where it can easily be seen and read. This not only meets the objectives of the current list of disclosures, it also allows patients

to review their rights at any time during the course of their care at the dialysis facility.

Section 405.2138 also states that the CEO is responsible for the development of, and adherence to, procedures implementing the patients' rights policies. In § 494.70, we are proposing to change this requirement by holding the facility accountable for the outcome, which is to ensure that each patient's rights and the ability to exercise them are protected.

We are proposing to retain the patients' rights enumerated in § 405.2138(a)(1) through (a)(5) and include them in the proposed § 494.70(a).

Proposed § 494.70(a)(1) requires the dialysis facility to inform patients of their right to be treated with respect, dignity, and recognition of their individuality and personal needs as well as sensitivity to the patients' psychosocial needs and ability to cope with ESRD.

Proposed § 494.70(a)(2) requires a dialysis facility to provide information to patients in an understandable manner. The existing requirement at § 405.2138(c) requires dialysis facilities to provide translators "where a significant number of patients exhibit language barriers." Presumably, under this existing requirement, if a single patient has language difficulty, the facility does not need to act to address this patient's needs. We are proposing to modify this requirement. Since written information is not required, the dialysis facility has the flexibility to decide the best vehicle for providing information to patients. We believe this more outcome-oriented requirement provides a facility with the latitude to devise its own means to ensure the outcome is met.

Proposed §§ 494.70(a)(3) and (4) would require a dialysis facility to inform patients regarding privacy and confidentiality, and also expands those rights to include specific references to privacy and confidentiality in all aspects of the patient's treatment as well

as the patient's medical records. These requirements include existing provisions from § 405.2138(c) and (d). Staff should be instructed that any discussions with dialysis patients or relatives regarding treatment, the patient care plan, and medical conditions should be held in private and kept confidential. There should be reasonable precautions to keep both written and verbal patient information private. Staff should be aware of the need to speak at a volume and at a proximity to patients such that privacy is reasonably protected. Facility staff must make efforts to protect patient information and physical privacy. While recognizing the patient's right to privacy and confidentiality, we are not necessarily advocating physical barriers in the dialysis clinical area that provide patient privacy because patients should be in view of staff at all times during treatment to ensure safety. However, in situations when there is patient body exposure during therapy, the staff should be instructed to provide temporary screens, curtains, or blankets.

We are proposing at § 494.70(a)(5) to retain the existing requirement under § 405.2138(b)(1) that describes the right of patients to participate in the planning of their medical treatment and to refuse to participate in experimental research (or any part of their care). Section 494.70(a)(5) requires a facility to inform patients regarding their right to participate in all aspects of their care. Although we recognize that a facility cannot require its patients to participate in the care process, we expect the facility to work closely with patients and encourage patient participation to ensure that a care plan is developed that is suitable to the needs and concerns of both the patient and staff. The facility should notify patients in advance, if possible, of any changes in the treatment plan recommended by the physician and the basis for the changes. The facility should also encourage patients to disclose any concerns they may have with the proposed changes.

Proposed § 494.70(a)(5) would also require the facility to inform patients of the right to establish an advance directive. Advance directives establish in writing an individual's preference with respect to the degree of medical care and treatment desired or who should make treatment decisions if the individual should become incapacitated and lose the ability to make or communicate medical decisions. Advance directives include written documents including living wills and durable powers of attorney for health care, as recognized by State law.

Congress passed section 4206 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101-508) to ensure that patients receive information regarding their right to execute or not to execute advance directives. While the OBRA 1990 requires hospitals, skilled nursing facilities, HHAs, managed care plans, and hospice programs participating in the Medicare program to establish and maintain written policies and procedures regarding advance directives, it does not specifically mention dialysis facilities.

In proposing to add advance directives to the patients' rights condition for coverage we took several factors into consideration. First is the chronic nature of ESRD. Kidney impairment is irreversible and permanent, and a regular course of dialysis or transplantation is essential to maintain life. In addition, we considered the amount of time a patient spends in the dialysis unit, and also the rapidly changing demographics of the ESRD patient population. The average age of the ESRD patient population is increasing annually. Elderly ESRD patients now comprise a large percentage of the total ESRD patient population. Data compiled by the United States Renal Data System, from 1990 to 2001, shows the following rate of new cases of ESRD for patients 65 years of age and older:

Age (in years)	Year											
	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001
65–69	7,177	7,982	8,597	8,895	9,852	9,643	10,390	10,829	11,078	11,225	11,415	11,545
70–74	6,159	7,260	8,093	8,533	9,664	9,678	10,753	11,248	11,648	12,005	12,276	12,367
75–79	4,587	5,367	5,997	6,293	7,243	7,404	8,481	9,339	10,133	11,170	11,407	11,408
80–84	2,386	2,754	3,228	3,427	4,051	4,290	4,959	5,725	6,125	6,785	7,349	7,477
85+	961	1,113	1,277	1,481	1,659	1,833	2,248	2,598	3,110	3,587	3,870	4,146

The emergence of an older, sicker ESRD patient population has motivated the Renal Physicians Association (RPA) and the NKF to develop guidelines for

implementation of advance directives in dialysis facilities, and we are encouraging dialysis facilities to adopt voluntary consensus guidelines for

advance directives. The guidelines can be obtained through the NKF's Web site at: http://www.kidneyva.org/public_ed/orderforms.pdf and through the RPA

Web site at <http://www.renaldm.org/publications/index.cfm>.

After taking these factors into account, we believe it is prudent to consider adding advance directives as a requirement in the patients' rights condition of this proposed rule.

Existing § 405.2138(a)(5) requires that patients be informed of their suitability for transplantation or home dialysis. We have strengthened this requirement at § 494.70(a)(6) by proposing that patients be informed about alternative treatment modalities by requiring dialysis facilities to address all treatment choices. The treatment modality selected may directly affect the quality of life for dialysis patients. This choice is a very personal one, with important implications for how likely the patient is to be rehabilitated to the highest possible level. To assist dialysis patients in achieving the optimal quality of life, patients need education about each modality and must have access to the widest array of treatment choices possible.

For example, a successful kidney transplant is the most desirable treatment for many ESRD patients and facilities should make every effort to both educate and inform patients regarding the transplantation option. Also, forms of dialysis that can be performed at home have been shown to have a positive influence on the patient's quality of life. Home dialysis affords patients' control over scheduling and setting, and it can be done in comfortable, familiar surroundings. Also, home dialysis is generally perceived to be less disruptive to family life and employment. We propose to require that a facility inform patients about all available treatment modalities and settings, so patients can make an informed decision regarding the most appropriate course of treatment that meets their needs.

Open communication between the facility staff and the patient and patient access to treatment information are vital tools for enhancing the patient's participation in his or her coordinated care planning. Proposed § 494.70(a)(7) requires that patients be informed of the facility's patient care policies, including its patient isolation policies.

Proposed §§ 494.70(a)(8) through (10) retain existing requirements in § 405.2138(a)(2) through (4) that patients be fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers; be informed by a physician regarding his or her own medical condition unless contraindicated; and be informed of services available in the facility and charges not covered by Medicare.

Proposed § 494.70(a)(11) would require that patients be informed of the right to receive the necessary services outlined in the patient plan of care in proposed § 494.90. The importance of the patient plan of care is discussed in section V.C. of this preamble.

Proposed § 494.70(a)(12) would retain the existing requirement at § 405.2138(a)(1) that patients be informed of the rules and expectations of the facility regarding patient conduct and responsibilities. The success of the dialysis treatment is as contingent upon patients adhering to their responsibilities as it is upon other important factors. There is a discussion of the dialysis facility's responsibility regarding disruptive and difficult patients in section VI.E.9. of this preamble.

Proposed § 494.70(a)(13) would require facilities to inform patients regarding the facility's internal grievance process and their right to express grievances against the facility using the internal grievance process through a representative chosen by the patient (if so desired).

Proposed § 494.70(a)(14) strengthens the existing requirement for facilities to inform patients regarding the various external grievance mechanisms available to them, including how to contact the ESRD network and the State survey agency, and how to file external grievances without reprisal or denial of services, through a representative chosen by the patient or anonymously (if so desired). We believe that patients must be made aware of every grievance option available to them, including, at a minimum, contacting the two entities with the statutory responsibility under Federal law for addressing patient grievances (that is, the ESRD networks and the State survey agencies).

In proposed §§ 494.70(b)(1) and (2), we would require a facility to inform patients regarding its transfer and discharge policies and provide 30 days notice in advance of reducing or terminating patient care services following the discharge and transfer procedure outlined in § 494.180(f). The facility would be exempt from the 30-day notification requirement in cases when there was an immediate threat to the health and safety of others. Proposed §§ 494.70(b)(1) and (b)(2) and the procedure outlined at § 494.180(f) have been proposed, in part, in response to the "disruptive" or "challenging" patient issue. Increasing numbers of staff and patient grievances presented to the ESRD networks and the State survey agencies involve allegations of disruptive behavior by patients and allegations of inappropriate patient

discharges from facilities for noncompliance or disruptive behavior. We would not expect a patient to be involuntarily discharged from a dialysis facility for failure to follow the instructions of a facility staff member. However, it may be necessary to discharge a disruptive patient in order to protect the rights and safety of other patients in the facility, or to protect the safety of facility staff.

We believe that a dialysis facility has both the resources and a responsibility to make a good faith effort to work with every patient, including patients perceived to be disruptive or challenging, to provide the necessary assessment, training, knowledge, and motivation to facilitate good outcomes of care. This process begins when the facility interdisciplinary team performs the comprehensive patient assessment described in proposed § 494.80, with periodic reassessments as needed; continues through the care planning process described in proposed § 494.90; as well as the facility's quality assessment and performance improvement (QAPI) program described in proposed § 494.110. We believe the disruptive or challenging patient problem is multifaceted, and even conscientious assessments, care planning, and QAPI programs by a facility will not always be successful in mitigating the disruptive behavior of some patients. In those instances when good faith efforts by a facility have been unsuccessful and the facility has determined that it wants to discharge or transfer the patient, facilities must follow the procedure outlined in proposed § 494.180(f), and arrange to transfer or discharge the patient, as appropriate.

We also recognize there will be rare instances when a facility must act immediately to discharge a patient. Such instances could be, for example, when a patient physically harms or threatens other patients and staff, a patient who brings weapons or illegal drugs into a facility, or a patient who is verbally abusive and disruptive to such an extreme degree that the facility is unable to operate effectively. In those and comparable circumstances, we would propose to shorten the 30-day notification requirement. We are soliciting comments on the proposed §§ 494.70(b)(1) and (b)(2), as well as suggestions for addressing the disruptive or challenging patient issue in the proposed ESRD conditions.

If a patient chooses not to use a facility's internal grievance process, or when grievances cannot be resolved at the facility level, the patient may elect to register a grievance with the

appropriate ESRD network or make a complaint directly to the State survey agency at any time. We believe it is essential that we require that patients be informed of every grievance and complaint option currently available to them under the law.

Proposed § 494.70(c) would require dialysis facilities to prominently display a copy of the patients' rights as well as the telephone numbers for the appropriate ESRD network and State survey agency in order to afford patients the opportunity to contact either entity, if desired. Dialysis patients have the right to be advised of and to use grievance processes developed by the facility, the ESRD network and the State survey agency.

B. Patient Assessment (Proposed § 494.80)

The proposed patient assessment condition at § 494.80 underscores our belief that systematic patient assessment is essential to improving quality of care and patient outcomes. The information generated from the patient assessment is a vital tool for developing a patient's care plan and subsequent treatment. A comprehensive patient assessment allows the dialysis facility to monitor the patient's progress toward achieving the desired care outcomes and adjust the plan of care and treatment prescription as necessary.

The existing regulations in part 405 subpart U do not state that a patient will receive a comprehensive assessment. However, two sections of the existing regulations, §§ 405.2136(g)(1) and 405.2137(b)(1), provide a basis for a patient assessment. For example, § 405.2136(g)(1) holds the patient's physician responsible to prescribe a planned regimen of care, "which covers indicated dialysis and other ESRD treatments, services, medications, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge." That section also states that such plans are made with the input of the professional personnel providing care to the patient. Existing § 405.2137(b)(1) states that a patient care plan "reflects the psychological, social, and functional needs of the patient," and indicates ESRD and other care needed to achieve the long- and short-term treatment goals.

Therefore, while the existing regulations indicate that a specialized care plan must be developed based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs, it does not specify the criteria that a facility must include in a patient

assessment. Over the past 25 years, research has improved our knowledge of the components important to assessing and treating the dialysis patient so that improvements in quality of life and morbidity and mortality rates have been achieved.

We believe that a comprehensive patient assessment that includes clinical interaction with the patient is a prerequisite for the delivery of quality care and is the basis for determining a patient's functional status and identifying the services necessary to address the patient's needs. Accurate and accessible patient information generated from the comprehensive assessment is critical to the development of a successful patient care plan and the achievement of desired patient outcomes.

We do not believe that expanding the existing requirements in this proposed condition will impose any additional burden on facilities. Rather, we believe quality-oriented facilities already routinely perform comprehensive patient assessments upon initiating treatment. Further, we believe most facilities already have this information in different parts of the medical record since an appropriate and effective treatment plan cannot be developed without an initial assessment.

We are proposing at § 494.80 to add a patient assessment condition for coverage that would make the ESRD facility, through the patient's interdisciplinary team, responsible for providing each of its patients with an individualized and comprehensive assessment of his or her needs. The members of the interdisciplinary team (see proposed § 494.10) would include the patient (if he or she chooses), a registered nurse, a physician, a social worker, and a registered dietitian. With the team concept, the goal is to obtain input from each designated health professional as well as from the patient to develop an assessment that identifies the patient's needs and allows for planning for necessary services. The proposed team members represent vital components of the patient's medical treatment and psychosocial development. These professionals are also key to a successful transition to dialysis as well as to maintaining the patient's quality of life. An assessment that involves the patient as a key member of the interdisciplinary team is important to the successful delivery of service and the patient's adherence to the program.

In proposed § 494.80(a), we list the assessment criteria. The minimum proposed elements of a patient's assessment include the following:

- Evaluation of current health status, including comorbid conditions and medical condition.
- Evaluation of the appropriateness of the dialysis prescription, blood pressure control, and fluid management needs.
- Laboratory profile and medication history.
- Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of recombinant erythropoietin.
- Evaluation of factors associated with renal bone disease.
- Evaluation of nutritional status.
- Evaluation of psychosocial needs.
- Evaluation of dialysis access type and maintenance.
- Evaluation of the patient's ability, interests, preferences, and goals, including level of participation in the dialysis care process; modality and setting (for example, home dialysis, including home hemodialysis or peritoneal dialysis); and expectations for care outcomes.
- Evaluation of suitability for transplantation referral, based on criteria developed by the transplant surgeon at the transplant center that would receive such transplantation referral including the basis for referral or nonreferral.
- Evaluation of family and other support systems.
- Evaluation of current physical activity level.
- Evaluation of vocational and physical rehabilitation status and potential.

Other information to be included in the initial assessment would be determined by the interdisciplinary team based on the specific characteristics and needs of the patient.

We recognize that inclusion of a minimum set of assessment criteria may appear to be inconsistent with our goal of eliminating unnecessarily prescriptive and process-oriented requirements. However, we believe it is appropriate and necessary for every patient assessment to focus not only on the patient's medical needs, but also on his or her psychosocial and rehabilitation needs. Further, these assessment criteria would assure that needed information would be available for the patient plan of care and the facility's quality assurance and performance improvement program.

We propose criteria for the frequency of assessment and reassessment of new patients in §§ 494.80(b)(1) and (2). A timely, comprehensive assessment is critical for planning patient care and achieving desired patient outcomes. We

believe this requirement, though process-oriented, is necessary to prevent harm to the patient. By permitting facilities 20 calendar days to complete assessments, we are providing a reasonable timeframe for every member of the team to assess the patient prior to development of the treatment plan.

We also recognize that patients who are new to dialysis need time to adjust and adapt to the treatment. Initially, patients may experience a great deal of anxiety while learning self-care skills, modifying their diet, changing their behavior, and perhaps dealing with access issues. The level of compliance with the renal regimen may be set by the time the person has been on dialysis for 4 to 6 months (Sciarini, pp. 299–305). Because of this period of adjustment, and the opportunity to establish the patient's adherence to the renal regimen, proposed § 494.80(b)(2) would require a follow-up comprehensive reassessment for new patients within 3 months after the completion of the initial comprehensive assessment. Three months was chosen so that the window of opportunity for establishing adherence to the renal regimen by a new patient is not missed. We recognize the additional burden this 3-month reassessment will place on the interdisciplinary team. However, an updated plan of care and the attention to the patient's adjustment to the renal regimen may prevent problems in the coming months. The reassessment also ensures the continued accuracy and effectiveness of the treatment regimen.

Existing § 405.2136(g) states that the physician responsible for the patient's medical supervision evaluates the patient's needs and prescribes a planned regimen of care for dialysis. Sections 494.80(c)(1) and (2) propose a schedule for the assessment of the treatment prescription for hemodialysis and peritoneal dialysis patients. Studies indicate that ESRD patient mortality is lower when patients receive sufficient dialysis treatments. There has been considerable research recently indicating that the dose of dialysis is an important determinant of survival and morbidity of patients on hemodialysis ((Held, pp.871–875); (Owen, pp.1001–1006); (Parker, pp.981–989); and (Parker, pp.670–680)). The delivered dose of dialysis (Kt/V or an equivalent measure) indicates how well the dialysis treatment is working. Kt/V is the dialyzer clearance of urea (K) times the time of treatment (t), divided by the volume of distribution of urea (V), which yields a dimensionless value. Adequacy of dialysis clinical practice guidelines are available in the National Kidney Foundation's Kidney Disease

Quality Initiative (NKF–K/DOQI). As previously discussed in this preamble, the NKF–K/DOQI has established clinical practice guidelines for ESRD patients. This systematic, evidence-based approach to developing guidelines used focus workgroups to identify target issues and conducted extensive literature searches to extract relevant clinical study reports for each target issue. Clinical practice guidelines were derived from this information. The guidelines are available for public review and comment, and they continue to be reviewed. Health care professionals and providers, ESRD networks, managed care groups, industry, government, patient associations and individuals are invited to provide comments to the NKF–K/DOQI workgroups. These comments are reviewed and when appropriate, incorporated in future editions.

An important initiative of this project is the development of guidelines for the dose of dialysis, including standard methodology(ies) for measuring the dialysis dosage.

To ensure that ESRD patients receive sufficient dialysis, the delivered dose of dialysis needs to be measured. Therefore, in keeping with the NKF's K/DOQI clinical practice guidelines, we propose in § 494.80(c) to specify that the delivered dose of dialysis for the patient's hemodialysis treatment prescription must be measured at least monthly, and the patient's peritoneal dialysis treatment prescription should be assessed at least every 4 months. More frequent monitoring may be necessary for new dialysis patients or when the dialysis prescription is changed. Less frequent monitoring of the adequacy of dialysis may compromise the timeliness with which deficiencies in the delivered dose of dialysis are identified and hence may delay implementation of corrective action.

In §§ 494.80(d)(1) and (2) we propose patient reassessment timeframes for both stable and unstable patients with respect to the standards specified in §§ 494.80(a)(1) through (a)(13). The comprehensive assessment process can be seen as part of a cycle. Through the use of the patient assessment, accurate and timely patient information is reflected in the plan of care. As the assessment changes, the plan of care must be revised accordingly. If the patient's condition is stable, we propose in § 494.80(d)(1) that the facility must perform comprehensive reassessments at least annually, which assures that patients are receiving a continuing program of care that meets their needs. This proposed timeframe minimizes the

facility burden because the existing § 405.2137(b)(4) requires care plan review every 6 months for stable patients. If the patient is unstable, we are proposing in § 494.80(d)(2) to require a monthly reassessment, to allow for the update of the plan of care. Existing § 405.2137(b)(4) also requires a monthly review of the care plan for patients whose medical condition has not become stabilized. In proposed §§ 494.80 (d)(2)(i) through (d)(2)(iv), we added criteria to specify at a minimum, which patients may be considered to be unstable patients. These criteria include extended or frequent hospitalizations, marked deterioration in health status, a significant change in psychosocial needs, or poor nutritional status, with unmanaged anemia and inadequate dialysis. Extremely frail patients may need monthly reassessments. However, we are not proposing a specific requirement for monthly reassessments for frail patients because we believe this type of requirement would be too prescriptive and limit the flexibility of dialysis facilities to make clinical determinations on a case-by-case basis.

The renal community has been unable to reach a consensus regarding the optimum frequency of assessments. Some believe that the proposed time periods create a strain on facilities, while others have encouraged us to propose more stringent timeframes. Because of the wide range of opinion in this matter, we are specifically soliciting public comments on whether the proposed 3-month timeframe for reassessment of new patients is reasonable and consistent with meeting the patient's needs.

C. Patient Plan of Care (Proposed § 494.90)

[If you choose to comment on issues in this section please include the caption "Plan of Care" at the beginning of your comments.]

The patient assessment serves as the basis for the patient plan of care. Existing § 405.2137 contains a large number of prescriptive requirements for the development of patient care plans. These requirements specify that there needs to be a patient long-term program and a patient care plan.

The patient long-term program described in existing §§ 405.2137(a)(1) through (a)(4) relates to the selection of a suitable treatment modality and treatment setting by the treatment team. It also requires active participation by the physician director in the unit where the patient is being treated, a formal review of the written long-term plan by the team every 12 months, patient involvement in the plan's development,

and a requirement to send the plan to the receiving facility within 1 day of an interfacility transfer.

The patient care plan in existing § 405.2137(b) requires a written care plan based on the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs. Additional requirements in existing §§ 405.2137(b)(1) through (b)(7) include a personalized care plan reflecting the patient's needs, a care plan developed by a professional team (including the physician responsible for the patient's care), the involvement of the patient (or the patient's parent or legal guardian), a monthly review for unstable patients, a 6 month review for stable patients, sending the plan to the receiving facility within one day for interfacility transfers, periodic monitoring of home dialysis patients, and monitoring for home dialysis patients who use erythropoietin.

In accordance with our goal of reducing Federal regulatory burden, we have simplified the proposed patient care plan condition (§ 494.90) by eliminating the separate requirement for a patient long-term program.

We propose to retain some of the existing requirements of § 405.2137 in the patient assessment condition (proposed § 494.80). We believe that the patient assessment and patient care planning processes are inextricably linked. That is, each patient assessment must be followed with a review and revision, if necessary, of the patient's plan of care.

The comprehensive plan of care is an individualized program that ensures that each dialysis patient receives personalized and appropriate patient care within the selected modality and setting of treatment. In proposed § 494.90 we would specify that the patient's plan of care must include measurable and expected outcomes and estimated timetables to meet the patient's medical and psychosocial needs as identified in the initial and subsequent comprehensive assessments. This section would also specify that the patient's plan of care must address all the services that are to be furnished to achieve and maintain the expected outcomes of care.

Existing §§ 405.2137(a)(1) and 405.2137(b)(2) specify the composition of the professional team responsible for the preparation of the long-term and the patient care plans. The facility's professional team currently writes a patient long-term program and a short-term care plan. However, proposed § 494.90 would require that a single patient plan of care be developed and this plan would address all of the

patient's needs. We are proposing in § 494.90 to retain the existing requirement that the patient plan of care to be developed by the interdisciplinary team. Although we would retain the existing §§ 405.2137 (a)(1) and (2), we have chosen to use the term "interdisciplinary team." The term "interdisciplinary team" is defined § 494.10 and described in § 494.80. In § 494.80, we are proposing that the interdisciplinary team consist of, at a minimum, the patient (if he or she desires) or his/her designee, a registered nurse, a nephrologist or physician treating the patient for ESRD, a social worker, and a dietitian. We are using the term "interdisciplinary team" instead of "professional team" because the term "interdisciplinary team" is commonly used in health care settings, including dialysis facilities.

Although existing § 405.2137(a)(1) specifies a transplant surgeon as a member of the professional team, we did not include a transplant surgeon as a member of the interdisciplinary team as defined in proposed § 494.10 and described in proposed § 494.80. We believe all eligible ESRD patients must be referred for transplantation. However, it may not be reasonable to have transplant surgeons sign every care plan. The existing interpretive guidelines for surveyors (Survey Procedures and Interpretive Guidelines for End-Stage Renal Disease Facilities, Appendix H, State Operations Manual) allow a transplant surgeon's designee, who could be a transplant coordinator or the treating nephrologist, to screen patients in the long-term care plan process (DHHS/CMS, April 1995). The designee would have to use screening criteria developed by the transplant surgeon. Because not every patient is medically suited for a transplant, we believe the transplant surgeon need not be involved with the team unless a possible candidate has been identified. We are proposing that the dialysis facility must have inclusion/exclusion criteria, defined by the transplant surgeon based at the transplant center that would receive the transplantation referral, to use in the evaluation of patients for transplant referral. Therefore, we propose to delete the requirement that a transplant surgeon directly sign the care plan. We believe transplant referral tracking must be part of the comprehensive plan of care condition (*see* § 494.90(c)), and we have also proposed to strengthen this requirement in the patient assessment (§ 494.80) and patient's rights (§ 494.70) conditions. We are soliciting comment on the appropriate role of the transplant

surgeon in developing the patient plan of care.

Existing § 405.2137(a)(1) also requires that the facility medical director and a physician from a facility that offers home dialysis (if the patient's present facility does not) be included in the team that develops the patient's long-term program. While we believe the involvement of these physicians would be valuable in most cases, we recognize that there are situations when the services of these physicians may not be needed. Thus, in keeping with our goal of eliminating unnecessary process requirements, proposed § 494.10 specifies the definition of "interdisciplinary team" without including the facility medical director and the home dialysis physician. Nonetheless, we encourage facilities to expand the interdisciplinary team to include as many health professionals as necessary to furnish the best care possible to their patients.

As required in existing § 405.2137 and in proposed § 494.10, a physician is part of the interdisciplinary team. We propose retention of this requirement because we believe the physician must play an integral role on the interdisciplinary team. The physician responsible for the patient's dialysis treatment works with the other team members to ensure the development of an appropriate care plan for the patient. We also expect the physician to see the patients and monitor their care.

Existing § 405.2137(b)(3) specifies that the patient may be involved in the development of the care plan and consideration is given to the patient's preferences. The patient's right to be informed about and participate within the interdisciplinary team is encompassed in proposed § 494.70(a)(5). The patient or his/her designee, if he or she desires, as a member of the interdisciplinary team, must collaborate to design a plan of care that enables the patient to reach his or her desired level of general health, activity, and quality of care. When a patient communicates his or her goals regarding their medical treatment, he or she plays a more active role in improving their quality of life. We have eliminated the phrase "due consideration is given to [the patient's] preferences" because we believe it implies the patient (or the patient's designee) is not an equal member of the team. Each patient must be given the opportunity to participate with the interdisciplinary team. However, we would not require them to do so in the proposed requirements because we recognize that some patients may not wish to participate in the team process. We are proposing that the patient or

designee must sign the plan of care to assure the patient is aware of treatment plans and goals regardless of whether the patient has opted to participate in the care planning team process.

The patient plan of care must include measurable and expected outcome targets or goals for each patient based on the individual patient's assessment. These outcome targets must allow the patient to achieve current evidence-based community-accepted standards. Currently, the K/DOQI clinical practice guidelines are the community-accepted standards for individual patient care and we expect ESRD facilities to reflect the current standards of care for dialysis adequacy and anemia management in the patient plan of care. As additional evidence-based community-accepted standards become evident, they could be targeted in the patient plan of care as well.

We propose that allowing the patient to achieve current evidence-based community-accepted standards for dialysis adequacy and anemia means (at § 494.90(a)(1)), that the patient plan of care should specify a minimum delivered threshold for Kt/V of at least 1.2 (single pool) for hemodialysis patients (NKF, Guideline 4); 1.7 (weekly) for continuous ambulatory peritoneal dialysis (NKF, Guideline 15); 2.1 (weekly) for continuous cycling peritoneal dialysis patients (NKF, Guideline 16); and 2.2 (quarterly) for intermittent peritoneal dialysis patients (NKF, Guideline 16). For anemia management (proposed § 494.90(a)(3)), the minimum specified threshold levels in the patient plan of care are: a hemoglobin level of 11 gm/dL or comparable hematocrit of at least 33 percent (NKF, Guideline 4).

There is significant correlation between achieving recommended NKF-K/DOQI values for the adequacy of dialysis and anemia management measures with positive outcomes in mortality, hospitalization, and/or quality of life. Thus, the advantages of assigning patient-level minimum targets and thresholds is that we would establish a process when patients whose values do not meet the criteria are evaluated for possible further intervention so that they can achieve values that are associated with better outcomes. It is understood that guidelines and standards, although evidence-based, are not appropriate for all patients in all situations. Thus these minimum thresholds serve as indicators for potential quality improvement activity.

We are proposing that outcomes specified in the patient plan of care must allow the patient to achieve

current evidence-based community-accepted standards.

However, we are soliciting public comments on this issue, and we will be guided by those comments in reaching a final determination on whether to require minimum threshold values for the patient plan of care as we develop the final rule for new ESRD conditions for coverage.

1. Development of the Patient Plan Of Care (Proposed § 494.90(a))

In developing this proposed rule, we determined that there is sufficient evidence to support the inclusion of minimum set of evaluative categories in the patient plan of care that have been shown by independent medical research to be important in achieving desirable patient outcomes. We are proposing (in § 494.90) that the patient plan of care must, at a minimum, address: (1) Dose of dialysis; (2) nutritional status; (3) anemia; (4) vascular access; (5) transplantation status; and (6) rehabilitation status. Each of these elements is discussed below.

a. Dose of Dialysis (Proposed § 494.90(a)(1))

There is a consensus in the renal community that adequacy of dialysis in terms of a Kt/V is an important clinical performance measure and the vast majority of dialysis facilities do use minimal target levels or goal levels or both to ensure delivery of quality care. We are proposing in § 494.90(a)(1) that the patient's interdisciplinary team assist and support the hemodialysis and peritoneal dialysis patient in achieving and maintaining an adequate dose of dialysis that meets evidence-based community-accepted standards as specified by the Secretary. We are soliciting comments on the possible use and appropriate minimum threshold values for the adequacy of dialysis.

b. Nutritional Status (Proposed § 494.90(a)(2))

Existing § 405.2163(d) states that the dietitian, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling on prescribed diets, and monitoring adherence and response to diets.

Our proposed requirement on nutrition at § 494.90(a)(2) would require the interdisciplinary team to provide the necessary care and services to achieve and sustain an effective nutritional status. Effective nutritional status encompasses acceptable levels of protein, calorie, and fluid intake as well as acceptable levels of nutrients in the

blood. We did specify that one patient plan of care nutritional measure, the serum albumin (a marker of visceral protein stores), must be monitored on a monthly basis to reflect current standards of practice.

The National Institutes of Health (NIH), in its Consensus Conference Report entitled "Morbidity and Mortality of Dialysis," identified nutritional status as an important indication of the renal patient's health (DHHS/NIH, pp.1–33). We recognize that nutrition plays an important role in the management of renal disease. However, we have found diverse opinions about using an objective measure as a clinical outcome measure for nutritional status. Potential clinical outcome measures of nutritional status include anthropometric measures, clinical signs of nutrient deficiency, urea kinetic modeling, prognostic nutrition indexing, and measurement of biochemical parameters. The NKF-K/DOQI clinical practice guidelines for Nutrition of Chronic Renal Failure (Guideline 1) state that, "there is no single measure that provides a comprehensive indication of protein-energy nutritional status." (NKF, pp. S17.) NKF-K/DOQI guideline 3 further states that, "serum albumin is a valid and clinically useful measure of protein-energy nutritional status in maintenance dialysis patients." (NKF, pp. S20.)

We invite comments on whether any additional specific nutritional outcome measures, such as other biochemical parameters of serum protein (total protein, transferrin, or prealbumin), or the protein catabolic rate or protein equivalent of total nitrogen appearance measure should be used as a patient plan of care outcome measure.

c. Anemia (Proposed § 494.90(a)(3))

Proposed § 494.90(a)(3) uses anemia, as measured by the hematocrit (or comparable hemoglobin) level, as a specified patient outcome. There is a consensus in the community that the use of hemoglobin, hematocrit or both to monitor anemia management are important clinical performance measures and the vast majority of dialysis facilities do use minimal target levels or goal levels or both for these measures to manage anemia in the dialysis patient. In § 494.90(a)(3) we propose that the patient's interdisciplinary team assist and support the hemodialysis and peritoneal dialysis patient in achieving and maintaining the expected hemoglobin/hematocrit level. The hemoglobin or hematocrit level must be measured at least monthly, as is the current standard practice. We are soliciting comments on

the possible use and appropriate minimum threshold values for anemia management.

Existing § 405.2163(g) address the patient's hematocrit or comparable hemoglobin level as a marker for the necessity for administering erythropoietin at home. The assessment criteria include: (1) Preselection monitoring (lab values and blood pressure); (2) hematocrit or comparable hemoglobin level less than 30 percent or medical justification for a higher hematocrit or comparable hemoglobin level; (3) a target hematocrit or comparable hemoglobin range for a patient receiving erythropoietin of 30 to 33 percent; and (4) the patient is under the care of a physician responsible for dialysis-related services. There are also additional process requirements. We are eliminating some of these process requirements and proposing that each patient be evaluated for anemia as specified in the patient assessment condition at § 494.90(a)(4). We are also proposing that any patient with a hematocrit of less than 33 percent or a hemoglobin of less than 11 gm/dL must be evaluated as a candidate for erythropoietin use. For home dialysis patients, we are proposing that the facility evaluate whether the patient can be trained to safely, aseptically and effectively administer erythropoietin, and store erythropoietin under refrigeration. The patient's response to erythropoietin, including blood pressure levels and the patient's utilization of iron stores, must be monitored on a routine basis.

Section 1881(b)(1)(C) of the Act specifies that the patient self-administering erythropoietin must be able to safely and effectively administer the drug in accordance with the applicable methods and standards established by the Secretary. Section 1861(s)(2)(O) of the Act states that Medicare will pay for erythropoietin as "medical and other services" if the patient self-administers the drug "subject to methods and standards established by the Secretary by regulation for the safe and effective use of such drug. * * *" Section 405.2163(g)(2) and (3) of the existing regulations specify the applicable methods as established by the Secretary. In keeping with our outcome-oriented focus, we are proposing to retain only those specific evaluation criteria that are clinically necessary and supported by the NKF-K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease, 2000 Update. Also, we are not proposing to retain all of the requirements in existing § 405.2137(b)(7) relating to the plan

providing for monitoring home use of erythropoietin. We believe these requirements are unduly prescriptive and may not reflect the most appropriate items to monitor for each individual patient. We want to provide flexibility to a facility to develop its own criteria to monitor all patients who are using erythropoietin.

In § 494.90(a)(3) we are proposing to provide the facility with the flexibility to develop their own assessment and patient plan of care criteria for patients for whom the use of erythropoietin would be appropriate. In addition, we are proposing in § 494.90(a)(3) that a dialysis patient's response, including blood pressure and utilization of iron stores, to erythropoietin must be monitored on a routine basis. The patient plan of care should ensure that the patient is trained and is competent to safely, aseptically, and effectively administer the drug; provide for monitoring and safe refrigerated storage for home use of erythropoietin; and target appropriate hematocrit or hemoglobin levels.

d. Vascular Access (Proposed § 494.90(a)(4))

Our existing regulations do not contain any specific requirements pertaining to hemodialysis vascular access. We note that the hemodialysis procedure is dependent on the availability of a patent vascular access. According to data from the United States Renal Data System access failure is the second most frequent cause of hospitalization among ESRD patients. Access failure is also one of the significant contributors to hemodialysis patient morbidity. The costs of vascular access failure are also significant. In 1999 the total Medicare ESRD program expenditure for vascular graft failure was more than \$97 million. Dialysis facilities may not have complete control over the type and placement of the access. However, it has been demonstrated that efforts to improve access patency can help to extend the life of an access. The NKF-K/DOQI provides vascular access clinical practice guidelines that address the importance of access monitoring and methods for improving the quality of patient care in this area (NKF, pp. S137–S181).

Therefore, we are proposing in § 494.90(a)(4) to include vascular access as a component of the patient plan of care with the following requirements for the interdisciplinary team:

- Evaluation of the hemodialysis patient for the appropriate vascular access type, taking into consideration

co-morbid conditions and other risk factors.

- Support and assist the patient in achieving and maintaining vascular access patency.
- Routinely monitor the hemodialysis patient's vascular access to prevent access failure, including routine monitoring of arteriovenous grafts and fistulae for stenosis.

e. Transplantation Status (Proposed § 494.90(a)(5))

Although we are proposing to remove the existing requirements for a separate long-term program from the conditions (*see* § 405.2137), we are proposing in § 494.90(a)(5) to retain the concept of transplant planning. Within the plan of care, the interdisciplinary team must address whether the patient is a transplant candidate and identify the plan for obtaining a transplant. The plan and the actions necessary to make the transplant a reality must be addressed in the plan of care. Necessary actions would include, for example, patient transplant referral for evaluation by a transplant center, communication with the transplant center, and monthly blood draws for antigen/antibody testing. We are soliciting public comment on whether the "necessary actions" listed above should be a requirement for dialysis facilities.

When the patient is not suitable for transplantation referral evaluation, the reason for nonreferral must be written in the patient's assessment and notated in the patient plan of care. The reason(s) for nonreferral must be consistent with the criteria developed by the prospective transplantation center and surgeon. In cases when the patient meets the transplantation criteria but declines referral, there must be documentation in the patient plan of care that the patient has made an informed decision to decline renal transplantation.

f. Rehabilitation Status (Proposed § 494.90(a)(6))

Existing § 405.2163 includes rehabilitation-related activities under the minimal service requirements for social services. Advances in technology and pharmacology have offered the possibility of significant improvements in the well-being of dialysis patients. More efficient dialysis equipment, the development of the synthetic hormone erythropoietin and active vitamin D, for example, represent important breakthroughs in quality-of-life areas. However, despite this improved potential for restoration, it is generally acknowledged that renal rehabilitation has not yet been addressed nationally in

a consistent, integrated fashion. Therefore, we are proposing to focus on rehabilitation outcomes through this requirement.

For dialysis patients, rehabilitation means restoring the mind and body to encourage the individual to maintain as full and active a life as possible. The Life Options Rehabilitation Advisory Council has defined the ideal process of rehabilitation for a dialysis patient as a coordinated program of adequate dialysis, education, counseling, and dietary regimens designed to maximize the vocational potential, functional status, and quality of life of dialysis patients (The Life Options Rehabilitation Advisory Council, p. 20). The ultimate goals of renal rehabilitation include employment for those who can work, enhanced physical fitness, increased individual control over the effects of kidney disease and dialysis, and the ability to maintain as active a lifestyle as possible. Many renal professionals equate successful renal rehabilitation with employment, in part because employment can be readily measured and documented, but factors other than employment must be examined in a complete discussion of rehabilitation or functional status of dialysis patients.

Comprehensive rehabilitation efforts can make the difference between an acceptable quality of life and mere existence. The improved overall health and outlook of successfully rehabilitated patients may have positive cost implications as well (Stewart, pp. 907–913). Patients who are rehabilitated to the point of employment may be able to offset Medicare costs, subject to Part 411, Subpart F, of our rules, if they have health insurance through their employment that would cover the costs of ESRD treatment in place of Medicare. Patients whose physical health improves to the point when they can manage self-care activities may allow an adult caregiver to re-enter the workforce. Even patients who cannot care for themselves, but whose outlook and quality of life are improved, can experience positive health consequences that reduce costs; thus keeping patients at home rather than in nursing homes decreases the costs of care as well. And costs notwithstanding, the achievement of these improvements in the patient's condition is inherently invaluable. (The Life Options Rehabilitation Advisory Council, p. 20).

Rehabilitation cannot be “done to” the patient. Active patient participation in rehabilitation is key to the success of any rehabilitation effort. Facility staff must inform and educate patients that their participation in rehabilitation

programs is critical to their well being, ongoing treatment, and attainment of a successful adjustment to their condition. The patient's responsibility to participate in rehabilitation efforts is no less essential than her or his compliance with any aspect of the management of her or his care.

In this proposed rule, we are separating the rehabilitation requirements (proposed § 494.90(a)(6)) into a distinct plan of care category, and we are implicitly extending the definition of rehabilitation to include education. We have chosen to include rehabilitation as a specific category because we want the interdisciplinary team to focus on providing patients with the opportunity and the education for rehabilitation. In addition, staff attitudes about rehabilitation may have a correlation to patients' own attitudes about their potential to regain functional status.

It is not sufficient for facility staff to merely provide information about rehabilitation to patients. Rather, the essential role of rehabilitation in the treatment and recovery process must be continuously conveyed to patients and their families. To that end, the proposed requirement for rehabilitation status requires that the interdisciplinary team play a critical role in supporting the patient and advising the patient on his or her rehabilitative efforts. Specifically, the interdisciplinary team must provide the necessary care and services for the patient to achieve and maintain an appropriate level of productive activity, including vocational, that permits the patient to resume, to the extent feasible, activities engaged in prior to kidney failure. As part of this requirement, rehabilitation should be included in the patient's treatment prescription; the patient's involvement in rehabilitation activities should be incorporated in patient education materials; and facility patient support groups focusing on rehabilitation activities could be offered. Under this condition, facility staff should encourage and educate patients on the benefits of rehabilitation. The importance of rehabilitation as part of the treatment and recovery process must be conveyed, so patients come to recognize it as a benefit to themselves. The team must reinforce activities that lead to successful rehabilitation. The interdisciplinary team must provide care and services to younger patients to enhance the possibility of a successful transition to adult life and responsibilities. Although rehabilitation services may not be needed by pediatric patients, there may be educational needs and developmental needs that the interdisciplinary team must consider

when writing and implementing the patient plan of care.

This proposed condition does not hold facilities accountable for rehabilitative outcomes that are beyond their control; instead, this proposed standard requires that interdisciplinary team staff use a combination of medical treatment, education, counseling, and dietary regimens to maximize dialysis patients' rehabilitation activity. Patients may be able to lead more active and productive lives if other rehabilitation interventions such as physical, occupational, and recreational therapy, counseling, and education are made available to them on a regular basis. Joint goal-setting by informed patients and the facility staff assists this process. We believe the interdisciplinary team should refer patients to appropriate agencies and health professionals for additional services that the facility cannot provide.

This proposed rule does not incorporate the use of any particular measure of rehabilitation status because we do not believe there is consensus in the renal community about a specific measurement at this time.

g. Social Services

We would like to specify social service outcomes that must be included in the patient plan of care. However, we believe the social worker should identify social service outcomes based on the patient assessment (described at § 494.80(a)) as part of the plan of care goals for each patient.

Complex emotional and social factors affect the dialysis patient, including, but not limited to, changes in self-image, loss of independence, changes in financial security, loss of physical integrity, problems with sexual functioning, changes in roles, and coping with the anxiety and discomfort associated with treatment. We believe that the interdisciplinary team could influence many of these factors. We are soliciting comment regarding the most effective way to address these factors within a patient plan of care requirement that supports an effective level of emotional and social well-being for the patient.

Work is being done on a variety of assessment instruments that could measure the emotional and social well-being of patients. We considered the current experiences with such instruments as the Kidney Dialysis Quality of Life instrument, the RAND Short Form-36, and the Duke Health Profile ((Hays, pp. 329–338); (Rand Corporation, (1997)); and (Parkerson, pp. 1056–1069), respectively). However, at this time we do not believe that there

is a consensus on a single instrument or a level of psychosocial achievement for dialysis patients that could be included as a specific measure for a patient plan of care requirement.

As specified in existing § 405.2163(c), the social worker is responsible for counseling the patient and the patient's family, assisting the patient with the emotional adjustment to ESRD and dialysis treatment, performing crisis intervention, coordinating referrals and other community services, and arranging other benefits. Social workers can, in some instances, provide some of the necessary care and services for the patient to achieve and sustain an effective level of emotional and social well-being. For example, a necessary care and services component of social services is facility staff counseling and educating the patient and providing necessary information for the patient to have a smooth transition to life on dialysis. The social worker has an important role in addressing patient behavior that may be challenging or disruptive. The social worker is uniquely qualified to provide counseling, anger management, and emotional support services to patients with ESRD. In cases in which the social worker is not able to provide the necessary services for the patient to adapt to dialysis treatment, the social worker should refer patients to appropriate agencies and health professionals for additional services. We are soliciting comments regarding the potential for an outcome-based requirement for social services in the patient plan of care.

2. Implementation of the Patient Plan of Care (Proposed § 494.90(b))

The patient plan of care stems from the patient comprehensive assessment that identifies patient care needs. Proposed § 494.90(b)(1) would require that the patient's plan of care be completed by the interdisciplinary team, signed by the patient or the patient's designee, and implementation must begin within 10 calendar days after an assessment is completed. As stated in the patient assessment condition, the facility interdisciplinary team has 20 days from the initiation of dialysis treatment to complete the comprehensive assessment. After the assessment has been completed, the interdisciplinary team has 10 days to develop the patient's plan of care. This gives the dialysis facility a maximum of 30 days to complete the comprehensive assessment and the patient plan of care. We selected 10 days for completion of the patient care plan because the plan directs the patient's treatment, and

therefore, the plan of care should be initiated as soon as possible. Clearly, we are limiting a facility's flexibility when we identify a timeframe for development of the plan of care. However, we believe that a timely, accurate, comprehensive plan of care is critical for planning patient care and achieving desired health care outcomes. We believe that a maximum of 30 days to complete the assessment and patient plan of care is ample time, considering the seriousness of the condition that necessitates the dialysis. We are soliciting comments on both the appropriateness of prescribing a timeframe as well as the suitability of the proposed timeframe.

We propose at § 494.80(d) that patients be reassessed as needed but no less frequently than annually. The patient plan of care would also be reviewed at least annually since we are proposing that every comprehensive assessment must be followed by completion and implementation of the plan of care. Existing § 405.2137(b)(4) states that care planning is conducted monthly for unstable patients and every 6 months for those patients who have become stabilized. While we have retained patient plan of care monthly timeframes for unstable patients (proposed at § 494.80(d)(2)), we believe that the 6-month review requirement for stable patients may be unnecessarily burdensome.

The individualized patient plan of care is not static and will require adjustments as the needs of the patient change, particularly if the patient is not stable. We propose at § 494.90(b)(3) that the interdisciplinary team must adjust the patient plan of care to achieve and sustain the specified patient outcomes goals. New strategies may need to be implemented as assessment, response, and patient preference information requires. If the targeted plan of care goal is achievable but is not being attained, the facility must implement an improvement plan to reach the goal.

We recognize that patient outcomes are determined in part by factors outside of the dialysis facility's control, such as demographics, the systemic effects of the underlying renal disease, and patient preferences and compliance. Further, we recognize that health care delivery is dynamic and that all patients may not be achieving for example, the expected delivered dose of dialysis at any specific point in time. If the patient is unable to achieve the desired health outcomes, the plan of care should be adjusted to reflect the patient's condition along with an explanation, and any opportunities for improvement in the patient's health should be

identified. The explanation for not achieving the specific level of care may include patient preferences and patient noncompliance.

Proposed § 494.90(b)(4) would specify that the facility must ensure every patient is seen at least monthly by a physician providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician or communicated from the physician's office and placed in the beneficiary's medical record. We are proposing this requirement based on a continuing concern of beneficiaries regarding the amount of interaction between patients and their physicians. We chose the time period of at least once a month because physicians have traditionally been paid for their services to renal patients on a monthly basis through the monthly capitation payment. Patients who are not stable will need to see the physician more frequently than our proposed minimal timeframe. According to preliminary information from the Dialysis Outcomes and Practice Patterns Study (DOPPS), better patient outcomes are associated with high levels of patient contact from the physician. Almost 70 percent of the dialysis patients sampled in the United States, as part of the DOPPS, see their physician once per week or more frequently, as reported by the nurse. However, we are concerned about the suggestion that as many as 5 percent of the dialysis patients may see their physician less often than once a month. While we are proposing a minimum monthly physician visit (without specifying any duration for the visit itself), we do not want to discourage more frequent visits. On November 7, 2003, we published a final rule (68 FR 63196, 63216) regarding the revisions to the payment policies under the physician fee schedule for calendar year 2004. This rule aligns payment incentives with the frequency of the physician's evaluation of the dialysis patient. In addition, the rule assigned new G codes that associate a higher payment to a physician who provides more visits within each month to an ESRD patient. Physicians should see patients and monitor their care as often as is medically necessary to ensure that they are progressing towards the specified outcomes.

We believe it is important for physicians to see in-center hemodialysis patients periodically while they are undergoing dialysis in order to monitor the quality of care they are receiving and to address the patient's particular clinical concerns and needs while in the treatment environment. We believe

periodic in-center monitoring by the patient's hemodialysis physician is an accepted medical practice and would not impose any additional burden on dialysis facilities. We are soliciting comments regarding whether physicians should be required to see their in-center patients periodically while those patients are being dialyzed in the dialysis facility. Such in-center visits would not be in addition to the monthly requirement proposed in § 494.90(b)(4).

3. Transplantation Referral Tracking (Proposed § 494.90(c))

We are proposing at § 494.90(c) that the interdisciplinary team track the results of each kidney transplant center referral and monitor the status of any facility patients who are on the transplant wait list. The routine exchange of information between the dialysis facility and the transplant center is important so that both facilities know who is active on the transplant wait list, who is temporarily or permanently inactive, and who is under evaluation. In addition, there may be a need to coordinate histocompatibility testing, which must be completed on a monthly basis. We invite comment on the coordination of the transplant process and the method and frequency of communication with the transplantation center.

4. Patient Education and Training (Proposed § 494.90(d))

The existing regulations do not specifically address patient education and training for in-center patients. However, in § 494.90(d), we are proposing to stipulate that the patient plan of care must include, as applicable, education and training for patients and families in all relevant aspects of the dialysis experience, dialysis management, quality of life, rehabilitation, and education regarding renal transplantation. When kidneys fail, the resulting physical changes stimulate a chain of psychological and physiological events that alter the lives of the affected individuals and their families. The education of patients and their families goes beyond providing the necessary information for patients to make an informed choice regarding treatment modality. Because the life changes associated with beginning dialysis are so profound, patients and their families need to be educated and trained about strategies for successful adaptation to dialysis, optimizing functional status, employment options, and many other issues. Patients and their families must learn about the disease and the possibilities of life beyond it and then assume

responsibility for their own health by complying with the treatment plan and participating actively in rehabilitation activities. Educating and training patients and their families is key to a successful transition to a life with dialysis.

However, not all elements of the existing § 405.2137 will be retained in proposed § 494.90. In accordance with our approach to consolidate all similar standards, we propose to move the requirements in existing § 405.2137(b)(5) regarding the transfer of the patient's medical records to the proposed medical records condition for coverage (§ 494.170), and move the requirements in existing § 405.2137(b)(6) regarding the monitoring of home dialysis patients to the proposed Care at Home condition for coverage (§ 494.100). We believe that this reclassification will improve the proposed regulation's organization.

D. Condition: Care at Home (Proposed § 494.100)

[If you choose to comment on issues in this section please include the caption "Care at Home" at the beginning of your comments.]

1. Dialysis of the ESRD Patient in the Home Setting

Home dialysis has been shown to have a positive effect on a patient's quality of life. Home dialysis affords the patient control over the scheduling and setting; it can be done in comfortable, familiar surroundings; and it is less disruptive to family life and employment than in-center dialysis.

The existing requirements for home dialysis are located in four sections: (1) Definitions (§ 405.2102); (2) patient care plan (§ 405.2137(b)); (3) medical records (§ 405.2139); and (4) minimal service requirements (§ 405.2163(e) and (g)).

Existing § 405.2102 defines home dialysis as dialysis performed by an appropriately trained patient at home.

Existing § 405.2137(b) states that home dialysis patients will receive a written care plan with the same criteria that are specified for in-center patients. Section 405.2137(b)(6) requires the ESRD facility to conduct periodic monitoring of the patient's home adaptation, including visits to the home by "qualified facility personnel" as appropriate. Section 405.2137(b)(7) contains patient care plan requirements that apply to home dialysis patients who use erythropoietin, including: (1) Monitoring diet and fluid intake; (2) medication usage; (3) hematocrit and iron stores; (4) reevaluations of the dialysis prescription; (5) a method for physician follow-up on blood tests and

a mechanism to inform the physician of the results; (6) training the patient to identify signs of hypotension and hypertension; and (7) decreasing or discontinuing erythropoietin usage if hypertension is uncontrolled.

Existing § 405.2139 requires facility to maintain "complete medical records" on all patients, including its home patients. Section 405.2139(d) contains requirements regarding medical records information generated by self-dialysis patients and entries of medical records information by trained self-dialysis patients, or "trained assistants," countersigned by facility staff.

Existing §§ 405.2163(e)(1) through (6) list a facility's home dialysis support services including: (1) Surveillance of the patient's home, including periodic visits; (2) consultation for the patient with a qualified social worker and qualified dietitian; (3) a record keeping system that assures continuity of care; (4) installation and maintenance of equipment; (5) testing and appropriate treatment of the water; and (6) ordering supplies on an ongoing basis.

Existing § 405.2163(g)(1) through (4) requires the facility or physician responsible to make a comprehensive patient assessment that includes the following: (1) Preselection monitoring, including the patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure; (2) conditions the patient must meet, including a hematocrit (or comparable hemoglobin) hematocrit level of 30 percent (for patients initiating erythropoietin treatment), or a level of 30 to 33 percent (for patients already under the care of a dialysis facility or physician); (3) a requirement that patients or caregivers must be trained to inject erythropoietin, read and understand drug labeling, and observe aseptic techniques; and (4) the assessment must find that erythropoietin can be refrigerated in the patient's residence and potential risks and hazards related to the drug and syringes are understood by the patient.

In § 494.100, we proposed requirements that are only applicable to home dialysis. Since not every facility chooses to provide home dialysis, this condition would apply only to a facility that provides these services.

We propose in the opening paragraph of § 494.100 to retain the implicit requirement in existing § 405.2163 that services to home patients are at least equivalent to those provided to in-center patients. Home dialysis patients are patients of the ESRD facility; and therefore, they are entitled to the same rights, services, and efforts to achieve

expected patient outcomes as any other patient of the facility.

We are proposing to address home dialysis training in § 494.100(a). In our deliberations regarding home dialysis training requirements, we took into account the considerable lifestyle changes associated with initiating home dialysis and the unique needs of patients and caregivers engaged in home dialysis. Patients and their caregivers need to be trained and educated about strategies for successfully adapting to dialysis at home, ways to optimize functional status, proper self-dialysis procedures, and many other issues. Therefore, the processes of educating and training patients and their caregivers are crucial to a successful transition to a life with dialysis and to achieving good patient care outcomes.

In the opening paragraph of § 494.100(a), we are proposing that before the initiation of home dialysis, when the caregiver changes, or when the home modality changes, that the facility's interdisciplinary team is responsible for providing self-dialysis training to the home patient, the patient's designated caregiver, or both. Self-dialysis (as defined in existing § 405.2102(b)(2)(ii) and proposed § 494.10) means dialysis performed with little or no professional assistance by an ESRD patient who has completed an appropriate course of training. Home dialysis training may be only be provided by a dialysis facility certified to provide home dialysis services. Durable medical equipment (DME) companies cannot provide home dialysis training. We are proposing in § 494.100(a)(1) to modify the existing requirement at § 405.2102(d)(3) that self-dialysis training must be conducted by a registered nurse with 18 months of clinical experience and at least 3 months of specialized experience in training dialysis patients in self-care. We are proposing to modify these requirements to state that self-care training must be conducted by a registered nurse who meets the personnel qualifications specified in § 494.140(b)(2) (that is, 12 months clinical experience and an additional 3 months of clinical experience in the specific modality for which the registered nurse will provide training). As previously stated, home dialysis training is crucial to achieving desired patient outcomes; and therefore, we believe the initial training a patient receives must be provided by an experienced health care professional.

Existing § 405.2102 requires that a facility provide a training program for self-dialysis and home dialysis patients, if it chooses to provide this service, but

it does not specify the content of that training program. Therefore, we are proposing the following subject areas for home dialysis training programs in §§ 494.100(a)(3)(i) through (a)(3)(x). These types of programs would, at a minimum, be required to provide training in the following:

- The nature and management of ESRD.
- The full range of techniques associated with the applicable type of home dialysis, including effective use of dialysis supplies and equipment in achieving the physician's prescription of Kt/V or URR, and effective erythropoietin administration (if prescribed) to achieve a hematocrit level of at least 33 percent or a hemoglobin level of 11 gm/dl.
- Nutritional care planning.
- Achieving and maintaining emotional and social well-being.
- How to detect, report, and manage potential complications.
- Availability of support services and how to access and use available support services.
- How to self-monitor health status and record and report health status information.
- How to handle medical and non-medical emergencies.
- Infection control precautions.
- Proper waste storage and disposal procedures.

While we recognize that specifying the topics for a training program appears to be inconsistent with our goal of reducing process-oriented requirements, we believe it is critical and necessary that the items listed above be required, so that patients and caregivers are fully informed regarding the health and safety procedures that must be followed and precautions that must be taken when providing dialysis at home.

Home patients are not seen 3 times a week by facility staff like in-center patients; and therefore, the quality and content of home training given to patients and their caregivers is an extension of the care and monitoring that would normally be provided in the dialysis facility. In addition, the facility is responsible for ensuring that home dialysis patients are achieving the desired outcomes, and this training will inform home care patients or their caregivers or both of the plan of care that must be followed (see proposed § 494.90) to achieve the expected results.

We propose in §§ 494.100(b)(1) through (3) that the dialysis facility: (1) Record who received the training described in § 494.100(a)(3) and indicate that the patient or caregiver demonstrated adequate comprehension;

(2) retrieve and review self-monitoring data from patients or caregivers at least every 2 months; and (3) maintain this information in the patient's medical record. The goal of the proposed standards is that facilities effectively coordinate the care of all patients, including home dialysis patients, to achieve the desired outcomes. As previously stated, we recognize that home patients do not see facility staff as frequently as in-facility patients, so the purpose of this proposed requirement is to ensure that the facility's interdisciplinary team periodically monitors the care of home dialysis patients' plans of care.

Existing § 405.2139(d) requires dialysis facilities to collect medical information generated by self-dialysis patients, but it does not specify the frequency of the data collection. By proposing at § 494.100(b)(2) that the home patient's facility collect and review information at least every 2 months, we ensure the interdisciplinary team can determine if the patient is having problems with any aspect of the dialysis therapy at regular intervals. We would recommend that the facility collect data that will enable it to determine if home patients are adhering to the plan of care and achieving expected outcomes. Based on the data received, the facility staff can determine if the patient or caregiver needs to be retrained or, in some cases, determine that the patient is no longer a suitable candidate for self-care dialysis. As with in-facility patients, the goal of collecting data on home dialysis patients is to ensure that they are achieving the expected outcomes.

We propose to retain many of the existing support services requirements at § 405.2163(e) in proposed § 494.100(c). We have always taken the view that the law and the regulations require that the facility provide all of these support services, regardless of whether the dialysis supplies are provided by the dialysis facility or a durable medical equipment (DME) company, to the extent that they are medically necessary for a beneficiary's care. In addition to meeting other requirements, the proposed Care at Home condition is intended to assure that home dialysis patients, including those residing in nursing facilities (NFs) or skilled nursing facilities (SNFs), are receiving care that is comparable to the care provided to in-facility patients. Thus, the support services provided to home dialysis patients should parallel the treatment provided to patients in a dialysis facility.

We are proposing in § 494.100(c)(1)(i) to retain the existing requirements at

§ 405.2137(b)(6) regarding periodic surveillance of the patient's home adaptation, including provisions for visits to the home by facility personnel.

In addition, we are proposing in §§ 494.100(c)(1)(ii) through (iv) to retain existing requirements in §§ 405.2137(b) and 405.2163(e) to: (1) Coordinate the home patient's care by a member of the facility interdisciplinary team; (2) develop and periodically review the patient's plan of care (see § 494.90) to address the patient's needs and achieve expected outcomes of care; and (3) consult with the members of the interdisciplinary team as needed.

Existing § 405.2163(e)(2) requires consultation with a qualified social worker and dietitian. We are proposing in § 494.100(c)(1)(iv) to strengthen this requirement by including any member of the patient's interdisciplinary team because some home dialysis patients may experience problems or have needs that require consultation with several members of the interdisciplinary team, and we do not want to limit their access to appropriate care. In addition, we recognize that patients who are new to dialysis therapy need a period to adjust and adapt to their treatment. Initially patients may experience anxiety while learning self-care skills, how to perform the dialysis treatment, how to modify their diet, and how to change their behavior.

We also believe the interdisciplinary team must be responsible for the development and periodic review of the patient's individualized, comprehensive care plan based on the comprehensive assessment (see § 494.80) that specifies the services necessary to address the patient's needs and includes measurable and expected outcomes. We are proposing in § 494.100(c)(1)(iii) to expand the existing requirements by including a statement that the patient's comprehensive plan of care will be developed and reviewed by the interdisciplinary team to address the patient's needs and to achieve the expected outcomes of care. To that end we are encouraging and recommending that dialysis facilities adopt the same clinical performance measures for home patients as those that are used for in-center patients. As previously stated in the discussion of the patient plan of care condition for coverage (§ 494.90), the goal is to obtain input from each member of the interdisciplinary team as well as from the home patient so as to develop a comprehensive plan of care that indicates the services necessary to address the home patient's needs. The home dialysis patient's plan of care should stipulate the services that are to

be furnished to achieve and maintain the expected outcomes of care.

We are proposing in § 494.100(c)(1)(v) to retain and expand the existing requirement at § 405.2163(e)(5) to monitor the quality of the water used by home hemodialysis patients. We are specifically including onsite evaluation of the water system. Since we have incorporated by reference the AAMI standards regarding water quality at § 494.40(a)(1)(i) and (ii), we are also proposing that a facility adhere to the applicable AAMI guidelines in determining whether the home dialysis patient's water system meets acceptable standards. If water supplies are biologically or chemically contaminated, contaminants may be passed to the patient during the dialysis session, leading to infection or other adverse consequences. Therefore, a dialysis facility must monitor the quality of water used in treatments, as well as monitor the equipment used in water treatment. Because water is one of the most important aspects of health and safety, we are proposing in § 494.100(c)(1)(v) to require that the facility conduct onsite evaluation of the patient's water system if the AAMI-specified analysis of the water quality indicates contamination or if the home patient demonstrates clinical symptoms associated with water contamination. The dialysis facility must ensure that any problems with the water treatment system are corrected. If the problem cannot be corrected immediately, the dialysis facility must arrange for backup dialysis until the water quality at the patient's home can be adequately restored.

We are proposing in § 494.100(c)(1)(vi) to retain the existing requirements of section 1881(b)(9) of the Act and §§ 405.2163(e)(4) and (e)(6) of the regulations that require the facility to install and maintain medically necessary home dialysis supplies and equipment prescribed by the attending physician. In addition, for those home patients not receiving equipment and supplies from a DME company the dialysis facility must also purchase and deliver the necessary home dialysis supplies and equipment.

Furthermore, we propose in § 494.100(c)(1)(vii) to require the facility to plan for and arrange for emergency backup dialysis services. This plan should address how emergency situations will be dealt with, and should hemodialysis be required, include a plan for obtaining this service.

We are proposing in § 494.100(c)(2) to retain the requirement at § 405.2163(e)(3) that a facility maintain a record keeping system that promotes

continuity of care. The medical record is used for diagnosing, treating, and caring for the patient. We believe this requirement is vital to the effective coordination of services provided to home dialysis patients because the medical record indicates what care has actually been provided and what outcomes have been achieved. The medical record documents the services provided by the interdisciplinary team members and provides an accurate picture of the patient's progress in achieving care goals. Further, it provides the data for evaluation and documentation of the quality and appropriateness of care delivered. Adequate record keeping is vital to ensure continuity of care and to ensure that the home dialysis patient is receiving quality care.

In addition, the patient's supplier is often not part of the facility staff; and therefore, it may be difficult to ascertain the services they provide the home patient. In some instances, the services of home patients are not effectively coordinated. As a result, the facility staff is often not able to provide comprehensive care to home patients, and the quality of care suffers. In an effort to encourage facilities to coordinate services effectively, § 414.330(a)(2)(ii)(C) would require that the patient's supplier report to the facility, every 30 days, all services and items furnished to the beneficiary so that the information can be documented in the patient's medical record. One of our primary goals is to have the care of home patients parallel the care of in-facility patients, and this can only be accomplished if all information on patient care is reported to the facility. We selected 30 days because monthly reporting and billing is commonly used by dialysis facilities and by suppliers and we believe that this will not produce additional burden. All patient data are necessary to effectively evaluate the patient's dialysis prescription and make changes to the patient plan of care. A less frequent reporting timeframe would compromise efforts to correct deficiencies in the patient's plan of care (for example, adjustments to the dialysis prescription) by the patient's physician and other necessary corrective actions by the patient's interdisciplinary team. We welcome comments on the proposed timeframe for the patient's supplier to report to the facility.

2. Dialysis of ESRD Patients in Nursing Facilities and Skilled Nursing Facilities

The existing regulations allow hemodialysis to be provided within NFs and SNFs when there is a certified

hemodialysis facility on-site or adjoining the NF or SNF and when the patient is a home dialysis patient who has been appropriately trained. In a March 19, 2004 letter to State survey agency directors entitled, "Clarification of Certification Requirements and Coordination of Care for Residents of Long-term (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services" (Reference: S&C-04-24), we clarified certification requirements and coordination of care expectations for residents of LTCs who receive dialysis. On July 8, 2004, we sent State survey agency directors and addendum to the March 19, 2004 letter that included as an attachment follow-up questions and answers regarding the scope of the guidance and the responsibilities of the providers (Reference: S&C-04-37). In this proposed rule, we are soliciting comments on a wide range of issues affecting the population of patients who are nursing home residents and who desire to be dialyzed in the nursing home. We have received inquiries as to whether an institutionalized setting such as a long-term care facility may be considered to be a beneficiary's "home" for self-dialysis purposes. In the past we have provided guidance in response to these inquiries. Home dialysis is currently only an option for NF or SNF patients when certain conditions are satisfied: (1) The NF or SNF must be considered to be the patient's home (for short NF or SNF stays, such as rehabilitation or brief recovery time admissions, the nursing home would not be considered the patient's home since the expectation is that the patient would soon be discharged and return to their own home); (2) the patient (and his or her family member or caregiver) must complete the home dialysis training; (3) all home dialysis patients must have their own dialysis machine, equipment, and supplies; and (4) home dialysis patients must receive their support services from a certified dialysis facility.

Currently the NF or SNF patient who requires hemodialysis may be transported to a certified outpatient hemodialysis facility or may receive treatment from a certified hemodialysis facility available within or adjoining the NF or SNF. We recognize the hardship placed on long-term care patients who must be transported to offsite dialysis facilities 3 times per week. Since there is potential growth for home dialysis in NFs and SNFs because of changing demographics in both the ESRD population and the general population, it may be appropriate for us to provide further guidance regarding the

regulatory expectations for the provision of dialysis in the NF or SNF.

Dialyzing patients in NFs or SNFs without a certified ESRD facility within or adjoining the NF or SNF may present both opportunities and risks. Dialysis patients who remain in the NF or SNF are less likely to miss medication administration, treatment regimens, meals or planned activities during time that would otherwise be spent in waiting and transportation to and from a dialysis facility. We know that some patients would prefer to stay in their residence and dialyze while others would prefer to be transported to a certified dialysis facility for care. We believe that both choices should be available for NF or SNF residents, and we believe that both choices should provide patient protections for health and safety. In addition, we believe that patients receiving dialysis in a NF or SNF should not be deprived of essential services that they would normally receive in an outpatient dialysis facility. Finally, we need to assure that, in providing hemodialysis treatments in a NF or SNF, the care of other residents in the NF or SNF not requiring dialysis is not negatively impacted. We are soliciting comments on whether the current home dialysis regulations need to be modified to protect this vulnerable population, and if so, in what ways and under what particular set of circumstances.

In the current ESRD regulations, the home dialysis training requirement presents a significant barrier in providing home dialysis to NF or SNF residents as the patient may be untrainable and may not have a ready caregiver who could be co-trained to assist the resident in performing dialysis. The patient's role in home dialysis is defined at § 405.2102 under the definitions section of the requirements. The regulations require the patient to take part in the training. We have received correspondence requesting that the home-dialysis training requirement be waived for NF or SNF residents. It has been our long-standing policy to encourage home dialysis. We are also aware of the current limitations relative to severely debilitated patients who are ineligible for home dialysis based on the training requirement. Given the relative acuity of nursing home patients, there are safety concerns associated with allowing patients in nursing homes to be home dialysis patients. These patients may be less able to voice symptoms/problems than the typical ESRD home patient. In addition, the dialysis care of a patient who requires nursing home services may be more complex than the dialysis

care of an independent home dialysis patient, and given their frailty, these patients may be more vulnerable than an independent home dialysis patient. Because of this, we have significant safety concerns about encouraging home dialysis, provided by multiple caregivers, who may not have any dialysis experience, in this setting.

Home dialysis patients may choose to obtain their dialysis supplies and equipment from either the dialysis facility that provides the home training and support services (Method I payment) or from a DME company (Method II payment). The dialysis facility may have more patient contact and be more able to determine that necessary supplies are provided at the right time and in the right amounts to meet the needs of home patients due to the enhanced patient contact. If hemodialysis were provided to NF or SNF residents within the home dialysis model, these patients would continue to be able to choose between Method I and Method II.

In order to address the issue of home dialysis in the NF or SNF, we believe there needs to be clarity about the various roles and responsibilities of the certified ESRD facility providing dialysis care and the responsibilities of the NF or SNF when there is no certified ESRD facility onsite or adjoining the NF or SNF. While we have addressed many of these concerns relative to the existing regulations through guidance to the State survey agency directors, the important issues that we would have to address through new rulemaking and the issues on which we request comment are discussed below.

a. Delineation of Responsibility

We believe the home hemodialysis services provided in a NF or SNF should be provided under the direction of a certified dialysis facility that is responsible for the dialysis care provided to the ESRD patients, for assuring that the NF or SNF is capable of providing appropriate pre- and post-dialysis care, and for assuring that there is coordination of care between the two entities, that is, the nursing home and the ESRD facility. In order to assure that roles and responsibilities are clearly delineated prior to the initiation of care, we believe there should be a written agreement (specifying responsibilities and the coordination of care) between all parties providing the care, including the NF or SNF (and the DME supplier, if applicable).

b. Applicable ESRD Conditions for Coverage

Consideration must be given as to whether home dialysis care provided in a NF or SNF must comply with all of the proposed conditions for coverage, except § 494.120, that governs special purpose dialysis facilities and the specification at § 494.180(d) that services must be provided on or contiguous with the premises.

c. Nursing Coverage

The existing regulations (§ 405.2162(b)) require that a licensed health professional (for example, physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care whenever patients are being dialyzed. This proposed rule would require (proposed § 494.180(b)(2)) that a registered nurse be on the premises whenever in-center patients are being treated. We believe that there would be a comparable risk to patient health and safety if a licensed nurse was not on the premises of the NF or SNF and available during multiple simultaneous home NF or SNF dialysis treatments. Consideration must be given as to whether this registered nurse could be a NF or SNF registered nurse trained by the ESRD facility, or a registered nurse provided by the ESRD facility to be available during NF or SNF hemodialysis treatments.

If the NF or SNF were allowed to provide this registered nurse to be available during hemodialysis treatments then the implications for care (requiring registered nurse attention) provided to other NF or SNF residents must be considered. We are considering whether a limitation of the NF or SNF registered nurse's duties is necessary, so that the nurse is available to meet dialysis needs while another nurse tends to the NF or SNF residents (for example, such as the absence of direct NF or SNF resident care responsibilities and allowance of only administrative duties). When considering whether the NF or SNF registered nurse may be the licensed individual responsible for overseeing resident care when residents are being dialyzed, the provision of training by the ESRD facility for this individual also must be addressed.

While the registered nurse would oversee the dialysis, a trained caregiver would administer the dialysis treatment. In a typical home dialysis patient situation, the ratio of patient to caregiver is one-to-one. We solicit comments on whether we should address patient to caregiver ratios in a

situation when the NF or SNF is considered the patient's residence.

d. Training

We believe that training provided by the certified ESRD facility should be specified and the ESRD facility should be responsible for providing training to NF or SNF staff and to all caregivers who will be working with the ESRD patients. These caregivers could possibly include the nursing and support staff of the residential institution, dialysis facility nurses and patient care technicians, and the caretaker that may be provided by the DME supplier, if available and the patient is a Method II home dialysis patient. We note that Medicare does not provide additional reimbursement for caregiver services within the current payment system. We believe that caregiver-training requirements that are similar to the training specifications for home dialysis patients may be appropriate.

e. Monitoring

If we were to propose requirements on this topic, we believe that the certified ESRD facility should be responsible for monitoring the care of the ESRD patient in the NF or SNF. We also believe that the dialysis facility should assure that trained caregivers be present in the room with the patient at all times while the hemodialysis is being provided. This ensures that a knowledgeable individual is available to assist the patient if any problems arise.

We believe that the ESRD facility should—(1) periodically assess the ability of the staff (NF or SNF staff and caregiver) responsible for care of the ESRD patient to assure that they are competent in their tasks; (2) retrieve and review complete data, including laboratory data, clinical data, outcome data, and interdisciplinary team notes to assure that adequate care is being provided; (3) monitor the care of the patients, using appropriate clinical standards; and (4) work with the NF or SNF staff to monitor whether dialysis treatments being provided in the nursing home negatively impact the care of other NF or SNF residents and correct such impact as appropriate.

We believe that the dialysis facility should ensure that care being provided to patients receiving dialysis in a NF or SNF is comparable to the care provided to facility patients. Thus, the support services provided to NF or SNF residents should parallel the treatment provided to patients in a dialysis facility. Therefore, we believe that the dialysis facility providing dialysis in a NF or SNF must also: (1) Provide

periodic monitoring of the institutional residence to assure that appropriate care is being provided; (2) provide monitoring of supplies and equipment; (3) maintain medical records in both the NF or SNF and at the certified ESRD facility; and (4) assure that patient rights are protected as they would be in a dialysis facility, including access to a formal grievance process by the patient or the patient's guardian or advocate.

We want to ensure that the health and safety of NF or SNF hemodialysis patients is protected and so we are soliciting comment on the provision of hemodialysis in the NF or SNF on the issues discussed above. Specifically, we solicit comment on what competency requirements and experience/qualifications should be proposed for the caregiver (who is not a patient's family member) and for the registered nurse, what restrictions should be placed on the caregiver or the registered nurse or both, and whether caregiver to patient ratio limits should be proposed. We are interested in any suggestions regarding this issue to provide for the specific needs of this vulnerable population, and on how we can make these requirements more flexible to meet the needs of the providers, while providing appropriate patient protections.

E. Condition: Quality Assessment and Performance Improvement (Proposed § 494.110)

[If you choose to comment on issues in this section please include the caption "QAPI" at the beginning of your comment.]

An integral part of our effort to move toward a patient outcome-based system is the facility level quality assessment and performance improvement (QAPI) program. We propose to require that a dialysis facility create its own tailored program for quality improvement based on the framework provided in this condition. Existing §§ 405.2112(c) and 405.2113(a) address quality standards for patient care in the context of the ESRD network organization's role. Although § 405.2134 requires each dialysis facility to participate in network activities and to pursue network goals, there is currently no clear Federal requirement for an ongoing facility-specific, patient-centered continuous quality improvement program. The focus on outcomes in this proposed rule is a result of the fundamental shift in approach to performance expectations within the health care industry and efforts within the renal community to define and examine outcomes.

In 2000, the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS) conducted an extensive review to ascertain the effectiveness of our monitoring of the ESRD program. Their subsequent report was entitled "External Quality Review of Dialysis Facilities: A Call for Greater Accountability" (DHHS/OIG, June 2000). The purpose of this review was to "assess external mechanisms HCFA relies upon to monitor the quality of care provided by dialysis facilities to Medicare beneficiaries with ESRD." This OIG report provides a thorough review of the external quality oversight of dialysis facilities in the United States and the roles played by CMS, the State survey agencies, and the ESRD networks. The OIG recommended that dialysis facilities be required to conduct their own quality improvement programs. The OIG also recommended that facilities be required to establish internal systems for identifying and analyzing the causes of medical injuries and medical errors. Another recommendation was to require facilities to monitor patient satisfaction. The Institute of Medicine's (IOM) 1991 report, "Report on Kidney Failure and the Federal Government" suggests that relating the conditions for coverage to patient outcomes would assist the quality assurance efforts of the ESRD program (IOM, 1991).

The 2001 IOM report, "Crossing the Quality Chasm: A New Health System for the 21st Century" addresses the need to narrow the quality chasm between the potential benefits of medical science and technology and the actual level of health care provided in the United States (IOM, 2001). The report offers a strategy and action plan for building a stronger health system over the coming decade. The report presents multiple challenges to health care leaders and points out that all organizations can improve their performance by incorporating care process and outcome measures into their daily work. In addition, many renal groups (including the RPA, the American Nephrology Nurses Association, the NKF, and the American Association of Kidney Patients) have developed similar positions. We believe that the quality improvement activities in this proposed rule and the data systems of the future will provide an opportunity to focus more closely on patient outcomes. We believe that it is critically important that dialysis facilities examine the adequacy of their information technology and identify opportunities to improve and expand the use of such technologies to

prevent medical errors and improve the quality of care. This Administration is committed to working with other public and private stakeholders to develop means for improving and expanding the use of information technologies (such as bar coding and computerized physician order entry systems) in health care settings.

Proposed § 494.110 would require that a facility develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program that reflects the complexity of the dialysis facility's patient population and its processes of care. The dialysis facility must take actions that result in performance improvements in the quality of patient care. We believe that dialysis facilities need to have a continuous quality improvement system in place to continually assess and improve health care delivery. The facility's quality improvement program should monitor the systems and processes of care that are used to achieve the targeted patient outcomes. This approach calls for facilities to systematically collect and analyze clinical data about the components of their care processes. The majority of facilities already collect clinical performance measures as described in the 2002 OIG report, which describes the quality improvement programs of large dialysis corporations (DHHS/OIG, January 2002). The 5 largest dialysis corporations (representing 67 percent of the total number of dialysis facilities) routinely collect data on at least 14 clinical performance measures; and therefore, requiring collection of those clinical performance data would not impose an additional data collection burden on most dialysis facilities. These types of data can be used to assess facility care processes and to identify opportunities for improvement. Once the opportunity has been identified, the facility should develop and implement an intervention strategy that focuses on the processes that need improvement, and then evaluate whether the improvement strategy achieved the desired results. The facility should reexamine goals that have been achieved and, if applicable, undertake new interventions to further increase the quality of care processes, outcomes, and patient satisfaction. The facility must continue to track its performance to assure that improvements in patient outcomes and patient satisfaction are sustained. This is what is meant by the cycle of continuous quality improvement.

This QAPI approach demands an evaluation of organizational

performance and a patient-centered focus. The evaluation includes measuring actual performance, as well as the impact of the performance on patient outcomes and satisfaction. The evaluation answers the question: "Did that process, treatment or procedure produce the targeted outcomes?" The approach gives the facility the ability to analyze interdependent processes of care and adjust them to optimize the system for providing care.

1. Program Scope (§ 494.110(a))

We are proposing in § 494.110(a) to require that the dialysis facility's QAPI program address at least the following areas: (1) Adequacy of dialysis; (2) nutritional status; (3) anemia management; (4) vascular access; (5) medical injuries and medical errors identification; (6) hemodialyzer reuse program (if applicable); and (7) patient satisfaction and grievances. We believe that these areas are reflective of: (1) the degree to which the facility achieves desirable patient outcomes; the extent of patient safety within the facility; and (2) the level of satisfaction attained as the patient experiences the continuum of care.

Adequacy of dialysis has become an important clinical performance measure for benchmarking the quality of dialysis care. We believe that it is appropriate and necessary to consider using consensus performance measures in our health and safety standards for facilities. The NKF-K/DOQI guidelines for hemodialysis adequacy (guideline 4) provide minimal adequacy of hemodialysis levels of Kt/V of 1.2 and URR of 65, but do not suggest optimal dialysis target levels, based on their conclusion, after a literature review, that there is not sufficient data to make that determination (NKF, 2000).

The Hemodialysis Study sponsored by the National Institutes of Health began in 1995 and was a comprehensive randomized clinical trial of dose and flux interventions to identify improvements in therapy that will reduce hemodialysis mortality. The study entitled "Effect of Dialysis Dose and Membrane Flux in Maintenance Hemodialysis," confirmed that the minimum dosage of thrice weekly hemodialysis as stated in the NKF-K/DOQI Guideline 4 (that is, Kt/V of 1.2 and URR of 65) is adequate and that, in general, a high dosage and special high-flux filters provide no added benefit in terms of survival, rate of hospitalization, and albumin levels to patients (Eknoyan, pp. 2010–2019). The Hemodialysis Study also found statistically nonsignificant data suggesting that higher dialysis dosage

appeared to reduce mortality and hospitalization for women in those who had been receiving hemodialysis longer than 3.5 years when they joined the study (DHHS/NIH, 2002).

A recent retrospective study suggests that the recommended minimal urea reduction ratio of 65 percent may be too low to provide for an optimal mortality benefit (Szczech, pages 738 through 745). Also, we recognize that there are several possible methods for calculating Kt/V. In addition, a major concern for accurate measurement of either URR or Kt/V is that small differences in the method and timing of the blood draw used for the postdialysis blood urea nitrogen (BUN) blood sample can make clinically important differences in the resulting hemodialysis adequacy estimates.

We acknowledge the need for consistency in the techniques used for blood withdrawal as well as the method or formula used to calculate the Kt/V value. We considered proposing requirements that specified pre and postdialysis blood draw methods and Kt/V calculation methods that might allow for more accurate benchmarking. However, we are not proposing a specific methodology at this time, because we believe it would be more appropriate to recommend and encourage dialysis facilities to adopt the methodology(ies) recommended by a consensus process such as the NKF-K/DOQI.

Despite these difficulties, dialysis facilities do use adequacy of dialysis as one of their benchmarks when evaluating the quality of peritoneal and hemodialysis patient care. The CMS ESRD CPM Project calculates the adequacy of dialysis measures for hemodialysis and peritoneal dialysis patients (that is, URR and Kt/V) that can be used by facilities and ESRD networks for benchmarking and comparison purposes. The CMS "Dialysis Facility Compare" website provides facility-specific adequacy-of-dialysis information in terms of what percentage of patients are receiving at least the minimal dose of dialysis (defined as a URR $\geq$ 65 percent). The use of minimal performance levels for adequate dialysis is widely used to allow for comparisons. However, facilities are encouraged to evaluate the needs of individual patients and to deliver the amount of dialysis that will promote optimal health outcomes for that patient.

In addition, we are proposing in § 494.110(a)(2)(ii) that the dialysis facility's QAPI program must also address nutrition. The nutritional status of the dialysis patient impacts the patient's morbidity, mortality, and

overall quality of life. The nutritional status of the patient may be affected by medical symptoms, physiological responses to ESRD, the dialysis process itself, anemia, endocrine disorders, etc. The importance of nutritional status in dialysis patients is recognized in the K/DOQI clinical practice guidelines for nutrition of chronic renal failure and in the ESRD CPM Project's inclusion of serum albumin levels. Under the plan of care condition (proposed § 494.90) we are proposing that the serum albumin level be monitored on a monthly basis. The facility may track the serum albumin levels or any other pertinent markers of nutritional status as part of its QAPI program. The goal is to identify care system opportunities for improving patient nutritional outcomes and then develop and implement interventions that will potentially achieve the targeted outcomes.

We are also proposing in § 494.110(a)(2)(iii) that the QAPI program must include anemia management. Existing §§ 405.2137(b) and 405.2163(g) address the patient's hematocrit level as the indicator for the necessity for administering erythropoietin. In 1996, anemia was the subject of the first National Cooperative Project conducted by the ESRD networks. The reasons for selecting anemia both for the study and as an outcome measure included: (1) The prevalence of anemia among the Medicare population; (2) a consensus among the renal community that anemia is a major quality-of-life problem for dialysis patients and that proper drug manipulation can improve this condition; (3) the fact that commonly used measures of anemia (hematocrit and hemoglobin levels) are routinely collected by us when facilities bill Medicare for erythropoietin on the outpatient billing form; and (4) the relatively straightforward and easily accomplished process for monitoring hematocrit (or hemoglobin) levels.

The United States Renal Data System (USRDS) Annual Data Report and the ESRD CPM Project provides regional and national anemia data that allow for facility benchmarking. The NKF-K/DOQI clinical practice guidelines for Anemia of Chronic Kidney Disease (Guideline 4) recommend an evidence-based target for hemoglobin of 11–12 g/dL (and hematocrit of 33 to 36 percent) for erythropoietin therapy. In May 2000, according to the 2001 Atlas of ESRD in the United States (USRDS), 12 percent of prevalent dialysis patients (that is, patients who have received chronic renal replacement therapy for at least 90 days) with erythropoietin claims had hematocrits less than 30 percent and the

risk of hospitalization is increased with hematocrit levels less than 30 percent. The 2001 ESRD Clinical Performance Measures (CPM) Project Annual Report revealed that 74 percent of in-center hemodialysis patients who were prescribed erythropoietin during the last 3 months of 2000 had a mean hemoglobin of equal to or greater than 11gm/dL (which is approximately equal to a hematocrit of 33 percent). This same report reveals that 63 percent of peritoneal dialysis patients prescribed Erythropoietin during the study period had a mean hemoglobin of equal to or greater than 11 gm/dL. This proposed rule uses anemia, as measured by the hematocrit or hemoglobin level, as an element of patient outcomes for both hemodialysis and peritoneal dialysis patients.

Vascular access insertions and complications (for example, infection) have received increasing attention over the past few years. The current ESRD network quality improvement project, Fistula First, is focused on vascular access. Complications associated with vascular access account for about 18.3 percent of ESRD patient hospitalizations (USRDS data from 2000) and is associated with high financial costs and diminished quality of life for the hemodialysis patient. Therefore, we are proposing in § 494.110(a)(2)(iv) that vascular access management be included in the facility's QAPI program. Facilities should look for opportunities to improve patient outcomes related to vascular access by reviewing ESRD Fistula First data and ESRD CPM Project data in conjunction with the NKF-K/DOQI clinical practice guidelines for vascular access. The ESRD CPM Project and the USRDS Annual Data Report provide regional and national data pertaining to vascular access. The NKF-K/DOQI clinical practice guidelines for vascular access provide valuable information useful to a facility QAPI program regarding vascular access management.

We are proposing in § 494.110(a)(2)(v) to require a patient safety component specific to medical injuries and medical errors identification as part of each facility's QAPI program. The IOM published a report entitled "To Err is Human: Building a Safer Health System," that focused on the magnitude of medical errors, serious adverse events and the risks of medical care in the United States (IOM, 2000). Medical injuries and medical errors were also identified by the OIG as areas in which we should facilitate the development of publicly accountable means for identifying serious medical injuries and analyzing their causes. The OIG found

that medical injuries are not systematically monitored in dialysis facilities.

The Renal Physicians Association (RPA), in partnership with the Forum of ESRD networks and the Patient Safety Foundation, has formed a Patient Safety Committee to address patient safety in dialysis facilities. The Committee's report describes the work of 42 stakeholder representatives from 34 organizations as they engage in collaborative action planning (The Renal Physicians Association, 2001). The group identified challenges in improving patient safety, action options, and priorities. These participants have expressed their commitment to interorganizational collaboration on selected actions in the launch of the next phase of this initiative. The Phase I Report supports for the incorporation of patient safety activities into the conditions for coverage for ESRD, to encourage universal engagement in patient safety participation. This initiative provides resource information that may be useful to facilities as they develop their QAPI program to reduce medical errors and injuries.

We propose in § 494.110(a)(2)(vi) that if a dialysis facility reprocesses hemodialyzers they must include reuse systems in their QAPI program. The AAMI Reuse of hemodialyzers RD47 chapter (incorporated by reference in both the existing and the proposed conditions) includes guidelines for a reuse quality assurance program under section 14. Section 14 outlines quality assurance program areas that include: (1) Records that serve as the quality assurance foundation; (2) schedule of quality assurance activities; (3) patient considerations; (4) equipment; (5) physical plant; (6) supplies; (7) dialyzer labeling; and (8) reprocessing and preparation for dialysis. Since these activities are the same in the proposed conditions for coverage as in the existing conditions for coverage, there is no additional regulatory burden. Continuous quality management in the reuse area is important to ensuring patient safety.

Assessment of patient satisfaction was identified by the OIG as a means of identifying patient concerns often missed by the complaint process. The OIG recognized that patients play an increasingly important role in their own health care, and that techniques of assessing patient satisfaction have become increasingly sophisticated. We concurred with the OIG's recommendation. Therefore in § 494.110(a)(2)(vii), we are proposing that dialysis facilities include patient satisfaction in their QAPI programs. The

OIG further recommended that we exert leadership to facilitate the development of a common instrument that facilities and others could use to assess patient satisfaction. Many facilities do currently use a patient survey as a means to assess patient satisfaction and some have experience in utilizing the results for quality improvement efforts.

We are proposing that facilities monitor patient satisfaction and grievances as part of the QAPI program and have the flexibility to use the method of their choice to meet this requirement. Tracking patient satisfaction and grievances allow the facility to identify any areas in which patients have expressed concerns. The facility can analyze this information and determine what aspect of facility operations needs improvement. CMS has an Intra-agency Agreement with AHRQ to develop a standardized patient experience of care instrument and survey protocol. In 2003, AHRQ conducted a feasibility study to assess the feasibility and applications (that is, quality improvement and public reporting) of a survey that measures dialysis patients' experience of care in renal dialysis facilities. In the August 25, 2003 **Federal Register** (68 FR 51017), AHRQ published a notice that identified and cataloged existing surveys and survey results made available to the team and presented the exhaustive literature review that was performed. In addition, a Technical Expert Panel consisting of ESRD patients and professionals was consulted. AHRQ's ESRD Consumer Assessment of Health Plan Survey (CAHPS) Feasibility Final Report and the CMS response can be found on <http://www.cms.hhs.gov/quality> (follow the ESRD link to the CAHPS link).

In the Feasibility Report, AHRQ recommended that a standardized survey for measuring in-center hemodialysis (ICH) patients' experience and ratings of their care be developed that could serve several important and distinct purposes. An ICH CAHPS survey would provide information for consumer choice, reports that facilities can use for internal quality improvement and external benchmarking against other facilities, and finally, information that we can use for public reporting and monitoring purposes. The survey would be in the public domain and consist of a core set of questions that could be used in conjunction with existing surveys.

In a January 30, 2004 **Federal Register** notice (69 FR 4520) published as part of the Paperwork Reduction Act (PRA) process, a draft survey and pilot test plan were issued. On July 23, 2004, a

second **Federal Register** notice (69 FR 44012) was published and the package including the draft survey and pilot test plan was submitted to OMB at that time.

We will take into consideration the practical difficulties and potential burden on facilities that may result from requiring the use of a common instrument for assessing patients' experience of care. However, we invite comment on the value of utilizing one common survey that can yield information permitting comparisons of facilities across the nation.

We are also interested in how facilities will assess the effectiveness of their internal grievance adjudication process, track the outcomes of patient grievances, and identify meaningful criteria for evaluation and tracking purposes. We are soliciting comment on how evaluating and tracking grievances can be used to improve patient outcomes of care.

2. Monitoring Performance Improvement (Proposed 494.110(b))

We will specifically expect a facility whose treatment outcomes vary significantly from accepted standards to identify the reasons for poor outcomes and implement improvement projects to achieve expected outcomes. Therefore, we are proposing in § 494.110(b) that the dialysis facility must take actions that result in performance improvements and must track performance to assure standards are met and that improvements are sustained over time. This action stimulates the provider to continuously examine and improve performance. In addition, we are retaining the requirement in existing § 405.2134 that requires a dialysis facility to participate in ESRD network activities and pursue Network goals.

3. Prioritizing Improvement Activities (Proposed 494.110(c))

The principal focus of the facility's continuous quality improvement program should be to establish a strategy to prioritize improvements in facility services so that performance improvements lead to better outcomes of care and increased satisfaction for patients. To this end, the proposed § 494.110(c) requires the dialysis facility to set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes. The facility must immediately correct any identified problems that directly or potentially threaten the health and safety of patients. Under the continuous quality improvement system, facilities should be analyzing care processes that

determine how the facility's performance has affected—positively and negatively—patients, especially in terms of what the patient actually experiences. This proposed requirement emphasizes the need for the facility to focus on the areas of performance where problems have been specifically identified, especially in areas relating to outcomes of patient care. By prioritizing areas of improvement, facilities can: (1) Identify areas where outcomes indicate a need for improvement; (2) define measures to improve outcomes; (3) review implementation of improvement actions; and (4) determine the success of the actions implemented to improve the performance measures.

With an effective QAPI program, the dialysis facility can identify and reinforce the activities that it is performing well and seek and respond to opportunities for improvement on a continuous basis. We intend that as a result of this proposed requirement the facility itself will be the catalyst that precipitates continuous improvements. The dialysis facility may choose to inform their patients of facility's quality improvement activities and may want to engage patients who are dialyzing in their facility of these activities. The patient's role in achieving quality improvement goals in areas such as adequacy of dialysis and vascular access should be acknowledged. Partnering with the patients to make improvements may be an important aspect of a successful QAPI program.

The proposed QAPI Condition discussed in this section of the preamble encompasses a facility's internal approach to improving the quality of dialysis care. We are considering putting into place, within these conditions, minimum clinical standards that would serve as external stimuli for further improvements in the quality of dialysis services. The following is a discussion of how minimum clinical standards could be implemented and specific areas for which we are soliciting public comment.

4. Facility Specific Standards for Enforcement

In this proposed rule, we have discussed and taken an approach to quality assurance that relies exclusively upon the facility's own process for setting, monitoring, and maintaining clinical standards as the basis for evaluating its performance. This approach is consistent with our overall approach to quality improvement. However, dialysis care is provided in as homogeneous a medical context as any service and may well be susceptible to

measurement against baseline clinical expectations.

The OIG's Report of 2000 on *External Quality Review of Dialysis Facilities: A Call for Greater Accountability* encourages the use of standardized performance measures to hold individual facilities accountable for quality of care. OIG also recommends an approach that reflects a balance between collegial and regulatory modes of oversight. Their report addresses the use of standardized performance measures both to engage in quality improvement activities and to enforce minimum standards.

Supporters of an approach requiring adherence to clinical standards for ESRD facilities argue that: (1) There is specificity and relative homogeneity in the services delivered; (2) there are significant risks to patient safety if care is not delivered appropriately; (3) the renal community has been proactive in defining and using clinical standards; (4) there are correlations between having acceptable NKF-K/DOQI-derived measures for adequacy of dialysis and anemia and positive outcomes for individual patients; and (5) the data systems supporting ESRD program operations are comprehensive and unique.

We are soliciting comments on the feasibility of using commonly agreed-upon clinical standards in our requirements and enforcement efforts. In setting the minimum clinical standards for performance, we would use selected clinical practice guidelines developed by the NKF-K/DOQI, which were developed with broad community input and consensus, and have gained extensive national and international acceptance. We would initially establish minimal expectations about adequacy of dialysis rates and anemia levels, but we would continuously look to science for updated standards.

The method for applying these standards would be to require that a dialysis facility must maintain minimum clinical standards (that is, adequacy of dialysis and anemia levels) for all patients. If the patient's outcomes did not meet the clinical expectations, the interdisciplinary team would be required to make adjustments. If the patient is unable to achieve the minimum expected clinical outcomes, a member of the interdisciplinary team would need to enter an explanation in the patient's medical records. If the minimum expected clinical outcome is achievable but is not being achieved, the interdisciplinary team would be expected to develop and implement an improvement program to achieve and maintain the expected outcome.

We would periodically establish our requirements and publish them in the **Federal Register**. The standards that we would use if this approach were adopted are as follows:

- The minimum delivered threshold for Kt/V is—
 - 1.2 (single pool) for hemodialysis patients (as specified in the NKF-K/DOQI Clinical Practice Guidelines For Hemodialysis Adequacy: Update 2000, Guideline 4);
 - 1.7 (weekly) for continuous ambulatory peritoneal dialysis patients (as specified in the NKF-K/DOQI Clinical Practice Guidelines for Peritoneal Dialysis Adequacy: Update 2000, Guideline 15);
 - 2.1 (weekly) for continuous cycling peritoneal dialysis patients (as specified in the Peritoneal Dialysis Adequacy: Update 2000, Guideline 16); and
 - 2.2 (weekly) for intermittent peritoneal dialysis patients (as specified in the Peritoneal Dialysis Adequacy: Update 2000, Guideline 16).
- For anemia management, the minimum required levels would be—
 - A hemoglobin level of 11 gm/dL (as specified in the NKF-K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease: Update 2000, Guideline 4); or
 - A comparable hematocrit of at least 33 percent (as specified in the NKF-K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease: Update 2000, Guideline 4).

To make this approach work, we would need to address and mitigate the disadvantages that arise from assigning minimum numerical target values. We would be required to go through a rulemaking process each time we wanted to update the numerical values to correspond with any scientific advances. NKF-K/DOQI clinical practice guidelines for adequacy of dialysis and anemia are designed for assessing individual patient care based on individual patient characteristics. We would need to address the issue of using these as measures for facility-wide performance. Can this effectively be done or would a risk adjustor need to be developed to avoid disadvantaging facilities that have a different case mix? We are also soliciting comments on methods for using current NKF-K/DOQI clinical practice guidelines as facility-wide measures. For example, comments on the use of the statistically based threshold measures of performance would be especially helpful. Under such an approach, facilities in which a predetermined portion of patients fail to

meet the selected clinical standards over some period of time, using a standard deviation, percentile-based, or some other method, need to develop a corrective action plan. We are specifically soliciting comments on this issue.

If we were to codify a clinical standards condition, the text would read as follows:

Condition: Clinical Standards

The dialysis facility must maintain minimum clinical standards for all patients. If the patient's care does not meet such standards, the interdisciplinary team must make adjustments. If the patient is unable to achieve the minimum expected clinical outcomes, a member of the interdisciplinary team must provide an explanation in the patient's medical records. If the minimum expected clinical outcome is achievable but is not being achieved, the interdisciplinary team must develop and implement an improvement program to achieve and maintain the patient's expected level of general health.

Standard: Performance Expectations

(a) *Dose of dialysis.* The interdisciplinary team must assist and support facility patients in achieving and maintaining the expected dose of dialysis as specified by the Secretary and published in accordance with the notification requirements in paragraph (d)(i) of this section.

(b) *Anemia.* The interdisciplinary team must assist and support facility patients in achieving and maintaining the expected hematocrit/hemoglobin level as specified by the Secretary and published in accordance with the notification requirements in paragraph (d)(i) of this section. The patient's hematocrit/hemoglobin levels must be measured at least monthly.

(c) *Additional clinical standards.* Facilities are responsible for assuring that their patients achieve at least a minimum performance level on additional clinical standards that may be selected by the Secretary. The methodology and minimum performance expectations will be determined in accordance with the NTTAA guidelines.

(d) *Notification.* CMS will publish a **Federal Register** document that proposes or finalizes—

(i) The current minimum expected outcomes for dose of dialysis and anemia referenced in paragraphs (a) and (b) of this section.

(ii) Other standards upon development and acceptance of the standards by the Secretary.

F. Condition: Special Purpose Renal Dialysis Facilities (Proposed § 494.120)

[If you choose to comment on issues in this section please include the caption "Special Purpose Renal Dialysis Facilities" at the beginning of your comment.]

Special purpose renal dialysis facilities are dialysis units approved on a short-term basis (currently, for no more than 8 months) to provide dialysis services to a group of patients otherwise unable to obtain treatment in the geographic area served by the facility.

The existing requirements for special purpose renal dialysis units are in § 405.2164. That section states that special purpose units must comply with the conditions specified at §§ 405.2130 through 404.2164, with the exception of §§ 405.2134 to 405.2137 (that is, conditions relating to participation in network activities and the patient long-term care program). Existing § 405.2164(b) requires a special purpose facility to consult with the patient's physician to ensure that care provided is consistent with the care plan and long-term care plan required in existing § 405.2137. Existing § 405.2164(c) requires the "period of approval" (that is, Medicare certification), not to exceed 8 calendar months.

In the May 11, 1983 **Federal Register** (48 FR 21254), we published a final rule that provided for time-limited approval of special purpose renal dialysis facilities. These facilities were established for two purposes: (1) To serve ESRD patients in a vacation area (such as a vacation camp) when the area is too remote from existing approved facilities to allow convenient access by patients; or when a convenient approved facility does not have sufficient available capacity to serve a number of vacationing patients; and (2) to serve ESRD patients on an emergency basis when approved permanent facilities close due to natural disasters, strikes, or bankruptcies, and the backup facilities in the area cannot accommodate the patients of the closed facilities. In the May 11, 1983 final rule, the last provision was added specifically, "to ensure continuous access to care in the event that an approved permanent facility is closed because it cannot achieve adequate revenues under the prospective reimbursement system." The certification period of 8 months was determined to be appropriate in response to public comments urging that the original temporary certification proposal (of 6 months) be extended.

Following the publication of the May 11, 1983 final rule, we developed a

certification and approval process and a separate series of provider numbers for ESRD facilities approved as special purpose renal dialysis facilities.

In our deliberations regarding any possible revisions to this condition, we found that very few vacation camps have requested approval for certification as special purpose renal dialysis facilities. In March 2001, for example, Medicare records indicated that only one vacation camp in the United States was certified as a special purpose renal dialysis facility. We now question whether the requirements for vacation camp renal facilities to be certified as a special purpose renal dialysis facility are too onerous.

A search on the web lists 36 camps for ESRD patients throughout the United States. Some of the camps do not accept hemodialysis patients or accept hemodialysis patients for weekend only camps. These camps do not have a need for hemodialysis services. Other camps provide transportation to a certified hemodialysis facility off the campgrounds. Since the number of United States certified hemodialysis facilities has doubled in the last decade to approximately 4,000, transporting campers to a nearby dialysis facility may be feasible in many locations. It is not clear whether there remains a need to continue to establish vacation camp special purpose renal dialysis facilities in the conditions for coverage.

However, we are proposing to retain this condition in order to address the possible needs of patients who, as a result of the emergency conditions listed above, or participation in a remote vacation camp, need dialysis services on a short-term basis, and to ensure that facilities providing this type of care are properly certified for participation in the Medicare program. We are also proposing to reduce the burden of the requirements that a vacation camp must meet in order to be certified as a special purpose renal facility. Vacation camps generally operate during the summer months, when schools are closed, and usually offer sessions lasting up to 2 weeks. The task of meeting the ESRD conditions for coverage in order to offer a few camp sessions each year (with the exception of the conditions relating to participation in network activities and the patient long-term care program), may deter vacation camps from providing hemodialysis services and seeking Medicare certification.

Therefore, we are proposing in § 494.120 that a special purpose renal dialysis facility would be approved to furnish dialysis at special locations, that is, vacation camps that serve ESRD patients in a temporary residence, or

facilities established to serve ESRD patients under emergency circumstances. A vacation camp must be operated under the direction of a certified renal dialysis facility that assumes full responsibility for the care provided to patients.

Proposed § 494.120(a) maintains the 8-month approval period in the existing § 405.2164(c). In view of the history of the few Medicare-certified special purpose dialysis facilities, we believe a 8-month approval period is adequate.

Proposed § 494.120(b) would retain the existing service limitation requirement (specified in § 405.2164(d)) that limits the special purpose unit to providing services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility.

In addition, we are proposing in § 494.120(c)(1) that a special purpose renal dialysis facility would be approved as a vacation camp by demonstrating compliance with the following standards and conditions for coverage:

- Infection control (§ 494.30)).
- Water quality (§ 494.40); if the facility uses home portable water treatment systems, the facility would instead comply with the provision regulating home monitoring of water quality (§ 494.100(c)(1)–(v)).
- Reuse of hemodialyzers and other dialysis supplies if reuse is performed (§ 494.50).
- Patients' rights (§§ 494.70(a) and (c)).
- Laboratory services (§ 494.130); a facility would be required to have a plan for obtaining laboratory services for cases when it is necessary for patient safety.
- Medical director responsibilities for patient care policies and procedures (§ 494.150(c) and (d)).
- Medical records (§ 494.170).

We are proposing in § 494.120(c)(2) to specify that a special purpose renal dialysis facility certified due to emergency circumstances may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility and is approved by demonstrating compliance with § 494.120(c)(1) and the following additional conditions:

- Compliance with Federal, State, and local laws and regulations (§ 494.20).
- Physical environment (§ 494.60).
- Patients' rights (§§ 494.70(a) through (c)).
- Personnel qualifications (§ 494.140).
- Medical director (§ 494.150).

- Governance (§ 494.180).

While the certification of a special purpose unit is time-limited and the patient's treatment in the unit will be limited, we believe that every effort must be made to ensure that the quality of care provided is comparable to that provided to any dialysis patient in a Medicare-approved unit. However, we believe requiring compliance with any additional requirements would be too burdensome for a special purpose unit.

We are proposing in § 494.120(d) to retain the existing requirement that a special purpose unit consult with the patient's physician, with an added provision that this consultation must occur before the initiation of dialysis in the special purpose unit. This provision is added to ensure that the special purpose unit is fully aware of the patient's current medical condition and that the special purpose unit can provide dialysis services consistent with the patient's plan of care described at § 494.90.

In addition, we are proposing in § 494.120(e) to require the special purpose unit to document care provided to the patient and forward that documentation to the patient's regular dialysis facility within 30 days of the last scheduled treatment in the special purpose unit.

We are soliciting comments on whether vacation camps should continue to be included under the special purpose renal dialysis facility condition for coverage.

G. Laboratory Services (Proposed § 494.130)

[If you choose to comment on issues in this section please include the caption "Laboratory Services" at the beginning of your comment.]

In 1994, we revised existing § 405.2163 to stipulate that the dialysis facility must make available laboratory services (other than tissue pathology and histocompatibility) and that all laboratory services must be performed by an appropriately certified laboratory in accordance with the Clinical Laboratory Improvement Amendments (CLIA) regulations at 42 CFR 493. Existing § 405.2163(b) also requires a dialysis facility that furnishes laboratory services to furnish these services in accordance with applicable requirements established for certification of laboratories under the CLIA. Independent dialysis facilities must be certified under CLIA to perform and bill most laboratory tests to the Medicare program. This section also allows a dialysis facility that does not provide laboratory services to make

arrangements to obtain these services with a laboratory certified under CLIA.

We are proposing in § 494.130 to retain the existing requirements governing laboratory services in § 405.2163(b) without change.

VI. Provisions of Proposed Subpart D: Administration

A. Personnel Qualifications (Proposed § 494.140)

[If you choose to comment on issues in this section please include the caption "Personnel Qualifications" at the beginning of your comment.]

The existing personnel qualifications of dialysis facility staff can be found in § 405.2102. Those requirements list the education and experiential requirements for chief executive officers, physician-directors, nurses responsible for nursing services, dietitians, medical records practitioners, transplantation surgeons, and social workers.

In existing § 405.2102(e), a physician-director must be board eligible or board certified in internal medicine or pediatrics with at least 12 months of experience or training in the care of patients at ESRD facilities.

Existing § 405.2102(d) defines the nurse "responsible for nursing service" as a person who is licensed as a registered nurse by the State in which practicing, with at least 12 months experience in clinical nursing, with at least 6 months experience in nursing care of patients with permanent kidney failure or patients undergoing kidney transplantation, or 18 months of experience in nursing care of the patient on maintenance dialysis. This section also states that if the same individual is assigned responsibility for self-care dialysis training, that individual must have at least 3 months experience in training ESRD patients for self-care.

Existing § 405.2102(b) defines a dietitian as a person who—

- Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976 and has at least 1 year of experience in clinical nutrition; or
- Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics and at least 1 year of experience in clinical nutrition.

Existing § 405.2102(f) defines a social worker as a person who is licensed in the State in which practicing, has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school accredited by the Council on Social Work Education, or has served for at least 2 years as a social worker with at least 1 year in a dialysis or

transplantation program before September 1, 1976 and consults with a social worker holding a masters degree.

ESRD is an extremely complex disease requiring highly technical and complex treatment, and patients with this disease have special needs that require highly specialized care that can only be provided by qualified personnel. As the demographics of the dialysis population continue to change, producing a more elderly patient population with more co-morbid conditions, direct patient care needs and the skill needed to meet those needs will continue to increase. Also, as we move away from unnecessary process and procedural requirements in the conditions for coverage towards better patient outcomes, it becomes even more important to have qualified, experienced, and well-trained staff to achieve the targeted clinical outcomes for each patient.

In the past, industry representatives have supported the retention of minimum personnel qualifications in the conditions, and we are proposing to retain most of the existing personnel qualifications requirements in this proposed rule. We are also proposing changes where we believe they are needed, and those changes are discussed in the preamble discussion that follows.

In § 494.140, we are proposing to consolidate all of the personnel qualifications requirements into a single condition, entitled "Personnel qualifications." In addition, proposed § 494.140 would require that a dialysis facility's staff (whether employees or contractors) meet the personnel qualifications and demonstrated competencies necessary to serve the general needs of its patients. We also propose that the dialysis facility's staff must have the ability to sustain and demonstrate the skills needed to perform the specific duties of their positions.

We recognize that facilities are not always able to directly employ individuals to perform all required services; and therefore, facilities may continue to furnish services through qualified personnel by arrangement. Any position in a facility may be filled by a contracted employee, but the contracted employees must meet the personnel requirements as well as the demonstrated skills and competencies in proposed § 494.140 to ensure that patients receive quality care from all personnel.

The expected outcome is the coordinated, comprehensive interdisciplinary delivery of appropriate and effective services provided by

skilled professionals. These professionals would meet the requirements in this proposed rule and would adhere to the facility's policies and procedures. The dialysis facility has the flexibility to assign specific duties to each staff member (either employee or contractor) who provides services in the facility, as long as the required outcomes required are being met.

1. Medical Director (Proposed § 494.140(a))

In proposed § 494.140(a) we would maintain some of the qualification requirements for a physician director. However, we propose to change the word "physician" to "medical" to be consistent with current standards of practice in the industry. The medical director of a facility is responsible for the development of patient care policies and the delivery of services. For this reason, we chose to require that the medical director be trained in nephrology and have experience in the care of dialysis patients to emphasize the need for experience in managing dialysis care and associated medical conditions. The medical director of a dialysis unit must have a thorough knowledge and understanding of the complexity of ESRD and its effects on the dialysis patient.

The existing regulation at § 405.2102 requires that the director of the facility be either board certified or board eligible. There has been considerable disagreement within the medical community as to whether board certification or eligibility is an important indicator of professional competence. In view of the diversity of opinion in the industry and the absence of any indication that the quality of care would decline if this requirement were deleted, we are proposing to eliminate the requirement that the medical director be either board certified or board eligible. Thus, we propose to require only that the medical director be a physician who has completed a board-approved training program in nephrology and has at least 12 months experience providing care to patients receiving dialysis. We are retaining the alternate option for situations when a physician who meets this criterion is not available that allows another physician to direct the facility, subject to the approval of the Secretary. In the absence of a compelling reason for maintaining the grandfathering provision for the physician director under § 405.2102(e)(2), we have not incorporated this provision in our proposed personnel qualifications for the medical director at § 494.140(a).

2. Nursing Services (Proposed § 494.140(b))

In § 494.140(b) we propose a Nursing Services standard that would include the necessary qualifications for 4 nurse categories: (1) The nurse responsible for nursing services in the facility; (2) the nurse responsible for training in self-care; (3) the charge nurse with responsibility for each patient shift; and (4) any nurse who provides care and treatment in the unit.

We are proposing in § 494.140(b)(1)(i) to retain the existing requirement at § 405.2162(a) that each facility employ at least 1 full time qualified nurse responsible for nursing service in the unit. In proposed § 494.140(b)(1)(ii) and (iii) we would maintain the existing requirements that the nurse responsible for nursing services in the unit be a registered nurse who meets the practice requirements of the State in which he or she is employed, and has at least 12 months of experience in clinical nursing with an additional 6 months of experience in providing nursing care to patients on maintenance dialysis.

We are proposing in § 494.140(b)(2) to specify the requirements for the nurse responsible for training in self-care. For a detailed discussion of these nursing requirements see section V.D.1. of this preamble.

We are proposing in § 494.140(b)(3)(i) to retain with minor modifications the existing requirement at § 405.2162(b)(1) that the individual responsible for each shift be a licensed health professional such as a registered nurse (RN) or a licensed practical nurse (LPN) who meets the practice requirements of the State in which he or she is employed. We recognize that in some instances, a licensed practical nurse is able to demonstrate the knowledge, training, and experience to serve as the charge nurse in a dialysis unit and this is currently the practice in some units. In proposed § 494.140(b)(3)(ii) we would specify that the charge nurse must have at least 12 months experience in nursing care, including 3 months of specialized experience in providing clinical nursing care to patients on maintenance dialysis.

We are proposing in § 494.140(b)(4) that each nurse who provides care and treatment to patients must be either a registered nurse or a licensed practical nurse who meets the practice requirements of the State in which he or she is employed.

3. Dietitian (Proposed § 494.140(c))

Renal dietitians are important and necessary members of the patient's interdisciplinary care team. Some of the

responsibilities of the renal dietitian are: (1) Counseling patients on management of protein, sodium, potassium, phosphorus, and fluid controlled diets, translating the chemistry of these limits into meals for patients; (2) monitoring vitamin and mineral supplementation, including iron levels and their effect on erythropoietin; (3) managing glycemic control of diabetic patients by manipulation of diet; and (4) assessing nutritional status by using clinical and biochemical measures.

We believe that these kinds of activities will require a dietitian with specialized experience in clinical nutrition. The specialized training and experience would ensure that dialysis facilities have a dietitian knowledgeable about medical nutrition therapy, physiology, and food composition. This specialized knowledge is critical if a dietitian is to effectively manage the complex tasks necessary in treating a dialysis patient, so the patient is able to manage his or her own disease.

We are proposing in § 494.140(c) to retain requirements comparable to the existing requirements laid out under the definition of "qualified personnel" at § 405.2102(b). We propose that the dialysis facility dietitian be a registered dietitian with the Commission on Dietetic Registration, the official credentialing agent for the American Dietetic Association. We also propose that the dietitian meet the practice requirements of the State in which he or she is employed and have a minimum of 1 year of professional work experience in clinical nutrition as a registered dietitian in order to qualify to perform the special responsibilities of renal dietitians discussed above.

4. Social Worker (Proposed § 494.140(d))

We are proposing in § 494.140(d) to retain the existing requirements for social workers at § 405.2102(f), except for the "grandfather clause" which exempted individuals hired prior to the effective date of the existing regulations (that is, September 1, 1976) from the social work master's degree requirement and substituted an experience criterion, which is 1 year in a dialysis setting; and a criterion requiring including a consultative relationship with a social worker with a master's degree. Since this clause only applied to social workers without a master's degree, already employed in a dialysis or transplantation setting as of 1975, we question whether there is any need to retain it.

We recognize the importance of the professional social worker, and we believe there is a need for the

requirement that the social worker have a master's degree. Since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we believe qualified master's degree social workers (MSW) trained to function autonomously are essential. Social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. The dialysis patient needs psychosocial evaluations, a treatment plan based on the patient's current psychosocial needs, and direct social work interventions. Facility social worker services include counseling services, long-term behavioral and adaptation therapy, and grieving therapy. We believe that MSW training provides the necessary education and experience in these areas. We have removed the requirement for specialization in clinical practice, because this designation is not available in all States and may prove to be a barrier to social workers entering practice in the dialysis arena.

While nonprofessional personnel may serve in a supportive capacity, we do not believe they can be employed in place of a fully-credentialed MSW. We recognize that dialysis patients also need other essential services including transportation and information on Medicare benefits, eligibility for Medicaid, housing, and medications, but these tasks should be handled by other facility staff in order for the MSW to participate fully with the patient's interdisciplinary teams so that optimal outcomes of care may be achieved.

5. Dialysis Technicians (Proposed § 494.140(e))

There are no Federal requirements for dialysis technicians in the existing ESRD conditions for coverage with the single exception of reuse technicians, who are covered by the AAMI guidelines. When the existing conditions for coverage were published in 1976, dialysis technicians were an emerging occupation. At that time it was common for one nurse to provide dialysis care to two dialysis patients at a time. Currently, dialysis patient care technicians are the primary caregivers in most facilities and it is not unusual for a single technician to provide dialysis care to three or four patients at a time.

The discussion that follows applies primarily to dialysis technicians who provide direct patient care. Training and

other requirements for reuse technicians are described in specific sections of the AAMI guidelines, which have been incorporated by reference in existing § 405.2150(a)(1) and in this proposed rule (*see* § 494.50).

As we researched this issue, we reviewed past and current efforts by the States to regulate dialysis technicians. The States are currently using a variety of approaches and methodologies to regulate dialysis technicians, including minimum qualification requirements, mandatory competency testing, registration, licensure, and certification. We also looked at the typical scope of practice for this occupation in dialysis facilities, and took into account the public policy positions and statements from national associations and organizations that advocate uniform Federal guidelines for dialysis technicians.

Arizona, Ohio, and Oregon now require dialysis technician certification via a nationally standardized examination. California and Texas require specific training and testing, but allow a nationally standardized certification examination to be substituted for their training and testing requirements. Georgia identifies a standardized training program for hemodialysis patient care technicians (PCTs), but does not require technicians to pass a national certification test unless a facility's training program fails to provide adequate training. The three organizations that provide nationally recognized standardized certification examinations are listed later in this section of the preamble.

Other States including Connecticut, South Dakota, Kentucky, Utah, Virginia, Washington, New Mexico, and the District of Columbia require certain training and competencies for dialysis technicians. States with past or ongoing efforts to regulate the practice of unlicensed dialysis technicians and technical staff include Colorado, Illinois, Louisiana, Maryland, New York and Oklahoma.

Some national associations (for example, the American Nephrology Nurses Association (ANNA) and the National Association of Nephrology Technicians (NANT)) have advocated uniform training and certification requirements for dialysis technicians for several years and continue to advocate for these measures at the State and national level. Their primary concern is to ensure that care is provided by qualified and trained health care workers who are able to demonstrate the necessary competencies to perform the assigned duties of their positions.

Since 1990, NKF's Public Policy Board has been interested in evaluating and defining the proper role of, and training needed by, dialysis technicians. In 1992, NKF's Dialysis Technician Task Force published an extensive list of tasks that define the "patient care role description" as well as the appropriate areas of required training (NKF, pp. 229–232). The authors of that article advocated, among other things, that technicians should have at least a high school diploma or equivalency; take training courses in the basic sciences; report directly to a registered nurse; and be able to effectively perform specific tasks, subject to individual State licensure and scope of practice laws and regulations. The article also recommended a basic training course curriculum for renal technicians which included, among other things: (1) An introduction to dialytic therapies; (2) principles of hemodialysis; (3) the effects on the patient of kidney failure; (4) dialysis procedures; (5) hemodialysis devices; (6) water treatment; (7) reprocessing (if applicable); (8) patient education; (9) infection control; and (10) the techniques used in quality assurance and continuous quality improvement.

The adverse outcomes for dialysis patients of improper care from inadequately trained dialysis technicians could include blood leaks, access damage, incorrect dialysis concentrate, infection, and hypotension. Increased numbers of patient hospitalizations, which in turn result in higher costs to both public and private payers, could also be a direct outcome of poor patient care from dialysis technicians.

In most dialysis facilities, renal technicians now provide a large percentage of direct patient care services. In most instances, care is provided under the supervision of a registered nurse. However, the degree of supervision and the technician-to-patient ratio will often vary from facility to facility.

A wide variety of tasks are performed by dialysis technicians, depending on the limitations of State law. These tasks include, but are not limited to the following:

- Preparing dialysis apparatus.
- Performing equipment safety checks.
- Initiating dialysis (including cannulation and venipuncture with large gauge needles).
- Intravenous administration of heparin and sodium chloride solutions.
- Subcutaneous or topical administration of local anesthetics in conjunction with placement of fistula needles.

- Intraperitoneal administration of sterile electrolyte solutions and heparin for peritoneal dialysis.

- Monitoring patients during dialysis.
- Taking vital signs.
- Documenting tasks and patient observations.
- Equipment maintenance and repair.
- Water systems monitoring and maintenance.
- Quality control measures.
- Inventory.

One of the options we considered was requiring certification for dialysis technicians. Certification is a voluntary process by which recognition is granted to an individual who has met certain qualifications. Certification is typically awarded upon the successful completion of an approved competency examination. The goal would be a national, standardized requirement for education, training, and competency testing for dialysis technicians. In considering this option, we noted that some States have chosen to develop their own competency examinations or to recognize competency examinations prepared and administered by one of the three national organizations that provide competency testing and certification for dialysis technicians. Those organizations are the Nephrology Nursing Certification Commission (NNCC), the Board of Nephrology Examiners Nursing and Technology (BONENT), and the National Nephrology Certification Organization (NNCO). The common goal of these organizations is to administer an effective test that serves as a basis to certify technicians for initial or more advanced competencies in knowledge, skill and abilities.

In our deliberations on whether to propose Federal requirements for dialysis technicians engaged in direct patient care, we are reminded that Medicare has had a longstanding policy of respecting State control and oversight of health professionals. The Congress has left this licensure function to the States and Medicare recognizes State-defined scope-of-practice laws under which health care professionals are licensed in the United States.

After careful consideration, we do not believe it would be prudent to propose a national certification requirement for dialysis technicians at this time. We take this position for several reasons. First, there is no consensus within the renal community regarding the efficacy of technician certification to produce improved patient outcomes of care. Second, there is no standardized national certification test at this time, and the individuals and organizations, including the States, who advocate or

have adopted certification are not in agreement regarding which certification test is the most effective. Some States have designed, or are in the process of designing, their own competency examinations, while others have recognized one or more of the existing examinations as evidence of compliance with their requirements. Finally, a Federal certification requirement entailing mandatory competency examinations would necessitate additional costs for transportation, lodging, fees, and preparatory materials associated with the examination. Those costs would have to be borne by either the individuals seeking certification, the dialysis facilities, or both. Without clear evidence that certification would produce better patient outcomes, we are reluctant to propose any new requirements that would drive up costs for technicians in current practice, dialysis facilities, or both. Therefore, for these reasons, we believe it is more prudent at this time, not to propose a national certification requirement for dialysis technicians. Instead, we are proposing in § 494.140(e) a set of minimum qualifications for dialysis technicians that will include a minimum education requirement, minimum requirements for on-the-job training and experience, and proposals for the composition of an effective technician-training program.

We are proposing in § 494.140(e)(1) to specify that dialysis technicians meet all applicable State requirements (for example, credentialing, certification, and licensure) in the State in which they are employed. As stated above, we believe technicians in any Medicare-approved facility should comply with any existing State requirements for their profession.

In proposed § 494.140(e)(2) we would require dialysis technicians to have at least a high school diploma or equivalency. We are proposing this criterion for two reasons. First, some of the States that regulate dialysis technicians (for example, Connecticut and Ohio) require dialysis technicians to have a high school education or equivalency.

Second, other States (for example, Texas, California, Oregon, and New Mexico) that require (among other options) certification by one of the national certification organizations (that is, NNCC, NNCO, BONENT) also require a high school diploma or equivalency because that is a prerequisite for taking the certification examination. We concur with the position taken by States that regulate dialysis technicians and the national technician certification organizations because we believe a

minimal education requirement is appropriate and necessary to enable an individual to complete the wide variety of patient care functions.

We are proposing in § 494.140(e)(3) to require that each technician complete at least 3 months experience, following the facility's training program (also required by § 494.180(b)(5)). This experience must be gained under the direct supervision of a registered nurse with a focus on the operation of kidney dialysis equipment and machines and providing direct patient care with particular sensitivity to the management of difficult patients. We see dialysis technician training as a cycle that proceeds from written instruction that would provide a basic foundation of knowledge, to a necessary period of on-the-job training under the supervision of a knowledgeable professional trained in all aspects of patient care, including medical emergencies.

While written instruction is essential, we also believe properly supervised on-the-job training must follow to allow the technician to take maximum advantage of the information provided in the training program before the dialysis technician is allowed to provide direct patient care with minimal supervision. We believe 3 months of effective on-the-job, supervised training is necessary before a technician is permitted to care for patients without close and direct supervision.

We have made this proposal for several reasons. As discussed in section VI.A.2 of this preamble, a registered nurse has the necessary professional training and expertise to coordinate care in the unit, perform patient assessments, respond to clinical questions from staff and patients, and coordinate ongoing care. Dialysis technicians, as the primary caregivers in most dialysis units, function as extensions of the unit's professional nursing staff. We believe it is essential that a unit's registered nurse provide the "hands-on" direct supervision to impart this training to new dialysis technicians. For example, in the patient outcomes environment these regulations are designed to encourage, it is essential that technicians understand the significance of continuous quality improvement (that is, collecting data, keeping logs, the clinical importance and meaning of target patient outcome measures, and recognizing and reporting medical errors). We also believe a registered nurse can be very effective in instructing new dialysis technicians in necessary aspects of patient care, such as ensuring patient privacy and confidentiality, and demonstrating good interpersonal skills when dealing with

patients, including disruptive or challenging patients. In addition, a registered nurse is best equipped, through training and experience, to ensure that every technician can demonstrate the basic skills needed to provide routine patient care (for example, initiating, monitoring, and terminating dialysis; proper aseptic techniques; recognizing and reporting medical errors; and dealing with medical emergencies). For all of these reasons, we believe a 3-month period of direct supervision by a registered nurse is essential to ensure patient health and safety and to ensure that dialysis technicians that provide direct patient care can do their part to ensure that the unit meets its patient outcomes goals. We invite comments on the 3-month training proposal.

We are proposing implementation of a training program that is specific to technicians who monitor the water treatment system. Water purity is important to protecting patient safety and the water must be adequately monitored and properly collected for testing as specified at proposed § 494.40. The technician who carries out water testing and monitoring of the water treatment system must be appropriately trained following a program that has been approved by the medical director and governing body. Typically, facility patient care technician training programs contain a water treatment system training module. This module may form the basis of a training program that could be used to train a water treatment technician.

6. Other Personnel Issues

Existing § 405.2136(f)(1)(vi) requires the facility have patient care policies that cover pharmaceutical services. There is currently no Federal requirement for a pharmacist to play a role on the multidisciplinary team within the dialysis facility. The dialysis facility generally has some access to the pharmacist who is dispensing outpatient medications to the dialysis patient. A hospital-based dialysis unit might be able to use the hospital pharmacist as a resource. There may also be limited pharmacy resources available to the average dialysis facility that is administering intravenous drugs and making adjustments to a patient's medication regimen. It has been suggested by some in the renal community that there should be a requirement within the proposed conditions for coverage for each dialysis facility to ensure a routine assessment of patient medications by a pharmacist. The reasons for this recommendation are: (1) Most dialysis patients take an

average of 12 medications, which increases the risk of adverse drug events; and (2) the patients' have complex pathophysiology, which affects how medications can be used safely (Kaplan, pp. 316–319). There are a number of publications that describe the contributions of pharmacists to the improved care of various patient populations while simultaneously reducing medication-related costs.

Therefore, we have proposed, as part of the new patient assessment condition at § 494.80(a)(3), that facilities conduct a laboratory profile and medication history on each patient as part of their comprehensive patient assessment. However, we have not proposed a specific requirement for pharmaceutical services. We invite comments regarding what role, if any, the pharmacist should play within the dialysis facility as well as the facility's appropriate responsibility for pharmaceutical services and the efficient use of medications in the new conditions for coverage.

B. Condition: Responsibilities of the Medical Director (Proposed § 494.150)

[If you choose to comment on issues in this section please include the caption "Responsibilities of the Medical Director" at the beginning of your comment.]

The requirements for the director of a renal dialysis facility are found in existing § 405.2161. Section 405.2161 requires the director to be a physician who devotes sufficient time to his or her director responsibilities to plan, organize, conduct, and direct the professional ESRD services of the facility. Existing § 405.2161 also states that the physician-director may also serve as the chief executive officer (CEO) of the unit.

Existing § 405.2161(a) states that the director must meet the qualifications described in § 405.2102 (that is, be board eligible or board certified and have at least 12 months of experience or training in the care of patients in ESRD facilities). Existing § 405.2161(b) requires the physician-director to: (1) Participate in the selection of a suitable treatment modality for all patients treated in the unit; (2) assure adequate training of nurses and technicians in dialysis techniques; (3) assure adequate monitoring of the patient and the dialysis process, including periodic monitoring of self-dialysis patients; (4) assure the development of a patient care policy and procedures manual and its implementation; and (5) assure that patient teaching materials are made available for self-dialysis and home dialysis patients.

The June 2000 OIG Report was an extensive review to ascertain our effectiveness in monitoring the ESRD program. The report contained several recommendations regarding ways we should revise the ESRD conditions for coverage in order to strengthen the accountability of dialysis facilities that participate in the Medicare program. One of those recommendations was to reinforce the accountability of the dialysis facility's medical director for the provision of patient care. Specifically, the report stated the following: "While the governing body of the facility is the basic source of accountability, the medical director should clearly be empowered as the on-site agent most directly responsible for the quality of care being delivered. In this capacity, the medical director should clearly have the authority to develop and monitor quality improvement efforts, to serve as an educational resource for medical and nursing staff, and, when individual staff are not performing adequately, to bring that to the attention of the facility's designated governing authority."

In response to the OIG's recommendations, we are proposing in § 494.150 to retain medical director as a separate condition for coverage and strengthen the medical director's role. Section § 494.150 would require each dialysis facility to have a medical director who meets the qualifications for that position at § 494.140(a) and who is responsible for the delivery of patient care and patient outcomes in the facility.

We are proposing in § 494.150(a) to assign the operational responsibility for the facility's quality assessment and performance improvement (QAPI) program (§ 494.110) to the medical director. While the facility's governing body is ultimately responsible for allocating the necessary resources (for example, dedicated staff and computers) to establish a QAPI program, we believe the medical director is best qualified to ensure that the facility's QAPI program is effectively developed, implemented, maintained, and periodically evaluated. We are also proposing that the medical director ensure that all clinical staff in the facility, including attending physicians, actively participate in achieving the performance goals and objectives specified in the facility's QAPI program. It is essential for an effective QAPI program that the attending physician and nonphysician staff, who treat patients in the facility, "buy-in" to the facility's quality improvement initiatives and actively participate in achieving the facility's QAPI goals. In order for this to happen,

we believe the medical director should be given the responsibility to ensure that all staff that treat patients actively participate in the facility's QAPI program. In that capacity we would expect the medical director to make a special effort to educate and encourage facility staff, including attending physician and nonphysician staff, who have not actively participated in the facility's QAPI program. In those rare instances when in-house or attending physician or nonphysician staff will not actively participate in the facility's QAPI program, we would expect the medical director to refer those individuals to the facility's governing body through its CEO or administrator. The governing body (*see* § 494.180) has the final legal responsibility and authority for the operation of the facility and the ultimate responsibility for the facility's compliance with Federal Medicare regulations.

In assuming operational responsibility for QAPI, this requirement emphasizes the importance of the medical director utilizing the best practices within a strong QAPI program. Under this requirement, we would expect the facility's medical director to seek and use comparative data with other facilities when available and use the facility's historical data to demonstrate internal improvements in outcomes over time. This standard also underscores the medical director's ongoing responsibility to ensure that each patient treated in the facility achieves the best possible outcomes of care.

We propose in § 494.150(b) to retain the existing requirement at § 405.2161(b)(2) for the medical director to ensure that staff in the unit are adequately trained. We believe that all patient care personnel in the facility should receive the necessary education and ongoing training to furnish services effectively, efficiently, and completely.

We are proposing in § 494.150(c)(1) to retain the existing requirement § 405.2161(b)(4) for the medical director to assure the development of a "patient care policies and procedures manual" for the facility. While our goal throughout this proposed rule has been to eliminate unnecessary process requirements, we believe that a comprehensive patient care policies and procedures manual within a dialysis unit is an essential reference for clinical staff within the unit. The manual is also an opportunity for the medical director to incorporate improved treatment methodologies and current medical practices into day-to-day patient care within the facility in order to ensure better outcomes of care.

We are proposing in § 494.150(c)(1) that the medical director participate in the development, periodic review, and approval of the patient care policies and procedures manual. We are also proposing in § 494.150(c)(2) that the medical director, as the individual with direct responsibility for the manner in which patient care is administered within the facility, be responsible to ensure that these patient care policies and procedures are adhered to by staff who treat patients in the dialysis facility, including attending physician and nonphysician staff. In those instances when facility staff or attending physicians or nonphysicians have not, or will not, follow the facility's written patient care policies and procedures, we would expect the medical director to educate and encourage those individuals to follow facility policies and procedures. In those rare instances when the medical director has been unsuccessful in achieving compliance, we would expect the medical director to refer the matter to the facility's governing body (*see* § 494.180).

We are proposing in § 494.150(c)(2)(ii) that the medical director ensure that the interdisciplinary team follows the facility's patient discharge and transfer policies and procedures described in § 494.180(f). In section VI.E9 of this preamble, we proposed that all patients be informed of a facility's transfer and discharge policies and be given 30 days notice in advance of a facility reducing or terminating on-going care. In addition, we are proposing that the medical director monitor and review each involuntary patient discharge to ensure that the patient's interdisciplinary team has performed the tasks required in § 494.180(f).

In a January 2002 report (Building on the Experiences of Dialysis Corporations, OEI-01-99-0052), the OIG recommended that the ESRD conditions for coverage specify the responsibilities of the Medical Director in situations when there is a quality problem related to an ESRD facility physician. The OIG recommendation follows:

CMS should also address in the Conditions what medical directors are expected to do when a quality problem is attributable to an attending physician who is not performing adequately. It should make clear that: (1) Medical directors have the authority to conduct or initiate peer review and to address performance problems through directed education, and (2) for more serious situations, the medical director's responsibility to report a physician to an authoritative body, such as the End-Stage Renal Disease Network and/or the State Medical Board.

We are soliciting comments on adding language to this regulation under the Medical Director condition to more specifically state Medical Director responsibilities in regard to ESRD facility attending physicians.

C. Relationship With ESRD Network (§ 494.160)

[If you choose to comment on issues in this section please include the caption "ESRD Network" at the beginning of your comment.]

Existing §§ 405.2110 through 405.2113 contain provisions that relate to the designation of the ESRD networks, the functions of the ESRD networks, and the role of the medical review boards. These provisions focus primarily on the role and responsibilities of the ESRD networks, rather than establishing conditions for Medicare coverage that must be met by dialysis facilities. Therefore, we are not incorporating these requirements in the proposed ESRD conditions for coverage. These regulations will remain in part 405 and any revisions will be addressed in a separate notice of proposed rulemaking.

While we believe that the role and responsibilities of the networks do not need to be included in the proposed conditions for coverage, we believe that dialysis facilities must continue to share information with the networks. Thus, we propose to require at § 494.160 that each facility cooperate with the ESRD network serving its designated area in fulfilling the terms of the Network's scope of work contract with CMS, similar to the requirement under existing § 405.2134 concerning participation in network activities. In addition, we believe that this proposed condition pertains directly to the dialysis facility rather than the network and is a condition that a dialysis facility must meet in order to qualify for Medicare approval.

D. Condition: Medical Records (§ 494.170)

[If you choose to comment on issues in this section please include the caption "Medical Records" at the beginning of your comment.]

The patient's medical record presents a total picture of the care provided by the dialysis facility. The medical record—

- Serves as an organized plan for treatment and is used for diagnosing, treating, and caring for the patient;
- Facilitates communication among the various health care professionals providing services to the patient;

- Provides a focal point for coordinating the actions of the interdisciplinary team;
- Provides an accurate picture of the patient's progress in achieving care goals;
- Provides the team interdisciplinary members with data for evaluating and documenting the quality and appropriateness of care delivered; and
- Provides evidence of the facility's implementation of policies and procedures relating to patient care.

The existing Medical records requirements at § 405.2139 contain a large number of prescriptive requirements. These requirements include the following:

- Requires that each medical record contain sufficient information to identify the patient, justify the diagnosis and treatment, and document the results accurately.
- Prescribes the content of the medical record to include, for example, patient assessment information, evidence the patient was informed of the assessment, identification and social data, consent forms, medical and nursing history, diagnostic and therapeutic orders, observations and progress notes, laboratory results, and, if necessary, a discharge summary.
- Requires written policies and procedures to protect medical records information.
- Requires the facility to designate a medical records supervisor and includes a list of duties and responsibilities for that individual.
- Requires medical records to be completed promptly and states that all clinical information pertaining to the patient be maintained in a centralized location.
- Requires facilities to maintain medical records in compliance with State laws, or for 5 years in the absence of State requirements.
- Requires a facility to maintain adequate facilities, equipment, and space conveniently located, to provide efficient processing, viewing, filing, and prompt retrieval of medical records.
- Requires that a facility provide for the interchange of medical and other information "necessary or useful" in the care and treatment of patients transferred between treating facilities.

In keeping with our goals to eliminate unnecessary requirements and to reduce burden on dialysis facilities, we are retaining only those minimum facility requirements that we believe would be necessary in a patient outcome-oriented environment.

In the proposed medical records condition for coverage (§ 494.170), we would state that the facility must

maintain complete, accurate, and accessible medical records on all patients, including home dialysis patients for whom the facility has signed a backup agreement with a DME supplier to provide support services to the patient or whose care is under their supervision. The proposed rule emphasizes that a facility must maintain complete medical records for all patients under its supervision, including home patients.

We propose to no longer prescribe the elements that facilities must include in the patient medical record. Instead, we believe that facilities should have the flexibility to decide what information must be included in the medical record as long as the services provided are consistent with the patient's diagnosed condition. We believe facilities will document patient outcomes (such as Kt/V and hematocrit levels), results of assessments and reassessments (*see* § 494.80), changes in the care plan (*see* § 494.90), and other pertinent information even though the elements are not prescribed, because this information is necessary to track patient progress, implement the patient care plan, record information needed to comply with the patient discharge or transfer procedure (*see* § 494.150(e)), and effectively manage a facility quality assessment and performance improvement program (*see* § 494.110). The patient's plan of care condition (*see* § 494.90(b)) would require the facility to monitor and track patient progress toward the desired outcomes, and inherent in these requirements is the need to document patient results in some form.

We are proposing at § 494.170(a)(1) to retain the existing § 405.2139(b) that requires a facility to protect its patients' medical records against loss, destruction, or unauthorized use because the records are crucial to the patient's care.

However, we propose to eliminate the requirement at § 405.2139(b) that the facility must have written policies and procedures for recordkeeping. We believe this existing requirement is too restrictive and inflexible. The facilities must protect medical record information and keep all patient records confidential. Therefore, as long as there is a system in place to achieve the outcome, we believe that it is not necessary to require the facility to have written policies. However, facilities may find it necessary to have written procedures to ensure that they achieve the expected outcome.

The existing requirement at § 405.2139(b) mandates confidentiality in the handling of patient information

and requires facilities to safeguard patients' records by making them available only to authorized individuals. Under this requirement, a patient may refuse release of records to any individual outside the facility, except in specific situations such as a patient's transfer to another health facility or the release of information required by law.

We are proposing in § 494.170(a)(2) that the patient's medical record be released only under the following circumstances: (1) The transfer of the dialysis patient to another facility; (2) certain exceptions provided for in law; (3) provisions allowed under a third party payment contract; (4) approval by the patient; or (5) inspection by authorized agents of the Secretary as required for the administration of the Medicare program.

We are proposing in § 494.170(a)(3) to maintain the existing requirement at § 405.2139(b) that the facility obtain written authorization of the patient or legal representative for release of information not required or authorized to be released by law.

We are proposing in § 494.170(b)(1) to retain the existing requirement at § 405.2139(d) that current medical records and those of discharged patients are completed promptly. In a dialysis unit, it is essential that each clinical event be documented as soon as possible after its occurrence. Documentation must be current so that the medical records provide an up-to-date picture of the status of the patient at all times. We recognize that stating that medical records should be completed promptly is somewhat vague and subject to interpretation. We invite comments on the addition of a specific timeframe for the completion of patient medical records.

In proposed § 494.170(b)(2) we would maintain the existing requirement at § 405.2139(d) that all clinical information pertaining to a patient is centralized. Regardless of how the medical record is completed and maintained (on paper or electronically), each member of the interdisciplinary team has access to the most recent information on the patient's condition and prescribed treatment.

We are also proposing, in § 494.170(b)(3), that the dialysis facility is responsible for completing, maintaining and monitoring medical records for its Method II home dialysis patients and its other home patients. Under Method II, home dialysis patients elect to receive all equipment and supplies from a DME company. The DME supplier must have a backup agreement with a dialysis facility that provides support services to the patient.

We have mentioned Method II specifically in this proposed requirement because Method II requires that the patient's ESRD facility is fully aware of the equipment and supplies being used by the patient in order to accurately update the patient's medical record. Our new focus on achieving better patient outcomes is contingent upon accurate and current medical records for Method II and all other home dialysis patients.

In proposed § 494.170(c), we would make minor revisions to the existing requirement at § 405.2139(e) that medical records be retained for a period of time not less than that determined by State statute governing records retention or statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years or until the patient becomes of age under State law, whichever is longer. The facility's policy for the retention and preservation of records must conform to the requirements of State law or regulations. In this case, the date of discharge means the latest date the patient was discharged from any type of service provided by the dialysis facility.

As previously stated, existing § 405.2139(f) requires the dialysis facility to maintain adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (for example, reviewing, filing, and prompt retrieval) and statistical medical information (for example, required abstracts, reports). The rationale for this requirement was that patient records should be easily retrievable and available to all facility staff and that medical records of patients undergoing treatment should be located close to the treatment area so that no time is lost in obtaining records for review and documentation. Although we agree that patient medical records should be accessible, we do not believe the prescriptive requirements in existing § 405.2139(f) are necessary. As a result, we are proposing to eliminate this requirement. We believe that facilities already provide easy access to all patient medical records to ensure that all staff can promptly retrieve and review patient information.

In § 494.170(d) we are proposing to retain the requirement in existing § 405.2139(g) that requires the facility to provide for prompt transfer of medical information between treatment facilities. The intent of this requirement is to facilitate continuation of care whenever a patient has to either temporarily leave the facility (for example, for vacation or hospitalization) or transfer permanently to a new

facility. We believe that it is essential to the continuation of care that a patient's medical history and plan of treatment follow the patient. In addition, we are proposing to require that the facility exchange all medical records within 1 working day. The requirement that information be transferred within 1 working day is in existing § 405.2137(b)(5) (Patient long-term program and patient care plan), which states that if the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day of the transfer. However, we believe the requirement should apply not only to the care plan, but to any medical record information, including, but not limited to, nutritional information, social work services, and rehabilitation status.

Because dialysis patients must receive frequent treatments at prescribed intervals, this proposed requirement would minimize disruption in care. Without the medical information, the patient might receive inappropriate treatment. Requiring that the facility transfer information within 1 working day would minimize the possibility of a breakdown in communication between facilities. It would also ensure that the patient continues to receive care in accordance with his or her designed plan of treatment.

Finally, we are proposing to eliminate the requirement at existing § 405.2139(c) that the facility designate a staff member to serve as the medical records supervisor to facilitate the recordkeeping process. The current functions of the medical record supervisor include, but are not limited to: (1) Ensuring that the medical records are documented, completed, and maintained in accordance with accepted professional standards and practices; (2) safeguarding the confidentiality of the records in accordance with established policy and legal requirements; (3) ensuring that the records contain pertinent medical information and are filed for easy retrieval; and (4) obtaining the services of a qualified medical records practitioner when necessary. In keeping with our goal of eliminating process requirements that are not predictive of good outcomes for patients or necessary to prevent harmful outcomes for patients, we are proposing to eliminate the requirement that a facility designate a medical records supervisor.

E. Condition: Governance (Proposed § 494.180)

[If you choose to comment on issues in this section please include the caption

“Governance” at the beginning of your comment.]

1. Existing Requirements for Governing Bodies

The existing requirements for the dialysis facility’s governing body are found at § 405.2136. Section 405.2136 states that the facility governing body or designated person(s) so functioning has the full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules relative to its own governance and to the health and safety of patients, acts upon recommendations from the Networks, and appoints a CEO who is responsible for the overall management of the facility.

Existing § 405.2136(a) covers the full disclosure of ownership for facilities that are independently owned, controlled by a partnership, or wholly or partially owned by corporate entities.

Existing § 405.2136(b) requires the governing body to develop, delineate, and review annually written operational objectives for the facility. These objectives apply to, among other things, services provided and admission criteria.

Existing § 405.2136(c) requires the appointment of a full-time or part-time CEO who acts as the facility’s administrator. The CEO’s responsibilities for the operation of the facility include the following:

- Implementing facility policies.
 - Coordinating administrative functions.
 - Authorizing expenditures.
 - Familiarizing staff with facility policies, rules and regulations and applicable Federal, State and local laws and regulations.
 - Maintaining and submitting required records and reports.
 - Developing, negotiating and implementing contracts.
 - Developing and implementing accounting and reporting systems, an annual budget, tracking expenses and revenues, submitting reports;
 - Ensuring the facility employs the necessary number of qualified personnel, that those personnel are assigned appropriate duties, and have opportunities for continuing education and related developmental activities.
- Existing § 405.2136(d) requires the governing body, through the CEO, to develop and implement personnel policies and procedures, covering, for example, assigned duties, health and safety hazards, supervising trainees, maintaining personnel records for staff, maintaining written personnel policies, orientation and in-service education,

and maintaining written personnel manuals.

Existing § 405.2136(e) requires the facility to develop detailed, written arrangements for the use of outside resources, as needed, through its CEO who will serve as a consultant with the responsibility to continually assess performance and use documentation (that is, dated, signed reports).

Existing § 405.2136(f) specifies that the ESRD facility must have written patient care policies, and that policies are—

- Developed by the physician responsible for supervising or directing the provision of ESRD services or the facility’s organized medical staff (if there is one) with the advice of (and with provision for review of such policies from time to time, but at least annually, by) a group of professional personnel associated with the facility, including but not limited to, one or more physicians and one or more registered nurses experienced in rendering ESRD care; and
- Approved by the governing body. The governing body is also responsible for periodic review of the implementation of policies to ensure that the intent of the policies is carried out.

Under this section patient care policies must include the following: (1) Scope of services; (2) admission and discharge policies; (3) medical supervision and physician services; (4) patient long-term programs and care plans; (5) medical and other emergencies; (6) pharmaceutical services; (7) medical records; (8) administrative records; (9) maintenance of the physical plant; (10) consultant qualifications and activities; and (11) home dialysis support services. This standard also requires the medical director to execute these patient care policies, schedule hours of operation (when feasible) that are convenient to patients, and evaluate patients’ progress toward goals in their long-term programs and care plans.

Existing § 405.2136(g) requires the governing body to ensure that every patient is under the continuing care of a physician and that a physician is available in emergency situations. This standard requires the physician responsible for the patient’s care to evaluate the patient’s immediate and long-term needs and prescribe a planned regimen of care. The standard also requires the governing body to ensure that there is always medical care available for emergencies with a list of physicians to contact posted at the nursing/monitoring station.

Existing § 405.2136(h) requires the governing body to designate a qualified physician as director of the ESRD facility and establish written policies regarding how medical appointments should be developed, maintained, and if necessary, terminated.

2. Overview of the Proposed Governance Requirements

Consistent with the shift from process-oriented requirements to a more patient-centered, outcome-oriented approach, we are proposing significant revisions to the governance condition. In developing these proposed revisions for the Governance condition we sought to identify requirements that are covered in other parts of this proposed rule, as well as any other redundant, unnecessary or overly burdensome requirements that are unrelated to better patient outcomes. At the same time, we want to retain those structural requirements that might be indicative of better patient outcomes or offer necessary protections to patient health and safety. We also want to be responsive to a recommendation from the OIG (in its June 2000 report) to “strengthen the accountability of the dialysis facility governing body” (DHHS/OIG, June 2000). In that report, the OIG made the following recommendation: “The governing body should be held clearly accountable for the overall quality outcomes provided by the facility. Moreover, since most dialysis facilities are now part of national or multi-national corporations, the governing bodies should ensure that authoritative representatives are readily available to respond to queries and/or visits by State survey agencies or Networks.” (DHHS/OIG, June 2000.)

We believe that the performance of certain basic organizational functions is a minimum condition for an environment in which appropriate patient-centered care can occur. Therefore, the proposed Governance condition, § 494.180, requires the necessary minimum administrative features to allow the governing body to safely and effectively run a facility in an outcomes environment while being responsive to the patients and to the OIG’s recommendation to strengthen the accountability of the governing body.

3. Governance Condition (Proposed § 494.180)

In proposed § 494.180 we state the dialysis facility must be under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility. The

Medicare program requires that each dialysis facility be independently certified, and therefore, each facility must independently achieve compliance with the conditions for coverage. It is essential that surveyors and networks be able to identify the group or individual with legal responsibility and accountability for managing patient health care, safety, and protection of patient rights and for the operation of each dialysis facility.

4. Designating of a Chief Executive Officer or Administrator (Proposed § 494.180(a))

Proposed § 494.180(a) retains the existing requirement for the governing body or responsible party(ies) to appoint an individual who will serve as the facility's CEO or administrator. We are proposing to use these terms interchangeably (that is, CEO and administrator) because the duties would be the same regardless of the title assigned. We have previously proposed that the facility's medical director (*see* § 494.150) assume certain clinical responsibilities for the care provided within the unit. We recognize that in smaller units it would be possible for the same individual to perform the duties of both medical director and CEO/administrator and these regulations do not preclude that. However, in a typical unit we believe the volume, scope, and complexity of administrative, financial, and operational responsibilities requires the day-to-day attention of a separate CEO/administrator position. Therefore, we are proposing to retain this position and the performance of certain duties and responsibilities by the occupant of this position in these proposed conditions.

We are proposing in § 494.180(a) that the CEO/administrator exercise overall management responsibility for the facility and oversee staff appointments, fiscal operations, the relationship with the ESRD network, and the allocation of necessary staff and other resources for the facility's QAPI program (*see* § 494.110).

5. Adequate Number of Qualified and Trained Staff (§ 494.180(b))

Proposed § 494.180(b) would retain and consolidate some of the existing requirements at §§ 405.2136(c)(3)(viii) and 405.2162(b)(2).

We propose at § 494.180(b)(1) to retain the existing requirement at § 405.2162(b)(2) that a dialysis facility ensure an adequate number of qualified personnel are present whenever patients are undergoing dialysis. Under the existing requirement, every approved dialysis facility must maintain staff-to-

patient ratios that are appropriate to the level of dialysis care being given in order to meet the needs of its patients. The determination and allocation of appropriate staff-to-patient ratios is left to each dialysis facility. State agency surveyors would assess facility compliance with this requirement by evaluating whether routine care is being delivered, assessments are conducted as the patient's condition changes, routine monitoring adheres to facility policy, and patients care provided by staff during surveys (for example, equipment alarms are responded to promptly). In our deliberations regarding "adequate staff", we noted that there is no national consensus within the dialysis industry regarding the appropriate staff-to-patient ratios. We also noted the wide variety of State staff-to-patient ratio requirements. For example, some States have staff-to-patient ratio requirements for registered nurses. Connecticut requires that 50 percent of a dialysis unit's patient care staff be registered nurses. New Jersey requires a registered nurse for the first nine patients in the unit. Georgia and South Carolina mandate a registered nurse for every 10 patients, while Texas requires a registered nurse for every 12 patients. Washington requires two registered nurses per shift. Oregon requires that a written staff plan for registered nurses be on file with the State.

Some States have staff-to-patient ratios for patient care technicians. Maryland, Massachusetts, New Jersey, Washington, Puerto Rico, and the Virgin Islands require a three-to-one patient-to-staff care technician ratio. Georgia, South Carolina, and Texas require a four-to-one patient-to-patient care technician ratio. Nevada has a 100 to 1 patient-to-staff ratio for social workers and renal dietitians. Further complicating the wide variation in State regulations are decisions involving scope of practice and the various nurse practice acts administered by the State boards of nursing. For the reasons cited above, we are not proposing any Federal staff-to-patient ratios.

However, we are interested in strengthening the existing requirement while at the same time preserving the facility's flexibility in determining the appropriate staff-to-patient ratio.

One alternative to mandated staff-to-patient ratios is an acuity-based staffing system developed by each dialysis facility. This type of system would take into account the number of patients treated on each shift, individual patient characteristics, patient needs, the expertise and experience levels of facility staff, the physical layout of the facility, available technology, and the

availability of support services. An acuity-based staffing plan, including some or all of the criteria listed above, could be developed by the nurse responsible for nursing services in the facility and approved by the medical director. It could also be incorporated into the facility's QAPI program (*see* § 494.110) as a means of achieving desired outcomes of care specified in the facility's individual patient plans of care (*see* § 494.90). We are soliciting public comment on whether we should include a requirement for an acuity-based staffing plan in § 494.180(b)(1) to ensure that every dialysis facility has "adequate staffing" and appropriate staff-to-patient ratios to meet the needs of its patients.

We are proposing in § 494.180(b)(2) that a registered nurse must be present in the facility at all times that patients are being treated. We have made this proposal for several reasons. As previously discussed in this preamble, the rapidly changing demographics of the dialysis patient population has resulted in an older, sicker patient population. An older patient population with more serious co-morbid conditions elevates the potential for medical emergencies (for example, heart attack, stroke, severe reactions to chemicals). A registered nurse has the professional training and expertise to properly react to these types of emergencies. Properly trained dialysis technicians and licensed practical nurses may be effective in providing day-to-day patient care, but may lack the training and expertise to react to critical medical emergencies. Therefore, we believe that having a registered nurse on the premises when treatment is being provided is a necessary health and safety measure for dialysis patients. Registered nurses, by training and professional expertise, are also needed to provide other important patient care functions that occur routinely while patients are being dialyzed. Those functions include: (1) Assessing patient needs; (2) developing treatment plans; (3) coordinating ongoing care in the unit; (4) continually evaluating the ability of the other nursing and technical staff to use the most current skills and techniques; (5) answering clinical questions from patients and staff; (6) and providing direct supervision for dialysis technicians during their 3-month training period (*see* proposed § 494.140(e)(3)).

At § 494.180(b)(3), we are proposing to retain the existing requirement that all employees have appropriate orientation to the facility and their work responsibilities upon employment. In addition, at § 494.180(b)(4), we are

proposing to retain the existing requirement that all employees have an opportunity for continuing education and related development activities.

At § 494.180(b)(5), we are proposing a new requirement for a written approved training program, designed by the facilities, that is specific to dialysis technicians. As discussed earlier in this preamble, dialysis technicians are now the primary caregivers in many dialysis units, and we have proposed minimum Federal requirements for this occupation because we believe properly trained dialysis technicians are essential in achieving good patient outcomes of care (*see* § 494.140(e)). Many States that regulate dialysis technicians require training programs that include: (1) The initiation of dialysis; (2) monitoring and termination of dialysis; (3) possible complications of dialysis; (4) water treatment; and (5) infection control procedures.

We are proposing that every dialysis patient care technician-training program contain criteria that would provide at least a minimal set of skills. When State requirements meet or exceed these proposed patient care technician-training requirements, the State requirements would have to be met. The criteria we are proposing include the following competencies: (1) Principles of dialysis; (2) care of the patient with kidney failure, including interpersonal skills; (3) dialysis procedures and documentation, including initiation, monitoring, and termination of dialysis; (4) possible complications of dialysis; (5) water treatment; (6) infection control; (7) safety; and (8) dialyzer reprocessing, if applicable. We invite public comment on the basic criteria proposed for § 494.180(b)(5)(i) through (viii).

6. Medical Staff Appointments (Proposed § 494.180(c))

In § 494.180(c) we propose to retain some of the existing requirements at § 405.2136(h) that the governing body be responsible to oversee appointments to medical staff. We propose to expand this requirement to include all medical staff appointments, including appointments and credentialing for attending physicians, physician assistants, and nurse practitioners. However, consistent with our goal to reduce unnecessary process-oriented requirements and regulatory burden, we are not proposing to retain the existing requirement in § 405.2136(h) for the governing body to establish written policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff (if the facility has a

medical staff). Consistent with the new patient outcomes in this regulation, we are proposing to add a new requirement at § 494.180(c)(2) that the governing body be responsible for ensuring that all attending physicians, physicians assistants, and nurse practitioners who provide care in the facility are informed regarding all patient care policies and procedures as well as the QAPI program. We believe adding this new requirement will assist the facility medical director in achieving better patient outcomes through direct care and through the QAPI program without adding any unnecessary burden to a dialysis facility. We are soliciting comments on our proposal to delete process requirements for medical staff appointments and add a new governing body requirement to inform the facility's medical staff regarding the facility's patient care policies and the facility's quality assurance and performance improvement program.

7. Furnishing Services (Proposed § 494.180(d))

Proposed § 494.180(d) would retain the existing requirement § 405.2102 for the governing body to ensure that (except for home care services provided pursuant to § 494.100) services are furnished directly (*see* § 494.10) on its main premises or on other premises that are contiguous with the main premises under the direction of the same professional staff and governing body as the main premises. We believe this requirement is essential to ensure that dialysis services are not provided in uncertified locations.

8. Internal Grievance Process (Proposed § 494.180(e))

In § 494.180(e), we are proposing to require that facilities have an internal grievance process. We believe a good internal grievance process is an invaluable tool in resolving patient grievances in a positive and expeditious manner for both the patient and the facility. The grievance process must include a clearly explained procedure for the submission of grievances, timeframes for reviewing the grievance, and a description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance. The grievance process must be implemented so that the patient may file a grievance with the facility without reprisal or denial of services.

9. Discharge and Transfer Policies and Procedures (Proposed § 494.180(f))

We are also proposing that the facility's discharge and transfer policy

be designed to ensure that no patient, including disruptive or noncompliant patients, is discharged or transferred from the facility unless one of the following situations applies:

- The patient or payor will no longer reimburse the facility for covered services;
- The facility ceases to operate;
- The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs;
- The facility has determined the patient's behavior is so disruptive or abusive that the facility is unable to deliver care to the patient or to operate effectively.

We are proposing that the governing body assign the medical director the responsibility to monitor and review every patient discharge of an abusive or disruptive patient to ensure that the patient's interdisciplinary team has reassessed the patient and documented the ongoing problem(s) and efforts to resolve the problem(s); obtained a written physician's order which must be signed by the medical director and (if applicable) the patient's attending physician; and that a documented attempt has been made to place the patient in another facility. The State survey agency and the ESRD network must be notified of the involuntary discharge of any patient. We believe, as the individual in charge of patient care in the facility, the medical director (*see* proposed § 494.150(c)(2)(ii)) is the appropriate individual to ensure that a patient's interdisciplinary team has followed the procedure described in § 494.180(f) before any transfers or discharges from the facility. We also believe it is important to allow facilities the flexibility to make these determinations on a case-by-case basis without the imposition of prescriptive criteria that would define disruptive or abusive behavior. However, the facility's interventions and reasons for involuntary discharge of a disruptive or abusive patient must be clearly documented in the patient's medical record. We invite comments on our proposal to hold the dialysis facility accountable for their staff adherence to facility's patient discharge or transfer policies and procedures.

10. Emergency Coverage (Proposed § 494.180(g))

Proposed § 494.180(g) would require the governing body to be responsible for emergency coverage. Emergency coverage is not the same thing as emergency preparedness (*see* § 494.60(d) in the proposed physical environment condition). As previously

discussed, emergency preparedness applies to medical and nonmedical emergencies related to fire, equipment or power failures, care-related emergencies, water supply interruptions, and natural disasters. The emphasis in emergency preparedness is on the facility staff's ability to manage and respond appropriately to these facility-wide problems. Emergency coverage, as proposed in § 494.180(g), relates only to patient medical emergencies. Specifically, proposed § 494.180(g)(1) would require the governing body to ensure that patients and staff have written instructions for obtaining emergency medical care. We believe giving patients and staff written instructions is both prudent and necessary to ensure that every patient has the necessary information if and when a medical emergency should arise.

Proposed § 494.180(g)(2) would retain the existing provision at § 405.2136(g)(2) that requires the dialysis facility to post, at the nursing/monitoring station, a roster of physician names to be called for emergencies, when they can be reached, and how they can be reached.

Proposed § 494.180(g)(3) retains and combines existing provision at § 405.2136(g)(2) which requires the governing body to ensure emergency care is always available, and existing § 405.2160 which requires the facility to have an agreement with a hospital to provide inpatient care and other services to patients at all times. However, our proposed agreement requirement at § 494.180(g)(3) is much less prescriptive than the existing requirement at § 405.2160, which is a condition-level requirement. For example, § 405.2160 requires a dialysis facility to have an agreement with a renal dialysis center, which is defined in existing § 405.2102 as a hospital that is qualified to provide the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients. Existing § 405.2160 also contains explicit requirements for the affiliation agreement, that is, the agreement must (1) include the basis for working relationships between staff of both facilities to ensure that services are available promptly; (2) specify transfers for only medically appropriate circumstances as determined by the medical director or attending physician; (3) prescribe an interchange (within 1 working day) between facilities of the patient's long-term plan and patient care plans; and (4) specify security and accountability for patients' personal effects. Our proposal, at § 494.180(g)(3) states simply that the dialysis facility must have an arrangement with a

hospital that can provide inpatient care, other hospital services, and emergency services which are available 24 hours a day, 7 days a week; services will be made available promptly; and there are reasonable assurances in the agreement that patients from the dialysis facility will be accepted and treated in emergencies. This is consistent with our goal of transitioning from unnecessary procedural and process requirements to a patient-outcomes environment in which a dialysis facility will have more flexibility in determining how necessary services, including emergency services, are provided to its patients.

11. Furnishing Data and Information for ESRD Program Administration (Proposed § 494.180(h))

We propose in § 494.180(h) that dialysis facilities furnish data and information electronically and in intervals that conform to specifications established by the Secretary. While reporting data and information is an existing requirement in § 405.2133, the proposal to require the ESRD CPM data and to require electronic data reporting are new requirements. The CPM project, a quality improvement initiative between CMS, the ESRD networks, and ESRD facilities was discussed in section II.E.4.1 of this proposed rule. Currently, dialysis facilities participate in this project voluntarily. We are proposing full participation in reporting the existing CPMs by all dialysis facilities. We have received recommendations from the OIG "External Quality Review of Dialysis Facilities/A Call For Greater Accountability," the IOM "Crossing the Quality Chasm, 2001", and Medicare Payment Advisory Commission (MedPAC) "Improving Quality Assurance for Institutional Providers" to require facilities participating in Medicare to report on performance measures to stimulate improvements in the quality of care and to achieve a degree of accountability for performance ((DHHS/OIG, 1999), (IOM, 2001), and (MedPAC, 2000) respectively). The requirement for full CPM reporting is an important step in moving in that direction.

Section 4558(b) of Pub. L. 105-33 requires us to develop a method to measure and report the quality of dialysis services provided in the Medicare program. To comply with this requirement, we developed the CPMs from the NKF-DOQI (now NKF-K/DOQI) clinical practice guidelines. The CPM project assists providers in the assessment of care provided to ESRD patients and stimulates improvement in that care. The processes used to develop the CPMs and the DOQI guidelines were

also discussed in section II.E.3 and 4 of this preamble.

Dialysis facilities and ESRD networks have used the ESRD CPM project annual reports for benchmarking purposes and as a means of identifying opportunities to improve care. The approach of this proposed rule is to decrease process requirements and instead look to outcomes of patient care so that quality may be assessed and reported. The CPMs will be a part of the vehicle by which we measure and report on the quality of dialysis services provided in the Medicare program.

The CPM data collection tools were briefly described in section II.E.5 of this preamble. Data elements included on these forms are intermediate outcome measures and process markers for adequacy of hemodialysis and peritoneal dialysis, anemia management, nutrition (albumin), and vascular access management.

The CMS VISION software will provide the electronic means for collection of the ESRD administrative forms (that is, CMS-2728, CMS-2746, and CMS-2744) as well as the CPM data (CMS-820 and CMS-821). In the future, CMS VISION software may also collect other information such as patient experience of care survey data. The VISION program will utilize an encryption technology that assures privacy, confidentiality, and security for electronic communications. The requirement for full CPM reporting on all patients by all facilities will be implemented only when the VISION software is fully operational. Vision software will be provided to independent dialysis facilities and small to medium size corporate dialysis facilities at no cost. Specifications are being provided for developing an interface between the major corporate dialysis facilities' databases and the CMS database to enable ESRD administrative data and CPM data to be transmitted electronically with minimal effort from dialysis facility staff. There are initial costs for major corporate dialysis facilities as they develop the software interface and for initial training. For a more detailed discussion of these costs see section IX. of this preamble.

The Secretary will determine the frequency of CPM data collection. Facilities currently report (via billing submissions) monthly URR values for all hemodialysis patients and monthly hematocrit levels for all patients receiving erythropoietin.

The CPM data collection would provide a means for the reporting of facility-specific performance measures capturing information related to the

quality of care delivered. This kind of information is especially important if a fully-bundled payment system for the ESRD program expands the composite rate structure to include all outpatient routine dialysis payments. We are concerned that this change in the payment structure could provide financial incentives to reduce services provided to ESRD beneficiaries; thereby compromising quality of care. Any shift in payment policy necessitates a strong external monitoring process to ensure that an acceptable level of care continues. The reporting of facility-specific performance measures and the development of standards would provide us with the means externally to evaluate and monitor dialysis facilities to ensure that the necessary services have been provided and to assist patients to reach optimal outcomes.

We are looking at the feasibility of developing minimum performance standards. There are widely accepted (K/DOQI) clinical practice guidelines and clinical performance measures (CPMs) in existence. However, there is no consensus for minimum performance standards. Dialysis facility performance is generally compared to performance of other facilities in the network or to national performance data. Facilities whose performance measures fall well below the comparison group are generally identified as needing improvement. However, we do not have defined thresholds that tell us, for example, that if a dialysis facility provided a KT/V of 1.2 or higher to at least 85 percent of its hemodialysis patients, that facility is providing an acceptable level of care.

An additional problem in using minimum standards for accountability purposes is the possibility of "cherry picking" and decreased access to dialysis for some patients. Dialysis facilities may have a disincentive to accept patients likely to be more difficult to manage as well as patients that are more resource-intensive and who are less likely to achieve acceptable levels on the performance measures. This raises the issue of the necessity of risk adjusters to be used in developing the bundled payment rate, as well as developing performance standards for accountability. We are looking at these difficult issues and considering the implications of any changes in payment and performance accountability. We are soliciting comments on how the incentives to "cherry pick" could be minimized. Any performance standards that we may use for dialysis facilities would be developed in conjunction with the NTTAA process discussed in section II.E.6 of this preamble.

This proposal, which requires CPM reporting, is specific to the CPMs as they currently exist. The process for updating, revising, and expanding the CPMs will be done in conjunction with the NTTAA process. A voluntary consensus standards body, which as yet has not been identified, would likely plan, develop, establish, or coordinate voluntary consensus standards using agreed upon procedures in conjunction with the NTTAA.

In the February 19, 1998 **Federal Register** (63 FR 8546), the Office of Management and Budget published a notice regarding the Federal participation in the development and use of voluntary consensus standards. We will use the policies established in this publication and the Administrative Procedure Act (APA) when adopting voluntary consensus standards. If we adopt voluntary consensus standards that are not legally binding, we would publish them as a notice in the **Federal Register**.

The ESRD CPM project data, which would provide the use patterns of 100 percent of dialysis patients, would provide an array of possibilities for facilities to compare performance and practice patterns at facility, State, network, and national levels in order to identify opportunities for improvement in the care of dialysis patients.

This information would provide independent dialysis facilities with the same type of information that some dialysis chain corporations have been able to collect on their own dialysis facilities across the nation. These CPM data would expand the breadth of data that have been previously available even to the large dialysis corporations.

The ESRD networks would use the CPM data elements and calculated measures in order to assist dialysis facilities with quality improvement activities and as a benchmark to look at their own performance.

The State survey agencies would receive facility profiles as well as data for dialysis adequacy, vascular access, anemia management, and nutrition for use in their survey activities.

At a minimum, we would use the following facility-specific information for public reporting on our Dialysis Facility Compare Web site:

- Number of patients included in each calculation.
- Percent of patients treated in the facility with a Kt/V $\geq$ 1.2.
- Percent of patients treated in the facility with a hemoglobin $\geq$ 11 gms/dL.

Public reporting of performance measures provides an important resource to dialysis patients and their families. The Dialysis Facility Compare

website provides detailed information about Medicare-certified dialysis facilities and allows for comparison of facility characteristics and quality measures. We are evaluating the information reported on the Dialysis Facility Compare website for usability and to ensure that the publicly reported information meets the needs of the beneficiary. The availability of information will permit patients to become more active participants in their facilities' quality improvement process. Informed patients make better health care choices and are more active participants in their medical care.

12. Disclosure of Ownership (Proposed § 494.180(i))

In § 494.180(i) we are proposing to retain the existing § 405.2136(a) that the dialysis facility must provide complete information to the State survey agency regarding persons who have any direct or indirect ownership of the facility in whole or in part in compliance with the requirements of §§ 420.200 through 420.406. This requirement, reporting ownership interests of 5 percent or more, is a conforming change to comport with the existing requirements in § 420.201, which have been in effect since 1992.

VII. Other Proposed Changes and Issues

A. Proposed Cross-Reference Changes

[If you choose to comment on issues in this section please include the caption "Cross-Reference Changes" at the beginning of your comment.]

We are proposing to make technical changes in the following sections of the regulations to correct cross-references to the sections in part 405, subpart U that are proposed to be relocated or deleted: §§ 410.5, 410.50, 410.52, 410.152, 410.170, 413.170, 413.172, 413.198, and 414.330.

B. Proposed Additions to Part 488

[If you choose to comment on issues in this section please include the caption "Part 488" at the beginning of your comment.]

We are proposing to add a new subpart H to part 488. Proposed subpart H would consist of the existing sanction provisions in part 405 subpart U. The existing sanction provisions are in §§ 405.2180, 405.2181, 405.2182, and 405.2184 and are summarized as follows:

- Section 405.2180 specifies the basic sanction, which is termination of Medicare coverage, and the basis for reinstatement of coverage after termination.
- Section 405.2181 specifies the alternative sanctions denial of payment

of any patients accepted for care after the effective date of the sanction, and gradual reduction of payments for all patients) and the circumstances under which they might be imposed.

- Section 405.2182 specifies the notice procedures that we will follow and the appeal rights of sanctioned suppliers.

- Section 405.2184 specifies (in greater detail) the rights of suppliers that appeal proposed imposition of an alternative sanction.

We propose to redesignate these provisions (with technical and cross-reference changes) as §§ 488.604, 488.606, 488.608, and 488.610 respectively.

VIII. Reference Materials

A. New Provisions of Part 494

This proposed rule contains a number of requirements that are not included in the existing regulations. For information and ease of reference, outlined below is a list of the new provisions, grouped by condition:

Condition	New provisions
Infection control (§ 494.30)	§ 494.30(a)—Infection control procedures (including the Recommended Infection Control Practices for Hemodialysis Units At a Glance CDC guidelines). § 494.30(a)(2)—Patient isolation procedures.
Water quality (§ 494.40)	§ 494.40—Incorporates by reference the updated 2001 American National Standard/Association for the Advancement of Medical Instrumentation guidelines for water purity.
Physical environment (§ 494.60)	§ 494.60(e)—Fire safety.
Patient rights (§ 494.70)	§ 494.70(a)(5)—Advance directives. § 494.70(a)(14)—Complaint systems. § 494.70(b)—Discharge and transfer policies. § 494.70(d)—Posting of rights.
Patient assessment (§ 494.80)	§ 494.80(a)(2)—Appropriateness of dialysis prescription. § 494.80(a)(5)—Renal bone disease. § 494.80(a)(8)—Dialysis access type and maintenance. § 494.80(a)(10)—Suitability for transplantation referral, including basis for referral or non-referral. § 494.80(b)—Frequency of assessment. § 494.80(c)—Assessment of treatment prescription. § 494.80(d)—Patient reassessment.
Patient plan of care (§ 494.90)	§ 494.90(a)(1)—Dose of dialysis. § 494.90(a)(2)—Nutritional status. § 494.90(a)(3)—Anemia. § 494.90(a)(4)—Vascular access. § 494.90(a)(5)—Transplantation status. § 494.90(a)(7)—Rehabilitation status. § 494.90(b)—Implementation of patient plan of care. § 494.90(b)(3)—Direct physician/patient interaction. § 494.90(c)—Transplantation referral tracking.
Care at home (§ 494.100)	§ 494.100(a)—Training. § 494.100(b)—Home dialysis monitoring. § 494.100(c)—Support services.
Quality assessment and performance improvement (§ 494.110).	§ 494.110(a)—Program scope. § 494.110(a)(2)(i)—Adequacy of dialysis. § 494.110(a)(2)(ii)—Nutritional status. § 494.110(a)(2)(iii)—Anemia management. § 494.110(a)(2)(iv)—Vascular access. § 494.110(a)(2)(v)—Medical injuries and medical error identification. § 494.110(a)(2)(vi)—Hemodialyzer reuse. § 494.110(a)(vii)—Patient satisfaction. § 494.110(b)—Monitoring performance improvement. § 494.110(c)—Prioritizing improvement activities.
Special purpose renal dialysis facilities (§ 494.120).	(§ 494.120)—Definition.
Personnel qualifications (§ 494.140)	§ 494.140(b)—Nursing services. § 494.140(e)—Dialysis technicians.
Responsibilities of the medical director (§ 494.150).	§ 494.150(a)—Quality assessment and performance improvement program. § 494.150(b)—Staff education, training, and performance. § 494.150(c)—Patient care policies and procedures.
Governance (§ 494.180)	§ 494.180(c)—Medical staff appointments. § 494.180(d)—Furnishing services. § 494.180(e)—Internal grievance process. § 494.180(f)—Discharge and transfer policies and procedures. § 494.180(g)—Emergency coverage. § 494.180(h)—Furnishing data and information for ESRD program administration.

B. ESRD Crosswalk (Cross Refers Existing Requirements to Proposed Requirements)

Existing conditions (part 405, subpart U)	Existing citation	Proposed conditions (part 494)	Proposed citation
Scope of subpart	405.2100(a)	Basis and scope	494.1
Objectives of ESRD program	405.2100(b)	Deleted.	
Definitions	405.2101	Deleted.	
Agreement	405.2102	Definitions	494.10
Arrangement		Deleted	
Dialysis		Deleted	
End-stage renal disease		Deleted	406.13(b)
ESRD facility (introductory text)			
(a) Renal transplantation center		Retained in 405, Subpart U	494.10
(b) Renal dialysis center		Deleted	
(c) Renal dialysis facility		Definitions	494.10
(d) Self-dialysis unit		Deleted	
(e) Special purpose renal dialysis facility		Special purpose renal dialysis facilities.	494.120
ESRD service (introductory text)		Retained in 405, Subpart U	
(a) Transplantation service		Deleted	
(b) Dialysis service		Deleted	
(1) Inpatient dialysis		Deleted	
(2) Outpatient dialysis		Deleted	
(i) Staff-assisted dialysis		Definitions	
(ii) Self-dialysis		Deleted	494.10
(3) Home dialysis		Care at home	
(c) Self-dialysis and home dialysis		Deleted	494.100
Furnishes directly		Governance	
Furnishes on the premises		Retained in 405, Subpart U	494.180(d)
Histocompatibility testing		Deleted	
Medical care criteria		Deleted	
Medical care norms		Deleted	
Medical care standards		Deleted	
Medical care evaluation study		Deleted	
Network ESRD		Retained in 405, Subpart U	
Network organization		Retained in 405, Subpart U	
Organ procurement (introductory text)		Deleted	
(a) Chief executive officer		Governance	
(b) Dietitian		Personnel qualifications	494.190(a)
(c) Medical record practitioner		Deleted	494.150(c)
(d) Nurse responsible for nursing services		Personnel qualifications	
(e) Physician-director		Personnel qualifications	494.150(b)
(f) Social worker		Personnel qualifications	494.150(a)
(g) Transplantation surgeon		Retained in 405, Subpart U	494.150(d)
Designation of ESRD networks	405.2110	Retained in 405, Subpart U	
[Reserved]	405.2111	Deleted	
ESRD network organizations	405.2112	Retained in 405, Subpart U	
Medical review board	405.2113	Retained in 405, Subpart U	
[Reserved]	405.2114	Deleted	
Minimum utilization rates: General	405.2120	Retained in Subpart U	
Basis for determining minimum utilization rates	405.2121	Retained in Subpart U	
Types and duration of classification according to utilization rates.	405.2122	Retained in Subpart U	
Reporting of utilization rates for classification	405.2123	Retained in Subpart U	
Calculation of utilization rates for comparison with minimum utilization rate(s) and notification of status.	405.2124	Retained in Subpart U	
Minimum utilization rates	405.2130	Retained in Subpart U	
Provider status: renal transplantation center or renal dialysis center.	405.2131	Retained in 405, Subpart U	
[Reserved]	405.2132	Deleted	
Furnishing data and information for ESRD program administration.	405.2133	Governance	494.190(f)
Participation in network activities	405.2134	Relationship with ESRD network.	494.170
Compliance with Federal, State, and local laws and regulations.	405.2135	Compliance with Federal, State, and local laws and regulations.	494.20
Governing body and management	405.2136	Governance	494.180 (introductory text)
(a) Disclosure of ownership	405.2136(a)	Governance	494.180(g)
(b) Operational objectives	405.2136(b)	Deleted	
(c) Chief executive officer	405.2136(c)	Governance	494.180(a)
(d) Personnel policies and procedures	405.2136(d)(1,3-5,7)	Deleted	
(d)(2) Infection control/Incident reports	405.2136(d)(2)	Infection control and Quality assessment and performance improvement.	494.30(a) & 494.110(a)(5)

Existing conditions (part 405, subpart U)	Existing citation	Proposed conditions (part 494)	Proposed citation
(d)(6) Facility personnel educational programs	405.2136(d)(6)	Personnel qualifications	494.140(e)
(e) Use of outside resources		Medical Director	494.150(c)
(f) Patient care policies	405.2136(e)	Deleted	
(g) Medical supervision and emergency coverage ..	405.2136(f)	Medical Director	494.150(d)
(h) Medical staff	405.2136(g)(1)	Patient plan of care	494.90 (introductory text)
.....		Care at home and Govern- ance.	494.100(c) & 494.180(b)
.....	494.2136(g)(2)	Governance	494.180(e)
.....	405.2136(h)	Governance	494.180(c)
Patient long-term program and patient care plan	405.2137 (introductory text).	Patient care plan	494.90 (introductory text)
(a) Patient long-term program	405.2137(a)	Deleted	
(b) Patient care plan	405.2137(b)	Patient care plan	494.90 (introductory text)
(b)(1) Personalized care plan	405.2137(b)(1)	Patient care plan	494.90 (introductory text)
(b)(2) Developed by a professional team	405.2137(b)(2)	Patient care plan	494.90 (introductory text)
(b)(3) The patient is involved	405.2137(b)(3)	Patient rights	494.70(a)(5)
(b)(4) Frequency of care plan review	405.2137(b)(4)	Patient plan of care	494.90(b), (1)
(b)(5) Transfer of care plan	405.2137(b)(5)	Medical records	494.170(d)
(b)(6) Care plan for the home dialysis patient	405.2137(b)(6)	Care at home	494.100 (introductory text)
(b)(7) Erythropoietin for the home dialysis patient ...	405.2137(b)(7)	Patient plan of care	494.90(a)(3)
Patient's rights and responsibilities	405.2138(a)–(d)	Patient rights and medical records.	494.70(a) and 494.170(a)
.....	405.2138(e)	Patient rights	494.70(c) (13 and 14)
Medical records	405.2139	Recordkeeping	494.170 (introductory text)
(a) Medical record contents	405.2139(a)	Deleted	
(b) Protection of medical record information	405.2139(b)	Recordkeeping	494.170(a)
(c) Medical record supervisor	405.2139(c)	Deleted	
(d) Completion and centralization	405.2139(d)	Recordkeeping	494.170(b)
(e) Retention and preservation	405.2139(e)	Recordkeeping	494.170(c)
(f) Location and facilities	405.2139(f)	Deleted	
(g) Transfer of medical information	405.2139(g)	Recordkeeping	494.170(d)
Physical environment	405.2140(a) (introductory text).	Physical environment	494.60 (introductory text)
(a) Building and equipment	405.2140(a)(1)		
(a)(1) Fire	405.2140(a)(2), (3)	Physical environment	494.60(e)
(a)(2), (3) Equipment and areas are hazard free		Physical environment	494.60(a), (b)
(a)(5) Water quality requirements	405.2140(a)(5)		
(b) Favorable environment for patients	405.2140(b) (introductory text).	Water quality	494.40
(b)(1) Infection prevention		Physical environment	494.60(c)
(b)(2)(4) Adequate treatment areas/Heating and ventilation systems.	405.2140(b)(1)	Infection control	494.60(c)
(b)(3) Nursing station	405.2140(b)(2)(4)	Physical environment	494.60(c)
(b)(5) Special dialysis solutions	405.2140(b)(3)	Deleted	
(c) Contamination prevention	405.2140(b)(5)	Deleted	
.....	405.2140(c)	Infection control and Reuse of.	494.30(a) and 494.40
(d) Emergency preparedness	405.2140(d)	Hemodialyzers	(introductory text), (a)
Reuse of hemodialyzers and other dialysis supplies	405.2150 (introductory text).	Physical environment	494.60(d)
(a) Hemodialyzers	405.2150(a)(1–3)	Reuse of hemodialyzers and Bloodlines.	494.50 (introduction)
(b) Transducer filters	405.2150(b)	Reuse of hemodialyzers and Bloodlines.	494.50 (introduction), (a), (b)
(c) Bloodlines	405.2150(c)	Infection Control	494.30(a)(1)
Affiliation agreement or arrangement	405.2160 (a), (b)(1), (b)(3)	Reuse of hemodialyzers and Bloodlines.	494.50(c)
.....	405.2160(b)(2)	Governance	494.180(e)(3)
Director of a renal dialysis facility or renal dialysis cen- ter.	405.2161	Medical records	494.170(d)
.....		Personnel qualifications	494.140(a)
Staff of a renal dialysis facility or renal dialysis center ...	405.2162 (stem statement)	Medical Director	494.150
Adequate numbers of personnel are present to meet patient needs.	405.2162(a)	Governance	494.180(b)
(a) Registered nurse	405.2162(b)	Governance	494.180(b)
(b) On-duty personnel	405.2162(b)	Care at home	494.100(a)
(c) Self-care dialysis training personnel	405.2162(c)	Patient plan of care	494.90 (introductory text)
Minimal service requirements for a renal dialysis facility or renal dialysis center.	405.2163		
(a) Outpatient dialysis services	405.2163(a)	Patient plan of care	494.90
(b) Laboratory services	405.2163(b)	Care at home	494.100
(c) Social services	405.2163(c)	Laboratory services	494.130
.....		Patient Assessment	494.80(a)

Existing conditions (part 405, subpart U)	Existing citation	Proposed conditions (part 494)	Proposed citation
(d) Dietetic services	405.2163(d)	Patient plan of care	494.90(a)
(e) Self-dialysis support services	405.2163(e)	Care at home	494.100(a)
(f) Participation in recipient registry	405.2163(f)	Patient Assessment	494.80(a)
(g) Use of erythropoietin at home	405.2163(g)	Patient plan of care	494.90
(h) Responsibilities of the physician/facility for use of erythropoietin at home.	405.2163(h)	Care at home	494.100(c)
Conditions for coverage of special purpose renal dialysis facilities.	405.2164	Patient plan of care	494.90(c)
Director of a renal transplantation center	405.2170	Patient Assessment	494.80(a)(4)
Minimal service requirements for a transplantation center.	405.2171 (introductory text).	Patient plan of care	494.90(a)(3)
Termination of Medicare coverage	405.2171(a)–(e)	Care at home	494.100(a)(2)
Alternative sanctions	405.2180	Care at home	494.100(b)(2)
Notice of sanction and appeal rights: Termination of coverage.	405.2181	Special purpose renal dialysis facilities.	494.120
Notice of appeal rights: Alternative sanctions	405.2182	Retained in 405, Subpart U	
	405.2184	Retained in 405, Subpart U.	
		Termination of Medicare coverage.	488.604
		Alternative sanctions	488.606
		Notice of appeal rights: Termination of coverage.	488.608
		Notice of appeal rights: Alternative sanctions.	488.610

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VIII. Collection of Information Requirements and Response to Comments

A. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

Section 414.330 Payment for home dialysis equipment, supplies and support services. Suppliers must report to the ESRD facility providing support services, every 30 days, all data for each patient regarding services and items furnished to the patient in accordance with § 494.100(c)(2) of this chapter.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2).

Section 488.60 Special procedures for approving end stage renal disease facilities. An ESRD facility that wishes to be approved or that wishes an expansion of dialysis services to be approved for coverage, in accordance with part 494, must submit the documents and data as outlined in § 488.60(a)(1) through (a)(4).

We estimate that it will take 250 facilities on an annual basis 40 hours each to gather and submit the necessary documentation for consideration of approval.

Section 494.30 Condition: Infection control. The dialysis facility must maintain current infection control information including the most current CDC guidelines for the proper techniques in the use of vials and ampules containing medication. In

addition, facilities must report infection control issues to the dialysis facility's chief executive officer or administrator (see § 494.180(a)) and the quality improvement committee.

While these requirements are subject to the PRA, the fact that they are usual and customary business practices, exempts the burden associated with these requirements from the PRA as stipulated under 5 CFR 1320.3(b)(2).

The facility must document the incidence of infection to identify trends and establish baseline information on infection incidence, develop recommendations to prevent infection transmission and take corrective actions to reduce future incidents, and report incidences of communicable diseases as required by Federal, State and local laws.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and may be required under State or local law, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.40 Condition: Water quality. If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine described at § 494.30(c)(2)(i) the facility must immediately notify the medical director.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2).

Section 494.50 Condition: Reuse of hemodialyzers and bloodlines. The dialysis facility must monitor patient reactions, undertake evaluation of its dialyzer reprocessing and water purification system, and report any adverse outcomes to FDA and other Federal, State, or local governments agencies as required by law.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice and is required under other Federal, State, and local laws, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.70 Condition: Patients' rights. The dialysis facility must inform patients (or their representatives) of their rights and responsibilities when they begin their treatment. The facility must also inform patients of the facility's policies for transfer, discharge, and discontinuation of services to patients.

We estimate that 4,317 facilities will need 8 hours each on an annual basis to disclose the necessary information. This is based on the belief that the materials will be standardized and incorporated into the facility's entrance materials.

In addition, the dialysis facility must prominently display a copy of the patients' rights in the facility. These rights must include the current State agency and ESRD network telephone compliant numbers and it must be posted in a place where it can be easily seen and read by patients.

We estimate that 4,317 facilities will need 1 hour each on an annual basis to comply with this requirement.

Section 494.90 Condition: Patient plan of care. The interdisciplinary team must develop and implement a written, individualized comprehensive plan of care that meets the requirements of § 494.90.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.100 Condition: Care at home. The dialysis facility must document in the patient's medical record, that the patient, the caregiver, or both received and comprehended required training. In addition, the facility must document, in the patient's medical record, that the self-monitoring data and other information from self-care were reviewed, at least every 2 months.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.110 Condition: Quality assessment and performance improvement. The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven interdisciplinary quality assessment and performance improvement program that reflects the complexity of the dialysis facility's organization and services.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated

under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.120 Condition: Special purpose renal dialysis facilities.

Facilities must contact the patient's physician prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the plan of care (specified in § 494.90).

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Facilities must document all care provided in the special purpose facility and forward the documentation to the patient's dialysis facility within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.170 Condition: Medical records. The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

The dialysis facility must obtain written authorization from the patient or legal representative before releasing information that is not compelled by law.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2).

Patient records must be retained for a period of time not less than that required by State law, or in the absence

of State law, 5 years from the date of discharge, including death for adults and 3 years for minors or until the patient reaches legal age under State law, whichever is longer.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

When a dialysis patient is transferred, the transferring facility must provide the receiving facility with all medical records and other information necessary or useful in the patient's care or treatment.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

Section 494.180 Condition: Governance. The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

The dialysis facility must have a written agreement, that meets the requirements in § 494.180, with a hospital that can provide inpatient care, other hospital services, and emergency medical care that is available 24 hours a day, 7 days a week.

While this requirement is subject to the PRA, the fact that this requirement is a usual and customary business practice, or is required under other Federal, State, and local laws, or both, exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2) or (b)(3) or both.

The facility must provide each patient with written notice 30 days in advance of the facility reducing or terminating ongoing care after following the procedure specified in § 494.180(f).

We estimate that 500 facilities will need 1 hour on an annual basis to provide the required disclosure. This is

based on the assumption that the disclosure will be standardized and will not be required by the majority of facilities.

The dialysis facility must furnish data information electronically to CMS at intervals specified by the Secretary, which meet the requirements referenced in this section.

While these requirements are subject to the PRA, they are currently approved under the following OMB approval numbers: 0938-0046, 0938-0360, 0938-0386, 0938-0657, and 0938-0658.

In accordance with §§ 420.200 through 420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency.

While these requirements are subject to the PRA, it is currently approved under OMB approval number 0938-0086.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements in §§ 414.330, 488.60, 494.40, 494.50, 494.70, 494.80, 494.90, 494.100, 494.110, 494.120, 494.170, and 494.180. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Dawn Willingham, Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher J. Martin, CMS Desk Officer, *Christopher_J._Martin@omb.eop.gov*. Fax: (202) 395-6974.

B. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

X. Regulatory Impact Analysis

[If you choose to comment on issues in this section please include the caption

“Impact Analysis” at the beginning of your comment.]

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Public Law 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule is a proposed revision of the Medicare conditions for coverage for end-stage renal disease (ESRD) facilities. The conditions for coverage are the basic health and safety requirements that an ESRD supplier of services must meet in order to receive payment from the Medicare program. This proposed rule would incorporate new scientific advances and current medical practices in treating ESRD while removing numerous burdensome process and procedural requirements contained in the existing conditions for coverage. While it is not possible at this point to determine definitively the additional costs to the Medicare program resulting from this rule, we believe that the impact will be below the \$100 million threshold; and therefore, believe that this proposed rule is not a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Individuals and States are not included in the definition of small entity. According to the latest numbers from the Small Business Administration's North American Industrial Classification System, 37 percent (1,751) of dialysis facilities have revenues of \$29 million or less annually; and therefore, are considered to be small entities. Thirty of these facilities have annual revenue less than \$100,000. It is possible that this proposed regulation could cost some of these small facilities an additional \$6,545 (about 6.5 percent of \$100,000). However, this is an essential upgrading

necessary to bring these facilities into conformity with what is becoming standard practice in the renal field and to provide essential quality in health care, potentially saving lives. For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural facilities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Since this rule applies only to dialysis facilities, it has no impact on small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This rule has no impact on the expenditures of State, local or tribal governments, and the impact on the private sector is estimated to be less than \$110 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have any effect on State and local governments. The costs associated with treating ESRD are currently a Medicare-covered benefit for individuals with ESRD. This rule will not increase the costs of the Medicare program.

B. Impact of the Proposed Policy Changes

1. Retained Requirements

We note that we have retained a number of requirements from the existing regulations in this proposed rule. Therefore, these requirements do not add any new financial burden for dialysis facilities. These requirements include the following:

- Special procedures for approving end stage renal disease facilities.
- Infection control.
- Water quality.
- Reuse of hemodialyzers.
- Patient plan of care.

2. Physical Environment and Emergency Preparedness

The existing regulations require dialysis facilities to have written policies and procedures for handling emergencies with annual reviews, testing, and revisions, and staff training to handle any emergency or disaster. Facilities are now expending resources to develop procedures and train staff for natural disasters that had never been known to occur in their region. The proposed rule requires only that the staff be able to demonstrate the ability to manage emergencies that are likely to occur in the facility's geographic area. Although an annual review would still be required, the proposed rule does not require the involvement of the CEO in this activity. We estimate a typical facility will expend 4 hours less of staff time for this activity at \$50 per hour, with a net savings of \$200 per year for an overall savings of \$947,000.

The proposed rule requires that the facility meet the 2000 edition of Life Safety Code (LSC) requirements of the National Fire Protection Association. Most dialysis facilities currently meet most of the provisions required in Chapter 21 of the LSC because of State and local building codes as well as facilities' own liability purposes. However, there may be some burden for existing facilities in regard to the installation and maintenance of the fire department alarm connection. We estimate that approximately 1,136 facilities will need to be upgraded to meet this requirement. The one-time cost to install a fire department or central monitoring station connection is estimated to be \$1,000 per facility. The monthly fee for the monitoring station and telephone cost is estimated to be about \$80. Thus, we estimate the additional overall cost of compliance for facilities in the first year will be \$2,226,500, with the annual cost thereafter being \$1,090,560 (\$80 month X 12 months X 1,136 facilities).

This estimate does not take into account any specific waivers or acceptance of a State code in lieu of the LSC that may decrease the burden. If the health and safety of patients and staff are not adversely affected, the proposed rule would permit us to waive specific provisions of the LSC, which, if rigidly applied, would result in an unreasonable hardship on the facility. In addition, the proposed rule specifies that the Secretary, may accept a State code in lieu of the LSC, if it adequately protects patients.

The proposed rule requires that every dialysis facility have access to a defibrillator. As discussed earlier in this

preamble, USRDS data on causes of death among hemodialysis patients between 1997 and 1999 indicates that nearly half (49 percent) of the deaths were attributable to cardiovascular conditions, with cardiac arrest ranking first among the specified causes.

One study found that the typical dialysis facility faces one cardiac arrest each year (Becker, pp. 1509–1512). The study estimated the cost of AEDs at \$3,000, with a useful life of 10 years, that is, \$300 annually for each life potentially saved. Currently, AEDs can be purchased for \$2,000 with a useful life of 10 years (that is, an AED can be use at a cost of \$200 each year for 10 years).

Since 19 percent of dialysis facilities are hospital-based, it is presumed that these facilities have already met the requirement, since they have access to an in-hospital defibrillator. However, we assume that all of the remaining 81 percent of facilities would have to acquire this piece of equipment. The only ongoing annual costs for maintaining the equipment are those for testing and replacing batteries, and these costs are negligible. The cost of AEDs in 81 percent of dialysis facilities is estimated to be \$7,670,700. We have requested public comment regarding the AED proposal as well as comments regarding the appropriateness of waivers or a phase-in period or both for small rural dialysis facilities.

3. Patients' Rights

The existing regulations require dialysis facilities to have written patients' rights policies and procedures and a list of numerous persons to whom the patient rights policies must be made available. The proposed rule details basic information that must be provided to patients (for example, advance directives and how to contact entities in regard to complaints) but only requires that patient rights be prominently displayed. Proposing minimum contents in the patients' rights condition, and proposing only that these rights be posted, will limit the administrative burden. We estimate that this will save the typical facility about 2 hours of staff time at \$15 per hour, that is, \$30 annually, for an overall savings of \$142,050.

The existing regulations require translators when a significant number of patients exhibit language barriers. The proposed rule would delete this requirement and specify information be given to patients in a manner that assures their understanding. However, translators could still be used and facilities would have more flexibility in overcoming language barriers in lieu of

hiring translators. This results in a net reduction in facility costs.

The existing regulations require that advance notice be given to patients who are being terminated from a dialysis facility. The proposed rule is more specific and requires that written notice be given 30 days in advance. However, since involuntary terminations are a relatively infrequent occurrence, we consider the financial impact on dialysis facilities to be negligible.

We estimate that 569 facilities will need 1 hour at \$15 an hour on an annual basis to provide the required disclosure for a total annual cost of \$8,535 ($569 \times 1 \times 15$). This is based on the assumption that the disclosure will be standardized and will not be required by the majority of facilities.

4. Quality Assessment and Performance Improvement

Existing regulations are not comparable to the proposed rule's requirement that the facility develop, implement, maintain, and evaluate a data-driven QAPI program. However, quality improvement efforts are considered part of the professional staff's job and the renal community has developed considerable consensus in recent years in regard to clinical performance data. The top 5 dialysis chains, representing two-thirds of all dialysis facilities are already collecting and reporting standardized data on 14 data elements, some of which are reported to the USRDS.

This proposed rule simply requires the facilities to use this data internally, in a formal QAPI program that each facility has the flexibility to develop to suit its own purposes. The two-thirds of dialysis facilities in the top five chains are already complying with this requirement and many others also consider use of this data as part of their standard practice. We estimate that the QAPI requirements would impose a burden on no more than 10 percent of the dialysis facilities (that is, 473 facilities).

Assuming that a facility were initiating a QAPI program only as a result of this proposed rule, this may entail a 1-hour meeting of 4 staff persons quarterly, with each staff person having an additional hour of work each month beyond the meeting (that is, 16 staff hours of meeting time + 48 staff hours beyond meetings = 64 hours annually). Assuming that the average staff cost is \$25, the total additional cost to the facility would be \$1,600 annually. The total cost for 473 facilities would be \$756,800.

5. Medical Records

In the proposed rule, essential requirements in regard to retention, preservation, and transfer of medical records would be retained. However, the existing regulations are highly prescriptive in not only requiring the designation of a medical records supervisor, but in detailing that person's duties, specifying categories of information to be included in the medical record, requiring written policies and procedures to protect medical records information, and even addressing spatial issues in regard to the maintenance and processing of medical records. The proposed rule would delete many of these requirements, giving the facility flexibility in deciding how the medical records are to be maintained and what is to be in them, as long as they facilitate positive patient outcomes. This reduces burden on the dialysis facilities. We estimate that this will save the typical facility about 40 hours of a medical records professional's time, at \$15 per hour, that is, \$600 annually for an overall savings of \$2,841,000.

6. Governance

The existing regulations specify the minimum requirements for CEO education and experience, whereas the proposed rule would delete these requirements.

However, the proposed rule would add new requirements, for a training program for water treatment system technicians and a written training program for dialysis patient care technicians, in regard to the operation of kidney dialysis equipment and machines and the provision of patient care. This training program would be developed or adopted by the facility and must be approved by the medical director and the governing body of the facility. The water system training program may be written, audiovisual, or computer based. Since the major dialysis chains all have training programs for their dialysis patient care technicians and water treatment technicians, and the majority of dialysis facilities are affiliated with these chains, a large portion of facilities already meet this requirement. In addition, at least 11 States already have some form of credentialing (training; competency exam; certification) requirements for dialysis patient care technicians, so dialysis facilities in these States, if they are unaffiliated with a major chain, may simply declare that meeting the State credentialing requirement is equivalent to completion of their training program. Even facilities that are not affiliated with a major dialysis chain and are in

a State where there are no credentialing requirements for dialysis technicians, are not likely to be burdened with the requirement to develop a dialysis training program, since they can request medical director and governing body approval to use a packaged curriculum that includes a water treatment system module, which has been developed by organizations in the renal field and is available to any dialysis facility without cost.

7. Clinical Performance Measures

The proposed rule would add a requirement that all dialysis facilities electronically collect and report ESRD CPM Project data on all patients. The data include several measures of dialysis adequacy, vascular access, anemia management and nutrition.

Any potential burden added by this requirement is mitigated by the following:

- More than half the dialysis facilities already collect data on at least 14 clinical performance measures, including measures that evaluate adequacy of dialysis treatment, anemia, nutritional level, vascular access, bone disease, and hypertension. Many units affiliated with the major dialysis chains have integrated their electronic data systems for quality management with their data systems for patient management, to minimize the data reporting burden. These facilities understand that it is important to collect and to use the data to allow an accurate comparison of the facility's performance relative to that of its peers, since these comparisons can serve to identify significant opportunities for improvement.

- CPM data is already reported to CMS on a voluntary basis for a 5 percent national sample of patients, so many facilities are already familiar with the data reporting and collection process.

- The CPM data set will become a part of the Consolidated Renal Operations in a Web-enabled Network (CROWN) data system, and CMS will supply VISION software free to dialysis facilities to permit them to enter CPM data electronically directly into the system. VISION is available for general use and is currently being used by 138 independent dialysis facilities. Any dialysis facility that chooses to voluntarily participate in the CPM Project will be allowed to do so before the publication of a final rule. This could substantially reduce the number of facilities that need to be brought on line before the effective date of the final rule.

- Training for purposes of implementing the CPM requirement will

be provided by CMS and its ESRD Networks without cost to the dialysis industry, and some of the training will be done using an Internet Web tool.

However, we do estimate that there will be some additional costs involved in: (1) Travel costs to training sites for some dialysis facility or chain representatives; (2) computer hardware and Internet Service Provider (ISP) connections for some facilities; and (3) collecting and transmitting data on the residual patients who are not served by the major dialysis chains and who are not part of the 5 percent sample of patients in the current CPM project. The detail in these estimates is as follows:

- Estimated costs for travel to training sites will be approximately \$200 for each facility/chain representative and we estimate that 2,000 persons will be sent for training, most representing chains of dialysis facilities. The total cost of travel to training would, then, be \$400,000, and this would be only for the initial year of implementation;

- Very few dialysis facilities would have to purchase computer hardware to implement this requirement, possibly no more than 142 (3 percent of total facilities). We estimate the cost of this purchase to be \$1,000. Thus, the total cost for purchasing hardware would be \$142,000, and this would be only in the initial year of implementation. We estimate ISP costs to be \$150 annually ($\$150 \times 142 \text{ facilities} = \$21,300$);

- The estimated 5 percent annual growth rate in the ESRD population would mean that in 2005 there will be approximately 337,839 ESRD beneficiaries. We believe that the larger chains are already collecting CPM data on approximately 65 percent of these patients. Since the CPM project requires submission of this data on a 5 percent sample, we assume that the burden is only in regard to 95 percent of the remaining 35 percent of patients. Thus, we estimate that additional CPM data collection and reporting will be required for 112,331 patients annually ($337,839 \times .35 \times .95$). Based on current CPM project norms, we assume: One-half hour to abstract the data from the medical record by staff who are typically paid \$25 per hour, for a cost of \$1,404,142 ($112,331 \times .5 \times \25) annually; and key-entry at the rate of 12 patients per hour by staff who are typically paid \$12 per hour, for a cost of \$112,331 annually.

Thus, in the first year of implementation, the total financial impact on the dialysis facilities of implementing the CPM requirement is estimated to be \$2,079,774; thereafter, the cost would be approximately \$1,537,774 ($\$1,404,142 + \$112,331 + \$21,300$) annually for collecting and

transmitting the data and paying the ISP.

COST ESTIMATE FOR THE COLLECTION OF CPM DATA

\$400,000	for travel to training (first year).
\$142,000	for computer hardware (first year).
\$1,537,474	for abstracting & key-entry of CPM data and ISP annually.
\$2,079,774	Total

The following chart provides an overall estimate of the impact of the proposed rule:

OVERALL IMPACT OF THE PROPOSED RULE ON THE ECONOMY

4,735 facilities disaster planning burden @ \$200	=	-\$947,000
1,136 facilities (24%) LSC upgrades @ \$1,960	=	+2,226,560
3,835 facilities (81%) purchasing AEDs @ \$3,000	=	+7,670,700
4,735 facilities (patient rights distribution) @ \$30	=	- 142,050
473 facilities (QAPI) @ \$1,600	=	+756,800
4,735 facilities (medical records burden) @ \$600	=	-2,841,000
569 facilities (30-day discharge notice) @ \$15	=	+8,535
CPM reporting requirement (detailed above)	=	2,079,774
Total impact on the economy	=	+8,812,319

C. Anticipated Effects of the Revised ESRD Conditions on Suppliers of ESRD Services

The Medicare conditions for coverage for ESRD facilities have not been revised in their entirety since their original publication in 1976. The revisions in this proposed rule reflect, for the most part, advances in dialysis technology and standard care practices. Transplant centers will not be affected because they are not included in this rule. One of the major purposes of this revision is to be responsive to regulatory reform initiatives, eliminating unnecessary procedural requirements and focusing on better patient outcomes of care.

D. Alternatives Considered

1. Maintenance of Existing Regulations

One alternative would be to keep the existing regulations. However, the current regulations inhibit our ability to ensure better outcomes of patient care, collect electronic data for quality assurance and quality improvement, incorporate new CDC and AAMI guidelines and fire safety standards and reduce current facility burden by eliminating numerous process and procedural requirements.

2. Infection Control

One alternative was not proposing an exception to the CDC recommendation for monthly and semiannual screening for hepatitis C. We retained the exception because blanket screening for

hepatitis C is not a Medicare-covered service.

Another alternative was to propose compliance with all of the CDC guidelines in the RR05 report rather than just the crucial "Recommended Infection Control Practices for Hemodialysis Units At a Glance" (At a Glance) requirements. However, although we encourage compliance with the entire report, we decided against proposing compliance with the entire report. Our rationale was compliance with guidelines in the entire report would reduce flexibility and add unnecessary burden for dialysis facilities since some of the guidelines exceed the scope of these health and safety requirements.

A third alternative was to propose compliance with AIA Guidelines for Design and Construction of Hospitals and Health Care Facilities. The AIA guidelines provide instructions regarding dialysis unit design as it relates to infection control. While some states have adopted specific AIA guidelines as minimal standards, we believe it would be too burdensome on dialysis facilities to propose to incorporate AIA guidelines as federal requirements.

3. Water Quality

One alternative was to propose to continue to require compliance with portions of the current AAMI guidelines,—ANSI/AAMI RD5: 1992 Appendix B5. However, we decided to propose compliance with portions of the

newer AAMI document—RD62: 2001 and additional requirements that are compatible with ANSI/AAMI RD52: 2004 because RD62 and RD52, are the state-of-the-art water quality guidelines. We have asked for comments on this proposal.

4. Reuse of Hemodialyzers and Bloodlines

One potential cost-saving alternative was to remove the proposal that dialyzers exposed to more than one germicide were acceptable for reuse. We decided against this proposal because exposure to different germicides may cause membrane leaks and we have no scientific evidence to support the safety of using dialyzers exposed to more than one germicide.

5. Physical Environment and Emergency Preparedness

One alternative was to remove the proposal that every dialysis facility have a defibrillator. We retained this proposal because a Seattle study (Becker, pp. 1509–1512) identified dialysis centers as having a relatively high incidence of cardiac arrests over a 7-year period. Also, automated external defibrillators are now required on airliners and in other public places because the technology is simple to use, staff can be trained on the use of such equipment, and the technology has been proven to save lives.

A second alternative was to propose a waiver or phase-in period for defibrillators in small rural satellite

dialysis facilities with very low utilization. We are considering this alternative and have requested public comments on the defibrillator proposal.

6. Patients' Rights

One alternative was to remove the proposal for advance directives. We retained this proposal because of the nature of ESRD and the aging dialysis population.

Another alternative considered was not proposing that dialysis facilities have an internal grievance procedure. We did not adopt this alternative because we believe an internal grievance process is essential to allow patients to express their concerns directly to the facility in which they receive dialysis.

7. Patient Assessment

One alternative was to include "extremely frail patients" in the proposal to reassess unstable patients monthly. This proposal was not adopted in order to ensure that dialysis facilities retain the flexibility to make clinical determinations on a case-by-case basis.

Another alternative was to remove the proposal for a 3-month timeframe to reassess new patients. We are aware that the dialysis industry has not reached consensus regarding the appropriate frequency for reassessments, and therefore, we have requested comments on the current proposal to reassess new patients 3 months after starting dialysis.

8. Patient Plan of Care

One alternative was to retain the existing requirement for an individualized care plan with a 6-month review and a long-term program with an annual review. We did not adopt this approach because it was less burdensome to propose a single individualized plan of care (without a long-term program) to be reviewed annually.

Another alternative was to propose to adopt specific evidence-based NKF-K/DOQI clinical practice guidelines as numerical minimum target values within the patient plan of care condition (that is, adequacy of dialysis and anemia management). This issue is discussed in detail in the preamble and we are requesting public comments on the issue.

9. Quality Assessment and Performance Improvement

One alternative was to propose a QAPI program without specific threshold criteria. We determined, based on the work of the NKF-K/DOQI committees (adequacy, nutrition, anemia, and vascular access), AAMI

guidelines (reuse), and specific recommendations from the OIG (medical error identification and patient satisfaction) that there was sufficient basis to include 7 basic criteria. We have requested public comment on QAPI.

10. Special Purpose Renal Dialysis Facilities

One alternative was to remove this condition entirely based on historically low levels of participation. We determined that eliminating this condition would be detrimental to the small number of vacation camps that choose to participate and it would also inhibit access to care during natural disasters.

Another alternative was to retain the current 8-month certification period and the current certification requirements. We believe that the current certification requirements are onerous; we believe that this is demonstrated by the lack of participation in Medicare by vacation camps. We believe proposing to reduce the number of certification requirements addresses this issue. The existing 8-month certification period is also excessive (that is, vacation camps are typically not open for 8 months and natural emergencies are of shorter duration). The current proposal represents a significant reduction in administrative burden for special purpose units.

11. Personnel Qualifications

One alternative was to retain the existing requirement that at least a licensed practical nurse must be on the premises during dialysis. We decided to propose that a registered nurse be on the premises during dialysis to protect patient health and safety and because this did not represent an increase in burden for dialysis units.

Other options were to propose no Federal requirements for dialysis technicians, or, to propose minimal Federal requirements for dialysis technicians and include proposals for competency testing and certification. A detailed discussion of this issue is in section VI.A.5 of this preamble. We determined that minimal Federal requirements are needed at this time because dialysis technicians are the primary caregivers in most dialysis facilities. However, we did not propose competency testing or certification and have requested public comment.

12. Medical Director

One alternative was to propose to eliminate the medical director condition and propose that other health care professionals run dialysis facilities.

However, a June 2000 OIG report strongly recommended that we strengthen the role of the facility's medical director. In response to that recommendation, we proposed to retain the condition with a clarification of the medical director's responsibilities to include overseeing both the QAPI program and all involuntary patient transfers or discharges. We do not believe that this approach would impose an additional cost burden on dialysis facilities. We have requested public comments on these proposals.

13. Governance

One alternative considered was to remove the proposal for a 30-day advanced notice before involuntary patient discharge or transfer and retain the existing requirement (*see* § 405.2138(b)(2)) for patients to be "given advance notice to ensure orderly transfer or discharge." We did not adopt this alternative because: (1) A 30-day advance notice for discharge and transfer has been consistent with the existing requirements in NFs, SNFs, and hospital swing-beds for over 12 years; (2) the dialysis patient population is increasingly older and many are nursing home residents with co-morbid conditions; and (3) large dialysis chains have emerged that can offer more flexibility and options for a patient involuntarily discharged from a facility by providing numerous units nearby or within commuting distance of that patient's place of residence. We have added a proposal to waive the 30-day notice under unusual circumstances.

This proposed rule contains a requirement for every dialysis facility to report ESRD CPM Project data to CMS. One option considered was to propose that less than 100 percent of facilities be required to participate. However, section 4558(b) of Pub. L. 105-33 requires CMS to monitor the quality of care delivered to dialysis patients. To date, CMS has been collecting a 5 percent CPM patient sample on a voluntary basis. CPM electronic data collection has been pilot-tested and is expected to be ready for general use in 2005. A gradual voluntary phase-in will be undertaken for facilities that want to participate before full implementation. We believe that 100 percent CPM data collection is necessary to comply with the intent of the statute. The large chain dialysis facilities and many other dialysis facilities already collect this data for benchmarking and quality improvement purposes, and therefore, this will not create a significant new burden for the industry. However, small rural facilities may have a difficult time coming into compliance, and therefore,

we are considering a phase-in period for these facilities.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 494

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this proposed rule, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart U—Conditions for Coverage of End-Stage Renal Disease (ESRD) Services

1. The authority citation for part 405, subpart U continues to read as follows:

Authority: Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b-8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

2. The title of the subpart is revised to read as follows:

Subpart U—Conditions for Coverage for Suppliers of Renal Transplantation Services and Requirements for ESRD Networks

§§ 405.2100, 405.2101, 405.2135 through 405.2164, and 405.2180 through 405.2184 [Removed and Reserved]

3. Sections 405.2100, 405.2101, 405.2135 through 405.2164, and 405.2180 through 405.2184 are removed and reserved.

4. Section 405.2102 is revised to read as follows:

§ 405.2102 Definitions.

As used in this subpart, the following definitions apply:

ESRD Network organization. The administrative governing body to the network and liaison to the Federal government.

Histocompatibility testing. Laboratory test procedures which determine compatibility between an organ donor and a potential organ transplant recipient.

Network, ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Organ procurement. The process of acquiring donor organs. (See definition of Organ procurement organization in § 486.302 of this chapter.)

Renal transplantation center. A hospital unit which is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A Renal Transplantation Center may also be a Renal Dialysis Center.

Transplantation service. A process by which (1) a kidney is excised from a live or cadaveric donor, (2) that kidney is implanted in an ESRD patient, and (3) supportive care is furnished to the living donor and to the recipient following implantation.

Transplantation surgeon. A person who—

(1) Is board eligible or board certified in general surgery or urology by a professional board; and

(2) Has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 410.5 [Amended]

2. In § 410.5(a), the reference “Part 405, subpart U” is revised to read “Part 494”.

§ 410.50 [Amended]

3. In § 410.50(b), the reference “§ 405.2163(b)” is revised to read “§ 494.130”; and the reference “subpart M of part 405” is revised to read “part 494”.

§ 410.52 [Amended]

4. Section 410.52 is amended as follows:

a. In paragraph (a)(4), the reference to “§ 405.2163” is revised to read “§ 494.90(a)(3)”.

b. In paragraph (b), the parenthetical statement “(Section 405.2137 of this chapter contains specific details.)” is revised to read “(Section 494.90 of this chapter contains details on patient plans of care.)”

§ 410.152 [Amended]

5. In § 410.152(e)(1), “subpart U of part 405” is revised to read “part 494”.

§ 410.170 [Amended]

6. In § 410.170(c), the reference to “§ 405.2137(b)(3)” is revised to read “§ 494.90”.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww).

2. In § 413.170, paragraph (a) is revised to read as follows:

§ 413.170 Scope.

This subpart implements sections 1881(b)(2) and (b)(7) of the Act by—

(a) Setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system for outpatient maintenance dialysis furnished in or under the supervision of a dialysis facility under part 494 of this chapter (referred to as “facility”). For purposes of this section and §§ 413.172 through 413.198, “outpatient maintenance dialysis” means outpatient dialysis provided by a dialysis facility, home dialysis or self-dialysis as defined in

§ 494.10 of this chapter and includes all items and services specified in §§ 410.50 and 410.52 of this chapter.

* * * * *

3. In § 413.172, paragraph (b) is revised to read as follows:

§ 413.172 Principles of prospective payment.

* * * * *

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered outpatient maintenance dialysis. Approved ESRD facility means—

(1) Any independent or hospital-based facility (as defined in accordance with § 413.174(b) and (c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

(2) Any approved independent facility with a written agreement with the Secretary. Under the agreement, the independent ESRD facility agrees—

(i) To maintain compliance with the conditions for coverage set forth in part 494 of this chapter and to report promptly to CMS any failure to do so; and

(ii) Not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part.

* * * * *

§ 413.198 [Amended]

4. In § 413.198(a), the phrase “approved under subpart U of part 405,” is revised to read “under part 494”.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

1. Part 414 is amended as follows:

1a. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

§ 414.330 [Amended]

2. In § 414.330(a)(2)(iii)(B), the reference “subpart U of part 405” is revised to read “part 494”; and in § 414.330(a)(2)(iii)(B)(i), the reference to “subpart U” is changed to read “part 494”.

3. In § 414.330(a)(2)(iii)(B)(1) the references “subpart U” are revised to read “part 494”.

4. In § 414.330(a)(2)(iii)(B)(7) the references “subpart U” are revised to read “part 494”.

5. Section 414.330(a)(2)(iii)(C) is added to read as follows:

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) * * *

(2) * * *

(iii) * * *

(C) Agrees to report to the ESRD facility providing support services, every 30 days, all data for each patient regarding services and items furnished to the patient in accordance with § 494.100(c)(2) of this chapter.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

1. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1895hh).

2. In § 488.60 paragraph (a) is revised to read as follows:

§ 488.60 Special procedures for approving end stage renal disease facilities.

(a) *Consideration for approval.* An ESRD facility that wishes to be approved or that wishes an expansion of dialysis services to be approved for coverage, in accordance with part 494 of this subchapter, must secure a determination by the Secretary. To secure a determination, the facility must submit the following documents and data for consideration by the Secretary:

(1) Certification by the State agency referred to in § 488.12 of this part.

(2) Data furnished by ESRD network organizations and recommendations of the Public Health Service concerning the facility's contribution to the ESRD services of the network.

(3) Data concerning the facility's compliance with professional norms and standards.

(4) Data pertaining to the facility's qualifications for approval or for any expansion of services.

* * * * *

3. A new subpart H, consisting of §§ 488.604, 488.606, 488.608, and 488.610, is added to read as follows:

Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End Stage Renal Disease (ESRD) Facilities

Sec.

488.604 Termination of Medicare coverage.

488.606 Alternative sanctions.

488.608 Notice of alternative sanction and appeal rights: Termination of coverage.

488.610 Notice of appeal rights: Alternative sanctions.

Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End Stage Renal Disease (ESRD) Facilities

§ 488.604 Termination of Medicare coverage.

(a) Except as otherwise provided in this subpart, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in part 494 of this subchapter will result in termination of Medicare coverage of the services furnished by the supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required at § 494.160 of this subchapter, coverage may be reinstated when CMS determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in part 494 of this subchapter, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

§ 488.606 Alternative sanctions.

(a) *Basis for application of alternative sanctions.* CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that—

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass the supplier's geographic area; and

(2) This failure does not jeopardize patient health and safety.

(b) *Alternative sanctions.* The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of the sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of the sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) *Duration of alternative sanction.* An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the

requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

§ 488.608 Notice of alternative sanction and appeal rights: Termination of coverage.

(a) *Notice of alternative sanction.* CMS gives the supplier and the general public notice of the alternative sanction and of the effective date of the sanction. The effective date of the alternative sanction is at least 30 days after the date of the notice.

(b) *Appeal rights.* Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this subchapter.

§ 488.610 Notice of appeal rights: Alternative sanctions.

If CMS proposes to apply an alternative sanction specified in § 488.606(b), the following rules apply:

(a) CMS gives the facility notice of the proposed alternative sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, CMS provides an informal hearing by a CMS official who was not involved in making the appealed decision.

(c) During the informal hearing, the facility—

(1) May be represented by counsel;

(2) Has access to the information on which the allegation was based; and

(3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

(d) If the written decision of the informal hearing supports application of the alternative sanction, CMS provides the facility and the public, at least 30 days before the effective date of the alternative sanction, a written notice that specifies the effective date and the reasons for the alternative sanction.

1. Part 494 is added to read as follows:

PART 494—CONDITIONS FOR COVERAGE FOR END STAGE RENAL DISEASE FACILITIES

Subpart A—General Provisions

Sec.

494.1 Basis and scope.

494.10 Definitions.

494.20 Condition: Compliance with Federal, State, and local laws and regulations.

Subpart B—Patient Safety

494.30 Condition: Infection control.

494.40 Condition: Water quality.

494.50 Condition: Reuse of hemodialyzers and bloodlines.

494.60 Condition: Physical environment.

Subpart C—Patient Care

494.70 Condition: Patient rights.

494.80 Condition: Patient assessment.

494.90 Condition: Patient plan of care.

494.100 Condition: Care at home.

494.110 Condition: Quality assessment and performance improvement.

494.120 Condition: Special purpose renal dialysis facilities.

494.130 Condition: Laboratory services.

Subpart D—Administration

494.140 Condition: Personnel qualifications.

494.150 Condition: Medical director.

494.160 Condition: Relationship with the ESRD network.

494.170 Condition: Medical records.

494.180 Condition: Governance.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 494.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following provisions:

(1) Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603), which extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation.

(2) Section 1138(a)(1)(B) of the Act, which requires hospitals to be members and abide by the rules and requirements of the Organ Procurement and Transplantation Network.

(3) Section 1861(e)(9) of the Act, which requires hospitals to meet such other requirements as the Secretary finds necessary in the interest of health and safety of individuals who are furnished services in the institution.

(4) Section 1861(s)(2)(F) of the Act, which describes “medical and other health services” covered under Medicare to include home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies.

(5) Section 1862(a) of the Act, which specifies exclusions from coverage.

(6) Section 1881 of the Act, which authorizes Medicare coverage and payment for the treatment of ESRD in approved facilities, including institutional dialysis services, transplantation services, self-care home dialysis services, and the administration of recombinant epoetin alpha (EPO).

(7) Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113), which requires Federal agencies to achieve greater reliance on voluntary standards and emphasize, where possible, the use of standards developed by private, consensus organizations.

(b) *Scope.* The provisions of this part establish the conditions for coverage of services under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility's services may be covered.

§ 494.10 Definitions.

As used in this part—

Dialysis facility means an entity that provides (1) outpatient maintenance dialysis services; or (2) home dialysis training and support services; or (3) both. A dialysis facility may be an independent or hospital-based unit (as described in § 413.174(b) and (c) of this chapter), or a self-care dialysis unit that furnishes only self-dialysis services.

Discharge means the termination of patient care services by a dialysis facility.

Furnishes directly means the ESRD facility provides the service through its own staff and employees or through individuals who are under direct contract to furnish these services personally for the facility.

Home dialysis means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training as described in § 494.100(a) of this part.

Interdisciplinary team means the group of persons, specified § 494.80 of this part, responsible for providing patient care to each dialysis patient.

Self-dialysis means dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a) of this part.

Transfer means a temporary or permanent move of a patient from one dialysis facility to another that requires a transmission of the patient's medical record to the facility receiving the patient.

§ 494.20 Condition: Compliance with Federal, State, and local laws and regulations.

The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure, staff licensure and other personnel staff qualifications, fire safety, equipment, building codes, drugs, medical device usage, and any other relevant health and safety requirements.

Subpart B—Patient Safety

§ 494.30 Condition: Infection control.

The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and

any adjacent hospital or other public areas.

(a) *Standard: Procedures for infection control.* The facility must demonstrate that it follows standard infection control precautions by implementing—

(1) The “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” with the exception of screening for Hepatitis C, found in “Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients” Morbidity and Mortality Weekly Report, volume 50 number RR05, April 27, 2001, pages 20 and 21, developed by the Centers for Disease Control and Prevention, which are incorporated by reference, to prevent and control cross-contamination and the spread of infectious agents. Incorporation by reference of the CDC “Recommended Infection Control Practices for Hemodialysis Units at a Glance,” was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.¹

(2) Patient isolation procedures to minimize the spread of infectious agents and communicable diseases; and

(3) Maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the—

(i) Handling, storage, and disposal of potentially infectious waste; and

(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

(b) *Standard: Oversight.* The facility must—

(1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit; and

(2) Designate a registered nurse as the infection control or safety officer, responsible for—

(i) Maintaining current infection control information including the most current Centers for Disease Control and Prevention guidelines for the proper techniques in the use of vials and ampules containing medication;

(ii) Reporting infection control issues to the dialysis facility’s chief executive officer or administrator (see § 494.180(a) of this part) and the quality improvement committee; and

(iii) Making recommendations regarding infection control training and improvements.

(c) *Standard: Monitoring.* The facility must—

(1) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; and

(2) Develop recommendations to minimize infection transmission and take actions to reduce future incidents.

(d) *Standard: Reporting.* The facility must report incidences of communicable diseases as required by Federal, State, and local regulations.

§ 494.40 Condition: Water quality.

The facility must be able to demonstrate the following:

(a) *Standard: Water purity.* Water used for dialysis meets the following water quality standards and equipment requirements of the Association for the Advancement of Medical Instrumentation (AAMI) published in “Water Treatment Equipment for Hemodialysis Applications,” ANSI/AAMI RD62: 2001, which are incorporated by reference. Incorporation by reference of the AAMI Water Treatment Equipment for Hemodialysis Applications, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.²

(1) Incorporated water quality requirements are those listed in sections—

(i) 4.2.1 and 5.2.1, Water Bacteriology;

(ii) 4.2.2 and 5.2.2 Maximum Level of Chemical Contaminants; and

(iii) 4.3, Water Treatment Equipment requirements.

(2) The requirements for frequency of water purity testing to insure meeting the AAMI limits specified in paragraphs (a)(1)(i) and (ii) of this section are as follows:

(i) Bacteria and bacterial endotoxin levels of water/dialysate must be monitored—

(A) In established systems at least monthly;

(B) In newly-installed systems at least weekly until an established pattern of compliance can be demonstrated;

(C) In accordance with the requirements of AAMI published in “Dialysate for Hemodialysis,” ANSI/AAMI RD52:2004 section 7.2.1, which

are incorporated by reference.

Incorporation by reference of the AAMI Dialysate for Hemodialysis was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.³

(ii) Chemical analysis of water purity must be done at least once a year and when—

(A) The system is installed;

(B) Membranes are replaced, if using a reverse osmosis system;

(C) Seasonal variations in source water suggest worsening water quality;

(D) Reverse osmosis rejection rates, which are monitored daily using continuous-reading monitors that measure product water conductivity, fall below 90 percent.

(b) *Standard: Reverse osmosis or deionization.* Each water treatment system must include reverse osmosis membranes or a deionization component with resistivity monitors.

(c) *Standard: Chlorine/chloramines.* The facility must ensure, on a daily basis, that the source water does not contain chlorine/chloramines or the facility must ensure that—

(1) The water treatment system includes a component or carbon tank which removes chlorine/chloramine along with a backup component or second carbon tank for chlorine/chloramine removal; and

(2) The water from the exit port of the first component or carbon tank which removes chlorine/chloramine is tested for chlorine/chloramine levels, at a minimum, before each patient shift or every 4 hours, whichever is shorter, during operation of the water treatment system.

(i) If the test results are greater than 0.50 mg/L for free chlorine or 0.10 mg/L for chloramines from the port of the initial component or carbon tank then the second component or carbon tank which removes chlorine/chloramine must be tested; and

(ii) If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (c)(2)(i) of this section the facility must—

(A) Immediately terminate dialysis treatment to protect patients from exposure to chlorine/chloramine;

¹ This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD and at the National Archives and Records Administration (NARA). For availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

² This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD and at the National Archives and Records Administration (NARA). For availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

³ This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD and at the National Archives and Records Administration (NARA). For availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

(B) Immediately notify the medical director; and

(C) Take corrective action.

(d) *Standard: Corrective action plan.* Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety.

(e) *Standard: Adverse events.* A dialysis facility must maintain active surveillance of patient reactions during and following dialysis. When clinically indicated (for example, after adverse patient reactions) the facility must—

(1) Obtain blood and dialysate cultures;

(2) Undertake evaluation of the water purification system; and

(3) Take corrective action.

(f) *Standard: Unused bicarbonate.* Once mixed, bicarbonate concentrate must be used within the timeframe specified by the manufacturer of the concentrate.

§ 494.50 Condition: Reuse of hemodialyzers and bloodlines.

The dialysis facility that reuses hemodialyzers or bloodlines must meet the requirements of this section. Failure to meet any of these requirements constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.

(a) *Standard: General requirements for the reuse of hemodialyzers and bloodlines.* Certain hemodialyzers and bloodlines—

(1) May be reused for certain patients with the exception of Hepatitis B positive patients;

(2) Must be reused only for the same patient; and

(3) Must be labeled for multiple reuse in accordance with the premarket notification provisions of section 501(k) of the Food, Drug, and Cosmetics Act and 21 CFR 876.5860.

(b) *Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines.* A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

(1) Meet the requirements of AAMI published in “Reuse of Hemodialyzers,” third edition, ANSI/AAMI RD47:2002/A1:2003, which is incorporated by reference. Incorporation by reference of the “Reuse of Hemodialyzers, third edition, RD47:2002/A1:2003” was approved by the Director of the Federal

Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.⁴

(2) Reprocess hemodialyzers and bloodlines—(i) By following the manufacturer’s recommendations; or

(ii) Using an alternate method and maintaining documented evidence that the method is safe and effective.

(3) Not expose hemodialyzers to more than one chemical germicide, other than bleach, during the life of the dialyzer. All hemodialyzers must be discarded before a different chemical germicide is used in the facility.

(c) *Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.* In addition to the requirements for hemodialyzer and bloodline reuse specified in paragraphs (a) and (b) of this section, the dialysis facility must adhere to the following:

(1) Monitor patient reactions during and following dialysis.

(2) When clinically indicated (for example, after adverse patient reactions), the facility must—

(i) Obtain blood and dialysate cultures; and

(ii) Undertake evaluation of its dialyzer reprocessing and water purification system. When this evaluation suggests a cluster of adverse patient reactions is associated with hemodialyzer reuse, the facility must suspend reuse of hemodialyzers until it is satisfied the problem has been corrected.

(iii) Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law.

§ 494.60 Condition: Physical environment.

The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

(a) *Standard: Building.* The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff, and the public.

(b) *Standard: Equipment maintenance.* The dialysis facility must implement and maintain a program to ensure that all equipment (including

emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer’s recommendations.

(c) *Standard: Patient care environment.* (1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff.

(2) The dialysis facility must—

(i) Maintain a temperature within the facility that is comfortable for the majority of its patients; and

(ii) Make reasonable accommodations for the patients who are not comfortable at the temperature that is comfortable for the majority.

(d) *Standard: Emergency preparedness.* The dialysis facility must implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility’s geographic area.

(1) *Emergency preparedness of staff.* The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following:

(i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of—

(A) What to do;

(B) Where to go;

(C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility; and

(D) How to disconnect themselves from the dialysis machine if an emergency occurs.

(ii) Ensuring that, at a minimum, patient care staff maintain current CPR certification; and

(iii) Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs;

(2) *Emergency preparedness patient training.* The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1)(i) of this section.

(3) *Emergency equipment and plans.* Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available. The facility must—

⁴ This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD and at the National Archives and Records Administration (NARA). For availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

(i) Have a plan to obtain emergency medical system assistance when needed; and

(ii) Evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary.

(e) *Standard: Fire safety.* (1) The dialysis facility must meet applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference in § 403.744(a)(1)(i) of this chapter).

(2) Chapter 5 of the 2000 edition of the Life Safety Code does not apply to a dialysis facility.

(3) If CMS finds that a State has a fire and safety code imposed by State law that adequately protects a dialysis facility's patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the Life Safety Code.

(4) After consideration of State survey agency recommendations, CMS may waive, for appropriate periods, specific provisions of the Life Safety Code if the following requirements are met:

(i) The waiver would not adversely affect the health and safety of the dialysis facility's patients; and

(ii) Rigid application of specific provisions of the Life Safety Code would result in an unreasonable hardship for the dialysis facility.

Subpart C—Patient Care

§ 494.70 Condition: Patients' rights.

The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights.

(a) *Standard: Patients' rights.* The patient has the right to—

(1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD;

(2) Receive all information in a way that he or she can understand;

(3) Privacy and confidentiality in all aspects of treatment;

(4) Privacy and confidentiality in personal medical records;

(5) Be informed about and participate, if desired, in all aspects of his or her care, including advance directives, and be informed of the right to refuse treatment and to refuse to participate in experimental research;

(6) Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis,

intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis), and in-facility hemodialysis;

(7) Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients;

(8) Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers;

(9) Be informed by a physician of his or her own medical status as documented in the patient's medical record unless the medical record contains a documented contraindication to do so;

(10) Be informed of services available in the facility and charges for services not covered under Medicare;

(11) Receive the necessary services outlined in the patient plan of care described in § 494.90 of this part;

(12) Be informed of the rules and expectations of the facility regarding patient conduct and responsibilities;

(13) Be informed of the facility's internal grievance process;

(14) Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency;

(15) Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of services; and

(16) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.

(b) *Standard: Right to be informed regarding the facility's discharge and transfer policies.* The patient has the right to—

(1) Be informed of the facility's policies for transfer, discharge, and discontinuation of services to patients; and

(2) Receive written notice 30 days in advance of the facility reducing or terminating ongoing care after following the procedure described in § 494.180(f) of this part. In the case of immediate threats to the health and safety of others, a shortened discharge procedure may be allowed.

(c) *Standard: Posting of rights.* The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network telephone complaint numbers, where it can be easily seen and read by patients.

§ 494.80 Condition: Patient assessment.

The facility's interdisciplinary team, consisting of, at a minimum, the patient (if the patient chooses) or the patient's designee, a registered nurse, a nephrologist or the physician treating

the patient for ESRD, a social worker, and a dietitian, is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.

(a) *Standard: Assessment criteria.* The patient's comprehensive assessment must include, but is not limited to, the following:

(1) Evaluation of current health status and medical condition, including comorbid conditions.

(2) Evaluation of the appropriateness of the dialysis prescription, blood pressure, and fluid management needs.

(3) Laboratory profile and medication history.

(4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoietin.

(5) Evaluation of factors associated with renal bone disease.

(6) Evaluation of nutritional status.

(7) Evaluation of psychosocial needs.

(8) Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts, and peritoneal catheters).

(9) Evaluation of the patient's ability, interests, preferences, and goals, including level of participation in the dialysis care process; modality and setting, for example, home dialysis, including hemodialysis or peritoneal dialysis; and expectations for care outcomes.

(10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient's medical record.

(11) Evaluation of family and other support systems.

(12) Evaluation of current patient physical activity level.

(13) Evaluation of vocational and physical rehabilitation status and potential.

(b) *Standard: Frequency of assessment for new patients.*

(1) An initial comprehensive assessment must be conducted within 20 calendar days after the first dialysis treatment.

(2) A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in § 494.90 of this part.

(c) *Standard: Assessment of treatment prescription.*

The adequacy of the patient's dialysis prescription, as described in § 494.90(a)(1) of this part, must be assessed on an ongoing basis as follows:

(1) *Hemodialysis patients.* At least monthly by calculating delivered Kt/V or an equivalent measure.

(2) *Peritoneal dialysis patients.* At least every 4 months by calculating delivered weekly Kt/V or an equivalent measure.

(d) *Standard: Patient reassessment.* In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted—

(1) At least annually for stable patients; and

(2) At least monthly for unstable patients including, but not limited to, patients with—

(i) Extended or frequent hospitalizations;

(ii) Marked deterioration in health status;

(iii) Significant change in psychosocial needs; or

(iv) Poor nutritional status, with unmanaged anemia and inadequate dialysis.

§ 494.90 Condition: Patient plan of care.

The interdisciplinary team must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must allow the patient to achieve current evidence-based community-accepted standards.

(a) *Standard: Development of patient plan of care.* The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following:

(1) *Dose of dialysis.* The interdisciplinary team must provide the necessary care and services to achieve and sustain the prescribed dose of dialysis.

(2) *Nutritional status.* The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective nutritional status. A patient's albumin level must be measured at least monthly.

(3) *Anemia.* The interdisciplinary team must provide the necessary care and services to achieve and sustain the expected hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit

must be measured at least monthly. If a patient has hemoglobin less than 11 gm/dL or hematocrit of less than 33 percent, the dialysis facility must conduct an evaluation to determine whether the patient is an erythropoietin candidate. For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoietin and store erythropoietin under refrigeration. The patient's response to erythropoietin, including blood pressure levels and utilization of iron stores, must be monitored on a routine basis.

(4) *Vascular access.* The interdisciplinary team must provide the necessary care and services to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions and other risk factors. The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for stenosis.

(5) *Transplantation status.* When the patient is a transplantation referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the—

(i) Plan for transplantation, if the patient accepts to transplantation referral;

(ii) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or

(iii) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with § 494.80(a)(10) of this part.

(6) *Rehabilitation status.* The interdisciplinary team must provide the necessary care and services for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years).

(b) *Standard: Implementation of the patient plan of care.*

(1) The patient's plan of care—

(i) Must be completed by the interdisciplinary team;

(ii) Must be signed by the patient or the patient's designee.

(2) Implementation of the plan of care must begin within 10 calendar days after completion the patient assessment as specified in § 494.80 of this part.

(3) If the expected outcome is not achieved, the interdisciplinary team, must adjust the patient's plan of care to achieve the specified goals.

(4) The dialysis facility must ensure that all dialysis patients are seen by a physician providing the ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically, while the hemodialysis patient is receiving in-facility dialysis.

(c) *Standard: Transplantation referral tracking.* The interdisciplinary team must track the results of each kidney transplant center referral and must monitor the status of any facility patients who are on the transplant wait list. The team must communicate with the transplant center regarding patient transplant status at least quarterly or more frequently if necessary.

(d) *Standard: Patient education and training.* The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, quality of life, rehabilitation, and transplantation.

§ 494.100 Condition: Care at home.

A dialysis facility that is certified to provide services to home patients must ensure, through its interdisciplinary team that home dialysis services are at least equivalent to those provided to in-facility patients.

(a) *Standard: Training.* The interdisciplinary team must provide training to the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in § 494.10 of this part) and when the home dialysis caregiver or home dialysis modality changes. The training—

(1) Must be provided by a dialysis facility that is approved to provide home dialysis services;

(2) For self-care, must be conducted by a registered nurse who meets the requirements of § 494.140(b)(2) of this part; and

(3) Must be conducted for each home patient and address the specific needs of the patient, in the following areas:

(i) The nature and management of ESRD;

(ii) The full range of techniques associated with treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective erythropoietin administration (if prescribed) to achieve and maintain a hematocrit level of at least 33 percent or a hemoglobin level of 11 gm/dL;

(iii) Implementation of a nutritional care plan;

- (iv) How to achieve and maintain emotional and social well-being;
- (v) How to detect, report, and manage potential dialysis complications;
- (vi) Availability of support resources and how to access and use resources;
- (vii) How to self-monitor health status and record and report health status information;
- (viii) How to handle medical and non-medical emergencies;
- (ix) Infection control precautions; and
- (x) Proper waste storage and disposal procedures.

(b) *Standard: Home dialysis monitoring.* The dialysis facility must—

(1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training;

(2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and

(3) Maintain this information in the patient's medical record.

(c) *Standard: Support services.*

(1) A dialysis facility must furnish directly home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company, that include, but are not limited to, the following:

(i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care.

(ii) Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team.

(iii) Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meet the measurable and expected outcomes as specified in § 494.90 of this part.

(iv) Patient consultation with members of the interdisciplinary team, as needed.

(v) Monitoring of the quality of water used by home hemodialysis patients in accordance with the requirements specified in § 494.40(a)(1)(i) and (ii) of this part and conducting an onsite evaluation of the water system. The dialysis facility must correct the water quality of the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if—

(A) Analysis of the water quality indicates contamination; or

(B) The home hemodialysis patient demonstrates clinical symptoms associated with water contamination.

(vi) Purchasing, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.

(vii) Identifying a plan and arranging for emergency back-up dialysis services when needed.

(2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services furnished by durable medical equipment (DME) suppliers referred to in § 414.330(a)(2) of this chapter.

§ 494.110 Condition: Quality assessment and performance improvement.

The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, interdisciplinary quality assessment and performance improvement program. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

(2) The dialysis facility must measure, analyze and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. The program must include, but not be limited to, the following:

(i) Adequacy of dialysis.

(ii) Nutritional status.

(iii) Anemia management.

(iv) Vascular access.

(v) Medical injuries and medical errors identification.

(vi) Hemodialyzer reuse program, if the facility reuses hemodialyzers.

(vii) Patient satisfaction and grievances.

(b) *Standard: Monitoring performance improvement.* The dialysis facility must continuously monitor its performance, take actions that result in performance

improvements, and track performance to ensure that improvements are sustained over time. Each facility must participate in ESRD network activities and pursue network goals.

(c) *Standard: Prioritizing improvement activities.* The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety. The facility must immediately correct any identified problems that threaten the health and safety of patients.

§ 494.120 Condition: Special purpose renal dialysis facilities.

A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve ESRD patients while the patients are in a temporary residence) and facilities established to serve ESRD patients under emergency circumstances.

(a) *Standard: Approval period.* The period of approval for a special purpose renal dialysis facility may not exceed 8 months in any 12-month period.

(b) *Standard: Service limitation.* Special purpose renal dialysis facilities are limited to areas in which there are limited dialysis resources or access-to-care problems due to an emergency circumstance. A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility.

(c) *Standard: Scope of requirements.*

(1) *Scope of requirements for a vacation camp.* A vacation camp that provides dialysis services must be operated under the direction of a certified renal dialysis facility that assumes full responsibility for the care provided to patients. A special purpose renal dialysis facility established as a vacation camp must comply with the following conditions for coverage—

(i) Infection control at § 494.30 of this part;

(ii) Water quality at § 494.40 of this part (except as provided in paragraph (c)(1)(viii) of this section;

(iii) Reuse of hemodialyzers at § 494.50 of this part (if reuse is performed);

(iv) Patients' rights and posting of patients' rights) §§ 494.70(a) and (c) of this part;

(v) Laboratory services at § 494.130 of this part;

(vi) Medical director responsibilities for staff education and patient care policies and procedures at § 494.150(c) and (d) of this part;

(vii) Medical records at § 494.170 of this part; and

(viii) When portable home water treatment systems are used in place of a central water treatment system, the facility may adhere to § 494.100(c)(1)(v) (home monitoring of water quality) of this part, in place of § 494.40 (water quality) of this part.

(2) *Scope of requirements for an emergency circumstance facility.* A special purpose renal dialysis facility set up due to emergency circumstances may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic areas served by the facility. These types of special purpose dialysis facilities must additionally comply with the following conditions:

(i) § 494.20 (compliance with Federal, State, and local laws and regulations).

(ii) § 494.60 (physical environment).

(iii) § 494.70(a) through (c) (patient rights).

(iv) § 494.140 (personnel qualifications).

(v) § 494.150 (medical director).

(vi) § 494.180 (governance).

(d) *Standard: Physician contact.* The facility must contact the patient's physician, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the patient plan of care (described in § 494.90 of this part).

(e) *Standard: Documentation.* All patient care provided in the special purpose facility is documented and forwarded to the patient's dialysis facility within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.

§ 494.130 Condition: Laboratory services.

The dialysis facility must provide or make available laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility, must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.

Subpart D—Administration

§ 494.140 Condition: Personnel qualifications.

The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated

competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.

(a) *Standard: Medical director.* (1) The medical director must be a physician who has completed a board approved training program in nephrology and has at least 12 months of experience providing care to patients receiving dialysis.

(2) If a physician, as specified in paragraph (a)(1) of this section, is not available to direct a certified dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.

(b) *Standard: Nursing services.* (1) *Nurse manager.* The facility must have a nurse manager responsible for nursing services in the facility who must—

(i) Be a full time employee of the facility;

(ii) Be a registered nurse who meets the practice requirements of the State in which he or she is employed; and

(iii) Have at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis.

(2) *Self-care training nurse.* The nurse responsible for self-care training must—

(i) Be a registered nurse who meets the practice requirements of the State in which he or she is employed; and

(ii) Have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training.

(3) *Charge nurse.* The charge nurse responsible for each shift must—

(i) Be a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed; and

(ii) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis.

(4) *Staff nurse.* Each nurse who provides care and treatment to patients must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed.

(c) *Standard: Dietitian.* The facility must have a dietitian who must—

(1) Be a registered dietitian with the Commission on Dietetic Registration;

(2) Meet the practice requirements in the State in which he or she is employed; and

(3) Have a minimum of one year's professional work experience in clinical nutrition as a registered dietitian.

(d) *Standard: Social worker.* The facility must have a social worker who—

(1) Holds a master's degree in social work from a school of social work accredited by the Council on Social Work Education; and

(2) Meets the practice requirements for social work practice in the State in which he or she is employed.

(e) *Standard: Patient care dialysis technicians.* Patient care dialysis technicians must—

(1) Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the State in which he or she is employed as a dialysis technician; and

(2) Have a high school diploma or equivalency;

(3) Have completed at least 3 months experience, following a training program that is approved by the medical director and governing body. This experience must be under the direct supervision of a registered nurse, and be focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills including patient sensitivity training and care of difficult patients.

(f) *Standard: Water treatment system technicians.* Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing body.

§ 494.150 Condition: Responsibilities of the medical director.

The dialysis facility must have a medical director who meets the qualifications of § 494.140(a) of this part to be responsible for the delivery of patient care and outcomes in the facility. Responsibilities include, but are not limited to, the following:

(a) Quality assessment and performance improvement program.

(b) Staff education, training, and performance.

(c) Policies and procedures. The medical director must—

(1) Participate in the development, periodic review and approval of a "patient care policies and procedures manual" for the facility; and

(2) Ensure that—

(i) All policies and procedures relative to patient care and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and

(ii) The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in § 494.180(f) of this part.

§ 494.160 Condition: Relationship with the ESRD network.

The dialysis facility must cooperate with the ESRD network designated for its geographic area, in fulfilling the terms of the Network's current statement of work.

§ 494.170 Condition: Medical records.

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

(a) *Standard: Protection of the patient's record.* The dialysis facility must—

(1) Safeguard patient records against loss, destruction, or unauthorized use.

(2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following:

(i) The transfer of the patient to another facility.

(ii) Certain exceptions provided for in the law.

(iii) Provisions allowed under third party payment contracts.

(iv) Approval by the patient.

(v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.

(3) Obtain written authorization from the patient or legal representative before releasing information that is not authorized by law.

(b) *Standard: Completion of patient records and centralization of clinical information.*

(1) Current medical records and those of discharged patients must be completed promptly.

(2) All clinical information pertaining to a patient must be centralized in the patient's record. These records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment.

(3) The dialysis facility must complete, maintain, and monitor home care patients' records, including the records of patients who receive supplies and equipment from a durable medical equipment supplier.

(c) *Standard: Record retention and preservation.* Patient records must be retained for a period of time not less

than that required by State law or, in the absence of State law—

(1) *Adults.* 5 years from the date of the patient's discharge, transfer or death; or

(2) *Minors.* 3 years or until the patient reaches legal age under State law, whichever is longer, from the date of the patient's discharge, transfer or death.

(d) *Standard: Transfer of patient record information.* When a dialysis patient is transferred, the dialysis facility releasing the patient must send the patient's medical record and other information necessary in the patient's care or treatment to the receiving facility within 1 working day of the transfer.

§ 494.180 Condition: Governance.

The ESRD facility is under the control of an identifiable governing body, or designated person(s), with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the ESRD Network.

(a) *Standard: Designating a chief executive officer or administrator.* The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to—

(1) Staff appointments;

(2) Fiscal operations;

(3) The relationship with the ESRD networks; and

(4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program described in § 494.110 of this part.

(b) *Standard: Adequate number of qualified and trained staff.* The governing body or designated person responsible must ensure that—

(1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients;

(2) A registered nurse is present in the facility at all times that patients are being treated;

(3) All employees have appropriate orientation to the facility and their work responsibilities upon employment;

(4) All employees have an opportunity for continuing education and related development activities; and

(5) There is an approved written training program specific to dialysis technicians that includes—

(i) Principles of dialysis;

(ii) Care of patients with kidney failure, including interpersonal skills;

(iii) Dialysis procedures and documentation, including the initiation, monitoring, and termination of dialysis;

(iv) Possible complications of dialysis;

(v) Water treatment;

(vi) Infection control; and

(vii) Safety; and

(viii) Dialyzer reprocessing, if applicable.

(6) When State requirements meet or exceed § 494.180(b)(5) the State requirements must be met.

(c) *Standard: Medical staff appointments.* The governing body—

(1) Is responsible for all medical staff appointments and credentialing, including attending physicians, physician assistants, and nurse practitioners; and

(2) Ensures that all medical staff who provide care in the facility are informed of all facility policies and procedures, including the facility's quality assessment and performance improvement program specified in § 494.110 of this part.

(d) *Standard: Furnishing services.* The governing body is responsible for ensuring that the dialysis facility furnishes directly (see § 494.10 of this part) services on its main premises or on other premises that are contiguous with the main premises and are under the direction of the same professional staff and governing body as the main premises (except for services provided under § 494.100 of this part).

(e) *Standard: Internal grievance process.* The facility's internal grievance process must be implemented so that the patient may file a grievance with the facility without reprisal or denial of services. The grievance process must include—

(1) A clearly explained procedure for the submission of grievances;

(2) Timeframes for reviewing the grievance;

(3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.

(f) *Standard: Discharge and transfer policies and procedures.* The governing body must ensure that all staff follow the facility's patient discharge and transfer policies and procedures. The medical director ensures that no patient is discharged or transferred from the facility unless—

(1) The patient or payer no longer reimburses the facility for the ordered services;

(2) The facility ceases to operate;
 (3) The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs; or

(4) The facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired, in which case the medical director ensures that the patient's interdisciplinary team—

(i) Documents the reassessments, ongoing problem(s), and efforts made to resolve the problem(s) and enters this documentation into the patient's medical record;

(ii) Obtains a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's discharge or transfer from the facility;

(iii) Attempts to place the patient in another facility and documents that effort; and

(iv) Notifies the State survey agency and the ESRD Network that services the area (where the facility is located) of the involuntary transfer or discharge.

(g) *Standard: Emergency coverage.* (1) The governing body is responsible for ensuring that the dialysis facility provides patients and staff with written

instructions for obtaining emergency medical care.

(2) The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached.

(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must—

(i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed.

(ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.

(h) *Standard: Furnishing data and information for ESRD program administration.* The dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and performance assessment. The data and information must—

(1) Be submitted at the intervals specified by the Secretary;

(2) Be submitted electronically in the format specified by the Secretary;

(3) Include, but not be limited to—

(i) Cost reports;

(ii) ESRD administrative forms;

(iii) Patient survival information; and

(iv) Existing ESRD clinical performance measures and any future clinical performance standards developed in accordance with the National Technology Transfer and Advancement Act process adopted by the Secretary.

(i) *Standard: Disclosure of ownership.* In accordance with §§ 420.200 through 420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

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Tommy G. Thompson,
Secretary.

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