Fresenius Medical Care
North America

October 4, 2010

Office of Management and Budget
Office of Information and Regulatory Affairs
ATTN: CMS Desk Officer

To Whom It May Concern:

Fresenius Medical Care North America ("FMCNA") is the largest integrated provider in the country of services and products for persons undergoing dialysis due to ESRD. FMCNA operates over 1,700 outpatient dialysis clinics and provides dialysis services to an estimated 130,000 individuals with kidney failure in the United States. We are pleased to have this opportunity to submit comments to the Office of Management and Budget on the use of the End Stage Renal Disease ("ESRD") Medical Evidence Report Medicare Entitlement and/or Patient Registration, Form Number CMS-2728. We will address the subjects included in the comment request.

(1) The necessity and utility of the form for the proper performance of the Agency's function

FMCNA supports the continued use of the Centers for Medicare and Medicaid Services' (CMS) Form CMS-2728. It has supported and informed many CMS initiatives, including, but not limited to, those related to data reporting and analytical studies performed by the United States Renal Data Systems (USRDS). It provides a national baseline source of information on individuals who begin therapy for end-stage renal disease that assists in initial care planning, projections, and prioritization of ongoing and potential issues. The data are also used in Hierarchical Care Complex (HCC) coding and risk adjustment for payment in Medicare Advantage.

(2) The accuracy of the burden CMS has estimated is involved with the use of this form

FMCNA has not evaluated the specific burden of completing Form CMS-2728 and the average time estimate of CMS may be sufficient for most instances. When complete information is available to outpatient dialysis facility personnel from hospital records and information provided by the individual's nephrologist, completing the form is not a major burden. The process requiring the most time and effort for outpatient dialysis facility personnel is related to obtaining clinical information such as laboratory test results, discharge diagnoses and/or past medical history (e.g., co-morbidity information) for individuals who initiate their first dialysis in the hospital setting, particularly hospitals that do not have Medicare certification as an ESRD provider or facility.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected

a. With regard to Quality, we recommend that:

1. CMS require provision of a mandatory discharge form for individuals who initiate their first dialysis in the hospital setting whose discharge plan requires referral for chronic outpatient dialysis therapy or, alternatively, a mandatory process for expedited release of laboratory test data and discharge diagnoses and/or medical history, including co-morbidity information, to the receiving outpatient dialysis provider/facility.

2. CMS create and provide conversion information for the list of diagnoses for primary causes of renal failure (ESRD) from ICD-9 to ICD-10, as CMS has mandated use of the latter beginning January 1, 2013 [45 CFR Part 162; CMS-0013-F; RIN 0958-AN25; Federal Register 74(11):3328-3362, 1/16/09].

3. CMS provide an accessible list of both ICD-9 and ICD-10 codes that are consistent with the comorbidity categories listed in question #17, even if they are not specifically to be provided using the ICD format.

b. With regard to Utility, we recommend:

1. The addition of a question with regard to the applicant's ability to both speak (Yes/No) and to read English (Yes/No) as this has a bearing on resource utilization in the care of the beneficiary.

2. The identification of the six chronic co-morbidity conditions that CMS has determined to be risk adjusters in the ESRD PPS system: prior diagnosis of hereditary hemolytic/sickle cell anemia, monoclonal gammopathy (without multiple myeloma), and myelodysplastic syndrome, as well as identification from the prior 90 days of the acute risk adjusters in the ESRD PPS system: bacterial pneumonia, gastrointestinal bleeding, and pericarditis.

3. The addition of a follow-up question for #17 regarding co-morbidity documentation:

i) #17.a. Congestive Heart Failure - regarding information on current left ventricular ejection fraction (LVEF), consistent with K/DOQI recommendations to obtain cardiac function studies for patients initiating dialysis. We believe this is especially useful for those with known cardiac morbidity such as CHF and is consistent with accepted principles for general medical practice.

ii) #17.m. Tobacco Use (Current Smoker) - to also document past history of tobacco use using a physician and patient agreed estimate of the number of total "pack-years" to date.

4. Modification to ancillary Question 18.d. from "If not AVF, then:" to "If catheter, then:" and, in addition to inquiring about the presence of an AVF and an AVG, include a third question if both responses were "no." That question should be: "Was the patient evaluated by a vascular surgeon?" Potential options include: Yes; No; and No–Referred with Appointment. This change supports the current drive to improve pre-ESRD and incident-ESRD care with specific reference to vascular access.

5. Addition of a new Question 18.e. to document: "Did the patient attend a kidney disease education program?" with answers: Yes, >3 months before dialysis initiation, Yes within 3

months of dialysis initiation, Referred but did not attend, No. This will help assess the national impact of attendance at formal kidney disease education program on pre-dialysis CKD care.

6. Addition of a question on home situation to indicate social support, with the following suggested options: Lives with spouse or significant other; Lives with minor dependent(s) and/or dependent other(s); and Lives alone. This information may provide information as to the relationship of home situation with choice of dialysis modality or setting.

7. Addition of serum sodium to the laboratory profile in Question #19 in order to provide a pre-dialysis baseline. Sodium can be a marker of illness and may provide information to assist in assessing prognosis or the impact of dialysate prescriptions.

8. Expansion of Question #24 to identify the setting of the first regular chronic dialysis treatment. Choices would be: Hospital Inpatient; Outpatient Facility; Other (blank line to identify). This information may provide useful resource utilization information as well as a perspective on potential association(s) with either early referral or quality of pre-ESRD CKD management, or both.

c. With regard to Clarity, additional guidance is requested on several issues.

1. Question #8 on Ethnicity – Up to how many generations can ethnicity be claimed?

2. Question #10 on Race – For individuals who are of mixed race and prefer to identify with one race over the other, especially when s/he does not necessarily reflect conventional classification stereotypes such as skin color, will the "Federal" definitions based on origin apply even if the individual objects? For example, based on the combined "Federal" definitions of Race and Ethnicity, how is it that a dark-skinned, Spanish-speaking person from the Dominican Republic is not considered black or Hispanic?

3. Question #13 on Height – Consider metric units only with CMS providing the conversion factor from inches to centimeters (e.g. 2.54 x height in inches).

5. Question #14 on Dry Weight - Consider metric units only with CMS providing the conversion factor from pounds to kilograms (e.g. 0.45 x weight in pounds).

6. Question #18 on Prior to ESRD Therapy – Consider adding an option for individuals evaluated from 3-6 months. Care becomes even more critical during that time period and it will be helpful to have a more granular picture of referral and to track outcomes of CKD care relative to time of referral.

(4) The use of automated collection techniques or other forms of information technology to minimize the information collection burden

A computerized method for the completion, authentication, and submission of the Form CMS-2728 is ideal. However, there are barriers related to each of these processes that need to be addressed.

a. Completion – acquiring all relevant data points and entering them into the electronic form to minimize manual input. The initial stage may include CMS allowing providers to have facsimile

forms populated electronically and then printed when it is completed for manual signatures. Provider's internal systems may be able to pre-populate certain fields such as patient name, social security number, etc. Multiple access to the same form can be assigned to include the patient's assigned social worker, clinical nurse manager, and physician to allow for efficient data entry. Future improvements may include use of electronic health records so HIPAA-compliant direct data downloads may be accessible from the physician's office or from the hospital systems.

b. Authentication - the process of obtaining an electronic signature from both the patient and physician needs to be evaluated. The initial stage may include an electronic signature that may be built-in to provider systems for attending physicians. However, patient signatures may still require printing out the forms. Potential improvement may include scanning patient-signed forms into the system. Future enhancements may include biometric patient signatures.

c. Submission – assuming that the authentication process has been accomplished electronically, a fully automated submission process is ideal but will be subject to availability of matching receiving computer systems for both the local Social Security and ESRD Network offices. In the early stage, an electronic HIPAA-compliant data download that may include a physician's electronic signature can be performed by providers to either one or both the local Social Security and ESRD Network Systems. It may initially involve having to send a printed copy with the patient's signature to either entity that can then be used to verify the patient-signed form and electronically approve the pre-transmitted data. Future enhancements will require a seamless electronic data transfer without the need for sending a manual form.

Again, we appreciate the opportunity to comment on the use of this important form. If you have any questions or wish to discuss our comments further, please contact me at 202-393-7713.

Sincerely,

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