# Medicare ESRD Network Organizations Manual

## Chapter 9 - Information Collection

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*(Rev. 10, 05-17-19)*



### 10 - Background
**(Rev. 1, 07-11-03)**

**ENO 900**

Under the Health Care Quality Improvement Program (HCQIP), one of the Network's responsibilities is to measurably improve the quality of ESRD patient care and outcomes. To meet this responsibility, the Network conducts improvement projects. The CMS encourages the Network to develop innovative approaches that include collaborative efforts with the renal community, communication with ESRD beneficiaries and providers, and monitoring of the health care services furnished to ESRD beneficiaries. The use of survey data collection methods to support and evaluate improvement projects is an innovative option that the Network may consider to be worthwhile. However, the Network must meet all applicable CMS statutory and regulatory requirements before implementing a survey.

**NOTE:** This instruction applies to all Network projects, regardless of whether they are conducted as a part of the Network's Statement of Work requirements or part of a special study. This instruction does not apply to medical record abstraction that the Network conducts as a part of a quality improvement project. This instruction also applies to any information collection instruments directed towards 10 or more **persons** as defined in §40

of this chapter. Therefore, this instruction applies to information collection activities directed towards beneficiaries, providers of all types, organizations, etc.

## 20 - CMS/Office of Clinical Standards and Quality (OCSQ) Requirements

**(Rev. 1, 07-11-03)**

**ENO 910**

In order to maintain the integrity of the information collection capabilities, it is imperative that the Network gives careful consideration to the need for every distinct information collection activity that the Network proposes to conduct, the use of the information that the Network intends to collect, and the quality of the instrument the Network proposes to use to collect that information. The Network should only use surveys if the Network cannot obtain that information from any other source. Any proposed information collection activity must meet the following CMS/OCSQ requirements:

- The instrument must be an integral part of a specific cooperative improvement project;

- The Network must explain the extent to which it has sought to verify that the information that the Network proposes to collect is not available from any other source (e.g., peer-reviewed published literature, Medicare claims data, Clinical Data Abstraction Center chart reviews, Behavioral Risk Factor Surveillance System, National Health Interview Survey, Medicare Current Beneficiary Survey, Health Plan Employer Data and Information Set, other Network projects/surveys, etc.); and

- The Network data collection to support the Network HCQIP activities must be approved by the Network PO.

## 30 - Statutory and Regulatory Requirements

**(Rev. 1, 07-11-03)**

**ENO 920**

Surveys and any other information that the Network collects must comply with the provisions of the Paperwork Reduction Act (PRA) of 1995 (Public Law 104-13). These provisions generally prohibit an agency from conducting or sponsoring a collection of information (as that term is defined in the PRA) unless, in advance thereof, the agency reviews the collection of information, publishes a 60-day notice in the Federal Register, evaluates comments received pursuant to such notice, and receives approval and a control number from the Office of Management and Budget (OMB). (See 44 U.S.C. 3506 and 3507.) Regulations at 5 CFR Part 1320 implement the provisions of the PRA. These regulations require OMB approval for a collection of information on identical or similar questions from 10 or more public respondents by means of a standardized format prior to

implementation. The provisions of the PRA apply to information collected through oral interviews and information collected in writing.
In the regulations at 5 CFR Part 1320, some items are not deemed to be "information" under the PRA, and thus do not require OMB clearance. Refer to 5 CFR Part 1320 for information on the additional PRA requirements. This manual provision addresses the requirement for OMB clearance. (See §50 of this chapter, which describes the process for seeking regular OMB clearance, and §60, which details those items pertinent to Network information collection activities.)

## 40 - Definitions
**(Rev. 1, 07-11-03)**

**ENO 930**

Items in the PRA have very specific definitions. Those used for this instruction are defined here as they are at 5 CFR Part 1320. (See the PRA regulation text for complete definitions.)

"**Burden** means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. A collection of information conducted or sponsored by a Federal agency that is also conducted or sponsored by a unit of State, local, or tribal government is presumed to impose a Federal burden except to the extent that the agency shows that such State, local, or tribal requirement would be imposed even in the absence of a Federal requirement." (5 CFR 1320.3(b)(1),(3))

"**Information** means any statement or estimate of fact or opinion, regardless of form or format, whether in numerical, graphic, or narrative form, and whether oral or maintained on paper, electronic, or other media." (5 CFR 1320.3(h))

"**Collection of information** means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to an agency, third parties, or the public of information by or for an agency by means of identical questions posed to, or identical reporting, record keeping, or disclosure requirements imposed on ten or more persons, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit. A collection of information may be in any form or format, including the use of report forms; questionnaires; surveys; reporting or record keeping requirements; interview guides; oral communications; telegraphic or telephonic requests; automated, electronic, mechanical, or other technological collection techniques; standard questionnaires used to monitor compliance with agency requirements; or any other techniques or technological methods used to monitor compliance with agency requirements." (5 CFR 1320.3(c))

"**Person** means an individual, partnership, association, corporation, business trust, or legal representative, an organized group of individuals, a State, territorial, tribal, or local

government or branch thereof, or a political subdivision of a State, territory, tribal, or local government or a branch of a political subdivision." (5 CFR 1320.3(k))

"**Practical utility** means the actual, not merely the theoretical or potential, usefulness of information to or for an agency, taking into account its accuracy, validity, adequacy, and reliability, and the agency's ability to process the information it collects (or a person's ability to receive and process that which is disclosed, in the case of a third-party or public disclosure) in a useful and timely fashion. In the case of record keeping requirements or general purpose statistics, practical utility means that the actual uses can be demonstrated." (5 CFR 1320.3 (l))

## 50 - Office of Management and Budget (OMB) Clearance
**(Rev. 1, 07-11-03)**

**ENO 940**

Unless a survey would not be subject to the PRA under the regulations, the Network must have prior OMB approval to conduct, or engage someone else to conduct, a survey that is part of the Network's Medicare contract. If the proposed survey requires OMB approval, the Network must submit Form OMB 83-I, "Request for OMB Review", a supporting statement, and related materials to the Network's project officer. The Network's project officer will then submit the Request to OMB through CMS' Reports Clearance Officer (RCO). The Network may initiate the survey only after the Network has secured proper approval from OMB through the RCO. The Network can contact its project officer for the Form OMB 83-I, supporting statement outline, and checklist of related materials.

## 60 - Items Not Subject to OMB Clearance
**(Rev. 1, 07-11-03)**

**ENO 950**

The Federal government has specified certain categories of items that generally do not constitute "information" for purposes of the PRA and, as such, are not subject to the general OMB clearance requirement at 5 CFR 1320. In planning a project, the Network will discuss with the Network's project officer the potential applicability of these categories to the Network's project and any information collection activities planned for the project. Only those categories likely to be applicable to the Network's projects are listed below. For a complete list of the categories, refer to 5 CFR 1320.3(h).

**5 CFR 1320.3(h)(5)** - "Facts or opinions obtained initially or in follow-up requests from individuals (including individuals in control groups) under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens."

**NOTE:** The OMB has delegated to the National Institutes of Health (NIH) its authority to determine whether a proposed collection of information falls outside the definition of "information" as a clinical exemption under 5 CFR 1320.3(h)(5). In cases where CMS' RCO deems it appropriate (e.g., longitudinal studies or studies of a sensitive nature), the RCO may refer a Network's project to NIH for such a determination.

**5 CFR 1320.3(h)(8)** - "Facts or opinions obtained or solicited at or in connection with public hearings or meetings."

**5 CFR 1320.3(h)(9)** - "Facts or opinions obtained or solicited through nonstandardized follow-up questions designed to clarify responses to approved collections of information." Moreover, 5 CFR 1320.4(a) lists certain collections of information that are not subject to the PRA, including the following:

**5 CFR 1320.4(a)(2)** - "Collections of information during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities."

## 70 - Request for Exception From OMB Review
**(Rev. 1, 07-11-03)**

**ENO 960**

The authority within CMS to decide whether a Network project falls outside the definition of "information," or is otherwise not subject to the requirements of the PRA, resides with CMS' RCO in Central Office. The OMB has the ultimate authority to determine whether a Network project is subject to the PRA. The RO must endorse a project before the RCO will consider whether an item is exempt from OMB clearance under 5 CFR 1320.3 or 5 CFR 1320.4. If a project is not subject to 5 CFR Part 1320, then any information collection activities that the Network conducts to support that project would be exempt from OMB review. All other information requests are subject to formal OMB clearance as described in §50. If the RCO determines that the project must be cleared by OMB, the Network should work with its project officer to submit the appropriate documentation for formal clearance to OMB (through the RCO).

Based on the provisions in the PRA, CMS developed criteria and a process for reviewing projects to determine whether OMB clearance is necessary. Follow this process for each project in which the Network intends to incorporate an information collection activity.

In order for CMS to determine whether the Network's project requires OMB clearance, the Network must submit electronically to the RCO (through its project officer) a Request for Exception from OMB Review. Any deviations from an electronic submission must be approved by the project officer. There is no specific format for the Request. The only requirement is that the Request must include sufficient information (as described below) for the RCO to determine whether the intent and concept of the **project** falls into one or

more of the categories described in §60. The Network should not submit to the RCO specific information on the actual survey instrument(s) to be used in the project unless specifically requested by the RCO. The request should only discuss the project intent and concept, and it must include the following elements:

**A. Opportunity for Improvement**

The Network should be sure to include information on the data source used to identify that an opportunity for improvement exists (e.g., CMS administrative data, national renal registry data, core indicators, etc.). Information collection instruments cannot be used to identify an opportunity for improvement; rather, they are used to provide useful information to assist the Network in designing and implementing effective interventions and/or to measure improvement.

**B. Planned Intervention Strategy for the Project**

The Network should include discussion on the proposed interventions for the project. Also, the Network should discuss whether it intends to use the information obtained through the survey to design and/or implement intervention strategies.

**C. Project Evaluation and Documentation of Results**

The Network must describe the method it will use to evaluate the impact of the project. If the Network plans to use the survey instrument as a part of the evaluation process, it must discuss the role of the survey in that process. The Network must also discuss how it intends to document the results of the project.

**NOTE:** The Network is encouraged to use information submitted in its Network Quality Improvement Project Report to complete its Request. The Network may attach a copy of the Project Report to its Request, but CMS will not accept the Project Report as a substitute for its formal Request for Exception from OMB Review.

Once the project officer receives the Network's Request for Exception from OMB Review, the project officer and RO scientific staff will have15 business days to initially review the Request and provide comments on its submission. The RO may ask to submit additional information. The RO will then have an additional 15 business days from the date of the resubmission to review the Request. If the project officer and scientific staff agree with the intent and concept of the project, the project officer will submit the Request electronically to the RCO. The RO Associate Regional Administrator for Clinical Standards and Quality will resolve any disagreements between the Network, the project officer, and/or the RO scientific staff on the project concept or design. The RCO will have 15 business days to review the Request and determine whether the proposed project is subject to OMB clearance. The RCO will express his/her decision in writing (e-mail is preferred; fax or hard copy letter is acceptable) to the project officer, who will in turn notify the Network in writing (again, e-mail is preferred; fax or hard copy letter is acceptable) of CMS' decision. As directed by the RCO (through the project officer), the

Network must submit additional supporting documentation to assist the RCO in making this determination.

## 80 - Survey Justification and Methods

**(Rev. 1, 07-11-03)**

**ENO 970**

The Network is encouraged to begin work on the survey instrument and supporting documentation at the same time that the Network's project proposal is under review by the RO and the RCO. If the RCO determines that the project is subject to the requirements of 5 CFR Part 1320, and the Network chooses to submit its project to OMB for formal review, the Network will be required to include the information described below in its submission to OMB. The Network must work with the RO and the RCO to prepare a Request for OMB Review, supporting statement, and related materials.
If the RCO determines that the project does not require OMB clearance, the Network will still be required to work with the project officer and the RO scientific staff in designing the information collection instrument(s) to be used in the project. Supply the following information to the project officer:

**A. Survey Justification**

The Network:

- Shows how, by whom, and for what purpose the survey information is to be used. States the purpose of the study. Describes what questions the survey is designed to address. Describes the subject population. Explains the circumstances that make the survey necessary.

- Provides documentation describing the process it used to verify that the information to be collected is not available through any other source (e.g., peer-reviewed published literature, Medicare claims data, ESRD Program Management and Medical Information System database, Networks' projects/surveys, etc.). The Network describes efforts to identify similar information collection activities previously conducted itself or by another entity. Shows specifically why any similar information already available cannot be used or modified for use for the purposes described above. The Network describes whether it has imported the project concept or survey design from another Network, or other entity.

- Describes any use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology that may reduce burdens.

- Indicates situations in which it project and/or survey results may be used at an aggregate level (e.g., regional, national, etc.)

- Explains any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

- Describes procedures it, its subcontractors, and its consultants will employ to maintain respondents' confidentiality.

**NOTE:** All survey activities must meet the confidentiality requirements specified at 42 CFR Part 480, §1160 of the Social Security Act, and Chapter 3 of this manual. Survey activities must also comply with the data requirements specified in sections G and H of the ESRD contract.

- The Network provides the following language, which must be included in the introduction of the survey collection instrument:

    1. The information provided by the respondent is voluntary.

    2. The identity of the respondent and the information provided by the respondent are confidential.

    3. The respondent's decision whether or not to participate in the survey will not affect his or her Medicare (or Medicaid, where applicable) benefits or reimbursements.

    4. An estimate of the total time it will take the respondent to answer the questions.

    5. The name of company or foundation requesting the information.

    6. A way in which the respondent may contact the requestor (toll free/collect phone number, or name and address) if he/she has questions or wants further information about the survey.

- The Network provides justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. Follow the guidelines outlined in OMB Directive No. 15, Race and Ethnic Standards for Federal Statistics and Administrative Reporting, and the subsequent revisions to that Directive, when asking questions related to race and ethnicity. The Network can obtain these documents through the Internet or from its project officer.

- The Network provides estimates of the cost to the Federal government of the survey. (Annualize the cost if applicable.)
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**B. Survey Methods**

The Network:

- Describes the sampling accuracy needed for the purpose described in §80.A. and any unusual problems requiring specialized sampling procedures. Provides a description of the sampling methodology, including how interviewees will be selected. Addresses whether proxies will be interviewed and any exclusion criteria used for interviewees.

- Describes who will conduct the surveys or whether they will be self-administered. If a subcontractor will be used, provides a resume or description of the subcontractor, including survey experience.

- Describes how the information collection instrument has been or will be field-tested.

- Describes expected response rates for the collection as a whole, and upon what evidence this estimate is based. Includes the actual response rates if any entity has previously conducted the collection.

- Describes methods to maximize response rates and to deal with issues of non-response. Shows that the accuracy and reliability are expected to be adequate for intended uses. Provides justification for any collection that will not yield reliable and valid data that can be generalized to the units studied.

- Provides an exact copy of the entire proposed survey questionnaire. Includes a description of any tests of procedures or methods to be undertaken to assess reliability and validity of questions to be developed.

**NOTE:** The Network is strongly encouraged to use measures that have already been developed and tested and are in the public domain rather than creating a new survey for a project. The Network is also encouraged to use an experienced consultant when developing new questions. The RO may request to see the resumes of any consultants used.

- Briefly discusses the qualifications of the individuals who will design statistical aspects of the project, data collection, and analysis.

**NOTE:** The Network is encouraged to consult with individuals or organizations with specialties in designing, collecting, and analyzing survey data.

The Network submits this information electronically to its project officer for review. The project officer and RO scientific staff must approve the information collection instrument(s) and the supporting documentation prior to implementation of the instrument(s). The project officer will have 15 business days to review the documentation

and the instrument(s), and to provide the Network with a decision on its submission. The RO may ask the Network to submit additional information. The RO will then have another 15 business days from the date of resubmission to review its documentation and to provide the Network with a decision.

The RO Associate Regional Administrator for Clinical Standards and Quality will resolve any disagreements between the Network, the project officer, and/or the RO scientific staff on the documentation provided to support the information collection activity and the actual instrument(s).

## 90 - Additional Considerations

***(Rev. 10, Issued: 05-17-19, Effective: 06-18-19, Implementation: 06-18-19)***

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

**ENO 980**

The Network **must** include the following items in its information collection activity:

**A. Beneficiary Notification Letter**

Before contacting a beneficiary to participate in a survey (either by mail or by phone), notify the beneficiary in writing of the possibility of his/her being contacted. The letter, which must go out over the Regional Administrator's signature, must:

- Identify the Network (e.g., the State's quality improvement organization for Medicare's ESRD program);

- Describe the nature of the survey (e.g., whether it is a mail or phone survey, the purpose of the survey, etc.);

- Inform the beneficiary that he/she is under no obligation to respond to the survey;

- Assure the beneficiary that the decision to respond or not to respond will not affect the beneficiary's Medicare (or Medicaid, where applicable) benefits; and

- Assure the beneficiary that his/her identity and the responses provided by him or her are confidential and that all information provided is protected by the Privacy Act.

The letter must be dated and must include a toll-free or collect phone number with the name of a contact person at the Network that the beneficiary can call if he/she has additional questions about the survey or prefers not to participate in the survey. Beneficiary Notification Letters must be received by the beneficiary at least fifteen (15) calendar days prior to the implementation of the survey.

The project officer must review and approve the content and format of the Beneficiary Notification Letter prior to its being mailed to the beneficiaries. The Network work with its Network project officer to secure the proper CMS authorization and signature for the letter. The letter must be written on CMS letterhead and may be mailed in an envelope using the Network's return address. The Network is encouraged to model its Beneficiary Notification Letter after previously approved letters, to expedite the review and clearance processes. Consider the time required for this review and clearance when planning its information collection activity.

The RO review of the Beneficiary Notification Letter may occur simultaneously with the RCO's review of the Network's Request.

**B. Beneficiary No-Contact List**

During the course of its work, the Network may encounter beneficiaries who indicate that they prefer not to participate in surveys that the Network conducts. The Network must maintain a list (including name, *Medicare beneficiary identifier*, address, and date of birth) of these beneficiaries and **must not** contact any of these beneficiaries to participate in a survey. Before sending a Beneficiary Notification Letter, the Network consults its Beneficiary No-Contact List to determine whether any of the beneficiaries that the Network intends to contact are on that list, and remove those beneficiaries from the survey sample. At such time that CMS may request it, the Network must provide to CMS the name, *Medicare beneficiary identifier*, address, and date of birth of all beneficiaries on its Beneficiary No-Contact List.

## 100 - Documentation for CMS
**(Rev. 1, 07-11-03)**

**ENO 990**

The Network submits a copy of the Beneficiary Notification Letter and the final survey instrument to its project officer before implementation of the survey.

## Transmittals Issued for this Chapter

| Rev # | Issue Date | Subject | Impl Date | CR# |
|---|---|---|---|---|
| R10ESRD | 05/17/2019 | Update to Publication (Pub.) 100-14 to Provide Language-Only Changes for the New Medicare Card Project | 06/18/2019 | 11284 |
| R01ESRD | 07/11/2003 | Initial Issuance of Manual in IOM | N/A | N/A |

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