



1275 K Street, NW, Suite 1000  
Washington, DC 20005-4006  
Phone: 202/789-1890  
Fax: 202/789-1899  
[apicinfo@apic.org](mailto:apicinfo@apic.org)  
[www.apic.org](http://www.apic.org)

**To: Clinical Standards Group, CMS Center for Clinical Standards and Quality**  
**From: Mary Lou Manning, PhD, CRNP, CIC, FAAN**  
**2015 President**  
**The Association for Professionals in Infection Control and Epidemiology (APIC)**  
**Date: April 1, 2015**

Thank you for the opportunity to provide suggestions for revisions to 42 CFR Part 494 Conditions for Coverage for End Stage Renal Disease Facilities. APIC is a nonprofit, multidisciplinary organization representing over 15,000 infection preventionists whose mission is to create a safer world through prevention of infection. Since patients undergoing dialysis are at high risk for developing healthcare-associated infections, APIC has a vested interest in incorporating evidenced-based infection prevention practice standards into the Conditions for Coverage (CfCs) for End-Stage Renal Disease (ESRD) Facilities in order to promote the safety of ESRD patients.

We have consolidated our suggestions regarding updates and changes to existing CfCs in the attached grid. The suggestions include updated references that reflect the most current available guidance. We also recommend new conditions for the following areas: establishing a requirement for ESRD facility infection preventionists; establishing a condition for ESRD patient engagement, and adding screening requirements for Hepatitis C Virus (HCV) to prevent transmission of HCV in ESRD patients.

Infection is a serious and often life-threatening complication for ESRD patients. Literature reviews have documented that programs in facilities with infection prevention infrastructure provide safer care to patients with less risk of healthcare-associated infection.<sup>1</sup> Hospital-based dialysis programs typically benefit from the infection prevention infrastructure of their parent organization whereas very few free-standing dialysis centers have an in-center infection prevention program. We are doubtful this will change without a formal condition requiring employment or availability of an individual with specific training in infection prevention. APIC believes that revising the CfCs to incorporate this requirement is necessary for patient safety and encourages CMS to do so.

Engaging and involving patients in their care is a key intervention cited by patient safety and dialysis advocates alike. Patients who are active participants in their care drive quality and improvement and often reduce their risk of harm by serving as the final safety checkpoint. APIC recommends that CMS incorporate a new condition that requires patient engagement in at least one aspect of dialysis care. Oversight of this standard can be routed through the facility Quality Assessment and Performance Improvement (QAPI) program. Examples of patient engagement include: requiring patient education courses; empowering patients to monitor for breaches in infection control practices; and patient-observed hand hygiene monitoring.

Hepatitis outbreaks continue to occur in dialysis centers.<sup>2</sup> According to the Centers for Disease Control and Prevention (CDC), Hepatitis C Virus (HCV) is the most common chronic bloodborne infection in the United States.<sup>3</sup> CDC recommends routine screening of patients who have received chronic or long-term



dialysis. Currently CMS does not require such screening in the CfCs. Improving the focus on safe injection as well as cleaning and disinfection practices, combined with oversight by an individual trained in infection prevention will impact the prevention of HCV. However, in light of continued issues with outbreaks of HCV in dialysis centers, APIC believes screening standards similar to those implemented for Hepatitis B should also be added. APIC recommends that CMS consider revising CfCs to include routine screening for HCV similar to the requirements already in place for Hepatitis B.

APIC thanks CMS for the opportunity to provide suggestions on possible revisions to the Conditions for Coverage of ESRD facilities.

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<sup>1</sup> Hess S, Bren V. Essential Components of Infection Prevention Programs in Outpatient Dialysis. *Semin Dial*. 2013 Jul-Aug;26(4):384-98. doi: 10.1111/sdi.12102. Epub 2013 Jun28.

<sup>2</sup> [Thompson ND](#), [Novak RT](#), [Datta D](#), [Cotter S](#), [Arduino MJ](#), [Patel PR](#), [Williams IT](#), [Bialek SR](#). (2009) Hepatitis C virus transmission in hemodialysis units: importance of infection control practices and aseptic technique. *11 Sep;30(9):900-3*. doi: 10.1086/605472.

<sup>3</sup> MMWR October 16, 1998 / 47(RR19);1-39 Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HVC related chronic disease. CDC

**APIC Recommended Revisions to  
Conditions for Coverage for End-Stage Renal Disease Facilities**

Section	Location	Current Language	Proposed Change	Rationale
494.30 Infection control	(a)(1)(i)	"The recommendations (with the exception of screening for hepatitis C), found in 'Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,' developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28."	<b>Remove:</b> "(with the exception for screening for hepatitis C)"	Hepatitis outbreaks continue to occur in dialysis centers. (access at <a href="http://journals.cambridge.org/abstract_S0195941700037589">http://journals.cambridge.org/abstract_S0195941700037589</a> )  According to the Centers for Disease Control and Prevention (CDC), Hepatitis C Virus (HCV) is the most common chronic bloodborne infection in the United States. (access at <a href="http://www.cdc.gov/mmwr/PDF/rr/rr4719.PDF">http://www.cdc.gov/mmwr/PDF/rr/rr4719.PDF</a> )  CDC recommends routine screening of patients who have received chronic or long-term dialysis.
494.30 Infection control	(a)(2)	The "Guidelines for the Prevention of Intravascular Catheter-Related Infection ...August 9, 2002"	<b>Replace:</b> with "Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011". (access at <a href="http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf">http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf</a> )  <b>Add:</b> CDC Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care (accessed at <a href="http://www.cdc.gov/HAI/pdfs/guidelines/Outpatient-Care-Guide-withChecklist.pdf">http://www.cdc.gov/HAI/pdfs/guidelines/Outpatient-Care-Guide-withChecklist.pdf</a> )  <b>Add:</b> CDC Approach to BSI Prevention in Dialysis Facilities (i.e., the Core Interventions for Dialysis Bloodstream	Update references with most current guidance.  Core Interventions in the CDC Guide to Infection Prevention in Outpatient Settings are best practices and set minimum standards for infection prevention in the outpatient care setting. These are consistent with CDC guideline and listed as a reference for Dialysis Safety under guidelines and recommendations.  Core interventions are best practices and most current, standardized dialysis-specific interventions to



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494.30 Infection control	(a)(3)	"Patient isolation procedures..."	<p><i>Infection [BSI] Prevention</i> (access at <a href="http://www.cdc.gov/dialysis/prevention-tools/core-interventions.html">http://www.cdc.gov/dialysis/prevention-tools/core-interventions.html</a>)</p> <p><b>Add reference:</b> <i>The Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007</i> (access at <a href="http://www.cdc.gov/hicpac/pdf/isolation/isolation2007.pdf">http://www.cdc.gov/hicpac/pdf/isolation/isolation2007.pdf</a>)</p> <p><b>Add reference:</b> <i>Management of Multidrug-Resistant Organisms In Healthcare Settings, 2006</i> (access at <a href="http://www.cdc.gov/hicpac/pdf/MDRO/MDROGuideline2006.pdf">http://www.cdc.gov/hicpac/pdf/MDRO/MDROGuideline2006.pdf</a>)</p>	<p>prevent access-associated bloodstream infections.</p> <p>Update references with most current guidance.</p>
494.30 Infection control	(a)(4)(ii)	"Cleaning and disinfection of contaminated surfaces..."	<p><b>Add reference:</b> <i>The Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008</i> (access at <a href="http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection Nov 2008.pdf">http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection Nov 2008.pdf</a>)</p> <p><b>Add reference:</b> <i>Guidelines for Environmental Infection Control in Health-Care Facilities: Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC)</i> (access at <a href="http://www.cdc.gov/MMWR/preview/MMWRhtml/rr5210a1.htm">http://www.cdc.gov/MMWR/preview/MMWRhtml/rr5210a1.htm</a>)</p>	<p>Update references with most current guidance.</p> <p>Maintaining a clean environment of care is critical to preventing healthcare-associated infections.</p>

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494.30 Infection control	(a)(5)	None – new addition.	<b>Add new section (a)(5):</b> Safe injection practices. Information on safe injection practices, including instructional videos and infographics can be accessed at: <a href="http://www.cdc.gov/injectionsafety/">http://www.cdc.gov/injectionsafety/</a>	These practices are part of Standard Precautions and are equally important as other components of Standard Precautions that are individually addressed.
494.30 Infection control	(b) Standard: Oversight	None – new addition.	<b>Add new section (b)(1):</b> “Provide infection prevention and control education to all staff upon hire and then every 6-12 months thereafter. Documentation of training, including the content, must be maintained onsite.”  <b>Renumber current sections (b) 1-3 as section (b) 2-4.</b>	Adding a training requirement to the facility oversight supports the requirement for assuring compliance with best infection prevention practices. CDC Core Interventions for Dialysis Bloodstream Infection Prevention recommends skills reassessment every 6-12 months. (Access at <a href="http://www.cdc.gov/dialysis/prevention-tools/core-interventions.html">http://www.cdc.gov/dialysis/prevention-tools/core-interventions.html</a> )
494.30 Infection control	(b)(3)	“Require all clinical staff to report infection control issues to the dialysis facility’s medical director...”	<b>Change to:</b> “Require all clinical staff to report infection control issues to the facility Infection Preventionist, the dialysis facility’s medical director, and the quality assessment and performance improvement committee.”  <b>Add language to 494.110 to complement this requirement.</b>	Requiring reporting to the facility infection prevention staff along with integrating such reporting into the existing Quality Assessment and Performance Improvement (QAPI) program attaches responsibility and promotes actions as the result of staff reporting.
494.30 Infection control	(c)	“The facility must report incidences of communicable diseases as required by	<b>Change to:</b> “The facility must report: (1) Incidences of communicable disease as required by Federal, State,	Strengthens reporting requirements and improves interfacility communication/transitions of care.



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		Federal, State, and local regulations."	and local regulations. (2) as required by the National Healthcare Safety Network (NHSN) Dialysis Event Reporting (access at <a href="http://www.cdc.gov/nhsn/dialysis/index.html">http://www.cdc.gov/nhsn/dialysis/index.html</a> ) (3) To the acute care setting when a bloodstream infection is identified."	
494.40 Water and dialysate quality	(a)	Reference "Dialysate for hemodialysis ANSI/AAMI RD52 2004"	<b>Update with current references:</b> (access at <a href="http://www.aami.org/publications/standards/dialysis.html">http://www.aami.org/publications/standards/dialysis.html</a> )	Update references with most current guidance. Just released in 2015 11 AAMI Hemodialysis standards; six of the 11 standards were published in 2014 (23500, 11663, 13958, 13959, 26722, and TIR58).
494.50 Reuse of hemodialyzers and bloodlines	(b)(1)	"Meet the requirements of AAMI published in 'Reuse of Hemodialyzers, third edition...'"	<b>Replace with:</b> ANSI/AAMI RD47:2008/(r)2013 Reprocessing of hemodialyzers, 4 <sup>th</sup> edition.	Update references with most current guidance from AAMI.
494.60 Physical environment	(a)	" <i>Standard: Building.</i> The building in which dialysis services..."	<b>Add:</b> (1) New design/construction and renovation should be consistent with the most recent Facility Guidelines Institute Guidelines for Design and Construction of Hospitals and Outpatient Facilities (FGI Guidelines).	The FGI Guidelines are used to formulate regulatory and code language, and as such, are used by authorities having jurisdiction when surveying facilities. The FGI Guidelines provide the basis for design elements such as hand hygiene stations and patient care space requirements aimed at reducing the risk for transmission of infection.
494.90 Patient plan of care	(a)	" <i>Standard: Development of patient plan of care.</i> The interdisciplinary	<b>Add:</b> (9) The initial indication and continued need for antibiotic therapy.	This supports the Department of Health and Human Services goal of antibiotic stewardship and outlined in the White House National Strategy for

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		team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following:		Combating Antimicrobial Resistant Bacteria.
494.110 Quality assessment and performance improvement	(ix)A-C	(A) Analyze and document incidence of infection to identify trends and establish baseline information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents.	<b>Change to:</b> (A) Report incidence of infection in the NHSN Dialysis Event Protocol using most current NHSN definitions and criteria (access at <a href="http://www.cdc.gov/nhsn/dialysis/dialysis-event.html">http://www.cdc.gov/nhsn/dialysis/dialysis-event.html</a> )  <b>Add:</b> (B) Analyze NHSN data and infection control issues reported to the dialysis facility's infection preventionist and medical director to identify additional opportunities for improvement. <b>Change</b> current (B) to (C) <b>Change</b> current (C) to (D)	APIC continues to support use of NHSN as the standardized electronic reporting methodology across healthcare settings.  Requiring reporting to the facility infection prevention staff along with integrating such reporting into the existing Quality Assessment and Performance Improvement program attaches responsibility, and promotes actions as the results of reports from staff.
494.140 Personnel qualifications			<b>Add:</b> (g) <i>Standard: Infection Preventionist.</i> (1) An individual(s) who develops and implements policies governing prevention and control of infections and communicable diseases as well as provides education and training related to prevention and control of infection. (2) The individual shall be qualified through education, training, experience, or certification or a	Requiring a qualified individual designated as the IP reinforces the importance of infection prevention and control in outpatient dialysis settings and aligns with requirements in other healthcare settings.  Literature shows that programs in facilities that have infection prevention infrastructure provide safer care to patients with less risk of

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			combination of such qualifications. (3) The infection preventionist's (IP) qualifications shall be documented and made available for inspection.	healthcare-associated infection (HAI). (Reference – Semin Dial. 2013 Jul-Aug;26(4):384-98.doi: 10.1111/sdi.12102. Epub 2013 Jun28.)