

2021

Outpatient Medical Director Toolkit

Developed by the Forum of ESRD
Networks' Medical Advisory Council
(MAC)

The Forum MAC has developed a series of QAPI toolkits to assist dialysis facilities in meeting the requirements of the Conditions of Coverage.

Tell us what you think!

Please take a moment to complete a short questionnaire about this Toolkit. We appreciate your insight and suggestions to make our resources better.

<https://www.surveymonkey.com/r/ForumResEval>



DEDICATION: to PETER DeOREO, MD, FACP

We dedicate this Toolkit and this work to Peter DeOreo, MD, FACP, who was the inspiration and leader for the first version of this Toolkit in 2012 and would have been again a leader on this updated version had it not been for his premature death in 2016. Dr. DeOreo was an active member of the Forum's Medical Advisory Council and Board of Directors. His legacy continues to inspire us to strive to always continue to improve patient care.

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This Toolkit is a guide, created by experienced professionals using the available evidence, produced by the Medical Advisory Council (MAC) of the National Forum of ESRD Networks. The details of the sections (e.g. water treatment) may change as technology and regulations change, and the MAC anticipates revisions and additions to the Toolkit overtime. The Toolkit is meant as a resource and should not be referenced as a regulatory statement. As with other MAC Toolkits (QAPI, Catheter Reduction, Medication Reconciliation, Vaccination and Assurance of Diabetes Care Coordination) this document is meant to help guide medical directors in meeting their obligations.

Table of Contents

GENERAL INFORMATION

Rationale/How to Use This Toolkit	5
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MEDICAL DIRECTOR SELF-ASSESSMENT

Governance	7
Self Assessment	21
Water Purification	25
Self Assessment	47
Dealing with Patient–Provider Conflict in the Unit	50
Infection Control	60
Emergency and Disaster Preparedness for Dialysis Medical Directors	68
COVID Infection Control for Dialysis Medical Directors	74
QAPI	86
Self Assessment	95
QAPI Meeting Management	97
QAPI Meeting: Data Recording Format	100
Self Assessment	105
The Regulatory Survey	106
Physician Leadership in the Outpatient Dialysis Clinic	114
Quality Incentive Program (QIP) for the Medical Director	117

RESOURCES

Quality Improvement Overview	126
PDSA Cycle	129
PDSA Worksheet	130
CQI Template: DM Care Coordination Project	131
QAPI Action Plan	135
QI Documentation	136
Measures Information	137
QAPI Meeting Minutes Template	142
Emergency Preparedness Interpretive Guidelines E-Codes for ESRD Facilities	145
Forum of ESRD Networks’/RPA Position on ESRD Patient Solicitation.....	151

MEDICAL DIRECTOR QUALITY ASSESSMENT and PERFORMANCE IMPROVEMENT (QAPI)

RATIONALE

The medical director of a dialysis facility serves as the team leader of an interdisciplinary team (IDT), collectively responsible for the safe provision of dialysis therapies in a reliable and reproducible way. The CMS Conditions for Coverage provides the medical director with broad authority to shape the operational procedures and governance of a dialysis facility; in exchange, the Conditions for Coverage also stipulate the medical director has substantial responsibility for assuring that dialysis facilities operate in a safe manner according to widely accepted standards of care and adhere to extant regulatory requirements.

Supplementing what has in the past been a relatively under-defined role of the medical directors, the purpose of this Medical Director Toolkit is to offer a comprehensive overview of the scope and breadth of the clinical and administrative responsibilities of the medical director of a dialysis facility.

HOW TO USE THIS TOOLKIT

The chapters of this toolkit cover key components of the medical director's job description. The topics include 1) governance and leadership, 2) water purification, 3) infection control, 4) quality assessment and performance improvement, staff training and competency, 5) QAPI meeting management, 6) the Medicare survey, and 7) CMS ESRD Quality Incentive Program (QIP). Each chapter explains the medical director's role in the topic, citing the applicable "V" tags from the interpretive guidance. Several chapters include a self-assessment quiz. The text addresses the issues raised in the quiz, allowing the medical director to define knowledge gaps and plan further study.

OTHER RESOURCES

The Conditions for Coverage Final Rule as published in the Federal Register on April 15, 2008:

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Downloads/ESRDfinalrule0415.pdf>

The series of toolkits published by the Medical Advisory Council (MAC) of the National Forum of ESRD Networks are additional references on key topics in the QAPI process.

<https://esrdnetworks.org/toolkits/professional-toolkits/>

These other toolkits have templates for problem solving and good discussion of the QAPI process.

The medical director should have good working knowledge of the Medicare Conditions for Coverage as detailed in the interpretive guidance:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter09-01.pdf>

There are several excellent reviews of medical director responsibilities that provide a good context and overview.

Maddux FW and A Nissenson. The Evolving Role of the Medical Director of a Dialysis Facility. *CJASN* 2015 Feb 6;10(2):326-30.

Gutman RA. Medical direction of dialysis--a critical leadership role. *Semin Dial*. 2007 May-Jun;20(3):257-60.

DeOreo PB. The medical directorship of renal dialysis facilities under the new Medicare conditions for coverage: challenges and opportunities. *Blood Purif*. Jan 2009;27(1):16-21.

Wish JB. What is expected of a medical director in the Centers for Medicare and Medicaid Services conditions of coverage. *Blood Purif*. Jan 2011;31(1)61-65.

GOVERNANCE



GOVERNANCE

INTRODUCTION

A framework for the governance of all dialysis units that serve the needs of Medicare beneficiaries (that is to say, essentially all dialysis units in the USA, with the partial exception of those operated by the VA) is specified by the Conditions for Coverage for ESRD Facilities (CfC). Fortunately, some flexibility in the administrative structure of facilities is incorporated into the CfC, to allow for the varying sizes, ownership, patient populations, and local conditions among facilities across the nation. The CfC have been in effect since 1976, but the revision adopted in 2008 significantly expanded the specifically enumerated responsibilities (and accountability) of the medical director of each facility. The purpose of this section is to review the latest requirements of the CfC for facility governance, with particular attention to those aspects of the medical director role that might draw the attention of state surveyors.

For this purpose, another document available on the CMS website ([cms.gov](https://www.cms.gov)) is a far more detailed and valuable resource than the CfC itself. This is the ESRD Basic Technical Surveyor Interpretive Guidelines (abbreviated herein as EBTSIG), which is the basic reference that state survey agencies use to determine if dialysis units are in compliance with the CfC. When state inspectors cite dialysis facilities for non-compliance with the CfC, they supply a “V-tag” with each citation, which references the system used within the EBTSIG that enumerates specific policy regulations in the CfC. With each section of this overview of dialysis facility governance, the relevant V-tags are listed.

The EBTSIG is accompanied by the Technical Surveyor Training Frequently Asked Questions (FAQs), also publicly available on the CMS website. Version 1.3 of the FAQ’s was the latest revision at this writing.

RELATIONSHIP BETWEEN THE DIALYSIS FACILITY AND THE ESRD NETWORK (V755, V772)

The 18 ESRD Networks are not part of CMS, but instead are regional not-for-profit agencies which contract with CMS to oversee and improve the quality of ESRD services provided to Medicare beneficiaries within the region. Each Network is governed by a Board of Directors and a Medical Review Board, consisting of volunteer representatives of the various professional disciplines, including physicians, as well as ESRD patients, from the region covered by the Network.

Prior to the provision of dialysis services, the governing body of each dialysis facility is required to sign an agreement to cooperate with the ESRD Network. “Cooperation,” as specified by the EBTSIG includes providing a prompt response to requests for information, data, providing a

corrective action plan requested by the Network, as well as participating in Network projects intended to improve the quality of care in an individual facility or in the facilities across the Network as a whole. Network personnel are permitted (and often required) to review individual patient records and are empowered to require copies of records and remove them from the facility.

The facility administrator is designated as the individual responsible for receiving and acting upon communications from the Network. While patient and facility information obtained by the Network are held confidential from public disclosure, Network personnel may communicate as they deem appropriate with CMS officials and state surveyors concerning quality of care issues, certain categories of patient grievances, and failure of facilities to provide requested information or meet set deadlines. Citations for failure to comply with the CfC may result. In extreme cases, Networks can (and have) recommended CMS sanction of facilities, resulting in partial or complete loss of Medicare reimbursement to the facility.

Each Network is required to maintain a website that includes a variety of information including data on quality metrics for facilities in the Network, as well as an annual report of Network activities. In addition, facilities receive feedback from their Networks generated by analysis of their data submitted to CMS, which often provides useful comparison of facility outcomes to local and regional averages. Networks are required to provide technical assistance to units which request it, not only with regard to dialysis expertise, but also in the areas of quality improvement, provider-patient conflict, and emergency preparedness.

GOVERNING BODY

Composition (V751)

The CfC does not specify the composition of the governing body; in fact, this entity may consist of a single person. The ownership of the facility must be clearly identified, and in the case of ownership by a corporation “with multiple widespread facilities” the EBTSIG specifies that the governing body must be “local”. In fact, the facility must notify its state agency of a change in ownership of a 5% or more share in the facility. The governing body may need to designate an individual as the administrator or CEO and must also appoint a medical director and nurse manager. The medical director and CEO roles are permitted to be filled by the same person. In practice, a facility governing body frequently includes the medical director, CEO, and nurse manager, even though these individuals report the results of their efforts to the governing body as a whole.

Responsibility and roles (V751-V764)

The governing body has the responsibility for the governance and operation of the facility, including the adoption of policies and procedures to guide the activities of the staff. Certain specific aspects of this responsibility are spelled out in the CfC: 1) staff appointments and verification of credentials; 2) “sound” fiscal operation; 3) cooperation with the ESRD Network; 4) provision of adequate staffing (including emergency coverage) by qualified personnel to provide dialysis safely, meet the needs of patients, and maintain an acceptable QAPI program; 5) provision of initial orientation and the opportunity for continuing education to all staff; 6) development of acceptable policies for patients to submit internal grievances, and for the involuntary discharge of patients; 7) an agreement with a hospital in the area to provide inpatient care (including dialysis) and emergency medical care 24 hours a day, 7 days a week; 8) arrangements to submit data electronically to CMS. Many of the standards that are specified in these areas are covered in more detail below.

PERSONNEL AND QUALIFICATIONS

Medical director (V682-683)

According to the CfC, the medical director must be board certified in internal medicine or pediatrics and must have completed a qualified nephrology training program which includes at least 12 months of experience in caring for patients receiving dialysis. What constitutes a “qualified” program is not specified by the CfC, but presumably a “qualified” program is presumably one which is accredited by the American Board of Medical Specialties, and permits individuals who satisfactorily complete the program to take the nephrology board certification exam in medicine or pediatrics. Notably, a requirement for board certification in adult or pediatric nephrology was considered but not adopted by CMS. The EBTSIG addresses the issue of maintenance of board certification. Recognizing that internal medicine or pediatrics board certification must have been achieved before nephrology subspecialty board certification, active nephrology board certification is acceptable even if the medicine or pediatrics board certification has lapsed. Thus, as long as the medical director has completed a qualified nephrology training program, maintenance of current board certification in internal medicine, pediatrics, nephrology, or pediatric nephrology should meet the qualification to be a facility medical director. Individuals who do not meet this qualification must have a waiver signed by the Secretary of the Department of Health and Human Services; such waivers have been issued on occasion in the past to individuals who were already serving as facility medical directors at the time the CfC were implemented. Undoubtedly the permission of the Secretary will be even more difficult to obtain

in the future unless a strong justification (i.e. remote geographical location with no qualified nephrologist available) could be provided.

Prior to the adoption of the current revision of the CfC in 2008, two or more qualified individuals could be designated “co-medical directors”. This is no longer acceptable; a single individual must be the designated medical director for each facility, even if some of the attendant tasks are delegated. Conversely, individuals who serve as medical directors of two or more facilities must be cognizant of the CMS expectation that adequately meeting the responsibilities associated with each facility should require at least 25% effort (0.25 FTE) or 10 hours weekly. Dialysis unit cost reports, which must be submitted to CMS, reflect this commitment. In practice, this requirement probably precludes individuals from serving as the medical director of more than two dialysis units and practicing full-time clinical medicine simultaneously. Practicing nephrologists who serve as medical directors of one or two dialysis units should not be asked by state surveyors to detail exactly which hours have been spent on which professional activities but should be prepared to offer documentation of a regular and active presence in each unit, particularly including activities not directly related to the care of individual patients. State surveyors or ESRD Network personnel may well ask unit staff, not just the medical director herself, about the level of the involvement of the medical director in unit activities.

Administrator (V752)

The CfC does not specify educational or professional attainments that must be met by the facility administrator. The FAQ’s specify that the administrator may also serve as the nurse manager, dietitian, social worker, or medical director if the qualifications for the professional position are met.

Nursing staff (V684-688)

The CfC specifies that the nurse manager must be a full-time employee of the facility (this is the only individual who must meet this requirement). If a facility is open less than 40 hours weekly, the employment hours of the nurse manager must include those hours. In addition, the individual must be a registered nurse (RN), have 12 months of clinical experience, and have an additional 6 months of experience in providing nursing care to individuals on dialysis. EBTSIG interprets these requirements to indicate that the nurse manager must be directly employed by the facility (not by, for example, an agency contract). Furthermore, this individual must be involved in hiring, evaluating, and terminating facility staff. The role may be shared, but a single individual must be designated as primarily responsible.

A charge nurse is required by the CfC to be responsible for each dialysis shift. According to the CfC, a charge nurse may be a registered nurse, licensed practical nurse, or vocational nurse if permitted by the applicable state regulations, subject to direct supervision by the RN if required

by the state. This individual must also have 12 months of clinical experience, including 3 months experience providing nursing care to dialysis patients. However, the medical director should be aware that a RN must be in the facility whenever patients are dialyzing (V759), whether the charge nurse is a RN or not, and that some state nursing boards prohibit the supervision of RN's by LPN's or vocational nurses.

The individual primarily responsible for home dialysis training and patient care must be a RN with 12 months experience, including 3 months in each modality (peritoneal dialysis or hemodialysis) offered in the program.

Social workers (V691)

Dialysis unit social workers are required to have a Master's degree in Social Work (MSW) from an accredited program in order to meet state licensure requirements. From the medical director's standpoint, this means that these individuals should be qualified to do much more than fill out paperwork. They should serve as a resource for patient and family counseling and conflict resolution and have training in the recognition and diagnosis of psychiatric conditions. Assistant social workers, supervised by an MSW, may have only bachelor's degrees and are permitted to help patients arrange transportation, apply for Medicare, etc. However, only the MSW can provide patient assessments for plans of care and serve on the interdisciplinary QAPI committee.

Dietitians (V689-690)

The renal dietitian responsible for care plan assessment and QAPI must be registered with the Commission on Dietetic Registration and must have 1 year of experience in clinical nutrition after registration. In many areas of the nation there are shortages of individuals who meet these qualifications and wish to work in dialysis, since such individuals frequently have more lucrative opportunities in less challenging work environments. The EBTSIG state that the governing body is required to make diligent efforts to fill this and other required positions (e.g. nurse manager, MSW), and that if the position is vacant more than a month, cross-coverage arrangements must be made.

Technical staff (V692-696)

Senior nephrologists will recall without much difficulty a time when all direct patient care in dialysis was delivered by nurses. At the time the original CfC were drafted (1976), this was undoubtedly the case in nearly all dialysis units. The role of technicians was limited to water systems and setting up dialysis machines. At the time when the latest revision of the CfC took effect (2008), however, most direct patient care in dialysis was performed by patient care technicians (PCTs) who do not have nursing degrees or licensure.

The EBTSIG defines a PCT as an individual who has direct contact with patients during treatment or sets up machines for treatment. Thus, individuals who prepare dialysis machines to provide treatments must meet the requirements for PCTs, while those whose duties are limited to machine takedown after treatments or dialyzer reuse need not. PCTs must have a high school degree and now must pass a state or national certification exam within 18 months of assuming patient care duties. They also must obtain continuing education thereafter, as well as periodic recertification, to remain in that role. Completion of an approved training program is required before new PCTs can provide patient care, and approval of this training program is the responsibility of the medical director, though the training itself must be provided by a RN.

Technicians whose duties are limited to water system operation or dialyzer reuse must have documented training in the area of responsibility but need not meet the qualifications of a PCT as outlined above.

Note: For additional information on ethical practices for practitioners, please see the Joint Forum-RPA Position Paper provided in the appendix.

RESPONSIBILITIES OF THE MEDICAL DIRECTOR (V710)

Staff training (V713)

The medical director is responsible for patient safety in the facility, and therefore is held responsible for staff training in the areas of infection control, water quality, dialyzer reuse and maintenance of a sanitary and safe physical environment. State surveyors are instructed to use the applicable specific tags to cite facilities for specific deficiencies in these areas but do have the authority to cite the medical director if deficiencies are “serious or pervasive”. (V710) In addition to overall responsibility for the content of training programs in these areas, the medical director must certify the successful completion of the facility’s training program by each member of the technical staff in the areas applicable to the work duties of that individual.

Direct medical director responsibilities, aside from staff training, in the areas of quality assessment and performance improvement (QAPI, V712), water processing, and infection control are covered in detail in separate chapters of this toolkit. A brief discussion of the Conditions regarding dialyzer reuse and patient safety is provided here.

Reuse of dialyzers and bloodlines (V300)

The technical requirements for dialyzer reuse have been specified by the Association for the Advancement for Medical Instrumentation (AAMI); these requirements have been incorporated

into the CfC. From the medical director standpoint, certain principles on which these standards are based are important to know:

- 1) Reuse of dialyzers or bloodlines for hepatitis B surface antigen positive patients is prohibited. (V301)
- 2) Reused dialyzers and blood lines are, of course, employed to dialyze only that individual who was previously dialyzed with them. The documentation of reuse of a dialyzer is a medical record. Therefore, each dialyzer must be uniquely labeled so that the patient to whom it belongs can be readily identified, and each step-in reuse is signed, on paper or electronically, with a date and time by the individual responsible for carrying out that step. One must be able to reconstruct the process applied to each dialyzer, and requirements for legibility, secure storage, and confidentiality that must be met by medical records must also be met by reuse records. (V304-305)
- 3) The facility must have a reuse manual, readily available to staff (and surveyors) that contains all the policies, procedures, training materials, and manufacturer's specifications for reuse equipment, dialyzers, germicides, etc. (V306) OSHA requirements and materials safety data sheets for chemicals must also be readily available for reference.
- 4) Standard bloodborne pathogen infection control precautions are universally applied during reuse, regardless of the documented seropositive or negative status of the patient involved. (V311, V314)
- 5) The medical director must order reuse if the facility is to reuse dialyzers. Each patient's dialysis orders in a reuse-employing facility must specify whether that patient participates in the reuse program and must accommodate individual patient sensitivity to substances involved in reuse procedures. Written materials regarding dialyzer reuse must be provided to patients, and brochures and other materials that describe the services offered by the facility must specify that reuse is employed. (V312) The CfC do not formally require written informed consent for reuse by patients, but obtaining such consent is recommended by the National Kidney Foundation and the American Association of Kidney Patients.
- 6) Used and reprocessed dialyzers must be stored in identified areas separate from those where new dialyzers are stored. (V315) Air concentrations of certain chemicals in the reuse area must be monitored and kept below certain limits specified by AAMI. (V318) Before reprocessed dialyzers are introduced back into patient treatment, they must be tested for membrane leaks, the presence of residual germicides, and total cell volume (TCV). (V336) A dialyzer must be discarded if the TCV is less than 80% of that of a new dialyzer. Finally, the assignment of the reprocessed dialyzer to the correct patient must be checked and documented before use by the signature of two individuals; the CfC specify a preference that one of these individuals be the patient when possible. (V348)
- 7) Frequencies of internal audits of many of the above processes are specified in the CfC, and records of such audits are equally "fair game" for surveyors as are the processes themselves.

Physical environment of the unit; patient comfort and safety (V400)

The EBTSIG goes into considerable detail in these areas, but many of the specific requirements seem to be inherent in generally accepted standards of the operation and maintenance of any public health care facility. Therefore, one should sensibly expect (and in fact does find) provision for environmental safety and access for handicapped persons, the immediate availability of working resuscitation equipment and medications and CPR-certified staff, the acceptable disposition of biohazardous wastes, and compliance with fire safety codes. The CfC also require that the QAPI program monitor medical errors, adverse events, and environmental safety within the facility, and specify that these items are within the purview of the medical director. The EBTSIG and FAQ's contain a link to an award-winning website maintained by the Renal Physicians Association and the National Forum of ESRD Networks in this area: https://cdn.ymaws.com/www.renalmd.org/resource/resmgr/patient_safety_reports/posters/patient_safety_plan_basics_.pdf. The suggested safety program includes best practices in hand hygiene and in preventing patient falls, medication errors, incorrect dialysis prescription delivery, and non-adherence to policies and procedures; surveyors are evidently encouraged to look for issues in unit practice in these areas.

A few of the other requirements in this category of specific interest to facility medical directors are described below.

1. Environmental temperature control (V405)

One of the most common patient complaints recorded by CMS and the ESRD Networks is that the temperature in dialysis facilities is maintained at too low a level for comfort. Probably for this reason, there is a specific "V-tag" used to cite facilities in this area. The EBTSIG specifically recognizes that patients are too cold and staff too warm at usual room temperature. A "reasonable accommodation" for all is suggested, and routinely raising or lowering the thermostat to suit the preferences of any one person is unacceptable. Suggesting the use of blankets, caps, or gloves for patients is permitted, as long as it is remembered that such items are "dirty" from the infection control standpoint and staff should use personal protective equipment when handling them. Whether a blanket is in use or not, maintaining the visibility of the patient's face, vascular access, and bloodlines at all times is required.

2. Emergency and disaster preparedness (V408-416)

Each facility is required to have a detailed plan for emergency and natural disaster preparedness, covering contingencies that are reasonably probable in the facility's locale; one would be more likely to encounter an earthquake than a hurricane in Alaska, while the reverse is true in Florida. The plan must be updated, and staff trained annually. Fire drills, mock "codes", and rehearsals of other locally relevant situations are part of this training and are

expected to be held periodically. Furthermore, the dialysis facility must maintain communications with local disaster management agencies, in the form of a letter that is sent at least annually to the agency, reminding them of the unit's presence and potential patient needs. Periodic reminders should be sent to power and water utilities as well.

Finally, patient training and periodic updates are also required. This includes emergency contact information, possible sites to obtain treatment if the home facility cannot open, and dietary management if treatment cannot be obtained at all for a prolonged interval. The ESRD Networks are charged by CMS with providing centralized resources for emergency and disaster planning, as well as coordinating dialysis services during actual emergencies. A cooperative effort between the Networks and disaster relief agencies has resulted in the Kidney Community Emergency Response (KCER) Coalition website, www.kcercoalition.com, which contains virtually all the information needed for facilities to generate their own plans.

3. Emergency physician coverage and hospital care (V770)

Each dialysis unit is required to have a signed agreement with a hospital in the area, or at least a letter from a hospital, which states that the hospital agrees to provide access for the unit's patients to 24-hour emergency services and facilities for inpatient care, including inpatient dialysis. In addition, the unit must have a roster that enables contact of the physician or licensed practitioner responsible for each patient at any time, including details of cross-coverage arrangements.

PATIENT RIGHTS

As has been the case with some previous sections of this chapter, much of the material in the CfC concerning patients' rights is common to all health care settings. These include i) the right to be treated with respect and dignity, ii) the right to privacy and confidentiality in examinations, treatment discussions, and medical record keeping, and iii) the right to be informed of (and participate in) the plan of care. (V452-455) Other aspects of the CfC, unique to dialysis, are described below.

Grievances (V765)

The medical director is not held directly responsible for unit policies regarding patient satisfaction surveys or grievances but should encounter them in the context of the QAPI program. The regular administration of patient satisfaction surveys is required by the CfC. The 2012/2014 QIP specifies that facilities should use the In-center Hemodialysis CAHPS (Consumer Assessment of Healthcare Providers and Systems) survey. Upon admission, the facility is also required to inform the patient

of the grievance procedure, and that complaints and grievances may be submitted verbally or in written form to the facility itself or to the ESRD Network. The medical director should also be aware that the facility policy must include language that prevents retaliation in any form, particularly discrimination in care practices, by professional staff or unit employees against patients who submit grievances (V457).

Aside from complaints about treatment times and promptness, and physical environment of facilities, most patient grievances revolve around staff professionalism, or the lack thereof. Many or most of the PCTs have not had the educational opportunity to learn much about professionalism. Medical and nursing staff can lapse into unprofessional behavior under stress, even though they have had training in professionalism. Medical directors who wish to minimize the need for patients to file grievances would do well to incorporate some training in professionalism into the educational program required for PCT's in the facility, and to set clear expectations for interpersonal boundaries and a clear example of professional demeanor in the unit.

Treatment options in ESRD (V458)

All Medicare beneficiaries must be informed in an unbiased fashion of available treatment options for ESRD, including home dialysis (V512-513) and alternative dialysis schedules that might facilitate employment, even if they are not offered at the facility. (V458) Such information must be documented in the plan of care by the interdisciplinary team, which includes the patient himself. Furthermore, transfer to a facility that does offer the patient's desired treatment option must be facilitated if the patient requests it.

All patients must also be informed upon entry to the facility about transplantation as an option for the treatment of ESRD. (V554) The plan of care must include a statement concerning renal transplantation: either that the patient is considered unsuitable for transplantation, that the patient refuses transplantation, or that the patient has been or will be referred for transplant evaluation.

Care plans and physician visits

Care plans (V540) are generated and updated by an interdisciplinary team (IDT) consisting of (at least) a dialysis nurse, social worker, dietitian, and the patient's physician (or designated colleague). The patient is invited (in fact, encouraged) to attend the team meeting as well. (V541) State surveyors require evidence of an actual meeting of the IDT, either face-to-face or by conference call, to be reflected in the meeting minutes and the contemporaneous dating of signatures on the plan. The initial comprehensive assessment and plan of care (V502-515) must be generated within 30 days (or 13 dialysis treatments) of admission (V557); the required frequency of updates may vary between monthly and annually, depending on the "stability" of

the patient as defined by the IDT; patients who meet Unstable criteria as described in Interpretive Guidance (V520), however, require a care plan update within 30 days of returning to the outpatient unit.(V558)

Unstable Criteria described by CMS in CfC and Interpretive Guidance V520 includes:

- (i) Extended (hospitalizations > 15 days) or frequent hospitalizations (>3 hospitalizations in a month);
- (ii) Marked deterioration in health status which interferes with the patient's ability to follow aspects of the treatment plan;
- (iii) Significant change in psychosocial needs which interferes with the patient's ability to follow aspects of the treatment plan; or
- (iv) Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis

Also, according to Interpretive Guidance (V520): *Facilities must have a method for classifying patients as "unstable." Documentation should be available of a monthly re-assessment and plan of care revision that addresses the issues related to the classification of the patient as "unstable" until the issues have been resolved or the IDT (including the patient if possible) determine that the condition is chronic and the active care plan adequately addresses the issues.*

In order to comply with the CfC, the medical director must ensure that each member of the medical staff attends IDT care plan meetings to update care plans in a timely fashion, and that every patient be seen by a physician (or advanced practice providers [APPs] including nurse practitioners or physician's assistants) at least monthly. (V560) The patient can be seen in the office to fulfill this requirement. There is an additional requirement that the patient is seen by the physician or APPs during dialysis quarterly.

Involuntary discharge and involuntary transfer (V766)

Involuntary discharges of patients will hopefully be rare occurrences; the governing body is specifically charged in the EBTSIG with the mission of "decreasing the potential for involuntary discharges." A key facet of decreasing the potential for involuntary transfer and involuntary discharge is proactively identifying and addressing areas of patient/provider conflict which in itself may be a precursor to further conflict or escalation which could culminate in an involuntary separation of the patient from the unit. To this end, it is the responsibility of the medical director to ensure the unit is familiar with strategies to de-escalate and address points of conflict, as well as ensuring the unit leadership is availing themselves of Network resources and personnel. Involving Network-based patient advocates can assist the facility in resolving points of conflict, ensure that patients have a sense they are being heard, and (ideally) avoiding involuntary transfer and discharge altogether.

Both the attending nephrologist and facility medical director must sign the order for any involuntary discharge. The medical director must sign the order, even if he is not the patient's attending physician. Because an involuntary discharge may well place a patient's life in jeopardy, these events must be reported to the state agency and ESRD Network. (V767)

An abbreviated involuntary discharge procedure is permitted in the case of an "immediate severe threat" to the facility patients or staff. A patient who brings a weapon into the facility and threatens someone with it would be the best example, and documentation of the threat should include an emergency 911 call to local police. In such cases, and only in such cases, can the patient be immediately discharged. Verbal abuse, no matter how impassioned or obscene, is not considered an immediate severe threat in this context. In such situations, the Network must be immediately notified as to the immediate discharge and provided with supporting documentation.

Other reasons for involuntary discharge may include prolonged inability to contact the patient, or non-payment of fees. Finally, the patient may be discharged if his behavior is so disruptive or abusive that the ability of the facility to deliver his care or the care of others is seriously impaired (V767). In such cases, there should be documentation of prior assessments and attempts to resolve the issues in the patient's record. Note that non-adherence to medications or dialysis schedules is not considered a sufficient reason by itself for involuntary discharge. A 30-day written notice of the intent to discharge must be provided to the patient AND the ESRD Network, and the medical director is held responsible for contacting other facilities in the area to make a good faith attempt to place the patient. It is important to note that while contact with other facilities is essential to a good faith effort to place the patient at an alternative facility, the patient's personal health information remains protected by HIPAA provisions. Communication regarding the patient facing involuntary transfer or discharge should be limited to the provision of relevant medical records from the dialysis facility and should be limited to the transmission of signed and dated medical records. However well intentioned, conversations between the medical director or attending physician and the proposed accepting physician at another facility regarding a patient facing involuntary transfer or discharge are considered "hearsay" under V767 of the CfC and are not appropriate.¹ The ESRD Network is charged with providing assistance to place patients who are involuntarily discharged.

¹ V 767: "Because the goal of contacting another dialysis facility is for continuity of care, the HIPAA privacy rule does not require patient consent to contact that other dialysis facility. However, it does limit sharing of protected health information to medical records requested by the other provider and prohibits sharing information obtained through hearsay. Good faith efforts should be made to find the closest facility to the patient's residence that will accept the patient in transfer. The applicable patient's medical record must include evidence of those placement efforts."

The EBTSIG specifies that non-compliance with the involuntary discharge policy is considered a Condition-level deficiency in state surveys.

The medical director may encounter the situation where a staff nephrologist (or the medical director himself) feels the need to unilaterally terminate an existing physician-patient relationship with a dialysis patient. Of course, such termination is subject to the conditions regarding patient abandonment specified by individual state laws and state medical board rules, which generally include the provision of notice of intent to terminate the patient's care a specified number of days in advance, and a good faith effort to transfer the patient's care. If there is no other medical staff member with privileges in the facility willing to accept the patient, the facility will be unable to dialyze the patient due to the absence of valid medical orders to do so. In such cases, the facility administrator may not feel the need to regard this as a reportable "involuntary discharge" because the facility was still willing to dialyze the patient if a staff physician had written the orders. Reporting the patient's situation to the ESRD Network as far in advance of the threatened termination of care at the facility is still strongly advised; the Network may well be able to mediate the issue or assist in finding the patient an acceptable alternative situation if necessary.

SELF ASSESSMENT: GOVERNANCE**Instructions: Select the one best answer.**

1. The Conditions for Coverage for End-stage Renal Disease Facilities:
 - a) have been in effect without substantial revision since 1976
 - b) are Federal regulations that do not necessarily apply to the inspections carried out by individual state survey agencies
 - c) Require that a single qualified individual be designated as the medical director for each dialysis facility
 - d) Specify that one individual cannot be both the medical director and chief executive officer for a dialysis facility

2. Unless requirements are waived by approval of the Secretary of HHS, the medical director of a dialysis facility:
 - a) must maintain current board certification in nephrology
 - b) must be board-eligible in internal medicine or pediatrics and have 12 additional months' experience in the care of dialysis patients
 - c) must be board-certified in internal medicine or pediatrics and must have completed a board-qualified nephrology training program
 - d) must be a licensed physician or nurse practitioner with 5 years experience, including 12 months experience supervising other health care workers, in the care of dialysis patients

3. According to Federal regulations, the ESRD Networks:
 - a) are required by HIPAA to have a signed release from the patient to review medical records
 - b) may review dialysis unit laboratory data for quality assurance purposes as long as it is stripped of patient identification
 - c) may review patient records only within a facility as part of a site visit
 - d) have the authority to require the dialysis unit to provide medical records or laboratory data for any patient at any time

4. Patients may justifiably be discharged involuntarily from dialysis facilities for:
 - a) non-payment of fees
 - b) bringing a loaded firearm into a facility
 - c) chronic non-compliance with dialysis treatments and schedules
 - d) a or b

5. Involuntary discharges from dialysis facilities:
 - a) must be reported to the ESRD Network and the state agency responsible for the facility
 - b) are the responsibility of the attending nephrologist, not the medical director

- c) generally require two weeks advance notice unless there is an immediate threat to patient or staff safety in the facility
 - d) may be applied to patients who file frivolous or multiple grievances with the Network
6. The responsibility of the medical director in quality assurance and performance improvement (QAPI) in the dialysis unit is:
- a) to be aware of the activities of the quality improvement committee in the dialysis unit
 - b) to sign off on the minutes of QA meetings at least monthly
 - c) to detect shortcomings in dialysis unit performance and suggest remediation measures to the unit administrator and nursing supervisor
 - d) to design and lead QAPI efforts, take personal responsibility for QAPI projects and results, and report results to the governing body
7. Care plans for Medicare beneficiaries with ESRD:
- a) may optionally include input from social workers and dietitians if available and relevant to the patient's particular case
 - b) Need not explicitly address transplantation if the patient is not a suitable candidate
 - c) Must be revised and updated monthly if the patient is deemed unstable
 - d) Must include the medical director as part of the patient's multidisciplinary team
8. Informed consent for treatment in a dialysis facility must include:
- a) Home treatment options even if the facility has no home dialysis program
 - b) Notification of the patient that the facility practices dialyzer reuse if it does
 - c) Discussion of the opportunity for renal transplantation
 - d) All of the above
9. The medical director of a dialysis facility receives a call that the total chlorine in treated water for dialysate is 0.2 ppm, versus a usual baseline of less than 0.1. The change in performance of the water system is most likely due to malfunction of:
- a) the carbon tanks
 - b) the deionizer
 - c) the reverse osmosis membrane
 - d) No malfunction, this small variance is within the expected performance of the system
10. Dialysate water is tested for chlorine/chloramines:
- a) every hour
 - b) every 4 hours
 - c) daily
 - d) weekly

11. On reviewing water system logs during an unscheduled visit to the unit, the Medical Director notes that the recorded outlet pressure for the RO system has been greater than the inlet pressure all week. The data indicate:
 - a) partial occlusion of the outflow
 - b) clogging of the RO membrane by inadequate prefiltration
 - c) episodes of reversal of flow through the system
 - d) Misunderstanding and logging errors by the technical staff

12. Mitigation of recurrent positive water cultures in a dialysis unit may include:
 - a) Installation of submicron filters in the water delivery system
 - b) Provision of air gaps in plumbing leading to sampling outlets
 - c) Sterilization or replacement of dialysate lines to each dialysis machine
 - d) All of the above

13. The governing body of a dialysis facility:
 - a) must include at least the administrator, medical director, and nurse manager
 - b) is not responsible for its own governance; this is the responsibility of the owner
 - c) is not responsible for the fiscal management of the dialysis facility; this is the responsibility of the owner
 - d) must maintain current records that clearly identify the ownership of the facility

14. A dialysis facility must:
 - a) be located within 10 miles of a hospital
 - b) have an agreement with a hospital for emergency care and inpatient dialysis
 - c) be located within 10 miles of an emergency room
 - d) have an agreement with a local EMS provider for patient transportation to a qualified emergency medical facility

15. Present and on duty on the dialysis facility treatment floor while patients are being treated must be:
 - a) a patient care technician with current state certification
 - b) a charge nurse plus at least one patient care technician per four patients
 - c) a registered nurse with a current state license
 - d) a qualified and licensed practical nurse, vocational nurse, or registered nurse

16. Medical staff members of a dialysis facility must:
 - a) demonstrate participation in QAPI activities designed to improve the care of their patients
 - b) attend at least 50% of the meetings of the Quality Improvement Committee
 - c) be re-credentialed yearly by the governing body
 - d) maintain hospital privileges at hospitals contracted with the facility

17. The individual designated by the governing body to be responsible for receiving and acting on correspondence from the ESRD Network is the:
- administrator or CEO
 - facility social worker
 - medical director
 - any of the above
18. The governing body is required to ensure that:
- a written policy for handling patient grievances is approved and implemented
 - a reasonable time frame is specified for investigating and acting upon patient grievances, including communication of the outcome back to the patient
 - No reprisal or adverse incentive is applied to patients who register grievances
 - All of the above
19. An example of a condition level deficiency in dialysis unit governance that might be cited in a state survey is:
- A private holding company located in another state buy the dialysis unit. It has no local employees, so despite patient concerns, it contracts with a separate management company to bring in a governing body, medical director, and staffing for the unit.
 - A dialysis unit has a poor outcome in anemia management identified by its ESRD Network, and does not respond to a Network request for a corrective action plan.
 - The policy approved by the governing body specifies a time frame for closing. patient grievances of ten days, but the unit fails to meet this standard in three consecutive cases due to a four-week gap in social work coverage.
 - All of the above

ANSWER KEY: 1. C 2. C 3. D 4. D 5. A 6. D 7. C 8. D 9. A
10. B 11. D 12. D 13. D 14. B 15. C 16. A 17. A 18. D 19. B

WATER PURIFICATION



WATER PURIFICATION

INTRODUCTION

There is nothing more important for the safe delivery of hemodialysis than SAFE water. Water purification systems provide one of the greatest hazards in hemodialysis if the water treatment components fail to function accurately or if water quality testing is not performed and monitored.

The CMS ESRD Conditions for Coverage (CfC) are specific to §494.40 Condition: Water and Dialysate quality. V Tags 176 through 278 incorporate by reference AAMI/ANSI RD 62:2001 Water Quality for Hemodialysis and AAMI/ANSI RD 52:2004 Dialysate for Hemodialysis. The CMS standard is for water and equipment in use to meet the water and dialysate quality standards and equipment requirements found in the listed references.

The Medical Director has the ultimate responsibility for ensuring the quality of water used for dialysis. If standards are not met, it is the Medical Director who may be cited as the negligent party. This person must exercise oversight and validate this responsibility by meeting with the interdisciplinary team on a monthly basis at the Quality Assessment and Process Improvement (QAPI) meeting and interacting with the personnel responsible for day-to-day operations of the water systems. All documentation of water quality testing, including bacterial and endotoxin studies must be reviewed and signed off by the medical director.

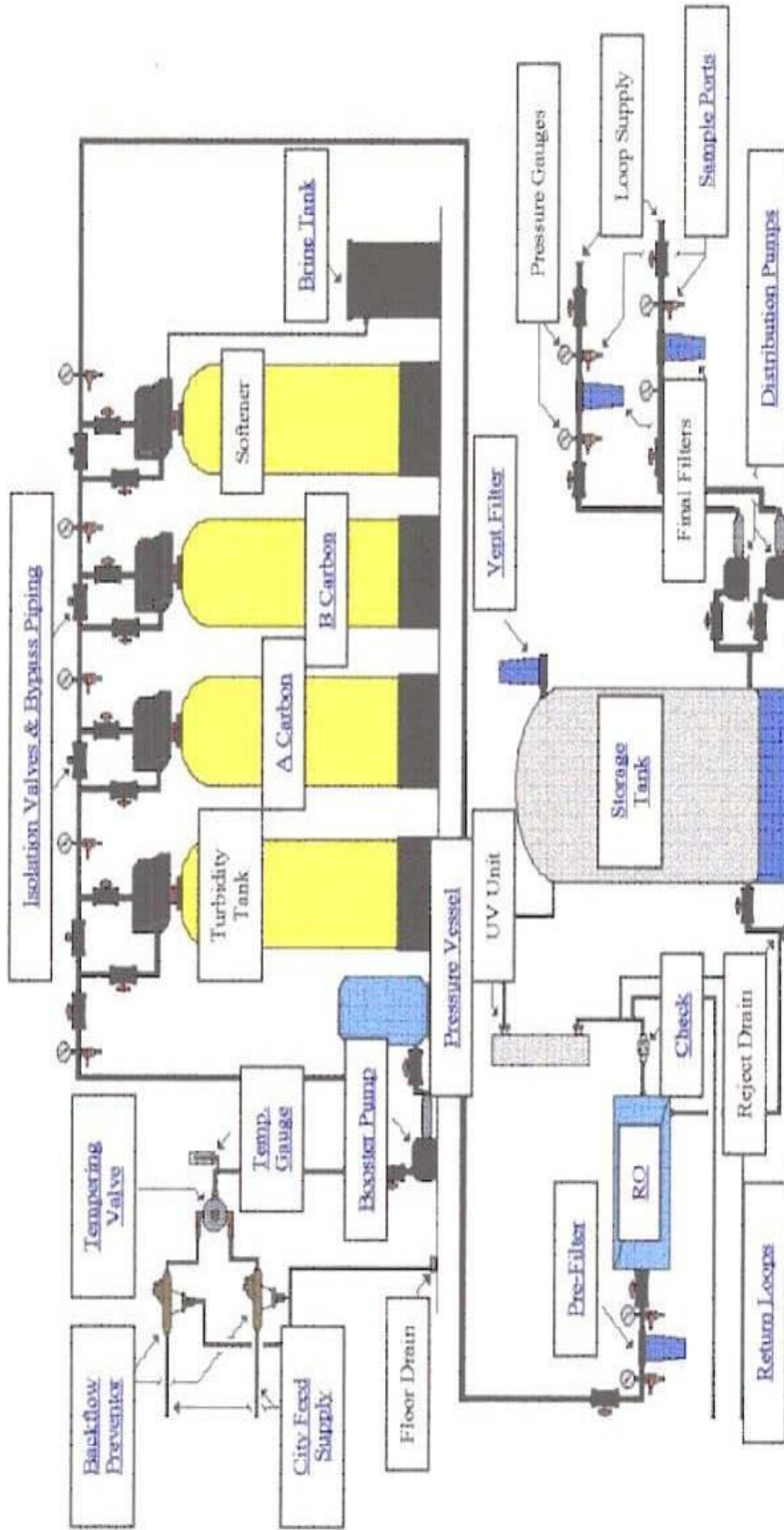
The following information highlights ***key points*** within water purification and should be used in conjunction with comprehensive water quality publications.

PREPARATION OF PURIFIED WATER FOR HEMODIALYSIS (V175-176, V184-V187)

The major components include:

1. Tap Water (FEED WATER)
2. Sediment (Depth/Multimedia or cartridge) Filter for removal of large particles to allow maximum efficiency of downstream equipment
3. Water Softener (or chemical descalent) to reduce calcium and magnesium to avoid overloading RO filter
4. Carbon tanks for absorption of chlorine and chloramines, which are extremely toxic
5. Reverse osmosis (RO) filter to remove 90% of solutes entering the filter and/or Di-ionization
6. Holding tank for storage as applicable
7. Distribution Pump
8. Distribution Loop

Water System Flow Diagram



TAP WATER (V177-178)

Analyzed for inorganic solutes, which are to be within limits set by the Association for the Advancement of Medical Instrumentation (AAMI) as seen in table 1.

Frequency of analysis to be performed:

1. At initial setup of equipment.
2. Seasonally as source of water varies; and
3. Annually

Sites to sample

1. Incoming tap water
2. Post RO or DI (whichever is online and last)
3. Post Portable ROs

Contaminant / Maximum Concentration	(mg/L)
Calcium	2 (0.1 mEq/L)
Magnesium	4 (0.3 mEq/L)
Potassium	8 (0.2 mEq/L)
Sodium	70 (3.0 mEq/L)
Antimony	0.006
Arsenic	0.005
Barium	0.10
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Lead	0.005
Mercury	0.0002
Selenium	0.09
Silver	0.005
Aluminum	0.01
Chloramines	0.10
Free Chlorine	0.50
Copper	0.10
Fluoride	0.20
Nitrate (as N)	2.0
Sulfate	100
Thallium	0.002
Zinc	0.10

Table 1— Maximum allowable chemical contaminant levels in water used to prepare dialysate and concentrates from powder at a dialysis facility and to reprocess dialyzers for multiple uses (Reproduced from ANSI/AAMI RD 62:2001)

SEDIMENT (MULTIMEDIA) FILTER (V188)

- A. Pre-Water Treatment System
 - Blend Valve
 - Back-flow Preventer
 - Booster Pump
- B. Pre-treatment
 - System (Sediment) Filters- Cartridge or Multi-Media (V188-V189)
 - Carbon Filters (V192-V197)
 - Water softener or chemical descalent (V190-V191)
 - RO- Prefilter
- C. Water Treatment
 - Reverse Osmosis (V199-V200)
 - De-ionization (V202-V206)
- D. Water Storage and Distribution loop (V208-V211)
 - Endotoxin filters (Ultrafilter) (V207)

A. PRE-WATER TREATMENT SYSTEM**Blend Valve**

- Blend Valve uses thermostatic motor to mix the hot and cold water to a setting (ie 77°F) +/- 5°F of set point.
- Ideal Temperature: 77° F to achieve maximum efficiency of RO system.
 - Cold water thicker than warm water
 - Thinner warm water mixes with bicarb better
 - Thinner warm water passes through RO membrane faster
 - Warmer water results in a greater volume being produced by the RO.
 - In northern climates, where the incoming water temperature can drop considerably during winter, the RO may not be able to provide enough water for hemodialysis operations
 - Warm water easier to warm up to treatment temperature by dialysis machine
- Blend valve is not a CMS requirement- It is an optional feature.

Backflow Preventer



- Required by plumbing codes on inlet of Dialysis Treatment System.
- Often placed following blend valve, before pretreatment
- Purpose: Prevents back pressure or syphonage to potable water supply system.

Booster Pump



- Provides proper feed water pressure to water system, (regardless of fluctuations in city supply pressure)
- Pressure regulator often installed to prevent over-pressure of water
- Proper sizing needed to prevent over pressure

B. PRE-TREATMENT

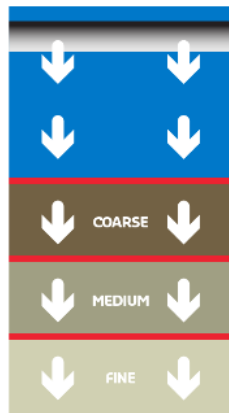
Sediment Filter (V188-V189)

- 1st component of water treatment system
- Protects equipment following it (carbon, RO, etc..)
- Removes small particulate matter (silt) in water supply
- 2 Options: multi-media filter or cartridge filter
 - a. Multi-media (depth) filter (V188)
 - b. System Filter: Multi-Cartridge Filter (V189)



Multi-media (depth) filter (V188)

- i. Bed of media-larger on top and smaller on bottom
- ii. Water flows from top to bottom
- iii. Particles trapped as water filtered downward
- iv. Monitor pressure drop across filter
 - 1. Pressure across filter is to be measured at the start of each operating day.
 - 2. The psi should be according to the manufacturer’s directions for use (DFU).
 - 3. Pressures are used to measure the resistance of flow which would indicate a problem with the filter.
- v. Advantage: no filter to replace
- vi. Disadvantage: must be backwashed per manufacturer guidelines
 - 1. If backwashed, perform outside facility operating hours.
 - 2. It should be noted that not all sediment filters can be backwashed.
 - 3. Verify daily timer used to initiate backwashing cycles set to the correct time of day



System Filter: Multi-Cartridge Filter (V189)

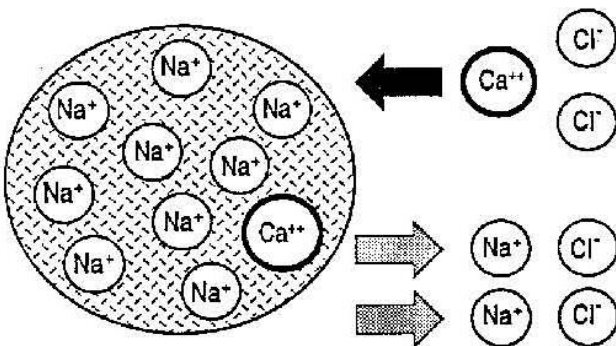
- i. Cartridge(s) contained within opaque filter housing with seals to separate feed and product water streams
- ii. Monitor pressure drop according to manufacturer instructions
- iii. Replace filters when maximum pressure drop reached according to manufacturer instructions
- iv. Advantage – no need to backflush

Protect RO Membranes from scale (hardness) Water Softener vs Chemical Feed System (V190-191):

Salt Regenerated Water Softener



- Removes Calcium, magnesium ions
- Exchanges for sodium ions
- Capacity limited- must be regenerated.
 - Regeneration includes:
 - Backwash cycle- remove particulates
 - Regenerate after facility operating hours
 - Regeneration time always visible
 - Brine Cycle- strong salt solution- overcome attraction of resin beads for hardness ions and replace with sodium
 - Rinse Cycle- remove any remaining salt solution
- Pressure across softener should be according to the manufacturer’s directions for use (DFU).
- Post softener hardness at the end of each day less than 1 GPG
- Brine tank to be checked at the start of each operating day.
- Verify brine tank contains sufficient supply of undissolved sodium chloride (~2/3 full)
- Verify control valve timer, when present, indicates the correct time of day.
- Sanitize brine tank q3-4 months



Chemical Feed System



Antiscalent chemical that bonds to hardness ions and prevents from scaling on membrane

- Chemical Feed System- antiscalent chemical:
- bonds to hardness ions
- Prevents scaling on RO membrane
- Easy to maintain:
 - No need to monitor hardness
 - No Brine tank to monitor or clean
 - No regeneration or backwash cycle
 - Keep tank filled with antiscalent to the fill line

Carbon Tanks (V192-197)

- Chlorine and chloramine added to water by municipal water supplier to prevent harmful bacteria in drinking water
- Chloramine = chlorine + ammonia
 - 3x more difficult to remove from water than chlorine
- Chlorine and chloramine are harmful to our patients
 - Can cause hemolysis which can potentially be fatal
- Backwashing Carbon vs Exchange Tank Carbon
- Backwashing: usually 2 tanks: worker/polisher
- Regular bacteria monitoring important
- Exchange tank carbon: several tanks- workers/polisher
- Only component of water treatment system that cannot be bypassed
- Two tanks in series are needed in case the first tank fails during operation.

Backwashing Carbon vs Exchange Tank Carbon



- Backwashing: usually 2 tanks: worker/polisher
 - Regular bacteria monitoring important



- Exchange tank carbon: several tanks-workers/polisher
 - If there is an exchange system in place, then there must be an established frequency to exchange the tanks to ensure that the tanks are never exhausted.
 - Measure pressure change across each tank at start of each day, which should be according to the manufacturer's directions for use (DFU).

It is requirement for Medical Director to make sure there is enough carbon for Empty Bed Contact Time (EBCT) of 10 minutes

- Calculation should be performed annually for all water treatment systems, and signed by Medical Director + Posted in Water Treatment Room
- Calculation of EBCT:
 - 1st add Product Flow from RO + Concentrate Flow (while RO is working) to calculate Total Flow in gallons per minute (gpm)
 - Total Flow x 10/7.48= Cubic Feet of Carbon needed
 - Then multiply Cubic feet of carbon/tank x # of tanks= Carbon in Use
 - Carbon in Use should be > Carbon Needed

Example of Calculation of EBCT Posted in Water Treatment Room of Dialysis Unit:

BMC North County Dialysis Center

EBCT

Empty Bed Contact Time, 10 Minute

Carbon Needed

Product Flow = 5.0 gpm +
Concentrate Flow = 5.0 gpm =
Total Flow = 10.0

Total Flow X 10 / 7.48 = Cubic Feet needed
10.0 X 10 / 7.48 = 13.4 cf carbon

Carbon in Use

4 tanks
3.5 cubic feet per tank =
14 cubic feet

Updated September 6, 2016 by EAS, Reviewed by DH

MEDICAL DIRECTOR:
David Henner
David E. Henner, DO 09/08/2016

Chlorine/Chloramine Testing (V196)

- Take the sample to measure between first i.e.. worker(s) and second i.e.. Polisher(s) tanks at start of operating day.
- Total Chlorine Level (Free Chlorine + Chloramine) must test to <0.1 mg/L
 - If tested separately, chloramine must test <0.1 mg/L and free chlorine <0.5 mg/L
- If Post-worker test negative, then test prior to each clearly designated shift, or if no designated shift, then every four hours during operating day
 - Staff performing test needs to have color-blind testing performed and documented as passing test in their files
 - Consider having 2 staff members perform test as double check: ie RN verifies tech and both initial result on daily water testing log
- **Chlorine/Chloramine- Actions if 1st Sample Port Positive (V197)**
 - If post worker, positive, test post polisher immediately

- If Post polisher test positive-> Take patients off dialysis, and shut down unit immediately + notify Medical Director
 - If post-polisher test negative, test every hr up to maximum 72 hrs.
 - Notify Medical Director
 - Order new carbon tanks ASAP
- If tanks not replaced within 72 hrs, shut down unit
- Any chlorine breakthroughs must be immediately reported to the medical director and be included as an action step to investigate and identify cause(s), and review policy and practice within the QAPI process
- Chlorine breakthroughs are very serious conditions that warrant corrective actions. Those corrective actions may include backwashing carbon tanks, rebedding or replacement of the tanks or addition of an adjunct system such as chemical injection to address extremely high chlorine or chloramines load from the municipal supplier. Testing must confirm acceptable levels of chlorine/chloramines before dialysis treatments can be resumed. Remember that the assistance of your water vendor may be needed to investigate the cause(s) of the breakthrough.

RO Pre-filter



- Protect RO unit from small particulate matter
- Measure pressure change across filter at start of each day, which should be according to the manufacturer's directions for use (DFU).

c. WATER TREATMENT

Reverse Osmosis (RO) Equipment (V199-201)

- Main “Water Treatment” of water treatment system
- Using hydrostatic pressure, forces feed water through RO membranes
- Product water = “Permeate” (good water)
 - Measured in conductivity- μS
- Reject = “concentrate”- sent to drain
- Set to remove more than 90 percent of solutes across the RO equipment
 - $\% \text{ Rejection} = \frac{\text{conductivity of permeate}}{\text{conductivity of incoming water}} \times 100$
- Efficiency measured by conductivity at start of each operating day.
- Measure pressure across filter at start of each operating day, which should be done according to the manufacturer’s directions for use.
- RO recovery~50%- 50% product flow, 50% concentrate
- Lower temperature and pressure=lower product flow
- Disinfect monthly
- Clean RO quarterly, or per manufacturer guidelines
- Temperature to be monitored continuously with the measuring equipment visible at all times to achieve temperature constancy.
- Tap water to be delivered to system by booster pump at a pressure defined according to the specifications of the equipment in service. Generally, this is required so that water can be pushed through the system and through the RO. Some areas do not require one, as the city water has enough pressure.
- It is important to set water rejection rates as a measure of quality of water. All manufacturers do not incorporate preset limits which would activate audible alarms when quality of product water diminishes, but all do offer a process to follow in determining a limit to set. The medical director and chief water technician should determine set point(s)/rates and be able to discuss how determinations were made.
- RO systems are not meant to remove chlorine/chloramines. RO systems/devices remove dissolved inorganic solutes, as well as bacteria and bacterial endotoxins.
- When the RO system is the last chemical purification process in the water treatment system, it should include a process (i.e., divert to drain) to prevent patient exposure to unsafe water product. In the absence of an automatic divert to drain valve for the RO, facility staff must know how to manually stop water flow to the dialysis machines and



other dialysis related equipment (i.e., concentrate mixing stations, reprocessing/reuse equipment) should the water quality alarm sound.

Deionization (V202-V206)

- Deionization (DI) is an alternative water treatment component and is not required in every facility.
- Measured in Resistivity (megohm)
- DI can be used as emergency back-up to RO or to polish RO.
- If used as polisher, RO should be worker and DI polisher.
 - DI usually set up as worker/polisher as well when following RO.
 - Exchange tanks at least every 3 months, or more often as indicated by resistivity measurements (when worker is spent and <1megohm). If polisher DI is below 1 megohm, must bypass DI if used as polisher to RO (run on RO permeate) until DI tanks exchanged.
- Deionizers must be monitored continuously using resistivity monitors that compensate for temperature and are equipped with audible and visual alarms. Patients should not be dialyzed on DI water with resistivity less than 1.0 megohm-centimeter measured at the output of the deionizer. Resistivity must be continuously monitored and readings documented on log sheet twice each treatment day.
- An audible and visual alarm shall be activated when the product water resistivity falls below preset limits and the product water stream is prevented from reaching any point of use by an automatic divert to drain.
- There must be an ultrafilter or other bacteria and endotoxin reducing device following the DI tanks to remove microbiological contaminants that may originate in the deionizer resin bed.
- DI tanks should be stored dry and should not be stored wet. Once they become wet the facility has the responsibility to flush the tanks daily and perform bacterial and endotoxin monitoring. Once they are used, they should not be stored again.

Carbon tanks should remain in place to remove chlorine and chloramines. DI tanks do NOT remove viruses or bacteria.



D. WATER STORAGE AND DISTRIBUTION SYSTEM (V208-V211)

- Direct Feed- RO product water flows directly into loop or dialysis machine
 - Usually used for portable RO systems or small, acute systems
 - Loop returned to RO feed to recapture product water

- Advantage: offers least favorable environment for bacterial proliferation
- However:
 - 1) purification cascade must be sized to provide sufficient water to meet the peak demand and
 - 2) System must have sufficient pressure at the end of the purification cascade to distribute the water to the points of use
- Storage tank-indirect (Most common)
 - RO product water flows into storage tank
 - Treated water pumped by recirculation pump in distribution loop and back to storage tank

Water Storage (V208-210)

- Water storage and distribution systems should be designed specifically to facilitate bacterial control, including measures to prevent bacterial colonization and to allow for easy and frequent disinfection.
- Routine monitoring of water storage tanks for bacteria and endotoxin levels is generally done indirectly by monitoring the water at the first outlet to the distribution loop.
- If direct monitoring of a water storage tank is done as part of an investigation, bacteria and endotoxin levels should be recorded on a log sheet.

Storage Tank



- Should be sized as small as possible to meet peak usage (usually <250 gallons)
- Conical shaped with drain at bottom
- Vent through air filter
- Spray mechanism to wash down top of tank
- Vent filter- replace annually
- Disinfect with loop monthly

Distribution Loop and Piping (V211-212)



- Dual Distribution Pumps- good idea to provide redundancy
- Continuous recirculation loop
- Avoid dead legs > 3 inches
- Avoid uneven, slanted pipe cuts, right angles
- Flow should be more than 3 feet per second measured indirectly or more than 1.5 feet per second measured directly with the purpose to reduce bacterial films.
- Shall be constructed of material that does not contribute to chemical or bacterial contamination. Unacceptable materials include but are not limited to aluminum, copper, lead, and zinc.

Endotoxin Retentive Filters (V207)



- Validated for endotoxin and bacterial removal
 - Removes endotoxins down to 0.05-0.2 micron
- Usual position is post storage tank or DI
- Measure pressure change across filter at start of each day, which should be according to the manufacturer's directions for use (DFU).

Portable RO or DI for Acute and Home

- Designed to be used in same area as dialysis patient care (supervised)
- Must test for total chlorine before each treatment
- Sample for bacteria and endotoxins at least monthly before disinfection, and disinfect at least monthly
- Special microbial needs- downtime leads to bugs
 - Disinfect at least monthly
- Portable DI- worker/polisher
 - Disinfect filter housings and tubing monthly
 - Exchange tanks q 3 months



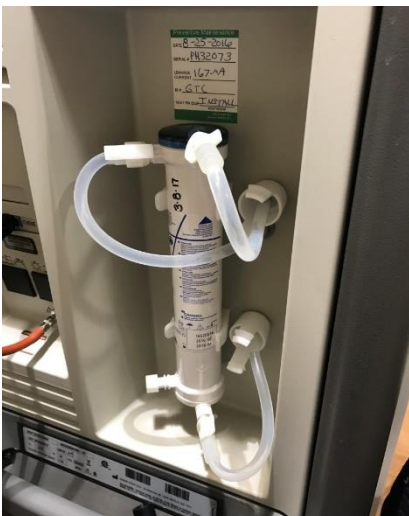
Dual Stage Endotoxin-Grade Filter in Distribution Loop

- Optional - not required by CMS regulations, but may help provide additional layer of protection for patient/dialysis machine from bacteria or endotoxins that may be present in loop
- Designed to help remove bacteria or endotoxins that may be present in water distribution loop.



Wall Box

- Usually mounted at dialysis station prior to wall box (inside cabinet), or may be placed after wall box (outside cabinet)
- Validated for endotoxin and bacterial removal
- Typically needs to be changed annually

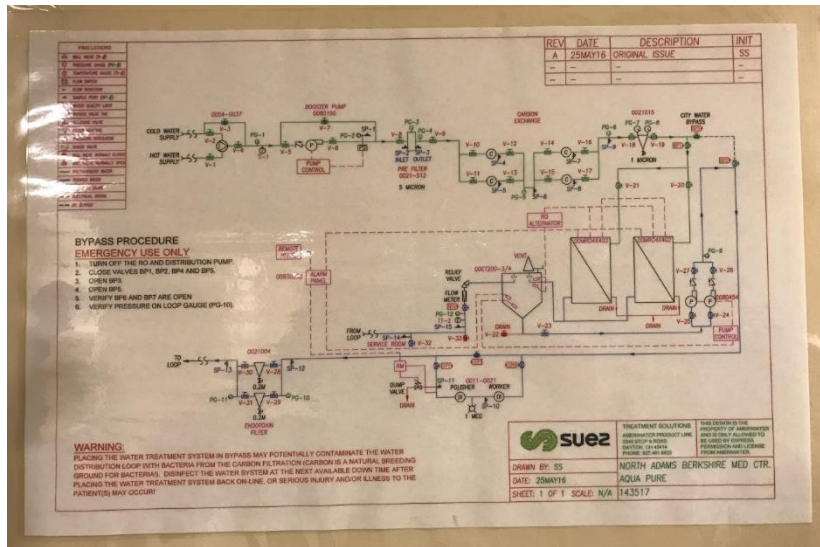


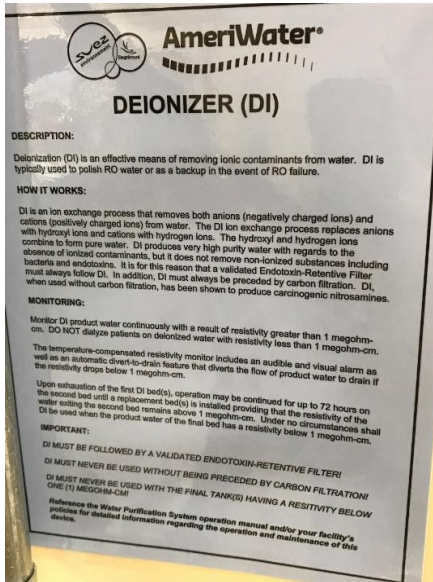
Endotoxin-Grade Filters for Dialysate

- Not required by CMS regulation.
- May help prevent bacteria or endotoxins in dialysate (from bicarb solution or internal pathway of machine) from reaching dialyzer or patient
- Typically placed after dialysate proportioned in machine, just prior to dialyzer
- Typically need to be changed after around 100 uses; the number of uses should be monitored and logged.

Labeling Requirements (V187)

- AAMI and FDA, CMS
- Schematic
 - From CMS Interpretive Guidance: V187 ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 8 Environment: *schematic diagrams/labels* Water systems should include schematic diagrams that identify components, valves, sample ports, and flow direction.
 - Additionally, piping should be labeled to indicate the contents of the pipe and direction of flow.

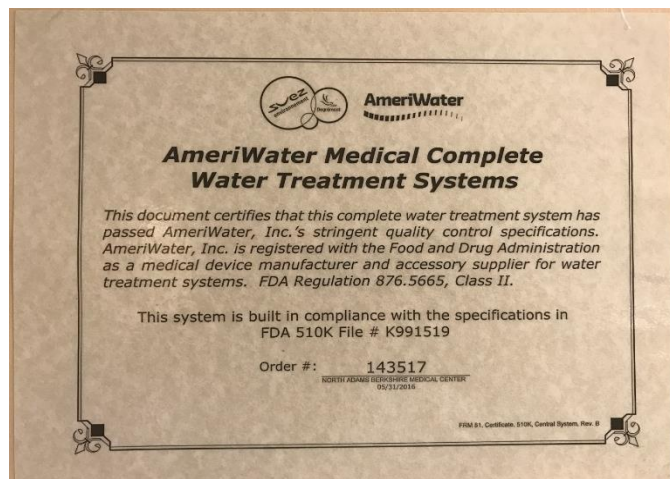




If water system manufacturers have not done so, users should label major water system components in a manner that not only identifies a device but also describes its function, how performance is verified, and what actions to take in the event performance is not within an acceptable range.

510K Certificate

CMS Interpretive Guidance: Under FDA regulations at the time these regulations were published, all water treatment devices and systems installed after May 30, 1997 must meet review requirements under section 510(k) of the Food, Drug, and Cosmetic Act (21 USC sec. 360(k)) as described in Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis. Equipment installed prior to that date is not required to have evidence of FDA 510(k) approval. Regardless of when a water purification system was installed, the system must yield water and dialysate that meets these AAMI standards and must be monitored and maintained in accordance with the ANSI/AAMI RD52 guidelines, as incorporated by reference in these regulations.



Water Sampling for Microbial Testing

V252 RD52: Microbial monitoring methods: monthly water samples/method

- Culture water:
 - New systems: Weekly until pattern established
 - Established systems: Monthly unless greater frequency dictated by historical data at institution
- Monitoring: Direct plate counts and measurement of endotoxins
- Sample collection: Collect water samples directly from outlet taps in different parts of the water distribution system.
- Sample collection ports must be rinsed for at least 1 minute at normal pressure and flow rate. Note that sample port cannot be cleaned or disinfected as it could potentially skew the test results.

Dialysate Sampling V253 RD52:2004 Microbial monitoring methods:

Dialysate: *monthly dialysate sample/collection/frequency:*

- Culture Dialysate:
 - New systems: Weekly until pattern established
 - Established systems: Monthly unless greater frequency dictated by historical data at institution
- Sample Collection: Collect dialysate samples from at least two machines monthly, and from enough machines so that each machine is tested at least once per year.

Actions if Dialysate > Action Level

- Conduct investigation including:
 - Retesting + machine
 - Reviewing compliance with disinfection and sampling procedures
 - Evaluating microbiological data for the previous 3 months to look for trends
- Notify and discuss with Medical Director

Current CMS Standard RD52:2004:

Action Levels - Water and Dialysate

ANSI/AAMI Bacteriology of water: *max & action levels:*

- Maximum allowable levels:
 - Total viable microbial count (TVC) <200 CFU/mL
 - Endotoxin concentration (LALs) <2 EU/mL
- Action levels:
 - Total viable Microbial count (TVC) <50 CFU/mL
 - Endotoxin concentration <1 EU/ml

AAMI 23500 Updated Standards (2019): Water and Dialysate Microbial Levels

Water:

Contaminant	Maximum Allowable Level	Action Level
TVC	<100 CFU/ml	50 CFU/ml
Endotoxin	<0.25 EU/ml	0.125 EU/ml

Dialysate:

TVC and Endotoxins in Standard and Ultrapure Dialysis Fluid			
Contaminant	Standard dialysis fluid		Ultrapure dialysis fluid
	Max allowable	Action level	Maximum Allowable level
TVC	<100 CFU/ml	50 CFU/ml	<0.1 CFU/ml
Endotoxin	<0.5 EU/ml	0.25 EU/ml	<0.03 EU/ml

Potential Benefits of Ultrapure Water for dialysate compared to Standard Dialysate:

- Reduced inflammation (i.e. lower β 2-microglobulin and associated amyloid disease)
- Improved responsiveness to erythropoietin (lower ESA doses possible)
- Improved nutritional status
- Improved preservation of residual renal function

Alternative Water Supply (V202-206)

Disinfection of Loop/RO

- What Should be Disinfected:
 - RO, Storage Tank, Distribution Loop, Bicarb Mixing, Bicarb Distribution and Loop, Dialysis Machine, Reuse Machine and Rinse Station
 - Disinfectants:
 - Bleach 1:100 (not in RO membranes)
 - Peracidin 1:100
- The recommended frequency is at least monthly for water distribution and RO (bicarb mixing tank and machines- daily)
 - All systems need regular disinfection to prevent biofilm
- Ozone- Potential to be best disinfectant- dissipates, no rinse needed

Heat Disinfect System (V217-V218)

(V217) Hot water (>80C) may be used to control bacterial proliferation in water storage and distribution system

- Systems need to be constructed from heat-resistant materials
- Follow manufacturer instructions

**Potential Advantages:**

- May minimize risk from human error
- May yield more consistent results with each disinfection
- May reduce operating and labor costs
 - Possible better disinfection: bacteria killed at >7-log₁₀
- Newer systems may meet AAMI 23500 standards
- Newer systems could be fully automatic and operate on a weekly disinfection schedule
- Dialysis Machine Draw Off: Disinfects feed water hose between station wall box and dialysis machine

DOCUMENTATION OF MEASUREMENTS (V259-278)

- All documentation must be maintained on a log sheet, which is signed, timed and dated to the same standard as the patient's medical records.
- *"IF IT WAS NOT DOCUMENTED, IT WAS NOT DONE"*
- Although not a function of water purification, those medical directors that oversee dialysis facilities that reuse hemodialyzers and/or bloodlines should refer to the AAMI "Reuse of Hemodialyzers," third edition, ANSI/AAMIRD 47:2002/A1:2003 and V Tags (V300-383) for guidance.

References:

ANSI/AAMI RD52:2004: [Dialysate for Hemodialysis](#)

ANSI/AAMI/ISO 11663:2009: [Quality of dialysis fluid for hemodialysis and related therapies](#)

ANSI/AAMI/ISO 23500:2011: [Guidance for the preparation and quality management of fluids for hemodialysis and related therapies](#)

AAMI TIR43:2011: Technical Information Report: [Ultrapure dialysate for hemodialysis and related therapies](#)

CMS: [CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES: Interpretive Guidance 2008](#)

[Water Treatment and Monitoring for Dialysis](#): by Ameriwater

ESRD Survey Training: [ESRD Core Survey Field Manual Version 1.8](#)

Permission obtained by MAC Chair from Ameriwater to include pictures of water system components as examples for purpose of educating Medical Directors

SELF-ASSESSMENT: WATER PURIFICATION

1. Under normal circumstances, Chlorine/Chloramines testing is required to be performed:
 - a. Daily
 - b. Weekly
 - c. Monthly
 - d. Between every shift
 - e. Hourly

2. Which of the following pretreatment components of the water system can NOT be bypassed in the event of a temporary water issue:
 - a. Multimedia/sediment filter
 - b. Carbon tanks
 - c. Water softener
 - d. Cartridge filter

3. Water softeners and Anti-Scalent Systems remove hardness from the water to help prolong the life of the RO membranes. Which ions are being removed:
 - a. Potassium
 - b. Calcium and Magnesium
 - c. Chloride
 - d. Bicarbonate

4. Which of the following processes best explains how RO works?
 - a. Sodium moves actively across semipermeable membrane in exchange for potassium
 - b. Sodium moves down its concentration gradient passively across semipermeable membrane
 - c. Water moves passively across semipermeable membrane from an area of low solute concentration to an area of high solute concentration
 - d. Water is actively pumped through a semipermeable membrane from an area of higher solute concentration to an area of low solute concentration

5. Which of the following best describe the function of the back-flow preventer:
 - a. prevents back pressure or back syphonage to the potable water supply
 - b. prevents water from going back to the storage tank from the loop
 - c. prevents product water from going back to RO
 - d. prevents water from going back through carbon tanks after it enters RO

6. If the test for chlorine/chloramine is positive at the 1st sample port after 1st carbon tank(s), but negative at the next sample port after 2nd carbon tank(s), which of the following is true:
 - a. All dialysis treatments must be stopped immediately without exception
 - b. Dialysis patients need to be immediately evacuated and the Emergency Plan needs to be activated
 - c. Dialysis treatments may continue, but chlorine/chloramine testing needs to be performed every hour at the sample port after 2nd carbon tank(s), and the Vendor should be called to replace carbon tanks ASAP
 - d. Dialysis treatments may continue without any further testing

7. If the test for chlorine/chloramine fails (positive test) at both 1st sample port after 1st set of carbon tanks the sample port after 2nd set of carbon tanks, which of the following is true:
 - a. The carbon tanks can be bypassed to continue dialysis
 - b. The patients can continue dialysis, but need to switch from RO to DI
 - c. Dialysis treatments need to be stopped immediately
 - d. The carbon tanks should be immediately backflushed
 - e. Dialysis treatments can continue as long as conductivity alarm does not sound

8. If RO system fails, which if the following is true:
 - a. The RO can never be bypassed, and dialysis must be immediately stopped
 - b. The RO alarm should be disabled so it doesn't sound, and treatments should continue
 - c. The water softener should be backlashed immediately
 - d. If available, DI back-up system can be used until the RO issue is fixed, or DI is spent

9. Which parameter is monitored continuously by the RO for permeate?
 - a. Chloramines
 - b. Conductivity
 - c. Empty Bed Contact Time
 - d. Endotoxins

10. Which of the following best describes the good (product) water that is produced by the RO after it goes through RO membranes:
 - a. Reject
 - b. Hard
 - c. Permeate
 - d. Concentrate

11. Which of the following describes the water that is sent down the drain by the RO, and not used for dialysate:
 - a. Permeate
 - b. Concentrate
 - c. Product
 - d. Hard

12. How is dialysis water loop monitored for presence of bacteria?
 - a. Water is cultured from multiple sample ports along loop onto culture plate and incubated at least monthly
 - b. Chlorine/Chloramines are tested daily
 - c. Water hardness is checked daily
 - d. LAL assay is performed at least monthly at multiple sites along water loop
 - e. Both A and D are correct

13. If Endotoxin LAL testing at 0.25 EU/ml is positive at one site in loop, but negative at stations, machines, and beginning and end of the loop:
 - a. There is likely water loop biofilm with breakthrough contamination. Take all patients off dialysis and close unit immediately
 - b. Sample port contamination. Repeat LAL testing at single site that was positive
 - c. False negative results in loop. Stop dialysis and disinfect loop immediately

- d. Problem with LAL test itself. Send LAL test to another lab.
14. If LAL tests at 0.25 EU/ml are positive in multiple sites along loop, including end of loop and post RO, but negative at machines tested: The most likely explanation for these results, and the most reasonable next plan is:
- Sample port contamination. Repeat testing but no other action required
 - Loop has GNR present producing endotoxin, but the endotoxin filter on back of machines has prevented Endotoxins from getting into dialysate. Disinfect loop ASAP.
 - Loop has GNR present producing endotoxin, but machines have killed bacteria with acid, so no further action is required.
 - Machine problem. Remove 2 machines from unit and disinfect in bleach
15. Why is LAL test important?
- To make sure no chloramines are present in water
 - To make sure the number of endotoxins in water that are released by Bacteria is below the AAMI Standard allowable levels
 - To make sure ultrapure water contains no ions
 - To make sure no acid leaks into water
16. What is most important reason to remove Chlorine and Chloramines in water pretreatment system:
- Because Chlorine has bad taste in water
 - Chlorine and Chloramines can lead to hemolysis, arrhythmias, chest pain, or death
 - To avoid a reaction with sodium in blood leading to salt formation
 - So, the RO doesn't have to work so hard
 - To prevent clogging of RO membranes
17. What is primary reason regular loop disinfection important:
- To control bacterial growth and prevent biofilm
 - To kill any hepatitis B that may have leaked from one patient to another
 - To prevent buildup of calcium in pipes
 - To remove any chloramines from water
18. How often is it required to disinfect loop at a minimum:
- Daily
 - Monthly
 - Annually
 - Only when there is growth in microbial cultures
19. What does AAMI Standard "Action level" for microbial testing refer to:
- The level at which you must shut down unit immediately if you exceed it
 - The level at which no humans can survive
 - The level at which some form action should be taken in response to result, including retesting sample or disinfecting loop
 - The level at which you should stop disinfecting loop because no more action is required

ANSWER KEY: 1. D 2. B 3. B 4. D 5. A 6. C 7. C 8. D 9. B 10. C
11. B 12. E 13. B 14. B 15. B 16. B 17. A 18. B 19. C

DEALING WITH PATIENT-PROVIDER CONFLICT IN THE UNIT



DEALING WITH PATIENT-PROVIDER CONFLICT IN THE UNIT

Patient-provider conflict presents unique challenges for the safe provision of dialysis care. Conflicts between patients and providers may result in responses from either party that could result by virtue of these actions in “contributing to an environment that impedes the safe and effective delivery of care for themselves and others and/or that comprises the safety or effectiveness of the healthcare team.” These situations may result when patients 1) express themselves in the dialysis facility in a manner that may be interpreted by others as being aggressive, threatening, or disrespectful of other patients or their caregivers; 2) fail repeatedly to comply with schedules and treatment recommendations where these patient choices adversely affect the care of other patients; 3) fail to demonstrate self-awareness of the consequences of their actions on other patients; or 4) fail to demonstrate improvement in their actions when meaningful council has been provided and strategies to mitigate the sources of the conflict explored. Patients who overtly threaten other patients or any staff with physical or emotional harm are by definition “at risk” or “difficult patients” and this one circumstance requires specified responses defined by the conditions-for-coverage and involving immediate response and the ESRD Network’s participation. In this context, the patient should not be deemed a “difficult patient” if a simple intervention from the facility social worker, nursing staff or provider can resolve the conflict (see [Decreasing Patient-Provider Conflict \(DPC\) Provider Manual](#) for more information on this subject).

In this section we will address the medical director’s contribution to dealing with patient-provider conflict and specifically with a “difficult patient” as defined above. An optimal approach to dealing with such a patient is best considered in the context of the National Task Force statement on decreasing dialysis patient-provider conflict and the supporting tools for the proper handling of a difficult patient where involuntary discharge is a possibility. The National Task Force has developed a number of tools that detailed in the [Decreasing Patient-Provider Conflict Provider Manual](#). The taxonomy and the processes are outlined in the pathway shown below for decreasing patient-provider conflict. The rationale for the National Task Force’s recommendations is documented in an executive summary included in the manual and summarized separately in the [Final Report](#). Each of these documents are available at <https://esrdncc.org/index/decreasing-dpc>

DPC TAXONOMY

When conflict occurs in the dialysis facility, the contributing behaviors can be organized into three categories (Taxonomy) based on who is placed “at risk”:

1. Behaviors by a patient, staff, family members or others may result in placing the **patient’s** own health, safety and well-being at risk.

2. Behaviors by patients, staff, family members or others may put the safety and effective operations of **the dialysis facility** at risk.
3. Behaviors by patients, staff, family members or others may put the health, safety or well-being of **others** at risk. Others include patients, staff, or anyone else in the dialysis facility.

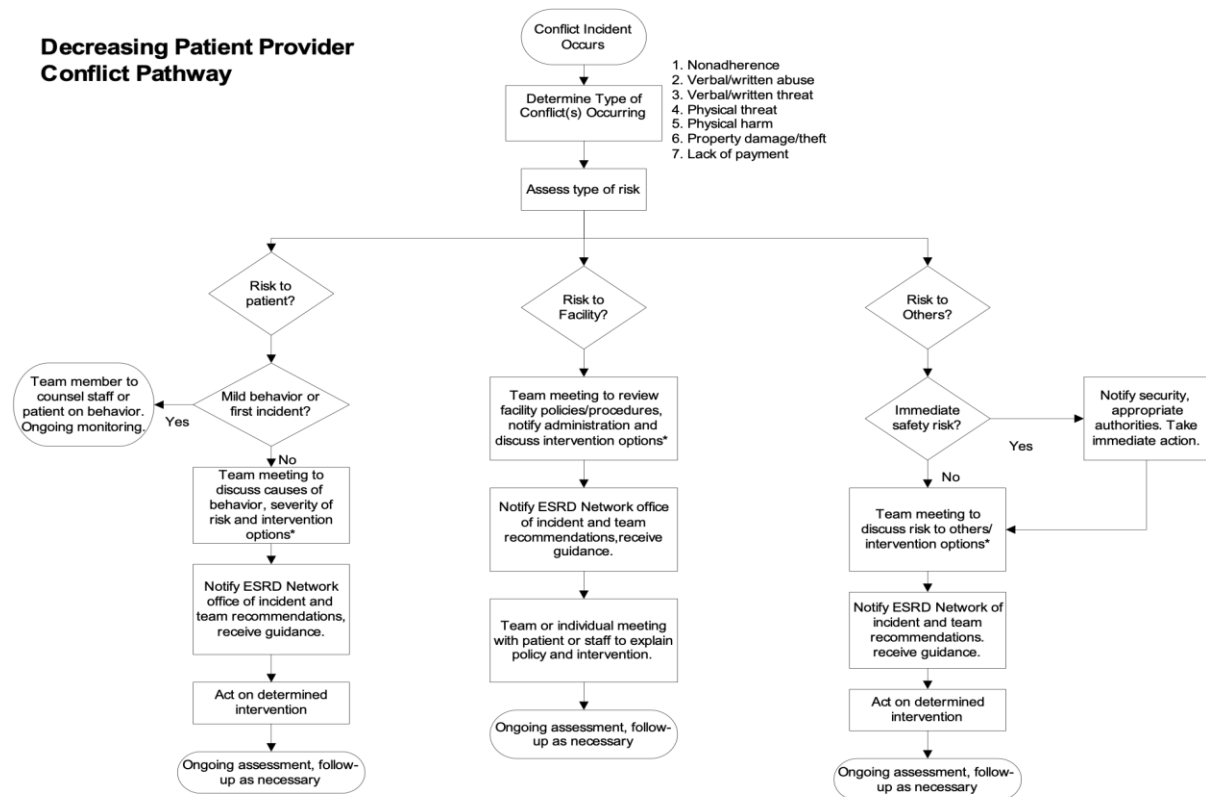
The table below includes behaviors that define types of conflict. This list is not all-inclusive but explains the main behavioral contributions to conflict and specific examples of behavior by patients, staff, family members or others that contribute to putting the patient, the facility, or others at risk.

Glossary	Taxonomy		
	Patient at Risk	Facility at Risk	Others at Risk
<p>1. Nonadherence: Noncompliance with or nonconforming to medical advice, facility policies and procedures, professional standards of practice, laws and/or socially accepted behavior toward others (Golden Rule).</p>	<p>a. Patient Example: Missed or shortened treatments may result in need for hospitalization or death.</p> <p>b. Staff Example: Negative comments or scolding of a patient for nonadherence that may lead to conflict. Withholding opportunity to reschedule missed treatment. Amplify the intensity of patient’s nonadherence response.</p>	<p>c. Patient Example: Unreasonable refusal to allow certain staff to provide care, causing disruption in facility schedule, or refusing to follow clinic rules and policies.</p> <p>d. Staff Example: Unreasonable refusal to care for a particular patient, refusal to enforce policies and procedures, unauthorized manipulation or change of a prescribed treatment or physician’s orders. Staff’s threatening to abandon the care setting or quit if they are required to care for a particular patient.</p>	<p>e. Patient Example: Actions that encourage other patients to miss treatments or not follow treatment requirements or clinic policies</p> <p>f. Staff Example: Inconsistent or otherwise non-transparent enforcement of dialysis schedule and/or not providing full dialysis treatments. Not following facility policies and procedures that would provide intervention for patients’ nonadherence. Treating some classes of patients differently when insisting of adherence to unit procedures.</p>
<p>2. Verbal/written abuse: Any words (written or spoken) with an intent to demean, insult, belittle or degrade facility or medical staff, their representatives, patients, families or others.</p>	<p>a. Patient Example: Name-calling, insults, use of obscenities, verbal or written sexual harassment.</p> <p>b. Staff Example: Demeaning words directed at patients, use of disrespectful language. Verbal or written sexual harassment.</p>	<p>c. Patient Example: Verbal incidents that cause disruption or delay in the ongoing treatment of other patients.</p> <p>d. Staff Example: Insults or demeaning words directed at other staff, causing disruption or delay in the facility operations.</p>	<p>e. Patient Example: Verbal or written abuse directed at other patients or others in the facility.</p> <p>f. Staff Example: Verbal or written abuse directed at others at the facility.</p>

<p>3. Verbal/written threat: Any words (written or spoken) expressing an intent to harm, abuse or commit violence directed toward facility or medical staff, their representatives, patients, families or others.</p>	<p>a. Patient Example: Threatening statements directed toward others that intimidate, cause fear, or disrupt other patients accessing safe care.</p> <p>b. Staff Example: Threatening statements that cause patients to feel intimidated, fearful or otherwise unsafe receiving treatment in the facility.</p>	<p>c. Patient Example: Threats that result in the need for facility use of additional resources (e.g. security guard) for the safety and protection of patients, staff and visitors.</p> <p>d. Staff Example: Threats directed at a patient or patients that result in patient transfer to another facility. Legal action against staff or the facility may occur as a result of a verbal threat.</p>	<p>e. Patient Example: Threats or statements that create an unsafe environment for other patients, staff and others.</p> <p>f. Staff Example: Threats or statements that create an unsafe environment for patients, staff and others.</p>
<p>Glossary</p>	<p>Taxonomy</p>		
	<p>Patient At Risk</p>	<p>Facility At Risk</p>	<p>Others At Risk</p>
<p>4. Physical threat: Gestures or actions expressing intent to harm, abuse or commit violence toward facility or medical staff, their representatives, patients, families, or others.</p>	<p>a. Patient Example: Threat of self-harm (e.g. suicide, pulling out needles or catheter) or other actions such as raising one’s hand as if to strike.</p> <p>b. Staff Example: Threatening to hurt patient during needle insertion or other threatening actions such as threatening to perform a procedure without patient’s consent.</p>	<p>c. Patient Example: Threats that result in need for facility use of additional resources (e.g. security guard) for the safety and protection of patients, staff and visitors</p> <p>d. Staff Example: Threats directed at a patient or patients that result in patient transfer to another facility. Legal action against staff or the facility may occur as a result of a physical threat.</p>	<p>e. Patient Example: Threatening to use and/or possession of a weapon or any instrument capable of injuring others with the intent to intimidate or harm others, either in the facility or on the premises.</p> <p>f. Staff Example: Threatening to use and/or possession of a weapon or any instrument or medical device capable of injuring others with the intent to intimidate or harm others, either in the facility or on the premises.</p>

<p>5. Physical harm: Any bodily harm or injury, or attack upon facility or medical staff, their representatives, patients, families or others.</p>	<p>a. Patient Example: Any incidents of physical harm such as changing machine settings, pulling own bloodlines, refusing medication.</p> <p>b. Staff Example: Withholding treatment from the patient without just cause. Intentionally causing pain or injury to patient or patient’s access.</p>	<p>c. Patient Example: Incidents that result in law enforcement intervention and facility use of additional resources (e.g. security guard) for the safety and protection of patients, staff and visitors.</p> <p>d. Staff Example: Physical harm directed at patient(s) that result in patient transfer to another facility. Legal action against staff or the facility may occur as a result of harm.</p>	<p>e. Patient Example: Incidents of physical harm to others in the facility (e.g. other patients, visitors, medical or facility staff), including sexual harassment.</p> <p>f. Staff Example: Incidents of physical harm to others in the facility (e.g. other patients, visitors, medical or facility staff).</p>
<p>6. Property damage/theft: Theft or damage to property on premises of ESRD facility</p>	<p>a. Patient Example: Vandalism or damage to dialysis equipment or facility premises.</p> <p>b. Staff Example: Stealing from patient.</p>	<p>c. Patient Example: Intentional and malicious damage of equipment/property.</p> <p>d. Staff Example: Intentional and malicious damage of equipment/property.</p>	<p>e. Patient Example: Stealing or damaging the property of others.</p> <p>f. Staff Example: Stealing or damaging the property of others.</p>
<p>7. Lack of payment: Refusal to maintain or apply for coverage or misrepresentation coverage.</p>	<p>a. Patient Example: Refusing to apply for insurance coverage for which patient is eligible.</p> <p>b. Staff Example: Intentionally providing inaccurate or inadequate information to a patient about insurance resources.</p>	<p>c. Patient Example: Withholding or refusing to deliver insurance payments to facility.</p> <p>d. Staff Example: Uninsured or underinsured patients affect facility’s ability to provide adequate staffing.</p>	<p>e. Patient Example: Lack of payment may result in the elimination of some patient services, for example, preferred dialysis shift schedule.</p> <p>f. Staff Example: Reduced hours, layoffs or reassignment to another facility location if facility is unable to operate due to inadequate revenues.</p>

There are many potential unintended consequences of failure to address any of these patient-provider conflicts. A patient who does not agree to or adhere to treatment prescriptions may affect the morale of the caregivers including family members and friends who contribute to care (care-partners) on the team and by example, encourage less than optimal acceptance of treatment recommendations by other patients. Their actions will affect the treatment experience for other patients even if the patient’s challenging behaviors is not posing a defined persistent or immediate risk to other patients or to the facility and staff.



* Intervention options: Rule out any metabolic causes for behavior, patient/staff counseling, patient/staff education, patient/family meetings including review of care plan, review of policies/procedures, ethics committee review, patient psychiatric evaluation referral and treatment, patient behavior contract, patient dismissal/discharge or staff suspension or termination only if all other interventions have failed or there is an immediate safety risk.

DEALING WITH THE PATIENT EXHIBITING DIFFICULT BEHAVIOR: GENERAL CONSIDERATIONS

A systematic approach is required involving all members of the healthcare team including the patient's attending physician and the medical director. If involuntary discharge is anticipated as a possible outcome of the process, **the medical director is responsible for ensuring that all elements of the involuntary discharge process are completed including the notification requirements of the ESRD Network and the state department of health.** (See Checklist Below)

INVOLUNTARY DISCHARGE CHECKLIST FOR DIALYSIS FACILITIES

If you have made the decision to involuntarily discharge a patient for any reason other than severe and immediate disruptive behavior (for example: non-payment, ongoing abusive or disruptive behavior, physician discharge, unable to provide medical care, other) make sure that you have covered the following, in accordance with the Conditions for Coverage §494.180 (f):

- Notify the Network of the potential IVD as early intervention may prevent the situation from escalation to the point of discharging the patient.
- A comprehensive reassessment (offer the KDQOL) and revision of the plan of care for each patient considered for potential IVD as these patients would be considered unstable.
- Document** in patient's medical record the ongoing problem.
- Document** the impact of behavior on other patients/staff in Facility Governing Body records.
- Document** all steps to resolve the problem (including behavioral agreements and patient/staff meetings) and adherence to the facility policy regarding disruptive/abusive behavior.
- Document** patient response to each step taken and the reassessment of the situation.
- Obtain a written physician's order signed by **both** the Medical Director **and** the patient's attending Physician agreeing with the patient discharge.
- Send all agreements, letters of notification of discharge or other written communication with the patient regarding the problem to the Network.
- Contact another facility, attempt to place the patient there, and document your efforts.
- Send all medical records requested by the Network in a timely manner.
- Notify the State Survey Agency of the involuntary discharge with in ten days of discharge and send verification of discharge to the Network.

DEALING WITH PATIENT-PROVIDER CONFLICT: THE MEDICAL DIRECTOR'S RESPONSIBILITIES

The Decreasing Dialysis Patient-Provider Conflict Provider Manual includes a series of steps that can be employed to build a robust process for dealing with any difficult patient in the dialysis facility, for proper training of all members of the team, and for continuously assessing and improving the quality of these processes.

The medical director has some unique roles in these processes. In addition to ensuring compliance with dialysis conditions of coverage and all relevant state and federal regulations for documentation and notification, the medical director is responsible for ensuring a systematic process that protects and respects patients, staff, and the patient with whom there is conflict is in place and employed. These processes can be summarized below.

Step 1: Define boundaries of acceptable and unacceptable behaviors. It is impossible to address the needs of the dialysis facility and of the patient in question without *a priori*, clearly defined boundaries of unacceptable behaviors that conform to established rules of conduct for a medical facility. Such unacceptable behaviors might include: 1) interference with the care or privacy of another patient; 2) insulting or insensitive language when dealing with other patients or care-partners (family caregivers); and 3) inappropriate demands for service; e.g. insisting on being initiated ahead of other scheduled patients, specific schedules, etc. Such boundaries should be determined by the facility governance led by the medical director. The Decreasing Patient-Provider Conflict Provider Manual includes a detailed description of tools for defining identifying patient-provider conflicts that result in “difficult” patient situations, resolving conflict, and tools for team building and training.

Step 2: Define who is responsible for each component of the identification of the problem, discussion about and determination of the intervention, and implementation of the intervention. This is an essential activity of the medical director. The medical director will build on the team concept to deal with the difficult patient.

- i. The social worker and/or the medical director (the latter with the knowledge of the attending physician) will interview the patient involved in the conflict to determine if the patient’s behavior is related to issues (potentially rectifiable) that the patient is having with processes of care, and whether there are reasonable changes in the processes suggested by this dialogue that should be considered. The medical director is responsible for ensuring that such a dialogue with the “patient” has occurred.
- ii. The medical director, DON, and social worker will remind the patient involved in the conflict of their rights (including the right of confidentiality) and their responsibilities and the rights of the facility to protect other patients and the care-partners.

- iii. The medical director will inform the patient of the respective roles of the attending physician and of the medical director. The medical director sets policy and ensures a safe-care environment; the attending physician provides direct patient care.
- iv. The medical director must ensure professionalism from the entire healthcare team when dealing with a problem patient. The medical director must ensure that the patient's rights and privacy have been respected.

Step 3: **Develop a systematic approach** to dealing with the "problem" situation resulting in the patient-provider conflict. Once the patient and the behaviors in question are identified, the medical director will oversee a corrective action plan (CAP) **developed** by the care team and if possible, the patient in question. The patient will be required to ultimately indicate assent to the plan. The primary goal of any corrective action plan should be to sufficiently improve the situation to allow the patient to continue to receive safe and effective care in the current dialysis facility. The ESRD Networks can provide support for these and all subsequent steps even if involuntary discharge is not anticipated. The corrective action plan should be modeled using the tools included in this toolkit.

1. A CAP should be acknowledged by the medical director and the patient's assent/agreement should be obtained. Sometimes devices, such as behavior agreements between the patient and the healthcare team, can be employed but generally these are reserved for very specific definable behaviors. These agreements, which are distinct from the CAP, should be reserved for those situations that do not appear to be amenable to dialogue. They must be agreed upon by the patient and must have the endorsement of the medical director. Documentation of all steps is essential.
2. If involuntary discharge from a dialysis facility is anticipated as the consequence of failure to resolve, involvement of the appropriate services of the ESRD Networks (or their equivalent entities) is key and mandated. Documentation of all antecedent discussions and steps to alleviate the problems leading to the specific situation of the patient-provider conflict must be made. The checklist is a tool that can be used to help ensure that all proper steps are completed. Importantly, initiating formal procedures leading to an involuntary discharge requires notification of the ESRD Network 30 days prior to the discharge and the respective state department of health at the time of discharge, as indicated on the checklist above.
3. Patients who are felt to pose an immediate threat to the physical safety of staff or other patients should be dealt with **immediately**. State laws and regulations that require protection of the other patients and of the staff must be followed and must be with the knowledge of, consultation with, and assistance from the ESRD Networks. The conditions

of coverage and OSHA mandate safe environments for patients and staff, respectively. If a patient is threatening immediate physical harm to another patient or to a member of the staff, law-enforcement (the police) should be called to intervene immediately and to safely remove the threatening patient from the facility.

INFECTION CONTROL



INFECTION CONTROL

The regulations concerning infection control are listed in the section titled Patient Safety. There are 29 V-Tags in the Patient Safety section (§ 494.30, V110 to 148) and 1 in the Patient Care section (§ 494.110, V637). Citation in both sections underlines the overlap between patient safety and QAPI theory and practice. Prevention of infection is the most important patient safety challenge facing dialysis providers.^{1,2}

In 2001, the Centers for Disease Control and Prevention (CDC) published recommendations for infection control practices in hemodialysis facilities.³ CMS incorporated these recommendations in the Conditions for Coverage.⁴ Table 1 summarizes the components of the infection control program.

Table 1. Components of a comprehensive infection control program to prevent transmission of infections among chronic hemodialysis patients.³

1. Infection control practices for hemodialysis units
 - a. Infection control precautions specifically designed to prevent transmission of blood-borne viruses and pathogenic bacteria among patients.
 - b. Routine serologic testing for hepatitis B virus and hepatitis C virus infections*.
 - c. Vaccination of susceptible patients against hepatitis B.
 - d. Isolation of patients who test positive for hepatitis B surface antigen.
2. Surveillance for infections and other adverse events.
3. Infection control training and education

*CMS does not require regular testing for HCV. If the facility does not have a practice of regular testing, then at a minimum, serum ALT levels should be followed monthly.

To meet the regulations and the V-tags, the medical director must ensure that infection control policies and procedures exist that implement these components. There must be a QAPI process that audits the training, competence, and the adherence of the staff to these policies and procedures. There must be a process that identifies and reports infection control issues to the medical director and QAPI team.

In addition to the concepts listed in the CDC 2001 document, the Association for Professionals in Infection Control and Epidemiology (APIC) published a guide to the elimination of infection in hemodialysis.⁵

Prevention of cross-contamination is the core of infection control. Policy, procedures, schedules and workflow should prevent or minimize the exposure of one patient to the bacteria and viruses infecting or colonizing another patient. Ideally, a vacated dialysis station should be cleaned and disinfected before the next patient is set up for treatment. Nothing from a patient station should be taken to a clean area or another patient station without its being cleaned and disinfected.

When cleaning and disinfecting is not possible (e.g. rolls of tape), the item should be restricted to that patient's use or discarded.

Clean areas, used to prepare patient set ups and medication, must be adequately separated from dirty areas, where refuse and equipment from the dialysis process are cleaned or discarded. Convenient supplies of disposable gloves, sinks, and hand washing agents to facilitate appropriate glove changes and hand hygiene should be located in multiple locations throughout the dialysis area and at convenient disposal of the staff.

Medication preparation areas should be away from the patient stations. Trays or carts containing medications for more than one patient should not be brought to the dialysis station. Medication vials designed for single administration should not be punctured for multiple uses nor should residual contents be pooled. Insofar as feasible, multiple dose vials should be assigned uniquely to each patient.⁶

Since access infections are a major source of nosocomial infections, procedures for cleaning, preparing and securing needle access should be reviewed and consistently practiced. The medical director should assure that antibiotics are used according to culture and sensitivity reports and that vancomycin is not used when a narrower spectrum penicillin or cephalosporin would suffice. Care of dialysis catheters that cannot be easily removed is a critical aspect of dialysis infection control.⁷

Appropriate agents for cleaning blood spills, dialysis machines and equipment should be available. The staff should know the difference between cleaning and disinfection and the agents and concentrations necessary for each task.

With the new Conditions for Coverage, it is necessary to provide isolation rooms for hepatitis B surface antigen positive patients in all newly constructed or expanded facilities. Hepatitis B immunization is recommended for susceptible staff and patients. Facilities should track the immunization status of the patients with regard to hepatitis B, influenza, and pneumococcal pneumonia.⁸

Another chapter in this toolkit addresses water treatment and surveillance. From an infection control perspective, it is necessary to emphasize that water meeting AAMI standards is NOT sterile. The water for dialysis and the spent dialysate are potentially infectious. Facilities that practice re-use of hemodialyzers must assure that the blood compartment of the dialyzer is not contaminated during the reprocessing procedure.

The practices listed and referenced above are the infection control program, which must be monitored by the medical director and the QAPI team. The Conditions for Coverage (V-637) require that a facility must:

- (A) analyze and document the incidence of infection, in order to identify trends and establish baseline information on infection incidence;
- (B) develop recommendations and action plans to minimize infection transmission and promote immunization;
- (C) take actions to reduce future incidents

These requirements form the core of a QAPI (plan-do-check-act) process. Step 2 in table 1 lists surveillance as a key component of a comprehensive infection control strategies. The facility should maintain “line lists” with the details of cultures, timing, source, results and sensitivities. These lists help identify clusters and patterns that may point to systematic breaches of infection control practice. The QAPI team should also monitor other incidents and adverse events that might lead to breaks in infection control.

CDC maintains the National Healthcare Safety Network (NHSN).⁹ This is a secure, internet based patient infection event reporting utility. There is a specific site for reporting dialysis infection related events.¹⁰ For instance, to qualify for maximum credit in the CMS quality incentive payment (performance in 2022 for payment in 2024), facilities must enroll and report at least 3 consecutive months of dialysis infection events. Participation in the dialysis module for NHSN will enhance the facilities’ ability to establish baseline rates and to track infection incidence. The website has a utility that calculates infection rates and provides national comparative data.






In addition to the NHSN dialysis module, CDC maintains a dialysis safety site.¹¹ This site has resources and references for disaster recovery, infection control guidelines and references. The site lists the Dialysis Blood Stream Infection (BSI) Prevention Collaborative.¹² CDC recently published the improvement measured in the incidence of BSI of facilities that have enrolled in the collaborative and have identified 9 effective interventions associated with infection reduction, listed in Table 2.¹³¹⁴

Table 2. CDC’s core interventions for dialysis BSI prevention.

-
1. Monthly surveillance and feedback using NHSN
 2. Monthly hand hygiene surveillance
 3. Catheter care/vascular access observations
 4. Patient education/engagement
 5. Staff education and competency
 6. Catheter reduction
 7. Chlorhexidine for skin antisepsis prior to catheter insertion
 8. Catheter hub cleansing after cap is removed and before accessing.
 9. Antimicrobial ointment or Chlorhexidine impregnated sponge dressing.
-

The 9 steps presuppose an active level of staff involvement. The staff ideally would perform audits for adherence and develop a culture of gentle, respectful mutual admonition.

There are multiple resources available for designing and monitoring the QAPI program for infection control. The CDC BSI collaborative site lists the following resource links and downloadable references and tools:

- Recommended Staff Competencies
- Key Areas for Patient Education
- Protocol: Scrub-the-Hub for Hemodialysis Catheters  [PDF - 1.75 KB]
- Protocol: Hand Hygiene and Glove Use Observations
- Audit Tool: Hemodialysis Hand Hygiene  [PDF - 66 KB]
- Audit Tool: Basic components of fistula / graft care observations  [PDF - 238 KB]
- Audit Tool: Catheter accessing and disengaging observations  [PDF - 204 KB]
- Audit Tool: Catheter exit site care observations  [PDF - 221 KB]

The MAC of the National Forum of ESRD Networks published a catheter reduction toolkit.¹⁵

Finally, the Networks' websites are a valuable resource for QAPI resources and templates. Several Network websites have simple spreadsheets and checklists that can advance the QAPI task aimed at infection control. These include:¹⁶

- Infection tracking log
- *Infection Control Action Plan*
[Word Doc, 36 KB]
- [Audit Tool: Infection and Exposure Control](#) [Word Doc, 296 KB]
- *Barriers Questionnaire* [Excel file, 19 KB]
- *Data Collection Tool Master*
[Excel file, 32KB]

The medical director as the chair of the QAPI team has an opportunity to improve patient safety and the quality of care by implementing a program of evidence-based practices, infection surveillance, training, auditing, and education. Infection can no longer be considered the inevitable and unavoidable consequence of dialysis care. It falls to the medical director to establish a culture of quality and safety in the dialysis that has a goal of eliminating infection in dialysis patients.

References:

Patel PR, Thompson ND, Kallen AJ, Arduino MJ. Epidemiology, surveillance, and prevention of hepatitis C virus infections in hemodialysis patients. *Am J Kidney Dis.* 2010;56:371-378.

² Patel PR, Kallen AJ, Arduino MJ. Epidemiology, surveillance and prevention of bloodstream infections in hemodialysis patients. *Am J Kidney Dis.* 2010;56:566-577.

³ Center for Disease Control and Prevention. Recommendations for preventing transmission of infections among chronic hemodialysis patients. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm>. Accessed April 15, 2012.

⁴ Center for Medicaid and State Operations/Survey & Certification Group. ESRD Interpretive Guidance Update. October 3, 2008. <http://esrdnetworks.org/resources-conditions-for-coverage/SC-09-01%20ESRDIGs1%201%20memo.pdf>. Accessed April 15, 2012.

⁵ APIC. Guide to the Elimination of Infections in Hemodialysis. 2010. Washington, DC. (www.apic.org).

⁶ CDC. [Infection Control Requirements for Dialysis Facilities and Clarification Regarding Guidance on Parenteral Medication Vials](#). MMWR 2008;57(32):875-6. Accessed April 4, 2012.

⁷ Healthcare infection control practices advisory committee (HICPAC). Guidelines for the prevention of intravascular catheter-related infections, 2011.

<http://www.cdc.gov/hicpac/BSI/BSI-guidelines-2011.html>. Accessed April 4, 2012.

⁸ Centers for Disease Control and Prevention. Guideline for vaccinating kidney dialysis patients and patients with chronic kidney disease. Summarized form the Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2006.

http://www.cdc.gov/diabetes/pubs/pdf/CKD_vaccination.pdf. Accessed April 15, 2012.

⁹ Centers for Disease Control and Prevention. The National Health Care Safety Network (NHSN). <http://www.cdc.gov/nhsn>. Accessed April 15, 2012.

¹⁰Centers for Disease Control and Prevention. The National Health Care Safety Network (NHSN). Dialysis Facility Enrollment. <http://www.cdc.gov/nhsn/dialysis/cms-dialysis-enroll-steps.html>. Accessed April 15, 2012.

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²Centers for Disease Control and Prevention. Blood stream infection (BSI) prevention collaborative.

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⁴Centers for Disease Control and Prevention. Blood stream infection(BSI) prevention collaborative tools and resources.

<http://www.cdc.gov/dialysis/collaborative/tool-resources/index.html>. Accessed April 4, 2012.

⁵ Forum of ESRD Networks. Catheter Reduction Toolkit. Revised August 2011. Available on the National Forum of ESRD Networks 'website: <http://esrdnetworks.org/mac-toolkits/download/download-write-able-forms-catheter-reduction-toolkit-1>.

⁶ Network 9/10 QAPI infection control resources.

http://www.therenalnetwork.org/qi/qi_QAPI_InfectionControl.php. Accessed April 15, 2012.

Surveyors issue V-Tags to cite deficiencies. Currently there are thirty (30) V-Tags for infection which are as follows:

Tag Number	Regulation
V-110	Infection Control Policies and Procedures and documentation review
V-111	Sanitary environment
V-112	Competence of an Infection Control program
V-113	Wearing gloves
V-114	Sufficient number of sinks
V-115	Staff wearing personal protective Equipment (PPE)
V-116	Items taken into the dialysis station
V-117	Separate clean and contaminated areas, designated areas for medication preparation
V-118	Intravenous medication administration
V-119	Designated area for supply cart
V-120	Use of external venous and arterial pressure transducer filters
V-121	Handling, storage, and disposable of potential infection waste
V-122	Cleaning and disinfection of contaminated surfaces, medical devices, and equipment
V-124	Routine testing for Hepatitis B
V-125	Investigation of hepatitis B seroconversion
V-126	Hepatitis B vaccination of all susceptible patients and staff members
V-127	Hepatitis B screening of patients and staff
V-128	Isolation of hepatitis B positive patients
V-129	Mandatory hepatic B room or waiver
V-130	Separate dedicated supplies and equipment for Hepatitis B patients
V-131	Staff caring for Hepatitis B patients

V-132	Infection control training and education of staff annually
V-142	Monitoring and implementing biohazard and infection control policies and activities
V-143	Aseptic techniques for dispensing intravenous medications
V-144	Reporting infection control issues to the dialysis facilities Medical Director and Quality Improvement Committee
V-145	Reporting incidents of communicable disease as required by federal, state, and local regulations.
V-146	Addressing the risk intravascular catheters and measures to reduce the risk.
V-147	Education, training, and surveillance of staff who manage intravascular catheters including use of antibiotic lock solution
V-148	Surveillance of catheter related infections
V-637	Cites the components of the QAPI process needed to discover, document, and implement actions necessary to prevent, reduce, and remediate infection and cross contamination events.

Implementation of a comprehensive Infection Control program consists of three (3) elements that will avoid infection control deficiencies:

1. Periodic review and implementation proper infection control practices in the dialysis unit.
2. Surveillance for infections and other adverse events
3. Training and education of staff and patients

EMERGENCY AND DISASTER PREPAREDNESS



EMERGENCY AND DISASTER PREPAREDNESS FOR DIALYSIS MEDICAL DIRECTORS

Included in the CMS ESRD CfC and accompanying Interpretive Guidance from 2008 is a standard on Emergency Preparedness V408 *“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.”* The Interpretive Guidance further describes requirement of dialysis facilities for Emergency Preparedness of staff (V409), emergency preparedness patient training (V412), Emergency equipment (V413), and emergency plan to obtain emergency medical assistance when needed (V414). V415 states that facilities must *“Evaluate at least annually the effectiveness of the emergency and disaster plans and update them as necessary”*. V415 further describes that the annual evaluation should include review of any medical or nonmedical emergencies that occurred in the past year, looking for opportunities for improvement. It further states that drills or mock emergencies should be conducted at least annually to evaluate the staff and the plan itself. V416 describes the requirement for facilities to contact their local emergency management agencies at least annually, so the agency is aware of the needs of dialysis facility in case of emergency.

On 9/16/2016, CMS released a new rule on Emergency Preparedness that amended the CfC for several different providers of healthcare including ESRD (Part 494- Conditions for Coverage for End- Stage Renal Disease Facilities- specifically, 494.62 Condition of participation: Emergency Preparedness):

<https://www.federalregister.gov/documents/2016/09/16/2016-21404/medicare-and-medicaid-programs-emergency-preparedness-requirements-for-medicare-and-medicaid>

According to CMS, *“This final rule establishes national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to plan adequately for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems”*. This rule added details to requirements for ESRD facilities to meet the CfC on emergency preparedness.

Following this new rule, CMS issued Interpretive Guidance on the rule (State Operations Manual Appendix Z-Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance) which specified new *“E-codes”* for providers (including ESRD facilities) to follow, and state survey agencies to survey based on these new codes. This Interpretive Guidance on Emergency Preparedness has received several updates, most recently on February 1, 2019, which revised the E-codes and added emerging infectious diseases (EID) to the definition of *“all-hazards approach”* amongst other updates.

On September 26, 2019, CMS further amended the Emergency Preparedness CfC as part of the “Omnibus Burden Reduction (Conditions of Participation) Final Rule CMS-3346-F”:

<https://www.federalregister.gov/documents/2019/09/30/2019-20736/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and>

According to CMS fact sheet on this rule:

<https://www.cms.gov/newsroom/fact-sheets/omnibus-burden-reduction-conditions-participation-final-rule-cms-3346-f>

“The Omnibus Burden Reduction (Conditions of Participation) Final Rule removes Medicare regulations identified as unnecessary, obsolete, or excessively burdensome on hospitals and other healthcare providers to reduce inefficiencies and moves the nation closer to a healthcare system that delivers value, high quality care and better outcomes for patients at the lowest possible cost.” The rule was released as part of CMS’ “Patients over Paperwork” and “Meaningful Measures” initiatives. According to CMS in the Fact Sheet on this rule as it relates to ESRD Emergency Preparedness CfC, “We have decreased the requirements for facilities to conduct an annual review of their emergency program to a biennial review”, “Eliminating the requirement that the emergency plan include documentation of efforts to contact local, tribal, regional, State, and federal emergency preparedness officials and a facility’s participation in collaborative and cooperative planning efforts”, and “Decreasing the training requirement from annually to every two years”. This rule once again amended “Part 494-Conditions for Coverage for End Stage Renal Disease Facilities”, specifically 494.62.

To assist Medical Directors and dialysis facilities in complying with these new regulations on emergency preparedness, we have added the checklist, located under the appendix to this toolkit. This checklist lists all the updated (updated Feb 1, 2019) emergency preparedness Interpretive Guidance E-Codes and includes summary of specifics on each E-code for ESRD Facilities. It also incorporates the updated CfC for emergency preparedness for ESRD facilities as per CMS-3346-F rule above (Omnibus Burden Reduction rule). By utilizing this checklist, Medical Directors can help ensure that their dialysis facilities are meeting the latest requirements by CMS on Emergency Preparedness.

The first key item addressed by this checklist and CMS rules include the requirement for ESRD Facilities to “develop and maintain an emergency preparedness plan that must be evaluated and updated” at least every 2 years. The 2-year review must be documented to include the date of the review and any updates made to the emergency plan based on the review. The plan must include conducting facility-based and community-based risk assessments. The risk assessments should identify hazards using an “all hazards” approach, and facilities are required to document both facility-based and community-based risk assessments. When identifying hazards in the risk

assessment, facilities should consider particular hazards most likely to occur in their surrounding areas that would affect their operations including natural disasters, man-made disasters, equipment and utility failures (including loss of power, water, gas etc.), interruptions in communication including cyber-attacks and EIDs (Influenza, Ebola, COVID, etc..).

The plan should also address strategies for addressing staffing shortages, surge capacity, evacuation plan, services that facility would be able to provide in an emergency and succession planning. In addition, the plan should address continuity of operations planning including essential personal, essential functions, alternate facility identification and location, etc. Lastly, the plan should include a process for collaboration with local, state, and federal officials' efforts to maintain integrated response during emergency. For dialysis facilities, this includes collaboration with the local ESRD Network, and KCER. See more below on role of Networks and KCER.

The next E-codes in the CMS Interpretive Guidance (and checklist) then describe implementing policies and procedures based on the emergency plan which must be reviewed and updated every 2 years. A system to track location of staff and patients must be included in plan/policies and procedures. The policies and procedures should also address medical documentation and emergency credentialing process. Next, CMS describes the requirement for a communication plan that includes how facility will coordinate with emergency management agencies and systems. The communication plan must include the name and contact information for staff, physicians, other dialysis facilities, entities providing services under arrangement, and local (in addition to federal, state, tribal, regional, etc..) emergency preparedness staff.

The next sections of these CMS rules involve training, testing, and orientation programs which must be updated at least every 2 years. The dialysis facility must conduct exercises to test the emergency plan every year, but the updated CMS CfC for Emergency Preparedness based on the Omnibus Burden Reduction (Conditions of Participation) Final Rule CMS-3346-F, allow for flexibility in timeframe for testing. Specifically, the updated rule calls for full-scale community-based or facility-based exercise every 2 years, and if facility involved in actual emergency that requires activation of emergency plan, the facility is exempt from engaging in its next full-scale exercise. In years opposite the full-scale exercise, facilities may conduct a second full-scale exercise or a mock disaster drill or tabletop exercise. Facilities should document lessons learned following exercises or real-life emergencies and develop after action reports (AAR) which detail: 1) what was supposed to happen; 2) what occurred; 3) what went well; 4) what the facility can do differently or improve upon; and 5) a plan with timelines for incorporating necessary improvement.

Lastly, the updated CMS rules on emergency preparedness describe how a dialysis facility that is part of an integrated healthcare system can participate in a unified emergency preparedness

program. The facility still needs to show that each individual facility actively participated in the program and the plan must address each facility's unique circumstances, patient population and services offered. Each facility also must maintain individual training records of staff and records of all required training exercises.

THE ROLE OF NETWORKS AND KCER

In an emergency, the local Network works with dialysis facilities to track and report the status of facility operations (open/closed/altered schedule), while also coordinating with federal, state, and local government agencies as needed to assist with patient safety and ensure dialysis facilities are prioritized to be open. The local Network will contain an Emergency Updates Page which shows the operational status of facilities during an emergency. In addition, the ESRD Network webpages and some other nephrology platforms often contain useful resources for Healthcare Providers (including Emergency Preparedness, preparing an AAR, etc.) and resources for patients. Patient resources contained on the ESRD Network page may include a patient communication plan, preparing for emergencies, in addition to resources from KCER and weather-specific resources on hurricanes and flooding, winter storms, extreme heat, tornados, etc.

KCER stands for "Kidney Community Emergency Response" and is under contract by CMS. According the "Kidney Community Emergency Response" (KCER) website (www.kcercoalition.com) the KCER "provides technical assistance to End Stage Renal Disease (ESRD) Networks, kidney organizations, and other groups to ensure timely and efficient disaster preparedness, response, and recovery for the kidney community. The KCER Program's disaster preparedness resources help save lives, improve outcomes, empower patients and families, educate healthcare workers, build partnerships with stakeholders, promote readiness in the community, and support the ESRD Networks." The KCER Website contains great resources for dialysis facilities, medical directors, ESRD Networks, and patients. The site contains updated information on the CMS emergency preparedness rules described above, examples of emergency management plans for different types of disasters, and community resources. For patients, the website contains resources (such as patient hotlines for dialysis organizations and contact information for local ESRD Networks) in order to help patients best prepare and respond to an emergency situation.

NKF Presentation on Emergency Preparedness

See this link for Forum leaders presenting at the virtual NKF Spring Clinical Meeting in April 2021. David Henner, DO and Donald Molony, MD presented on the topic of emergency preparedness including an overview of the regulations pertaining to emergency preparedness, and the role of

the ESRD Networks and KCER during an emergency to support dialysis facilities. They also shared their experiences and lessons learned related to multiple recent natural disasters, as well as their experiences participating in the mock full-scale disaster drills in coordination with local emergency response partners:

<https://esrdnetworks.org/resources-news/disaster-planning-resources-links/general-information-helpful-links/>

COVID-19 INFECTION CONTROL



COVID INFECTION CONTROL FOR DIALYSIS MEDICAL DIRECTORS

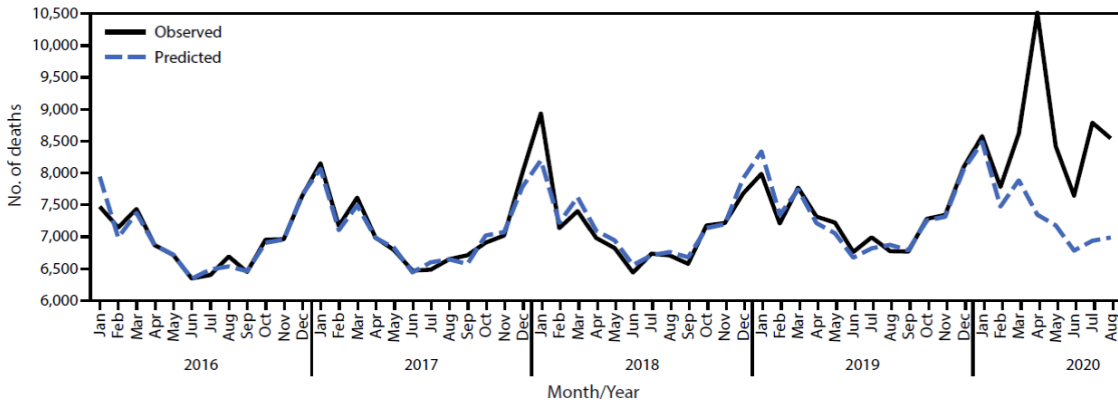
COVID Pandemic of 2020 and 2021

The virus causing severe acute respiratory syndrome (SARS) in the form of a viral respiratory illness caused by a coronavirus called “SARS-associated coronavirus” (SARS-CoV), also known as the “Novel coronavirus disease 2019” or “COVID-19” and also most recently referred to as “Covid”, is a highly infectious, rapidly spreading viral disease with an alarming case fatality rate up to 5%.^{1,2} COVID infection first affected dialysis patients in China and South Korea in January and February 2020. By March 2020, the first cases of COVID 19 among US dialysis were reported including first in Washington, then in California and New York.

The first reported dialysis patient infected by COVID and reported as a stand-alone case report in a peer reviewed journal was a 56-year-old non-diabetic male with ESRD secondary to IgA nephropathy undergoing thrice-weekly maintenance hemodialysis for 3 years, who presented to an urgent care, 3 emergency rooms, 1 cardiology clinic, and 2 dialysis centers in California and Utah. During this interval, he reported nausea, vomiting, diarrhea, and low-grade fevers but was not suspected of COVID infection until he developed respiratory symptoms and was admitted to the hospital. Imaging studies upon admission were consistent with bilateral interstitial pneumonia. Within the first 24 h, he deteriorated quickly and developed acute respiratory distress syndrome (ARDS), requiring intubation, and increasing respiratory support and did not survive.¹

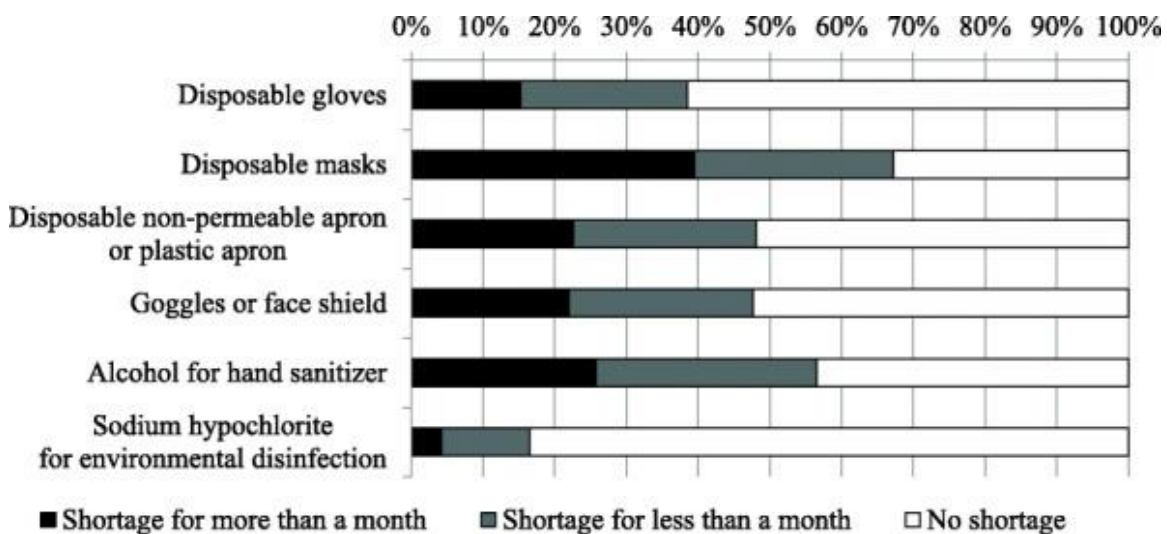
In the first several months of COVID pandemic in early 2020 excess death rates were reported in dialysis patients (see [Figure 1](#)).³ During the COVID pandemic in 2020 and throughout the first half of 2021, as many as 25% of all estimated 550,000 dialysis patients in the USA were thought to be infected but many survived.⁴ The strongest risk factors associated with higher likelihood of Covid infection among ESRD patients were exposure to infected persons at home, at work, or in the dialysis clinic or failure to maintain social distancing or having proper facial mask. After stringent infection prevention steps were taken, the incidence of in-center transmission of Covid decreased in US dialysis clinics,³ while it is unclear whether these measures had a bearing on the high mortality of Covid infected dialysis patients.

FIGURE 1. Observed* and predicted† monthly deaths among patients with end-stage renal disease — United States, January 1, 2016–August 31, 2020.³



A Japanese dialysis group examined the shortage of personal protective equipment (PPE) during the COVID pandemic in dialysis facilities using a nationwide questionnaire survey in the context of their study of infection prevention measures for patients undergoing hemodialysis during the COVID pandemic in Japan.⁵ The investigators examined the duration of shortage of the following PPE during the COVID pandemic: disposable gloves, masks, apron, goggles, face shields, and disinfectants such as alcohol for hand sanitizer and sodium hypochlorite for environmental disinfection (Figure 2). There were 222 facilities (10.0%) that experienced a shortage of all the items listed above. Notably, 67% of the facilities reported a shortage of disposable masks (28% for less than a month, 40% for more than a month). Alcohol for hand sanitizer was also in short supply in 57% of the facilities (31% for less than a month, 26% for more than a month).

FIGURE 2. Distribution of the period of shortage of personal protective equipment. The distribution of the period of shortage of six personal infection-protective equipment and disinfectants in dialysis facilities is shown. The black bar indicates shortage for more than a month, the gray bar for less than a month, and the white bar for no shortage.⁵



COVID Screening to Reduce the Risk of Outbreak in the Dialysis Clinic

In-center hemodialysis patients are at increased risk of COVID infection. Preventive strategies are needed to reduce the risk of in-center COVID transmission from other patients and dialysis staff including education of patients and healthcare providers. Screening for COVID signs and symptoms along with identification and separation of infected or symptomatic patients under the designation of “Person Under Investigation” (PUI) are critical measures during the time of pandemic or regional outbreaks. The symptoms associated with COVID are non-specific and include:⁶ fever (44–98% of patients), dry cough (68–76% of patients), muscle pain (18% of patients) and fatigue (18% of patients). Other symptoms include loss of taste or smell, brain fog, and gastrointestinal symptoms including vomiting and diarrhea. Initial data on infectivity suggest a maximum likelihood of reproductive number for COVID of 2.8, that is, a person with the disease is likely to transmit it on average to a maximum of 2.8 other people if no one in their community is immune.⁶ Reported mortality data vary widely from <1% (South Korea) to >7% (Italy).

Due to data indicating resolution of viral shedding, the Centers for Disease Control and Prevention (CDC) advise that immunocompetent non-ESRD individuals may return to the general population without the need for PCR testing if 10 days have elapsed since the first signs of infection (or test positivity) if they are without fever for over 24 hours without the use of antipyretics. For immunocompromised non-ESRD patients or those with severe disease, they recommend 20 days from symptom onset (or test positivity) and lack of fever for over 24 hours without the use of antipyretics.

Healthcare workers infected with COVID are recommended to quarantine and then return to work with the same guidance.

The management of the ESRD patient has been a more complicated issue, as there has been some conflicting data regarding the duration of viral shedding after illness. The ability to discharge and ESRD patient from an isolation dialysis unit and return to them to their home outpatient facility has been managed differently by different providers, however, the CDC currently recommends the use of the same criteria used for immunocompetent non-ESRD patients (10 days have elapsed since the first signs of infection (or test positivity) as long as they are without fever for over 24 hours without the use of antipyretics). Testing Covid PCR to document a negative result prior to readmission to the home dialysis unit has been advocated by some dialysis providers, however, it has been shown that many COVID-19 positive ESRD patients will have persistently positive PCR tests for weeks or months following recovery. ⁴

Many persons including ESRD patients may remain symptomatic for a long period after they recover from acute Covid infection, the so-called long-hauler (overhaul) Covid that is often

associated with weeks to months of such non-specific symptoms as fatigue and drowsiness or neurologic, cardiac, gastro-intestinal, and respiratory symptoms.

Home dialysis including peritoneal dialysis or hemodialysis is more likely to ensure social distancing and lower the risk of exposure to Covid infected patients. An observational experience during the COVID pandemic of over 3600 home and 9800 in-center dialysis patients in Ontario, Canada found a lower burden (absolute risk reduction of 44%) of COVID-19 infection, hospitalization, mortality, and ICU admission in those receiving home dialysis. Among patients infected with COVID, however, the authors observed no differences between groups in the adjusted odds of hospitalization and ICU admission or 30-day mortality [see “COVID-19 among Adults Receiving Home versus In-Center Dialysis, Perl et al, CJASN Sep 2021, 16 (9) 1410-1412; DOI: 10.2215/CJN.04170321] During Covid surges some East Coast medical centers reinvigorated acute peritoneal dialysis for management of acute kidney injury (AKI) at a time where there was a shortage of dialysis nurses and technicians and insufficient hemodialysis or CRRT machines. Some patients who recovered from acute COVID may have protracted AKI and may still require dialysis even after being discharged from the hospital. These patients need dialysis therapy in an ambulatory dialysis clinic.

Many dialysis nurses, patientcare technicians, nephrologists and other dialysis providers and affiliated have contracted COVID, and many exposed staff and colleagues may undergo a period of self-quarantine after Covid exposure. If they remain asymptomatic, the total duration of self-quarantine should not be longer than 10 days.

Keeping the Dialysis Clinic Ready for COVID Surges and Other Outbreaks

The nationwide vaccination of the adult persons in the USA starting in December 2020 has had a major impact on controlling the rate of COVID infection including among ESRD patients. However, according to *the Center for Disease Control and Prevention (CDC)* all U.S. outpatient dialysis facilities should be prepared for the possible arrival of patients with COVID at all times.

<https://www.cdc.gov/coronavirus/2019-ncov/downloads/COVID-outpatient-dialysis.pdf>

All outpatient dialysis facilities should ensure their staff are trained, equipped, and capable of practices needed to:

- Prevent the spread of respiratory infections, including COVID, within the dialysis facility.
- Promptly identify and isolate patients with possible COVID and inform the correct dialysis facility staff and public health authorities.
- Provide dialysis for a limited number of patients with confirmed or suspected COVID as part of routine operations.

- Potentially provide dialysis for a larger number of COVID patients in the context of an escalating outbreak.
- Monitor and manage any healthcare personnel that might be exposed to COVID.
- Communicate effectively within the dialysis facility and plan for appropriate external communication related to COVID.

The following checklist from the CDC website is not a list of mandatory requirements; rather, it highlights important areas that the CDC recommends outpatient dialysis facilities review in preparation for potential arrivals of COVID patients.

Elements to be assessed, each to be assessed at 3 levels of “completed”, “in-progress” or “not-started”.

1. Infection prevention and control policies and training for healthcare personnel (HCP),

- A. Facility leadership including, but not limited to, the Chief Medical Officer, quality officers, medical directors, facility administrator, nurse manager, infection prevention personnel, chief operating officer, nephrologists, advanced practice providers (APPs) has reviewed the Centers for Disease Control and Prevention’s COVID guidance for dialysis facilities.

Facility provides education and job-specific training to HCP regarding COVID including:

- B. Signs and symptoms of infection.
- C. Importance of hand hygiene, respiratory hygiene, cough etiquette and wearing a facemask or cloth face covering for source control.
- D. Use of personal protective equipment (PPE) including competency evaluation.
- E. Triage procedures and patient placement.
- F. Healthcare professional (HCP) sick leave policies.
- G. Self-monitoring for fever or respiratory symptoms including not reporting to work when ill.
- H. How and to whom suspected and confirmed COVID cases should be reported

Facility provides education to patients about the following:

- I. COVID (e.g., symptoms, how it is transmitted).
- J. Importance of immediately informing HCP if they feel feverish or ill.
- K. Actions they can take to protect themselves (e.g., hand hygiene, covering their cough, maintaining social distancing and wearing a facemask or cloth face covering).
- L. Actions the facility is taking to keep them safe (e.g., visitor restrictions, changes in PPE)

2. Process for rapidly identifying and isolating patients with confirmed or suspected COVID:

- A. Facility has notified patients to call ahead and report fever or symptoms of respiratory infection including but not limited to fever, cough, muscle pain, fatigue, and gastrointestinal symptoms.
- B. Facility has a system to receive and triage phone calls from patients with symptoms of fever or respiratory infection as listed above.
- C. Facility has a system to screen patients at presentation to the facility for fever or respiratory infection.
- D. Signs are posted in triage areas (e.g., at entrance, and in waiting areas) advising patients with fever or symptoms of respiratory infection to immediately notify triage personnel so appropriate precautions can be put in place. Cloth face coverings or facemasks are provided to all patients upon entry to the facility (if they are not already wearing one) and must cover nose and mouth until they leave the facility.
- E. Alcohol based hand sanitizer for hand hygiene is available at each entrance, in waiting areas and near treatment stations.
- F. Facility provides tissues and no-touch receptacles for disposal of tissues in waiting rooms and in dialysis treatment areas. Facility has space in waiting area for ill patients to sit separated from other patients by at least 6 feet, or a process that allows medically stable patients to wait outside the facility.
- G. Facility has a process to ensure patients with confirmed or suspected COVID are placed in the appropriate treatment area as soon as possible to minimize time in waiting areas. Facility has a process in place for immediate notification of facility leadership when a suspect case is identified.
- H. Facility has a process to notify local or state health department of a suspect case.

3. Patient placement:

- A. Confirm the number and location of available isolation rooms (not being used for hepatitis B surface antigen positive patients) in the facility.
- B. For patients with undiagnosed respiratory infection, facility has an isolation room (not being used for hepatitis B surface antigen positive patient) to dialyze patient.
 - If an appropriate isolation room is unavailable, facility has a designated dialysis station(s) at a corner or end-of-row, away from the main flow of traffic, separated by at least 6 feet from nearest patient (in all directions), to dialyze a masked symptomatic patient.
- C. Facility maintains at least 6 feet of separation between masked patients with undiagnosed respiratory illness and other patients during dialysis treatment.
- D. For patients with suspected or diagnosed COVID, facility has a plan to dialyze patients in the facility. The same strategies used for dialyzing patients with undiagnosed respiratory

infections can be used and are stated in dialysis guidelines.

www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/dialysis.html

- E. Facility has a plan for cohorting patients and health care providers (HCP if they are dialyzing multiple patients with suspected or confirmed COVID [e.g., in the same section of the unit and/or on the same shift - consider the last shift of the day]. If diagnosis is known, patients with different respiratory infection diagnoses should not be cohorted.
- F. Facility has plans to minimize the number of HCP who enter the isolation dialysis room (or isolation station) (e.g., having dedicated HCP to care for patients with suspected or confirmed COVID)

4. Transmission-Based Precautions:

- A. Facility has a procedure for assessing supply (inventory) of personal protective equipment (PPE) and other infection prevention and control supplies (e.g., hand hygiene supplies).
- B. Facility has a contingency plan to optimize PPE use during shortages.
- C. Facility is providing all staff with face covering or face masks that are to be worn at all times while in the facility. Cloth face coverings should NOT be worn instead of a respirator or facemask if more than source control is required.
- D. HCP wear the following PPE when caring for patients with suspected or confirmed COVID unless the suspected diagnosis requires Airborne Precautions (e.g., tuberculosis):
 - a. Gloves
 - b. Isolation gown
 - c. Eye protection (e.g., goggles or face shield)
 - d. An N-95 or higher-level respirator is preferred, if available and the facility has a respiratory protection program with fit-tested HCP; facemasks are an acceptable alternative
- E. HCP receive appropriate training, including “just in time” training on selection and proper use of (including putting on and removing) PPE, with a required demonstration of competency.
- F. Facility has a process for auditing HCP adherence to recommended PPE use

5. Movement of patients with confirmed or suspected COVID within the dialysis facility

- A. Patient movement outside of the isolation room (isolation station) will be limited to essential purposes.
- B. Patient will be required to wear a facemask or face covering during their time in the dialysis facility.

6. Hand hygiene (HH):

- A. HH supplies including alcohol-based hand sanitizer are readily accessible in patient care areas, including areas where HCP put on and remove PPE.
- B. Facility has a process for auditing HCP adherence to recommended hand hygiene practices.

7. Environmental Cleaning:

- A. Facility has a plan to ensure proper cleaning and disinfection of environmental surfaces and equipment in the patient isolation room or station.
- B. All HCP with cleaning responsibilities understand the instructions for use and contact time for selected products.
- C. Facility has a process to ensure shared or non-dedicated equipment is cleaned and disinfected after use and according to manufacturer's recommendations.
- D. Facility uses an EPA-registered hospital-grade disinfectant on hard non-porous surfaces. Refer to List N (www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2) on the EPA website for EPA-registered disinfectants that have qualified under EPA's emerging viral pathogens program for use against SARS-CoV-2.
 - a. When using products from List N, facilities should ensure the products also have a bloodborne pathogen claim (e.g., hepatitis B, HIV)

8. Monitoring and managing HCP:

- A. Facility has sick leave policies that are non-punitive, flexible and allow ill healthcare personnel (HCP) to stay home.
- B. Facility has a process to conduct active-and/or self-monitoring of HCP if required by public health.
- C. Facility has a process to conduct symptom and temperature checks of HCP prior to the start of the shift.

9. Visitor access and movement within the dialysis facility:

- A. Facility has a plan to restrict visitors who are ill from entering the facility. Visitors entering the facility will be required to wear a facemask or a cloth face covering at all times.
- B. Visitors are screened for symptoms of acute respiratory infection before entering the facility.
- C. A facility may enact policies to restrict or abolish visitors during times where either COVID patients are in the facility or when the case load in the facility or community is increasing.

10. Facility maintains situational awareness of COVID both at the national and local level:

- A. Facility regularly monitors the situation on CDC's coronavirus disease (COVID) web page. www.cdc.gov/coronavirus
- B. Facility knows who to contact at their local health department for information on local COVID transmission
- C. Facility knows where COVID testing is being performed locally and has a plan to refer patients who need COVID testing

COVID VACCINATION (see also [Vaccination Toolkit](#))

Vaccines against COVID-19 became available in the US in December 2020, with current data as of November 2021 indicating approximately 192 million people fully vaccinated and another 30 million partially vaccinated (Coronavirus (COVID-19) Vaccinations - Statistics and Research - Our World in Data). Data regarding available vaccines and vaccine efficacy in the general population is shown in table 1. The 2-dose series of mRNA vaccines have also exhibited robust efficacy in the dialysis population (less so in renal transplant recipients receiving long-term immunosuppression), however, it has also been noted that antibody titers decline much more rapidly in the ESRD population compared to general population. This latter finding has further supported the call to prioritize patients with altered immune systems (including patients with chronic kidney disease) for a vaccine booster, a process actively ongoing in US dialysis facilities at the time of this writing. Efforts to overcome vaccine hesitancy (in dialysis patients and healthcare workers alike) has been another hurdle that remains an active focus in the response to the COVID-19 pandemic. As of November 4, 2021, CMS has issued a rule that all eligible staff at health care facilities participating in the Medicare and Medicaid programs must be vaccinated against COVID-19.

For more detailed information regarding COVID-19 vaccination, we direct you to the Forum's [Vaccination Toolkit](#).

TABLE 1. Available COVID vaccines as of early 2021

Vaccine	Type	Doses	Efficacy	Trial Size	Variant Protection	US Authorization
Pfizer	mRNA	2	95% ¹	44K	UK/SA ⁴	Yes (16+)
Moderna	mRNA	2	94% ²	30K	UK/SA ⁴	Yes (18+)
J&J	Adenovirus vector (DNA)	1	72%	44K	57% SA ⁵	Yes (18+)
Novavax	Protein	2	89% ³	15K	86% UK ⁵ 60% SA ⁵	No
Astra-Zeneca	Adenovirus vector (DNA)	2	62%	9K	75% UK ⁵ 22% SA ⁵	No

Vaccination against COVID is often associated with general side-effects can include fevers, chills, malaise and myalgias within the first 24 to 48 hours in a third to half of ESRD patients who receive the mRNA vaccines. 8,9 These symptoms are successfully managed with symptom-based care and are self-limiting. Concerns, or hesitancy, regarding COVID vaccination have created opportunities to improve vaccine (and healthcare, in general) "literacy" through educational campaigns led by numerous healthcare organizations including the National Forum of ESRD Networks

As of mid-2021 it is widely unknown how dialysis clinics should screen patients who have developed symptoms after COVID vaccination. Currently it is not known whether dialysis patients who received two doses of the mRNA vaccine should receive a 3rd booster vaccine injection after several months of the second dose. It is generally believed that the risks of COVID in the dialysis population exceeds the potential risk of the vaccine and that the safety and efficacy of currently deployed vaccines for dialysis patients is acceptable.

Data Collection and Reporting

As of May 2021, the CDC's Division of Healthcare Quality Promotion recommends proactive reporting of "Weekly Cumulative COVID-19 Vaccination Data" by dialysis facilities. The objective of this initiative is to ensure that future COVID-19 vaccination data is thoroughly collected and accurate for future analyses. that dialysis facilities can confidently report cumulative Covid vaccination data for future analyses. Cumulative vaccination data is defined as the total number of individuals who have ever received COVID vaccine since it became available in December 2020.

Incident vaccination data is the number of new individuals who received COVID vaccine within a specific week."

As of late 2021, COVID vaccination has been demonstrated to dramatically decrease the rates of severe illness, hospitalization and death, and remain the most cost-effective means of controlling infection. Their use should be actively promoted, in a non-confrontational way, while also confirming that should the patient contract COVID-19, treatment options are available and should be sought in a timely manner. Unfortunately treating the disease is much more costly than vaccination.

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QAPI
Quality
Assessment and
Performance
Improvement



QUALITY ASSESSMENT and PERFORMANCE IMPROVEMENT (QAPI)

The current Medicare conditions for coverage make the medical director responsible for the quality of care in the dialysis facility (§494.150, §496.110, V626). The medical director's role is leadership, visibility, and support of staff. The medical director is the leader of the QAPI interdisciplinary team (IDT).

The 2012 edition of the Medical Director Toolkit focused on the goals of the QAPI team and the methodology employed. The 2008 Conditions for Coverage highlighted that the professional staff must be represented (physician, RN, dietitian, social worker) and added that "the facility has the option of including facility patients when appropriate."

There has been increasing recognition that providers must ensure that the patient is at the center of everything we do in healthcare and that one way to do this is by giving the patient "a seat at the table" where key decisions are made. Aligned with this thinking, the National Quality Strategy embraced by CMS aims to achieve the goal of better care by prioritizing involvement of patients and family members in that care and using a lever of measurement and feedback, inherent attributes of the QAPI process. In 2019 CMS felt that the time had come to clarify that the "option" of including patients in the QAPI IDT was a matter of defining the "appropriate" means by which patients could routinely be incorporated.

To this end, the 2019 Network Scope of Work mandated that "the Network shall provide technical assistance to project-participating dialysis facilities on *Incorporating patient, family and caregiver participation into the Quality Assurance Performance Improvement (QAPI) Program and governing body of the facility*. As such Network websites now offer readily accessible material on how to do this and other support for this initiative. Key elements for success are:

- Recruit patients and family members whose experiences may motivate them to participate
- Orient the participants in the QAPI process, work of the committee, time commitment, basic concepts of HIPAA
- Actively encourage participation
- "Prescriptive" nature of some of what QAPI committees are required to discuss may not align with patient centered concerns; get feedback on what patients find to be of value; some patients may wish to specialize. Debrief patients after meetings.
- Patient specific discussions (grievances, morbidity, mortality) should be reserved for a non-patient executive session to ensure that individual health information is protected. The QAPI committee with patient membership should be looking at aggregate data, trends, and improvement activities (see next section).

Quality assessment and performance improvement is an activity that supports all the services and processes of care in the facility, including home therapies. QAPI is an attitude. It is a habit of mind that considers every component of care to be continuously improvable (CQI, continuous quality improvement). In the ideal situation QAPI and patient care activities are coextensive because staff members would be always mindful of ways to make care safer and better.

The method of quality improvement is typically reduced to a 4-step cycle of planning, doing, checking, and acting (PDCA). QAPI might be better abbreviated as **qApl**. The **A**ssessment components are the planning and checking. The **I**mprovement components are the doing and acting.

The multitude of check sheets, Pareto charts, cause and effect diagrams, flow charts, run sheets, control charts, etc. make the activity appear to be more intimidating than it needs to be. Fundamentally the dialysis facility has structures and processes that affect outcomes of care. When outcomes of care differ from desired outcomes, it is the task of the medical director and the QAPI/IDT to study and to improve the process.

The fundamental assumption is that outcomes of care are being measured, reviewed and compared to some standard. For example, the core service of a dialysis facility is dialysis. In the ideal state, each dialysis treatment should deliver a dose (Kt) adequate to achieve a $Kt/V \geq 1.2$, comfortably reach a target weight that leaves the patient normotensive and in an acceptable fluid status in a time frame that doesn't result in an ultrafiltration rate exceeding 10 ml/kg/hour.

What percentage of treatments meets *all three* of those criteria? Since Kt/V is usually measured once a month, how representative of the other 11 or 12 treatments is the modeling day treatment? What indicators are in place to monitor and measure the adequacy of dialysis on *each* treatment? How does the staff know that it is doing a good job every treatment, every day?

The next concern in outcome analysis is the stability of the process. How do the indicators change from treatment to treatment, from day to day? Do they aggregate tightly around an average? Is that average at or above the goal or standard? There are two signals here: the average and the variation around the average. It is possible to have a process that consistently produces a narrow range around a substandard average. Also possible is a process that has an acceptable average but wide variation around the average. In the first case the process is "in control" but substandard. In the second case the process is not "in control." While the second case achieves the desired outcome "on the average", it is not consistent, stable, or predictable.

The first step is to "plan." Get the right people around a table with the necessary data. Some of the people should be relatively naïve to the topic at hand. These team members don't bring a lot of preconceptions about what "should" happen. Examine the cases (success and failure). Look at each treatment that was substandard. Identify a cause or causes for each case. Tabulate

all the causes (e.g., which causes explain the majority of the failures). Typically 20% of the causes are related to 80% of the failures.

Pick a high frequency cause. For example, if the team identifies that treatment time is frequently identified as a reason for failure then the team could dissect every structure and process that contributes to treatment time. The discussion (sometimes called brainstorming) should be free flowing, have a stream of consciousness, and be non-judgmental. Record the comments/suggestions. Then go through them considering the upsides, downsides, and work-arounds for each suggestion.

Describe the process of prescribing treatment time (flow charting). What are the steps? How does the prescribed treatment time get implemented and by whom? Are the prescribed times adequate? What rules are used to assign a time? Are the rules correct? Do the delivered treatment times match the prescription? Can the schedule accommodate the anticipated times? Keep questioning the process with “if not, why not?” questions until no further questions come to mind.

What component of the prescription and delivery of time are most amenable to change? Avoid attempting to perfect the system in one cycle. Seek to make it better. A solution that fixes 80% of the failures is a “good” plan. The residual 20% failure rate can be addressed in a second PDCA cycle. If an 80% solution to the residual failures is implemented, the net result of these two “rapid cycles” will result in a net 95% improvement.

An advantage of going for a “merely good” solution is that it increases the probability of success. Nothing empowers the interdisciplinary team (IDT) more than reaching goals. Celebration of the successes increases confidence and shows how QAPI is a process that is parallel and supporting of clinical care, not an event with lists of tasks that takes place once a month at an onerous meeting.

It is key that the team agrees on measurable goals to be met in a defined time frame. It is key that the team identifies the members who are accountable for specific tasks. The planning meeting should result in a specific goal statement with stated accountabilities.

The team needs to define the indicators that point to the effectiveness of the planned solution. These indicators need to be recorded in real time and reviewed. Everyone in the facility needs to know about the QAPI project. All need to understand the rationale, the changes, and the goals. Here the medical director’s visibility, endorsement and support can make or break the project. Most PDCA cycles require staff to change some comfortable routine. The medical director’s teaching about the change supports the staff responsible for implementing the change.

Advertising the project and getting staff buy in are necessary preconditions for the “DO” cycle. The team implements the proposed change and tracks the agreed upon indicators. At the end of the time period, the team analyzes (“checks”) the results. This second assessment step is a more focused version of the initial planning step. The tools and analysis are the same.

Were goals met? Again, “if not, why not?” questions structure the conversation. What solutions (plans) are necessary for the next cycle of improvement? Timelines, goals, and accountabilities are just as necessary in this phase as in the planning phase. At some point, the team concludes that the changes have been effective. The “acting” phase of the cycle requires implementation of policies and procedures that finalize the change. Key in this step is follow up to see that the change has “stuck.”

The QAPI/PDCA process is an effective tool for “fixing” things and improving care. The QAPI/IDT is also responsible for setting goals and evaluating the overall care of the facility. How does the QAPI/IDT team decide whether the care they provide for patients is good care?

Another powerful tool of the QAPI process is benchmarking, comparing delivered care to external national or regional standards or model facilities. Here the team is challenged by defining the domains of care and then finding data to benchmark their quality outcomes. In the era of bundling and prospective payment, this is even more critical as the QAPI/IDT is faced by a series of cost vs. quality decisions.

The QAPI process requires that the IDT meet monthly to review and document their QAPI activities. Records of QAPI activities including minutes or another method of demonstrating analysis and action must be available for review of oversight entities (e.g., state surveyors, ESRD Networks). A sample template of QAPI meeting minutes is available in the appendix.

PATIENT SAFETY AND ERROR REDUCTION

Patient safety is an important responsibility of the medical director and the QAPI/IDT. The methods of patient safety are the same as those of clinical quality, but the questions are different. In QAPI the facility monitors the process and outcomes of frequent, routine, planned events. In patient safety the team monitors and studies rare, undesirable, unplanned events and near misses (falls, medication errors, prescription errors, adverse dialysis events etc.). The credibility of this activity depends on effective error and injury reporting. The safety culture of the facility determines how successful the program will be. Creating teams to fix system and process errors by creating system solutions, rather than identifying the failure(s) of individual team members, is an approach that is more likely to improve patient safety.

Any change in practice can have unintended consequences. Changes from PDCA cycles are not immune from causing unexpected harm. The culture of safety and quality anticipates these

unintended consequences and incorporates appropriate indicators into the implementation process.

Safety rounds are an effective way for the medical director and facility management to promote a culture of safety. The task is simple: Facility leadership should circulate through the unit, listening, observing and soliciting comments from the staff. What “near misses” have they observed? What ideas do they have to make care better and safer? Engaging staff at the point of care in conversations about how to make the process of care safer will put it foremost in mind, which in turn will cause them to think about their own practices, as well as recognize and identify problems around them.

ESRD NETWORKS

The Networks are funded by CMS to assist dialysis facilities in monitoring and improving care. They are a valuable resource. They can consult with the QAPI/IDT to help in problem solving. Participation with Network initiatives are mandated by CMS rules. The benefits of Network participation far outweigh the task of compliance.

TOOLS AND RESOURCES

CMS Documents. The links below reach the source documents for the Medicare Conditions of Coverage. The first is the text of the rules. The second is the text of the rules annotated for the state surveyors with “V tags” used in defining facility compliance. The third summarizes the QIP metrics for Payment Years 2019 through 2024. It also contains a link where one can find the QIP data for individual dialysis facilities (this may provide good topics for QAPI projects).

<https://www.cms.gov/CFCsAndCoPs/downloads/ESRDfinalrule0415.pdf>

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/surveyorlaminates.zip>

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/ESRD-QIP-Summary-Payment-Years-2019-2024.pdf>

Veterans Administration Patient Safety Resources. It is the National Center for Patients Safety (NCPS). This link is a great source on the tools of root cause analysis, non-punitive error reporting and the culture of safety. It is a good complement for the AHRQ website listed below.

<https://www.patientsafety.va.gov/>

AHRQ Patient Safety. The Agency for Healthcare Research and Quality website has very useful tools and references on all areas of patient safety and quality. It is worthwhile to browse the resources available on this site.

<https://www.ahrq.gov/patient-safety/settings/esrd/resource.html>

<https://www.ahrq.gov/patient-safety/resources/index.html>

<https://www.ahrq.gov/sops/index.html>

<https://www.ahrq.gov/cpi/about/otherwebsites/psnet.ahrq.gov/index.html>

<https://www.ahrq.gov/professionals/systems/hospital/engagingfamilies/guide.html>

CDC Making Dialysis Safer for Patients Coalition. The CDC has created a set of guidelines to enhance patient safety.

<https://www.cdc.gov/dialysis/guidelines/index.html>

RPA (Renal Physicians Association) Patient Safety. The RPA took leadership in promoting and adopting patient safety science to nephrology and ESRD practice. This site has a core of very useful patient safety videos.

<https://www.renalmd.org/page/PatientSafety>

ESRD Network

Each ESRD Network has a web site containing information useful to Medical Directors. The web site of the National Forum of ESRD Networks has links to the 18 regional Networks (accessed by clicking on the map). Since information may vary between Network websites you may want to review more than one site. In addition, a call to your local Network may be useful to obtain pertinent information about specific issues you want to explore further. We encourage Medical Directors to become involved in the work of their local Network as both a community service and a learning experience.

<https://www.esrdnetworks.org>

5 Diamond Safety Program: Another excellent educational endeavor created by Network 5 is the 5 Diamond Patient Safety Program which provides training in many aspects of improving the safety of dialysis patients.

<https://www.5diamondpatientsafety.org>

Coalition for the Supportive Care of Kidney Patients: An additional important Network initiative involves quality of life and end of life planning. The web site for the Coalition for the Supportive Care of Kidney Patients offers information that can help guide a Medical Director in this area.

<https://www.kidneysupportivecare.org/for-professionals/>

Comparative Data Sources: For purposes of benchmarking and trending, there are excellent web resources available to the QAPI/IDT.

The annual data report of the United States Renal Data System (USRDS) is a review of CKD and ESRD demographics, epidemiology, economics, and outcomes. It is an excellent document to use in planning and goal setting.

<https://www.usrds.org>

Each year the University of Michigan Kidney Epidemiology and Cost Center under contract with CMS publishes a dialysis facility report (DFR). This report displays critical information about the dialysis unit. It cites comparative data from the state, region, and country. The link below gives information about the report, methods, and interpretation.

<http://www.dialysisdata.org>

The information is available to the public via the Dialysis Compare website and in downloadable form at:

<https://data.medicare.gov/data/dialysis-facility-compare>

In this era of prospective payment and bundling it is important to monitor the unintended consequences. The DOPPS practice monitor shows current year data from the DOPPS stratified random sample of US hemodialysis units. It is an excellent site to review trends in current practice

<http://www.dopps.org/DPM>

With the emphasis on increasing the use of AV fistulas and decreasing catheters, the Fistula First Catheter Last Workgroup coalition website provides useful information.

<https://esrdncc.org/en/fistula-first-catheter-last/ffcl-resources/ffcl-professionals/>

Starting in 2014, CMS required facilities to arrange for the administration of the “In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS)” survey. The website provides all the information necessary for using, scoring, and interpreting the survey. Consumer experience of health care is an important aspect of patient centered care.

<https://ichcahps.org/>

The appendix includes a summary of the QAPI process, an excerpt from the MAC QAPI Toolkit which is available to download from the Forum website. The Toolkit provides a template of the PDCA cycle that can be used a starting point for any QAPI/IDT activity.

<https://esrdnetworks.org/toolkits/professional-toolkits/qapi-toolkit/>

SELF-ASSESSMENT: QAPI

1. As a medical director in a dialysis facility owned by a large national chain, I am exempt from the QAPI requirements of the conditions for coverage because the company has a national quality program
 - a. True
 - b. False

2. The Medical Director's role in the QAPI program
 - a. A consultant whose presence at the meetings is optional
 - b. A participant who may offer suggestions but has no authority
 - c. Leader of the QAPI team, accountable for the outcomes

3. I can share the responsibilities for the QAPI process with my partners who practice in the dialysis unit.
 - a. True
 - b. False

4. The Medical Directors "operational responsibility" for the QAPI program includes which of the following
 - a. Review of quality indicators
 - b. Education of facility and medical staff on QAPI objectives
 - c. Inclusion of all staff in participating towards achievement of the QAPI objectives
 - d. All of the above

5. The Medical Director may choose to cooperate or not to cooperate with quality improvement projects of the ESRD Network
 - a. True
 - b. False

6. The Measures Assessment Tool (MAT)
 - a. Is a matrix of clinical performance indicators that fall under the responsibility of the medical director
 - b. Are specified in the ESRD Interpretive Guidance, and provide the basis for many Medicare survey and certification activities
 - c. Contain both patient level and facility indicators and outcomes

7. Characteristics of an effective QAPI program include
 - a. measurable improvement in health outcomes
 - b. reduction in medical errors
 - c. uses indicators or performance measures that are tracked over time
 - d. results in actions that result in performance improvement
 - e. all of the above

8. In addition to dialysis adequacy, anemia management, mineral metabolism, and nutrition, the medical director and the QAPI team should monitor
 - a. Water Quality
 - b. Infection Control
 - c. Adverse Dialysis Events
 - d. Patient satisfaction
 - e. All of the above

9. The minutes of the QAPI meetings should include
 - a. Reports from the ESRD Network
 - b. Review of performance against national standards such as the Dialysis Facility Report, e-Lab etc.
 - c. Results of State and Medicare Surveys
 - d. All of the above

10. QAPI
 - a. Is an activity performed once a month at the IDT meeting
 - b. Is a habit of mind and practice that informs every aspect of patient care

11. As a dialysis unit medical director, I am...
 - a. Attending a monthly meeting with unit management to oversee QAPI activities
 - b. Scheduling meetings with all health care professionals involved in achieving patient care outcomes (e.g., nephrologists, surgeons, interventionalists) to discuss and address facility-specific outcomes and/or issues
 - c. Using a routine QAPI agenda and meeting minute templates to focus and document QAPI activities accordingly
 - d. All of the above

ANSWER KEY: 1. B 2. C 3. A 4. D 5. B 6. D 7. E 8. E 9. D 10. B 11. D

QAPI MEETING MANAGEMENT



QAPI MEETING MANAGEMENT

The QAPI meeting is the point in time when the QAPI/IDT stops to consider the progress they have made toward their goals, to define the gaps yet to be bridged and to plan the next steps. Members should leave the meeting with an understanding of the *status quo* and their roles in moving forward.

The minutes of the QAPI meeting give proof that there is “an effective, data-driven, QAPI program with participation by the professional members of the IDT (V 626).”

The minutes provide the evidence that the facility is in compliance with the regulatory requirement of QAPI. There are 3 components. First the *scope* of the program is to include indicators or performance measures for all aspects of clinical and technical service and their outcomes. Second *monitor* and *act* to improve performance. Third *prioritize* improvement activities.

It is important that the meeting takes place at a certain time and date and that all members are on time and prepared. The meeting should have a chairperson, a facilitator to keep the discussion on point, and a recorder to track the decisions, actions, deadlines, and accountable members. The medical director must be at the meeting. Ideally, the medical director should chair the meeting and prepare the agenda.

The agenda should cover the core of the QAPI topics defined in the scope of the program. The conditions for coverage define the minimum content of the QAPI process (V625 to 640). The required topics include at least adequacy of dialysis, nutritional status, mineral metabolism and renal bone disease, anemia management, vascular access, medical injuries and medication errors identification, hemodialyzer reuse program (if practiced), patient satisfaction and grievances, and infection control.

Additionally, the agenda must include results of state surveys, reports from the ESRD Network, and reports from any regulatory or inspection agency.

The minutes should include reports on the status of the technical infrastructure (water system, dialysate distribution systems, dialysis machines, etc).

The team should list the topics and identify the indicators that define the system of care. There should be a control document listing each topic and its indicators.

Ideally, members should distribute their reports (preferably by electronic means to minimize paper consumption) in advance of the meeting to devote as much meeting time to discussion and analysis and as little time to listing of data elements.

The team should design a process that minimizes data retrieval and re-copying of last month's data to this month's flow sheet. Some find it helpful to keep a master data sheet (shareable Excel spreadsheet, for example) that shows each month's summary results in a column (month) and row (data topic) and a set of minutes that refer to the master data sheet listing the details of conclusions and plans.

The facility should have a Quality Plan. The plan should define the membership of the QAPI team, the members' responsibilities, and the process of goal setting and decision making. The plan should list the meeting times. The plan should have copies of the control documents, improvement forms, meeting minute templates. How will changes suggested by PDCA cycles be implemented, by whom and by what authority. How will changes in policy and procedure be monitored for compliance and effectiveness. If PDCA activities results are implemented as "pilot projects," the QAPI team should have a standard format for proposing and analyzing the results.

The attached summary sheet is an example that some have found useful in following progress from month to month without excessive recopying. The form allows the team to establish and list goals, then show the results. It helps organize the agenda and avoids duplication within the minutes.

QAPI MEETING: DATA RECORDING FORMAT

Centers for Dialysis Care

Annual QAPI Summary 2012

Facility _____

		2012					
Indicator	GOAL	YTD	January	February	March	April	
Census (state the source for this data)							
Beginning							
IN							
OUT							
Deaths							
difference							
End							
Deaths < 360 first HD ever							
Transplant							
Treatments (State source for this data)							
Total							
# Total Missed Tx							
% Missed Tx							
# missed due to hosp							
% missed due to hosp							
# Other missed							
% Other missed							
Adequacy (state the source for this data)							
% Kt/V ≥ 1.4	89						
% Kt/V ≥ 1.2	98						
% URR ≥ 65%	98						
BP & Weight (state the source for this data)							
% > Dry Wt + 0.5 kg							
% > 150/90							
% >10 ml/kg/hr							
Anemia (state the source for this data)							
HGB % < 10	9						
HGB % > 12	4						
10 ≤ HGB % ≤ 12	87						
# of Pts Transfused							
# patients EPO > 8000 units							
Bone (state the source for this data)							
8.2 ≤ Ca % ≤ 10.1							
3.5 ≤ P % ≤ 5.5							
P ≤ 6							
100 ≤ % PTH ≤ 500							
Nutrition (state the source for this data)							
% Albumin ≥ 3.8	65						
# Pts Wt Loss ≥ 5%							
Transplant Educ (state the source for this data)							
On WL							

Centers for Dialysis Care

Annual QAPI Summary 2012

Facility _____

% On WL						
New Pts last month						
TP Education Compl						
%NP Trnsplnt Educ	100					
Ann Education Compl						
% Ann Education Compl	100					
Access (state the source for this data)						
% AVF	58					
%AVG						
%AVG w/ AVF						
% Cath < 90 days						
% Cath >= 90 days						
%Cath w/ AVF						
% Cath w/ AVG						
% Other						
# New Pt AVF						
# New Pt AVG						
# New Pt Cath Only						
# AVF to get to 66%						
AFM Due						
AFM Done						
% AFM Done						
Infection (state the source for this data)						
# Blood Cultures						
# Pats w/ Blood Cultures						
# Positive Cultures						
# Pats with > 1 dose ABX						
# Access Pos Cultures						
# Access Infections						
# pts with catheter related blood stream infections						
# pts with catheter exit site infections						
# pts with AVF caused blood stream infections						
# pts with AVF-Button Hole caused blood stream infections						
# pts with AVG caused blood stream infections						
# Sentinel Organism						
# ADE (fever/chills)						
Hepatitis B (state the source for this data)						
# Pts Ab < 10						

Centers for Dialysis Care

Annual QAPI Summary 2012

Facility _____

# Pts Tested for Ag						
% Tested						
# Seroconversion						
Vaccinations (state the source for this data)						
% Pts PneumV ≤ 5 yrs						
% Pts with Influenza						
% Pts refused Influenza						
Hospitalizations (state the source for this data)						
# Hosp Admits						
# 30 day re-admits						
ANNUAL						
TB Risk						
Pat Sats Survey						
Dialysis Facility Report						
Network E-Lab						
Risk Management (state the source for this data)						
Total Treatments						
Pt Falls						
Pt Injury not fall						
Customer Service						
ODH Survey						
# Staff Needle Stick						
# Staff Back Injuries						
# ER transports						
# medication errors*						
Safety Security Conduct						
Level 4 Events						
Renal Network Compliance						
Dialysis Facility Report						
e-lab report						
Other in Minutes						
External Reporting						
ODH Corrective Action Plan						
Fire Marshal Corrective Action						
Board Of Health Reporting						
Other External Report						
MSW (state the source for this data)						
KDQOL 4 mos due						
KDQOL 4 mos done						
KDQOL Annual due						
KDQOL Annual done						
HCTA active						
Voc Rehab Referrals						
Nursing (state the source for this data)						

Centers for Dialysis Care Annual QAPI Summary 2012 Facility _____

Med Reviews Due					
Med Reviews Done					
# of unstable Pt					
% of unstable pts					
# Initial CIA due					
# initial CIA done					
% Initial CIA done					
# 90 day CIA due					
# 90 day CIA done					
% 90 day CIA done					
# Annual CIA due					
# Annual CIA done					
% Annual CIA done					
# Unstable CIA due					
# Unstable CIA done					
% Unstable CIA done					
# RIA due					
# RIA done					
% RIA done					
Fire Safety / Emergency Prep					
Fire Drills					
Fire Detection & Suppression					
Technical					
Biomed Equip Insp/PM					
Bldg & Grounds Equip					
% Water Cultures over AL					
% Water LAL over AL					
Culture Action Plan in Place					
% Machine Cultures over AL					
% Machine LAL over AL					
Culture Action Plan in Place					
SDS					
patients on special baths					
Treated Water System					
REUSE					
Reuse Quality Control					
Ave Reuse per Failed Dialyzer					
Patients < 10 Reuses					
Patients 10-24 Reuses					
Patients 25-49 Reuses					
Patients > 49 Reuses					
patients on single use					
patients not on heparin					
Audits					

Centers for Dialysis Care Annual QAPI Summary 2012 Facility _____

Ohio Pharmacy Board						
Infection Control						
Medical Records						
Other Audit						
Technical Reuse						
Technical Water						
Technical SDS						
Staff Training and Education						
Done						
Due						

SELF ASSESSMENT: QAPI MEETING MANAGEMENT

Questions for the medical director:

1. I attend monthly meeting with unit management to oversee QAPI activities

_____ YES

_____ NO

2. I schedule meetings with all health care professionals involved in achieving patient care outcomes (e.g., nephrologists, surgeons, interventionalists) to discuss and address facility-specific issues?

_____ YES

_____ NO

3. I use a routine QAPI agenda / meeting minutes template to focus and document activities accordingly?

_____ YES

_____ NO

ANSWER KEY: All answers = "Yes"

THE REGULATORY SURVEY



DIALYSIS FACILITY READINESS: THE ESRD REGULATORY SURVEY

In order for CMS to ensure that a dialysis facility is abiding by the ESRD Conditions for Coverage (CfC), inspection of the facility is required. This inspection, commonly referred to as a survey, is conducted by a representative of the state's department of health organization and/or possibly by CMS Regional Office Representative(s). The Medical Director for the facility is responsible for all aspects of the dialysis facility, so it is essential to be familiar with the survey process so as to offer leadership and support to the facility staff. It is also imperative that the Medical Director is viewed as an active and willing participant in the process by the survey team.

The ESRD facility survey is not something that is prepared for overnight. For physicians familiar with the hospital setting, the ESRD survey process can be compared to a hospital Medicare survey or a Joint Commission (JCAHO) survey. A constant state of readiness is required. This readiness is not an "ad hoc" state; it should be a permanent state, demonstrating that the facility always provides the highest quality of safe and effective care for its patients.

The facility staff, under the leadership of the Medical Director, must fully understand and have the ability to clearly document their actions related to the requirements of the CfC. Through this documentation, it needs to be evident to the survey team that the facility continuously practices in accordance with the Federal regulations.

There are different types of ESRD Medicare Surveys. When an application for a new facility is submitted to the state, an "initial" survey is performed. This survey will verify initial compliance with the CfC. The Federal survey may be preceded by a state licensing survey if required by the facility's state regulations, ensuring that the facility's physical plant is in compliance with the state's health care facility rules. The initial Medicare survey will be completed after the facility begins to dialyze a few patients, thus the necessity to have patients receiving care in the facility. Patients receiving care at the time of initial survey should reflect the services being requested and/or provided (i.e., in-center, peritoneal dialysis, home hemodialysis, etc.). The state surveyors review the full spectrum of delivered care as it relates to the CfC. It should be noted, however, that the facility may not bill ESRD Medicare for its services until it is surveyed and in receipt of Medicare certification, reflecting compliance with the CfC, from CMS.

While it is the goal of CMS to have facilities surveyed once every three years, because of funding constraints and individual state health department priorities, many facilities may not have a re-certification survey completed for longer than this three-year goal. CMS and State agencies utilize Dialysis Facility reports to assist in determining which facilities are to be surveyed during the fiscal year.

In addition to regular re-certification surveys, a facility may find that it is the subject of a survey based on a complaint or grievance. If a complaint or grievance is filed with the state department of health, an ESRD Network, or CMS, as part of the complaint/grievance process, the state may visit the facility and complete a state licensing survey, a focused Medicare survey or a full Medicare survey. It is important to recognize that the state survey team may enter any Medicare-certified dialysis facility for survey activities. Dependent upon initial findings, the survey may be specific to complaint/grievance issue(s) or transition to an overall survey for any issues identified related to CfC compliance.

The survey process may take from 1 to 4 days, depending on the type of survey and the findings along the way. The survey in all circumstances will be unannounced.

The ESRD Core Survey:

In an effort to streamline the survey process and focus on the key areas that affect patient safety and quality, in 2014 CMS began a new survey process to survey dialysis facilities known as the ESRD Core Survey. According to CMS (wording from the ESRD Core Survey Field Manual): “The ESRD Core Survey process is intended to efficiently utilize survey resources to identify deficient facility practices which most impact patient safety and clinical outcomes. The Core Survey focuses on clinical areas where performance improvement is indicated at the individual facility based on facility-specific data and information.”

The ESRD Core Survey process was developed with the intention of assessing individual dialysis facilities and their staff (not corporate-based or regional).

The ESRD Core Survey Manual describes the expectation of a dialysis facility’s QAPI program to engage staff in order to monitor clinical outcomes and to monitor facility operations, and to conduct performance improvement actions when indicated, to improve quality and patient safety. As part of the Core Survey, it is expected that dialysis facilities will conduct audits to monitor the competence and compliance of their staff in performing technical and patient care procedures, including those requirements in the ESRD Cfc and those recommended by the CDC. Audits are expected to be conducted by trained, qualified observers. The observers are expected to have completed training to appropriately evaluate the accuracy of the procedure being audited. Areas of required audits include infection control, water testing, dialysis fluid (including acid concentrate) mixing and testing, dialysis equipment operation, and dialyzer reprocessing/reuse procedures if reuse is being used in the facility. Audits should demonstrate whether staff demonstrated competency in the procedure being audited, and when any lapse in practice is observed, the facility is expected to show actions to achieve performance improvement.

The most current version of the ESRD Core Survey Field Manual can be found (and downloaded) at this website:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-certification/guidanceforlawsandregulations/dialysis.html>

The same website also includes the most current Core Survey Data Worksheets, Laminates, and a link to the CMS CfC Interpretive Guidance, which is the document that details all of the CfC, with the associated V-codes that are used by state surveyors to designate different areas of dialysis quality that are being assessed during the survey (ie Hand Hygiene, Catheter Care, Chloramine Testing, Comprehensive Assessments, etc..). The V-Codes within the Interpretive Guidance are also used to indicate area of citation when a surveyor finds areas of deficiency during the Core Survey.

How is the Core Survey Conducted?

The ESRD Core Survey may be conducted using one of two methods:

- 1) Using the Core Survey Manual including the Core Survey worksheets (which are associated with specific survey tasks), or
- 2) Surveyors may use Surveyor Technical Assistant for Renal Disease (STAR), which is automated, ESRD survey software which has been provided to all State Survey Agencies (SA).

The Core Survey process is organized by specific “tasks”, which are areas included in the survey that are specific to dialysis facilities and the care of dialysis patients. The process includes assessing “core” activities for each task, and “triggers” for each task which indicate deficiencies in practice. When a surveyor identifies a trigger during a Core Survey task, more investigation may be conducted into that area to determine if a citation (indicated by areas described in the cfc Interpretive Guidance as V-code) is warranted.

The ESRD Core Survey Manual is organized by chapters or “tabs”. The 1st tab describes the Core Survey Process, including tasks and triggers for each task. The 2nd tab includes “laminates” which summarize key areas of Core Survey and may help also serve as reference tools for Medical Directors to help facilities to be prepared for survey. The laminates include “Outline of ESRD Core Survey Process”, “ESRD Core Survey Triggers”, “ESRD Facilities V-Tags & Identifiers”, and “Infection Control/Requirements for Isolation Room/Area”.

The 3rd tab “Presurvey Preparation & Introductions” may be the most important tab for Medical Directors to study and use. This tab includes the “ESRD Core Survey Data Worksheet” which

describes the information that the surveyor will ask facilities to have ready during the survey, and the timeframe in which they will request the information. Some of the information is required within 3 hours of the start of the survey. Therefore, it is highly recommended for Medical Directors to ensure that their facilities keep the information in this Core Survey Data Worksheet updated each month and ready for a survey, since the survey timing will be unannounced, and it will be very difficult and stressful for staff in dialysis facility to pull together all of this information within the 3-hour time frame, unless it is prepared ahead of time, and always up to date.

The main areas of the Core Survey Worksheet that should be kept up to date is the Entrance Conference Materials List. The Entrance Conference Materials List includes information requested within 3 hours and by the end of day 1 and day 2 of start of survey. The Medical Director should be aware of this data monthly, and a good practice might be to review this data during QAPI each month.

The following is the list of information on the Core Survey Worksheet that surveyors will request, and the timeframe to provide the information (from FY2017):

Needed within 3 hours:

- List of current patients by name, separated into modalities
- List of facility key personnel: medical director, administrator, nurse manager, social worker, dietitian, chief technician, and home training nurse(s)
- Current in-center hemodialysis patient schedule by days & shifts with any isolation patients identified (seating chart or assignment sheet)
- List of patients admitted to this facility within the past 90 days who are currently on census (do not include visiting patients) separated by modality with date of admission
- List of patients who have been designated as “unstable” for any month in the past 3 months, including reason for unstable and month
- List of all patients who were involuntarily discharged (not transferred to another outpatient dialysis facility) from this facility in the past 12 months
- List of all discharged patients categorized as “lost to follow up” (i.e., not transferred out or discontinued dialysis) for the past 12 months
- List of home dialysis (HD or PD) patients scheduled to be seen at the facility during the survey
- List of residents of long-term care facilities WHO RECEIVE THEIR HD or PD AT THE LTC facility and the name of the LTC where they are receiving dialysis
- Hospitalization logs with admitting diagnoses listed for 6 months
- List of current patients readmitted to the hospital within 30 days of discharge in past 6 months, separated by modality
- Infection logs for past 6 months

- List of in-center HD patients who are dialyzed with 0 K+ or 1.0 K+ dialysate
- All patients' individual laboratory results for hemoglobin, Kt/V, uncorrected calcium, phosphorus and albumin for the current 3 months; separated by modality

Materials needed by the end of Day 1 of survey:

- Vaccination information:
 - # of patients who received a complete series of hepatitis B vaccine
 - # of patients who received the influenza vaccine between August 1 and March 31
 - # of patients who received the pneumococcal vaccine
- Staff schedule for the last two weeks by day
- Policy and procedure manuals for patient care, water treatment, dialysate preparation and delivery, and dialyzer reprocessing/reuse, if applicable
 - Anemia management protocol
- Patient suggestion/complaint/grievance log for past 6 months
- Adverse events (e.g., clinical variances, medical errors) documentation for the past 6 months
- QAPI team meeting minutes for past 6 months and any supporting materials
- Copy of CMS-approved waivers for medical director and/or isolation room
- Facility Life Safety Code attestation or waiver (required if in-center or home training tx area does not provide exit at grade level or if the facility is adjacent to an industrial high hazard occupancy)
- Staff practice audits for infection prevention while performing direct patient care (12 months)
- For Water and Dialysate Review: logs for:
 - Daily water system monitoring-2 months
 - Total chlorine testing-2 months
 - Bacterial cultures and endotoxin results-water and dialysate-6 months
 - Chemical analysis of product water-12 months
 - Staff practice audits for water testing, dialysate mixing & testing and microbiological sampling-12 months
- For Equipment Maintenance Review:
 - Documentation of preventative maintenance and repair of hemodialysis machines-12 months
 - Documentation of calibration of equipment used for machine maintenance-12months
 - Documentation of calibration of equipment used to test dialysate pH/conductivity-2 months
- For Dialyzer Reprocessing Review, if applicable, logs for:
 - Bacterial cultures and endotoxin results from reuse room sites-6 months
 - Preventative maintenance and repair of reprocessing equipment-12 months

- Reuse QA audits-12 months

Materials needed by noon on Day 2 of survey

- Completed “Personnel File Review” Worksheet (or same information generated electronically)
- Completed “CMS 3427-End Stage Renal Disease Application and Survey and Certification Report”

The rest of the tabs review in detail the process the surveyors will go through conducting the Core Survey, including the information they may ask for and some of the interview questions they may use when interviewing staff. The Medical Director should be familiar with these questions so she/he can help the staff in the dialysis facility remain prepared for a survey. The tabs also include some of the observations that surveyors will perform, and it may be helpful for Medical Directors to familiarize themselves with these observations.

The ESRD Core Survey will include a Presurvey, in which the surveyors will review the facility’s current Dialysis Facility Report (DFR) for key outcomes data and will note where facility does not meet national averages and will review the facility survey history. In addition, the surveyors will contact the facility’s ESRD Network prior to the survey. Based on the presurvey, the surveyors will determine data-driven focus areas for the survey.

The survey itself will begin with introductions, followed by an Environmental “Flash” Tour, then an Entrance Conference. During the Entrance Conference, the surveyors will present the facility with the Core Survey Worksheet to fill out. Following the Entrance Conference, the surveyors will conduct observations of hemodialysis care and infection control, conduct patient interviews, and may interview staff including the water treatment and equipment technicians, Medical Director, Nurse Manager, Home Training Nurse, Dietitian and/or Social Worker. Surveyors will also review Medical Records of patients and Personnel. Examples of these reviews and interviews are included in the ESRD Core Survey Manual. Then the surveyors will review the facility QAPI program and will end the survey with an Exit Conference.

Prior to the Exit Conference, the surveyors will meet as a survey team to discuss survey findings and determine preliminary level of deficient practices and will plan to present their findings at the exit conference. The findings will then be presented to the facility leadership during the exit conference.

Following the survey, the facility will receive a letter from the surveyors detailing citations found during the survey, including the condition or V-code (from the CfC Interpretive Guidance) that is

out of compliance, their findings as well as actions or in-actions that lead to the citation. The letter which the facility receives will include directions regarding submission of the actions the facility must take to correct the violation, and the timeframe for the facility to correct the deficiency. Typically, the facility may have approximately 10 days to complete a corrective action plan, and return this to their State Surveyors, and may need to be in full compliance within 30 days of the survey. For Conditional Level Noncompliance (noncompliance with condition in the CfC), the state surveyors may resurvey the facility around 30 days after survey to ensure the facility is then in full compliance. If facility remains out of compliance, then the facility may be in jeopardy of losing their CMS certification. In the event that the survey team feels that a violation is so egregious that the facility should not continue to treat patients until the violation is corrected, the facility may be notified that the processes cause “immediate jeopardy” to the lives of patients. This finding is serious and will require swift action on part of the facility team. If the survey team finds that the facility is in full compliance with the CfC, the facility will receive a letter stating that fact.

Accreditation Organizations (AOs) and “deemed status”

Original ESRD law prohibited “Deemed status” for outpatient dialysis. Deemed status means that CMS accepts the Accreditation Organization’s (AO) standards as equal to the CMS ESRD CfC. Due mainly to long waits for Initial surveys of ESRD facilities (was considered Tier 3 for state surveyors), there was a great lobbying effort to Congress, and in 2018 language was included in the Budget Bill to now allow “deemed status” for ESRD, and to require initial ESRD surveys to be done within 90 days of facilities being ready to open. The bill was passed and signed into law.

Now it is possible for a dialysis facility to achieve certification by CMS based on the successful completion of an initial survey by either a state agency (as has been done up until now), or an accreditation organization with deemed status. A facility or corporation may choose to contract with an AO with deemed status (notice will be made publicly when an AO achieves deemed status) and pay for a survey under the AO standards. The AO standards must be equivalent to the CMS regulations, but also may include additional requirements, or be written in a different way. Similar to state surveys, AO surveys are expected to be unannounced. All AO are required to be national organizations, so AO surveys should be similar in different states. The maximum accreditation period by AO is 3 years and resurvey is required to continue accreditation. If a dialysis facility is accredited with an AO, in the event a survey is needed due to a complaint, the AO will perform the investigation if there isn’t a potential serious threat to patient safety. However, the state surveyors will still complete the survey if complaint related to serious patient safety threat, as authorized by CMS.

Physician Leadership in the Outpatient Dialysis Clinic



PHYSICIAN LEADERSHIP IN OUTPATIENT DIALYSIS CLINICS

One of the most important roles of dialysis clinic medical directors is the leadership position entrusted to them. The Outpatient Dialysis Medical Director is a position of leadership, and the nephrologist director serves as the leader of the kidney care team. This expectation may be in contrast to the fact that many practitioners may not have acquired essential skills or formal training for such a leadership position.

Some organizations and professional societies may offer leadership courses or abbreviated workshops including around the time of their annual conferences, and course participants often receive a certificate in addition to CME and MOC credits.

Additionally, the dialysis medical director may be expected to innovate and to embrace Practice transformations towards value-based care are occurring with both Federal mandatory (ESRD Treatment Choices) and voluntary (Kidney Care Choices) programs, as well as commercial payor programs.

There is a need for more women and minority physicians in the leadership positions to expand diversity in nephrology and dialysis leadership roles.

The management of dialysis operations and other aspects of nephrology practices continue to evolve and become more complicated and challenging. To assist nephrologists and practice administrators with efficiently managing the business aspects of practice, the dialysis medical director should ideally be familiar with population health, benchmarking, revenue cycle best practices, ESCO and ETC management strategies and opportunities to maximize utilization of advanced practitioners to improve patient outcomes.

The dialysis medical director as a leader is expected to have sound knowledge in additional areas beyond focused dialysis domain including CKD and nutrition, hypertension management, and acid-base and electrolyte disorders, among others. Ideally, the fundamental knowledge and leadership in the in-center hemodialysis domain is to be supplemented with deep knowledge in home dialysis therapies, self-care in the dialysis unit and transitional dialysis.

The nephrology and dialysis leader of the contemporary era is expected to have a proactive role to patient representation of the clinic as well as other kidney patient and renal support networks.

Another important role for the physician leader in pertaining to the burnout of the nephrologists and Advanced Practice Providers (Nurse Practitioners and physician assistants) due to high work burden as well as to himself/herself as a result of multiple administrative burdens placed on nephrologists. Nephrologist leader is expected to keep up with the dynamic aspects of legislative and regulatory developments, changes in the Medicare ESRD systems and physician fee schedule,

Quality Payment Program, etc. Additionally, ensuring excellence in nephrology practice, the medical director leader is expected to deliver relevant, timely and practical educational presentations and updates for other nephrologists, dialysis staff and patients to be used in the practice settings.

The following is a list of some ideal skill sets to possess as the nephrology leader:

- Understand the compliance and regulatory processes, and implement these effectively into QAPI program.
- Ability to conduct and successfully implement conflict resolution.
- Effectively negotiate under challenging circumstances.
- Create win/win situations for all parties including patients, dialysis staff and other providers.
- Better train dialysis teams and improve their performance.
Cultivate a growth-based mindset within the organization the dialysis center is affiliated.
Accurately measure the financial health of the operation and affiliated organizations, institutions, and other stakeholders.

Quality Incentive Program (QIP) for the Medical Director



QUALITY INCENTIVE PROGRAM (QIP) FOR THE MEDICAL DIRECTOR

History

The statutory basis for the QIP is section 1881 (h) of the Social Security Act which was added to by the Medicare Improvements for Patients and Providers Act in 2008 by section 153b, as amended by section 3401 (h) of the Affordable Care Act in 2010 and the Protecting Access to Medicare Act in 2014. The goals of the legislation were to promote patient health by providing a financial incentive for dialysis facilities to deliver high-quality patient care and specifically authorize a payment reduction if a facility did not meet or exceed the minimum Total Performance Score (TPS) of up to 2%. The Centers for Medicare and Medicaid Services (CMS) is responsible for rulemaking concerning the QIP and by statute must: (1) select measures; (2) establish the performance standards that apply to the individual measures; (3) specify a performance period with respect to a year; (4) develop a methodology for assessing the total performance of each facility based on the performance standards with respect to the measures for a performance period; (5) apply an appropriate payment reduction to facilities that do not meet or exceed the established TPS ; and (6) enable public reporting of the results.

Certain aspects of patient care must be included by statute in the measures selected for inclusion in the QIP. These include anemia, adequacy, patient satisfaction, iron management, bone mineral metabolism and vascular access. As of 2016, conditions treated with oral-only drugs reflecting outcomes must be included. These statutory requirements are the basis for certain measures that might otherwise appear to have become irrelevant in current management of patient's with ESRD.

Measure Selection

This is the most mature program outside the hospital initiatives in the CMS Quality Payment Program. The initial final rule in 2011 contained 3 quality metrics for performance year 2010 to determine payment in year 2012. These included a measure reflecting adequacy (URR – Urea Reduction Ratio), and two measures covering anemia management (hemoglobin > 10 g/dL and < 12 g/dL). The QIP for performance year 2016 and payment year 2018 migrated the various measures to the domains of the National Quality Strategy consisting of a Safety subdomain, Patient and Family Engagement/Care Coordination subdomain, and a Clinical Care subdomain along with 5 reporting measures for a total of 16 measures. The current QIP for performance year 2019 and payment year 2021 has modified the domains to a Clinical Care domain, Patient and Family Engagement domain, Care Coordination domain and Safety domain. These include 9 clinical and 3 reporting measures with the removal of 4 reporting measures (serum phosphorus, anemia management, pain assessment and follow-up, healthcare personnel influenza vaccination) with a significant redistribution of domain weights and the weights of individual measures within each domain (Figure 1). The final PPS 2019 rule included the measures for

performance year 2020 and payment year 2022. The domains will remain unchanged; however, a new clinical measure will be included under the Care Coordination domain, the Prevalent Patients Waitlisted (PPPW). This will decrease the final weights of the Standardized Hospitalization ratio (SHR) and Standardized Readmission Ratio (SRR) and a new reporting measure will be included under the Safety domain, the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) decreasing the weights of the NSHN BSI clinical measure and NSHN Dialysis Event Reporting measure. The final rule for the PPS 2020 may result in additional changes to these measures.

Figure 1:

**QIP PY 2021-PPS 2019 Final Rule
Finalized Measure Domain Weighting**

Domain	Weight (TPS)	Measures/Measure Topics	Weight (Measure)
Safety	15%	NSHN BSI Clinical Measure NSHN Reporting Measure	9% 6%
Patient and Family Engagement	15%	ICH CAHPS Measure	↓ 15%
Care Coordination Measure	30%	SRR Measure SHR Measure Clinical Depression and Follow-Up Reporting Measure	↑ 14% ↑ 14% ↑ 2%
Clinical Care Measure	40%	Dialysis Adequacy Measure Vascular Access Type Measure Topic Hypercalcemia Measure STrR Measure UFR Reporting Measure	↓ 9%(+3) ↓ 12%(+6) ↑ 3% ↑ 10%(-12) ↑ 6%(+3)

QIP Scoring Methodology and Payment Penalties

The QIP remains a “penalty” rather than a “reward” pay-for-performance program. In other words, a facility that does not meet or exceed the minimum TPS will have a payment reduction. If the facility meets or exceeds the minimum TPS, payment remains the same. The fact that this aspect of the QIP is required by statute is not appreciated by many nephrologists.

The facility TPS is based on a 100 point scale with 5 categories of possible penalties. A facility can completely avoid any penalty by achieving a TPS equivalent or greater than the minimum TPS for a given payment year. This varies each year, however for the current performance year or payment year 2021 is 56 points (Figure 2). Additional penalty categories include 0.5%, 1.0%, 1.5% and 2.0%. The penalty is assessed for the entire calendar year as the percentage of a facility’s annual Medicare revenues.

Figure 2:

**QIP PY 2021- PPS 2019 Final Rule
Payment Reduction Scale - Finalized**

FACILITY TOTAL PERFORMANCE SCORE	PAYMENT REDUCTION
100 - 56 points	0%
55 - 46 points	0.5%
45 - 36 points	1.0%
35 - 26 points	1.5%
25 - 0 points	2.0%

The TPS is based on the individual measure scores within each of the 4 domains. The CMS currently assigns a higher weight to measures that focus on outcomes rather than clinical processes. The weights of any measures WITHIN a given domain that a facility does NOT receive a score will be redistributed proportionally to the remaining measures within that domain. If there are NO scores for any measures within a given domain, the domain's weight will be redistributed proportionally to the remaining domains/measures. A facility must have at least 1 measure score in any 2 of the 4 Measure Domains.

The minimum TPS is calculated annually by scoring each clinical measure at the National Performance Score (NPS) of facility performance for the measurement year 2 years prior to the current measurement year. For the current payment year (2019) year, this would be the NPS in 2017. Each reporting measure must equal the 50th percentile of facility performance on the 5-payment year 2019 reporting measures based on performance in 2017. The methodology has remained consistent for many years enabling a facility to optimize their score by either achievement or improvement to maximize performance, and for the current performance year (2019) includes the following performance thresholds: (1) Achievement Threshold– 15th percentile of performance nationally during 2017; (2) Benchmark – 90th percentile of performance nationally during 2017; (3) Improvement Threshold – a given facility's performance rate during 2018; (4) Performance Period – the current year (2019); (5) Performance Standard – 50th percentile of national performance rates during 2017; (6) Performance Rate – a facility's raw score based on specifications for each measure. Minimum data requirements exist for each

measure and will determine whether or not that measure will be included in a facility’s TPS. (Figure 3).

Figure 3:

**QIP PY 2021-PPS 2019 Final Rule
Minimum Data Requirements**

Measure	Minimum Data Requirements	CCN Open Date	Small Facility Adjuster
Adequacy	11 QPts	N/A	11-25 QPts
VAT: Catheter	11 QPts	N/A	11-25 QPts
VAT: Fistula	11 QPts	N/A	11-25 QPts
Hypercalcemia	11 QPts	N/A	11-25 QPts
NHSN BSI	11 QPts	Before 1/1/2018	11-25 QPts
NHSN DE	11 QPts	Before 1/1/2018	N/A
SRR	11 Index DCs	N/A	11-41 Index DCs
STrR	10 PtYrs at risk	N/A	10-21 PtYrs at risk
SHR	5 PtYrs at risk	N/A	5-14 PtYrs at risk
ICH CAHPS	30+ completed	Before 1/1/2018	N/A
Depression Screening	11 QPts	Before 7/1/2018	N/A
UFR	11 QPts	Before 7/1/2018	N/A

CMS does consider removing a quality measure if 1 or more of the QIP measure removal factors exist: (1) measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made (in other words, the measure is topped out); (2) performance or improvement on a measure does not result in better or the intended patient outcomes; (3) a measure no longer aligns with current clinical guidelines or practice; (4) a more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available that is more proximal in time to the desired patient outcome; (5) a measure that is more strongly associated with the desired patient outcomes for the particular topic becomes available; (6) collection or public reporting of a measure leads to negative or unintended consequences ; (7) not feasible to implement the measure specifications; (8) associated costs outweigh the benefits of continued use of the measure.

CMS strategic goals now include a Meaningful Measures Initiative which is being used as the framework for all of the Quality Payment Programs to include the QIP (Figures 4 and 5).

Figure 4:



Figure 5:



The total number of facilities receiving a penalty has varied since the inception of the QIP with the initial penalties assessed in 2012 and the current penalties finalized for 2019. 26.4% of facilities will be penalized this year (Figure 6).

Figure 6:

Penalty	PY 2012	PY 2013	PY 2014	PY 2015	PY 2016	PY 2017	PY 2018	PY 2019
0.5%	16.6%	-	2.7%	3.9%	3.5%	14.8%	9.5%	17.2%
1.0%	6.0%	3.2%	1.0%	0.7%	0.8%	3.3%	2.7%	6.0%
1.5%	7.7%	3.5%	0.3%	0.4%	0.6%	0.8%	1.0%	2.0%
2.0%	0.6%	2.8%	0.8%	0.6%	0.4%	0.4%	1.9%	1.2%
Total	30%	10%	5%	6%	5%	19.3%	15.1%	26.4%

Role of the Medical Director in Optimizing Facility Performance on the QIP

The QIP should ideally facilitate the application of evidence and data into clinical practice to both drive both policy and incentivize better care. ESRD data are aggregated at the dialysis facility level and reported through the CMS Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) and the Centers for Disease Control and Prevention (CDC) using the National Healthcare Safety Network (NHSN). The nephrology community has been in the vanguard of healthcare in its reliance on population-based metrics to both describe performance and improve delivered care. The CMS is explicit about utilizing this approach to drive the continued migration from volume to value-based care for Medicare beneficiaries and tries to select measures for the QIP that span multiple domains of the National Quality Strategy. The National Quality Forum (NQF) is the chosen entity for endorsement of facility-based measures for use in the QIP. Despite a detailed and transparent process for endorsement and selection of measures, the fact remains that the majority of measures in current use in the QIP are not evidence based. The evidence in support of the majority of these measures is observational, and although some (access, adequacy) appear to be self-evident; they are not supported by rigorous, randomized controlled trials.

The goal of the Medical Director should always align with the dialysis provider to achieve the best possible facility performance on each measure used in the assessment of the Quality of Care delivered to each patient in a given facility. The QIP is likely to be one of several groups of measures used to gauge process of care and outcomes. The QIP, however, remains the one program where underperformance could result in a significant financial penalty and burden for the facility. Attention should be directed each month during the Quality Assessment and Improvement meeting with facility staff to a review of facility performance on each of the QIP measures with the objective of at least meeting the minimum TPS to avoid the application of a financial penalty for that year. Since the QIP remains a “penalty” rather than a “reward” pay-for-performance program, this should inform the efforts of the Medical Director.

RESOURCES



QUALITY IMPROVEMENT

There is no one right way to do quality improvement. The important thing is to identify and describe the problem(s), analyze the causes, determine what resources are available, brainstorm and prioritize solutions, and implement a plan. The results determine whether improvement occurred, quantitate it, and analyze the findings. There are numerous templates that can be utilized. So called “rapid cycle change” seeks to simplify and accelerate the process, and asks three questions: What are we trying to accomplish, what changes will bring about an improvement, and how will we know a change is an improvement? It forgoes complex flow charts and step by step instructions in favor of small-scale changes that can be tested, revised and staged.

We have outlined the basic processes of a QAPI project below in narrative form. The facility should use its internal, interdisciplinary resources to “fill in the blanks” to design its own project. Importantly, the facility should feel free to start with a small piece of the identified problem, work through the QAPI process, then use the information and experience gained to tackle the next project.

Problem: Define the problem that needs to be addressed. It could be an outcome or a process.

Goal: State what you would like to see instead. **Important:** You can do this in stages. You do not have to address all aspects of the problem or even all patients in the first project.

GET STARTED

First, decide what data you need from patient charts, facility logs, etc.

Next, decide which persons at your facility should be included in the team effort. The team should be interdisciplinary, tailored to the problem.

To get started, consider what the root causes and barriers prevent your facility from performing optimally. These may be personnel factors, patient factors, equipment or physical plant issues, lack of processes or faulty processes, language barriers, financial or reimbursement problems, etc.

Decide on an “AIM” Statement; what are you trying to accomplish? Establish goals. For example, you may aim for 90% success in reaching an identified clinical goal or may want to see a particular clinical process performed the same way 100% of the time.

How will you measure improvement? This may require chart audits, review of logs, observation of practices in the facility, questionnaires or other means of assessing improvement.

Measurement: decide on a numerator and an appropriate denominator.

Brainstorm potential solutions based on barriers / root cause prioritized by your QI team. You can prioritize the root causes as well as the solutions. Prioritization will help you determine which root causes are most critical and significant. Potential solutions can be prioritized by how “doable” they are, as well as by their anticipated impact. Not all root causes or solutions need to be addressed in every QAPI project.

PLAN: Plan a specific intervention(s). Keep it simple and focused; do not over-reach. Your initial project may be quite limited; you may learn more than you think. You can use what you learn to determine what the next project should be.

Designate personnel and resources for each intervention.

Consider whether to target a specific subgroup for initial intervention.

Determine a timeline; when and how will you collect your follow-up information?

DO: Implement your intervention. Each intervention should have a timeframe and designated personnel.

Collect your follow-up data at the agreed-upon timeline.

Tabulate and/or graph your data, using numerators and denominators where appropriate. Calculate percent changes. **Document.**

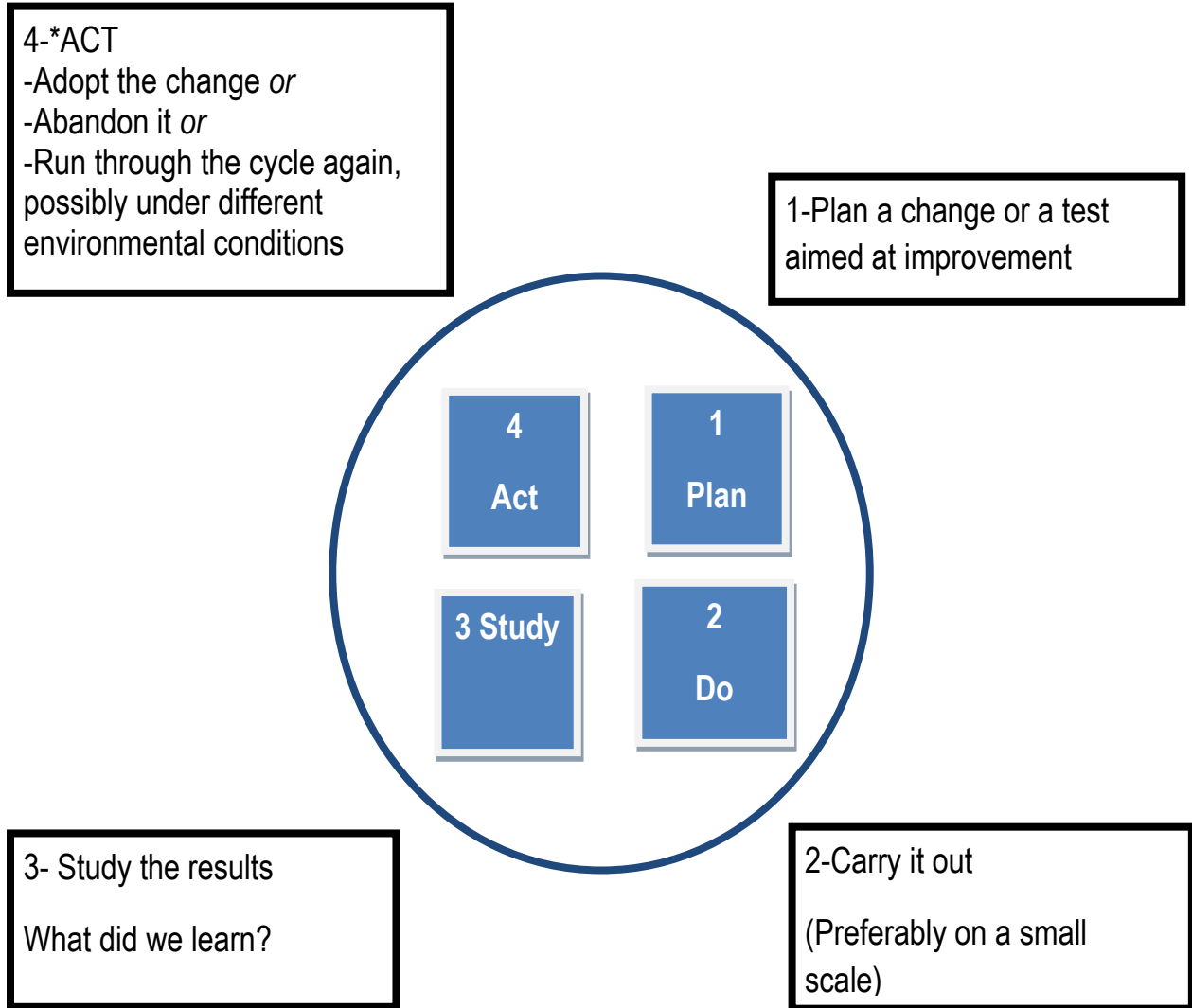
STUDY: Examine your results and re-evaluate with your team. Is the process working? If not, why not? What is working well? If necessary, re-evaluate the root causes/barriers as well as your interventions.

Document your progress and findings and revisions in goals and interventions as appropriate.

ACT: If you have not met your goals, begin again with your new plan. If you met your goals, consider whether to expand to another aspect of the problem.

DO NOT HESITATE TO INVOLVE YOUR ESRD NETWORK AND MEDICAL REVIEW BOARD QI RESOURCES. The outline above is intentionally simplified. Your Network Quality Improvement Director will have expertise as well as additional resources and references for you. The National Forum of ESRD Networks has a toolkit available that will explain in greater detail the theory and techniques of QAPI (Quality Assessment and Performance Improvement).

PDSA CYCLE



Begin a new PDSA Cycle!

QI PROJECT PHASES	ACTIVITIES	KEEP IN MIND
Plan	Make a plan for the change, collect baseline data, plan to carry out the cycle (who, what, where, when)	Brainstorming, motivating
Do	Carry out the plan, document problems and unexpected observations, continue to monitor data	Flowchart, run chart
Study	Complete the analysis of the data, compare data to predictions, summarize what was learned	Fishbone diagram, Pareto chart, control chart, histogram
Act	What changes are to be made? Develop ongoing evaluation/monitoring, next cycle?	Flowchart, brainstorming

PDSA WORKSHEET (Adapted from the Institute for Healthcare Improvement © 2004)

CYCLE #:

DATE:

	<p>Task:</p> <p>Project:</p> <p>Contact:</p>
BACKGROUND:	
PLAN: What is the objective of this improvement cycle?	
Predictions (what do we want to have happen):	
Plan for change or test: who, what, when, where	
Plan for collection of data: who, what, when, where, how will we collect it?	
DO: Was the cycle carried out as planned? What did we observe that was not a part of our plan?	
STUDY: How did or didn't the results of this cycle agree with the predictions that we made earlier?	
List what new knowledge we gained by this cycle:	
ACT: List actions we will take as a result of this cycle:	
Plan for the next cycle:	

CQI TEMPLATE-DM CARE COORDINATION PROJECT

EXAMPLES: FOCUS/PDCA

Element	Date	Discussion
<p style="text-align: center;">F</p> <p>Find a process or problem area to improve</p> <ul style="list-style-type: none"> ▪ Define the process ▪ Identify the customers ▪ Decide who will benefit from improvement ▪ Understand how the process fits within the organizational system and priorities 		<p>Examples:</p> <ul style="list-style-type: none"> ▪ It is not consistently clear which care provider is responsible for diabetic patients' blood sugar management. This poses a safety problem for patients and as a consequence may result in multiple people trying to manage diabetic medications, or no one managing BS control. The patient is at serious risk for medical complications ensuing from a lack of communication regarding insulin dosages and/or oral hypoglycemic doses. ▪ There is no process in place for communicating critical information to the provider managing the BS. ▪ Eliminating duplicative efforts among care providers and identifying one provider to manage BS control may ultimately improve glycemic control for patients. ▪ Identifying one provider and a process to communicate diabetes care information will improve continuity of care when patients are hospitalized, as well as decrease the amount of time spent by providers during rounds when reviewing aspects of diabetic management.
<p style="text-align: center;">O</p> <p>Organize an objective team that knows the process/problem</p> <ul style="list-style-type: none"> ▪ People knowledgeable about and involved in the selected process ▪ Manageable team size ▪ Membership representative of various levels of the organization ▪ Develop method to document team progress 		<p>Examples:</p> <ul style="list-style-type: none"> ▪ Team members will include a nephrologist, the dietitian from the unit who is responsible for reviewing monthly lab work, the administrative assistant at the facility who is responsible for generating the monthly lab requests, a NP from the nephrology group, and a medical assistant from the endocrinologist's office that works most closely with the group coordinating this effort.

<p style="text-align: center;">C</p> <p>Clarify current knowledge about the process/problem</p> <ul style="list-style-type: none"> ▪ Gather and review current knowledge of the process ▪ Analyze the process to distinguish between expected and actual performance 		<p>Example: Barriers to identifying a care manager:</p> <ul style="list-style-type: none"> • The facility does not routinely ask or document which provider is managing the diabetic control • There is no designated place in the chart to document who is the diabetic care provider • Diabetic patients are not identified <p>Example: Barriers to communication of laboratory data:</p> <ul style="list-style-type: none"> • Blood sugar and/or A1C not ordered or available in the facility • The patient will not go see the identified managing DM provider • The DM provider does not see the lab results • The clinic does not have a process for communicating laboratory or medication data to the diabetic provider <p>Example: Barriers to diabetic medication reconciliation:</p> <ul style="list-style-type: none"> • The facility does not receive any information from the DM provider, including medication changes • The diabetes provider is not familiar with which medications are not appropriate for ESRD patients, or the dosage adjustments for other medications. • The diabetic care provider is unfamiliar with insulin management of peritoneal dialysis patients • The clinic does not have a process for communicating medication data to the diabetic provider • Lack of process for medication reconciliation between the patient, facility, diabetes provider <p>Example: Barriers involving patient self care:</p> <ul style="list-style-type: none"> • The patient does not report medication changes to the diabetes provider or to the dialysis facility • No one knows what medications the patient is actually taking • The patient gets conflicting instructions from dialysis and non-dialysis diabetes providers • Patients believe that diabetes control is no longer important since they already have renal failure • Language barriers
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<p style="text-align: center;">U</p> <p>Understand sources of variation</p> <ul style="list-style-type: none"> ▪ Plan and implement data collection ▪ Measure the process, using performance indicators ▪ Ascertain specific, measurable, and controllable variations ▪ Learn the causes of variation 	<p>Examples:</p> <ul style="list-style-type: none"> • The 20 patients who had a diabetic care provider identified all belonged to Nurse Practitioner A and Physician C. • Physician C communicates directly via secure e-mail with each diabetes care manager when patients begin seeing her for CKD care, or begin dialysis at her facility. An agreement is reached regarding which provider will be in charge of BS management, BP management, lipid control, and coordinating other exams. • Nurse Practitioner A is a strong advocate of patient diabetes self-management. She is also a Certified Diabetic Educator (CDE). • Nurse Practitioner A has established a contact person at each diabetes care manager’s office to communicate information back and forth. • Physician C meets quarterly with the DM managers who provide care to her patients. Diabetic patient statuses are reviewed. The meeting is conducted similarly to the monthly patient care meetings at her facility. <p>Examples of Potential Measures:</p> <ul style="list-style-type: none"> • % of patients with designated provider: Numerator: # diabetic patients w designated diabetes care manager Denominator: total # diabetic patients dialyzing at facility during collection period • % of time laboratory results are communicated to the diabetic care provider at designated intervals: Numerator: # DM patients whose lab results are communicated monthly to DM care manager Denominator: total # diabetic patients dialyzing at facility during collection period
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<p style="text-align: center;">S</p> <p style="text-align: center;">Select an improvement or intervention</p> <ul style="list-style-type: none"> • Identify the potential action to improve the process • Support the decision with documented evidence 	<p>Example: Identify a care manager:</p> <ul style="list-style-type: none"> • Include identification of a diabetic care manager in the intake assessment of all new diabetic patients • Establish a designated place in the patient medical record with the name and contact information of the diabetic care manager <p>Example: Communication of laboratory data:</p> <ul style="list-style-type: none"> • Document in the medical record the method by which information will be transmitted to the diabetic care manager (if it is not the attending nephrologist or physician extender); by fax, electronically (if possible), patient’s own diabetic care record, other. • Establish processes for transmitting information; determine what data should be communicated, at what intervals, by what method, and by whom. • Create a spreadsheet with the contact information and dates of laboratory information communication to the care manager(s) • Establish protocols to ensure that all diabetic patients have blood sugar and A1C tests done per K/DOQI guidelines for CKD patients • Include a diabetic care management section in the patient care plans; has the facility communicated with the diabetic care provider and is there evidence of care coordination (e.g., have medication changes been communicated?). <p>Example: Diabetic medication reconciliation:</p> <ul style="list-style-type: none"> • Provide diabetic care managers with diabetic medication guidelines for CKD patients (K/DOQI). • Review medication lists and pill bottles with patients at specific intervals and following hospitalizations • Send a letter to outside diabetic care managers that outlines what the facility can provide (e.g., quarterly A1C results, dietician services) and what it will need from the care provider (e.g., updates re: medication changes, dietary recommendations). • Provide the patient with a diabetic care record that can be updated regularly by the various care providers to include laboratory results and medications. <p>Example: Enhance diabetic self care:</p> <ul style="list-style-type: none"> • Provide the patient with a diabetic care record that can be updated regularly by the various care providers to include laboratory results and medications.
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QAPI ACTION PLAN - SAMPLE: DESIGNATION OF DM CARE PROVIDER

FACILITY:		CONTACT:			TEAM MEMBERS: Medical Director Nurse manager Facility nurse Dietitian Nephrologists Administrative Assistant
GOAL: Each patient will have an identified diabetic care provider					
PROBLEM STATEMENT: (Example) It is unclear who is responsible for managing hypoglycemic medications for diabetic patients					
ROOT CAUSE(S): (Example) There is no designated place in the medical record for identifying who the diabetic care provider is. (Example) There is no process for determining who the diabetic care provider is.					
ACTION PLAN	RESPONSIBLE TEAM MEMBER	START DATE	ESTIMATED COMPLETION DATE	ACTUAL COMPLETION DATE	COMMENTS (STATUS, OUTCOMES, DISPOSITION, ETC.)
<ol style="list-style-type: none"> 1. Designate staff member(s) in dialysis facility responsible for determining who the diabetic care provider is 2. Establish a consistent place in the medical record for designation of the diabetic care provider including contact information 3. Include identification of the diabetic care provider in the patient assessment so that it can be clarified during patient care conference as necessary 4. Create plan to address the patient with no identified diabetic care provider 5. Audit medical records 6. Re-assess 					

QUALITY IMPROVEMENT DOCUMENTATION

Topic Area:

Identified Opportunity for Improvement: *A brief description of the area you wish to improve. For example; the patient and the facility are unclear about which provider is responsible for managing diabetic medications.*

QI Goal: *A specific goal for improvement-narrative (goal should be specific, measurable, achievable, realistic, and timed) For example: identify the diabetic care manager for all diabetic patients of Dr. Jones*

Date QI Process began: *Enter the date you began the QI process*

Date QI Process completed: *Enter the date the QI process was completed. If the process is ongoing, please state is as such.*

Date of QI Re-measurement (frequency): *Enter the frequency and date of re-measurement*

Measurement: **Numerator:** *Enter the number of measurement items completed successfully relative to the goal*

Dominator: *Enter the total number of measurement items relative to the goal*

Goal: *Enter the goal you expect to achieve (goal should be specific, measurable, achievable, realistic, and timed)*

Team Leader: *Person responsible for coordinating the project For example; the dietician*

Team Members: *People assisting with the project: Nephrologist, admin assistant, RN's who do initial assessments*

QI Outcome: *Measurement results*

MEASURES INFORMATION

Below are examples of measures that might help you develop a Quality Improvement Project focused on Diabetes Management.

Outcome measures generally tell you how a system is performing; **process measures** tell you if the steps or parts of the system are performing as planned; **balancing measures** tell you if you are having unanticipated consequences as a result of your improvement efforts, i.e., are improvements in one area having a negative (or positive) effect in another.

Concept/Goals	Potential Measures	Numerator	Denominator	Comments/ Inclusion Criteria
Coordination of Care Measures: EXAMPLES ONLY				
Outcome Measures				
100% will have designated diabetes care manager	% diabetics with designated diabetes care manager (DCM)	# diabetics with designated diabetic physician	Number of diabetic patients during qtr (or month)	Evidence in medical record, or on patient DM care record. Diabetics under care of nephrologist for 30 days before audit. Only diabetic HD patients of Physician C will be audited.
Medications will be reviewed monthly for 100% of diabetic patients	% diabetics with monthly medication updates	# diabetics with documentation of monthly medication review	Number of diabetic patients during qtr (or month)	Diabetics under care of nephrologist for 30 days before audit. Only diabetic HD patients of Physician C will be audited.

Concept/Goals	Potential Measures	Numerator	Denominator	Comments/ Inclusion Criteria
100% of patients will have their diabetes care team identified	% diabetics with designated: <ul style="list-style-type: none"> • Ophthalmologist • Podiatrist • Dentist • Pharmacy 	# diabetics with designated physician xxx documented on chart	# of diabetic patients during qtr (or month)	Diabetics under care of nephrologist for 30 days before audit. Only diabetic HD patients of Physician C will be audited.
Process Measures				
100% of HgbA1c results will be communicated to DCM within 3 days of receipt of results. Critical values will be communicated immediately upon receipt.	% of diabetics whose HgbA1c results are communicated to DCM	# of diabetics with HgbA1c results available, which were communicated to DCM	# of diabetic patients during qtr (or month)	Monthly (quarterly, weekly). Include only those diabetic patients for whom HgbA1c was drawn, who were under the care of Physician C for 30 days prior to the audit
100% of medication changes are communicated to DCM within 7 days of change	% of diabetics whose medication changes are communicated to DCM	# of diabetics with medication changes, which were communicated to DCM	# of diabetic patients during qtr (or mth)	Monthly (qtrly, wkly). Include only those diabetic patients for whom HgbA1c was drawn, who were under the care of Physician C for 30 days prior to the audit
Balancing Measures				
Time spent on chart audits	Ave. time/chart	# diabetic charts audited	Total amt. of time spent auditing diabetic pt. charts	Time in minutes

Concept/Goals	Potential Measures	Numerator	Denominator	Comments/ Inclusion Criteria
Staff satisfaction with process	Staff satisfaction survey	# responses “agree” or “strongly agree” that process is improved	Total # of questions regarding staff satisfaction	Survey only participants in the process change. Use Likert scale to tally.
Medical Management of Diabetes Measures: EXAMPLES ONLY				
Outcome Measures				
All diabetic patients will have HgbA1c results between: xxxx & xxxx	% of patients with HgbA1c <7	# diabetic patients with documented Hgb A1c <7 in qtr (or mth)	Number of diabetic patients during qtr (or mth)	Diabetics under care of nephrologist for 30 days before audit.
BPs for diabetic patients will be maintained @ ≤ to 130/80	% of patients with BP ≤ 130/80	# of times on off-dialysis days for which diabetic patients have documentation of am BP results ≤ 130/80	Total # of times am BP results are documented	Diabetics under care of nephrologist for 30 days before audit. Must have both systolic and diastolic meeting target for BP control on off-dialysis days. Review self care BP record of patients
All diabetic patients will maintain an LDL <100	% of patients with LDL < 100	# diabetic patients with LDL < 100 in qtr (or mth)	Number of diabetic patients who had LDLs drawn in qtr (or mth)	Diabetics under care of nephrologist for 30 days before audit.
90% of diabetic patients will be vaccinated for pneumococcal pneumonia	% of patients vaccinated for pneumococcal pneumonia	# diabetics with documentation that received pneumovax vaccine	Total # of diabetic patients	Diabetics under care of nephrologist for 30 days before audit.

Concept/Goals	Potential Measures	Numerator	Denominator	Comments/ Inclusion Criteria
Process Measures				
All diabetics undergo quarterly lipid testing	% of patients with ≥ 1 LDL drawn per qtr	# diabetics with quarterly lipid test	# diabetic patients with lipid test done per qtr	Diabetics under care of nephrologist for 90 days before audit.
Diabetic patients shall have HgbA1c drawn quarterly	% of patients with Qtrly HgbA1C drawn	# diabetic patients with documented Hgb A1c testing in quarter	Number of diabetic patients during quarter	Diabetics under care of nephrologist for 90 days before audit.
All diabetics undergo at least quarterly foot exams	% of patients with quarterly foot exam	# diabetics with foot evaluation (podiatrist or pldorthist or negative neuropathy screen) < 1 year	Number of diabetic patients during quarter	Diabetics under care of nephrologist for 90 days before audit.
All diabetic will receive annual retinal exam	% of patients with annual retinal exams	# diabetics with retinal exam within the last 12 months	Number of diabetic patients during quarter	Diabetics under care of nephrologist for 90 days before audit.
All diabetics will have a semi-annual dental exam	% of patients with semi-annual dental exams			
Balancing Measures				
Reduce limb amputations	Hospitalization rate for limb amputations	# diabetic patients hospitalized for amputations		Diabetics under care of nephrologist for 30 days before audit.

QAPI MEETING MINUTES TEMPLATE

Date:	Time:	Location:	Next meeting date:
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ATTENDEES: (NAME / INITIALS)

TOPIC / AGENDA ITEM	DISCUSSION	FOLLOW-UP AND/OR ACTIONS REQUIRED FOR NEXT IDT MEETING
<p>1. INTRODUCTIONS</p> <p>2. ANNOUNCEMENTS</p> <p>3. OVERVIEW OF AGENDA</p>		
<p>ADEQUACY OF HEMODIALYSIS (i.e., Kt/V, URR, % of residual renal function, etc.)</p> <ul style="list-style-type: none"> • Background: • Goals: • Activities: • Measures to Date: 	<p>Nurse Manager:</p> <p>Medical Director:</p> <p>Dietitian:</p> <p>Social Worker:</p>	

<p>ADEQUACY OF PERITONEAL DIALYSIS</p> <p>(if applicable)</p> <p>[i.e., CrCl, Kt/V_{urea} , PET testing, etc.]</p> <ul style="list-style-type: none"> • Background: • Goals: • Activities: • Measures to Date: 	<p>Nurse Manager:</p> <p>Medical Director:</p> <p>Dietitian:</p> <p>Social Worker:</p>	
<p>NUTRITION (i.e., albumin, PCR, dry weights, etc.)</p> <ul style="list-style-type: none"> • Background: • Goals: • Activities: • Measures to Date: 	<p>Nurse Manager:</p> <p>Medical Director:</p> <p>Dietitian:</p> <p>Social Worker:</p>	
<p>MINERAL METABOLISM (i.e., calcium, phosphorus, PTH)</p> <ul style="list-style-type: none"> • Background: • Goals: • Activities: • Measures to Date: 	<p>Nurse Manager:</p> <p>Medical Director:</p> <p>Dietitian:</p> <p>Social Worker:</p>	
<p>ANEMIA MANAGEMENT (i.e., Hgb, ESA / Iron, use of transfusions, etc.)</p> <ul style="list-style-type: none"> • Background: • Goals: • Activities: • Measures to Date: 	<p>Nurse Manager:</p> <p>Medical Director:</p> <p>Dietitian:</p> <p>Social Worker:</p>	

<p>VASCULAR ACCESS MANAGEMENT (i.e., rates per access, per dysfunction, per complications, referral, etc.)</p> <ul style="list-style-type: none"> • Background: • Goals: • Activities: • Measures to Date: 	<p>Nurse Manager:</p> <p>Medical Director:</p> <p>Dietitian:</p> <p>Social Worker:</p>	
<p>MEDICAL INJURIES / MEDICAL ERRORS (i.e., medication errors and/or reconciliation issues, patient safety/falls, etc.)</p> <ul style="list-style-type: none"> • Background: • Goals: • Activities: • Measures to Date: 	<p>Nurse Manager:</p> <p>Medical Director:</p> <p>Dietitian:</p> <p>Social Worker:</p>	
<p>HEMODIALYZER REUSE ISSUES (if applicable)</p> <p>[i.e., Audits, number, % of clearance, etc.]</p> <ul style="list-style-type: none"> • Background: • Goals: • Activities: • Measures to Date: 	<p>Nurse Manager:</p> <p>Medical Director:</p> <p>Dietitian:</p> <p>Social Worker:</p>	
<p>PATIENT SATISFACTION (i.e., KDQOL, etc.)</p> <ul style="list-style-type: none"> • Background: • Goals: • Activities: • Measures to Date: 	<p>Nurse Manager:</p> <p>Medical Director:</p> <p>Dietitian:</p> <p>Social Worker:</p>	

<p>GRIEVANCES (i.e., number, types of complaints etc.)</p> <ul style="list-style-type: none"> • Background: • Goals: • Activities: • Measures to Date: 	<p>Nurse Manager:</p> <p>Medical Director:</p> <p>Dietitian:</p> <p>Social Worker:</p>	
<p>INFECTION CONTROL / INFECTIOUS DISEASE SURVEILLANCE</p> <p>(i.e., septicemia, access-related, etc.)</p> <ul style="list-style-type: none"> • Background: • Goals: • Activities: • Measures to Date: 	<p>Nurse Manager:</p> <p>Medical Director:</p> <p>Dietitian:</p> <p>Social Worker:</p>	
<p>IMMUNIZATIONS (i.e., Influenza, Hepatitis B, Pneumococcal Pneumonia)</p> <ul style="list-style-type: none"> • Background: • Goals: • Activities: • Measures to Date: 	<p>Nurse Manager:</p> <p>Medical Director:</p> <p>Dietitian:</p> <p>Social Worker:</p>	

Emergency Preparedness Interpretative Guidance E-Codes for ESRD Facilities

This Interpretive Guidance on Emergency Preparedness has received several updates, most recently on February 1, 2019, which revised the E-codes and added emerging infectious diseases (EID) to the definition of “all-hazards approach” amongst other updates.

To assist Medical Directors and dialysis facilities in complying with the new regulations on emergency preparedness, this checklist is available as a downloadable Excel spreadsheet at the Forum website and can be used to help ensure your dialysis facility is meeting the latest requirements by CMS on Emergency Preparedness.

E-codes spreadsheet:

<https://esrdnetworks.org/toolkits/professional-toolkits/outpatient-medical-director-toolkit/>

Citation	Description
<p>E-0004</p>	<p>Emergency Plan. The ESRD facility must develop and maintain an emergency preparedness plan that must be [evaluated], and updated at least every 2 years</p>
	<p>The 2 year review must be documented to include the date of the review and any updates made to the emergency plan based on the review.</p>
	<p>Plan includes conducting facility-based and community-based risk assessments to assist facility in addressing needs of patients and identifying continuity of business operations to provide support during emergency.</p>
	<p>Supports, guides, and ensures a facility's ability to collaborate with local emergency preparedness officials</p>
	<p>Identify hazards in risk assessment- consider particular hazards most likely to occur in surrounding area including:</p> <ul style="list-style-type: none"> • Natural disasters • Man-made disasters, • Facility-based disasters that include but are not limited to: <ul style="list-style-type: none"> o Care-related emergencies; o Equipment and utility failures, including but not limited to power, water, gas, etc.; o Interruptions in communication, including cyber-attacks; o Loss of all or portion of a facility; and o Interruptions to the normal supply of essential resources, such as water, medical supplies, etc. • EIDs such as COVID-19, Influenza, Ebola, Zika Virus and others. <ul style="list-style-type: none"> o EIDs may require modifications to facility protocols to protect the health and safety of patients, such as isolation and personal protective equipment (PPE) measures.
	<p>Contracts to re-establish essential utility services during an emergency should describe:</p> <ul style="list-style-type: none"> - the timeframe in which the contractor is required to initiate services - how they will be procured and delivered in facility's local area - contractor will continue to supply essential items throughout and to the end of emergencies of varying duration
	<p>Show risk assessment; how it was conducted. Should include hazards identified.</p>

<p>E-0006</p>	<p>Develop emergency preparedness plan based on facility-based and community-based risk assessment using an “all-hazards” approach. Facilities must document both risk assessments.</p> <p>Consider:</p> <ul style="list-style-type: none"> • Identification of business functions essential to facility’s operations that should be continued during an emergency; • Identification of all risks or emergencies that the facility may reasonably expect to confront; • Identification of all contingencies for which the facility should plan; • Consideration of the facility’s location; • Assessment of natural or man-made emergencies which may cause the facility to cease or limit operations; • Determination of arrangements with other health care facilities or entities that might be needed to ensure essential services could be provided during an emergency. <p>Strategies for addressing staffing shortages; surge capacity strategy (if the facility would take on additional patients during an emergency situation)</p> <p>Back - up evacuation plan</p>
<p>E-0007</p>	<p>Mobility:</p> <ul style="list-style-type: none"> -properly identify patients who would require additional assistance -ensure means of transport are accessible and available -those involved in transport, as well as patients, are made aware of procedures to evacuate <p>Address types of services that facility would be able to provide in an emergency</p> <p>Succession Planning: staff to assume critical roles in the absence of administrator or person legally responsible for operations of the facility.</p> <p>Continuity of operations planning:</p> <ul style="list-style-type: none"> -essential personnel -essential functions -critical resources -vital records -IT data protection -alternate facility identification and location -financial resources
<p>E-0009</p>	<p>Include process for collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain integrated response during disaster or emergency situation (no longer required to include documentation of efforts to contact such officials)</p>
<p>E-0013</p>	<p>Develop and implement emergency preparedness policies and procedures (P&P), based on the emergency plan (plan as per E-0004 above).</p> <ul style="list-style-type: none"> -P&P must be reviewed and updated at least every 2 years. -P&P expected to align with identified hazards within facility’s risk assessment and facility’s overall emergency preparedness program -P&P may be incorporated into emergency plan, or be part of SOP. Should be central place to house emergency P&P for review during survey

E-0018	System to track the location of on-duty staff and sheltered patients in the facility's care during an emergency (system can be electronic or hard-copy- if electronic, should be back up hard copy in case of power outage).
	Name and location of patient/on-duty staff if moved to a new location during the emergency
	If staff or patients relocated, document name and location of the receiving facility or other location for sheltered patients and on-duty staff who leave the facility during the emergency.
	Safe evacuation from the dialysis facility, which includes staff responsibilities, and needs of the patients
E-0023	P&P must address system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains availability of records.
	Ensure patient records are secure and readily available to support continuity of care during an emergency
E-0024	P&P must address use of volunteers in emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.
	Include privileging and credentialing processes in emergency preparedness P&P
E-0029	Emergency communication plan contains how facility coordinates patient care within facility, across healthcare providers, and with state and local public health departments.
	Communication plan includes how facility coordinates with emergency management agencies and systems to protect patient health and safety in the event of a disaster.
	Plan must be reviewed every 2 years and updated as necessary
E-0030	Communication plan must include: Name and contact information for (i) staff (ii) entities providing services under arrangement (iii) Patients' physicians (iv) Other dialysis facilities (v) Volunteers
	Information readily available and accessible to leadership and staff during an emergency event.
	If electronic data storage, need back-up with hard copies, or demonstrate capability to reproduce contact lists or access this data during emergencies.
	All contact information must be reviewed and updated as necessary at least every 2 years
	Contact information contained in the communication plan must be accurate and current
	Facilities must update contact information for incoming new staff and departing staff throughout the year and any other changes to information for those individuals and entities on the contact list.
E-0031	Communication plan must contain contact information (updated at least every 2 years) for: (i) Federal, state, tribal, regional, and local emergency preparedness staff (ii) Other sources of assistance
	Communication Plan must have primary and alternate means for communicating with -facility staff -federal, state, tribal, regional, and local emergency management agencies

E-0033	Communication plan must include: method for sharing information and medical documentation for patients under its care with other health providers to maintain the continuity of care.
	A means, in the event of an evacuation, to release patient information
	A Means of providing information about general condition and location of patients
	Ensure that information necessary to provide patient care is sent with an evacuated patient to the next care provider and would also be readily available for patients being sheltered in place.
	Provide information to receiving facilities during an evacuation, within a timeframe that allows for effective patient treatment and continuity of care.
	Do not delay patient transfers during an emergency to assemble all patient reports, tests, etc. to send with patient. Send all necessary patient information that is readily available
E-0034	Plan must include means of providing information re occupancy, needs, and ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee
	Occupancy reporting: reporting number of pts currently at the facility receiving treatment and care
	Consider how facility's occupancy affects its ability to provide assistance
E-0036	Develop and maintain emergency preparedness training, testing and patient orientation program based on emergency plan, risk assessment, P&P, and communication plan
	The training, testing and orientation program must be reviewed and updated at least every 2 years
	Training and testing program must reflect the risks identified in risk assessment and be included in emergency plan
	Ex: if facility closed would include include, training and testing on how the facility will communicate facility closure to required individuals and agencies, testing patient tracking systems and testing transportation procedures for safely moving patients to other facilities.
	For facilities with multiple locations, such as multi-location organization, facility's training and testing program must reflect the facility's risk assessment for each specific location
	Training refers to facility responsibility to provide education and instruction to staff and patients (orientation) to ensure all individuals are aware of the emergency preparedness program
	Testing is concept in which training is operationalized and the facility is able to evaluate the effectiveness of training as well as the overall emergency preparedness program
	Testing includes conducting drills and/or exercises to test the emergency plan to identify gaps and areas for improvement.
E-0040	Testing. The dialysis facility must conduct exercises to test the emergency plan at least annually. The dialysis facility must do all of the following:
	(i) Participate in a full-scale exercise that is community-based every 2 years; or (A) When a community-based exercise is not accessible, an individual, and a facility-based functional exercise every 2 years; or (B) If the dialysis facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the dialysis facility is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

<p>(ii) Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise, that may include, but is not limited to the following: (A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or (B) A mock disaster drill; or (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.</p>
<p>(iii) Analyze the dialysis facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the dialysis facility's emergency plan, as needed.</p>
<p>Contact local and state agencies and healthcare coalitions, where appropriate, to determine if an opportunity exists and determine if their participation would fulfill this requirement</p>
<p>Document the date, the personnel and the agency or healthcare coalition that they contacted.</p>
<p>Facilities responsible for resourcing their participation and ensuring that all requisite documentation is developed and available to demonstrate their compliance with this requirement</p>
<p>Facilities encouraged to engage with area Health Care Coalitions (HCC) (partnerships between healthcare, public health, EMS, and emergency management) to explore integrated opportunities. HCCs plan and conduct coordinated exercises to assess the health care delivery systems readiness</p>
<p>If unable to identify full-scale community-based exercise, can fulfill this requirement by conducting individual facility-based exercise, documenting emergency that required full activation of emergency plan, or conducting a smaller community-based exercise with other nearby facilities.</p>
<p>Facilities that conduct individual facility-based exercise will need to demonstrate how it addresses any risk(s) identified in its risk assessment</p>
<p>Each facility is responsible for documenting their compliance and ensuring that this information is available for review at any time for a period of no less than three (3) years.</p>
<p>Document lessons learned following exercises and real-life emergencies and demonstrate incorporation of necessary improvements in emergency preparedness program. Complete an after action review process to help develop an actionable after action report (AAR).</p>
<p>Process includes a roundtable discussion that includes leadership, department leads and critical staff who can identify and document lessons learned and necessary improvements in an official AAR</p>
<p>AAR, at a minimum, should determine: 1) what was supposed to happen; 2) what occurred; 3) what went well; 4) what the facility can do differently or improve upon; and 5) a plan with timelines for incorporating necessary improvement.</p>
<p>If part of healthcare system, facility can elect to participate in system's integrated and unified emergency preparedness program and exercises. Facility still responsible for documenting and demonstrating facility's compliance with the exercise and training requirements.</p>

<p>E-042</p>	<p>As part of the Integrated Healthcare System must do all of the following:</p> <ol style="list-style-type: none"> 1) demonstrate that each separately certified facility actively participated in the development of the unified emergency preparedness program 2) be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered <ul style="list-style-type: none"> - Each facility should designate personnel who will collaborate with the healthcare system to develop the plan; Need documentation to verify each facility participated in development of plan 3) demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance. 4) include a unified and integrated emergency plan <ul style="list-style-type: none"> must include the following: <ol style="list-style-type: none"> i) documented community-based risk assessment, utilizing an all-hazards approach ii) documented individual facility based risk assessment for each facility 5) include integrated policies and procedures that meet the requirements of a coordinated communication plan in training and testing programs.
	<p>All components of emergency preparedness program required to be reviewed and updated at least every 2 years must include all participating facilities. Each facility must be involved in annual reviews and updates of program.</p>
	<p>The healthcare system and each facility must document each facility's active involvement with the reviews and updates, as applicable.</p>
	<p>Each facility must maintain individual training records of staff and records of all required training exercises.</p>

Approved by RPA Board of Directors 10/22/2011

Approved by the National Forum of ESRD Networks, 12/6/2011

RPA/Forum of ESRD Networks Position on ESRD Patient Solicitation

Introduction

The RPA, in cooperation with the National Forum of ESRD Networks, seeks a good working environment in which physicians can competitively interact with one another without conflict, hard feelings or ill will, and in which the interests of the patient remain paramount. To that end, this statement is based on certain ground rules that have their cornerstone in medical ethics and professionalism to ensure that physician contact with patients is appropriate.

This document describes the issue, highlights relevant literature on the issues of professionalism and ethics in medicine, and provides selected examples of state statutes addressing the issue. The position statement concludes with specific principles to guide professional ethics in nephrology regarding ESRD patient solicitation.

Content

The issues which have come to the attention of the RPA and the ESRD Networks are:

- Nephrologists approaching patients under the treatment of other nephrologists with the purpose of influencing the patient to change physicians or dialysis facilities, or instructing nurses to contact patients with that intent.
- Nephrologists accessing records of patients who are cared for by a different nephrology practice with the purpose of contacting those patients to influence them to change the facility where they receive treatment.

Background Research

In seeking to develop a position on appropriate structures for addressing the issues noted above, the RPA and the National Forum of ESRD Networks found that behavior of this nature is addressed both in the body of literature relevant to professional and ethical behavior in the practice of medicine, and, within the U.S., in state statute. Samples of the relevant literature and state statutes are described below.

Relevant Literature

In one contribution to the relevant literature, Bernard Lo in his book *Resolving Ethical Dilemmas: A Guide for Clinicians*, includes the following passages:

The Fiduciary Nature of the Doctor-Patient Relationship—Physicians have special responsibilities to act for the well-being of patients because patients are often impaired

in significant ways by their illness. Furthermore, the stakes are high; poor decisions might place patients' health or lives at risk.

Definition of a Fiduciary Relationship—Legally, relationships between professionals and clients are characterized as fiduciary. The term fiduciary is derived from the Latin word **fidere**, to trust. Fiduciaries hold something in trust for another. They must act in the best interests of their patients or client, subordinating their self-interest. Fiduciaries are held to higher standards than businesspeople, who use their knowledge and skill for their own self-interest, rather than for the benefit of their customers. Ordinary business relationships are characterized by the phrase *caveat emptor*, “let the buyer beware,” not by trust and reliance.²

The College of Physicians and Surgeons of Ontario in their “Principles of Practice” have offered an opinion on the fiduciary nature of medical practice as well, noting:

The doctor-patient relationship is the foundation of the practice of medicine. It reflects the values of compassion, service, altruism, and trustworthiness. Trustworthiness is the cornerstone of the doctor-patient relationship; without trust a good doctor-patient relationship cannot exist.

Physicians have a fiduciary duty to their patients—because the balance of knowledge and information favours the physician, patients are reliant on their physicians and may be vulnerable. The patient must always be confident that the physician has put the needs of the patient first. This principle should inform all aspects of the physician's practice.³

A pertinent paper titled “Ethics in Medicine” by the University of Washington School of Medicine addresses the difference between a profession and a business, noting that:

The line between a business and a profession is not entirely clear, since professionals may engage in business and make a living by it. However, one crucial difference distinguishes them: professionals have a fiduciary duty toward those they serve. This means that professionals have a particularly stringent duty to assure that their decisions and actions serve the welfare of their patients or clients, even at some cost to themselves. Professions have codes of ethics which specify the obligations arising from this fiduciary duty. Ethical problems often occur when there appears to be a conflict between these obligations or between fiduciary duties and personal goals.⁴

² Lo B. *Resolving Ethical Dilemmas: A Guide for Clinicians*. 4th ed. Philadelphia: Wolters Kluwer-Lippincott Williams & Wilkins, 2009, p. 32.

³ The College of Physicians and Surgeons of Ontario. *Principles of Practice and Duties of Physicians. A. Individually to the Patient*. Available at: <http://www.cpso.on.ca/policies/guide/default.aspx?id=1702&terms=Principles+of+Practice>. Accessed on: September 27, 2011.

⁴ University of Washington School of Medicine. *Ethics in Medicine: Professionalism*. Available at: <http://depts.washington.edu/bioethx/topics/profes.html>. Accessed on: September 27, 2011.

Examples of Relevant State Statutes

Every state in the U.S. has a medical practice act or similar promulgation that addresses physician professionalism, ethics, and conduct. These documents may be of more direct importance to physicians, as non-compliance with these regulations may result in disciplinary action affecting the individual physician's ability to practice medicine. Passages from two examples of the relevant regulations are included below, from Colorado and West Virginia. The Colorado document speaks in more general terms regarding physician professionalism and ethics, and, while brief, the West Virginia passage specifically addresses the issue of patient solicitation.

Colorado Medical Practice Act:

"Without regard to whether an act or failure to act is entirely determined by a physician, or is the result of a contractual or other relationship with a health care entity, the relationship between a physician and a patient must be based on trust and must be considered inviolable. Included among the elements of such a relationship of trust are:

- Open and honest communication between the physician and patient, including disclosure of all information necessary for the patient to be an informed participant in his or her care.
- Commitment of the physician to be an advocate for the patient and for what is best for the patient, without regard to the physician's personal interests.
- Provision by the physician of that care which is necessary and appropriate for the condition of the patient and neither more or less.
- Avoidance of any conflict of interest or inappropriate relationships outside of the therapeutic relationship.

The relationship between a physician and a patient is fundamental, and is not to be constrained or adversely affected by any considerations other than what is best for the patient. The existence of other considerations, including financial or contractual concerns is and must be secondary to the fundamental relationship."

West Virginia Medical Practice Act:

"Soliciting patients yourself or by an agent is unprofessional conduct that can result in censure or loss of license."

Summary

There is a preponderance of literature and state regulation addressing the issues of professionalism and ethics in medical practice, and while sub-issues surrounding nephrology practice are not specifically discussed, concerns regarding physician conflict of interest and solicitation of patients are addressed in detail. It may be appropriate in certain circumstances for nephrologists to recommend to an ESRD patient to change dialysis facilities if it is in the patient's best interest and can be accomplished with minimal disruption to the patient's therapy. However, in light of the literature and regulations discussed above, it is also evident that the practice of nephrologists (or individuals under their direction) in issuing unsolicited notifications to dialysis patients not under their care to change the facility at which they receive their dialysis

treatment constitutes unprofessional behavior on the part of the nephrologist or his/her representatives.

Principles of Professional Conduct

1. Notifications by nephrologists other than the treating nephrologists with the intent of soliciting a patient either to change physicians, change practices or change dialysis facilities constitute unethical behavior.
2. If it is the patient's own nephrologist, the nephrologist could recommend transferring from one unit to another if the nephrologist believes it is in the patient's best interest, but the nephrologist must disclose if he/she has a financial interest in either unit and make this recommendation in a transparent and non-coercive manner.
3. Similarly, in both the initial enrollment of a patient and if and when the patient is referred for vascular access services, the nephrologist must disclose if he/she has a financial interest in either the dialysis unit or the vascular access center, and should make this recommendation in a transparent and non-coercive manner.
4. Nephrologists, their nursing staff, or other representatives must be as transparent as possible in their interactions with dialysis patients and their families and disclose potential conflicts of interest.
5. Nephrologists must strive to be in compliance with their state's medical practice acts or other relevant state statutes. According to state law, nephrologists' conduct that is not in compliance with these state regulations should (or must if required by state law) be reported to the appropriate state licensing board.