Revisions to Form CMS-3427 – End Stage Renal Disease Application and Survey and Certification Report

Issue #	Page #	Section	Action to be performed	Changes to the Application	Reason for the Change
1.	All	Each Page	Revise as follows	Add the draft watermark and removing the date from the footer on each page; renumber answers for ASPEN programming as indicated	Revising the application; therefore, this date will change and draft watermark is needed for posting.
2.	1	Heading	Revise to add the PRA Disclosure Statement as follows	**PRA Disclosure Statement** According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-0360**. The time required to complete this information collection is estimated to average of **20 minutes** per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.	OMB requires the PRA Disclosure Statement to be on all CMS forms.
3.	1	Part 1	#2-Revise as follows with addition in red text	Name of Dialysis Facility	Revised for clarification purposes. "Dialysis" clarifies the type of facility applying for ESRD certification because this form also asks for information about other facility types (hospitals, nursing homes, etc.)
4.	1	Part 1	#15- Revise as follows with additions in red text.	Dialysis Facility Administrator Name Business Address	Revised for clarification purposes. As above "Dialysis" clarifies the type of facility applying for ESRD certification. Applicants are to report their business address instead of their residential address.
5.	1	Part 1	#17- Reword, reorder, delete to revise as follows with additions in red text with "not" underlined, and deletions in strikethroughs	Is this dialysis facility independent (i.e., not owned or managed by a hospital)? Is this dialysis facility owned and managed by a hospital and on the hospital campus (i.e., hospital-based)? Is this dialysis facility owned and managed by a hospital and located off the hospital campus (i.e., satellite)? ~~Is this facility no owned or managed by a hospital (i.e., independent)?~~ ~~If owned and managed by a hospital: hospital name____ CCN_~~	Revised for clarification purposes and underlined "not" in response to comment received from dialysis provider. Deleted hospital name and CCN because the information is not necessary since ESRD facility must use its own CCN even if hospital-based or satellite.
6.	1	Part 1	#18- Revise as follows with additions in red text	Is this dialysis facility located in a SNF/NF (LTC) (check one) If SNF/NF owned and managed by a hospital: hospital name:_____ CCN:_____ If Yes, SNF/NF name:_____ CCN:_____	Revised for clarification purposes. If the dialysis facility is located in or provides or supports dialysis in NF/SNF (LTC), the name of the LTC is collected in #22 and

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					instructions say to list additional LTCs in Remarks (#33).
7.	1	Part 1	#19- Revise as follows with addition in red text	Is this dialysis facility owned &/or managed by a multi-facility organization? Yes, Managed If Yes, name of multi-facility organization_____ Multi-facility organization's address_____	Revised for clarification purposes. "Dialysis" clarifies the type of facility applying for ESRD certification
8.	1	Part 1	#20- Revise as follows with additions in red text	Current modalities/services for dialysis facilities requesting recertification only (check all that apply): ☐ 1. In-center Hemodialysis (HD) ☐ 2. In-center Peritoneal Dialysis (PD) ☐ 3. In-center Nocturnal HD 4. ☐ ~~Reuse 5~~ Home HD Training & Support ☐ 5. HD in LTC ☐ 6. Home PD Training & Support ☐ 7. PD in LTC ~~Home Training & Support only~~ ☐ 8. Dialyzer Reuse	Revised for clarification purposes in question and instructions. Only currently certified facilities requesting recertification should complete this question. This change addressed a comment received from a dialysis provider indicating confusion about whether a *new* facility would include modalities and services it intends to offer as "current." Added modality because reuse and home training & support are services. All other options are dialysis modalities. Deleted "home training & support only" because a facility providing only home HD or only home PD should mark only the option(s) it provides.
9.	1	Part 1	#21- Revise as follows with additions in red text and deletions in strikethrough.	New modalities/services being requested (check all that apply; must have 1 permanent patient for any modality requested): ☐ 1. In-center HD~~N/A~~ ☐ 2.In-center PD ☐ 3. In-center Nocturnal HD ~~5. Reuse~~ ☐ 4. Home HD Training & Support ☐ 5. HD in LTC ☐ 6. Home PD Training & Support ☐ 7. PD in LTC ☐ 8. Dialyzer Reuse ~~Home Training & Support only~~ ☐ 9. N/A	Revised for clarification purposes in question and instructions to comply with the 2008 ESRD Conditions for Coverage that require 1 permanent patient for any modality requested. Added modality because reuse and home training & support are services. All other options are dialysis modalities. Deleted "home training & support only" because a facility providing only home HD or only home PD should mark only the option(s) it provides.
10.	1	Part 1	#22- Revise as follows to move the note first and added text in red and deletions in strikethroughs	**NOTE: For dialysis in more than 1 LTC facility, record this same information in the "Remarks" (item 33) section or attach list** 22. Does the dialysis facility have any ~~home~~ dialysis (PD/HD) patients physically receiving dialysis ~~in~~within long-term care (LTC) facilities? ☐ Yes ☐ No LTC (SNF/NF) facility name:_____ CCN:_____ Staffing for home dialysis in LTC provided by: ☐ 1. This dialysis facility ☐ 2. LTC staff ☐ 3. Other, specify ~~Type~~Number of dialysis residents by modality receiving dialysis ~~provided in~~within this LTC facility: ☐ 1. HD ☐ 2. PD	Revised for clarification purposes in the question and instructions to avoid confusion among applicants who have patients who do dialysis within the LTC facility instead of in the patient's private home. Added the number of dialysis residents by modality for each LTC facility to be able to help the ESRD surveyor know the patient census of dialysis treatments offered within the LTC facility.

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				~~For additional LTC facilities, record this information and attach to the "Remarks" (Item 33) section~~	
11.	1	Part 1	#24- Revise as follows with additions in red text; now on page 2	Number of **currently** approved in-center dialysis stations:____ Are ~~O~~onsite home training room(s) provided? ☐ 1. Yes ☐ 2. N/A	Revised for clarification purposes and to address comment received from a dialysis provider to indicate the station count is only for in-center dialysis and that home training room(s) are only reported as Yes or No.
12.	1	Part 1	#25-Revise as follows with deletions in strikethrough; now on page 2	Additional stations ~~being~~ requested ☐ None ~~☐ In-center HD ☐ In-center nocturnal HD ☐ In-center PD~~	Revised for clarification purposes and to address comment received from a dialysis provider.
13.	2	Part 1	#26-Revise as follows with additions in red text	How is isolation provided? ☐ 1. Room ☐ 2. Area (established facilities existing 2/9/2009 only) ☐ 3. CMS Waiver/Agreement (Attach copy)	Revised for clarification purposes to comply with the 2008 ESRD Conditions for Coverage. Survey & Certification Memorandum 09-13 states as of 2/9/09, new facilities must have an isolation room or waiver.
14.	2	Part 1	#28-Revise as follows with additions in red text and deletions in strikethrough	Days ~~&~~/times for in-center ~~patient~~ shifts or operating hours if home only (check all days that apply and complete time field in military time): 1st in-center shift starts or home only facility opens: M____ T____ W_____Th____ F____ Sat____ Sun____ Last in-center shift ends or home only facility closes: M____ T____ W_____Th____ F____ Sat____ Sun____	Revised to clarify facility operating hours for facilities that only provide home dialysis and to state patient in-center shifts start and end.
15.	2	Part II	#35 Revise as follows with additions in red text and deletions in strikethrough	Medicare Enrollment (CMS 855A ~~approved~~ recommended for approval by the ~~MAC/FI~~ Medicare Administrative Contractor) ☐ 1. Yes ☐ 2. No *(Note: approved CMS 855A required prior to certification)*	Revised to conform to the instructions in the CMS 855A, page 3.
16.	3	Instructions for Form CMS 3427	Revise 1st paragraph in instructions as follows with deletion in strikethrough and addition in red text	**PART 1 – DOCUMENTATION NEEDED TO PROCESS FACILITY APPLICATION/NOTIFICATION TO BE COMPLETED BY APPLICANT** A completed request for approval as a supplier of End Stage Renal Disease (ESRD) services in the Medicare program (Part I – Form CMS-3427) must-include • ~~A narrative statement describing the need for the service(s) to be provided, and~~ ~~A~~a copy of the Certificate of Need approval, if such approval is required by the state.	Revised to eliminate duplication since the narrative is included in Certificate of Need approval, if applicable.
17.	3	Instructions for Form CMS 3427	Revise as follows deleting strikethrough and adding red text	**TYPE OF APPLICATION (ITEM 1)** Check appropriate category. A "change of service" refers to an addition or deletion of services, e.g. home dialysis, dialysis in LTC, dialyzer reuse, in-center nocturnal HD, in-center PD, etc. "Expansion" refers to addition of in-center stations. If you relocate one of your services to a different physical location, you may be required to obtain a separate CCN for that service at the new location.	Revised for clarification purposes.

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18.	3	Instructions for Form CMS 3427	Revise as follows in red text.	**IDENTIFYING INFORMATION (ITEMS 2-~~24~~19)** Enter the name and address *(actual physical location)* of the ~~ESRD~~ dialysis facility where the services are performed. If the mailing address is different, show the mailing address in Remarks (*Item 33*). Check the applicable blocks (*Item 17* and *Item 18*) to indicate the dialysis facility's hospital and/or SNF/NF affiliation, if any. If so, enter the CCN of the hospital and/or SNF/NF. Check whether the dialysis facility is owned and/or managed by a "multi-facility" organization (*Item 19*) and provide the name and address of the parent organization. A "multi-facility organization" is defined as a corporation or a LLC that owns more than one dialysis facility.	Revised for clarification purposes and to correct Item numbers in the Identifying Information section.
19.		Instructions for Form CMS 3427	Revise as follows with deletions in strikethrough and additions in red text	**TYPES OF MODALITIES/SERVICES, DIALYSIS STATIONS, AND DAYS/HOURSOF OPERATION (ITEMS 20-~~28~~29)** ~~Provide information on current~~Check the modalities/services that are already offered ("current modalities/services") by a dialysis facility requesting recertification (*Item 20*). Check N/A or check each ~~New~~**NEW** modality/service for which you are requesting approval. Any new modality/service must be requested on the CMS-3427 and filed with the State agency. At the time of survey, one permanent patient must be on the dialysis facility's census in-center or in training/trained by the facility for each modality requested (*Item 21*). Note that dialysis facilities providing home therapies must provide both training and support. If you are requesting to offer home training and support **only** (*Item 21*), you must have a functional plan/arrangement to provide backup dialysis as needed. If you request any home training and support program (*Item 21*), you must also indicate "Yes" for a training room (only count stations for in-center dialysis, not for home training) (*Item 24*). **If you currently provide or support dialysis within one or more LTC facilities (SNF/NF), complete *Item 22* and list for all LTCs ~~(~~: name, CCN,~~ and address) participating in this services~~ staffing provided by, and number of dialysis patients treated by modality under Remarks (*Item 33*)~~ and complete Item 22~~. New requests for dialysis within any LTC facility require completion of *Item 22* (and 33 if applicable) and submission of this form to the State agency prior to survey.** You must answer *Yes* (*Item 22*) and have at least one LTC dialysis resident for addition of services for dialysis in LTC. Enter the number of additional in-center stations for which you are asking approval (*Item 25*). Provide information on isolation *(Items 26-27).* Dialysis facilities not existing prior to October 14, 2008 which do not	Revised for clarification purposes to address comment from provider that described confusion about how to complete these questions on the Form CMS-3427. Bolded text to draw greater attention to changes.

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				have an isolation room must attach evidence of CMS waiver and written agreement with geographically proximal facility with isolation room. Provide current information on all days and start time for the first shift ~~of patients~~ and end time for the last shift of in-center patients (in military time) for each day of operation. If the dialysis facility offers home training and support only, provide current operating hours for each day *(Item 28)*. Provide information on dialyzer reprocessing *(Item 29)*.	
20.	3	Under Staffing, revise as follows	Revise as follows with addition in red text.	**STAFFING (ITEM 30)** "Other" includes non-certified patient care technicians, administrative personnel, etc. To calculate the number of full-time equivalents of any discipline (*Item 30*), add the total number of hours that all members of that discipline work at this dialysis facility and enter that number in the numerator. Enter into the denominator the number of hours that facility policy defines as full-time work for that discipline. Report FTEs in 0.25 increments only. Example: An RD works 20 hours a week at Facility A. Facility A defines full time work as 40 hours/week. To calculate FTEs for the RD, divide 20 by 40. The RD works 0.50 FTE at Facility A.	Revised for clarification purposes.
21.	3	Under REMARKS	Move this section before Licensing and Certificate of Need and revise as follows with additions in red text.	Add: "You may use this block for explanatory statements related to Items 1-32. The administrator/medical director signs and dates. **Upon completion, forward a copy of the form CMS-3427 (Part I) to the State agency.**	Revised for clarification purposes and to indicate who at the facility must sign and date to attest that the information on the Form CMS-3427 is accurate.
22.	3	Under Licensing and Certificate of Need	Move this section after REMARKS and revise as follows with additions in red text.	LICENSING AND CERTIFICARE OF NEED, IF APPLICABLE (Items 31-32)'	Revised for clarification purposes to indicate that Certificate of Need may not be applicable and to add the Item numbers for this section
23.	3	Part II	Revise as follows with additions in red text and deletions in strikethrough	**PART II - SURVEY AND CERTIFICATION REPORT TO BE COMPLETED BY STATE AGENCY** The surveyor should review and verify the information in Part I with administrator or medical director and complete Part II of this form. Recognize that CMS cannot issue a CCN for an initial survey until all required steps are complete, including recommended approval of the CMS-855A ~~approved by~~ the applicable MAC. Complete the Statement of Deficiencies (CMS Form 2567) in ASPEN. Complete the CMS-1539 in ASPEN entering recommended action(s). All required information must be entered in ASPEN and uploaded in order for the survey to be counted in the state workload.	Revised for clarification purposes and to conform to the instructions for the CMS-855A.