Supporting Statement: End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration (CMS-2728; OMB Control number: 0938-0046)

A. Background

This request is to revise the previously approved collection of the CMS-2728.

The End Stage Renal Disease (ESRD) Medical Evidence (CMS-2728) is completed for all ESRD patients either by the first treatment facility or by a Medicare-approved ESRD facility when it is determined by a physician that the patient's condition has reached that stage of renal impairment that a regular course of kidney dialysis or a kidney transplant is necessary to maintain life.

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.

The data collection captures the specific medical information required to determine the Medicare medical eligibility of End Stage Renal Disease claimants. It also collects data for research and policy on this population.

The three main data systems available for evaluating the ESRD program and for monitoring epidemiology, access, and quality and reimbursement effects on quality are: (1) The United States Renal Data System (USRDS) provides basic data on patterns of incidence of ESRD in the United States. The USRDS database is intended to be used for biomedical research by investigators throughout the United States and abroad. The USRDS data is intended to supplement (and not replace) public use files produced by CMS. (2) United Network for Organ Sharing (UNOS) focus is on organ donation, transplantation and educational activities. (3) The ESRD Program Management and Medical System (PMMIS), maintained by CMS, provide the foundation data for the USRDS. This system, as required by Public Law 95-292, section C(1) (A), is designed to serve the needs of the Department of Health and Human Services in support of program analysis, policy development, and epidemiological research.

The ESRD PMMIS includes information on both Medicare and non-Medicare ESRD patients and on Medicare approved ESRD hospitals and dialysis facilities. The methods of ESRD data collection (e.g., use of same forms, sharing of analysis) by CMS, UNOS, and USRDS have all agreed on a common data collection process that will provide needed additional information on the ESRD population.

Due to response by the provider community the CMS-2728 for has been revised by adding questions, clarifying questions, updating sex, gender, and race questions, updating reasons for kidney failure, updating comorbidities to be more reflective of adults and pediatric patients, adding questions related to social determinants of health and providing additional

guidance and clarity in the instructions.

B. Justification

1. Need and Legal Basis

Section 226A (2) of the Social Security Act specifically states that a person must be "medically determined to have end stage renal disease…." Similarly Section 188(a) of the law states "The benefits provided by parts A and B of this title shall include benefits for individuals who have been determined to have end stage renal disease as provided in Section 226A.

In addition, the ESRD Program Management and Medical Information System has the responsibility of collecting, maintaining and disseminating, on a national basis, uniform data pertaining to ESRD patients and their treatment of care. All renal facilities approved to participate in the ESRD program are required by P.L. 95-292 to supply data to this system. Also, the conditions of coverage for participating in the Medicare program (42 CFR 405.2133) st ate:

> "ESRD facility, laboratory performing histocompatibility testing, and organ procurement agency furnished data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not disclosed except as authorized by Department regulations on confidentiality and disclosure (42 CFR Part 5, 5b, and 20 CFR Parts 401 and 422 (Subpart E))."

In accordance with section 226A of the law, the primary purpose of this form is to have a patient medically determined, by a physician, to have end stage renal disease for purposes of filing for Medicare benefits. In addition, this form registers a patient with the United States Renal Data System (USRDS) which was mandated by 42 U.S.C. 241a, 289c, as last amended by P.L. 100-607, November 4, 1988 under the Health Omnibus Programs Extension of 1988, for research purposes.

2. Information Users

The data are provided to the United States Renal Data System (USRDS), through a contract with the National Institutes of Health, for use in studies relating to the ESRD program. Collection of the data are necessary for regular assessment and evaluation by concerned entities in the ESRD community at local, regional, and national levels of the financial, medical and social impact of ESRD care. The data are also used for the general administrative and data support required for successful implementation of various aspects of Sections 266A, 299I, and 1881 of P.L. 95-292.

Collection of these data are also necessary for entitlement of ESRD patients to Medicare benefits and also for the establishment and maintenance of a single, nationwide kidney disease registry for dialysis, transplant, and prospective transplant patients, and will store pertinent medical facts on each registrant.

In addition, the data are used for periodic generation of reports on various aspects of medical care and practice and other related statistics. The data will enable individual practitioners and facilities to review, compare, and improve ESRD patient treatment methods, which will permit local Medical Review Boards to more effectively monitor utilization and quality of medical care.

The data is used by the Centers for Medicare & Medicaid Services to monitor and assess the quality and type of care provided to renal patients.

3. Use of Information Technology

The current ESRD information management system is the ESRD Quality Reporting System (EQRS), which focuses on improved business processes within the ESRD program. EQRS launched on November 8, 2020 and combines the Consolidated Renal Operations Web-Enabled Network (CROWNWeb) system and the Renal Management Information System (REMIS).

EQRS brings together all of CMS' information systems that collect, maintain, and report on data about ESRD patients and provides electronic reporting tools for use by dialysis providers.

EQRS allows dialysis facilities to enter data via the Web and the ESRD forms, including the CMS-2728, are generated from within EQRS. The reporting of data directly from the dialysis providers via EQRS was mandated through the Conditions of Coverage for End-Stage Renal Disease Facilities; Final Rule. The Conditions for Coverage Final Rule was published on April 15, 2008 which mandated that all providers report data to CMS electronically.

CMS integrated REMIS into EQRS as the system to determine and communicate Medicare coverage periods for ESRD patients which allows EQRS to store and access information in the ESRD Program Management and Medical Information System Database. EQRS is also used by CMS and the renal community to monitor the Medicare status, transplant activities, dialysis activities, and Medicare utilization of ESRD patients and their Medicare providers.

4. Duplication of Efforts

The CMS-2728 is the only form completed by a physician to provide the medical information needed to determine a claimant's entitlement to ESRD Medicare. The evidence is not supplied by a physician anywhere else.

5. Small Businesses

Completion of CMS-2728 should not greatly impact the functioning of small businesses. The

CMS–2728 is the only form completed by all physicians to provide the medical information needed to determine a claimant's entitlement to ESRD Medicare.

6. Le ss Frequent Collection

This form is completed initially when a patient is determined to have end stage renal disease. It is also completed for purposes of re-entry into the Medicare program if a person's benefits have been terminated 36 months post-transplant or 12 months post stopping dialysis treatment in accordance with Section 226 A of P.L. 92-603.

If these data were not collected or less frequently, CMS would have no medical determination of ESRD as required by law. We would be unable to identify characteristics of the relationships between patients and treatment. Additionally, we would not be able to identify between the disease and comorbid conditions, and between the disease and death for this population.

7. Special Circumstances

The frequency of the collection (initially when a patient is determined to have end stage renal disease and for re-entry into the Medicare program if a person's benefits have been terminated 36 months post- transplant or 12 months post stopping dialysis treatment in accordance with Section 226 A of P.L. 92- 603), requires respondents to report information to the agency more often than quarterly.

8. Federal Register Notice /Outside Consultation

The 60-day Federal Register notice published December 16, 2022 (87 FR 76625).

There were numerous comments from the ESRD community. The comments ranged from ensuring education of patients related to treatment modalities transplant and home dialysis are understood by the patients to developing an avenue for the use of electronic signatures on the form to capturing information related to social determinants of health. There were also comments related to expanded gender options for inclusivity. There were some changes made to the form as a result of the comments. The comments were addressed in the response to comments document.

The 30-day Federal Register notice published May 30, 2023 (88 FR 34502).

9. Payment or Gift to Respondent

No payments or gifts are made to respondents.

10. Confidentiality

Confidentiality is retained in regular output reports by disclosing data in aggregate form; that is, no specific individual is identified (either individual patient or individual practitioner) and information on the individual is part of grouped items of data produced in summary outputs. Patients and physicians are not shown on output reports by name or by identification number. Normal precautions are taken to protect data and individual identities.

Procedures are established for maintaining confidentiality of individual patient records, including the requirement that non-government employees who handle the data be bonded.

The input is kept under strict controls; only certain authorized persons are allowed access. These persons are allowed access only in restricted areas and are required to identify themselves, the specific document referred to, and the reasons for access. Such data are kept under lock and key at all times, and may not be accessed except during normal working hours. Strict penalties will be applied to any employee who willfully and knowingly violates the prohibitions regarding confidential data.

The form requests patient identifying information as authorized by 42 CFR 405.2133:

> "The ESRD facility, laboratory performing histocompatibility testing, and organ procurement agency furnished data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not disclosed except as authorized by Department regulations or confidentiality and disclosure (see 45 CFR Part 5, 5b, and 20 CFR Part 401 and 422 Subpart E)." The data transmitted via EQRS are encrypted and secured."

The statement appearing on the form to obtain consent and pledge confidentiality is as follows:

> "The collection of this information is authorized by Section 226A of the Social Security Act. The information provided will be used to determine if an individual is entitled to Medicare under the End Stage Renal Disease provisions of the law. The information will be maintained in system No. 09-70-0520, "End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS)", published in the Privacy Act Issuance, 2002 Compilation, Vol. 67, No. 67, pages 41244-41250, June 17, 2002 or as updated and republished. Furnishing the information on this form is voluntary, but failure to do so may result in denial of Medicare benefits. Information from the ESRD PMMIS may be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual; an individual or organization for research, demonstration, evaluation, or epidemiological project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the Federal Register notice cited above. You should be aware that P.L. 100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches."

As required by the Privacy Act, Medicare publishes systems of records notices in the Federal Register that describe the data in each system and to whom Medicare may disclose the information. The information collected is part of a Privacy Act System of Records Notice

(SORN):

End Stage Renal Disease (ESRD) Program Management and Medical Information System (PMMIS) SORN# 09–70–0520

SORN history: 74 FR 30606 (6/26/09), *83 FR 6591 (2/14/18)

11. Sensitive Questions

There are no questions of a sensitive nature that are being required on this form.

12. Burden Estimates (2018)

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for all salary estimates. In this regard, the following table presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage for providers that are responsible for completing CMS- 2728 forms.

Table 1. Salary Estimates for Providers Completing CMS-2728 Form

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Physicians & Surgeons (All Other)	29-1210	$121.38	$121.38	$242.76

Except where noted, we have adjusted our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Table 2. Estimated Hour Burden

Respondents (Number of Open, Certified, Medical Dialysis Providers as of October 2022)	Respondents (Number of Open, Certified, Medical Dialysis Providers in 2018)	Completion Time per Response	Responses per Year (Number of CMS-2728 Forms Submitted from January 1, 2021 thru December 31, 2021)	Total Requested Burden Hours	Cost per Response	Estimated National Cost
7,828	7,311	1.25 hour	138,000	172,500	$242.76	$41,876,100 (172,500hours X $242.76)

13. Capital Cost

There are no capital costs.

14. Cost to Federal Government (2021)

Table 3. Cost to Federal Government (2021)

Social Security Administration Employee Salary Who Receives the Form	Time to Receive Form	Number of CMS-2728 Forms per Year	Total Requested Burden Hours	Cost per Response	Estimated National Cost
$52,002	.01 FTE	138,000	138,000	$12.50	$1,725,000

Forms are typically completed and printed by dialysis staff in EQRS and printed; however, forms may also be downloaded from CMS.gov. CMS no longer requests printing for additional blank triplicate CMS-2728 forms by the Government Printing office.

15. Changes to Burden

There is a change in total estimated burden hours of 69,000 (172,500 estimated hours-103,500 previously estimated hours) due to an increase in the time to complete the CMS-2728 forms by 30 minutes and a decrease in submission of CMS-2728 forms by 5,929 submissions (138,000 previously estimated submissions-132,071 submissions). Minor changes were made to the form to better align with the common verbiage used on standardized forms, by other Federal agencies, including the Census Bureau. The grammatical edits do not impact the estimations on burden within this section. Questions have been added to determine if a patient has experienced an acute kidney injury prior to the start of ESRD therapy which may impact burden by a minute. Questions were also added to determine if a patient received education about home or transplant options prior to the start of ESRD therapy which will add two minutes of burden. A question was added to confirm patients understand the information they have been provided about the option of a kidney transplant, which will add an estimated five minutes of burden. A question asking if a patient has received a referral to a transplant center and the date was added which is estimated to add an additional seven minutes of burden. Two questions were added regarding end of life care which is estimated to add three minutes of burden. Six questions were added related to health equity which is estimated to add twelve minutes of burden.

16. Publication and Tabulation Dates

Information from the CMS-2728 is entered into the ESRD Program Management and Medical Information System, which is a national system, used as a focal point for ESRD Data supplied to the ESRD Network Organizations, physicians, Health Systems Agencies, Regional Offices, Congressional Representatives, the National Institute of Health, and Private industries under the regulations on confidentiality and disclosure cited above. It is a system that provides timely administration in measuring and evaluating the care furnished those persons receiving benefits as a result of the ESRD Medicare provision. This

information provides the basis for the United States Renal Data System (USRDS) established in 1986 and operated by a coordinating center.

The report to be made from the data collected is the USRDS Annual Report. The Annual Data Report is divided into two volumes covering *Chronic Kidney Disease in the United States* and *End-Stage Renal Disease in the United States*. The ADR displays analytical results of USRDS data using graphs and maps.

17. Expiration Date

CMS will display the expiration date on the bottom left corner of the CMS-2728.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

This information collection does not employ the use of statistical methods.