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Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Submitted via regulations.gov

RE: [CMS-2728] Agency Information Collection Activities: Proposed Collection; Comment Request

DaVita appreciates the opportunity to comment on changes to the CMS-2728 form. We believe providers and organizations will positively benefit from clearer response options and improved instructions on filling out the form. As CMS notes the data reported on the CMS-2728 is used by the Federal Government, ESRD Networks, treatment facilities, researchers, and others to monitor and assess the quality and type of care provided to end-stage renal disease beneficiaries. Therefore, any changes to the form have a significant impact. It is imperative that any changes to CMS-2728 are appropriate, clear, and operable so that the data collection captures accurate and appropriate medical information needed to determine the Medicare medical eligibility of people with ESRD.

CMS has revised the CMS-2728 form by adding questions, clarifying questions, updating reasons for kidney failure, updating co-morbidities to be more reflective of pediatric patients, and providing additional guidance and clarity in the instructions. While we appreciate the updates to this important form we have several clarifying questions and suggestions. Please find our feedback in the subsequent sections of this letter.

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Timeline

We appreciate CMS making updates and refinements to this essential form. Given the importance of accuracy in regard to the 2728 form it is imperative that our internal systems can be updated to reflect demographic changes aligned to the reporting sections of the 2728 form. Given the interconnectedness of platforms and the change management required for implementation, we recommend at least a two-year buffer time from finalized form to the required collection start date.

Data Collection Standards

DaVita continues to advocate for CMS to use national standards so that data collection works for a variety of data systems. We believe this standardization is particularly important in regard to both Gender Identity and Comorbid Conditions.

Gender Identity.

We encourage CMS to use the Gender Identity USCDI Core data options. We also note that the CDC is considering implementing a Gender Identity question and the CDC intends to use the Gender Identity USCDI Core data options. While most of the CMS options can be mapped 1:1 there are slight differences in verbiage (e.g. CMS option is 'Decline To Answer' but USCDI is 'Asked but Unknown'). DaVita believes consistency is extremely important and suggests alignment to the USCDI gender identity standards[1][2]. We note that these categories should be able to withstand changes in accepted terminology and classification. Again, we recommend CMS clearly define and align the categories chosen so there is no room for misinterpretation.

Additionally, DaVita has found that it is important to provide implementation guidance to our internal teams when collecting potentially sensitive demographic data from our patients. It is critical that the data is accurate and patient provided. As we implement any changes to the demographic selection of the 2728 form, we will be developing updated training and resources to assist our teams in comfortably requesting demographic data from patients. We encourage and would be happy to assist CMS in creating resources to support the standard implementation of this data collection once final.

Comorbid options.

We are concerned that comorbid conditions are not inclusive of all options that are part of standard comprehensive health evaluations (CHE) required in other portions of the kidney care industry. Including those health evaluations used in the Kidney Care Choices (KCC) model. Given the patient populations are the same, consistency in comorbid data capture would be beneficial and options should be aligned across CMS-required activities. For example, the following ICD-10 codes meet HCC co-morbidities but it is unclear where these would be placed appropriately on the 2728 form.

- HCC 21: Protein Calorie Malnutrition
- HCC 22: Morbid Obesity
- HCC 23: Endocrine Metabolic Disorders
- HCC 33: Intestinal Obstruction/Perforation
- HCC 34: Chronic Pancreatitis
- HCC 35: inflammatory Bowel Disease
- HCC 39: Bone/Joint/Muscle Infections/Necrosis (under amputations?)
- HCC 51 & 52: Dementia
- HCC 59: Major Depressive Disorder
- HCC 75: Myasthenia Gravis, Guillain-Barre Syndrome and Inflammatory Neuropathy
- HCC 78: Parkinson's & Huntington's Disease
- HCC 79: Seizure Disorders and Convulsions

[1] https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1114.17/expansion
[2] https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1114.17/expansion

- HCC 112: Interstitial lung disease
- HCC 159: Partial- thickness Dermis Wounds
- HCC 176: Complications of specified implanted device or graft
- HCC 188: Artificial Openings for feeding or Elimination

Recommended Form updates:

We appreciate CMS' consideration of several suggested technical changes to the 2728 form below.

Field 19.

We ask that CMS clarify if options x through ii are only for Pediatric patients or if these options can be selected for all patients. We note that the current format makes it seem as if those options are only for pediatric patients.

Field 20(d).

This field addresses what access was used on the first outpatient dialysis, CMS had added a new peritoneal dialysis (PD) catheter option which is beneficial to those filling out the form. We believe this addition creates clarity and likely eliminates room for error in documentation. DaVita appreciates CMS including this addition.

Fields 20(f) and 20(g).

We are concerned 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. We suggest limiting these questions to only indicating that the patient did receive education rather than including the patient's understanding of that education.

Current:

- *f. Does the patient indicate they received and understood options for a home dialysis modality?*
- *g. Does the patient indicate they received and understood options for a kidney transplant?*

Suggested Changes:

- *f. Does the patient indicate they received options for a home dialysis modality?*
- *g. Does the patient indicate they received options for a kidney transplant?*

Recommended Instructions Updates:

We appreciate CMS' consideration of several suggested technical changes to the instruction section of the 2728 form below.

Field 13.

We suggest amending the instructions note to include "Checking Yes may terminate private/employer group health insurance".

Current:

- *Check the appropriate yes or no block to indicate if patient is applying for ESRD Medicare.* ***Note: Even though a person may already be entitled to general Medicare coverage, he/she should reapply for ESRD Medicare coverage.***

Suggested Changes:

- *Check the appropriate yes or no block to indicate if patient is applying for ESRD Medicare.* ***Note: Even though a person may already be entitled to general Medicare coverage, he/she should reapply for ESRD Medicare coverage. Checking YES may terminate private/employer group health insurance.***

Field 20.

First, we ask that CMS 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.

Current:

- *20. Prior to ESRD therapy, check the appropriate box to indicate whether the patient received Exogenous erythropoietin (EPO) or equivalent, was under the routine care of a nephrologist and/or was under the routine care of a kidney dietitian. Provide vascular access information as to the type of access used for the majority of the treatment (Arterio-Venous Fistula (AVF), graft, peritoneal dialysis (PD) catheter, or Central Venous Catheter (including port device) or other type of access) when the patient first received outpatient dialysis. If an AVF access was not used, was a maturing AVF or graft present? Was one lumen of the Central Venous Catheter used and one need placed in a maturing AVF or graft? Indicate if the patient experienced acute renal failure (the sudden inability for the kidney to filter waste products which may resolve or evolve to ESRD) and if dialysis was required. Indicate the patient received and understood options for a home dialysis modality. Indicate if the patient received and understood options for a kidney transplant?*

Suggested Changes:

- *20. Prior to ESRD therapy, check the appropriate box to indicate whether the patient:*
  (a) Received exogenous erythropoietin (EPO) or equivalent
  (b) Was under the routine care of a nephrologist and
  (c) Was under the routine care of a kidney dietitian.

(d) Provide vascular access information as to the type of access used for the majority of the treatment (Arterio-Venous Fistula (AVF), graft, peritoneal dialysis (PD) catheter, or Central Venous Catheter (including port device) or other type of access) when the patient first received outpatient dialysis. If an AVF access was not used, was a maturing AVF or graft present? Was one lumen of the Central Venous Catheter used and one need placed in a maturing AVF or graft?
(e) Indicate if the patient experienced acute renal failure (the sudden inability for the kidney to filter waste products which may resolve or evolve to ESRD) and if dialysis was required.
(f) Indicate the patient received options for a home dialysis modality.
(g) Indicate if the patient received options for a kidney transplant?

Further, we ask that CMS provide 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.*

Ensuring guidance is clear has implications outside of just the form alone. The CKCC Optimal Starts measure relies on the data that is captured on field 20(d) in the new 2728 form. We urge CMS to provide clear guidance on exactly how providers should treat the above patient scenarios. Standardization in how that particular field is filled out across providers will lead to increased data integrity and accurate capture of optimal start rates. We would be remiss if we did not point out that the last sentence for field 20 instructions should end in a period rather than a question mark.

Additionally, the note at the end of the instructions for field 20 is meant for field 21 and it is misleading for those looking for instruction specifically on field 20. We suggest that the note at the end of the instructions for field 20 be moved under field 21.

Field 23.

We suggest adding a space after (CCN).

Current:

- *Enter the 6-digit CMS Certification Number (CCN)of the dialysis facility in item 22.*

Suggested Changes:

- *Enter the 6-digit CMS Certification Number (CCN) of the dialysis facility in item 22.*

Field 24.

We suggest CMS update 'item 40' instead of 'item 39' in the note portion of the instruction text.

Current:

- ***Note:*** *Transitional Care Unit is not included in item 24 as it is not anticipated that it will become the long-term treatment center. It is included in item 39 because it can be a current setting when a transplant rejection occurs.*

Suggested Changes:

- ***Note:*** *Transitional Care Unit is not included in item 24 as it is not anticipated that it will become the long-term treatment center. It is included in item 40 because it can be a current setting when a transplant rejection occurs.*

Field 28.

We are concerned 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.

Current:

- *Enter whether the patient has been informed of and understands their options for receiving a kidney transplant.* ***Dialysis facilities are required to inform patients of their rights to transplant and other renal replacement modality options at 42 CFR § 494.70(a)(7).*** *To be informed a patient must understand the material. The patient must be able to repeat: benefits and risk of transplant as a treatment option, the referral and evaluation process, and post-transplant recovery and coordination. Additionally, the patient should be able to verbalize why they did not choose transplant as a treatment option.*

Suggested Changes:

- *Enter whether the patient has been informed of their options for receiving a kidney transplant.* ***Dialysis facilities are required to inform patients of their rights to transplant and other renal replacement modality options at 42 CFR § 494.70(a)(7).***

Field 33.

We suggest adding a space after (CCN).

Current:

- *Enter the 6-digit CMS Certification Number (CCN)of the hospital in Item 32 where the patient received a kidney transplant on the date entered in Item 31.*

Suggested Changes:

- *Enter the 6-digit CMS Certification Number (CCN) of the hospital in Item 32 where the patient received a kidney transplant on the date entered in Item 31.*

Field 48.

We suggest CMS change 'Item 48' to 'Item 47'.

Current:

- *Enter the National Provider Identifier (NPI) of physician in Item 48. (See Item 51 for explanation of NPI.)*

Suggested Changes:

- *Enter the National Provider Identifier (NPI) of physician in Item 47. (See Item 51 for explanation of NPI.)*

Field 51.

We suggest CMS change 'Item 48' to 'Item 49'.

Current:

- *Enter the National Provider Identifier (NPI) of physician in Item 48. The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandate the adoption of a standard unique health identifier for each health care provider. The National Provider Identifier (NPI) final rule, published on January 23, 2004, establishes the NPI as this standard. All health care providers and entities covered under HIPAA must comply with the requirements of the NPI final rule (45 CFR Part 162, CMS- 0045-F). Effective May 23, 2008, the NPI replaced the UPIN as a unique identifier. This change request updates chapter 14, of Pub.100-08, Medicare Program Integrity Manual, by removing information related to the issuance and maintenance of UPIN and replacing this information with information about obtaining NPI and UPIN data. The NPI registry allows users to perform simple queries to retrieve read-only information from NPPES. For example, users may search by the NPI or legal business name to locate the NPPES records and search for an individuals or organizations. The NPI Registry will return the results of the query to the user, and the user will click on the record(s) he/she wants to view. https://npiregistry.cms.hhs.gov/*

Suggested Changes:

- *Enter the National Provider Identifier (NPI) of physician in Item 49. The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandate the adoption of a standard unique health identifier for each health care provider. The National Provider Identifier (NPI) final rule, published on January 23, 2004, establishes the NPI as this standard. All health care providers and entities covered under HIPAA must comply with the requirements of the NPI final rule (45*

CFR Part 162, CMS- 0045-F). Effective May 23, 2008, the NPI replaced the UPIN as a unique identifier. This change request updates chapter 14, of Pub.100-08, Medicare Program Integrity Manual, by removing information related to the issuance and maintenance of UPIN and replacing this information with information about obtaining NPI and UPIN data. The NPI registry allows users to perform simple queries to retrieve read-only information from NPPES. For example, users may search by the NPI or legal business name to locate the NPPES records and search for an individuals or organizations. The NPI Registry will return the results of the query to the user, and the user will click on the record(s) he/she wants to view. https://npiregistry.cms.hhs.gov/

Field 52.

We ask the CMS to clarify if the "blue ink" expectation is from CMS or the social security administration (SSA). The guidance "If the physician chooses to use a wet signature it should be in blue ink." is not currently on the present 2728 form and we are concerned that this instruction may inhibit SSA from processing forms that do not meet this instruction expectation. We are concerned about form rejections and ask for clear guidance from CMS.

Finally, we note that formatting is inconsistent throughout sections and needs to be adjusted for readability (e.g. Gender Identity, Prior to ESRD Therapy questions, etc.) before any form changes are finalized. As always, DaVita is grateful for CMS' commitment to soliciting feedback through the public process. We welcome the opportunity to meet with CMS on any of the technical changes we have proposed. If you have questions regarding these comments, please contact Kayla L. Amodeo, PhD, Director of Government Affairs, at kayla.amodeo@davita.com or via phone at 202-210-1797.

Sincerely,

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