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
16		Table of Contents	
16		16000 - 16100	

NEW/REVISED MATERIAL - EFFECTIVE DATE: July 11, 2003

Section 16000 - Introduction describes the goal of the Health Care Quality Improvement Program.

Section 16005 - Quality Improvement Project (QIP) Process defines and lists the necessary elements of improvement projects.

Section 16010 - Selecting a Clinical Topic is deleted.

Section 16015 - Identifying Quality Measures is deleted.

Section 16020 - Measuring Baseline Performance on Quality Measures is deleted.

Section 16025 - Developing and Conducting Interventions discusses activities meant to change a process, situation, or behavior in the context of quality improvement projects.

Section 16030 - Re-measuring Performance on Quality Measures is deleted.

Section 16035 - Documenting and Disseminating Results describes methods for quantifying, evaluating, and assessing project results as well as the importance of feedback on shared findings while ensuring confidentiality of participants.

Section 16050 - CMS Project Support and Guidance Activities describe CMS-provided baseline and re-measurement data and assistance from QIO Support Centers (QIOSCs).

Section 16100 - Related Activities Through QIO, Carrier, Intermediary, and ESRD Network Cooperation encourages a spirit of collaboration with your many partners.

Section 16200 - Background was removed from Chapter 16 and added to Chapter 12 as §12600.

Section 16210 - CMS/Office of Clinical Standards and Quality Requirements was removed from Chapter 16 and added to Chapter 12 as §12610.

Section 16220 - Statutory and Regulatory Requirements was removed from Chapter 16 and added to Chapter 12 as §12620.

Section 16230 - Definitions was removed from Chapter 16 and added to Chapter 12 as §12620.

Section 16240 - Office of Management and Budget (OMB) Clearance was removed from Chapter 16 and added to Chapter 12 as §12630.

Section 16250 - Items Not Subject to Office of Management and Budget (OMB) Clearance was removed from Chapter 16 and added to Chapter 12 as §12630.

Section 16260 - Request for Exception From Office of Management and Budget (OMB) Review was removed from Chapter 16 and added to Chapter 12 as §§12640 and 12650.

Section 16270 - CMS Approval Process - Approval of Actual Activity: Information Collection Justification, Methods, and Instrument Submission was removed from Chapter 16 and added to Chapter 12 as §12660.

Section 16280 - Additional Considerations When Medicare Beneficiaries are Respondents was removed from Chapter 16 and added to Chapter 12 as §12670.

Section 16300 - Publications Policy was removed from Chapter 16 and added to Chapter 12 as §12500.

Section 16310 - Definition was removed from Chapter 16 and added to Chapter 12 as §12510.

Section 16320 - Requirements was removed from Chapter 16 and added to Chapter 12 as §12520.

Section 16330 - Disagreements was removed from Chapter 16 and added to Chapter 12 as §12530.

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 16 - Health Care Quality Improvement Program

TABLE OF CONTENTS (Rev. 3, 07-11-03)

16000 - Introduction
16005 - Quality Improvement Project (QIP) Process
16025 - Developing and Conducting Interventions
16035 - Documenting and Disseminating Results
16050 - CMS Project Support and Guidance Activities
16100 - Related Activities Through QIO, Carrier, Intermediary, and ESRD Network Cooperation

16000 - Introduction - (Rev. 3, 07-11-03)

The main objective of CMS' Health Care Quality Improvement Program is to analyze data from various sources and change the patterns of care in targeted areas. CMS chooses these areas based on their public health importance and on the feasibility of measuring and improving quality.

16005 - Quality Improvement Project (QIP) Process - (Rev. 3, 07-11-03)

A. Definition -- The definition of a Quality Improvement Project (QIP) evolves from the definition of a quality review study contained in 42 CFR 480.101. The regulations define a quality review study as "an assessment, conducted by or for a QIO of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem, and follow-up." Moreover, a QIP is a set of related activities designed to achieve measurable improvement in processes and outcomes of care. Improvements are achieved through interventions that target health care providers, practitioners, plans, and/or beneficiaries.

You are encouraged to be innovative in the development of project strategies and to build on project activities that other QIOs or other interested parties have developed and tested. You are accountable for demonstrating success in achieving the objectives in as efficient and effective manner as feasible. Continually evaluate your progress against the original objectives. Clearly document your project (see Chapter 8) so that your experiences can contribute to a growing understanding of what works and what does not work to improve care.

The names of participants in collaborative QIPs constitute quality review study information subject to the strict confidentiality provisions of 42 CFR 480.140 (see Chapter 10).

B. Elements of Improvement Projects -- The key elements of a project are to:

- Select a clinical topic;
- Identify quality of care measure(s). Quality of care measures (or quality measures) are also referred to as quality indicators;
- Measure baseline performance on quality measures;
- Develop and conduct interventions designed to affect the quality measure in the desired manner;
- Re-measure performance on the quality measures; and
- Document and disseminate results.

For the core QIO contract, CMS selected the clinical topics, identified the measures, and established the baseline and re-measurement strategies (See §16050). QIOs are charged with identifying and implementing intervention strategies to improve provider performance on those measures as well as documenting and disseminating their project results (See §§16025 and 16035).

If a QIO chooses to identify additional clinical topics on which to focus (with approval from CMS for a special study), the QIO should consider the key elements outlined above.

C. Improvement Projects Versus Research Studies -- In general, improvement projects should rely on scientific evidence from clinical research reported in the peer-reviewed literature, consensus that has already been developed, and, where possible, guidelines that have already been written. Carrying out improvement projects may involve applying the results of research studies and may utilize many of the tools and terminology of epidemiological, clinical, or health services research. However, they should not involve:

- Efforts to prove that a process of care is effective or ineffective; or
- Development of practice guidelines.

16025 - Developing and Conducting Interventions - (Rev. 3, 07-11-03)

The QIO is responsible for developing and conducting project interventions. The interventions you use in quality improvement projects should serve to change the processes or situations that serve as obstacles to optimal care or health status (e.g., those that discourage implementation of best practice guidelines). The success of an intervention is judged by its effect; that is, a good intervention is one that results in a positive change in the process, situation, or behavior. Your interventions must be designed to affect the practices or behaviors of those institutions or individuals directly involved in the provision and/or acceptance of health care.

Interventions are best when they are evidence-based and when you can propose methods to facilitate improvement. For example, if you can statistically demonstrate to representatives of a particular hospital that its average time to thrombolytic for acute myocardial infarction patients is significantly higher than that of the State and, at the same time, suggest changes in hospital practices that are designed to reduce that time, you will have a greater likelihood of success. You may use written communications, discussions with individual providers, presentations at conferences or special meetings, media releases, Web page presentations, or any of the communication devices available.

You should direct your intervention efforts toward convincing your target audience to make the appropriate change(s). In some instances, your intervention may directly target the individual or institution whose behavior you wish to change (e.g., a direct contact with beneficiaries designed to increase the flu immunization rate) while in other cases the intervention will be less direct (e.g., encouraging hospitals to institute procedures that promote flu immunization for all patients).

In developing and/or implementing intervention(s), you should take advantage of work that preceded your particular project. The Quality Improvement Organization Support Center (QIOSC) will be able to provide this type of information (See §16050). During the course of a project, you may determine there are additional target audiences or decide to redesign your intervention for a particular group based on your growing experience in the area.

16035 - Documenting and Disseminating Results - (Rev. 3, 07-11-03)

In addition to satisfying the reporting requirements specified in your contract, there are a number of activities you may undertake following completion of a project to document and disseminate your project results. For example:

- Quantify the effect of the project on improving care by addressing:
    - The number of beneficiaries and proportion of the universe of eligible beneficiaries in the State directly affected;
    - Expected cost savings (if applicable); and
    - The benefit(s) attributable to this project.
- Evaluate the project process by:
    - What worked and what did not work;
    - What factors associated with success or failure; and
    - Lessons learned.
- Assess the effect of the project on the capacity to affect improvement:
    - What factors led to capacity building; and
    - What obstacles were overcome or proved insurmountable.
- Share information concerning your improvement projects with individual partners, the medical and beneficiary community, and other QIOs, as appropriate. The information shared must conform to all QIO confidentiality requirements (See Chapter 10). Additionally, all publications must conform to the information collection and communications requirements (See Chapter 12) and to the HHS/CMS Outreach Publications Policy specified in your contract.

16050 - CMS Project Support and Guidance Activities -

(Rev. 3, 07-11-03)

CMS may direct all QIOs (or all QIOs in a region) to conduct quality improvement projects using standardized clinical topics. When this occurs, CMS is responsible for identifying the clinical topics and indicators and providing baseline and re-measurement data. In these projects, you are responsible for developing and implementing interventions and documenting and disseminating results. Your flexibility on these projects is more limited, and you will receive added guidance and direction from CMS, in addition to what is detailed in this Manual instruction. This section describes some of the project support and guidance that CMS furnishes on these national projects as well as details on what the QIO must accomplish in order to meet its contract requirements.

A. Standardized Baseline and Re-measurement Data -- CMS may determine the indicators that will be used in a particular project and, in those instances, will supply standardized baseline and re-measurement data for each QIO. These data may reflect different levels of aggregations, including national and/or regional averages, State-specific averages, identifiable sub-population averages (e.g., by gender, age, race or ethnicity, urban or rural residence, etc.), and/or provider-specific indicator measurements. When CMS supplies only some of these levels of aggregated data and the QIO determines that it would be useful to generate other levels of data, it should inform its Project Officer of these data needs and propose a method for generating the additional data in the most valid and cost-effective manner.

B. QIO Support Center (QIOSC) -- For certain topics, settings, populations, and project processes, CMS contracted with a single QIO to provide support for CMS and all QIOs in that particular area. The QIOSC will work in conjunction with the Topic Area Team (TAT) to make some or all of the following items available to all QIOs to support their project activities: information on the clinical topic (e.g., scientific, relevant activities of various organizations) from other QIOs, outside experts, etc.

- Information identifying vulnerable populations with:
    - Higher than average prevalence for the clinical condition;
    - Higher than average adverse outcomes due to the clinical condition; and/or
    - Lower than adequate health care services related to the clinical condition due to factors such as race/ethnicity, socio-economic status, language/cultural barriers, geographic location, and health status or physical disabilities.
- Training programs on such topics as defining quality indicators, abstraction tools, intervention approaches based on best practices, and using analysis software and/or other tools developed by the QIOSC.

- Revised national process and outcome measures (including risk adjustment methodologies) and additional measures relevant to quality improvement activities for the clinical condition (e.g., measures appropriate for other provider settings, special populations).

- Revised data collection instruments, data dictionaries, database specifications, etc., for national performance measures and additional measures relevant to quality improvement activities for the clinical condition.

- Standard data analysis software and consultation on its use.

- Information on relevant intervention-related activities, distinguishing effective practices (what works) and lessons learned (what does not work), distinguishing health care settings (e.g., managed care organizations, home health agencies, physicians' offices, outpatient facilities, skilled nursing facilities, nursing homes, ESRD facilities, etc.), and distinguishing major population groups, including vulnerable populations.

16100 - Related Activities Through QIO, Carrier, Intermediary, and ESRD Network Cooperation - (Rev. 3, 07-11-03)

As directed by CMS, cooperate with carriers, intermediaries, and ESRD Networks in your area by combining appropriate resources to identify provider/practitioner/plan variations in medical necessity, appropriateness of setting, Diagnosis Related Groups (DRG) validation, coding, and quality of care issues that have the potential for cooperative quality improvement project development.