CMS Manual System

Pub. 100-10 Medicare Quality Improvement Organizations

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
12		Table of Contents	
12		12100 - 12670	
12 - Exhibit		Exhibits 12-1, 12-2	

NEW/REVISED MATERIAL - EFFECTIVE DATE: August 15, 2003

All references to Health Care Financing Administration (HCFA) changed to Centers for Medicare & Medicaid Services (CMS), and all references to Peer Review Organization (PRO) changed to Quality Improvement Organization (QIO).

12110 - Beneficiary Helpline language was reorganized to simplify the flow of the information. It also describes the process for promoting QIO helpline numbers and the information to be provided by the helpline. In addition, the title was changed from "hotline" to "helpline."

12115 - Beneficiary Complaints describes the process that QIOs must follow to handle beneficiary complaints that are received through the helpline.

12200 - Physician/Provider Meeting Activities Required by Statute removes references to the Payment Error Prevention Program (PEPP).

12300 - QIO/Intermediary/Carrier Coordination Activities removes references to the Payment Error Prevention Program (PEPP).

12400 - Background renames the "Annual Report" to the "Annual Medical Services Review Report."

12410 - Confidentiality Requirements changes the reference from 42 CFR 476 to 42 CFR 480.

12420 - Report Requirements instructs the QIO to use the format provided by CMS to complete the report and deletes specific narrative sections from the report requirements.

12440 - Distribution Requirements indicates the methods QIOs may use to distribute their Annual Medical Services Review Report.

12500 - Publications Policy describes the steps a QIO must follow to publish a manuscript (related to its contract activity) in a peer-reviewed journal. This section previously appeared in Chapter 16 as §16300.

12510 - Definition describes the documents to which this policy applies. This section previously appeared in Chapter 16 as §16310.

12520 - Requirements describes the prerequisites for a QIO publication. This section previously appeared in Chapter 16 as §16320.

12530 - Disagreements describes how a QIO should handle a disagreement with a Project Officer's decision. This section previously appeared in Chapter 16 as §16330.

12600 - Information Collection Policy describes the steps a QIO must follow to conduct an information collection activity to support its contract activity. It revises the previous process. This section previously appeared in Chapter 16 as §16200.

12610 - CMS/Office of Clinical Standards and Quality Requirements indicates the criteria that must be met for an information collection activity. This section previously appeared in Chapter 16 as §16210.

12620 - Statutory and Regulatory Requirements - Paperwork Reduction Act (PRA) provides details of the Paperwork Reduction Act that are applicable to QIO information collection activity. This section previously appeared in Chapter 16 as §§16220 and 16230.

12630 - Statutory and Regulatory Requirements - Office of Management & Budget (OMB) Role provides details of the role of OMB in QIO information collection activity. This section previously appeared in Chapter 16 as §§16240 and 16250.

12640 - CMS Information Collection Approval Process describes the process a QIO must follow to receive CMS approval for its information collection activity. This section previously appeared in Chapter 16 as §16260.

12650 - CMS Approval Process - Approval of Proposed Activity - Information Collection Proposal Submission describes the steps a QIO must follow to receive CMS approval of the QIO's intent to conduct an information collection activity. This section previously appeared in Chapter 16 as §16260.

12660 - CMS Approval Process - Approval of Actual Activity - Information Collection Justification, Methods, and Instrument Submissions describes the steps a QIO must follow and the information it must provide to receive CMS approval of the QIO's information collection instrument. This section previously appeared in Chapter 16 as §16270.

12670 - Additional Considerations When Medicare Beneficiaries Are Respondents lists additional requirements for QIOs when conducting information collection activities with Medicare beneficiaries. This section previously appeared in Chapter 16 as §16280.

Exhibit 12-1 - Information Collection (IC) - Proposal Approval is the template the QIO must complete and submit to the Regional Office as described in §12640.

Exhibit 12-2 - Information Collection (IC) - Activity Approval is the template the QIO must complete and submit to the Regional Office as described in §12660.

Workload and Costs: These instructions do not represent an increase in workloads or costs.

NOTE: Normally red, italic font identifies new material. However, because this release is a new manual, normal text font is used for the initial release.

Quality Improvement Organization Manual

Chapter 12 - Communications, Outreach, and Program-related Information Activities

TABLE OF CONTENTS (Rev. 7, 08-15-03)

12100 - Background –

(Rev. 7, 08-15-03)

As specified in your contract, conduct activities in your area to inform beneficiaries about Medicare and the Quality Improvement Organization (QIO) program. Gear your activities toward educating beneficiaries about:

- The purpose of the QIO program;
- The rights of Medicare beneficiaries under the QIO program; and
- How these rights may be exercised.

Collaborate with organizations that serve the same geographic areas (e.g., Medicare carriers, intermediaries, State offices on aging, Social Security District Offices, etc.) and coordinate your activities with them. You may also subcontract portions of your activities where it results in more efficient and effective efforts.

12110 - Beneficiary Helpline –

(Rev. 7, 08-15-03)

The QIO shall maintain a cost-free helpline for beneficiary use (i.e., provide a toll-free number or agree to accept collect calls). The helpline must be staffed during normal working hours. Record beneficiary calls received outside of normal working hours and respond to them during the next business day. Voicemail or answering machine greetings for the helpline should:

- Repeat the number to which the beneficiary has been connected (and if the number is not a toll-free line, clarify that collect calls will be accepted);
- Identify normal business hours of operation;
- Identify general subject areas that can be addressed by the QIO;
- Briefly explain how a beneficiary can lodge a complaint; and
- Identify general information a beneficiary will need in assisting the Customer Service Representative (CSR) to handle his or her call.

It is recommended that QIOs maintain a separate toll-free number for provider and practitioner calls.

For all new outreach materials, QIOs shall publish and promote both their own toll-free number as well as 1-800-MEDICARE as the phone numbers to which beneficiaries should direct their Medicare-related inquiries. CSRs at the 1-800-MEDICARE call centers will refer all quality, complaint, and rights-related questions to the appropriate QIO.

Provide information regarding Medicare beneficiary rights and responsibilities, beneficiary protections (including Hospital-Issued Notices of Non-coverage (HINNs), discharge planning, and beneficiary complaints), and appropriate health education issues related to active projects (e.g., flu vaccinations). Make appropriate referrals when information or assistance that the beneficiary requests is not related to QIO activities or responsibilities.

If you cannot respond while the caller is on the telephone, follow-up either by telephone or in writing within 10 calendar days. Any information you give must meet the confidentiality and disclosure requirements set forth in §1160 of the Social Security Act (the Act) and 42 CFR 480 (See §§10000-10090).

Use the information collected from helpline calls to determine patterns of beneficiary information needs and to improve the helpline process. Document all calls to the helpline using the appropriate reporting system in the Standard Data Processing System (SDPS).

12115 - Beneficiary Complaints –

(Rev. 7, 08-15-03)

The cost-free phone line should also handle beneficiary complaints in accordance with §12110.

The QIO's Customer Service Representatives (CSRs) handling this phone line should be able to address the following regarding beneficiary complaints:

- Ensure complainants are aware of the complaint system;
- Explain the beneficiary complaint process;
- Identify beneficiary rights and responsibilities;
- Identify what issues are addressed by QIOs versus survey and certification agencies, Social Security Administration (SSA) offices, carriers, and fiscal intermediaries;
- Give the beneficiaries a clear and substantive answer to questions regarding beneficiary complaint issues and, if need be, refer the complainant to the proper agency for assistance.

12120 - Interaction With Beneficiary Groups –

(Rev. 7, 08-15-03)

Implement cost effective methods for interacting with beneficiaries and their representatives and for providing information on Medicare rights. Structure your activities to reach the maximum achievable audience. When possible, coordinate activities with other organizations that serve the beneficiary population. If you are unable to fulfill a request to meet with a beneficiary group (e.g., sending a speaker to make a presentation to a small group at a distant location would not be an effective use of resources), offer to help arrange for alternative presenters who could also provide the information (e.g., a representative from a local agency or Medicare contractor) or provide the information using an alternative method (e.g., video, brochures). Request partners to provide information on Medicare rights when they interact with beneficiaries. When presenting information on Medicare rights, also include health promotion and disease prevention topics, as appropriate to your contract activities.

12130 - Other Activities –

(Rev. 7, 08-15-03)

In addition to the activities described in the preceding sections, you may consider engaging in other activities that are cost effective ways of educating beneficiaries of their Medicare rights (e.g., brochures, videos, audios).

NOTE: CMS may also provide you with informational material (including camera-ready copies) for distribution.

12140 - Evaluation –

(Rev. 7, 08-15-03)

Evaluate the efficiency and effectiveness of activities you carry out to educate beneficiaries regarding their Medicare rights.

- Evaluate the number of beneficiaries reached in comparison to the Medicare population in your area.

- Determine if the information presented/disseminated meets the beneficiaries' needs (e.g., relevant topics and information) and is easy to understand.

- Determine if the information (e.g., in verbal form, brochures, videos) is presented/distributed effectively (e.g., evaluate the communication vehicle or format used, content, and visual presentation of written materials or delivery of verbal messages).

- Determine if the information presented/distributed achieves the desired outcome (e.g., increase in knowledge about rights/where to receive assistance with quality of care concerns).

- Determine if educational materials are produced/distributed in a cost effective manner (e.g., used/modified materials developed by other QIOs or community organizations).

- Evaluate your effectiveness in coordinating/networking with other Medicare contractors, State and local agencies, and organizations that serve the beneficiary population.

- Utilize your evaluation findings when developing and carrying out new educational initiatives.

Consider budget limitations when evaluating outreach and your communication efforts, and utilize inexpensive, simple evaluation methods whenever possible. Share evaluation methods used with other QIOs.

12200 - Physician/Provider Meeting Activities Required by Statute –

(Rev. 7, 08-15-03)

A. Authority and Scope -- §1154(a)(6)(B)(i) of the Act, as amended by §4094 of the Omnibus Budget Reconciliation Act of 1987, requires that you offer to provide for a physician representing your organization to meet (at a hospital or at a regional meeting) several times each year with medical and administrative staff of hospitals whose services you review. The purpose of these meetings is to discuss the results of your review of the respective hospitals' services that are billed to the Medicare program. This information is necessary for physicians and providers to understand how your review activities directly relate to your responsibilities to:

- Protect beneficiaries by ensuring that the quality of care they receive meets professionally recognized standards of health care;

- Protect the fiscal integrity of the Medicare Trust Funds by ensuring that Medicare pays for only those health care services and items that are or were reasonable and medically necessary, and that those services proposed to be provided are provided in the most economical (appropriate) setting; and

- Continuously improve the quality of care of beneficiaries.

Your meetings will provide an opportunity for you to present findings (positive and negative) found in your review activities and data analysis, and to then discuss solutions and/or provide education. The meetings will also provide an opportunity to discuss new ideas on how to best further the major goals of the QIO program.

B. Meetings with Hospital Medical and Administrative Representatives -- Meet with medical and administrative representatives of hospitals as provided in your Memorandum of Agreement (MOA) (See Chapter 3):

- Offer to meet with hospital representatives, at a minimum, twice a year in each geographical area of the State.

NOTE: Any meetings you initiate to further the purposes of the QIO program (such as improvement projects) and which involve multiple providers in your review area, count toward fulfilling this requirement for those providers in attendance.

- Plan the meetings as a means of sharing pattern analysis results and providing a forum for sharing of best practices.

- Discuss beneficiary protection issues.

- Focus the meetings on other specific topics of interest and concern to the hospitals.

- Solicit subjects for additional discussion topics from interested parties and organizations.

C. QIO Physician Representation -- Your physician representative must be present at all meetings at which physician participation is expected.

12210 - Physician/Provider Meeting Activities Required by QIO Contract –

(Rev. 7, 08-15-03)

Your contract also requires that you perform the following activities:

A. Meetings with Physician/Provider Organizations -- Meet at least twice a year with organizations directly affected by the activities of the QIO program. These organizations should include, but are not limited to, State and local provider organizations, medical societies, specialty societies, and State licensure agencies.

- Be responsive to requests from these organizations to meet on such issues as beneficiary protection, health care improvement projects, and related topics.

- Seek meaningful input from these organizations about the coordination of QIO activities.

- Have your physician representative present at all meetings at which physician participation is expected.

B. Documenting -- Maintain appropriate documentation that verifies all physician and provider meetings.

12300 - QIO/Intermediary/Carrier Coordination Activities –

(Rev. 7, 08-15-03)

A. Periodic Meetings -- Your senior administrative, medical, and outreach staff must conduct at least three meetings a year with the Medicare carrier's medical director, the intermediary's medical director, and appropriate staff. The objectives of these meetings are to coordinate policies and improve care for Medicare beneficiaries in the community. Use these meetings to inform intermediaries/carriers of your contract responsibilities, discuss issues of common interest and attempt to resolve issues such as data exchange problems, changes in procedures covered by Medicare, and provider concerns. Although face-to-face meetings are encouraged, teleconferences may be used. If there is more than one Medicare payer (i.e., carrier/intermediary) in your State, you may combine the meetings to save time and costs.

B. Coordination on Health Care Quality Improvement Projects (HCQIP) -- Inform intermediaries and carriers about HCQIP and educational projects with providers and beneficiaries in your State. Share data analysis and data presentation methods and successful ways to interact with providers and beneficiaries to change behavior. Coordinate with intermediaries and carriers in your State on HCQIP activities when it is mutually beneficial.

NOTE: You should discuss HCQIP activities at your periodic meetings (See §12300.A).

C. Memorandums of Agreement (MOAs) -- Your MOAs with intermediaries and carriers must include these coordination activities (See §§3100-3110).

D. Reporting Requirements -- You are not required to submit ongoing reports to CMS on the results of the QIO/intermediary/carrier coordination activities specified in §§12300 and 12310. However, you must maintain minutes of all meetings and be prepared to submit these minutes to CMS, if requested. For all other coordination activities, you need to maintain records in such a way that reports can be submitted to CMS, when requested.

12310 - Additional QIO/Carrier Coordination Activities –

(Rev. 7, 08-15-03)

A. Authority -- §4205(c) of the Omnibus Budget Reconciliation Act of 1990 requires you and Medicare carriers, in a manner specified by the Secretary, to coordinate physician review activities, and specifies that the following activities be addressed:

- Development of common utilization and medical review criteria;
- Criteria for targeting of reviews by you and carriers; and
- Improved methods for exchanging information among QIOs and carriers.

B. Carrier Notice and Comment Process -- Provide comments to the Medicare carrier(s), as appropriate, when the Medicare carrier(s) in your State provides proposed local medical review policies (or proposed changes to current local medical review policies) for comment. Adhere to the carrier timeframes for submission of comments on carrier proposed local medical review policies or changes.

C. QIO Medical Review Criteria -- Request and consider comments from your carrier(s) when formulating new or changing existing medical review criteria, guidelines, or screens. Develop with the carrier mutually acceptable timeframes for submission of comments on QIO proposed criteria or changes.

D. Carrier Advisory Committee (CAC) -- Your Medicare carrier(s) has established a CAC for your State that provides a forum for exchange of information between

physicians and Medicare. QIO senior medical staff must participate on the CAC implemented by your Medicare carrier(s) (See §7503 of the Carriers Manual for an explanation of the purpose, membership, role, structure, and process of the CAC).

12400 - Background –

(Rev. 7, 08-15-03)

Section1154(a)(6)(B)(ii) of the Social Security Act (the Act) requires you to publish and distribute, not less often than annually, to providers and practitioners whose services are subject to review, a report that describes findings, with respect to the types of cases in which you have determined that:

- Inappropriate or unnecessary care has been provided;
- Services were furnished in an inappropriate setting; or
- Services did not meet professionally recognized standards of health care.

12410 - Confidentiality Requirements –

(Rev. 7, 08-15-03)

Your report must be in the form of statistical data that does not implicitly or explicitly identify any individual patients, practitioners, or reviewers, and must not contain confidential information as defined in 42 CFR 480.101.

NOTE: Do not report any case-specific or summary statistical information that you referred to the Office of the Inspector General (OIG) or to any other Federal or State agency responsible for identifying and investigating fraud and abuse.

12420 - Report Requirements –

(Rev. 7, 08-15-03)

Using the format provided by CMS, develop a report that covers: for your first contract year, the 1st to 12th month; for your second contract year, the 13th to 24th month; and for your third contract year, the 25th to 33rd month (this will allow you sufficient time to complete your third-year report prior to the end of your contract).

NOTE: If the QIO contracts are extended beyond the original contract period, CMS will advise you of the timeframe that your third report and/or any subsequent reports will cover and when those reports will be due.

12430 - Publication Requirements –

(Rev. 7, 08-15-03)

Publish your report no later than three months after the last day of the period covered by the report. Since the report must be approved by your Project Officer before release, allow 20 working days for your Project Officer to review and provide comments. Submit a copy of your final report to your Project Officer.

12440 - Distribution Requirements –

(Rev. 7, 08-15-03)

If you maintain a Web site, publish your report on that site. If you do not maintain a Web site, consult with your Project Officer to determine how you will distribute the report. You are not required to notify any specific audience of the report's availability. However, you may want to inform providers and practitioners through routinely used channels, such as provider-targeted newsletters.

Copies of the report should also be available at any QIO meetings held annually as well as at other meetings with broadly based audiences at which QIO representatives might speak. Upon request, copies should also be sent to beneficiaries as well as to State and local medical societies, state hospital associations, State and local Offices of Aging, and senior citizen groups.

Mass mailing or other mass distribution of your report is not considered efficacious or cost effective.

12500 - Publications Policy –

(Rev. 7, 08-15-03)

The Centers for Medicare & Medicaid Services supports Quality Improvement Organization publications to the extent that they describe documented results of Health Care Quality Improvement Program activities and contribute to achieving the program's mission.

12510 - Definition –

(Rev. 7, 08-15-03)

As used in §§12500-12530, the term "publication" refers to any peer-reviewed, referenced, and/or refereed document which you submit on your own behalf to a professional or trade journal, and which results from a CMS-funded quality improvement activity. "Publication" does not refer to press releases, newsletters, brochures, pamphlets,

advertisements, or letters to the editor (with the exception of letters to the editor that include CMS data that has not previously been published elsewhere). If you are unsure if a document falls under the definition of "publication," consult your Regional Office (RO) Project Officer (PO) who has the discretion to decide whether a document requires CMS review. The POs may also expand the definition of "publication" if they believe such action is justified. The same criteria outlined in this instruction apply to abstracts submitted for publication or for presentation at professional meetings (excluding CMS, QIO, and/or American Health Quality Association sponsored meetings), although RO review time is shortened (See §12520.C).

12520 - Requirements –

(Rev. 7, 08-15-03)

Your publication must meet the following requirements:

A. Confidentiality -- All your publications must meet the confidentiality requirements specified at 42 CFR Part 480, §1160 of the Social Security Act (the Act), and Chapter 10 of the QIO Manual.

B. Disclaimer -- All your publications (except abstracts) must include the following disclaimer:

- The analyses upon which this publication is based were performed under Contract Number 500- - , entitled "Utilization and Quality Control Peer Review Organization for the State (Commonwealth) of _____," sponsored by the Centers for Medicare & Medicaid Services, Department of Health & Human Services. The content of this publication does not necessarily reflect the views or policies of the Department of Health & Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

- The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Centers for Medicare & Medicaid Services, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this contractor. Feedback to the author concerning the issues presented is welcomed.

- Any deviation from the above legend must be approved in writing by the contracting officer.

C. CMS Certification -- Provide CMS with manuscripts prior to submitting them for publication. Send the manuscript to your PO, who is responsible for reviewing and certifying that the manuscript meets the requirements listed above. POs have 30 calendar

days from the date of receipt of the manuscript to respond to you. Consider RO review time in relation to any deadlines imposed upon you by the journal or other publication. In the case of abstracts, your PO has 10 calendar days to respond to you. On an individual basis, you can request a more rapid reply from your PO (for either manuscripts or abstracts). Your PO has the discretion to honor or reject such requests. Work with your PO to establish a process for prompt and efficient review and comment on draft publications (e.g., method of submitting draft publication to your PO, beginning and ending dates of PO review time).

POs and/or other RO staff may provide you with substantive changes to the manuscript. Consider these substantive changes just as you would similar changes suggested by other peer reviewers. You must address any confidentiality and/or disclaimer issues raised by the PO. Once you have addressed these issues and your PO has certified that they have been adequately addressed, you may submit the manuscript for publication.

If you do not receive certification from your PO within 30 days of the PO's receipt of the manuscript (or within 10 days in the case of the abstract), you can assume certification and proceed with the publication.

D. Revisions to Original Manuscript -- Your PO will review the version of a manuscript which you will initially submit for publication. In situations where revisions to a manuscript are made between the time it is first submitted to a journal or other publication and when it is actually published, you are responsible for informing your PO of any changes to the manuscript which relate to QIO data and/or CMS policy. Your PO may decide to review revisions of the manuscript. However, POs are not required to do so. Ultimately, you are responsible for the manuscript as published. You are liable for any breaches of confidentiality or misrepresentation of CMS policy which result from the publication of a revision of the original manuscript and will be subject to any penalties which may be imposed for doing so.

E. Published Article -- Provide a copy of the article, as published, to your PO.

12530 - Disagreements –

(Rev. 7, 08-15-03)

Disagreements with the PO's determinations regarding the manuscript will be resolved by the contracting officer.

12600 - Information Collection Policy –

(Rev. 7, 08-15-03)

Under the Health Care Quality Improvement Program (HCQIP), Quality Improvement Organizations (QIOs) are charged with promoting medical practices that meet professionally recognized standards and will improve the quality of health care provided

to Medicare beneficiaries. One tactic that QIOs use to accomplish this goal is the implementation of cooperative projects. As part of such projects, CMS encourages QIOs to develop innovative approaches that include collaborative efforts with the medical community, use of evidence-based interventions to change behavior and improve care, communication with beneficiaries and providers, and monitoring of the health care services furnished to beneficiaries.

Information collected using surveys or other methods can provide valuable support to developing and evaluating interventions. The use of information collection methods to gather data that can support/facilitate the success of cooperative projects is an innovative option QIOs may consider worthwhile. However, such activities must meet all applicable CMS, statutory, and regulatory requirements before being implemented.

NOTE: This instruction applies to all QIO projects (7th Statement of Work or special study). It applies, more specifically, when the information collection activity is directed towards ten or more persons as defined in §12630 of this instruction. This instruction applies regardless of the target audience as long as ten or more "persons" are involved (i.e., whether directed towards beneficiaries, providers of any type, organizations, etc.). This instruction does NOT apply to medical record abstraction you conduct as a part of a quality improvement project.

12610 - CMS/Office of Clinical Standards and Quality Requirements –

(Rev. 7, 08-15-03)

In order to maintain the integrity of your information collection capabilities, it is imperative that you give careful consideration to:

- The precise information you want to collect (i.e., What are the overarching questions you believe need to be answered? What are you attempting to learn through the information collection activity about characteristics or aspects of the population? etc.).

- The need for the information you propose to collect (i.e., Will it provide the data necessary to answer the questions that you believe need to be answered?).

- The quality of the instrument you propose to use to collect that information (i.e., will it result in data that, when analyzed, and will it answer the questions that drive the information collection activity?).

- The proposed use of the information to be collected (i.e., How exactly will the information derived from the activity be used? Is it central or peripheral to a successful project intervention/project evaluation? etc.).

In order to develop a successful information collection proposal, you must establish a clear relationship between:

- The overarching questions for which the QIO believes it needs answers, and the data the QIO proposes to collect;

- The data collected, and the proposed analysis of the data; and

- The information that will result from that analysis, to the generation of answers to those "big picture" questions driving the information collection activity.

Any proposed information collection activity must meet the following CMS/Office of Clinical Standards and Quality (OCSQ) requirements:

- The information collection activity must be an integral part of a specific quality improvement project (clinical or non-clinical); and

- You must have verified that the information you propose to collect is not available from other sources.

- Other sources include peer-reviewed published literature, Medicare claims data, Clinical Data Abstraction Center (CDAC) chart reviews, Behavioral Risk Factor Surveillance System (BRFSS), National Health Interview Survey (NHIS), Medicare Current Beneficiary Survey (MCBS), Health Plan Employer Data and Information Set (HEDIS), and other QIOs' projects/information collection activities. The extent to which you have gone to verify this "information gap" must be documented in the materials you submit to your Project Officer (See Exhibits 12-1 and 12-2).

12620 - Statutory and Regulatory Requirements - Paperwork Reduction Act (PRA) –

(Rev. 7, 08-15-03)

A. Paperwork Reduction Act (PRA) Definitions -- The foundation for any information collection activity that a QIO might undertake is the Paperwork Reduction Act (PRA). Terms in the PRA have very specific definitions. Definitions at 5 CFR 1320 that are pertinent to QIO information collection activities are given below (See the PRA regulation text for complete documentation of 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).)

NOTE: For practical purposes, CMS recommends that QIOs think in terms of "**unit of information collection**" in place of the PRA's "person." That is, a unit of information collection would be considered the basic unit from which data are collected and the level at which those data are analyzed. Thus, a unit of information collection could be an individual, a focus group, a hospital, or a meeting, depending on what unit the QIO is interested in knowing more about.

- "**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).)

B. Compliance with the PRA -- Surveys and any other information collection activity 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: (1) reviews the collection of information, (2) publishes a 60-day notice in the "Federal Register", (3) evaluates comments received pursuant to

such notice, and (4) receives approval and a control number from the Office of Management and Budget (OMB). See 44 U.S.C. §§3506 and 3507.

C. Applicability of Statutory/Regulatory Requirements in QIO Program -- QIOs should always remember that information collection is a valuable tool applicable to both clinical and non-clinical quality improvement work. Since there are legal issues (for both CMS and QIOs) if information collection is undertaken without having appropriate approval, it is also a tool that could lead to litigation or be taken away, if misused. CMS believes it is better for a QIO to err on the side of caution and consult its Regional Office (RO) on all information collection activities, than it is to make mistakes.

The key issues for the utilization of information collection in the QIO Program are: (1) what qualifies as "information" under the PRA, and (2) what information collection activity requires or is excepted from OMB clearance. Items that are not considered "information" would not, in general, be subject to review by OMB (or CMS). Activities that are excepted from OMB clearance (See §12650) are still subject to CMS review (i.e., the QIO's regional Divisions of Clinical Standards and Quality (DCSQ)).

Differentiating between what is and is not subject to the PRA. Whether or not an information collection activity is or is not subject to the PRA rests, in general, on two criteria: number of "persons" from whom information is being collected and type of question(s) being used to collect that information.

Number of persons = 9 or fewer: If information is being collected from nine or fewer "persons" (as defined in the PRA), then the approval process is not required. Therefore, the information collection activity would not be subject to OMB clearance or CMS review.

Number of persons = 10 or more: If information is being collected from more than nine "persons," then, in general, the approval process would be required. Therefore, the information collection activity would be subject to OMB clearance and CMS review.

CMS guidance regarding (1) open-ended questions asked of (2) more than nine 'persons': While the Reports Clearance Officer has indicated that information collection activities meeting those two criteria would not be subject to the PRA, CMS requires RO involvement (review/approval) of any collection involving more than nine 'persons.' This is required no matter what type of queries, questions, or probes are used.

CMS also encourages QIOs to inform their Regional Offices when undertaking activities which do not require RO review and approval (e.g., those activities not considered information collection under the PRA) (for examples, see list below).

Items not subject to the PRA. The following is a list of things that are, in general, not subject to the Paperwork Reduction Act:

- Focus groups that use open-ended questions

- Consents
- Acknowledgments
- Receipts
- Screening tools used to determine focus group participants
- Publication order forms
- Reader response cards/feedback forms if questions are open-ended
- Web site feedback (suggestion box format only) and publication, etc. order forms
- Evaluation forms for meetings
- Follow-up contacts for meetings
- Discussion guides/prompts with open-ended discussion topics
- Phone scripts that are open-ended
- Continuing intermittent feedback from physicians
- A closed-ended question survey that goes to 9 or less "persons"
- Subcontract if CMS is not sponsoring the collection

12630 - Statutory and Regulatory Requirements - Office of Management & Budget (OMB) Role –

(Rev. 7, 08-15-03)

Activities that are considered “information collection” in the PRA must receive OMB clearance. The implementing regulations require OMB approval for any collection of information that gathers data from ten or more “persons” (public respondents) using a standardized format and identical or similar questions (Regulations at 5 CFR 1320 implement the provisions of the PRA). These provisions apply to information collected by any method (e.g., oral interviews or self-administered questionnaire). OMB clearance must occur prior to the conduct of the data collection activity.

A. Information Not Subject to OMB Clearance -- The Federal government has specified at 5 CFR 1320 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, although OMB may determine that any specific item constitutes

"information." In planning a project, discuss with your Project Officer the potential applicability of these categories to your project and any information collection activities planned for the project. Only those categories likely to be applicable to your 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." This is known as the "clinical" exemption.

NOTE: The clinical exemption (to OMB clearance) is the category under which most information collection activities conducted by QIOs will fall, including the clinical topics that are the focus of all institutional- and community-based health care quality improvement efforts. See §12660, "7SOW Task 1 Projects," below regarding the national-level exemption for 7th Scope of Work clinical topics.

NOTE: 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' Reports Clearance Officer (RCO) deems it appropriate (e.g., longitudinal studies or studies of a sensitive nature), the RCO may refer your 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 non-standardized follow-up questions designed to clarify responses to approved collections of information."

Other collections of information that are not subject to the PRA are listed at 5 CFR 1320.4(a). These include 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." This is known as the "audit" exemption.

B. OMB Clearance -- Unless a survey would not be subject to the PRA under the regulations as discussed above, you must have prior OMB approval to conduct, or engage someone else to conduct, a survey that is done as part of your Medicare contract. If the proposed survey requires OMB approval, you must submit Form OMB 83-I, Request for

OMB Review, a supporting statement, and related materials to your Project Officer. Your Project Officer will then submit the Request to OMB through CMS' Reports Clearance Officer (RCO). You may initiate the survey only after you have secured proper approval from OMB through the RCO. You can contact your Project Officer for the Form OMB 83-I, supporting statement outline, and checklist of related materials. These materials can also be found on the Internet at: http://www.hhs.gov/oirm/infocollect/

12640 - CMS Information Collection Approval Process –

(Rev. 7, 08-15-03)

Role of the Reports Clearance Officer (RCO) -- While OMB retains the ultimate authority to determine if a quality improvement (QI) project (clinical or non-clinical) is subject to the PRA, the authority within CMS to decide whether your QI project falls outside the definition of "information," or is otherwise not subject to the requirements of the PRA, resides with CMS' Reports Clearance Officer (RCO) in the Central Office.

NOTE: "Project" refers to the overall quality improvement project, whether it be clinical, as in 7SOW Task 1 or non-clinical as in 7SOW Task 3b, of which the proposed information collection activity would be part. "Project" is never used in the narrower sense to refer to the proposed collection activity.

The RCO will consider whether the QI project, under which the information collection activity will be carried out, is exempt from OMB clearance under 5 CFR 1320.3 or 5 CFR 1320.4. The RCO determination will be made only after the proposed activity has first been endorsed by the Regional Office (RO). If the RCO judges a QI project/topic not subject to 5 CFR 1320, then any information collection activities that you conduct to support that project would be excepted from OMB review. It will, however, be subject to the CMS review process described below.

If, however, the RCO determines that the project is not excepted from OMB review, the information collection activity is, therefore, subject to formal OMB clearance as described in §12630. You will need to work with your Project Officer to submit the appropriate documentation to OMB to apply for formal clearance to OMB. Documentation will be submitted through the RCO.

Review Process Developed by CMS -- Based on the provisions in the PRA, CMS developed a two-part process that covers all OMB clearance requirements.

- Proposal Approval -- Approval of the proposed information collection activity is the first component of the CMS process. This involves endorsement of the idea/concept by the RO and a decision by the RCO that the project is exempt from OMB clearance. While these two reviews focus on very different things, a single document, the Proposal Submission (See Exhibit 12-1), is used for both purposes. The RO reviews the document to determine if the activity described in a QIO's

write-up will add value to the associated quality improvement project (step one). If this decision is positive, the RO forwards the Proposal to the RCO for his/her decision as to whether OMB clearance is necessary (step two).

- 7SOW Task 1 Projects -- The introduction to Task 1, "Improving Beneficiary Safety and Health Through Clinical Quality Improvement," incorporates language that provides a national-level exception to OMB Clearance for information collection activities undertaken as part of Task 1 QI projects. This exception is based on the clinical exemption found in 5 CFR 1320.3(h)(5) and its applicability, therefore, to the clinical topics addressed in Task 1. Consequently, no Request for Exception must be submitted to the RCO for any information collection activity undertaken as part of a QI project to improve care for:

    - Acute myocardial infarction
    - Breast cancer
    - Diabetes
    - Heart failure
    - Pneumonia/adult immunizations
    - Surgical infection prevention
    - Clinical areas targeted by quality improvement projects in the nursing home, home health, and managed care settings.

- 7SOW, non-Task 1 projects -- Where information collection activities are related to projects that are part of Tasks 2 or 3 or to clinical topics not included in Task 1 (e.g., in a special study under Task 4), a Request for Exception is still required and the Information Collection Proposal Submission must be transmitted to the RCO.

- The national exemption applies only to RCO/OMB review -- The rest of the information collection approval process must be completed. This second component of CMS' review process is described briefly below. Complete requirements are provided in §12650.

- Activity Approval -- The second component of the approval process is the RO approval of the information collection activity itself. This stage requires (for all proposed information collections) submission of three documents: a justification for the proposed information collection, a description of the methodology to be used, and the final draft information collection instrument.

If the target respondent audience(s) includes Medicare beneficiaries then an additional document, the "Beneficiary Notification Letter," is required (See §12670).

12650 - CMS Approval Process - Approval of Proposed Activity - Information Collection Proposal Submission –

(Rev. 7, 08-15-03)

12650.01 - Regional Office (RO) Endorsement of Proposed Information Collection Intent and Concept

(Rev. 7, 08-15-03)

Proposal Submission document -- The Proposal Submission includes the information necessary for: (1) the RO to make a decision about endorsing the proposed information collection and (2) the RCO to determine whether the QI project meets a clinical or audit exemption. All Proposal Submissions must include the following information:

A. Exemption-related Information -- For possible "clinical" exemptions, the clinical topic or the patient care outcome which is the focus of quality improvement needs to be provided. For possible "audit" exemptions, evidence of, or results from, previous audit activities must be provided.

B. Information Collection Intent -- Briefly describe the general purpose of the information collection activity, including the key questions that the activity is intended to answer. This section must also include whether: (1) the information obtained through the activity will be used to design and/or implement interventions/intervention strategies, and if so, how; and/or (2) if you plan to use the activity as a part of an evaluation process, how the collected information will be used. Also, name the population of interest.

C. Opportunity for Improvement -- Describe the opportunity, including the numbers that demonstrate the presence of the opportunity and information on the data source(s) used to identify the opportunity's existence (e.g., CMS claims data, Clinical Data Abstraction Center chart abstraction, etc.). Proposals related to Task 1 QI projects do not need to provide this information since the opportunity is identified by the baseline data for each quality indicator provided by CMS at the beginning of the 7SOW.

NOTE: An information collection activity cannot be used solely to identify an opportunity for improvement (i.e., to establish an initial project baseline). Rather, it can only be used to provide useful information to assist you in designing and implementing effective interventions and/or to evaluate the impact of an intervention (i.e., to measure improvement). If initial baseline or re-measurement baseline data are collected in conjunction with the aforementioned utilities, it is allowable.

Format/submission -- The QIO should submit the required information using the Information Collection Proposal Approval Template (See Exhibit 12-1). The information submitted should cover all requirements described in §12650 above, so that RO staff (Project Officer and Scientific Officers) can determine whether the value added to the QI project by the proposed information collection activity will justify the resources required. CMS is looking for well thought out and thorough content, presented clearly and concisely, which should require no more than one-half (½) page. The Information Collection proposal document must be submitted electronically to your Project Officer. If you want to submit the document via any other mechanism, you must get approval from your Project Officer.

Timeline -- Once your Project Officer receives your Information Collection Proposal Submission, the Project Officer (and RO scientific staff) has fifteen (15) business days to review this document and provide comments to you. The RO may ask you to submit additional information. The RO will then have an additional fifteen (15) business days from the date of the resubmission of the paper for review/approval.

NOTE: The times allowed for review of all documents that are part of the CMS information collection review process are taken directly from the OMB clearance process. While you can discuss expediting review with your Project Officer, it is the QIO's responsibility to take these response times into its planning and proposed timeline for any information collection activity it wants to do. This means that no such activity can be done as a spur of the moment/"spontaneous" action.

Conflict resolution -- The RO Associate Regional Administrator for Clinical Standards and Quality will resolve any disagreements between you, the Project Officer, and/or the RO scientific staff on the proposed concept/idea and/or its approval.

Next step for all projects -- If your Project Officer and scientific staff agree with the intent and concept of the project, the Project Officer will inform you electronically. You can then move to the next action required of you by the information collection approval process - submission of documents related to the actual activity (See §§12660 and 12670).

12650.02 - RCO Approval of Request for Exception to OMB Clearance

(Rev. 7, 08-15-03)

If the proposed information collection activity is not part of a 7SOW, Task 1 project, then following Regional Office (RO) endorsement of the proposed activity's intent/concept (as documented in the Information Collection Proposal Submission), the Project Officer will transmit the Information Collection Proposal to the RCO. This second step of the approval process provides the RCO with information adequate to allow a determination of whether the QI project (clinical/non-clinical) meets one of the exemptions to OMB clearance (See §12640). The following information needed by the RCO is also provided in the Information Collection Proposal:

- The QI project topic (i.e., the clinical topic and focus for quality improvement/patient care outcomes (clinical exemption) or evidence/results of previous audit activities (audit exemption, under which any information collection activity related to payment error surveillance may fall)).

- How the information will be used (i.e., for intervention development and design and/or assessment of intervention/project impact.

Both pieces of information are necessary in order for the RCO to decide whether: (1) a proposed project falls into an exemption category, and (2) the information collected will be used solely to establish a baseline or opportunity for improvement.

Format/submission -- See "Format/submission" requirements in §12650.01 above. The same document, the Information Collection Proposal Submission, is used to submit information to the RCO.

NOTE: Unless otherwise requested, the RCO neither wants information about the activity's justification and methodology, nor wants to see the information collection instrument(s). All the information required by the RCO is described above.

Timeline -- The RCO has fifteen (15) business days (from the date the Project Officer submits your Proposal) to decide whether the proposed project/information collection is subject to OMB review. The RCO will convey his/her decision via email to your Project Officer, who will in turn notify you electronically of the RCO's decision.

If for any reason the RCO needs additional documentation to assist in making his/her determination, you will be notified of this by your Project Officer. If additional documentation is required, the RCO will again have 15 business days to make his/her determination from the date that documentation is submitted to the RCO by your Project Officer. The same process described above for informing you of the RCO's decision will be followed once a determination is made subsequent to the review of additional information.

Conflict resolution -- There is no appeal of the RCO's decision. When his/her decision is that the proposed information collection activity is subject to OMB Clearance, then you must provide the documentation described in §12640 if you want to proceed with the proposed information collection activity. Your Project Officer will help you with this documentation and with going through OMB clearance.

12660 - CMS Approval Process - Approval of Actual Activity - Information Collection Justification, Methods, and Instrument Submission –

(Rev. 7, 08-15-03)

The next component in the information collection approval process is approval of documents related to the actual information collection activity. The QIO must submit the following for Regional Office (RO) review and approval: a document justifying the information collection activity, a description of methods/methodology the QIO intends to use, and the proposed instrument. If Medicare beneficiaries comprise any of the respondent sample, you must also submit a Beneficiary Notification Letter (See §12670).

NOTE: For 7SOW, Task 1 projects, this follows RO endorsement/approval of the concept/idea behind the information collection activity. For other 7SOW projects, this follows the RCO's determination that the project is excepted from OMB clearance.

You can choose to work with your Project Officer and the RO scientific staff in developing the survey justification and in designing the survey methodology and information collection instrument(s) to be used in the project. However, whether or not you choose to use/work with RO staff, you are required to complete this part of the approval process.

Once you consider both the contents and formatting of the documents described below in final draft form, submit them to your Project Officer. CMS has two expectations related to these documents:

- The draft submitted must be a final draft. That is, complete, thorough and, in the case of the instrument, ready in both content and format to be pilot-tested or fielded, once RO review and approval have been completed.

- The draft submitted must represent the best work of the QIO. That is, it should not be simply the best that the person in charge of the related project can do but the best that the organization as a whole can do. This means that relevant internal expertise should be applied to the development and review of the contents of the information collection justification, methods, instrument, and, when necessary, beneficiary notification letter. If such expertise/experience does not exist within the QIO, then CMS expects that the QIO will engage appropriate outside consultation to ensure that the documents sent to the RO for review meet or exceed RO expectations.

12660.01 - Regional Office (RO) Approval of Information Collection Documents - Justification, Methods, and Instrument

(Rev. 7, 08-15-03)

A. Information Collection Justification -- The justification for the information collection activity has two objectives: first, to provide a clear statement of the purpose of the activity, and second, to demonstrate the need for the information collection. No information collection activity will be approved unless these two objectives are met.

- The Statement of Purpose should show why it is important/necessary to do the proposed information collection activity, that is, what value will be added to the project and why perceived returns justify the investment in/resources used by collecting this information. The justification should provide a:

    - Brief statement of the purpose of the project and explanation of the circumstances that make the survey necessary/integral to the successful completion of the project. This statement should also clearly address why collection of new information related to your targeted population is necessary. It should also include relevant characteristics and aspects, relative to the population/project that the results of this activity help you understand.

    - Description/summary of the overarching questions that the information collection activity is designed to address. Include the QIO's conceptual-/design-type purpose/thinking that is driving the proposed collection activity. DO NOT include the specific inquiries or probes that are proposed for the instrument.

    - Discussion of the purpose for which the information gained from the activity will be used, including how and by whom the information will be used. This should also describe situations in which your project and/or information collection results may be used at an aggregate level (e.g., regional, national, etc.). Make clear how responses to each of the above questions will be used relative to improving health care/health outcomes for Medicare beneficiaries.

    - Description of the population that will be the subject of the information collection activity.

    - Information about the source of the proposed activity's concept/design, if it has been imported from another organization, agency, etc.

    - If applicable, justification for any questions of a sensitive nature, such as regarding 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. You can obtain these documents from the Internet at: http://www.whitehouse.gov/omb/inforeg/statpolicy.html

- The Demonstration of Need should show why the QIO cannot get the information elsewhere or in some other way. This part of the justification should:

- Describe the process you 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, CDAC chart reviews, Behavioral Risk Factors Surveillance Survey, National Health Information Survey, Medicare Current Beneficiary Survey, Health Plan Employer Data and Information Set, other QIOs' projects/surveys, etc.).

- Describe your efforts to identify similar information collection activities previously conducted by you or by another association, organization, or agency. If any similar information is available, show specifically why it cannot be used or modified in order to fulfill the objectives described above. List resources searched.

Provide estimates of the cost to the Federal government for the survey (Annualize the cost, if applicable). This means actual costs, not labor hours, but should include, as best you can, components of costs (e.g., labor hours in developing and testing the instrument, cost of any consultant involvement, cost of analyzing data and writing up reports, etc.).

B. Information Collection Methods -- The methods to be used in different aspects of designing, administering, and analyzing the information collection activity, such as the sampling strategy, development of questions/queries, maximizing response rates, administering the instrument, and analyzing the collection data, need to be clearly and thoroughly documented. At a minimum, this documentation should address instrument design and administration and data analysis.

NOTE: You are encouraged to consult with individuals or organizations with specialties in designing, collecting, and analyzing data that can be collected through the information collection activity you propose.

- Design/Development

    - Sampling strategy -- Describe the type of sampling to be done (e.g., non-probability sampling such as convenience sampling, purposive or purposeful selection, etc.; probability sampling such as simple random sample, stratified random sample, cluster sample, etc.).

        - Provide sample size calculations based on population size (sampling frame), prevalence of the study variable(s), confidence levels/intervals, and estimated non-response rates. Include sampling accuracy (sample size and associated power) needed for the purpose described in your Information Collection Justification and describe any unusual problems requiring specialized sampling procedures.

        - Provide a description of the sampling methodology, including how interviewees will be selected. Address whether proxies will be interviewed and any exclusion criteria used for interviewees.

        - If a sampling strategy will be used that does not allow for generalization, the rationale needs to be provided as does how the utility of the data collected will be affected.

    - Questions -- Include a description of any tests of procedures or methods to be undertaken to assess reliability and validity of questions to be developed.

NOTE: You are strongly encouraged to use measures that have already been developed and tested and are in the public domain, rather than creating new measures. You are also encouraged to use an experienced consultant when developing new questions. The RO may request the resumes of any consultants you use.

    - Accuracy/validity -- Show that the accuracy and reliability (of the data being collected) are expected to be adequate for intended uses. Describe how the instrument will be pre-tested for reliability and validity.

        - Describe possible sources of bias and how you will deal with them. Provide justification for any collection that will not yield reliable and valid data that can be generalized to the units studied.

    - Field-testing -- Describe how the information collection instrument has been or will be field-tested. If the instrument has not been or will not be piloted, provide a rationale for this approach.

    - Response rates -- Describe expected response rates for the collection as a whole, and upon what evidence you base this estimate. Include the actual response rates if any entity has previously conducted a similar collection.

        - Describe methods to maximize response rates and to deal with issues of non-response.

- Implementation/administration

    - Use of technology -- Describe any use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology that may reduce the burden on the respondent.

    - Instrument administration -- Describe the process by which the instrument will be administered (e.g., mail, in-person, telephone). Describe who will be conducting the survey. If a subcontractor will be used, provide a resume or description of the subcontractor, including survey experience.

- If the survey is to be self-administered, possible biases should be included above in the accuracy/validity discussion. If the instrument is to be administered by telephone or some other technological method (see immediately above), possible biases related to the method of administration must also be included in the accuracy/validity discussion.

- Give an estimate of how long it will take for the respondent to provide his/her responses to the instrument, if a questionnaire is used, or time that participation will take for activities such as focus groups.

- Honoraria or other types of compensation for participants' time are not permissible. Meals are only permissible if the participants are required to work through lunch. It is recommended that all instruments, including those administered to focus groups be of a reasonable length.

- Confidentiality -- Describe the procedures you, your subcontractors, and your consultants will employ to maintain respondents' confidentiality and the confidentiality of all data collected, including hard copy and computer files.

➢ Data Analysis

- Data analysis strategy/plan -- Briefly discuss how you plan to analyze the data, including use of statistical methods, statistical testing, adjusting for possible biases, etc. This discussion should also include which tests might be used for which objectives of the analysis.

  - The plan should address both qualitative and quantitative analyses, as appropriate, and include any plans for interim analyses (e.g., process or implementation evaluations).

  - If applicable, describe how information collected in the survey will be used to account/adjust for confounders in multivariate regression models.

  - The connections between questions driving the need for this information collection activity, the data the QIO wants to collect, and the analysis of that data should be clearly and logically laid out. You should also describe the use of the information to be developed from the collected data.

C. Information Collection Instrument -- Provide an exact copy of the entire proposed survey questionnaire. The instrument should be the final draft version. Certain information in the introduction to the instrument is mandated and must be provided to the respondent before the instrument is administered. Most importantly, this language lets respondents know that opting out of participating will have no effect on the respondent or responding institution.

If a cover letter is sent to possible respondents and includes the language below, it must be repeated in the introduction to the survey instrument when the instrument is to be self-administered by the respondent. If the instrument is administered during a telephone interview, the introductory language must be repeated when the actual administration takes place, even if the language has been provided previously (e.g., when calling the respondent to set an interview time). (We suggest using some form of preliminary notification in all information collection activities, both as an advisory and possible means of increasing participation and getting better data.)

- Required Language Introducing Information Collection -- When providing the required information to the respondent, you should adhere to the following language as closely as possible (i.e., as appropriate and makes sense):

    - The information provided by the respondent is voluntary.

    - The identification of the respondent and the information provided by the respondent are confidential.

    - 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. (It is less confusing if this language is adapted to the type of respondent: if a beneficiary, use “his/her benefits;” if a respondent is responding on behalf of a provider, practitioner, etc. (i.e., has some institutional relationship), use “the institution’s reimbursements.”)

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

    - The name of the QIO collecting data.

    - Information to enable the respondent to contact the requestor (toll-free/collect phone number, or name and address), if he/she has questions or wants further information about the survey. Depending on the medium through which the respondent provides answers to the instrument, contact information could include electronic media such as an email address or Web site.

Format/submission -- Use the Information Collection - Activity Approval template (See Exhibit 12-2). The information submitted must be sufficient enough (as described above)

that RO staff can understand the justification for the information collection activity, the methods to be used, and the data analysis to be done. CMS is looking for well thought out and thorough content, presented clearly and concisely; there is, however, no suggested page length for these documents. The submitted instrument must be the final draft version, with all formatting complete. The supporting documentation must be submitted electronically to your Project Officer. If you want to submit the document via any other mechanism, you must get approval from your Project Officer.

Your Project Officer, in consultation with the RO scientific staff, must approve the information collection instrument(s) and all supporting documentation, prior to your implementation of the actual information collection activity. You may, therefore, want to consult with RO staff as you are developing these documents.

Timeline -- Your Project Officer will have fifteen (15) business days from receipt to review the justification and methods documents and the instrument(s) and to provide a decision to you. The RO may ask you to submit additional information. The RO will then have another fifteen (15) business days from the date of resubmission to review your documentation and to provide a decision.

Conflict resolution -- The RO Associate Regional Administrator for Clinical Standards and Quality will resolve any disagreements between you, the Project Officer, and/or the RO scientific staff on the documentation provided to support the information collection activity and the actual instrument(s).

NOTE: If you have discussed your proposed activity with your Project Officer and/or Scientific Officer(s) and expect your concept/idea to be endorsed by the RO, begin work on the required documents (justification, methods, instrument) at the same time that your proposed activity's concept/idea paper is under review by the RO and your Request for Exception, if required, by the RCO. If the RCO determines that the project is subject to the requirements of 5 CFR 1320, and you choose to submit your project to OMB for formal review, you will be required to include the information described in §12660 of this instruction with your submission to OMB. Work with the RO and the RCO to prepare a Request for OMB Review, supporting statement, and related materials.

12670 - Additional Considerations When Medicare Beneficiaries Are Respondents –

(Rev. 7, 08-15-03)

The CMS approval process involves one more mandatory step and submission of one more document if the targeted respondents include any Medicare beneficiaries. The QIO's implementation of the information collection activity involves two more steps.

A. CMS Approval -- If beneficiaries are proposed as respondents, you must notify each potential beneficiary respondent in advance of contacting him/her to administer the

instrument. The purpose of the notification is to give the beneficiary advance warning of the activity and the opportunity to opt out of participating.

- Beneficiary Notification Letter -- The letter that you propose sending to the beneficiary must be approved by the RO and must go out under the signature of your CMS Regional or Consortium Administrator.

- RO review of the Beneficiary Notification Letter may occur simultaneously with the RCO's review of your Request. It must be submitted to your Project Officer in final draft form and must include the following information:

    - Identification of your organization (e.g., the State's Quality Improvement Organization for the Medicare program).

    - Description of the nature of the survey (e.g., the purpose of the survey, how the instrument will be administered, e.g., by mail or telephone, etc.).

    - Voluntary nature of the beneficiary's participation (i.e., informing the beneficiary that he/she is under no obligation to respond to the survey).

    - Assurance that the decision to respond or not to respond will in no way affect the beneficiary's Medicare (or Medicaid, where applicable) benefits.

    - Assurance that the beneficiary's identity and the responses provided by him/her are confidential and that all information provided is protected by the Privacy Act and by the QIO confidentiality statute at §1160 of the Act, and the QIO confidentiality regulations at 42 CFR Part 480. Copies must be provided upon request.

    - Contact information: a toll-free or collect telephone number with the name of a contact person at the QIO whom the beneficiary can call if he/she has additional questions about the survey or wants to exercise his/her right not to participate in the survey (See §12670.B).

    - Date letter is to be sent to the beneficiary.

    - (Optional) You may also want to include the tentative time period that the beneficiary can expect to receive a mailed instrument or be called for a telephone interview. For example, if the notification letter is received by the beneficiary the first week of October, then the letter might inform him/her to expect to be contacted or receive a mailing no later than the middle of November.

Format/submission -- The draft submitted to the Project Officer must be in letter format and must be a final draft version. The Project Officer and Associate Regional Administrator for Clinical Standards and Quality will review and approve the content and

format of the Beneficiary Notification Letter prior to its being submitted for the Regional or Consortium Administrator's signoff. Work with your Project Officer to secure the proper CMS authorization and signature for the letter.

The letter must be written on CMS letterhead, but may be mailed in an envelope using your return address. RO staff will make sure the letter is properly formatted according to CMS standards and will return the signed original to you.

Timeline -- Your Project Officer will have fifteen (15) business days from receipt of the letter for the Project Officer and Associate Regional Administrator to review. If they have suggestions, changes, etc. that need to be made, the Project Officer will return the letter to you for modification. You are encouraged to model your Beneficiary Notification Letter after previously approved letters, so as to expedite the review and clearance processes. Once the Project Officer has received the revised letter, he/she has 15 days again for DCSQ review and to get the letter reviewed and signed by the Regional or Consortium Administrator.

As with other documents that must be submitted as part of the CMS information collection approval process, you should consider the time required for this letter's review and clearance when planning your information collection activity. Also, once your Project Officer has endorsed the information collection proposal, the notification letter can be submitted for review when submitting the documents supporting the activity or when the Request for Exception is sent to the RCO.

Conflict resolution -- The RO Associate Regional Administrator for Clinical Standards and Quality will resolve any disagreements between you and the Project Officer related to the Beneficiary Notification Letter. Decisions made by the ARA about the letter content, editing, formatting, etc. are final.

B. Additional Required QIO Information Collection Steps When Beneficiaries Are Respondents

- Pre-notification of Beneficiaries -- A Beneficiary Notification Letter must be sent to every beneficiary who could possibly be contacted to participate in the information collection activity. These letters must be sent in such a manner that they are received by the beneficiary at least fifteen (15) calendar days prior to the implementation of the activity. This timeframe is necessary in order to allow the beneficiary time to contact the QIO if he/she chooses not to participate and/or does not choose to be contacted for this or any other similar activity.

- Beneficiary No-Contact List -- Any beneficiary who informs the QIO that he/she does not want to participate in this activity must be entered onto a No-Contact List. This list must be maintained by the QIO at all times, since in the course of your work, you may encounter beneficiaries who indicate that they prefer not to participate in information collection or other activities that would require you contacting the beneficiary.

- The List must include each beneficiary's:
    - Name
    - Health Insurance Claim (HIC) number
    - Address
    - Date of birth
- Before any activity that would require direct contact with identified beneficiaries, including activities that require a Beneficiary Notification Letter, this list must be reviewed and any listed beneficiary removed from the sample/outreach mailing/etc. No beneficiary who is on the list should ever be contacted.
- Upon request from CMS, you must provide to CMS the name, HIC number, address, and date of birth of all beneficiaries on your Beneficiary No-Contact List. Personal information in the possession of CMS is protected from disclosure to third parties by the Privacy Act.

Exhibit 12-1

Information Collection (IC): Proposal Approval

IC Proposal Submission

Organization: _____ Type of IC Activity: _____ Date Submitted: _____
(e.g., survey, focus group, etc.)

IC Title: _____ Quality Improvement: Task # _____ Project Title: _____

PROPOSAL SUBMISSION (intent/concept/request for exception)	**Provide the following information clearly and concisely (one-half page).** The QIO is responsible for ensuring that all requirements included in the QIO Manual are addressed below.

Information Required	Information Provided by QIO
1a. For possible "clinical" exemptions (See §12650 of QIO Manual for more information on items not subject to OMB clearance), provide the clinical topic or the patient care outcome which is the focus of quality improvement 1b. For possible "audit" exemptions (See §12650 of QIO Manual for more information on items not subject to OMB clearance), provide evidence of, or results from, previous audit activities	
2. General intent/purpose of proposed IC activity, including: ▫ Key questions QIO wants to answer ▫ Role of information in intervention design/implementation and/or evaluation ▫ Population of interest	

3. Opportunity for improvement identified in the quality improvement project (Required for all proposed IC activities not targeting Task 1 quality indicators)	

Exhibit 12-2 - Information Collection (IC) - Activity Approval - (Rev. 7, 08-15-03)

Exhibit 12-2

Information Collection (IC): Activity Approval

IC Justification and Methods Submission

Organization: _____ Type of IC Activity: _____ Date Submitted: _____
(e.g., survey, focus group, etc.)

IC Title: _____ Quality Improvement: Task # _____ Title: _____

Information Collection Justification	**Provide the following information clearly and concisely.** The QIO is responsible for ensuring that all requirements included in the QIO Manual are addressed below.

Information Required	**Information Provided by QIO** The QIO is responsible for ensuring that all requirements included in the QIO Manual are addressed below.
1. Statement of Purpose	
a. Purpose of clinical/audit project, including: ▫ Circumstances that necessitate information collection (IC) activity	
b. Questions IC activity is designed to address	
c. Purpose for which information resulting from IC activity will be used, including:	

▫ How information will be used ▫ By whom information will be used ▫ Use of information at aggregate levels	
d. Population that will be subject of IC activity (i.e., respondents) ▫ Also address what the IC activity will help QIO understand about the population	
e. Source of proposed activity's concept/design, if imported from other entity	
f. Justification for any questions of sensitive nature, if applicable	
2. Demonstration of Need	
a. Process used to verify that desired information is not elsewhere available	
b. Efforts made to identify similar IC activities previously done by you QIO or another entity ▫ If existing, explain why information cannot be used or modified to fulfill purposes described in 1. above.	
c. Estimated actual cost to government of proposed IC activity ▫ Annualize, if applicable	

Exhibit 12-2

Information Collection (IC): Activity Approval

IC Justification and Methods Submission

Organization: _____ Type of IC Activity: _____ Date Submitted: _____
(e.g., survey, focus group, etc.)
IC Title: _____ Quality Improvement: Task # _____ Title: _____

Information Collection Methods	**Provide the following information clearly and concisely.** The QIO is responsible for ensuring that all requirements included in the QIO Manual are addressed below.

Information Required	**Information Provided by QIO** The QIO is responsible for ensuring that all requirements included in the QIO Manual are addressed below.
1. Design/Development	
a. Sampling strategy ▫ Sampling accuracy ▫ Unusual problems requiring specialized sampling procedures ▫ Sampling methodology ▫ Exclusion criteria for interviewees ▫ Use of proxies ▫ Rationale for use of non-generalizing sample and effect of such a sample on utility of data	
b. Information collection questions ▫ Tests, etc. used to assess reliability and validity of questions	
c. Accuracy/validity ▫ Adequacy for intended uses ▫ Possible sources of bias and how dealt with, including related to instrument administration	

▫ Rationale for any collection that will not yield reliable/valid data	
d. Field-testing ▫ Rationale if instrument has not been or will not be tested	
e. Response rates ▫ Expectation and evidence for such ▫ Actual response rates if previous experience with same/similar effort ▫ Maximizing response rates ▫ Dealing with non-response	
2. Implementation/Administration	
a. Use of technology	
b. Instrument administration ▫ How and by whom ▫ Information about subcontractor, if appropriate ▫ Explain any decision to pay or gift respondents	
c. Confidentiality procedures	
3. Data Analysis	
a. Data analysis strategy/plan ▫ Statistical methods ▫ Statistical tests ▫ Adjusting for biases ▫ Special consideration should be given to: connections between questions laid out in information collection	

purpose, proposed data to be collected and analysis of those data ▫ Use of information to be developed from data collected	