SUPPORTING STATEMENT
FOR THE PAPERWORK REDUCTION ACT SUBMISSION
CROWNWeb Third-Party Submission Authorization (CWTPAS)

A. Background

The Office of Clinical Standards and Quality (OCSQ) is replacing two legacy applications that collect information for the CMS-2728 End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration (OMB No. 0938-0046) and the CMS-2746 ESRD Death Notification (OMB No. 0938-0448). The new system, replacing these two legacy applications, is known as "Consolidated Renal Operations in a Web Enabled Network (CROWNWeb)." CROWNWeb is the system that is mandated for the Final Rule published April 15, 2008, with the title "Medicare and Medicaid Programs: Conditions for Coverage for End-Stage Renal Disease Facilities." Due to the sensitivity of the data available in CROWNWeb, CMS must ensure that only authorized individuals have access to CROWNWeb data, and that those individuals have access only to data necessary for their roles in the data-collection process. The term "authorized individuals" for these purposes includes dialysis facility personnel, ESRD Network Organization personnel, and third-party submitter personnel. ("Third-party submitters" are those organizations authorized by dialysis facilities to submit data about those facilities' patients to CMS.) The CROWNWeb Third-Party Submission Authorization Form will be used to document and implement appropriate controls on data submission and utilization.

B. Justification

1. Need and Legal Basis

CMS maintains a regulatory relationship with Medicare-certified dialysis facilities, and personally-identifiable information on ESRD patients is included in the data that these facilities are required to submit to CMS. The information required on the CWTPSA is necessary to identify and maintain records on authorized submitters.

The need and legal basis references are shown below.

http://www.cms.hhs.gov/InformationSecurity/12_Laws_Regs.asp
http://csrc.nist.gov/publications/PubsFIPS.html (particularly FIPS 198, 199 AND 201-1)
http://csrc.nist.gov/publications/PubsSPs.html (particularly SP 800-53 Rev 2)
http://csrc.nist.gov/publications/PubsByLR.html (SP 800-63 V1.0.2)

These references discuss the obligation of federal business systems owners to protect personal health information (and other confidential information) contained in those systems, and acceptable means of fulfilling those obligations, including requirements for approving and tracking potential users of those systems. Although Facility Administrators completing

the CWTPSA form need not be users of CROWNWeb, the federal government must maintain identifying information about them to properly execute its responsibility to protect the confidential information in CROWNWeb. (For ESRD patients tracked by CROWNWeb, such information may include identifying data, diagnoses and laboratory test results.)

2. Information Users

The CROWNWeb Third-Party Submission Authorization form is to be completed by "Facility Administrators" (administrators of CMS-certified dialysis facilities) if they intend to authorize a third party (a business with which the facility is associated, or an independent vendor) to submit data to CMS to comply with the recently-revised Conditions for Coverage of dialysis facilities. The CROWNWeb system is the system used as the collection point of data necessary for entitlement of ESRD patients to Medicare benefits and for Federal Government monitoring and assessing of the quality and types of care provided to renal patients. The information collected through the CWTPSA form will allow CMS and its contractors to receive data from authorized parties acting on behalf of CMS-certified dialysis facilities. CMS anticipates that roughly 3000 signed forms will be received by February, 2009, and that the total number of forms may reach 5100 by February, 2012.

3. Use of Information Technology

The use of the CWTPSA form will allow CMS and its contractors, the legislatively-mandated ESRD Network Organizations, to monitor the use of Third-Party Submission of ESRD data by dialysis facilities associated with a larger business entity and by independent dialysis facilities. Third-Party Submission itself is expected to offer major benefits to the public in general, to dialysis patients in particular, and to CMS-certified dialysis facilities. In many dialysis facilities, the information required by the new Conditions for Coverage for quality improvement is already collected in automated systems. Use of CROWNWeb, and in particular Third-Party Submission for CROWNWeb, makes this information available for quality-improvement purposes while minimizing the burden on dialysis facility staff.

The CWTPSA form is covered by the Health Care Quality Improvement System Privacy Impact Assessment.

4. Duplication of Similar Information

There is no other form in place or system available to collect this information.

5. Small Businesses

A small business would be described as a provider that is not a member of a chain organization and/or has a small dialysis patient population. These providers are legislatively required to maintain the same patient information and to report on this information in the same manner as all other providers of renal services. These businesses in particular may find

benefits and improve patient care through Third-Party Submission.

6. Less Frequent Collection

Due to the sensitivity of the data within CROWNWeb, the CROWNWeb Third-Party Submission Authorization must be collected in order to ensure that only authorized personnel have access to CROWNWeb data. Since CMS is requiring repeated and continuing data submission by all dialysis facilities, it is clearly beneficial to collect authorization information through the CWTPSA form rather than requiring third-party submitters to establish their status at the time of each submission. In addition, without this authorization large numbers of dialysis facilities will need to enter some of the same data both in their corporate systems and in CROWNWeb.

7. Special Circumstances

- Each CWTPSA form represents an authorization from one dialysis facility to one third-party submitter, remaining in effect until changed by the dialysis facility.
- There is no written response necessary in fewer than 30 days.
- No notarization is required; the CWTPSA form will be retained by CMS or its agent.
- The form has no connection to a statistical survey.
- There are no requirements for statistical data classification.
- The data collected on the CWTPSA form includes the facility administrator's name and business phone number.
- No trade secrets or confidential information are involved in this process.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice published on July 3, 2008.

The CWTPSA form is required for management of organizations submitting data for the Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) system. CROWNWeb is the system that is mandated for the Final Rule published April 15, 2008, with the title "Medicare and Medicaid Programs Conditions for Coverage for End-Stage Renal Disease Facilities."

9. Payment/Gifts to Respondents

No payments or gifts are made to respondents.

10. Confidentiality

Aside from the Facility Administrator's name, no confidential information is collected by the CWTPSA form. No confidentiality statement is necessary.

11. Sensitive Questions

The information collected on the CWTPSA form includes (asterisk denotes required fields):

Information about the Dialysis Facility

- Dialysis Facility Name*
- Dialysis Facility Corporate/Vendor Affiliation*
- Dialysis Facility Phone Number*
- Dialysis Facility Fax Number
- Dialysis Facility Business Address (including City*, State* and Zip Code*)
- CMS Certification Number (Medicare Provider Number)* or National Provider Identifier* (one or both must be shown)
- Dialysis Facility Contact Name, Phone Number, and e-mail address
- Dialysis Facility Administrator's Name* , signature*, phone number* and e-mail address*

Information about the Third-Party Submitter ("Corporate Entity or Vendor"):

- Organization Name*
- Organization Business Address (including City*, State* and Zip Code*)
- Organization Contact Name*, Phone Number*, Fax Number and e-mail address*

Information about the authority granted

- Allowed or not allowed: Transmit patient data; receive validation errors and returned patient data
- Allowed or not allowed: View patient data
- Allowed or not allowed: Update patient data

12. Burden Estimates (Total Hours & Wages)

We expect approximately 3000 dialysis facilities to submit CWTPSA forms in the first year. There are approximately 5100 dialysis facilities certified by the Medicare ESRD program; we expect that 1000 to 2000 of them will not choose to submit CWTPSA forms in the first three years.

Respondents:	5100
Completion Time:	5 minutes
Responses per year:	1 time effort
Total Burden:	425 hours (respondents x completion time)
Wages:	$254,410 (total burden x hourly rate of $50.00)

Note: $50.00 is an estimated hourly rate for facility administrators based on the $39.14 hourly rate for RN staff nurse used in the Conditions for Coverage for ESRD Facilities Final Rule dated April 15, 2008.

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* Required field

Startup mailing cost: $1,260 (first-class postage x 3000 forms)
Annual mailing cost: $ 420 (first-class postage x 1000 forms – assumes that one-third of the forms will need to be modified or renewed each year)

13. Capital Costs

No capital costs are expected.

14. Cost to the Federal Government

The Federal Government will cover the expense of CROWNWeb Help Desk activities related to these forms – receiving them, tracking them, and acting on them to grant or remove batch submission authority. The work will be contracted out and is expected to cost approximately $32,000.

15. Changes to Burden

The initial cost of this information collection activity will be higher than the continuing annual cost, since facilities' decisions on batch submission are expected to remain unchanged for several years in most cases. Between fifty and two hundred forms are expected each year after the first year. The amount of the CROWNWeb Help Desk cost attributed to this activity is estimated to be $10,000 for each year after the first year.

16. Publication and Tabulation Dates

The information collected on the CROWNWeb Third-Party Submission Authorization Form is used solely for the management of CROWNWeb third-party submission. No publication is anticipated.

17. Expiration Date

CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis. To include an expiration date would result in having to discard forms unnecessarily.

18. Certification Statement

There are no exceptions to the certification statement.