

Guide to Review of Quality of Care Issues for Physician Reviewers

Introduction for the Case Review Manager

The 7th Scope of Work (7SOW) has brought many changes to how QIOs perform their work. As part of this, the Beneficiary Complaint Response Program has been updated to provide a more systematic approach to identifying quality concerns. This has resulted in the development of a guide for Physician Reviewers: The **Guide to Review of Quality of Care Issues for Physician Reviewers** (called the “**Self-Study Guide**” hereafter). This guide has been developed to help Physician Reviewers (PRs) and others within each QIO to better understand the Response Determination Categories implemented for the 7SOW, and how to use them to make a determination *in any case involving quality of care issues*. All Physician Reviewers at each QIO should be trained in the use of these categories using this Self-Study Guide. It is also advisable for the Review Case Management staff to be trained in the use of these materials since they work directly with cases which must be assigned to these categories.

The Self-Study Guide contains the following pieces: Introduction to the Process for PRs, a Detailed Explanation of the Response Determination Categories, with Examples, a Quick Reference Guide on the Categories for PR use, a Flow Chart for PRs of the Process, a Self-Test, and a Reference Section. This Self-Study Guide has also been updated to reflect the changes resulting from the revisions in the Actions implemented in April, 2003.

The Reference section of this training material contains the latest QIP TOPS (Number: QIO 2003-xx) which describes the Revised QIO Case Review Process for Quality of Care issues, the Response Determination Categories and the April 2003 changes. It also contains the current Physician Reviewer Assessment Form (PRAF) and flow charts outlining all the steps of the review process.

The Medical Director, or Physician Consultant responsible for overseeing the quality of PR reviews, should review and become familiar with the contents of this guide. CMS recognizes that there may be variation in community standards used for determining quality issues in cases due to regional practice differences. The Medical Director should ensure that the responses provided for the examples and the self-test cases are consistent with community practice within each QIO. If you note any inconsistencies, the Guide should be updated to better reflect the style of practice within each state. The MBP QIOSC should be notified about the changes made and the rationale for these changes. The MBP QIOSC may incorporate these in later updates.

The Medicare Beneficiary Protection QIO Service Contractor (MBP QIOSC), at the request of CMS, has developed these materials to assist in training PRs and other reviewers on the Response Determination Categories. The MBP QIOSC is available to provide you with technical assistance on the implementation of these categories throughout the 7th Scope of Work. Please feel free to contact the QIOSC with questions or suggestions for improving this Guide.

MBP QIOSC Team:

Sue Jackson, Project Manager
415-677-2120
capro.sjackson@sdps.org

Mary Giammona, MD, MPH Medical Director
415-677-2110
capro.mgiammona@sdps.org

Amy Lerner, Training Manager
415-677-2115
capro.alerner@sdps.org

Wm. Patrick Neace, Project Coord.
415-677-2137
capro.wneace@sdps.org

Introduction for Physician Reviewers (PRs)

When providing peer review for cases with potential Quality of Care concerns, the PR is responsible for determining whether the quality of care rendered met professionally recognized or expected standards of care. As you can probably see, you have a **crucial role in Case Review**. And this role is expanded further, in the 7th Scope of Work (the QIO contract with the Centers for Medicare and Medicaid Services-CMS). Now, a *revised process for determining quality of care issues* has been introduced by CMS. This process places greater emphasis on a **systematic approach** to evaluating potential quality issues, for beneficiary complaints, and *any other quality cases*. In this process, PRs apply Response Determination Categories (RDCs) for each concern, select a general quality of care or “C” category for the concern and then propose an Action to be taken.

This *revised process* may appear similar to the assigning of levels that occurred in earlier scopes of work. However, because the focus in the 7SOW is **quality improvement**, the current process is quite different and ***not the same at all as the process of the past***, for it is looking at categories and improvement, rather than focusing on severity of concern. As any of you who are longstanding Physician Reviewers for the PRO/QIO program probably recall, the old process of assigning levels of severity was extremely unpopular in the medical community. That is why it is so important to stress that, while perhaps having some similarities structurally to that old process, the current process is very different. The emphasis now is on ways to work **with** physicians and practitioners in our communities so together we can improve the quality of care for our Medicare beneficiaries.

This Self-Study Guide has been developed to provide guidance for the application of the RDCs that are utilized for peer review of quality issues. This version of the Self-Study Guide has also been updated to incorporate the revisions that have been made in the Actions that PRs propose after selecting an RDC. These changes, implemented in April 2003, give more flexibility to the PR in specifying what proposed action is recommended to best address a quality of care concern. This Self-Study Guide relates only to the review of **quality** concerns within a case. Training on review of other issues is addressed separately by your QIO.

Please note also that this Self-Study Guide does NOT address or include instruction on the US Court of Appeals’ June 2003 decision in Public Citizen v. Thompson. Any necessary information on this decision is to be provided to you separately by your QIO, as well.

This Self-Study Guide DOES contain the following pieces: Introduction to the Process for Physician Reviewers (PRs), a Detailed Explanation of the Categories, with Examples, a Quick Reference Guide on the Categories for PR use, a Flow Chart for PRs of the Process, a Self-Test, and a Reference Section.

The Reference section of this training material contains the latest QIP TOPS (Number: QIO 2003-xx) which describes the Revised QIO Case Review Process for Quality of Care issues, the Response Determination Categories and the April 2003 changes. It contains the current Physician Reviewer Assessment Form (PRAF) and flow charts outlining all the steps of the review process, as well.

A psychiatric specialty example has also been added to the Self-Test, at the request of a number of reviewers. In the near future, more examples will be added with representative cases from additional specialties and subspecialties. If you have any comments or suggestions on the Self-Study Guide, please forward them to your QIO, so the Guide can continue to be improved and better serve the training needs of you, the QIO Physician Reviewer.

WHAT ARE THE OBJECTIVES OF A QUALITY REVIEW?

The objectives are:

1. to identify *quality concerns* about care rendered to Medicare patients as well as to identify *practice patterns* associated with positive or adverse outcomes
2. to identify any *systems of practice* that may negatively impact care that is rendered
3. to determine *the source(s)* or individuals, providers, etc. that are responsible for the quality concerns
4. to determine if a *significant departure from the expected standard* of practice has occurred
5. to determine if a *quality improvement plan* is required to ensure quality of care for similar cases in the future is improved
6. to provide *peer advice*, including citations from the medical literature as applicable, to help improve future care

Modified from Health Care Excel's Handbook for Physician Reviewers

WHAT ARE THE RESPONSE DETERMINATION CATEGORIES BEING USED AND HOW ARE THEY APPLIED?

After you review a case, for each concern raised, you will need to determine whether:

- **Care could have been better or**
- **No substantial improvement opportunities are identified**

One of these is the **first set of categories** you will assign, or **Step I**.

If you determine that **Care could have been better**, then you will proceed to the **second set of categories** and, in **Step II**, assign one of the following for each of the concerns:

- **Care was grossly and flagrantly unacceptable**
- **Care failed generally accepted guidelines or usual practice**
- **Care could reasonably have been expected to be better**

Together, these two steps comprise the **Response Determination Categories**.

HOW ARE THE GENERAL QUALITY “C” CATEGORIES ASSIGNED?

Once you have assigned the appropriate **Response Determination Category**, the General Quality “C” Categories are assigned. Your QIO may instruct you to select the applicable “C” category, or the Review Case Manager for the case may have proposed one for each concern, that you need to approve or modify. The “C” categories will be explained in greater detail later on in this Self-Study Guide. “C” categories are assigned to help identify the **underlying cause** or **major reason** for each significant quality concern in a case. This information will then be utilized for data analysis of trends by CMS.

HOW ARE ACTIONS ASSIGNED?

After the Response Determination Category and (if applicable) the “C” category have been determined, the PR is then asked to recommend one or more **actions** that should be taken for each determination in the case. Possible choices range from immediate referral to licensing agencies to recommendations for alternative approaches to improve future care. These will be covered in further detail in the Guide.

Category Determination

The following pages will offer information and some *interactive tools* to help you understand how to assign the Response Determination Categories and the “C” categories for quality of care concerns in a case. As we know, a variety of opinions can exist within the medical profession in determining standards of care in some areas, as well as in creating quality standards. Therefore, in subject areas where clear scientific evidence or data is not available, PRs need to use their clinical judgment and expertise in determining whether any potential quality issues identified are indeed quality of care concerns, and not merely an acceptable practice of medicine which is different from their own style.

LET’S REVIEW IN MORE DETAIL THE STEPS IN DETERMINING CATEGORIES:

There are **three steps** involved when determining which categories to assign to each concern in a case. The first two steps involve the **Response Determination Categories** and the third step involves the **Quality of Care Concern Categories or “C Categories.”**

The **first step** involves the broad or main finding. The **second step** is more specific, identifying the main reason that the broad finding is assigned. The **third step**, which QIOs call “C” Categories, have been in use for several years. Some PRs may already be familiar with these, as they might have used them in the past to code each case. In other QIOs, the Review Case Manager has proposed, and then confirmed these categories after reviewing the PR’s comments. These categories are significant for QIOs and for CMS as they are used to categorize and track trends within and among QIOs.

In **step three**, each concern is generally classified in *one category only*. If the complaint seems to fit more than one “C” Category, you need to make sure that it should not be divided into separate concerns. If it is in fact one concern, aim to choose the category closest to the root cause of the concern.

All of the Steps that were previously described can apply to cases from any review setting such as inpatient, ambulatory surgery, or outpatient care and managed care or fee for service (FFS) (with the exception of C.40 which will be addressed later in this document).

RESPONSE DETERMINATION CATEGORIES—More Details

Adapted from CMS directives

Step I

After reviewing the case, the PR should make a determination about the essential issues within the case. For each concern raised, the PR will determine if:

- **Care could have been better or**
- **No substantial improvement opportunities are identified**

If it is determined, for any possible concern, that *no substantial improvement* was necessary, neither Step Two nor Three is applicable. The category assigned would be:

- **No substantial improvement opportunities are identified**
and the PR would then go to the Action step.

Note: This category should be chosen when the care rendered was excellent. It should also be chosen when care was appropriate, *even if* you might have handled the case differently. Remember, “care could have been *different*” does not necessarily mean “care could have been *better*.” If you would like to inform the physician or provider about another way to handle similar circumstances in the future, you can offer advice (see Action step, below) even while selecting this broad category.

However, if the care could have been **better**, proceed to Step Two

Step II

Here, there are 3 possible categories to assign. They are:

- **Care was grossly and flagrantly unacceptable**

Care is grossly and flagrantly unacceptable when, in the opinion of the Reviewer, if uncorrected, it should result in consideration of enforcement actions related to licensure. Federal regulation, 42 CFR 1004.100 defines the “Serious risk” situations that may involve care that was gross and flagrant. A finding of gross and flagrant errors in care would indicate that initiation of sanction activity should be recommended.

If the case involves unacceptable practices which may result in immediate danger to the health and safety of other beneficiaries, PRs must also recommend immediate reporting to the licensing authority, in addition to recommending initiation of sanction activity. This circumstance exists when the care rendered represents an imminent danger to the health, safety or well-being of the beneficiary, or when the patient was placed unnecessarily in a high-risk situation, which could lead to substantial and permanent harm.

A case does not have to result in actual harm to the patient in order to be classified as gross and flagrant. Regardless of this action, the review process must continue, respecting all requirements and timeframes, to identify any other issues in the case.

Example:

In surgery, the wrong leg was amputated.

- **Care failed generally accepted guidelines or usual practice**

Care fails to follow accepted guidelines or usual practice when, in the view of the Reviewer, it is inconsistent with an explicit guideline, which has been adopted by a reputable organization, or usual practice. The QIO is also responsible to ensure that this individual case review finding is not part of a pattern of care that may support that “a substantial violation in a substantial number of cases” occurred as described in 42 CFR 1004.100.

Example:

A patient with an infection is prescribed a medication known to be ineffective against the causal agent.

- **Care could reasonably have been expected to be better**

Care could reasonably have been expected to be better when the Reviewer believes that best practice involves an alternate approach to either practitioner decision-making, or where a beneficiary could reasonably expect to receive better care.

Example:

The anti-hypertensive regimen prescribed for a patient with difficult-to-control hypertension does not include the most currently recommended combination of medications, which, in the Reviewer’s professional opinion, could result in improved control of the patient’s hypertension.

QUALITY OF CARE CONCERN or “C” CATEGORIES

Step III

Once the initial, broad categories have been assigned, the PR will then be asked to identify the underlying cause of the issue, choosing from a group of possible reasons. These are called General Quality of Care Concern, or “C,” Categories. According to CMS the “C” categories “...define the deficiencies in process which underlie the quality concern. The basis for confirming a quality concern does not depend on the occurrence of a significant adverse effect.” Both physician and non-physician reviewers can use the “C” Categories.

Often, when the PR receives a case, the non-physician reviewer has already assigned a temporary category of concern for each part of the complaint so that the PR can consider these during their review. As you review each concern in a case, it might be helpful to keep in mind the possible Response Determination Category as well as the best choice for the “C” Category. Often there are several “C” Categories that could be assigned. You need to select the one that best represents the major issues for each concern, or that may have led to the sequelae that are identified.

In many QIOs, PRs are already responsible for assigning these categories. Below is an introduction to these categories, excerpted from the *Health Care Quality Improvement Train-the-Trainer Conference, Fourth Scope of Work*.

“...CMS has created the “C” Categories to be comprehensive and mutually exclusive. When you are choosing a category, you need to choose the category that is most significant, and closest to the root cause of the concern. It is recognized that on occasion there might be a concern that truly requires more than one “C” category to be assigned, because of the complexity of the issue, even though it is still one concern. However, this should occur VERY infrequently.

C01- Apparently did not obtain pertinent history and/or findings from examination

This category is used for a failure to provide an accurate history; this is also for failure to include information obtained by the performance of an appropriate physical exam.

Example: a patient with complaints of recurrent dizziness for whom the physician did not note previous medications as part of the history or an adequate neurological examination as part of the physical

C02- Apparently did not make appropriate diagnoses and/or assessments

This category is used for a failure to perform an appropriate assessment and establish a diagnosis.

Example: a patient who is not diagnosed with myocardial infarction even though he has signs and symptoms of acute chest pain, diaphoresis, and EKG changes along with abnormal cardiac enzymes

- C03- Apparently did not establish and/ or develop an appropriate treatment plan for a defined problem or diagnosis which prompted this episode of care (excludes laboratory and/ or imaging [see C06 or C09] and procedures [see C07 or C08] and consultations [see C13 and C14])**
This category is used for a lack of organized, appropriate diagnostic and management plans related to the condition for which the patient was admitted; incomplete, inappropriate, or lack of treatment plan for principle diagnosis.
Example: a patient admitted with cardiac-related chest pain who is not placed on cardiac monitoring
- C04- Apparently did not carry out an established plan in a competent and/or timely fashion (e.g. omissions, errors of technique, unsafe environment).**
This category is used for failure to take necessary precautions; lack of appropriate equipment maintenance; medication errors; technical and/ or procedural errors; failure to follow physician's orders; delayed completion or reporting of studies.
Example: a patient at high risk for falls for whom fall precautions are not instituted and the patient suffered injury from a fall
- C05- Apparently did not appropriately assess and/ or act on changes in clinical/ other status results.**
This category is used for failure to recognize clinical changes which occur in the patient's condition; this category also applies if the clinical changes are noted but not acted on.
Example: a patient whose new finding of respiratory distress is not evaluated or treated
- C06- Apparently did not appropriately assess and/or act on laboratory tests or imaging study results.**
This category is used for a failure to provide ongoing monitoring and evaluation of the patient's laboratory or imaging studies by failing to evaluate and/ or act on diagnostic studies.
Example: a patient who is continued, unchanged, on antibiotic therapy after the organism is found to be resistant to the antibiotic being used.
- C07- Apparently did not establish adequate clinical justification for a procedure which carries patient risk and was performed.**
This category is used for failure to document accepted indications for a procedure.
Example: a patient whose medical record does not substantiate the need for the CABG which was performed.
- C08- Apparently did not perform a procedure that was indicated (other than lab and imaging, see C09).**
This category is used for failure to perform a medically necessary procedure that is indicated by the patient's condition.
Example: a patient demonstrating hemodynamic instability and shock who is not placed on intra-arterial monitoring

C09- Apparently did not obtain appropriate laboratory tests and/ or imaging studies.

This category is used for failure to order diagnostic (laboratory and/ or imaging) studies that are deemed appropriate for the patient's condition.

Example: a patient admitted with chest pain and diaphoresis where cardiac enzymes are not obtained.

C10- Apparently did not develop and initiate appropriate discharge, follow-up, and/ or rehabilitation plans.

This category is used for a lack of follow-up arrangements or plans for conditions continuing to require treatment and/or monitoring prior to or following discharge; failure to develop a plan that reflects an appropriate transition of care; failure to identify additional needed resources; failure to provide appropriate teaching; failure to transmit pertinent information.

Example: a patient with a urinary tract infection still present on discharge who is not continued on antibiotic therapy post-hospitalization.

C11- Apparently did not demonstrate that the patient was ready for discharge.

This category is used for failure to assure that the patient is stable enough for discharge to the setting into which the patient is being discharged.

Example: a patient post-surgery who is discharged with a temperature of 102.

C12- Apparently did not provide appropriate personnel and/ or resources.

This category is used for lack of sufficient staff to handle patient load; lack of credentialed staff for provision of offered services; equipment unavailable to carry out treatment plan.

Example: a patient who undergoes a thyroidectomy without sufficient blood products available in case of hemorrhage.

C13- Apparently did not order appropriate specialty consultation.

This category is used for those cases in which a specialty consultation that would have been necessary to adequately assess and treat the patient was not ordered. If there is a distinct clinical management concern over and above failure to order the consultation, cite that category as well, even if it is C.3.

Example: a patient in deteriorating condition is being treated medically for an obstructed bowel and surgical consultation has not been requested

Another concern may also seem to apply, depending upon the clinical circumstances, such as C.02 (if the diagnosis was missed), C.03 (if the medical regimen was inappropriate), C.04 (if a plan to obtain the consultation was not followed), or C.5 (if the signs of patient deterioration were not assessed or acted upon).

For this type of case, see if there is one "C" category that is really at the root of the problem (e.g. the diagnosis was missed, etc.) Then, choose that as the applicable cause of the concern.

C14- Apparently specialty consultation process was not completed in a timely manner.

This category is used when a specialty consultation is not ordered in a timely manner or is not completed in a timely manner. If the only issue is the delay, do not additionally cite C.03. If there is a distinct clinical management concern over and above the delay in ordering or completing the consultation, cite that category as well, even if it is C.03.

Example: a patient was admitted in unstable condition with acute myocardial infarction. The family physician orders an emergency cardiology consultation but the cardiologist does not respond for 24 hours. Or, for a similar patient, the family physician delays seeking cardiac consultation and the patient does not receive required thrombolytic therapy. Another distinct quality concern may apply about clinical management, and it should also be cited. In the second example, concern about the appropriateness of the treatment plan up to the point of seeking consultation may be categorized under C.03.

C40- Apparently did not follow-up on patient's (non) compliance (only applies to HMO or Managed Care patient)

This category is used when there is no follow-up on patient compliance with a previously prescribed treatment plan for a patient enrolled in an HMO or Managed Care Plan. (Note: Although this could clinically apply to any type of patient, CMS has assigned this only for a managed care patient for tracking purposes.)

Example: a diabetic HMO enrollee is repeatedly seen in the physician's office with uncontrolled diabetes. There is no documentation to confirm that the patient has been following previous diet and insulin instructions.

C99- Other quality concern not elsewhere classified.

This category is used in exceptional cases. The vast majority of cases should be able to fit into the above listed categories.

Note: Since the above listed categories don't address areas where physician documentation, or physician – patient communication needs improvement, C99 can be used until new categories are available.

LET’S REVIEW THE POSSIBLE ACTIONS TO BE RECOMMENDED:

There are *seven possible actions* that may be recommended as a result of the Response Determination Category, (Steps I and II), that you identify. You may recommend **one or more** of the following actions:

1. Initiation of sanction activity

Initiation of sanction activity should be recommended when care is (1) grossly and flagrantly unacceptable (section 1156 of the Social Security Act [the Act]).

2. Immediate referral to the licensing authority

Immediate referral to the licensing authority should be recommended when there is imminent danger to the health and safety of this or other beneficiaries which can not be appropriately addressed through improvement activities (changes in process or education) (section 1160(b) of the Act).

3. Initiation of intensified review activity

Intensified review activity can be recommended for the provider/practitioner when care failed generally accepted guidelines or usual practice that may indicate to the Physician Reviewer that the identified failure could have happened again in similar cases/ situations. This finding may also involve requiring a Quality Improvement Plan (QIP)—see below. If a QIP results in successful improvement, initiation of a sanction action is not needed. However, if there is no improvement, sanction activity should be undertaken as specified in 42 CFR 1001.40. Under the sanction procedures, at the discretion of the QIO, the provider/practitioner may have another opportunity under a corrective action plan to improve the identified failure.

4. Requiring a Quality Improvement Plan

Quality Improvement Plans (QIPs) should be recommended when there is a potential for better care to result from improvement in the system(s) or process of care delivery and/ or practitioner participation in an education program or change in practice. A QIP can be a useful tool in helping providers/ practitioners to better understand how to improve their practice, and can be required with any of the Step II Response Determination Category findings. QIPs are practical in situations where care could be improved through:

- Enhancing systems for the delivery of care
- Educational programs for practitioners
- Opportunities to otherwise improve care

If a QIP plan is created and accepted by all parties, CMS considers the QIO to be responsible for monitoring the progress of the plan’s implementation. The QIO will follow up to determine whether improvement has occurred. If no improvement is observed, the QIO will determine the action(s) that must be taken with respect to the provider/ practitioner to address/ resolve the situation.

5. Recommend that the provider/ practitioner consider an alternative approach to future care.

Recommendations that a provider/ practitioner consider an alternate approach to care should be made when the Reviewer wants to communicate to a practitioner about guidelines or usual practice. Such information can be provided when care was grossly and flagrantly unacceptable, or did not follow guidelines or usual practice, and development of a QIP was not recommended. Recommendations to consider an alternate approach can also be made when the care could reasonably have been expected to be better and a QIP has not been recommended.

This action is appropriate when the care given could have been improved through use of newer techniques, or adoption of new processes. When choosing this action, the PR needs to specify the alternative approach that, in his or her professional opinion, should have been used. In addition, in this situation, PRs may find it helpful to cite the medical literature, or references to new guidelines, or sources for standards of care that were not used by the physician or provider.

6. Offer advice to the provider/practitioner about an alternative approach to future care.

When care was adequate, but could have been optimized by applying a best practice or implementing up-to-date recommendations, then the Reviewer can choose to offer advice about these alternative approaches. This action can be taken when care could have reasonably been expected to be better. It is also the only action that can be chosen when no substantial improvement opportunities are identified, but where knowing about an alternate or different approach to care may be useful educational information for the physician or provider to consider for future cases.

7. No recommendations are made.

When no recommendations are made, no additional action needs to be taken.

Quick Reference Guide to Review Categories and Actions

Response Determination Categories

Step I

- No substantial improvement opportunities are identified (proceed to Action) or
- Care could have been better (proceed to Step II):

Step II

- Care was grossly and flagrantly unacceptable
- Care failed to follow generally accepted guidelines or usual practice
- Care could reasonably have been expected to be better

Quality of Care Concern Categories

Step III

If care could have been better, select a “C” category:

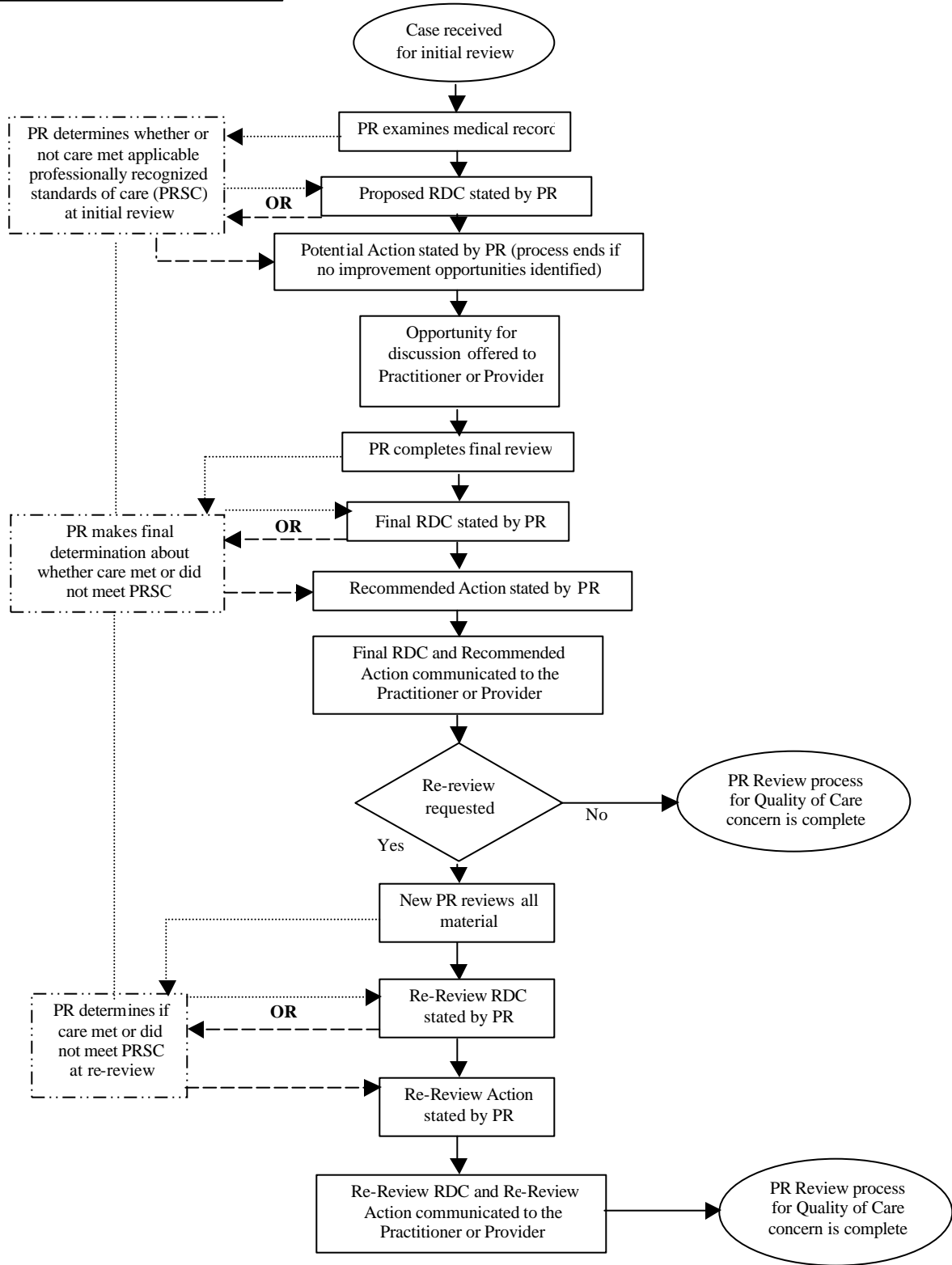
- C01- Apparently did not obtain pertinent history and/or findings from examination
- C02- Apparently did not make appropriate diagnoses and/or assessments
- C03- Apparently did not establish and/ or develop an appropriate treatment plan for a defined problem or diagnosis which prompted this episode of care (excludes laboratory and/ or imaging [see C06 or C09] and procedures [see C07 or C08] and consultations [see C13 and C14])
- C04- Apparently did not carry out an established plan in a competent and/or timely fashion (e.g. omissions, errors of technique, unsafe environment).
- C05- Apparently did not appropriately assess or act on changes in clinical/**other** results.
- C06- Apparently did not appropriately assess or act on laboratory or imaging results.
- C07- Apparently did not establish adequate clinical justification for a procedure which carries patient risk and was performed.
- C08- Apparently did not perform a procedure that was indicated (other than lab and imaging, see C09).
- C09- Apparently did not obtain appropriate laboratory tests and/or imaging studies.
- C10- Apparently did not develop and initiate appropriate discharge, follow-up, and/or rehabilitation plans.
- C11- Apparently did not demonstrate that the patient was ready for discharge.
- C12- Apparently did not provide appropriate personnel and/ or resources.
- C14- Apparently specialty consultation process was not completed in a timely manner.
- C13- Apparently did not order appropriate specialty consultation
- C40- Apparently did not follow-up on patient’s noncompliance.
- C99- Other quality concern not elsewhere classified.

ACTIONS

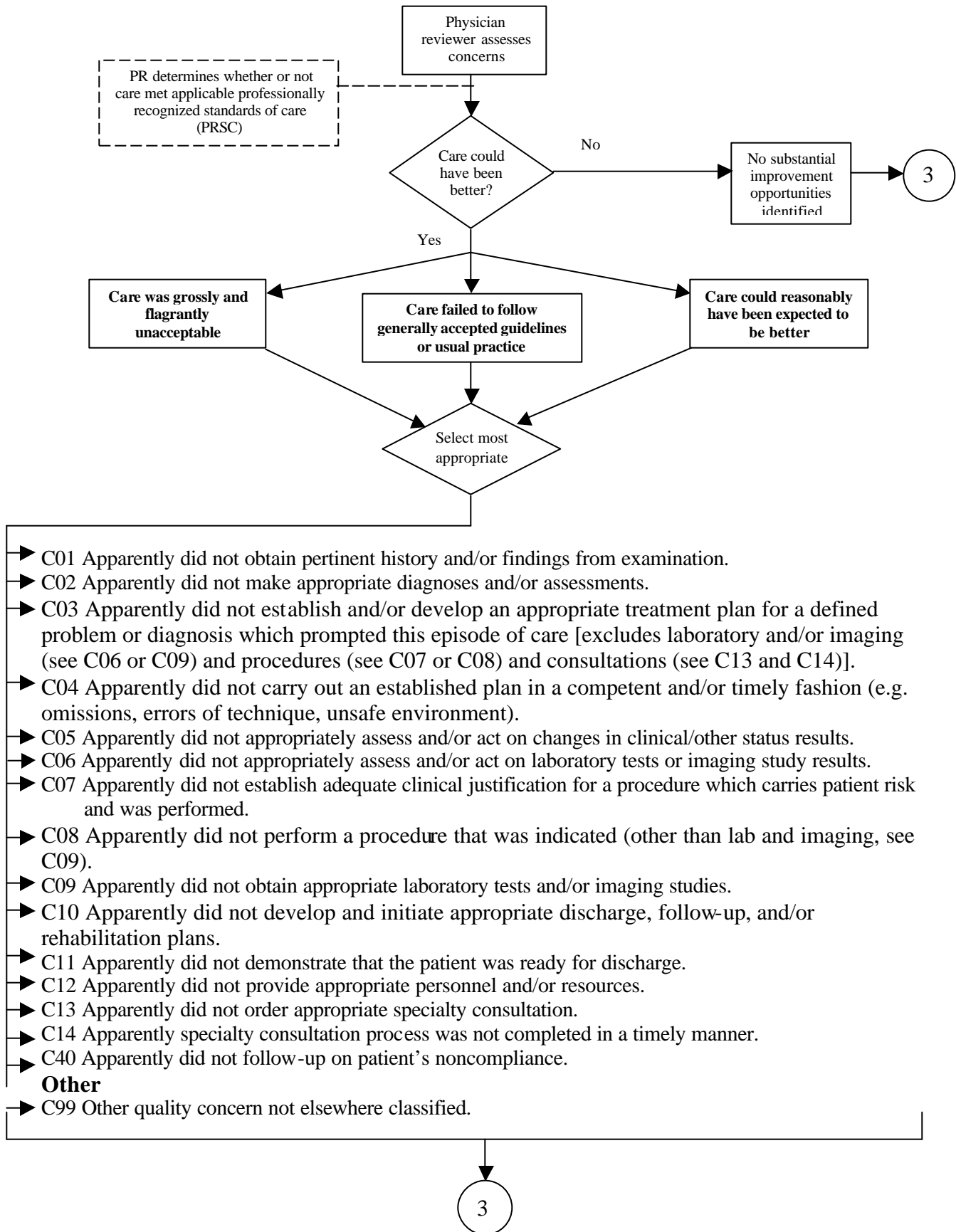
- Initiation of sanction activity.
- Immediate referral to licensing authority.
- Initiation of intensified review activity.
- Recommend that provider/ practitioner develop and implement a quality improvement plan (QIP).
- Recommend that the provider/ practitioner consider an alternative approach to future care.
- Offer advice to the provider/practitioner about an alternative approach to future care.
- No recommendations are made.

Applying Response Determination Categories (RDC) A Guide for the Physician Reviewer (PR)

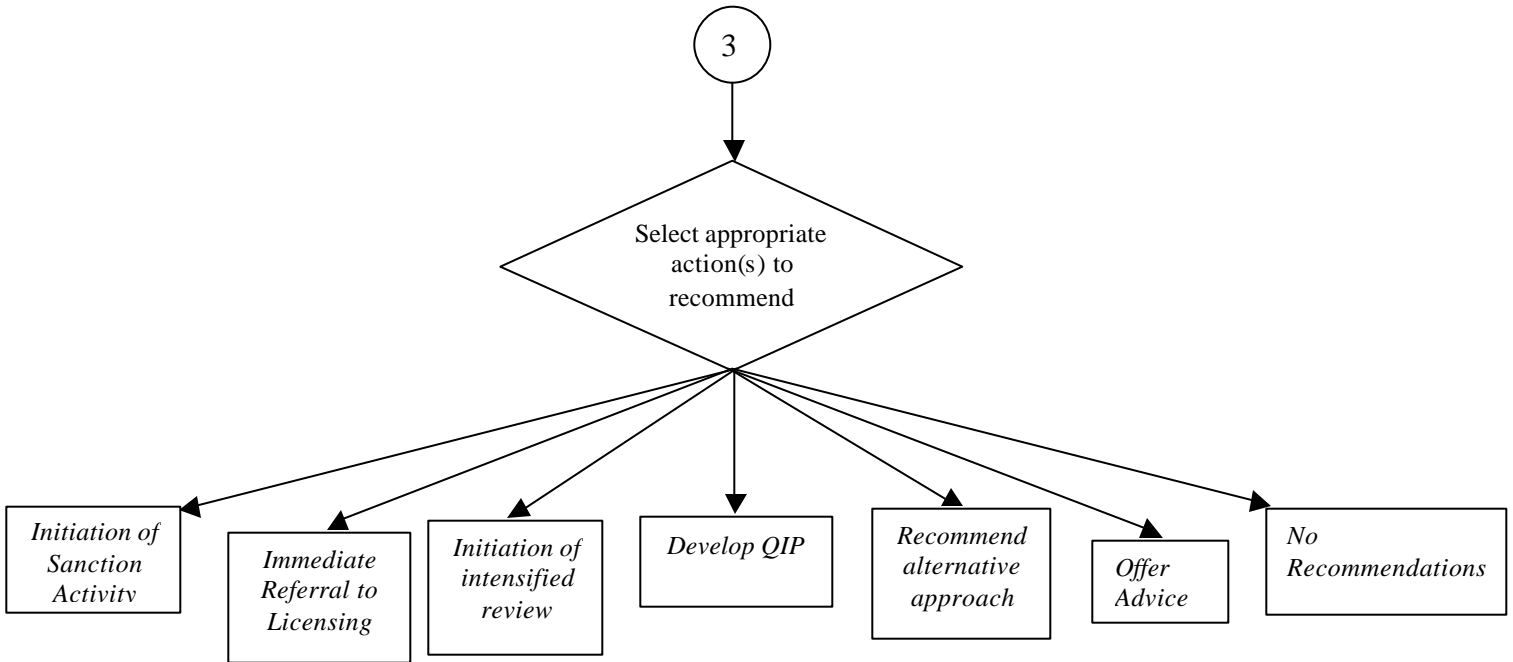
The PRSC determination is for **beneficiary complaints**. It has multiple arrows to accommodate varied placements of these steps by QIOs.



Physician Reviewer Flowchart for Identifying Response Determination Categories



Selecting Actions



Applying Categories Examples

The following cases are used to illustrate the application of the Response Determination Categories and actions outlined above. In these examples, the **Issue** summarizes the case. The **Decision** represents the way categories would be selected for all three steps in category determination. The **Recommendation** encompasses the Action step, and any other additional suggestions.

We understand that, in an actual review, you would have the entire medical record, and not just a small sample of clinical findings, but these vignettes are included to give you an idea of how the categories, and so forth, are applied. Also, we understand that, in particular, Physician Reviewers in specialty areas may have additional questions about some of these vignettes. **However, please try *not* to get distracted by the *details of the vignettes*; instead, try to focus on the overall message that the example is trying to convey.**

1. Issue

A son is concerned that a surgical error occurred during his 74-year-old mother's recent foot surgery. She has had repeated stasis ulcers that are non-healing. According to the record review, amputation of the right foot was recommended after vascular studies demonstrated severe ischemia not amenable to other treatment. Intraoperatively however, the left foot was removed in error.

Decision:

Step 1: Care could have been better

Step 2: Care was grossly and flagrantly unacceptable

Step 3: C.04 Apparently did not carry out an established plan in a competent and/ or timely fashion

Recommendation/ Action:

Due to the gross and flagrant nature of this error, you would need to recommend the initiation of sanction activity, which would include intensified review and a QIP, as well. Because such an error could put a patient in imminent danger, immediate referral to the licensing authority would also need to be recommended. In addition, continue reviewing the rest of the case, as other concerns or timeliness issues for other aspects of the review still need to be determined.

2. Issue

A 68-year-old man underwent a total hip replacement. Post-operatively, the patient developed a deep vein thrombosis (DVT). The patient is concerned that the DVT was the result of the care he received. Per the record, the patient did not receive pharmacological anticoagulant therapy after his surgery. During the opportunity for discussion, the physician stated that he never uses pharmacological anticoagulant therapy, only mechanical.

Decision:

Step 1: Care could have been better

Step 2: Care fails to follow accepted guidelines or usual practice

Step 3: C.04 Apparently did not carry out an established plan in a competent and/ or timely fashion (due to failure to take necessary precautions)

Recommendation/ Action:

Recommend that both the provider and the practitioner develop and implement a QIP, and also recommend initiation of intensified review activity.

This situation warrants a QIP as there is published clinical evidence which shows that the standard of practice is to use a combination of anticoagulant medication and mechanical treatment after this type of procedure, and the physician states that he routinely chooses not to use pharmacological options. This is both the provider and physician's responsibility, since the hospital is expected to have their Chief of Staff work with a physician when accepted practice is not being followed. Intensified review of similar cases after QIP implementation can then be done to ensure the updated approach is being carried out.

3. Issue

A home health agency had a confused, belligerent, 83-year-old patient who was verbally abusive and uncooperative. He had a physician order for "home health services as needed, until ready to be discharged from care." Due to the patient's behavior, he was discharged from care by the agency, without specifically contacting the patient's MD prior to making this decision. His family is concerned that he should still be getting home health agency visits. The record revealed that, although the patient's condition had clinically stabilized, home health care was discontinued without first notifying the physician about the problems with the patient's behavior.

Decision:

Step 1: Care could have been better

Step 2: Care failed to follow generally accepted guidelines or usual practice

Step 3: C.11 Apparently did not demonstrate the patient was ready for discharge.

Recommendation/ Action:

Recommend that the provider develop and implement a QIP.

A QIP from the home health agency is needed regarding the steps to be taken when a home health nurse identifies a problem in patient behavior, prior to discharging a patient. The physician should have been notified.

4. Issue

An 84-year-old patient with an exacerbation of COPD was admitted. The patient's daughter complained that the patient did not get good care. A review of the record reveals that the patient was managed with I.V. aminophylline and nebulized albuterol. She was put on Theo-Dur at discharge.

Decision:

Step 1: Care could have been better

Step 2: Care could reasonably have been expected to be better.

Step 3: C-03 Apparently did not establish and/or develop an appropriate treatment plan for a defined problem or diagnosis which prompted this episode of care.

Recommendation/ Action:

Recommend the practitioner consider an alternative approach to future care.

Although the care rendered was within the range of community practice, in the professional opinion of the PR, it was not consistent with current best practice. The PR recommendation would then need to be stated, e.g. to use systemic steroids during hospitalization of similar patients in the future, and use newer inhaled beta agonists and inhaled steroids upon discharge. These medications have been shown to provide more optimal clinical responses. Articles outlining this information could also be included with the recommendation.

5. Issue

A 73-year-old patient was told by her physician that a pacemaker would be placed, but it never was. She is concerned that she is not getting appropriate treatment. Review of the record shows that the physician had initially thought that pacemaker placement was indicated, but decided, based on the patient's age and co-morbidities, that an intensive trial of medical management was a better approach.

Decision:

Step 1: Care could have been better

Step 2: Care could reasonably have been expected to be better

Step 3: C-99 Other quality concern not elsewhere classified

Recommendation/ Action:

Recommend that the practitioner consider an alternative approach to future cases.

Although the overall care was acceptable, in the Reviewer's professional opinion, the instruction of, and communication with, the patient could have been improved. The PR would recommend that, for future, similar patients, the attending physician could consider giving a more detailed explanation to the patient of the rationale for the treatment plan, and for any changes in the treatment plan.

6. Issue

Beneficiary complained, through her son, that she was not given informed consent for her procedure. Review of the record indicates that the patient was alert, there was clear documentation of a consent discussion, and other family members were present during the discussion prior to her giving consent.

Decision:

Step 1: No substantial improvement opportunities are identified

Step 2: Not applicable

Step 3: No "C" category

Recommendation/ Action:

No recommendations made.

7. Issue

A 79-year-old patient complained that he was re-admitted to the hospital because his condition wasn't treated well the first time. The patient was originally admitted with urosepsis. IV Cipro was begun. A culture was taken, which grew Proteus resistant to Cipro. However, the patient was sent home on Cipro because the culture results were not available prior to the patient's discharge. His infection flared, and resulted in a second admission. During the opportunity for discussion, the MD admitted that he didn't check the culture results after the patient's discharge, nor had the hospital contacted him with the results.

Decision:

Step 1: Care could have been better

Step 2: Care failed to follow generally accepted guidelines or usual practice.

Step 3: C.06 Apparently did not appropriately assess and/ or act on laboratory tests or imaging study results.

Recommendation/ Action:

Recommend that both the provider and the practitioner develop a QIP to address this systems problem. The provider needs to ensure that practitioners are appropriately notified of any significant culture results. In addition, expected medical practice is to check the culture results of patients placed on antibiotics, and make any adjustments as necessary. The physician needs to establish a routine that ensures this is done regularly in the future.

Applying Categories Self-Test

Following are several examples that you can use to test yourself in assigning categories to quality of care concerns. Look at assigning all steps of categories and give your rationale. You may want to have the **Quick Reference Sheet** and **Physician Reviewer Flowchart** at hand to help refresh your thoughts about the categories as you make your decisions. When you are done, review the answer key to see how you fared. If you have questions about specifics, talk to the Medical Director or Physician Consultant at your QIO for more guidance.

We understand that, in an actual review, you would have the entire medical record, and not just a small sample of clinical findings, but these vignettes are included to give you an idea of how the categories, and so forth, are applied. Also, we understand that, in particular, Physician Reviewers in specialty areas may have additional questions about some of these vignettes. **However, please try *not* to get distracted by the *details of the vignettes*; instead, try to focus on the overall message that the question is trying to convey.**

Also, keep in mind that, especially for the “C” categories, there may be more than one justifiable answer. However, try to focus on identifying the **one root cause** category as much as possible.

1. **Issue:**

An 82-year-old patient complained that she developed a wound infection after extensive intra-abdominal surgery. In the review, you note that the surgeon did not use any antibiotic prophylaxis prior to surgery. You also note that the patient was on a proton-pump inhibitor (e.g. omeprazole). In his opportunity for discussion response, the surgeon states that he follows sterile procedures, and antibiotic use can lead to complications. He is aware of the applicable medical literature about antibiotic use in elderly patients such as this, but feels it doesn't apply to him. He states he has no intention of changing his practice pattern because there is no reason to do so.

Decision:

Step 1:

Step 2:

Step 3:

Recommendation/ Action:

2. **Issue:**

A 42-year-old patient, disabled due to pain, failed medical management for chronic pelvic pain. A hysterectomy was then performed. The patient is complaining that complications from the procedure are due to it being done incorrectly. The record documents a relatively short trial of conservative treatment and medical management. Then the patient insisted on a hysterectomy. Informed consent was given, the hysterectomy procedure was done correctly, apparently without problems, but wound dehiscence developed.

Decision:

Step 1:

Step 2:

Step 3:

Recommendation/ Action:

3. **Issue:**

An 84-year-old patient with chronic medical problems (diabetes, status post- renal transplant) and complications (hypertension, peripheral vascular disease) complained of leg pain. The daughter was concerned that her father's leg condition was not diagnosed or treated properly. According to the record, he was seen in the ER over a 3-week period on 4 different occasions by 4 different physicians due to leg pain. His leg was noted to be cool, with decreased pulses, but according to the family, this was longstanding. However, on week 4, the patient was admitted to the hospital because significant ischemia was present.

Decision:

Step 1:

Step 2:

Step 3:

Recommendation/ Action:

4. **Issue:**

Family complains that hip replacement surgery for their 79-year-old dad was not necessary. Upon review of the chart, there was no justification for the surgery found in the patient record. In the opportunity for discussion, the MD submitted outpatient documentation of the patient having severe DJD and failure of conservative treatment. X-ray results confirmed these findings.

Decision:

Step 1:

Step 2:

Step 3:

Recommendation/ Action:

5. **Issue:**

A 51-year-old patient with AIDS went to the ER complaining of profuse diarrhea. The ER physician hydrated the patient, performed a stool culture, ordered the culture results to be forwarded to the patient's primary care physician and began presumptive treatment. The culture result came back positive for *Campylobacter*. Neither the patient nor the physicians was notified. The patient subsequently developed sepsis and was later admitted.

Decision:

Step 1:

Step 2:

Step 3:

Recommendation/ Action:

6. **Issue:**

An 82-year-old patient with known coronary artery disease was admitted to same day surgery for a herniorrhaphy. Before the procedure, he developed severe chest pain, and experienced an MI. The wife complains that the patient was never instructed to take his heart medications the morning of the procedure. According to the response in the opportunity for discussion, there was no formal policy at the hospital about whether or not medications should be taken prior to a planned procedure, and how this was to be routinely communicated to patients.

Decision:

Step 1:

Step 2:

Step 3:

Recommendation/ Action:

7. **Issue:**

A 48-year-old patient complains that his back pain was not diagnosed correctly. According to the record, the patient presented with lower right-sided back pain and did not tell the physician about his significant past medical history (systemic lupus erythematosus) at his first visit. The physician examined the patient, ordered diagnostic tests and began oral medication treatment and PT. On the next visit one month later, the patient did not show any improvement, and at that time informed the physician about his medical history and chronic daily use of prednisone. The physician did not order any other evaluation, but pursued treatment of the back pain with more analgesia. The pain continued. After 3 months, the physician ordered a bone scan, which showed avascular necrosis of the right hip.

Decision:

Step 1:

Step 2:

Step 3:

Recommendation/ Action:

8. **Issue:**

A 74-year-old patient had an internal jugular line inserted for vascular access. The radiologist read the post procedure chest X-ray as normal. The next day, since the patient developed symptoms of shortness of breath, an X-ray was repeated. This showed a pneumothorax. When the initial X-ray was reviewed for comparison, a small pneumothorax was identified.

Decision:

Step 1:

Step 2:

Step 3:

Recommendation/ Action:

9. **Issue:**

An 82-year-old patient complained that, after foot surgery, he was unable to walk. He complained that the surgery was done incorrectly. The medical record shows that the doctor discussed in detail the risks, underlying condition, and expected outcomes of the procedure. Informed consent was clearly documented. The procedure was done appropriately.

Decision:

Step 1:

Step 2:

Step 3:

Recommendation/ Action:

10. **Issue:**

A 68-year-old patient with paranoid schizophrenia complained that he was chained to his bed in the hospital, poisoned and held against his will. The medical record shows that the patient had symptoms of psychosis that ultimately improved with adjustment of his medication regimen. The record also indicates that restraints were ordered during the first part of the patient's hospital stay because he needed IV antibiotics for a urinary tract infection, and kept trying to pull out the IV. The restraints were documented to have been appropriately monitored. The patient demonstrated increased agitation during this time period.

Decision:

Step 1:

Step 2:

Step 3:

Recommendation/ Action:

Answer Key

Decisions/ Recommendations:

1. Decision:

Step 1: Care could have been better

Step 2: Care was grossly and flagrantly unacceptable

Step 3: C.04 Apparently did not carry out an established plan in a competent and/or timely fashion

Recommendation/ Action:

Recommend the initiation of sanction activity. Antibiotic prophylaxis before surgery in a patient such as this would not be considered optional. The physician's position (that he does not and will not use antibiotic prophylaxis) makes a QIP or intensified review unlikely to be of help. Continue with the rest of the review process if applicable.

2. Decision:

Step 1: Care could have been better

Step 2: Care could reasonably have been expected to be better

Step 3: C.03 Apparently did not establish and/or develop an appropriate treatment plan for a defined problem or diagnosis which prompted this episode of care.

Recommendation/ Action:

Recommend that the practitioner consider an alternative approach to future care.

Care could have been improved by a longer course of medical management, which might have helped avoid surgery. The physician can also be informed regarding the benefit of a pain management referral, if a longer course of conservative treatment prior to hysterectomy is refused by a patient in future similar cases. Appropriate articles from the medical literature can also be cited.

3. Decision:

Step 1: Care could have been better

Step 2: Care could reasonably have been expected to be better

Step 3: C.05 Apparently did not appropriately assess and/ or act on changes in clinical/ other status

Recommendation/ Action:

Recommend that the provider develop and implement a QIP. This appears to be a systems failure, since appropriate case management and follow-up with a complex patient such as this did not appear to be in place. A QIP from the hospital is required addressing how it plans to implement case management of complex patients with chronic conditions. Each physician appeared to provide adequate care, but a coordinated, case management approach would likely have helped identify this problem sooner.

4. Decision:

Step 1: Care could have been better

Step 2: Care could reasonably have been expected to be better.

Step 3: C.99 Other quality concern not elsewhere classified

Recommendation/ Action:

Offer advice to the practitioner about an alternative approach to future care. The care was appropriate, but some areas could have been optimized. Better communication with a patient's family about the rationale for treatment decisions would be helpful for future cases. Better documentation in the inpatient record about the medical necessity of a procedure, and about any discussions held with the patient and family, would also be helpful.

5. Decision:

Step 1: Care could have been better

Step 2: Care failed to follow generally accepted guidelines or usual practice.

Step 3: C.06 Apparently did not appropriately assess and/ or act on laboratory tests or imaging study results.

Recommendation/ Action:

Recommend that the provider develop and implement a QIP. The ER physician's care is not at issue. However, a QIP is required from the hospital to ensure that appropriate procedures are in place to notify a patient, and the appropriate physicians, with positive laboratory results as soon as they become available.

6. Decision:

Step 1: Care could have been better

Step 2: Care failed to follow generally accepted guidelines or usual practice.

Step 3: C.04 Apparently did not carry out an established plan in a competent and/ or timely fashion

Recommendation/ Action:

Recommend that the provider develop and implement a QIP.

A QIP from the hospital is needed regarding establishing a protocol for when patients should take medications before same-day surgery. Training is also needed to coordinate the dissemination of this information among the physicians caring for the patient (e.g. surgeon, anesthesiologist) so that consistent application of the policy occurs.

7. Decision:

Step 1: Care could have been better

Step 2: Care could reasonably have been expected to be better

Step 3: C.02 Apparently did not make appropriate diagnoses and/ or assessments

Recommendation/ Action:

Recommend that the practitioner consider an alternative approach to future care. Intensified review may be warranted.

When the patient didn't improve, the physician should have more promptly explored other etiologies for the lower back pain (e.g. referred pain), especially in view of the history of chronic steroid use. The influence of co-morbidities on a patient's symptoms should be considered when evaluating complaints of pain. Review of additional cases might help determine if a QIP (e.g. with remedial education about common co-morbidities and their sequelae with regard to pain manifestations) is indicated.

8. Decision:

Step 1: Care could have been better

Step 2: Care could reasonably have been expected to be better.

Step 3: C.06 Apparently did not appropriately assess and/ or act on laboratory tests or imaging study results.

Recommendation/ Action:

Offer advice to the practitioner about an alternative approach to future care.

Although the Reviewer may want to acknowledge that subtle findings such as this may not be detected, it might help the physician in the future to have increased awareness about these types of abnormalities. Diligence in looking for subtle changes could help optimize future care.

9. Decision:

Step 1: No substantial improvement opportunities are identified.

Step 2: Not applicable

Step 3: Not applicable

Recommendation/ Action:

No recommendations are made.

10. Decision:

Step 1: No substantial improvement opportunities are identified.

Step 2: Not applicable

Step 3: Not applicable

Recommendation/ Action:

Offer advice to the practitioner about an alternative approach to future care.

The care that was given was appropriate. However, the reviewer could share with the attending physician a different approach to care that might have involved more aggressive pharmaceutical management to control the patient's behavior, rather than mechanical restraints, as this might have decreased the patient's agitation that was seen early in his stay.

Reference

Following are reference documents and tools to help Physician Reviewers understand and use the new **Response Determination Categories** effectively. Included in this section is the **TOPS** (CMS Operating Instructions) which includes the CMS guidance and addresses the use of these categories. Several flowcharts are also in this section, which can be used to ensure that cases are categorized properly and have the appropriate recommended actions.



**Department of Health & Human Services
Centers for Medicare & Medicaid Services**

7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, Maryland 21244-1850
Office of Clinical Standards and Quality

QIP TOPS
CONTROL QIO 2003-14
NUMBER:

DATE: December 22, 2003

FROM: Deputy Director
Quality Improvement Group
Office of Clinical Standards and Quality

SUBJECT: Revised QIO Case Review Process for Quality Issues

TO: Associate Regional Administrators, DCSQ
Regions I, VI, VII, IX
Chief Executive Officers, All QIOs

Policy Revision

This TOPS memo corrects and replaces QIO 2003-04 issued on May 21, 2003. In addition, it clarifies TOPS 2002-05, dated September 10, 2002. The changes explained here are effective immediately. The Medicare Beneficiary Protection QIOSC provided updated training on the use of Response Determination Categories (RDCs) on April 3, 2003 and April 10, 2003. These

changes and the overall use of the RDCs apply to any quality reviews conducted by a QIO. All quality of care cases initiated on or after February 3, 2003 for Rounds 1 and 2 QIOs, and on or after April 7, 2003 for Round 3 QIOs are eligible to have the RDCs applied to them. However, if prior to now, RDCs were not used on a quality case due to varied interpretations based on TOPS 2002-05, CMS will not require retrospective application of the RDCs. This TOPS in no way alters guidance issued to implement changes necessitated by the court order in the Public Citizen case. Those changes have been incorporated into the attached flowchart.

Under the Response Determination Categories explained below, the determination is considered resolved if a physician reviewer (PR) selects: Step 1: "Care could have been better", Step 2: "Care could reasonably have been expected to be better," and STEP 3: Action: "Recommend that the provider/practitioner consider an alternative approach to future care," or STEP 3: Action: "Offer advice to the provider/practitioner to consider as an alternative approach to future care," **and** the PR has also indicated that the care provided was acceptable or within the expected practice, but could have been improved based on the suggestions given. The QIO should query the PR for clarification of his or her intent if necessary. The QIO should state in the notice sent to the involved provider/practitioner that the issue was adequately addressed or resolved and that the purpose of the additional information given is for improving future care.

In addition, the action step "Immediate referral to the licensing authority and initiation of sanction activity" is now separated into two parts. This permits the PR to choose one or both actions when "Care is grossly and flagrantly unacceptable" is chosen as Step 2.

The previously released Response Determinations Categories are revised as follows:

Revised New Response Determination Categories

STEP 1. The PR evaluates the medical record and any other information available to conduct his or her review. When the evaluation is completed, the PR may determine that no substantial improvement opportunities are identified or care could have been better. If no substantial improvement opportunities are identified, the PR should go to step 3.

STEP 2. A PR may determine that care could have been better when:

A. Care was grossly and flagrantly unacceptable.

An example of grossly and flagrantly unacceptable care is when, in the opinion of the PR, if uncorrected the care delivered should result in consideration of enforcement actions related to licensure and/or initiation of sanction activity.

Please be aware that the terms 'gross and flagrant' and "serious risk" are defined in Part 1004 of Title 42 of the Code of Federal Regulations (CFR). 42 CFR 1004.1 defines both "gross and flagrant violation" and the "serious risk" situations that may involve care that was gross and flagrant. The examples cited in this TOPs do not override those definitions.

It should be noted that a PR recommendation about immediate referral to a licensing agency and/or initiation of sanction activity is then assessed by the usual QIO process.

This may include involvement of the Medical Director of the QIO, or the sanction review committee, or whatever process is in place in a QIO is involved to determine if a referral is to be made and the timing of the referral.

B. Care failed generally accepted guidelines or usual practice.

Care fails to follow accepted guidelines or usual practice when, based on the findings of the PR, it is inconsistent with an explicit guideline which has been adopted by a reputable organization, or usual practice. If a pattern of care is suspected as a result of the findings in such a case, that suspicion may support the QIO's finding that "a substantial violation in a substantial number of cases" occurred as described in 42 CFR 1004.1. The QIO is expected to monitor and, if indicated, pursue further evaluation.

C. Care could reasonably have been expected to be better.

Care could reasonably have been expected to be better when the PR believes that the beneficiary could reasonably have expected to receive better care or when the PR believes that the practitioner should have used an alternative approach to practitioner decision-making. A PR may determine that: Step 1: "Care could have been better" and Step 2: "Care could reasonably have been expected to be better" along with the "Action: Recommend that the provider/practitioner consider an alternative approach to future care" or "Offer advice to the provider/practitioner to consider as an alternative approach to future care." If either of these combinations of steps is selected, **and** the PR has also indicated that the care provided was acceptable or within the expected practice, but could have been improved based on the suggestions given, then this determination is considered a resolved concern and any alternative approach or advice is considered to be a suggestion for improving care in the future.

STEP 3. Actions

The PR may recommend one or more of the following actions:

1. Initiation of sanction activity.

Initiation of sanction activity should occur when care is (1) grossly and flagrantly unacceptable {section 1156 of the Social Security Act (the Act)}.

2. Immediate referral to the licensing authority.

Immediate referral to the licensing authority should be selected in cases where care is grossly and flagrantly unacceptable and there is immediate danger to the health and safety of other beneficiaries. These types of issues are not appropriately addressed through improvement activities (changes in process or education) (section 1160(b) of the Act).

3. Initiation of intensified review activity.

Intensified review activity may begin for the provider/practitioner when care failed to

meet generally accepted guidelines or usual practice and there are findings in the case that may indicate to the PR that the identified failure could happen again or could recur in similar cases/situations. If this action also leads to a quality improvement plan (QIP) and the QIP results in successful improvement, initiation of a sanction recommendation is not needed. If there is no improvement, sanction should be undertaken as specified at 42 CFR 1004.40. Under the sanction procedures, at the discretion of the QIO, the provider/practitioner may have another opportunity under a corrective action plan to improve the identified failure.

4. Recommend that the provider/practitioner develop and implement a Quality Improvement Plan (QIP).

QIPs are indicated when there is potential for better care to result from improvement in the system(s) or process of care delivery and/or practitioner participation in an educational program. QIPs can also be recommended when care could have reasonably been expected to be better.

5. Recommend that the provider/practitioner consider an alternative approach to future care.

Recommendations that a provider/practitioner consider an alternative approach to care should be made when the PR wants to communicate to a practitioner guidelines, usual practice, or information regarding best practices.

This recommendation should be made when care was grossly and flagrantly unacceptable, did not follow guidelines or usual practice, or could reasonably have been expected to be better, but development of a quality improvement plan was not recommended.

6. Offer advice to the provider/practitioner to consider as an alternative approach to future care.

This action should be selected when a PR has determined that the care provided was acceptable or within the expected practice, and no substantial improvement opportunities are identified, or care could reasonably have been expected to be better. In these instances, the PR may want to give advice about alternative approaches that could help optimize future care or that represent a different approach that may be helpful to be kept in mind in the future.

7. No recommendations are made.

NOTE: In determining what action to take in cases not involving grossly and flagrantly unacceptable care, the QIO should weigh the probable benefit to the care of Medicare beneficiaries against the cost of such action.

QIO Monitoring If a quality improvement plan is developed, the QIO follows up to determine whether improvement has occurred. If no improvement has occurred, the QIO determines the action that it must take with respect to the provider/practitioner to address/resolve the situation. Further action must be taken when the care was originally determined to have been grossly and flagrantly unacceptable. Further action may also be undertaken when care did not follow guidelines or usual practice, or when care could have reasonably been expected to be better.

Background

During the Response Determination Category trainings held by the MBP QIOSC, and in other communications received (e.g., at the 2003 AHQA Technical Conference), many QIO Medical Directors expressed concern with some aspects of the application of the above categories. They noted that if the category "care could reasonably have been expected to be better" is selected along with either the recommendation for an alternative approach to future care or the offer of advice, was used for cases where no quality of care concerns were found, it would still seem to imply that there is a confirmed concern. For that reason, we have clarified that when the PR's determination results in either of the above combinations, and the intention is to simply give advice, then the case would be considered resolved.

In addition, Medical Directors discussed that initiation of sanction activity may occur before or simultaneous to immediate referral to the licensing authority. Therefore, an option has been given to allow PRs to choose either or both of these actions, as appropriate.

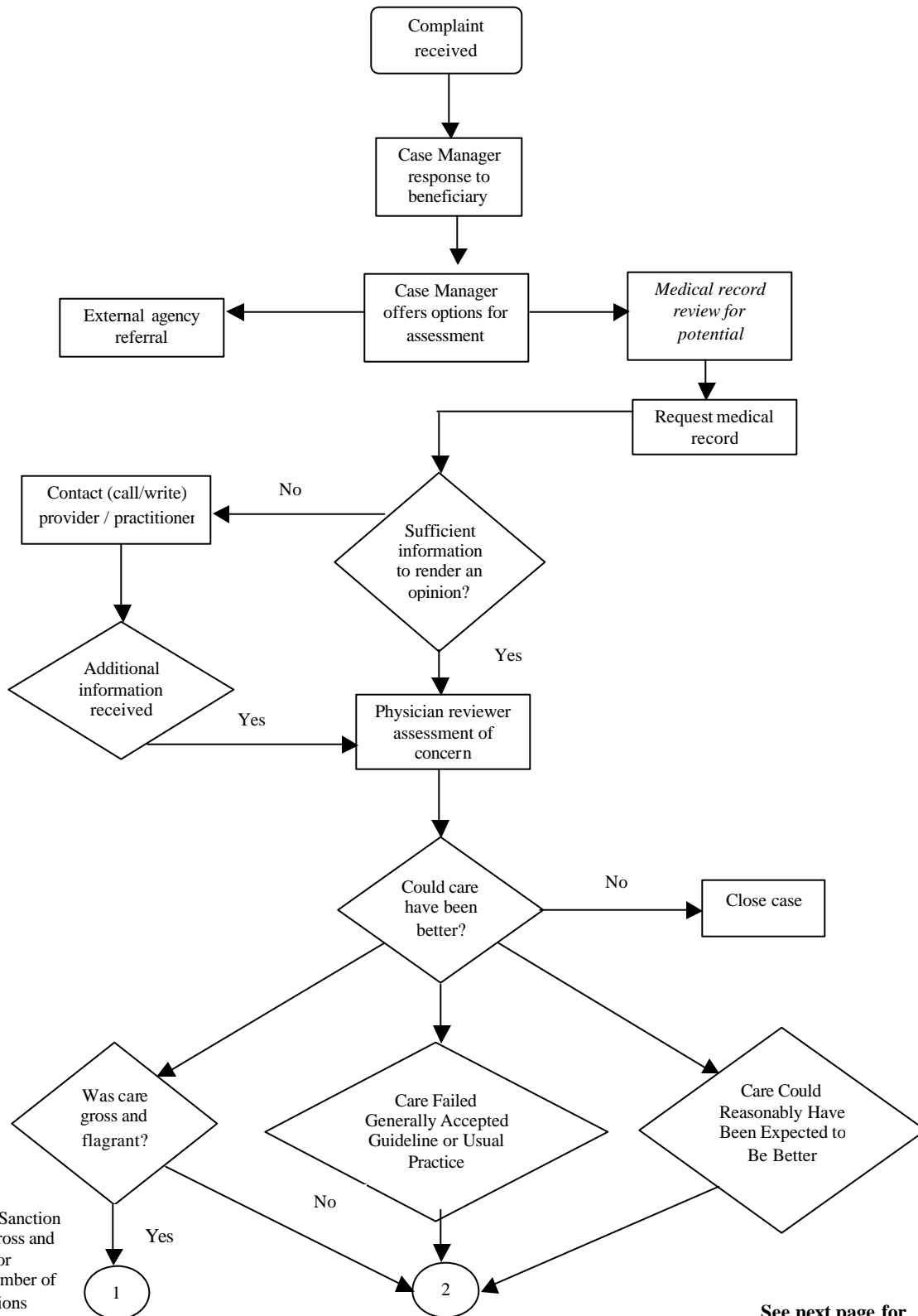
We will include the revisions into Part 5 of the QIO Manual in the near future.

If you have any questions, please contact Sheila Blackstock at (410) 786-3502 or Dr. Mary Giammona of the MBP QIOSC.

/s/

William C. Rollow, M.D., M.P.H.

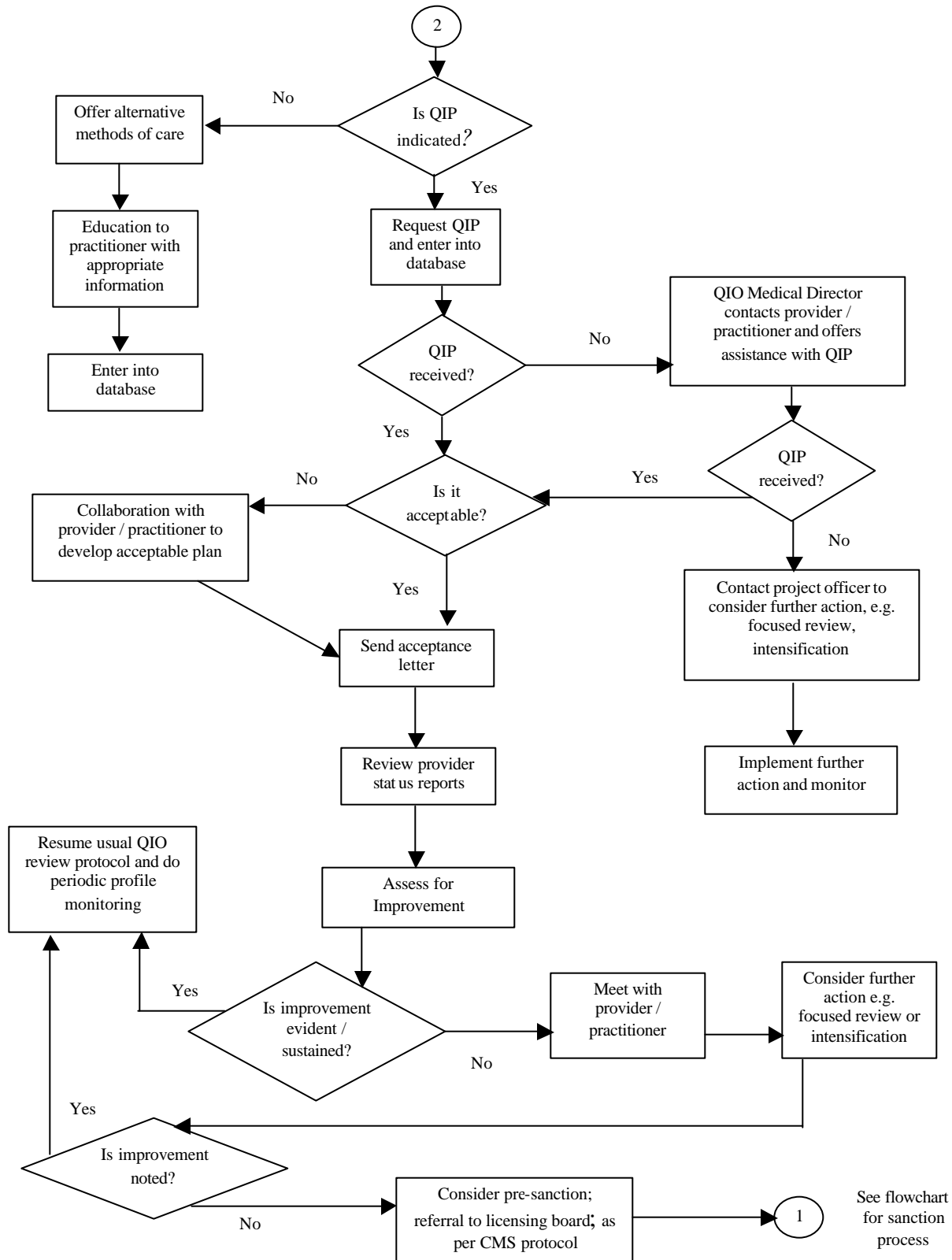
Review Process Flowcharts for Identification of Complaint Categories



Flowchart of Sanction process for Gross and Flagrant and/or substantial number of quality violations

See next page for continuing steps

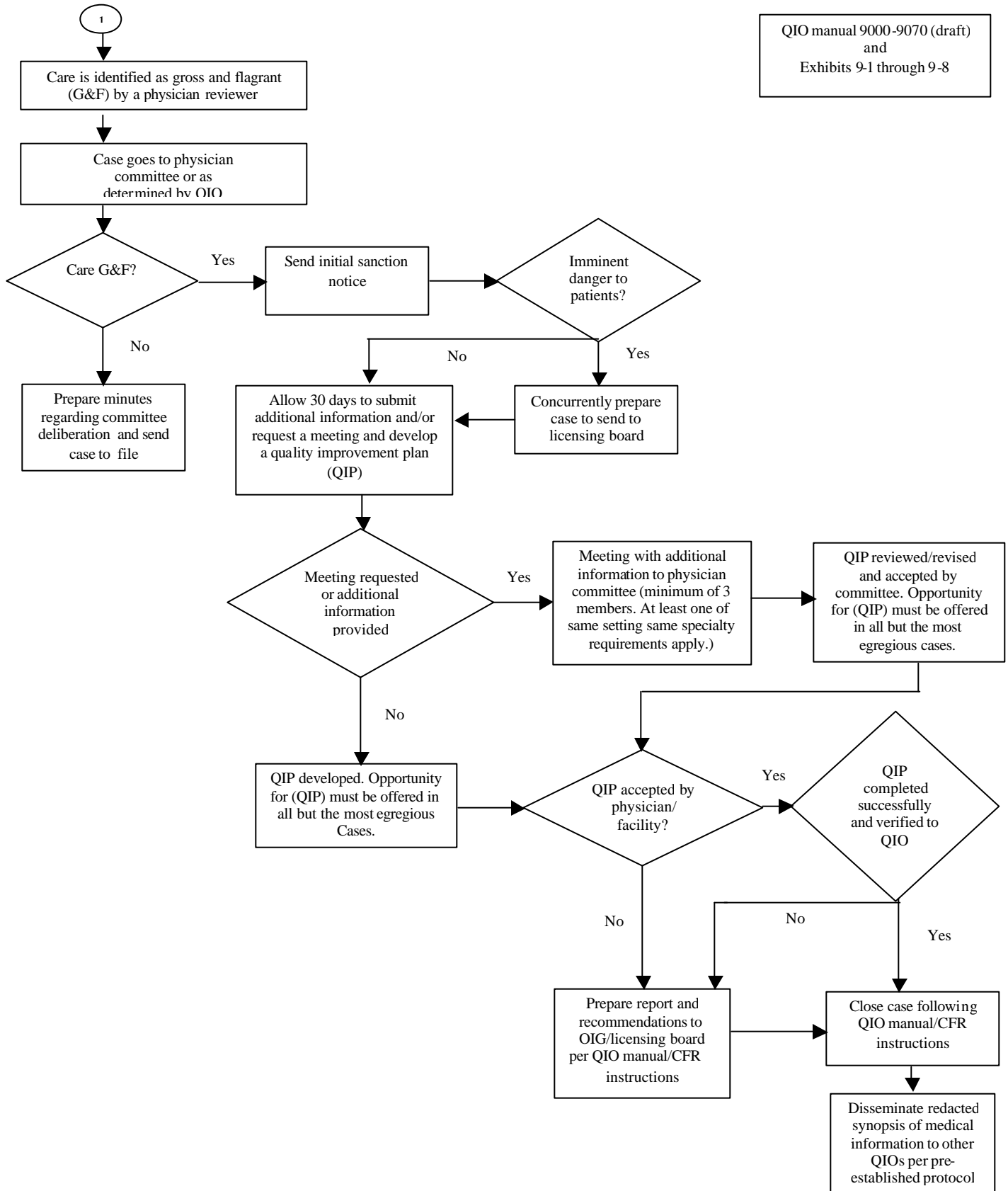
Complaint Response When Care Could Have Been Better – Continuing Steps



See flowchart for sanction process

Gross and Flagrant/Substantial Violations (Sanction Process)

QIO manual 9000-9070 (draft)
and
Exhibits 9-1 through 9-8



Evaluation

Please take a few minutes to help evaluate this self-study guide. You may have some valuable feedback that can help further enhance this program for others. Return the evaluation to your QIO.

1. Did you find the Self-Study Guide useful?

Yes

No

If yes, what was most useful in the Guide? _____

If no, what could have improved the Guide's usefulness for you? _____

2. Are there areas of the Guide that you found confusing or incomplete?

Yes

No

What was confusing or incomplete, and do you have any ideas for improving this area? _____

3. After completing working with the Self-Study Guide, do you feel confident in assessing cases?

Yes

No

If no, what would help you to feel more confident in categorizing cases? _____

4. Do you have any suggestions for improvement of this Guide, or any additional information that you feel should be included? _____