SUPPORTING STATEMENT
FOR THE PAPERWORK REDUCTION ACT SUBMISSION
CROWNWeb Batch Data Submission Authorization Form (CWBDSA)
(CMS-10268)

A. Background

The Center for Clinical Standards and Quality (CCSQ) maintains a computer system called "Consolidated Renal Operations in a Web Enabled Network (CROWNWeb)." CROWNWeb is the system that is mandated by 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 patient 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" -- also known as "Batch Submitters" -- are those organizations authorized by dialysis facilities to submit patient and clinical data electronically directly to CMS via CROWNWeb on their behalf.) The CROWNWeb Batch Data Submission Authorization (CWBDSA) Form will be used to document and implement appropriate controls on third-party/batch data submission and utilization.

The CWBDSA form (form number CMS-10268) is used by the CROWNWeb system that was released into production on June 14, 2012. There are no plans to add any additional CROWNWeb "third-party/batch submitters". Since there will be no expansion, CMS only expects to receive 50 to 100 CWBDSA forms annually to accommodate for the creation of new facilities under the current "third party/batch submitters".

B. Justification

1. Need and Legal Basis

CMS maintains a regulatory relationship with Medicare-certified dialysis facilities, and personally-identifiable information (PII) on ESRD patients is included in the data that these facilities are required to submit to CMS. The information required on the CWBDSA 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 the Facility Administrators completing the CWBDSA 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 personal identifying information, diagnoses and laboratory test results.)

2. Information Users

The CROWNWeb Batch Data 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, their corporate owner, or an independent vendor) to submit data to CMS to comply with the Conditions for Coverage of dialysis facilities [**Conditions for Coverage for End-Stage Renal Disease Facilities -- FINAL RULE; 42 CFR Parts 405, 410, 413, 414, 488, and 494 dated April 15, 2008]**. 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 CWBDSA form will allow CMS and its contractors to receive data from authorized parties acting on behalf of CMS-certified dialysis facilities. Since February 2009, CMS has received 4,160 CWBDSA forms and anticipates that they will continue to receive no more than 400 new CWBDSA forms annually to address the creation of new facilities under the current participating “third party/batch submitters”.

3. Use of Information Technology

The use of the CWBDSA form will allow CMS and its contractors, the legislatively-mandated ESRD Network Organizations, to monitor the use of Third-Party/Batch Submission of ESRD data by dialysis facilities associated with a larger business entity and by independent dialysis facilities. Third-Party/Batch 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/Batch Submission for CROWNWeb, makes this information available for quality-improvement purposes while minimizing the burden on dialysis facility staff.

All forms are mailed via USPS to the CMS contractor responsible for effectuating the delegation of authority or changes to the same. The CWBDSA 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/Batch Submission.

6. Less Frequent Collection

Due to the sensitivity of the data within CROWNWeb, the CROWNWeb Batch Data 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 CWBDSA form rather than requiring third-party/batch 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. As such, the CWBDSA form is completed once to initially establish the delegation of authority between the Dialysis facility and their Third party Submitter (usually their corporate owner). The form is then only submitted again if the original delegation of authority changes in any way; an example of this would be a change of ownership of the Dialysis Facility.

7. Special Circumstances

- Each CWBDSA 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 CWBDSA 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 CWBDSA 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 22, 2016 (81 FR 47807). There were no comments.

9. Payment/Gifts to Respondents

No payments or gifts are made to respondents.

10. Confidentiality

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

11. Sensitive Questions

There are no sensitive questions. The information collected on the CWBDSA form includes (asterisk denotes required fields):

Information about the Dialysis Facility

- Dialysis Facility Name*
- Dialysis Facility CROWNWeb Facility ID*
- Dialysis Facility Batch Org Facility Code*
- 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

* Required field

- 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*
- Corporate Entity or Vendor Number (CMS Use Only)

Information on 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)

Using calendar year 2016 as a base, CMS expects no more than 100 dialysis facilities to annually submit CWBDSA forms.

Respondents:	100
Completion Time:	10 minutes
Responses per year:	1 time effort
Total Burden:	17 hours (respondents x completion time)
Wages:	$1,139 (total burden x hourly loaded rate of $67.00)

Note: $67.00 is a national average hourly rate which includes employer-paid benefits (loaded rate) taken from Salary.com for Nurse Practitioners. This information was current as of 02/13/2017.

Annual mailing cost: $49 ($0.49 first-class postage x 100 forms)

Total cost (wages and mailing costs): $1,188

13. Capital Costs

No capital costs are expected.

14. Cost to the Federal Government

The Federal Government will cover the expense of Help Desk activities related to these forms received beyond calendar year 2010 – receiving them, tracking them, and acting on them to grant or remove batch submission authority. The work is contracted out and is expected to cost approximately $8,000 per year. The Government has one GS-13 employee who provides part-time (50%) oversight on this Help Desk contract.

15. Changes to Burden

The burden has been reduced since the last package because there are no plans to expand the CROWNWeb "third-party/batch submitters". The future forms are to accommodate the creation of new facilities under the current "third party/batch submitters".

16. Publication and Tabulation Dates

The information collected on the CROWNWeb Batch Data Submission Authorization Form is used solely for the management of CROWNWeb third-party/batch submission. No publication is anticipated.

17. Expiration Date

CMS will display the expiration date at the bottom of the first page of the form.

18. Certification Statement

There are no exceptions to the certification statement.