

CMS Response to Public Comments Received to CMS-2015-0140
for the Form CMS-3427

The Centers for Medicare and Medicaid Services (CMS) received comments to CMS-2015-0140 from one dialysis provider related to the Form CMS-3427. This is the reconciliation of the comments from that provider.

Comment:

The Centers for Medicare and Medicaid Services (CMS) received comments from a dialysis provider suggesting that in **Item 15** the Form CMS-3427 include the facility administrator's email address.

Response:

CMS appreciates the suggestion. The Form CMS-3427 currently in use (05/13) does not have the facility administrator's email address. The proposed Form CMS-3427 adds a field for the facility administrator's email address.

Comment:

The Centers for Medicare and Medicaid Services (CMS) received a comment from the dialysis provider that states for **Item 17** which asks about ownership or management, *"We have seen a number of errors in this section. For more clarity, we suggest that the word **not** in the third line be underlined."*

Response:

CMS thanks the commenter for the pointing out the need for clarification. The question asks about the dialysis facility's ownership or management. It asks if the dialysis facility is "independent," "hospital-based," or a "satellite" and the questions define those terms. We have reordered and reworded the questions from the Form CMS-3427 that was revised 05/13. For "independent" we underlined the word "not" in this parenthetical phrase ("not** owned or managed by a hospital") and we specified that facility in the questions refers to the *dialysis* facility to differentiate it from any other type of facility.**

Comment:

The Centers for Medicare and Medicaid Services (CMS) received a comment from the dialysis provider about **Item 18**, which asks if the facility is located in a SNF/NF, *"We suggest that the same questions be asked here that are asked in Item 17."*

Response:

CMS appreciates this suggestion, but disagrees. Item 18 seeks different information from Item 17. It asks if a dialysis facility is located in a SNF/NF, whether that SNF/NF is owned

by a hospital, and the name of the hospital. The currently proposed Form CMS-3427 clarifies and specifies if the question refers to the dialysis facility or the SNF/NF.

Comment:

The Centers for Medicare and Medicaid Services (CMS) received a comment from a dialysis provider for **Item 20**, which asks about current modalities/services that states: *“Provide clarification that ‘current services’ are those services that a new facility intends to offer when the facility is approved.”*

Response:

CMS appreciates this suggestion but disagrees. In Item 20, “current modalities/services” refers to services the currently certified dialysis facility offers when applying for recertification. We clarified in the form and the instructions that this question refers to dialysis facilities applying for recertification and defined “current modalities/services” in the instructions to be “modalities/services that are already offered (‘current modalities/services’) by a dialysis facility requesting recertification.”

Comment:

The Centers for Medicare and Medicaid Services (CMS) received two comments from a dialysis provider about **Item 21**, which refers to new modalities/services being requested:

“(a) In the absence of guidance that is typically provided in a State Operations Manual, provide clarification in the instructions as to whether the 3427 will need to be submitted - requesting new home dialysis (HD or PD) - prior to training a patient or after a patient has been trained so the training records can be reviewed.

(b) Given the fact that nocturnal hemodialysis is not a new service, but is hemodialysis on a night shift, please clarify in the instructions whether a 3427 must be submitted before adding a nocturnal shift.”

Response:

CMS thanks the commenter for these questions and suggestions. The ESRD State Operations Manual currently in CMS review will answer both of these questions. For (a), the instructions on the Form CMS-3427 have been revised to state: “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.”

For (b), as the commenter states, in-center nocturnal HD is a variation on daytime in-center HD. However, because this service is a nighttime treatment during which patients may sleep, there are unique health and safety considerations such as but not limited to policies and procedures, staffing and staff training, patient and equipment monitoring, technical considerations related to maintaining safe water and dialysate, reuse (if applicable), lighting for visualization of the dialysis access, patient comfort, and separate

QAPI data reporting. For these reasons, CMS has determined that in-center nocturnal dialysis must be separately approved.

Comment:

The Centers for Medicare and Medicaid Services (CMS) received this comment from the dialysis provider about **Item 22**, which seeks information about whether the dialysis facility has any HD and/or PD patients physically receiving dialysis within any LTC facilities: *“Provide clarification on the requirements of reporting long term care (LTC) facility information. Specifically, clarify whether LTC facility information should be reported each time a dialysis facility adds or eliminates a LTC facility in which its patients are dialyzing, or whether the current list of LTC facilities be updated at the time of surveys.”*

Response:

CMS appreciates the question from this commenter. We have revised the instructions to state: “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, staffing provided by, and number of dialysis patients treated by modality under Remarks (*Item 33*). 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.”

Comment:

The Centers for Medicare and Medicaid Services (CMS) received this comment from a dialysis provider about **Item 24**, which asks for the number of in-center stations and whether the facility has onsite training rooms: *“Clarify in the instructions that there is no specific count/number of training rooms. The number is usually related to the size of the facility and the number of patients who are being trained. Adding another treatment area should not require submission of a new 3427 if the facility is already approved for home training (PD or HD or both).”*

Response:

CMS appreciates this comment. Because of confusion and errors in completing the Form CMS-3427 for stations and training rooms, we have revised the form and instructions. The form now asks “Number of currently approved in-center dialysis stations” and Are onsite home training rooms provided? The instructions now say: “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*).”

Comment:

The Centers for Medicare and Medicaid Services (CMS) received this comment from a dialysis provider about **Item 25**, which asks for the number of additional stations requested for in-center HD, in-center nocturnal HD, in-center PD or none: *“This is confusing since in-center nocturnal*

HD stations are counted in the total approved in-center dialysis stations for a facility. We suggest removing in-center nocturnal HD from this question. As stated previously, nocturnal HD is an overnight shift, but it is still hemodialysis treatment. A facility can initiate a nocturnal shift just as it initiates an evening shift as the census increases or if some of the patients are working or going to school.”

Response:

CMS appreciates the dialysis provider bringing these concerns to our attention. Because of unique considerations with in-center nocturnal HD, CMS is now requiring facilities desiring to add the service of in-center nocturnal dialysis to request approval from the State agency. However, since new stations could be used for in-center HD, in-center nocturnal HD or in-center PD, we have revised Item 25 on Form CMS-3427 to ask only the number of additional in-center stations requested with an option to respond “none” if no new stations are being requested.