

**SUPPORTING STATEMENT FOR
ESRD BENEFICIARY SELECTION AND
SUPPORTING REGULATIONS CONTAINED IN
42 CFR 414.330, CMS-382**

A. Background

We are requesting a retention of the ESRD Beneficiary Selection form, CMS-382. This form is approved under OMB number 0938-0372. (Attachment included)

Centers for Medicare and Medicaid Services (CMS) regulations provide two (2) ways that a Medicare beneficiary dialyzing at home can choose to have the Medicare program pay for his/her dialysis care (exclusive of physician services.) The purpose of the Beneficiary Selection form is for a beneficiary to select the method that best suits his/her requirements.

After the Medicare beneficiary's selection has been made, the ESRD facility forwards the form to their Medicare Part A Intermediary. The intermediary receives, keys, and processes the form as part of the Common Working File (CWF). The CWF passes the data to the Health Insurance (HI) System within 24 hours.

B. Justification

1. Need and Legal Basis

Section 2145 of P.L. 97-35 amended section 1881 of the Social Security Act and changes the way the Medicare program pays for home dialysis services. When the law was enacted, facilities were required to have all Medicare home dialysis patients choose one of two payment methods. Medicare patients who currently dialysis in a facility but later become home dialysis patients must complete the form at the time they go to the home setting. (Patients who dialyze in a facility do not complete the form.) The two methods a Medicare beneficiary **dialyzing at home** can choose to have the Medicare program pay for his/her dialysis care (exclusive of physician services) are as follows:

METHOD I

The dialysis facility assumes responsibility for patient care. The facility provides all dialysis equipment and supplies needed to dialyze at home. It is required to order, store, deliver, and pay the manufacturers and suppliers for these items. The facility is further

required to furnish home support services to assist with any problems. The beneficiary's only financial responsibility, after the deductible has been met, is Medicare's 20 percent coinsurance requirement. All home dialysis treatments billed under Method I are reimbursed by the intermediary under the composite rate payment system. The composite rate payment is updated periodically by CMS. A beneficiary may change his/her selection by submitting a new ESRD Beneficiary Selection form; however, changes received during the calendar year are not effective until January 1 of the following year.

METHOD II

Under Method II, the beneficiary makes his/her own arrangement for securing the necessary supplies and dialysis equipment. Then, the supplier bills the Medicare program (Carrier) for payment. Under this arrangement, the beneficiary is responsible for the deductible and copayment amounts. Payment will be handled in the chosen method effective with the date the beneficiary makes the initial selection (date the form is signed). A beneficiary may change his/her selection by submitting a new ESRD Beneficiary Selection form; however, changes received during the calendar year are not effective until January 1 of the following year.

In addition, 42 CFR 414.330(a)(2)(ii) states that the patient certifies to CMS that he or she has only one supplier for all home dialysis equipment and supplies. This certification is made on CMS Form 382 (the "ESRD Beneficiary Selection" form). 42 CFR 414.330(B)(7) satisfies all documentation, recordkeeping and reporting requirements in Subpart U (Conditions for Coverage of Suppliers or ESRD Services) of this chapter. This includes maintaining a complete medical record of ESRD related items and services furnished by other parties. The facility must report, on the forms required by CMS or the ESRD network, all data for each patient in accordance with Subpart U. The above 42 CFR sites are attached. (Attachment II)

2. Information Users

The intermediaries and carriers are responsible for making correct payments of all renal dialysis claims under the Medicare program. The intermediaries and carriers determine payment for home dialysis services and supplies according to the methods selected by the beneficiary. Sixty (60) percent of the beneficiaries choose Method I. The intermediaries only pay for beneficiaries listed under Method I (composite rate). The remaining Forty (40) percent choose Method II. Under Method II, the beneficiary selects a single supplier to furnish needed equipment and supplies, and the supplier bills the carrier for payment. Automation for mailing of the CMS-382 forms from CMS to all Medicare renal providers takes place in October of the calendar year. Additional forms are available through normal supply channels. The facility has each of its new Medicare home dialysis

patients select a method to handle Medicare payment, sign and date the form. The facility sends the original to its Local Fiscal Intermediary, Attention: Medicare Program Administrator.

3. Improved Information Technology

This form is primarily a check-box selection sheet used by beneficiaries in choosing one of two ways that the Medicare program will pay for home dialysis services. The standardized format and simple check box method provide consistency and easy automation of information by CMS. Generally, this form is filled out only one time. It is filled out again only if the beneficiary wants to change the-payment method he/she originally selected.

4. Duplication of Similar Information

The nature of this request is unique. Form CMS-382 is the only source available for collecting this information.

5. Small Business

This form does not impact small businesses.

6. Less Frequent Collection

This is a one-time only form. The only exception would be if the beneficiary wanted to change the payment method. For example, the beneficiary moves to a new location and the new facility does not offer the original method selection.

7. Special Circumstances

This collection is consistent with guidelines in 5 CFR 1320.6.

8. Federal Register Notice /Outside Consultations

A 60-day Federal Register Notice was published on November 16, 2007.

We did not seek outside consultation because of the nature of the form. It is basically a check-box selection form, needing only the beneficiary's signature and date. It represents the simplest methods available for obtaining the selection information from beneficiaries.

9. Payments/Gifts to Respondents

There is no payment or gift to respondents.

10. Confidentiality

We do not pledge confidentiality.

11. Sensitive Questions

There are no sensitive questions associated with this form.

12. Estimate of Burden (Total Hours & Wages)

New ESRD home beneficiaries	7000
ESRD home beneficiaries to change method	<u>400</u>
Est. no. of forms to be completed yearly	7400

It is estimated it takes approximately 5 minutes for the beneficiary to complete this form. 7400 forms completed by beneficiaries annually X 5 minutes per form = 616.6 hours of respondent burden.

There are no wages associated with this collection as it only takes each beneficiary 5 minutes to fill out the form.

13. Capital Costs Estimated

There are no capital or start-up costs.

14. Cost to Federal Government

The total cost for printing and mailing is \$ 9,250.

15. Burden Changes

CMS made no changes to the 382 form.

16. Publication and Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

We request a waiver of the OMB expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

This collection does not employ statistical methods.