Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

QUALITY CONCERNS IDENTIFIED THROUGH QUALITY IMPROVEMENT ORGANIZATION MEDICAL RECORD REVIEWS

Daniel R. Levinson
Inspector General

May 2007
OEI-01-06-00170

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. Specifically, these evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness in departmental programs. To promote impact, the reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within HHS. OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

EXECUTIVE SUMMARY

OBJECTIVE

To determine (1) the extent to which Quality Improvement Organizations (QIO) identify quality-of-care concerns through medical record reviews, and (2) what interventions QIOs take in response to confirmed concerns.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) contracts with QIOs to oversee and enhance the quality of care within Medicare and to protect over 40 million Medicare beneficiaries. QIOs are organizations that comprise medical professionals who work with health care providers on quality improvement initiatives and review medical records to ensure that care meets professional standards. In December 2005, the Senate Committee on Finance requested that the Office of Inspector General (OIG) evaluate the QIOs' role in protecting beneficiaries from poor quality of care.

QIOs review medical records for quality, payment, utilization, or non-coverage concerns. For quality concerns, QIO reviewers conduct a full quality review. For other concerns, the reviewers screen for potential quality concerns. If this screening identifies a potential quality concern, the QIO conducts a subsequent full quality review on that case. In the first step of a full quality review, a nonphysician reviewer examines the medical records for potential concerns. CMS defines quality concerns as those in which care given "results in a significant or potentially significant adverse effect on the patient." If the nonphysician reviewer identifies a potential quality concern, a physician reviews the medical records to either confirm or resolve the concern. In cases with a confirmed concern, QIOs can recommend corrective actions meant to address the concern. QIOs have discretion in determining whether to recommend a corrective action, which can range from offering advice to providers about care to recommending that OIG sanction the provider.

We analyzed QIO-reported case review data for all cases that QIOs selected for review between February 1, 2003, and January 31, 2006. We also reviewed documentation and interviewed staff from three QIOs.

FINDINGS

QIOs selected over 300,000 cases for review between February 1, 2003, and January 31, 2006, and reviewed about 11 percent of them for quality of care. QIOs selected 318,018 cases for review during this time. The most common reasons QIOs selected cases were for payment-related reviews. QIOs completed full quality-of-care reviews on 34,768 cases. Beneficiary and anonymous complaints were the most common reasons QIOs performed quality reviews, accounting for 39 percent of all completed quality reviews.

QIOs confirmed a quality concern in about 19 percent of those cases that received a quality-of-care review. QIOs confirmed one or more quality concerns in 6,439 cases. QIOs assigned one of the two lowest classifications, "care could reasonably have been expected to be better," or "care failed to follow generally accepted guidelines and usual practice" to more than 80 percent of the cases with a confirmed quality concern. Cases that did not originally require a quality review proved to be a rich source of confirmed quality concerns. These cases, most of which were originally selected for payment-related reviews, comprised 61 percent of all cases with a confirmed quality concern.

QIOs recommended a corrective action in 72 percent of those cases with a confirmed quality concern. QIOs recommended 5,125 corrective actions in 4,645 cases with a confirmed concern (a single case can have multiple corrective actions). The two least severe corrective actions accounted for almost 70 percent of all recommended corrective actions. QIOs rarely initiated sanction activity in response to a confirmed concern. QIOs imposed no corrective actions in 1,794 cases (28 percent) with a confirmed quality concern.

CONCLUSION

Our evaluation documents the scope of QIOs' quality review activities between February 1, 2003, and January 31, 2006. QIOs have long had the potential to be an essential frontline mechanism through which Medicare can oversee the quality of care for which it pays.

However, QIOs assigned more than 80 percent of confirmed quality concerns to one of the two least serious classifications, "care could reasonably have been expected to be better" or "care failed to follow generally accepted guidelines or usual practice." Likewise, 70 percent of the corrective actions that QIOs recommended either called for

providers to consider an alternative approach to future care or offered advice. These are the two least severe corrective actions available to QIOs. QIOs recommended the two most severe actions, initiation of sanction referral and referral to a licensing board, in less than 2 percent of the corrective actions during this 3-year period.

Outside the QIO program and its authorities, Medicare has no other single mechanism with a comparable scope to perform case reviews and take such a range of corrective actions with providers. However, this review raises questions for CMS to consider in its administration of the QIO program. CMS should consider whether it needs to revisit its guidance regarding classifications of confirmed quality concerns and corrective actions.

AGENCY COMMENTS

CMS noted that it is currently evaluating the QIO case review process for reviewing and classifying quality-of-care concerns. CMS also recently implemented a revised array of quality improvement activities (formerly known as corrective action plans) for QIOs to recommend to providers. QIOs can recommend these new improvement activities even in cases where they did not identify quality-of-care concerns. CMS now requires QIOs to implement quality improvement activities in a certain percentage of cases in which QIOs do identify quality-of-care concerns. CMS's comments did not warrant any revisions to the results of our review.

TABLE OF CONTENTS

INTRODUCTION

OBJECTIVE

To determine (1) the extent to which Quality Improvement Organizations (QIO) identify quality-of-care concerns through medical record reviews, and (2) what interventions QIOs take in response to confirmed concerns.

BACKGROUND

Quality Improvement Organizations

The Centers for Medicare & Medicaid Services (CMS) contracts with QIOs, formerly known as Peer Review Organizations, to oversee and enhance the quality of care within the Medicare program and to protect over 40 million Medicare beneficiaries. QIOs are organizations that comprise medical professionals (largely physicians and nurses), epidemiologists and statisticians. In addition to contracting as Medicare QIOs, these 39 organizations often hold contracts to conduct medical review and quality improvement activities for States, the Department of Veterans Affairs, private health plans, and other entities. Further, CMS frequently contracts with QIOs to conduct special initiatives and demonstration projects.

Within Medicare, QIOs work with health care providers on quality improvement initiatives and review medical records to ensure that care meets professionally recognized standards. Pursuant to statute, QIOs must review the medical services rendered by individual practitioners and institutional providers to determine whether:

- services were reasonable and medically necessary and whether they were reimbursable under program guidelines,
- the quality of services met professionally recognized health care standards, and
- inpatient services could be effectively provided more economically in another setting.[1]

QIOs sign 3-year contracts, called statements of work, with CMS to provide services in the 50 States, the District of Columbia, Puerto Rico,

[1] Social Security Act § 1154(a)(1)(A-C).

and the U.S. Virgin Islands. Funding for the QIO program totaled $1.15 billion in the Seventh Statement of Work (from 2002-2005).[2]

In August 2005, QIOs began implementing the Eighth Statement of Work, which emphasizes broad activities aimed at improving the overall level of care provided by all Medicare providers but also retains their beneficiary protection role. Funding for the Eighth Statement of Work (2005-2008) is projected to increase to about $1.2 billion.[3]

Mandatory Review Responsibilities

In addition to having a contractual emphasis on improving the overall quality of care, QIOs also have a statutory and contractual responsibility to review individual instances of care provided to Medicare beneficiaries.[4] QIOs meet this mandate by reviewing medical records. See Table 1 on page 6 for a list of QIO review responsibilities.

Care provided by both institutional providers and individual practitioners can be subject to the medical record review process. In this report we use the term "provider" to include one or both of these groups unless specified otherwise.

Overview of the QIO Medical Record Review Process

QIOs review medical records for quality, payment, utilization, or non-coverage concerns. For quality concerns, QIO reviewers conduct a full quality review. For other concerns, the reviewers screen for potential quality concerns. If this screening identifies a potential quality concern, the QIO conducts a subsequent full quality review on that case. Quality concerns are those in which the care given "results in a significant or potentially significant adverse effect on the patient."[5]

In the first step of a full quality review, a nonphysician reviewer examines the medical records for potential concerns. If the reviewer identifies a potential quality concern, he or she refers the case to a physician reviewer who analyzes the clinical decisions made during

---

[2] The American Health Quality Association, "Medicare Beneficiary Protection by the Numbers." Available online at http://www.ahqa.org/pub/189_1085_5234.cfm. Accessed February 16, 2007.

[3] Ibid.

[4] Social Security Act § 1154(a)(4)(A) and QIO Seventh Statement of Work, Task 3: Improving Beneficiary Safety and Health Through Medicare Beneficiary Protection Activities.

[5] Centers for Medicare & Medicaid Services, "Quality Improvement Organization Manual," Chapter 4 – Case Review (4105), rev. 2, July 11, 2003.

care. If the nonphysician reviewer does not identify a potential quality concern, the quality review is completed. If the first-level physician review finds that care did not meet professional standards, the QIO offers the provider who rendered that care the opportunity to discuss the case and offer additional documentation. If the provider does not respond to this opportunity, the QIO reviewer makes a determination based on available data and the initial review. If the provider does respond with additional information, the QIO conducts a second-level physician review. If this review confirms the quality concern, providers who disagree can request a reconsideration. In this case, another QIO physician reviewer not involved in the prior reviews conducts a third-level review.

Following the review of all pertinent information in the final level of review, the reviewer makes a determination regarding the care given.[6] Once a quality concern is identified, the physician reviewer may determine that no substantial improvement opportunities could be identified, or that care could have been better. If the reviewer determines that care could have been better (confirms a quality concern), he or she classifies the care into one of three categories, based on CMS instructions:

- Care provided was a gross and flagrant violation;[7]
- Care failed to follow generally accepted guidelines/usual practice;[8] or
- Care could reasonably have been expected to be better.[9]

The governing statute, regulations, and the QIO Manual also require the reviewer to determine if the care constitutes a substantial

---

[6] Centers for Medicare & Medicaid Services, "Quality Improvement Organization Manual," Chapter 4 – Case Review (4310-4320), rev. 2, July 11, 2003.

[7] 42 CFR § 1004.1(b) defines a gross and flagrant violation as one that "occurred in one or more instances which presents an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations."

[8] Centers for Medicare & Medicaid Services, Transmission of Policy System Control Number: QIO 2003-14, December 22, 2003. CMS instructs QIOs that a concern given this classification may support a determination that "a substantial violation in a substantial number of cases" occurred as described in 42 CFR § 1004.1.

[9] Centers for Medicare & Medicaid Services, Transmission of Policy System Control Number: QIO 2003-14, December 22, 2003.

violation in a substantial number of cases.[10] The QIO database we analyzed does not indicate whether a particular case is part of such a violation. If the reviewer does not confirm a quality concern, no further action is necessary.

Corrective Actions Following Confirmed Concerns

When QIOs confirm a quality concern in the medical record review process, they must notify the provider(s) involved. Unless the concern poses severe risk, is a gross and flagrant violation, or is indicative of a pattern of poor care that would indicate a substantial violation in a substantial number of cases, CMS does not require the QIO to take further action.[11] CMS provides guidance to QIOs regarding corrective actions their physician reviewers can recommend in response to a confirmed quality-of-care concern.[12]

One corrective action QIOs can take is to recommend that the provider develop a quality improvement plan. Such plans are meant to improve the system or process of delivering care.[13] In contrast to the corrective action plans described below, the quality improvement plans are not identified in any statute or regulation or the QIO Manual, and CMS provides no guidance on their structure or requirements. QIOs may offer providers suggestions and guidelines for the plans; providers then develop and submit their plans to QIOs for approval. Providers must also evaluate the effectiveness of the plans and send results to the QIO. QIOs may request additional medical records for review to determine if the plan has been effective in addressing the concern.

For cases in which the QIO determines there is a gross and flagrant violation, or a substantial failure to comply with any obligation in a substantial number of cases, the QIO must determine if a corrective action plan is appropriate. If a corrective action plan is not appropriate, or if a provider has not successfully completed one, the QIO must recommend to the Office of Inspector General (OIG) that the provider be

[10] Social Security Act § 1156(a)(1)(A); 42 CFR § 1004.30(c); "Quality Improvement Organization Manual," Chapter 4 – Case Review (4000, 4105), rev. 2, July 11, 2003; Chapter 9 – Sanction and Abuse Issues (9000), rev. 12, October 3, 2003.

[11] Centers for Medicare & Medicaid Services, "Quality Improvement Organization Manual," Chapter 4 – Case Review (4700), rev. 2, July 11, 2003.

[12] Centers for Medicare & Medicaid Services, Transmission of Policy System Control Number: QIO 2003-14, December 22, 2003.

[13] Ibid.

sanctioned.[14] If OIG agrees with the sanction recommendation, it will either exclude the provider from Federal health care programs for no less than 1 year or impose civil monetary penalties.[15]

Among other factors, QIOs consider the severity of the case, previous problems, and previous attempts to resolve the issues to determine if a sanction referral is appropriate. A corrective action plan is specific to the sanction process, while quality improvement plans are used in less severe cases. Pursuant to statute, QIOs must also notify the State medical board or other appropriate licensing board when they determine that a physician or practitioner should enter into a corrective action plan.[16]

To determine which corrective action to take in response to concerns that are not classified as gross and flagrant, CMS instructs QIOs to weigh the probable benefit to the beneficiary's care against the cost of the action.[17] However, this instruction to weigh the cost and benefits does not exclude quality concerns that constitute a substantial violation in a substantial number of cases, which by statute and regulation must be treated the same as those concerns classified as gross and flagrant.[18]

CMS requires QIOs to enter their review findings into their data systems for pattern analysis. CMS instructs QIOs to analyze data on an ongoing basis to identify opportunities for improvement.[19]

---

[14] Social Security Act § 1156(b)(1) and 42 CFR § 1004.70.

[15] 42 CFR § 1004.20.

[16] Social Security Act § 1154(a)(9)(B).

[17] Centers for Medicare & Medicaid Services, Transmission of Policy System Control Number: QIO 2003-14, December 22, 2003.

[18] Social Security Act § 1156(a)(1); 42 CFR §§ 1004.30(c), 1004.40(a), 1004.80(c)(6).

[19] Centers for Medicare & Medicaid Services, "Quality Improvement Organization Manual," Chapter 5 – Quality of Care Review (5050), rev. 9, August 29, 2003.

Table 1: Mandatory QIO Review Responsibilities

Category	Authority	Description
Written beneficiary complaints	Social Security Act § 1154(a)(14)	Complaints filed by beneficiaries alleging poor quality of care
Alleged antidumping violations (violations of the Emergency Medical Treatment and Labor Act (EMTALA))	Social Security Act § 1154(a)(16)	Allegations of hospitals failing to provide appropriate medical screening examination, stabilizing treatment, or an appropriate transfer to another hospital, as required by law
Beneficiary appeals of notices of noncoverage, including Hospital-Issued Notices of NonCoverage (HINN) and Notices of Discharge and Medicare Appeal Rights (NODMAR)	HINN: Social Security Act § 1154(e)(1) NODMAR: 42 CFR § 422.622	Appeals by beneficiaries of notices issued by hospitals (HINN) or Medicare + Choice (now Medicare Advantage) programs (NODMAR) indicating that there is no coverage in place for inpatient hospital care
Hospital Payment Monitoring Program requirements	QIO Manual, Chapter 11 – Hospital Payment Monitoring Program § 11010	Referrals by special fraud contractors aimed at identifying area trends in inappropriate billing; review results are used to estimate State and national payment error rates
Hospital-requested higher-weighted diagnostic related group (DRG) validations	42 CFR § 476.71(c)(2)	Validations following all intermediary-approved requests by hospitals for higher weighted DRG adjustments
Requests for assistants at cataract surgery	Social Security Act § 1154(a)(8)	Preprocedural validation of the existence of a complicating medical condition warranting an assistant during a cataract surgery
Requests by CMS, fiscal intermediaries, and other designated CMS contractors	QIO Manual, Chapter 4 – Case Review § 4070	Review requests varying in scope and setting

Recent Interest in QIOs

In 2003, Congress directed the Institute of Medicine of the National Academy of Sciences (IOM) to conduct an evaluation of QIOs. This mandate included reviewing the extent to which QIOs improve the quality of care for Medicare beneficiaries and the extent to which other entities could perform such functions as well as or better than QIOs.[20]

IOM released a preliminary version of its report in February 2006. The report found that the quality of care received by Medicare beneficiaries has improved over time but that existing evidence was inadequate to determine the extent to which QIOs have contributed directly to that improvement. IOM recommended that case reviews be continued but that CMS consider removing this function from QIOs. CMS could instead contract at the national or regional level with a smaller number of organizations.[21]

A July 2005 Washington Post article criticized QIOs for lack of meaningful responses to beneficiary complaints and cited a decline in sanction recommendations made by QIOs over the past 2 decades.[22] In December 2005, the Senate Committee on Finance requested that OIG evaluate the QIOs' role in protecting Medicare beneficiaries from poor quality of care.

Previous Work

OIG has conducted several evaluations of QIOs' activities since their establishment in 1982. Past inspection reports covered topics such as the QIOs' role in identifying poorly performing providers, their sanction recommendation authority, and the beneficiary complaint process.[23]

---

[20] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173 § 109(d).

[21] Institute of Medicine of the National Academies, "Medicare's Quality Improvement Organization Program: Maximizing Potential," 2006.

[22] Gilbert M. Gaul, "Once Regulators, Now Partners," The Washington Post, July 26, 2005, p. A01.

[23] Department of Health and Human Services, Office of Inspector General, "The Sanction Referral Authority of Peer Review Organizations," OEI-01-92-00250, April 1993.

Department of Health and Human Services, Office of Inspector General, "The Medicare Peer Review Organizations' Role in Identifying and Responding to Poor Performers," OEI-01-93-00251, December 1995.

Department of Health and Human Services, Office of Inspector General, "The Medicare Beneficiary Complaint Process: A Rusty Safety Valve," OEI-01-00-00060, August 2001.

METHODOLOGY

Scope

We analyzed all cases QIOs selected for review between February 1, 2003, and January 31, 2006. This date range largely corresponds to the QIOs' Seventh Statement of Work. QIOs started to transition to the Eighth Statement of Work on August 1, 2005, and finished the transition on February 1, 2006. During this transitional period their case review responsibilities did not change.

Analysis

We use the term "case" to refer to a unique Medicare claim that a QIO selected for any type of review. We counted a case as receiving a quality review if the QIO completed the quality review process for that case (i.e., the case would receive no further reviews because of a provider appeal or request for rereview).[24] We also counted a case as receiving a quality review if, in the first step of a quality review, the nonphysician reviewer did not identify any potential quality concerns. This review is separate from the quality screening that QIO reviewers perform on payment, utilization, or noncoverage cases. We did not count this screening as a quality review.

We counted a quality concern as confirmed if the highest level of physician review resulted in a confirmed concern. We counted a case as having a confirmed quality concern if the QIO confirmed at least one quality concern from it. We counted a corrective action as recommended if the QIO recommended that action in response to a case with a confirmed quality concern.

We reviewed documentation detailing examples of recommended corrective actions and interviewed staff from three QIOs. We purposively selected the QIOs based on geographic diversity and size. Please see Appendix A for a full discussion of our methodology.

Limitations

We relied on case review data that were self-reported by QIOs for our analysis. We did not independently verify these data.

[24] We identified 606 cases in which the outcome of the review process was pending. We excluded these cases from our analysis.

Standards

We conducted this study in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

QIOs selected over 300,000 cases for review between February 1, 2003, and January 31, 2006, and reviewed about 11 percent of them for quality of care

QIOs selected 318,018 cases for review during this time period. These reviews covered payment and utilization issues, notices of noncoverage, and quality of care. The most common reasons QIOs selected a case were for payment issues. Cases selected as part of the Hospital Payment Monitoring Program (HPMP) and for higher weighted DRG requests accounted for almost 60 percent of all cases. No other single review category accounted for more than 7 percent of cases. See Table 2 below for the number of cases selected for review, arrayed by the original reason for their selection. (See Table B1 in Appendix B for a complete array of reasons for selection.)

Table 2: Cases by Original Reason for Selection

Reason for Selection	Number of Cases	Percentage
HPMP	95,526	30%
DRG Assignments	89,773	28%
Referrals	22,297	7%
Primary Data Collection	20,932	7%
QIO Selected	20,235	6%
Appeals	20,175	6%
Beneficiary and Anonymous Complaints	18,550	6%
HINN	17,287	5%
Other*	13,243	5%
Overall Total	318,018	100%

Source: Office of Inspector General analysis of case review data, 2006.

* Comprises nine reasons for selection.

Of the 318,018 cases, QIOs completed quality-of-care reviews on 11 percent of them (34,768 cases). The two most common reasons QIOs selected cases for review, HPMP and higher weighted DRG requests, do not require a full quality review. In these and most other types of cases, QIO reviewers must screen for potential quality concerns during the course of the original review. If the reviewer identifies a potential

quality concern, that case receives a subsequent full quality review. Some cases, such as most of those originating from written beneficiary complaints, automatically require a quality review.[25] Sixty-two percent of the cases that received a completed quality review did not originally require one (21,570 of 34,768 cases). See Table 3 below for the number of cases that received a quality review, arrayed by the original reason for their selection. (See Table B2 in Appendix B for a complete array of reasons for selection.)

Table 3: Cases That Received a Quality Review by Original Reason for Selection

Reason for Selection	Number of Cases	Percentage
Beneficiary and Anonymous Complaints	13,679	39%
HPMP	7,400	21%
DRG Assignments	5,737	17%
Referrals	4,642	13%
Intensified Review	1,622	5%
HINN	571	2%
Other*	1,117	3%
Overall Total	34,768	100%

Source: Office of Inspector General analysis of case review data, 2006.

* Comprises 11 reasons for selection.

[25] As shown in Table 3, not all beneficiary complaint cases selected for review received a completed quality review. We identified 625 cases in which the quality review had not started at the time we received the case review data, 234 cases in which the review was not yet completed, and 507 cases that the QIO determined did not require a quality review. We identified 1,610 cases for which we can not accurately determine the reason the QIO did not complete a quality review.

QIOs confirmed a quality concern in about 19 percent of those cases that received a quality-of-care review

QIOs confirmed one or more quality concerns in 19 percent of the cases on which they completed a quality review (6,439 of 34,768 cases). In these cases one or more physician reviewers confirmed a quality concern. QIOs confirmed 10,110 individual quality concerns in these cases (a single case can have multiple confirmed quality concerns). See Table 4 below for the number of cases that had a quality concern, arrayed by the original reason for their selection. (See Table B3 in Appendix B for a complete array of cases by reason for selection.)

Table 4: Cases With at Least One Confirmed Quality Concern by Reason for Selection

Reason for Selection	Number of Cases That Received a Completed Quality Review	Number of Cases With at Least One Confirmed Quality Concern	Percentage of Cases With a Confirmed Quality Concern
Beneficiary and Anonymous Complaints	13,679	2,574	19%
HPMP	7,400	1,335	18%
DRG Assignments	5,737	919	16%
Referrals	4,642	779	17%
Intensified Review	1,622	409	25%
HINN	571	163	29%
Other*	1,117	260	23%
Overall Total	34,768	6,439	19%

Source: Office of Inspector General Analysis of case review data, 2006.

* Comprises 11 reasons for selection.

Physicians were the source of the confirmed concern in 4,451 cases, and facilities were the source in 1,935 cases. Medicare Advantage plans were the source in 25 cases, and 28 cases had no attributed source. A specific physician or facility was the source of a confirmed concern in multiple cases in the time period we examined. For example, 282 physicians and 620 facilities were the source of a confirmed quality concern in more than one case. Because no classification exists in the database we analyzed regarding care that constituted a substantial

violation in a substantial number of cases, we were unable to learn whether QIOs determined if these providers met this condition.

QIOs assigned the lowest level of concern to half of the cases with a confirmed quality concern; rarely did QIOs assign the most severe level of concern

In 50 percent of the cases with a confirmed concern, QIOs assigned the lowest concern classification, "care could reasonably have been expected to be better." For example, we reviewed such a concern that dealt with a beneficiary who did not receive adequate pain management.

QIOs assigned the next level of classification, "care failed to follow generally accepted guidelines or usual practice," to concerns in about 31 percent of cases. For example, we reviewed a concern with this classification that involved a beneficiary who was inappropriately medicated, for which a QIO reviewer determined that the beneficiary received duplicate beta blocker medication.

QIOs assigned the most severe classification, "care provided was a gross and flagrant violation," in about 2 percent of cases. One example of such a concern we reviewed dealt with a beneficiary who died after being given an anesthesia drug to which she was allergic. While the allergy was known prior to surgery, that information was not noted on records used during the surgery. The QIO case review database did not record data on quality concerns classified as "substantial violations in a substantial number of cases." These types of cases are described in the statute, regulations, and QIO Manual as being equivalent to the "gross and flagrant" violations that are given the most severe classification.[26]

The data did not contain classifications for about 17 percent of cases.

Cases that did not originally require a quality review proved to be a rich source of confirmed concerns

Cases that did not originally require a quality review comprised 61 percent of the cases with a confirmed quality concern (3,927 of 6,439 cases). In these cases, a QIO reviewer identified a potential quality concern during a payment or other type of nonquality review, and the QIO subsequently performed a full quality review.

[26] Social Security Act § 1156(a)(1); 42 CFR §§ 1004.30(c), 1004.40(a), 1004.80(c)(6); "Quality Improvement Organization Manual," Chapter 4 – Case Review (4000, 4105), rev. 2, July 11, 2003; Chapter 9 – Sanction and Abuse Issues (9000), rev. 12, October 3, 2003.

QIOs originally selected most of these cases for payment-related reviews. Cases from the HPMP and higher weighted DRG assignments comprised 57 percent of these cases (2,254 of 3,927 cases). Because these two categories comprised the greatest number of all the cases QIOs selected for review, it is not surprising that they resulted in a large number of confirmed concerns. However, the number of payment-related cases that also received quality reviews does show that QIO reviewers are looking for and finding quality concerns in nonquality reviews.

Cases that did require a quality review accounted for 39 percent of all cases with a quality concern (2,512 of 6,439 cases). From this group, cases resulting from beneficiary complaints comprised the greatest number of cases with a quality concern.

QIOs recommended a corrective action in 72 percent of cases with a confirmed quality concern

In every case with a confirmed quality concern, QIOs must send a notification of their findings to the provider. Unless the concern poses severe risk, is a gross and flagrant violation, or is indicative of a pattern of poor care, CMS does not require the QIO to take further action.[27] QIOs did recommend 5,125 corrective actions in 4,645 (72 percent) of the cases with a confirmed concern. One case can have multiple corrective actions (e.g., a QIO may require a provider to implement a quality improvement plan and may also initiate intensified review on that provider). See Table 5 on page 15 for the frequency of QIO-recommended corrective actions.

The two least severe corrective actions accounted for almost 70 percent of all recommended corrective actions

The two most commonly recommended corrective actions, considering an alternative approach to future care and offering advice, comprised 68 percent of all recommended actions. QIOs can recommend that providers consider an alternative approach for any classification of a confirmed quality concern. This action is designed to communicate to the provider guidelines, usual practice, or advice regarding best

[27] Centers for Medicare & Medicaid Services, "Quality Improvement Organization Manual," Chapter 4 – Case Review (4700).

practices. Offering advice is similar to recommending an alternative approach but is used to address less serious concerns.[28]

In our review, an example of an alternative approach was a case in which the QIO questioned whether a beneficiary's course of treatment was aggressive enough. After the provider in question explained the rationale for this treatment more fully, the QIO deemed the concern resolved. It recommended to the provider that, in future cases, such explanations should be contained in the medical records so that all relevant personnel would be aware of the treatment plan.

A more intensive measure to address a confirmed concern is for providers to implement a quality improvement plan. QIOs instructed that providers implement quality improvement plans 1,283 times. Representatives from QIOs whom we interviewed told us that their QIOs typically let the provider develop the plan and then submit it for approval. The QIOs offer guidance to the provider on elements the plan must contain, such as the specific steps the provider will take to address the concern, how the provider will monitor the plan, and how it will be evaluated. Some QIOs send a tip sheet to the provider that lists and describes these elements.

In one quality improvement plan we reviewed, a provider developed education programs for staff that focused on increasing knowledge and critical thinking skills. The provider also revised policies and procedures and developed staff competency assessments. The case involved nursing staff not reporting a patient's deteriorating status to the physician timely. Other quality improvement plans we reviewed similarly consisted of staff training programs.

QIOs rarely initiated sanction activity in response to a confirmed concern

QIOs recommended the two most severe actions, initiation of sanction activity and referral to licensing boards, 31 and 54 times, respectively.[29] The initiation of sanction activity does not automatically mean that a QIO will make a sanction referral to OIG. The successful completion of a corrective action plan could resolve the case without the need for a sanction referral. QIOs classified care as a gross and flagrant violation

[28] Centers for Medicare & Medicaid Services, Transmission of Policy System Control Number: QIO 2003-14, December 22, 2003.

[29] When a QIO refers a case to OIG, the QIO must also provide notice to the State medical board or other appropriate licensing board. 42 CFR § 1004.70(c). However, not all cases referred to a licensing board are referred to OIG for sanctions.

in 19 of the 31 cases in which they initiated sanction activity. They classified care as a gross and flagrant violation in 17 of the 54 cases involving referral to licensing boards and as failing to follow generally accepted guidelines or usual practice in 33 of those cases.

Finally, QIOs initiated intensified review 264 times. QIOs can take this action when a confirmed quality concern appears to be the result of a systemic issue that spreads beyond that particular case.[30]

QIOs imposed no corrective actions in 1,794 (28 percent) cases with a confirmed quality concern

If a quality concern does not pose a severe risk or is not a gross and flagrant violation, CMS does not require QIOs to take further action unless a pattern of poor care emerges that would indicate a substantial violation in a substantial number of cases.[31] For example, we reviewed documentation from two cases in which a QIO confirmed a quality concern and did not take a corrective action. The QIO did not classify care in either case as a gross and flagrant violation. In both cases, the QIO stated that because the concern was a single instance of a problem and not indicative of a pattern of poor care, it would take no further action beyond notifying the provider of its findings.

Table 5: Number and Type of Recommended Corrective Actions

Corrective Action	Number of Times Recommended	Percentage of All Recommended Corrective Actions
Alternative Approach	2,054	40%
Offer Advice	1,439	28%
Quality Improvement Plan	1,283	25%
Intensified Review	264	5%
Referral to Licensing Body	54	1%
Initiation of Sanction Acitvity	31	<1%
Overall Total	5,125	100%

Source: Office of Inspector General analysis of case review data, 2006.

[30] Ibid.

[31] Centers for Medicare & Medicaid Services, "Quality Improvement Organization Manual," Chapter 4 – Case Review (4700).

CONCLUSION

Our evaluation documents the scope of QIOs' quality review activities between February 1, 2003, and January 31, 2006. We found that QIOs selected more than 300,000 cases for review, for issues ranging from hospital payments to beneficiary complaints. They found sufficient concern about quality of care to perform quality reviews on nearly 35,000 of those cases. QIO physician reviewers confirmed that quality-of-care concerns existed in about 6,500 cases. In response, QIOs recommended corrective actions to address the concerns in 72 percent of those cases.

These numbers show that QIOs are using their statutory authority to perform case reviews. In fact, QIOs have long had the potential to be an essential frontline mechanism through which Medicare can oversee the quality of care for which it pays.

However, QIOs assigned more than 80 percent of confirmed quality concerns to one of the two least serious classifications, "care could reasonably have been expected to be better" or "care failed to follow generally accepted guidelines or usual practice." QIOs assigned the most severe classification, "care provided was a gross and flagrant violation," in about 2 percent of cases. In addition, we could not determine from the data whether any case constituted a substantial violation in a substantial number of cases.

Likewise, 70 percent of the corrective actions that QIOs recommended either called for providers to consider an alternative approach to future care or offered advice. These are the least severe corrective actions available to QIOs. Further, QIOs recommended no corrective actions in 28 percent of the cases with a confirmed quality concern. QIOs recommended the two most severe actions, initiation of sanction referral and referral to a licensing board, in less than 2 percent of the corrective actions during this 3-year period.

Outside the QIO program and its authorities, Medicare has no other single mechanism with a comparable scope to perform case reviews and take such a range of corrective actions with providers. However, this review raises questions for CMS to consider in its administration of the QIO program. It should consider whether it needs to revisit its guidance regarding classifications of confirmed quality concerns, particularly with respect to care that might constitute a substantial violation in a substantial number of cases. CMS could also examine whether it needs to revise its guidance on corrective actions.

AGENCY COMMENTS

In its comments on our draft report, CMS noted that it is currently evaluating the QIO case review process for reviewing and classifying quality-of-care concerns. CMS also recently implemented a revised array of quality improvement activities (formerly known as corrective action plans) for QIOs to recommend to providers. QIOs can recommend these new improvement activities even in cases where they did not identify quality-of-care concerns. These cases would include such issues as poor communication with beneficiaries or insufficient billing and coding practices. CMS now requires QIOs to implement quality improvement activities in a certain percentage of cases in which QIOs do identify quality-of-care concerns. CMS's comments did not warrant any revisions to the results of our review. For the full text of CMS's comments, see Appendix C.

METHODOLOGY

Analysis of Case Review Data

QIOs collect and report case review data. For each case given a quality review, reviewers record the initial reason for the medical record review (e.g., a beneficiary complaint), their determination about the quality of care provided, the corrective action recommended to address any quality concerns, and the Medicare identification number of the provider under review, among other items. QIO reviewers enter these and other data into a database called the Case Review Information System (CRIS). CMS implemented this system during the QIOs' Seventh Statement of Work. (The CRIS is a module of CMS's Standard Data Processing System. The system is developed and maintained, under contract, by the Iowa Foundation for Medical Care QIO.)

We analyzed all cases QIOs selected for review between February 1, 2003, and January 31, 2006. This date range largely corresponds to the QIOs' Seventh Statement of Work. Although QIOs first transitioned to the Seventh Statement of Work on August 1, 2002, CMS did not require them to submit case review data to the CRIS until February 1, 2003. QIOs started to transition to the Eighth Statement of Work on August 1, 2005, and finished this transition on February 1, 2006. During this transitional period their case review responsibilities did not change.

We use the term "case" to refer to a unique Medicare claim that a QIO selected for review. Because a QIO can review one case for multiple reasons, we identified, by date, the original reason the QIO selected the case. From this reason for selection, we determined whether or not the case originally required a quality review.

We counted a case as receiving a quality review if the QIO completed the quality review process for that case (i.e., the case would receive no further reviews because of a provider appeal or request for rereview). We also counted a case as receiving a quality review if, in the first step of a quality review, the nonphysician reviewer did not identify any potential quality concerns.

We counted a quality concern as confirmed if its highest level of physician review confirmed the concern. That means any second- or third-level physician review had to uphold the initial finding of a

confirmed quality concern. We counted a case as having a confirmed quality concern if the QIO confirmed at least one quality concern from that case. We then counted only those cases for which the QIO completed the review process.

We counted a corrective action as recommended if the QIO recommended that action in response to a case with a confirmed quality concern. To identify cases that had no recommended corrective actions, we analyzed all confirmed quality concerns for a case and identified cases for which none of those confirmed concerns had a recommended action.

To determine how many providers rendered care in multiple cases with a confirmed quality concern, we analyzed all cases for which a physician or facility was the source of the concern and then identified physician or facility identification numbers that appeared in more than one case.

Data Request and Interviews with QIOs

We reviewed documentation and interviewed staff from three QIOs. We purposively selected the QIOs based on geographic diversity and size. We reviewed examples of corrective actions the QIOs recommended in response to both confirmed and resolved quality concerns. Our interviews covered how the QIOs performed pattern analysis, how their reviewers screened for quality concerns in nonquality reviews, and general topics pertaining to their case review activities.

Limitations

We relied on case review data that were self-reported by QIOs to the CRIS for our analysis. We did not independently verify these data.

APPENDIX ~ B

Table B1: Cases by Original Reason for Selection

Reason for Selection	Number of Cases	Percentage
HPMP	95,526	30%
DRG Assignments	89,773	28%
Referrals	22,297	7%
Primary Data Collection	20,932	7%
QIO Reason	20,235	6%
Appeals	20,175	6%
Beneficiary and Anonymous Complaints	18,550	6%
HINN	17,287	5%
Intensified Review	4,155	1%
Long Term Care Hospital Sample	2,779	<1%
EMTALA	2,751	<1%
NODMAR	2,351	<1%
Cost Outlier	796	<1%
Readmission	232	<1%
Sanction	106	<1%
Fraud and Abuse	59	<1%
Cataract Assistants	14	<1%
Overall Total	318,018	100%

Source: Office of Inspector General analysis of case review data, 2006.

Table B2: Cases That Received a Quality Review by Reason for Selection

Reason for Selection	Number of Cases	Percentage
Beneficiary and Anonymous Complaints	13,679	39%
HPMP	7,400	21%
DRG Assignments	5,737	17%
Referrals	4,642	13%
Intensified Review	1,622	5%
HINN	571	2%
Primary Data Collection	306	<1%
Appeals	216	<1%
Long Term Care Hospital Sample	204	<1%
Cost Outlier	99	<1%
Readmission	95	<1%
Sanction	60	<1%
QIO Selected	54	<1%
NODMAR	41	<1%
EMTALA	39	<1%
Fraud and Abuse	2	<1%
Cataract Assistants	1	<1%
Overall Total	34,768	100%

Source: Office of Inspector General analysis of case review data, 2006.

Table B3: Cases With at Least One Confirmed Quality Concern by Reason for Selection

Reason for Selection	Number of Cases That Received a Completed Quality Review	Number of Cases With at Least One Confirmed Quality Concern	Percentage of Cases With a Confirmed Quality Concern
Fraud and Abuse	2	1	50%
EMTALA	39	19	49%
NODMAR	41	15	37%
Appeals	216	77	36%
QIO Reason	54	16	30%
HINN	571	163	29%
Sanction	60	17	28%
Intensified Review	1,622	409	25%
Readmission	95	19	20%
Long Term Care Hospital Sample	204	40	20%
Beneficiary and Anonymous Complaints	13,679	2,574	19%
HPMP	7,400	1,335	18%
Referrals	4,642	779	17%
DRG Assignments	5,737	919	16%
Cost Outlier	99	14	14%
Primary Data Collection	306	42	14%
Cataract Assistants	1	0	0%
Overall Total	34,768	6,439	18.5%

Source: Office of Inspector General Analysis of case review data, 2006.

APPENDIX ~ C

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAY 11 2007

TO: Daniel R. Levinson
Inspector General

FROM: Leslie V. Norwalk, Esq.
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Quality Concerns Identified Through Quality Improvement Organization Medical Record Reviews" (OEI-01-06-00170)

Thank you for the opportunity to review and comment on the subject OIG draft report. We appreciate the OIG's efforts to ensure that the Medicare program has safeguards in place to identify and address quality of care concerns.

The Centers for Medicare & Medicaid Services (CMS) is committed to ensuring that Medicare beneficiaries receive quality health care. Since the establishment of the professional standards review organizations (PSROs) in 1972 by amendment to title XI of the Social Security Act (the Act), the program has evolved significantly to focus on quality improvement at the systems level versus the individual level. The PSRO program reviewed services and items reimbursed through Medicare. The purpose of these reviews was to determine whether such services and items were medically necessary, had a quality that met professionally recognized standards, and were provided in the most effective, economic manner possible. Initially, the program was viewed as a mechanism for containing costs and controlling medical practice, not necessarily improving clinical quality of care.

In an effort to increase the effectiveness of quality review organizations, Congress, through the Peer Review Improvement Act of 1982 (Title I, Subtitle C, of the Tax Equity and Fiscal Responsibility Act of 1982) authorized the utilization and quality control peer review organization (PRO) program. Section 1862(g) of the Act required the Secretary to contract with utilization and quality PROs to promote the economy, effectiveness, efficiency, and quality of services reimbursed through Medicare. PROs, now known as Quality Improvement Organizations (QIOs), continue these functions today. The focus of the program has moved away from a punitive approach, concentrating on individual providers and practitioners, to a systems approach developing collaborative relationships with the provider community.

The CMS continues to work with a more systemic approach to improving quality of care as this approach enables CMS to identify and correct deficiencies that have multiple contributing factors, as is typically the case in the delivery of health care. A punitive approach that targets practitioners on an individual level often fails to address multiple contributing factors of poor quality care. A systematic approach to quality improvement enables a collaborative relationship between the QIOs and providers that leads to opportunities for improvement as well as accountability. Except in egregious cases, providers are assisted in analyzing root causes, exploring system changes, and applying interventions that are intended to result in measurable outcomes. This systems-based approach is consistent with the Institute of Medicine's 2000 report "To Err is Human: Building a Safer Health System" and is the basis for many of the quality improvement activities conducted by QIOs in response to case review.

OIG Recommendation

Although the OIG did not include formal recommendations in its report, it was suggested that CMS consider whether it needs to revise its guidance to QIOs regarding classifications of confirmed quality concerns and recommending corrective actions.

CMS Response

Although no formal recommendation was made by the OIG, CMS is currently evaluating QIO case review processes for reviewing and classifying quality of care concerns and for implementing quality improvement activities (QIAs), formerly known as corrective action plans.

Currently, under section 1154(1)(B) of the Act QIOs are charged with ensuring that the quality of such health care services meet professionally recognized standards of health care. QIOs identify quality of care concerns through the medical record review process and implement QIAs when appropriate.

The system by which QIOs classify quality of care concerns provides a flexible, multi-tiered approach that maximizes opportunities for quality improvement in health care delivery systems. CMS has recently implemented a revised and more comprehensive array of QIAs. These activities address deficiencies in areas such as patient care by physician and other provider staff, safety of the environment, clinical topics, medical record documentation, and communication and patient rights. In a continuous effort to improve quality of health care services, QIAs may be implemented with providers even when quality of care concerns are not identified. These would include areas such as poor communication with the beneficiary or their representative, issuing improper notices to beneficiaries that services are being terminated, and insufficient billing and coding practices.

As part of the QIO performance evaluation, QIOs are now required to implement QIAs in a certain percentage of cases in which quality of care concerns have been identified. Depending upon the type of QIA, QIOs also monitor the impact of such activities. CMS recognizes the need for evaluating the effectiveness of QIAs over time in order to determine their full impact. We further agree that re-evaluation of our classification of quality of care concerns and our instructions regarding appropriate quality improvement activities is timely, as we continue to evaluate our case review processes for opportunities for improvement.

We appreciate the OIG's efforts in conducting its investigation of the extent to which QIOs identify quality-of-care concerns through medical record reviews and what interventions QIOs take in response to confirmed concerns. Using a systems-based approach to improve the safety and quality of health care, CMS will continue to evaluate and improve the process by which QIOs identify and classify quality of care concerns, and implement QIAs in an effort to impact health care services provided to Medicare beneficiaries.

ACKNOWLEDGMENTS

This report was prepared under the direction of Joyce M. Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston regional office, and Russell W. Hereford, Deputy Regional Inspector General.

Kenneth R. Price served as the team leader for this study and Ivan E. Troy served as the lead analyst. Central office staff who contributed includes Doris Jackson.