

CMS Response to Public Comments Received for CMS-2728

The Centers for Medicare and Medicaid Services (CMS) received comments from physician profession organizations, dialysis providers, schools of medicine, patient advocacy groups and nephrologists. This is the reconciliation of the comments.

Comment:

CMS received comments from a physician profession organization indicating a concern regarding instructions for a question that requires a patient to articulate the risk and benefits of a kidney transplant as well as the reasons they refused the transplant option as there is substantial information to cover with a patient new to dialysis.

Response:

CMS appreciates the comment and concern expressed by this commenter but the CMS-2728 form has a 45-day submission period. The nephrologist is not the only care provide that can educate the patient regarding kidney transplantation. CMS believes patients require this education to make an informed consent regarding End-Stage Renal Disease (ESRD) treatment modality options. While CMS understands there is a great deal of information for a patient to digest during the initiation of dialysis; however, CMS disagrees with the removal of the question as patients need information on treatment options to make informed decisions.

Comment:

CMS received a comment from a physician profession organization which “strongly encourages CMS to develop an option for electronic form completion and submission process so that the unnecessary documentation on and management of a physical paper form can be minimized.”

Response:

CMS appreciates the comment and thanks the commenter for the pointing out the obstacles related to the completion and submission of the CMS-2728 form. CMS does have an electronic documentation process in the ESRD Quality Reporting System (EQRS). However, the Social Security Administration (SSA) does not have an electronic submission process. CMS is in communication with SSA to collaborate on a submission process when it becomes feasible. CMS collaborated with SSA to accept electronic signatures, in addition, to a signature in ink.

Comment:

CMS received a comment from a physician profession organization regarding the timing of questions related to education of kidney transplant and home dialysis as treatment options. The commenter further has concerns regarding the sequencing of questions, such as, the number of session and/or minutes a patient dialyzes.

Response:

CMS appreciates comment and concern expressed by this commenter but disagrees with the commenter. Patients new to dialysis even those with emergent starts need to be educated about all treatment options in addition to in-center dialysis to make informed decisions on their course of treatment. CMS also disagrees with the commenter about documenting the number of sessions and/or minutes a patient dialyzes in the initial phase of treatment. While CMS understands that incremental dialysis occurs, CMS has concerns regarding the high mortality rate for dialysis patients in the first ninety (90) days of treatment.

Comment:

CMS received a comment from a physician profession organization regarding a concern “that the proposed changes include questions that compel the nephrologist to discern whether the patient understands the educational efforts being provided to them on modality choice.”

Response:

CMS appreciates comment and concern expressed by this commenter but disagrees with the commenter. CMS expects physicians to explain treatment options to patients so the patient can understand and make informed decisions regarding their care. CMS supports patient empowerment to choose their dialysis treatment modality, to that end, the patient must understand all treatment options.

Comment:

CMS received a comment from a physician profession organization recognizing “the unique conditions and patient care needs of pediatric ESRD patients require specialized consideration, and CMS’ proposal to collect information on pediatric-specific comorbidities to reflect the care and resources being delivered to this population more accurately is appropriate and welcome”

Response:

CMS thanks the commenter and agrees that collaboration with the provider community is an important step in collecting relevant, accurate information about the patients.

Comment:

CMS received a comment from a physician profession organization supporting “proposed to update the CMS-2728 form to include pediatric-specific comorbidities and we urge the agency to finalize their addition to Section A #19 of the form”.

Response:

CMS thanks the commenter and agrees that collaboration with the provider community is an important step in collecting relevant, accurate information about the patients.

Comment:

CMS received a comment from a dialysis provider with the suggestion to ask the patient to identify pronouns due to the requirement in some states.

Response:

CMS appreciates the comment and agrees that identifying patient pronouns is important and respectful to the patient. CMS will revise the CMS-2728.

Comment:

CMS received a comment from a dialysis provider with the suggestion to revise male and female in #9 Gender Identity to Cisgender man and Cisgender woman.

Response:

CMS appreciates the comment and agrees that revising male/female to cisgender man/cisgender woman is more aligned with the construct of gender than sex. CMS will revise the CMS-2728.

Comment:

CMS received a comment from a dialysis provider with the suggestion to add Middle Eastern North Africa as this is a recommendation for an additional category in the U.S. Census that is in the comment period.

Response:

CMS appreciates the comment and agrees adding Middle Eastern North Africa as an option to choose for #12 Race is a positive change to ensure patients can identify with the race of choice. CMS will revise the CMS-2728.

Comment:

CMS received a comment from a dialysis provider with the suggestion to add a section to collect data on sexual orientation.

Response:

CMS appreciates the comment and concern expressed by this commenter. CMS believes the collection of information about sexual orientation is unnecessary for Medicare entitlement and/or patient registration.

Comment:

CMS received a comment from a dialysis provider requesting “CMS clarify the difference between A#20(g) and B#28 as they both appear to be asking the same question”.

Response:

CMS appreciates the comment and understands there could be confusion. An option for N/A if the patient answered yes to question #20(g) will be added to question B#28.

Comment:

CMS received a comment from a dialysis provider requesting “CMS clarify how it will monitor whether the lab values were available to the facility or not”. Additionally, the dialysis provider had a concern that “If the facility uses dialysis facility admission lab values, the snapshot might show a more stable patient compared to those when the patient was hospitalized.”

Response:

CMS appreciates the comment and concern expressed by this commenter. CMS has not developed a monitoring process for the timing for laboratory values. CMS expects for the nephrologist and dialysis providers to answer the questions

appropriately as the document is signed by the nephrologist as a legal document. The person completing the CMS-2728 must identify if the laboratory values are prior laboratory values or admission laboratory values. CMS realizes that admissions might present more stable values.

Comment:

CMS received a comment from a dialysis provider requesting clarification of whether LDL or LDH should be reported for #21(g) as there was a discrepancy between the form and the crosswalk.

Response:

CMS appreciates the comment and concern expressed by this commenter. CMS acknowledges the discrepancy between the CMS-2728 and the crosswalk. The crosswalk has been changed to reflect LDL.

Comment:

CMS received a comment from a dialysis provider requesting choices for #29 be changed to “Cognitive Impairment, Patient did not receive information, Patient is not medically eligible, or Other”

Response:

CMS appreciates the comment, but disagrees. CMS finds value in differentiating the reasons a patient did not receive or did not understand transplant options. The nephrologists or dialysis facility staff should assess the patient’s acceptance and understanding of education in this case transplant education.

Comment:

CMS received a comment from a dialysis provider requesting to add the ability to indicate if a patient has engaged in advanced care planning.

Response:

CMS appreciates the comment, and agrees adding a section for advanced care planning is warranted. CMS will revise the CMS-2728.

Comment:

CMS received a comment from a physician profession organization requesting the primary cause of renal disease be revised.

Response:

CMS appreciates the comment and concern expressed by this commenter. While the commenter indicates there are opportunities to improve the list of IDC-10 codes, it was not an exhaustive list and did not provide IDC-10 codes for consideration of addition or removal.

Comment:

CMS received a comment from a physician profession organization requesting the addition of several laboratory values and maintaining the requirement to use laboratory values prior to the start of dialysis.

Response:

CMS appreciates the comment and concern expressed by this commenter. CMS agrees that cystatin C should be added to the list of laboratory values collected and will revise the CMS-2728. CMS understands the concern with the timing of the collection of the laboratory values. CMS heard concerns from dialysis providers that obtaining laboratory values from other providers is difficult and burdensome. However, CMS will change the period of time that must be observed prior to using admission laboratory values.

Comment:

CMS received a comment from a physician profession organization regarding the form functionality each of which will be answered separately. The first concern related to the instructions not providing a mechanism to enter a patient without a social security numbers or a Medicare Beneficiary Identifier.

Response:

CMS appreciates the comment and concern expressed by this commenter. The instructions on the CMS-2728 are for the completion of the form. The form entry is explained in the directions for data entry in the EQRS system.

Comment:

CMS received a comment from a physician profession organization regarding a concern related to question #20(d) not distinguishing the access used on the first outpatient

dialysis is for chronic dialysis. Additionally, the organization has concern about the use of the word “maturing” to describe a graft or a peritoneal catheter in question #20(d).

Response:

CMS appreciates the comment and concern expressed by this commenter. The CMS-2728 is only completed for chronic ESRD patients. Patients receiving dialysis for an acute treatment are not eligible to apply for the ESRD Medicare benefit. CMS notes the concern with the word “maturing” and will remove it from reference to graft and peritoneal catheter.

Comment:

CMS received a comment from a physician profession organization regarding the “use of hemodialysis hours (minutes) per session is not a helpful field as the answer will change frequently over the first month, especially for outpatient starts.”

Response:

CMS appreciates the comment and concern expressed by this commenter but disagrees with the commenter. CMS disagrees with the commenter about documenting the number of sessions and/or minutes a patient dialyzes in the initial phase of treatment. While CMS understands that incremental dialysis occurs, CMS has concerns regarding the high mortality rate for dialysis patients in the first ninety (90) days of treatment.

Comment:

CMS received a comment from a physician profession organization regarding “the concept of a physician writing a prescription in the inpatient setting for a “regular course of dialysis” is unlikely”

Response:

CMS appreciates the comment and concern expressed by this commenter. The term “regular course of dialysis” is used to differentiate dialysis used for an acute treatment from chronic dialysis that a patient with ESRD experiences. It is used to establish the date of first dialysis treatment as an ESRD patient. The prescription from the inpatient admission is not used to complete the CMS-2728.

Comment:

CMS received a comment from a physician profession organization regarding a concern that CMS-2728 “currently requires an original signature by all parties.” Additionally, the commenter requests to “consider a valid electronic signature as meeting criteria for 2728 form needs.”

Response:

CMS appreciates the comment and concern expressed by this commenter. CMS has made allowances for an electronic signature. Please see #52 in the instructions.

Comment:

CMS received a comment from a physician profession organization regarding a concern that CMS-2728 “has many areas that are not applicable or misleading for home dialysis patients.” Additionally, the commenter requests, “expertise in home dialysis review this form to ensure ease of use for patients receiving both in-center and home dialysis.”

Response:

CMS appreciates the comment and concern expressed by this commenter. CMS collaborated with nephrologists in the development of the CMS-2728. The purpose of the comment period was for anyone with concerns to share those. CMS will seek input from more nephrologist with experience in home dialysis for future revisions.

Comment:

CMS received a comment from a physician profession organization regarding a suggestion for the CMS-2728 to add a line for acute dialysis initiation date in an outpatient setting.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 form would only be completed for patients with ESRD. If a patient does not recover from an acute disease state requiring dialysis leading to chronic treatment, then the start date on the CMS-2728 would be the date the “regular course of dialysis” started or the acute treatment start date.

Comment:

CMS received a comment from a physician profession organization concurring “with CMS’ observation that the current phrasing of the question on the 2728 form inquiring whether a patient has been provided with information regarding kidney transplant, is not

sufficient to reflect true patient understanding or capture enough data to provide sufficient insights about the information provided.”

Response:

CMS thanks the commenter and agrees that collaboration with the provider community is an important step forward in educating and ensuring patient understand options regarding kidney transplant.

Comment:

CMS received a comment from a physician profession organization regarding the lack of data collection for the kidney transplant referral process and steps prior to initiating medical evaluation for kidney transplant.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 form does ask if the referral has been made and a date for the referral in question #30.

Comment:

CMS received a comment from a physician profession organization urging CMS to “ensure appropriate demographic information is collected to enable the agency and the research community to identify, understand, and maximize equitable access to kidney transplantation for all patients.”

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS will review possible additions to the CMS-2728 and other data collection systems for the inclusion of additional demographic information.

Comment:

CMS received a comment from a physician profession organization supporting the addition of question #20(g).

Response:

CMS appreciates the comment and thanks the commenter for supporting the addition of questions #20(g)

Comment:

CMS received a comment from a physician profession organization requesting a change to questions #28 to add “now” to the end of the sentence.

Response:

CMS appreciates the comment and thanks the commenter for suggesting the revision. The CMS-2728 will be revised to add “at the time of admission” to question #28.

Comment:

CMS received a comment from a physician profession organization providing support for the instructions related to “the new draft 2728 form directs dialysis facilities to revisit transplant options with a patient who is not considered informed about transplant at the time the 2728 form is originally completed and integrate them into the care plan.”

Response:

CMS appreciates the comment and thanks the commenter for supporting ongoing education of patients regarding kidney transplant options.

Comment:

CMS received a comment from a physician profession organization recommending the use of shared decision-making tools.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. However, recommending decision-making tools is outside the scope of the CMS-2728.

Comment:

CMS received a comment from a physician profession organization recommending revisions to question #29 clarifying that the patient was not assessed for transplant at the time of admission and that there are absolute contraindications to transplant.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 was modified to reflect the suggestions.

Comment:

CMS received a comment from a physician profession organization recommending the name of the transplant center the patient was referred to is added to question #30.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 was modified to reflect the suggestion.

Comment:

CMS received a comment from a physician profession organization recommending a clear definition of a referral is provided in the CMS-2728.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 instructions at #30 are clear that the patient should be connected to the transplant center. This would require a response from the transplant center acknowledging the connection.

Comment:

CMS received a comment from a physician profession organization recommending a change to question #38 to ask for the kind of transplant instead of the type of donor and to include choices for multi-organ and swap.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 has been revised to ask for the type of transplant rather than the type of donor, as well, as the addition of multi-organ and paired kidney exchange as options.

Comment:

CMS received a comment from a physician profession organization requesting the submission of the CMS-2728 when a transplant fails within three (3) years of the transplant to collect data about patients that lose their transplant early and those that are lost to follow-up by transplant centers.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 is an entitlement and/or registration form for Medicare benefits. Transplant patient have Medicare benefits for three (3) post-transplants. Patients that lose their transplant early are still recorded in EQRS as ESRD patients so no

data is lost. CMS does not see the CMS-2728 as a viable mechanism to identify patients lost to follow by transplant centers.

Comment:

CMS received a comment from a physician profession organization requesting the addition of a question, “Did the patient need dialysis post-transplant?”

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The question suggested is not within the scope of the CMS-2728; however, that data is already collected in EQRS if the dialysis was outpatient.

Comment:

CMS received a comment from a physician profession organization requesting a follow-up question to “Did the patient need dialysis post-transplant?” The question is “If yes, how many days passed from the time of transplant to the time of the first dialysis session?”

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The question suggested is not within the scope of the CMS-2728; however, that data could be calculated from the data in EQRS if the dialysis was outpatient.

Comment:

CMS received a comment from a physician profession organization requesting a follow-up question to “Did the patient need dialysis post-transplant?” The question is “If possible, collect information regarding the number of days of dialysis dependence.”

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The question suggested is not within the scope of the CMS-2728; however, that data could be calculated from the data in EQRS if the dialysis was outpatient.

Comment:

CMS received a comment from a physician profession organization requesting changes to the CMS-2728 for patients that have pre-emptive kidney transplants.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The commenter did not make any specific suggests regarding changes that could customize the CMS-2728 to pre-emptive transplant patients. CMS will consider this for future revisions.

Comment:

CMS received a comment from a physician profession organization requesting to develop a “interoperable centralized health information exchange that is accessible along entire transplant continuum (from nephrologists, CKD clinics, and dialysis providers through OPOs and transplant centers), using APIs”.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. This suggestion is outside the scope of the CMS-2728.

Comment:

CMS received a comment from a school of medicine requesting pre-transplant data be collected by the organ procurement organizations.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. This is outside the scope of the CMS-2728. However, a transplant center role was established in EQRS to facilitate the exchange of data between dialysis facilities and transplant centers.

Comment:

CMS received a comment from a school of medicine requesting social determinants of health (SDOH) data be collected to increase transparency and standardization transplant education.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. However, the commenter was not specific in the data that would be beneficial to collect.

Comment:

CMS received a comment from a patient advocacy group requesting question #20(g) be revised to specifically ask if the patient was educated about living donation as a transplant option.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 was revised to add a question about education about a living donor transplant.

Comment:

CMS received a comment from a patient advocacy group requesting question #28 be revised to “Does the patient understand their options right now”.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 was revised to be more specific about the patient’s understanding of transplant options at the time of admission.

Comment:

CMS received a comment from a patient advocacy group recommending the addition of a question, “If yes, was the patient placed on the kidney transplant waitlist before beginning dialysis?”

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. However, the United Network for Organ Sharing (UNOS) collects information about the status of patients on the kidney transplant waitlist. An addition of this question would be duplicative. UNOS data is merged with EQRS data. CMS is working with dialysis facilities to make this information available to improve communication between dialysis facilities and transplant centers.

Comment:

CMS received a comment from a patient advocacy group recommending a clear definition of a referral is provided in the CMS-2728.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 instructions at #30 are clear that the patient should be connected to the transplant center. This would require a response from the transplant center acknowledging the connection.

Comment:

Comment:

CMS received a comment from a patient advocacy group supporting the addition of question #20(f) to the CMS-2728.

Response:

CMS appreciates the comment and thanks the commenter for supporting ongoing education of patients regarding kidney home dialysis options.

Comment:

CMS received a comment from a patient advocacy group recommending the addition of a question similar to question #29, “asking why a patient declined home dialysis modalities with the same follow-up questions.”

Response:

CMS appreciates the comment and thanks the commenter for the recommendation to add a question similar to question #29 to determine the reasons a patient was not informed about home dialysis or does not understand the education provided. The CMS-2728 was revised to include a similar question.

Comment:

CMS received a comment from a patient advocacy group recommending the addition of questions related to SDOH. Each suggestion will be addressed separately. The first suggestion for an additional question is “are you currently concerned about where you will live over the next 90 days”.

Response:

CMS appreciates the comment and thanks the commenter for the recommendation to add a question related to housing insecurity. The CMS-2728 was revised to include a question regarding housing insecurity.

Comment:

CMS received a comment from a patient advocacy group recommends the addition of questions related to caregiving “do you have caregiver support to assist with home dialysis/kidney transplant” with a follow-up question to determine if the caregiver lives with the patient.

Response:

CMS appreciates the comment and thanks the commenter for the recommendation to add a question related to caregiving relationships for the ESRD community. The CMS-2728 was revised to include a question regarding caregivers.

Comment:

CMS received a comment from a patient advocacy group recommending the addition of questions related a patient’s immigration status. Additionally, the commenter recommends instructions on completing the CMS-2728 without a social security number and/or Medicare Beneficiary Identifier.

Response:

CMS appreciates the comment and concern expressed by this commenter. There is a mechanism to report citizenship status in EQRS. There have been concerns among the patient population regarding citizenship status. CMS believes this is sufficient and will not add a question regarding immigration status to the CMS-2728. Additionally, the instructions on the CMS-2728 are for the completion of the form. The form entry is explained in directions for data entry in the EQRS system.

Comment:

CMS received a comment from a patient advocacy group recommending the addition of questions related to transportation “do you have access to reliable transportation”.

Response:

CMS appreciates the comment and thanks the commenter for the recommendation to add a question related to transportation in the ESRD community. The CMS-2728 was revised to include a question regarding transportation.

Comment:

CMS received a comment from a patient advocacy group recommending the addition of questions related to language skills “do you understand health literature in English” and “would you like to receive translation services.”.

Response:

CMS appreciates the comment and thanks the commenter for the recommendation to add a question related to language skills in the ESRD community. The CMS-2728 was revised to include questions regarding health literacy.

Comment:

CMS received a comment from a patient advocacy group recommending the removal of “decline to answer” for race and gender questions.

Response:

CMS appreciates the comment and thanks the commenter for the recommendation to remove “decline to answer” from the race and gender questions in the CMS-2728. The CMS-2728 was revised to remove “decline to answer” from the race and gender questions.

Comment:

CMS received a comment from a patient advocacy group recommending dialysis facility staff and nephrologist engage patients as much as possible in completing the CMS-2728 form.

Response:

CMS appreciates the comment and thanks the commenter for the recommendation to encourage dialysis facilities and nephrologist to involve the patient in the completion of the CMS-2728 form. CMS supports this recommendation. There is language in the instructions of the CMS-2728 to support this.

Comment:

CMS received a comment from a dialysis provider recommending CMS allow a two (2) year buffer to allow providers to update internal systems to align with the CMS-2728.

Response:

CMS appreciates the comment and thanks the commenter for the recommendation to wait two (2) years to utilize the revised CMS-2728 form. CMS disagrees with this recommendation. The CMS-2728 is updated every three (3) years to wait two (2) years would seriously impact the value to the revisions in the CMS-2728. There is always the option for dialysis facilities to enter data through the single user interface after the questions have been answered by the patient along with other data collection if the provider cannot update their internal reporting systems.

Comment:

CMS received a comment from a dialysis provider recommending the use of USCDI gender standards in CMS-2728 as they are closely aligned with minor differences at present.

Response:

CMS appreciates the comment and thanks the commenter for the recommendation to align gender reporting to the USCDI standards. CMS appreciated the need for alignment of nomenclature and systems. CMS has made modifications to the gender identify field based on recommendations to align with the ESRD community.

Comment:

CMS received a comment from a dialysis provider recommending the additions of comorbidities to align with the Kidney Care Choices (KCC) model.

Response:

CMS appreciates the comment and thanks the commenter for the recommendation to add comorbidities to the CMS-2728. CMS will revise the CMS-2728 to add the comorbidities Protein Calorie Malnutrition, Morbid Obesity, Endocrine Metabolic Disorders, Intestinal Obstruction/Perforation, Chronic Pancreatitis, Inflammatory Bowel Disease, Bone/Joint/Muscle Infections/Necrosis, Dementia, Major Depressive Disorder, Myasthenia Gravis, Guillain-Barre Syndrome and Inflammatory Neuropathy, Parkinson's Disease, Huntington's Disease, Seizure Disorders and Convulsions, Interstitial lung disease, Partial- thickness Dermis Wounds, Complications of specified implanted device or graft, Artificial Openings for feeding or Elimination.

Comment:

CMS received a comment from a dialysis provider requesting clarification of comorbidities x through ii and if the options are only for Pediatric patients or can they be selected for all patients.

Response:

CMS appreciates the comment and thanks the commenter for the recommendation to clarify the comorbidity section of the CMS-2728. Yes, the comorbidities under the heading "Consider for Pediatric Patients" are only for pediatric patients. The instructions of the CMS-2728 will be changed to reflect this.

Comment:

CMS received a comment from a dialysis provider supporting the addition of question #20(d) to the CMS-2728.

Response:

CMS appreciates the comment and thanks the commenter for supporting ongoing education of patients regarding kidney home dialysis options.

Comment:

CMS received a comment from a dialysis provider expressing concern “that Fields 20(f) and 20(g) include subjective questions that absent a standard for assessing patient understanding the data collected will not be consistent across providers and organizations.”

Response:

CMS appreciates comment and concern expressed by this commenter but disagrees with the commenter. CMS expects physicians to explain treatment options to patients so the patient can understand and make informed decisions regarding their care. CMS supports patient empowerment to choose their dialysis treatment modality, to that end, the patient must understand all treatment options.

Comment:

CMS received a comment from a dialysis provider requesting a revision to the instructions, “Checking YES may terminate private/employer group health insurance”.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. CMS will revise the instructions to add “Additionally, if the patient has private insurance being dialysis starts the 30-month coordination of benefits period. If the patient doesn’t accept Medicare Part B during the 30-month window, they may lose the ability to apply until the General Enrollment Period (GEP) and will likely face gaps in coverage and a late enrollment penalty”.

Comment:

CMS received a comment from a dialysis provider requesting a revision to the instructions, “break out the instructions in field 20 to align with the individual questions (a through g) presented in the field 20 form section. As we noted above in our suggested form changes we recommend removing the word “understood” from the instructions as well.”. Additionally, there was concern about the question mark at the end of #20(g) and the placement of the “Note” for #21.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. CMS will revise the instructions to break out the individual questions a-g in #20; however, the wording about understanding education for transplant and home modalities will remain unchanged. The question mark at the end of #20 (g) was changed to a period and the “Note” for question #21 will remain where it is to provide context to the instructions.

Comment:

CMS received a comment from a dialysis provider requesting “clear guidance in the instructions section on what vascular access to select in field 20(d) in the following situations: 1. A patient begins with one type of access at the start of their first treatment, and then needs to switch to a second type of access during the same first treatment. 2. A patient with a concurrent AVF and CVC types of access used in first outpatient dialysis.”

Response:

CMS appreciates the comment and thanks the commenter for the opportunity. CMS believes the guidance for both questions are clear. If “A patient begins with one type of access at the start of their first treatment, and then needs to switch to a second type of access during the same first treatment.” The person completing the form would select the access that was used the longest for the first treatment or “for the majority of the treatment”. If “A patient with a concurrent AVF and CVC types of access used in first outpatient dialysis.” The person completing the form would select, “Was one lumen of the Central Venous Catheter used and one need placed in an AVF or graft?”

Comment:

CMS received a comment from a dialysis provider requesting the addition of a space after (CCN) in the instructions to #23.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 was modified to add a space after (CCN) in the instructions for #23.

Comment:

CMS received a comment from a dialysis provider suggesting #24 instructions be revised, “update ‘item 40’ instead of ‘item 39’ in the note portion of the instruction text.”

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 will be updated to the appropriate number after all the revisions have been completed.

Comment:

CMS received a comment from a dialysis provider expressing concern about the instructions for #28 “by the addition of “and understands” to this section. This is a dramatic shift from what this question previously expected and creates additional burdens on providers and organizations filling out this form. As we raised in a previous section assessing a patient’s understanding is subjective and absent a standardized way to assess patient understanding we recommend the 2728 form ask only if education has been delivered to the patient. Moving forward with this change will create significant inconsistencies across providers and organizations.”

Response:

CMS appreciates comment and concern expressed by this commenter but disagrees with the commenter. CMS expects physicians to explain treatment options to patients so the patient can understand and make informed decisions regarding their care. CMS supports patient empowerment to choose their dialysis treatment modality, to that end, the patient must understand all treatment options.

Comment:

CMS received a comment from a dialysis provider requesting the addition of a space after (CCN) in the instructions to #33.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 was modified to add a space after (CCN) in the instructions for #33.

Comment:

CMS received a comment from a dialysis provider suggesting #48 instructions be revised, to update item 47 to item 48 in the note portion of the instruction text.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 will be updated to the appropriate number after all the revisions have been completed.

Comment:

CMS received a comment from a dialysis provider suggesting #51 instructions be revised, to update item 48 to item 49 in the note portion of the instruction text.

Response:

CMS appreciates the comment and thanks the commenter for the suggestion. The CMS-2728 will be updated to the appropriate number after all the revisions have been completed.

Comment:

CMS received a comment from a dialysis provider asking for clarification, “y if the “blue ink” expectation is from CMS or the Social Security Administration (SSA).”

Response:

CMS appreciates the comment and thanks the commenter for requesting clarification. The SSA Program Operations Manual System (POMS) provides the guidance to use blue ink when signing the CMS-2728.

Comment:

CMS received a comment from a dialysis provider noting, “that formatting is inconsistent throughout sections and needs to be adjusted for readability”.

Response:

CMS appreciates the comment and thanks the commenter. CMS will review; however, 508 compliance must take precedence.

Comment:

CMS received a comment from a group of nephrologists from a medical school requesting to add the ability to indicate if a patient has engaged in advanced care planning.

Response:

CMS appreciates the comment, and agrees adding a section for advanced care planning is warranted. CMS will revise the CMS-2728.

