



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-13

DATE: November 21, 2008

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Waivers and Phase-In Time Extensions for the Implementation of the New End Stage Renal Disease (ESRD) Conditions for Coverage

Memorandum Summary

- **Effective Dates, New Regulation:** The new ESRD Conditions for Coverage were effective on October 14, 2008. However, there are separate effective dates for:
 - The construction of a separate isolation room for hepatitis B+ patients,
 - Code compliance for National Fire Protection Association's (NFPA) 2000 Life Safety Code (LSC),
 - Certification of patient care dialysis technicians, and
 - Mandatory electronic submission of data and information.
- **Waivers or Time Extensions:** In addition to the scheduled effective dates for the above aspects of the new ESRD Conditions, waivers and/or phase-in time extensions may be granted for some requirements of the Conditions. A grid describing options for waivers and phase-in time extensions is attached to this memorandum.
- **Model letters** that facilities may wish to use in providing information for waiver requests are also attached.

Background

The new ESRD Conditions for Coverage provide clearer and better provisions for patient safety and improved quality of care. While the overall effective date was October 14, 2008, the rule recognized that not all facilities may be in a position to fully meet all new or revised requirements of the Conditions for Coverage on that date. Therefore, the rule specifies separate effective dates for certain Conditions and provides that some facilities may request a waiver for certain other requirements. In this memorandum we describe the procedures we are implementing for requesting a waiver or time-limited extension of the time needed to phase-in the program improvements needed to achieve full compliance.

To facilitate review for any of these exceptions to the effective dates, the dialysis facility should contact the State Survey Agency or the Centers for Medicare & Medicaid Services (CMS) Regional Office to discuss the process.

With regard to life-safety code, States may request permission to use a State fire and safety code (State Code) in lieu of the LSC for Federal certification but only if the State Code applies to all provider/supplier types for which there are Medicare-certified providers or suppliers in the State. Currently, no State is approved to use its State Code in lieu of the Federal certification for LSC. If the State Code is approved by CMS as adequately protecting residents and patients, then the National Fire Protection Association's (NFPA's) 2000 edition of the LSC for Ambulatory Health Care Occupancies (Chapters 20 and 21) will not apply to dialysis facilities. The State application process is detailed in a Survey and Certification Letter dated September 5, 2008 (S&C-08-34).

CMS' approval of a facility's request for a waiver or time extension is not open-ended. CMS continues to have the goal of protecting the health and safety of patients, and any exception will be both time-limited and valid only so long as the facility continues to offer safe and healthy care to its patients. CMS may at any time, based upon evidence that a facility does not adequately protect patients, rescind a prior approval for an exception.

Model letters for facilities to use for waiver requests are included in this memorandum.

Effective Date: Immediately. Please ensure that all appropriate staff is fully informed within 30 days of the date of this memorandum.

If you have additional questions or concerns, please contact Judith Kari at judith.kari@cms.hhs.gov.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachments:

Grid for waivers (section 1 of grid) and phase-in time extensions (section 2 of grid) for ESRD Conditions

Model Letters for Waiver Requests

MODEL LETTER FOR ESRD WAIVER: Isolation Room for Hepatitis B+ Patients

Date

State Survey Agency
Survey & Certification, ESRD Specialist
Street Address
City, State, Zip code

Dear ESRD Specialist,

We are planning to open a new dialysis facility or we are planning to expand the square footage of our existing dialysis facility, and we are applying for a waiver of the requirement for an isolation room for dialyzing hepatitis B+ patients. We believe that there is sufficient capacity of isolation stations in isolation rooms to serve the needs of hepatitis B+ patients in our geographic area.

Our facility is name, and the facility is located at complete address, including zip code. Our existing facility has the following CMS certification number, CCN for existing facilities only.

Below is a list of the facilities within our geographic area that have isolation stations in isolation rooms. If we marked “written agreement” yes, we have attached a copy of the written agreement with that facility indicating their willingness to accept hepatitis B+ patients from our facility should we admit a hepatitis B+ patient or have a current patient seroconvert to hepatitis B+.

Name of facility	Distance from Our facility	Number of Isolation Stations in Isolation Room	Number of Patient Shifts	Number of Current Patients in Isolation	Written Agreement Yes/No

We appreciate your consideration of this request and await your response.

Sincerely,

Name

Contact information, including mailing address, phone, and email address

**MODEL LETTER FOR ESRD WAIVER: Life Safety Code Requirements for a New
ESRD Facility Based Upon “Unreasonable Hardship.”**

Date

State Survey Agency
Survey and Certification, Life Safety Code Specialist
Street Address
City, State, Zip code

Dear Life Safety Code Specialist,

We are writing to request a waiver of the Life Safety Code (LSC) requirement for insert identifying information and description of the specific provision for which a waiver is being requested for our facility, name of facility at complete address.

We feel that the rigid application of this provision of the Life Safety Code (LSC) would result in an unreasonable hardship for our dialysis facility in that describe the economic, logistical, or construction hardship that this provision would cause.

The following evidence is presented to demonstrate that this waiver would not adversely affect the health and safety of the dialysis facility's patients. Describe how the health and safety of the dialysis facility's patients will be protected even though a specific LSC provision will not be met.

We appreciate your consideration of this request and await your response.

Sincerely,

Name

Contact information, including mailing address, phone, and email address

MODEL LETTER FOR ESRD WAIVER: Qualifications for Medical Director

Date

State Survey Agency
Survey & Certification, ESRD Program
Street Address
City, State, Zip code

Dear ESRD Specialist,

We are writing to request a waiver of the requirement for Board certification, completion of 12 months training program in nephrology, and/or 12 months experience providing care to patient on dialysis for the medical director of our facility, name, address, and CMS certification number.

Our medical director, name, has been medical director at this facility since date. A brief resume is attached. A qualified physician is not available to serve as the medical director of this facility for the following reason(s): stated reason(s).

We understand that a facility may apply for a potentially renewable, time-limited waiver if one or more of the qualification requirements listed above for medical director are not met. We also understand that facility-based outcomes will determine the length of time of the applicable waiver. We understand that the facility-based outcomes will consist of a composite ranking drawn from the most recent twelve-month period for which CMS has facility-specific, statistically-developed and rank-ordered outcome data. The composite ranking will be generated by the Kidney Epidemiology and Cost Center of the University of Michigan.

We appreciate your consideration of this request and await your response.

Sincerely,

Name

Contact information, including mailing address, email address, and phone number

Procedures

for

ESRD Requests for Waivers or Time-Extensions

for

Certain Conditions for Coverage Specified in the CMS Administrative Rule

SECTION 1: WAIVERS

	<p><u>Waiver: Isolation Room</u></p> <p>New facilities & existing facilities which are expanding their capacity may apply for a waiver for an isolation room for hepatitis B+ patients.</p> <p>As of February 9, 2009, all new or expanding facilities must have an isolation room or be granted a waiver for this requirement, showing that there is sufficient capacity in their geographic area for isolation rooms.</p> <p>Waivers may be granted to varying extent based upon the availability of alternative isolation rooms in the proximate geographic area.</p>	<p>A “new” facility is a facility that has not obtained approval for all required building permits (or has not completed the required plan reviews in geographic jurisdictions that do not require building permits) prior to the effective date of these regulations, i.e. October 14, 2008</p> <p>An isolation “room” is a separate room with walls and a door to contain any spurting blood, body fluids, or other contaminants. The walls do not need to reach the ceiling, but should be at least 6 feet in height and must fully contact the floor in order to contain blood spills. The walls need to allow for continuous visual monitoring of the patients in the room.</p> <p>“Sufficient capacity” takes into account the availability of facilities with isolation rooms in a “proximate” geographic area. The “proximate” area should take into account the physical distance between a facility with at least one available isolation room/isolation station and the facility seeking a waiver.</p> <ul style="list-style-type: none"> • If the distance between these facilities is >60 miles, the facility cannot be granted a waiver of an isolation room/isolation station. • If the distance is 10-60 miles, a facility may request consideration of a waiver. • If the distance is <10 miles, then a facility will be granted a waiver automatically upon request in most cases. <p>In addition to the physical distance between facilities, “sufficient capacity” also requires a</p>	<p>A new or expanding dialysis facility may be eligible for a waiver of this requirement if:</p> <ol style="list-style-type: none"> 1. Facility-based isolation rooms for HBV+ patients are available locally <u>and</u> such rooms; 2. Sufficiently serve the needs of the patients in the geographic area, <p>Isolation room waivers may be granted at the discretion of, and subject to, additional conditions that are deemed necessary by the Secretary.</p> <p><u>Written requests for a waiver should be made to the applicable State Survey Agency.</u> A model letter is included with this grid. The written request must include information on the geographical proximity of facilities with isolation rooms and the accessibility of the isolation room(s) as validated in a written agreement between the facility requesting the waiver and the facility(ies) having the isolation capacity.</p> <p>The State Survey Agency may consult with the applicable End Stage Renal Disease (ESRD) Network to clarify questions regarding availability of isolation rooms/isolation stations.</p> <p>The State Survey Agency will communicate information regarding the waiver to the applicable CMS Regional Office. The CMS Regional Office will inform the facility about the decision regarding the waiver.</p> <p>Documentation of the decision should be entered in the “Remarks” section of the form CMS-3427</p>

V Tag	Section 1: Waivers	Guidance	Procedure
		<p>written agreement between facilities regarding their willingness and ability to take referred HBV+ patients.</p> <p>“Expanding” means that a facility increases the square footage of treatment space. Construction to comply with other Conditions for Coverage, e.g., to replace a flat-bottom water storage tank with one having a conical bottom or to add a carbon tank, is not considered expanding the treatment space. Each expansion requires a new consideration regarding isolation rooms, using the same criteria.</p>	<p>in order to maintain this information in the automated systems.</p>
V420	<p>Waiver: <u>Life-Safety Code</u></p> <p>A facility may apply for a waiver for one or more specific provision(s) of the Life Safety Code, for appropriate periods, if application of the provision(s) of the Life Safety Code (LSC) would result in an “unreasonable hardship” for the dialysis facility.</p> <p>A new or existing facility may request a waiver for a specific provision of the LSC. The facility must provide evidence that the waiver would not adversely affect the health and safety of the dialysis facility’s patients.</p>	<p>“Unreasonable hardship” may be an economic, logistical, or construction hardship.</p> <p>A “new” facility is a facility that has not obtained approval for all required building permits (or has not completed the required plan reviews in geographic jurisdictions that do not require building permits) by October 14, 2008.</p> <p>An “existing” facility is a facility that has a CMS Certification Number (CCN).</p> <p><u>Note:</u> The new life-safety code portion of the survey process will be phased in during 2009. CMS will issue a separate S&C Memorandum in December 2008 that will describe this process.</p>	<p>A new or existing facility may request a waiver for a specific provision of the Life Safety Code (LSC). <u>A new facility applies to the applicable State Survey Agency</u> for a waiver. A model letter for this application is attached.</p> <p>An <u>existing facility</u> requests a waiver for a specific provision of the LSC following a survey when a provision of the LSC is not met and is cited as a deficiency on the left side of the form CMS-2567. At that point, the facility may request a waiver through the State Survey Agency. The facility must request a waiver and cite “unreasonable hardship” and “no adverse effect” on the right side of the form CMS-2567, in lieu of a plan of correction. The facility should include justification statements explaining the “unreasonable hardship” and how the waiver will have “no adverse effect on the patient’s health and safety” In their comments on the right side of the form CMS-2567.</p> <p>Guidance on the LSC waiver process is found in Appendix I of the State Operations Manual</p>

V Tag	Section 1: Waivers	Guidance	Procedure
			(SOM). Information regarding waivers for LSC provision(s), will be communicated from the State Survey Agency to the applicable Regional Office. The CMS Regional Office will inform the facility about the decision regarding the waiver.
V683	<p>Waiver: <u>Medical Director Qualifications</u></p> <p>If a qualified physician is not available to serve as medical director of a certified dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.</p> <p>Potentially renewable, time-limited waivers for the qualifications of a medical director will be granted to dialysis facilities based upon facility outcomes. Because the medical director is responsible for the care and outcomes in the dialysis facility, outcomes are an important part of the waiver process. If a medical director is transferring to a new facility, outcomes of both the former and the current facility will be considered.</p>	<p>A “qualified medical director” is a physician who meets the following qualifications:</p> <p>(1) Is Board-certified in Internal Medicine/Pediatrics: According to the website of the American Board of Internal Medicine (ABIM) and the American Board of Pediatrics (ABP), a physician does not need to maintain certification in internal medicine or general pediatrics to recertify in nephrology or pediatric nephrology. Therefore, a medical director certified in nephrology or pediatric nephrology does not need to maintain current certification in internal medicine or general pediatrics. CMS accepts the position of the ABIM and ABP and accepts current board certification in internal medicine, pediatrics, nephrology, or pediatric nephrology as meeting this requirement;</p> <p>(2) Has completed a board-approved training program in nephrology; and</p> <p>(3) Has at least 12 months of experience providing care to patients receiving dialysis.</p>	<p>A facility may request a waiver to appoint (or retain) as medical director a physician who does not meet one or more of these qualifications if a physician who does meet these qualifications is not available to direct the dialysis facility. <u>The request (with a brief resume of the physician and an explanation as to why a physician meeting the board certification requirement is not available) should be submitted to the applicable State Survey Agency.</u> A model letter is attached.</p> <p>Waivers will be time-limited but potentially renewable. The time period will be driven by patient outcomes information from the most recent twelve-month period for which CMS has outcome data. Facilities whose outcomes are in the lowest quintile of all ESRD facilities ($\leq 20\%$) may receive a one-year waiver for the qualifications of their medical director. Facilities whose outcomes are in the upper four quintiles (21-100%) may receive a three-year waiver.</p> <p>The State Survey Agency will communicate information regarding the waiver to the applicable CMS Regional Office. The CMS Regional Office will inform the facility about the decision regarding the waiver.</p>

SECTION 2: PHASE-IN TIME EXTENSIONS

	<p>Phase-in Time Extension: <u>Single-Use Vials</u></p> <p>Facilities should apply single use to single-use vials.</p> <p>Facilities should have a plan for the conversion of single-use vials for single use.</p>	<p>Manufacturers of single-use vials for erythropoiesis stimulating agents estimate that full supplies of single-use vials should be available for all dialysis units by Spring 2009.</p> <p>This time extension that is intended to recognize the current shortage of single-use vials in the commercial marketplace.</p> <p>All facilities should have plans for fully complying with this regulation by June 30, 2009.</p>	<p>Facilities that currently use single-use vials multiple times must continue to follow the CDC guidance letter of 2002 in the use of those vials. Facilities need to have a plan to convert to the single use of single-use vials as soon as supplies are available. <u>No special letter-request needs to be submitted.</u></p> <p>During a State survey prior to June 30, 2009, facilities that are using single-use vials multiple times must provide the surveyor with the facility's plan for conversion to single-use vials.</p> <p>If a facility is surveyed prior to June 30, 2009, then the facility must present their plan for conversion to single-use vials. If a facility is surveyed after June 30, 2009, then the facility must have converted to single-use vials. If a facility does not comply with either of these scenarios, then the facility will be cited for noncompliance with this rule, and a plan of correction will be expected.</p>
	<p>Phase-in Time Extension: <u>Water Storage Tanks</u></p> <p>Water storage tanks should have a conical or bowl-shaped base and should drain from the lowest point in the base.</p> <p>If existing facilities with older flat-bottom water storage tanks can demonstrate a history of water and</p>	<p>The AAMI "action levels" for water and dialysate cultures are <50 cfu for bacteria and <1 EU for endotoxins.</p> <p>An "existing" facility is a facility that was in operation on October 14, 2008.</p>	<p>A facility that does not have a water storage tank with a conical or bowl-shaped base should be prepared to demonstrate a documented history of water and dialysate cultures being below AAMI action levels whenever a State survey is conducted. <u>No special letter-request needs to be submitted</u> for this time extension.</p> <p>If a facility continues to use a water storage tank without a conical or bowl-shaped base and the facility does not have a documented history of</p>

V Tag	Section 2: Phase-In Time Extensions	Guidance	Procedure
	dialysate cultures being below AAMI action levels, replacement of the existing tanks is not required.		water and dialysate cultures being below AAMI action levels, then during a State survey, the facility will be cited for noncompliance with this rule, and a plan of correction will be expected.
V519 V558	<p><u>Phase-in Time Extension: Interdisciplinary Assessment</u></p> <p>Comprehensive, interdisciplinary assessment, at least annually, for all stable patients, and implementation of the plan of care based on those assessments.</p> <p>Each facility needs to have a facility-wide plan to accomplish initial comprehensive, interdisciplinary assessments and plans of care for all existing patients by October 14, 2009.</p>	<p>A “facility-wide plan” for comprehensive, interdisciplinary assessments of all current stable patients as of October 14, 2008, is expected to include a schedule to allow completion of these assessments and implementation of the plans of care based on those assessments for all current patients by October 14, 2009. The facility-wide plan should reflect prioritization of those patients who fall farthest outside target ranges for the mandated areas of assessment and planning.</p> <p>Patients “new” to ESRD treatment or to their treatment modality, transient patients, transferred in patients, and unstable patients are not included in the phase-in time extension, but must follow the timelines, as specified in the Interpretative Guidance.</p>	<p>The facility-wide plan for completing the comprehensive assessments and plans of care should be available for review during any State survey. <u>No special request needs to be submitted</u> for this time extension. Facilities should follow the regulations and the Interpretive Guidance in ensuring that assessments and plans for all stable patients are completed by October 14, 2009.</p> <p>If a facility is surveyed prior to October 14, 2009, then the facility must provide an operational plan for patient assessments, and the complementary plans of care, for all patients who were on the census of that facility as of October 14, 2008. As the year between October 14, 2008, and October 14, 2009, progresses, more and more of the facility’s patients should have completed assessments and implemented plans of care.</p> <p>If a facility is surveyed after October 14, 2009, then all patients who were on the census of that facility as of October 14, 2008, must have a patient assessment and a complementary plan of care.</p> <p>If a facility does not comply with either of the scenarios described above, then the facility will be cited for noncompliance with this rule, and a plan of correction will be expected.</p>

	<p><u>Data Submission</u></p> <p>Effective February 1, 2009, dialysis facilities must submit data and information electronically in the format specified by the Secretary and at intervals specified by the Secretary</p>	<p>Facilities are expected to submit data electronically on existing and future clinical performance measures. The “electronic format” is the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) system. The “clinical performance measures” and the data elements required for electronic submission will be communicated to dialysis facilities through CROWNWeb communications.</p>	<p>The CMS Office of Clinical Standards and Quality (OCSQ) designs and maintains the CROWNWeb system. OCSQ continues to update its communications regarding the CROWNWeb system as issues are addressed. The Survey & Certification Group remains in close contact with OCSQ and will update our communications based on OCSQ’s continued resolution of issues (as discussed, for example in the 11/19/2008 Open Door Forum). In particular, we will update this Memorandum as we come closer to February 1, 2009.</p>