DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

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TO: Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services

FROM: Stuart Wright /S/
Deputy Inspector General
for Evaluation and Inspections

SUBJECT: Memorandum Report: *Quality Improvement Organizations' Final Responses to Beneficiary Complaints*, OEI-01-09-00620

This memorandum report provides information about Quality Improvement Organizations' (QIO) final responses to beneficiary complaints. Specifically, it provides information on (1) the number of QIO reviews of beneficiary complaints completed between August 1, 2008, and December 31, 2009, that included practitioner consent for disclosure; and (2) whether the final responses from QIOs met requirements for responding to complainants.

We found that QIOs completed 4,500 complaint reviews between August 1, 2008—when their current contracts began—and December 31, 2009. As part of those reviews, QIOs made 2,768 requests to practitioners for consent to disclosure, and 52 percent (1,449) of the practitioners consented.

We also reviewed in detail 120 final responses that QIOs sent to beneficiaries to determine whether the responses met program requirements. Sixty responses were cases in which the practitioners consented to disclosure, and 60 were cases in which practitioners declined to consent. We determined whether each response met the requirement that it state whether the beneficiary's care met professional standards, a requirement arising from both the Centers for Medicare & Medicaid Services (CMS) policy and a 2003 U.S. Court of Appeals decision. All 60 of the responses with practitioner consent met this requirement. Of the 60 responses without practitioner consent, all but 2 met the requirement. Our review showed that most QIO responses to complainants are meeting the terms of both the court decision and the CMS criteria regarding professional standards, as well as CMS's additional criteria.

When a practitioner consents to disclosure, CMS has two additional requirements: (1) the QIO response must contain a summary of the medical record, and (2) it must describe the corrective action that the QIO took in response to any confirmed quality-of-care concern. All of the 60 responses with practitioner consent contained a summary of the medical record, and 58 of

them described the corrective action taken. Of the two responses that did not describe the corrective action, one stated that the QIO would work with the practitioner to improve future care, and the other stated only that "appropriate action will be taken."

Of the 60 responses without practitioner consent, 58 met the minimum standard (i.e., specifying whether care met professional standards). Six of these fifty-eight responses, however, went beyond the minimum—they included information describing corrective actions that the QIOs took, even though CMS does not require such information for responses when the practitioner does not consent to disclosure. According to one of the three QIOs that sent these responses, the practitioners involved had not objected to including this information.

BACKGROUND

Quality Improvement Organizations

CMS contracts with QIOs to oversee and enhance the quality of care within the Medicare program and to protect over 40 million Medicare beneficiaries. QIOs conduct different categories of medical record reviews and work with health care providers on quality improvement initiatives. In carrying out these functions, QIOs serve as an essential frontline mechanism for beneficiary protection.

QIOs sign 3-year contracts with CMS to work in the 50 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. (Each State has one QIO, although a QIO can operate in more than one State.) Each 3-year contract is governed by a scope of work (SOW). The QIOs' 9th SOW began on August 1, 2008, and extends through July 31, 2011. Funding for the 9th SOW will total about $1.1 billion.[1]

QIOs have a statutory responsibility to review all written complaints from Medicare beneficiaries (or their representatives) alleging that the quality of medical services does not meet professionally recognized standards of health care.[2] The Office of Inspector General (OIG) examined this function twice in the past 15 years, and both times found that the QIOs' final responses to complainants lacked substance.[3] In its 1995 report, OIG recommended that QIOs respond substantively to complainants, and identified three elements that a response must describe to be substantive:

1. what the QIO did to investigate the complaint;
2. what the investigation revealed, including whether a quality-of-care problem was confirmed and, if so, the nature of the problem; and

[1] Department of Health & Human Services (the Department), *Fiscal Year 2010 Budget in Brief*. Accessed at http://www.hhs.gov/asrt/ob/docbudget/2010budgetinbriefl.html on September 10, 2010.

[2] Social Security Act, § 1154(a)(14).

[3] OIG, *The Beneficiary Complaint Process of the Medicare Peer Review Organizations*, OEI-01-93-00250, November 1995 and *The Medicare Beneficiary Complaint Process: A Rusty Safety Valve*, OEI-01-00-00060, August 2001. (Note that QIOs were previously known as "peer review organizations.")

3. what action the QIO took based on a confirmed quality concern.[4]

In its comments on our 1995 report, CMS stated that it would take this recommendation under advisement, but expressed concerns about balancing these responses with the rights of providers to refuse to consent to disclosure.[5]

Beneficiary Complaint Reviews

Reviews. For all written complaints, a QIO conducts a medical record review using nonphysician and physician reviewers. If the nonphysician reviewer identifies a potential quality-of-care concern, he or she refers the case to a physician. If the physician reviewer confirms a quality-of-care concern, the QIO offers the practitioner who rendered that care the opportunity to provide additional documentation and to request two additional levels of physician review. The final reviewer examines all pertinent information and makes a determination regarding the care given.[6]

If the final review confirms a quality-of-care concern, the QIO may take further action with the provider or practitioner, such as requiring a quality improvement plan or recommending alternative approaches to future care. However, CMS does not require the QIO to take further action unless the QIO establishes a pattern of concerns.[7] If the QIO establishes such a pattern, CMS instructs the QIO to work with the practitioner to identify remedial problems and develop an action plan.[8]

Notice of disclosure. When the case involves a specific practitioner, regardless of the outcome of the review, that practitioner may refuse to consent to the QIO's release of any information in its final response to the complainant that explicitly or implicitly identifies the practitioner. After the QIO completes the review, but prior to notifying the complainant of the review's outcome, it must provide notice of disclosure to the practitioner, who has 30 days to respond.[9]

Final response to complainant. The QIO must inform the complainant of its final disposition of the complaint.[10] However, the content of the response (beyond a standard introduction, including a summary of the complaint) depends on whether the practitioner consented to disclosure.

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[4] OIG, *The Beneficiary Complaint Process of the Medicare Peer Review Organizations*, OEI-01-93-00250, November 1995.

[5] Ibid.

[6] CMS, *QIO Manual*, Chapter 4—Case Review, Rev. 2, 07-11-03, §§ 4310–4320.

[7] Ibid. § 4700.

[8] Ibid. § 4705. CMS guidance does not define what constitutes a pattern of concerns.

[9] 42 CFR § 480.133(a)(2)(iii) and CMS, *QIO Manual*, Chapter 5—Quality of Care Review, Rev. 9, 08-29-03, § 5025(B).

[10] Social Security Act, § 1154(a)(14).

Final response when practitioner consents to disclosure. If the practitioner consented to disclosure, the QIO's response indicates whether the care received by the complainant met recognized standards of quality. The response also gives a complete summary of the review's findings and the action taken in response to any confirmed quality-of-care concern.[11]

Final response when practitioner declines to consent to disclosure. If the practitioner did not consent to disclosure, CMS does not require the response to include a summary of the medical record or information on any corrective actions taken. Until 2003, CMS instructed QIOs to state only that they had conducted a review but could not provide any information identifying the involved practitioner.[12] Following a court decision, CMS changed its guidance (see below).

Public Citizen v. Department of Health & Human Services

In 2001, the advocacy group Public Citizen brought suit against the Department and CMS regarding the processes for notifying beneficiaries who submit complaints to a QIO. Public Citizen maintained that CMS's regulations and manual sections regarding practitioner consent were contrary to the Peer Review Improvement Act of 1982,[13] which requires QIOs to inform complainants of the final disposition of their complaints. The court ruled that CMS's regulations and manual sections prohibiting disclosure of the results of investigations were invalid because they were contrary to section 1145(a)(14) of the Social Security Act. The court ordered CMS to send a letter to QIOs informing them that they are required to disclose the results of reviews to complainants.[14]

The Department appealed the decision, and in 2003 the U.S. Court of Appeals for the District of Columbia Circuit upheld the district court's decision. The Court of Appeals stated that QIOs must notify complainants of the results of their reviews, meaning, at a minimum, the determination as to whether the quality of the services that the beneficiary received met "professionally recognized standards of health care."[15] The court did not require QIOs to include in the final response a summary of the medical record or to describe corrective actions taken. Following the 2003 court decision, CMS required QIOs' final responses to state whether a beneficiary's care met professional standards, regardless of whether the practitioner consented to disclosure.[16]

See Table 1 for the criteria for QIO final responses to complainants. The court decision mandates one element that QIOs must include in all final responses. CMS requires three elements when the practitioner consents to disclosure and one when the practitioner does not.

[11] CMS, *QIO Manual*, Chapter 5—Quality of Care Review, Rev. 9, 08-29-03, § 5030(A).
[12] Ibid., § 5030(C).
[13] P.L. 97-248, Social Security Act, §§ 1101–1183.
[14] Public Citizen, Inc. v. U.S. Department of Health & Human Services, 151 F. Supp. 2d 64 (D.D.C. 2001).
[15] Public Citizen, Inc. v. U.S. Department of Health & Human Services, 332 F.3d 654 (D.C. Cir. 2003).
[16] CMS, Transmission of Policy System, Control Number: QIO 2003-08, August 11, 2003.

Table 1: Summary of Criteria for QIO Final Responses

Entity	Final Response to Complainant Includes:	Practitioner Consent Given	Practitioner Consent Not Given
Court of Appeals	Whether care met professional standards	Required	Required
CMS	Whether care met professional standards	Required	Required
CMS	Summary of the medical record	Required	Not Required
CMS	Description of any corrective action taken	Required	Not Required

Source: Public Citizen, Inc. v. U.S. Department of Health & Human Services, 332 F.3d 654 (D.C. Cir. 2003); CMS, *QIO Manual*, Chapter 5—Quality of Care Review, Rev. 9, 08-29-03, §§ 5030(A) and 5030(c) and Transmission of Policy System Control Number: QIO 2003-08, August 11, 2003.

METHODOLOGY

Scope

We analyzed data on the number of beneficiary complaint reviews from QIOs for 48 States and the District of Columbia. We also analyzed final responses sent from QIOs for the 20 States with the largest Medicare populations. Those States are (from largest to smallest Medicare population): California, Florida, New York, Texas, Pennsylvania, Ohio, Illinois, Michigan, North Carolina, New Jersey, Georgia, Virginia, Massachusetts, Tennessee, Missouri, Indiana, Washington, Wisconsin, Arizona, and Alabama. In 2008, these 20 States accounted for 75 percent of the total Medicare population.

Data Sources and Collection

Number of complaint reviews. We obtained from QIOs information on:

- the number of complaint reviews that each QIO completed between August 1, 2008, when the current SOW began, and December 31, 2009;
- the number of requests for practitioner consent to disclosure made as part of those reviews; and
- the number of those practitioners who consented to disclosure.[17]

We received data for QIOs representing 48 States and the District of Columbia. Two QIOs did not respond to our request; we made three attempts to collect the data from them.

Final responses. For the 20 States with the largest Medicare populations, we obtained from each QIO 6 six recent final responses sent to beneficiaries at the conclusion of a complaint review. Specifically, we obtained the three most recent responses with practitioner consent to disclosure and the three most recent responses without practitioner consent for disclosure. This gave us

[17] One QIO began the 9th SOW on December 22, 2008.

120 total responses, 60 of which included practitioner consent for disclosure and 60 of which did not.

Data Analysis
We calculated the total number of complaint reviews that QIOs completed and the total number of practitioner disclosure requests that QIOs made as part of those reviews. We then calculated the percentage of complaint reviews in which the practitioner consented to disclosure. We compared the contents of each final response with the 2003 Court of Appeals decision and CMS's criteria, as summarized in Table 1.

Limitations
We did not independently verify the QIO data on numbers of completed reviews, practitioners, and consent rate. The results of our analysis of whether final responses met requirements are limited to the 120 letters we reviewed; we cannot project these results to the universe of final response letters.

Standards
This study was conducted in accordance with the *Quality Standards for Inspections* approved by the Council of the Inspectors General on Integrity and Efficiency.

RESULTS

QIOs Obtained Consent for Disclosure in About Half of Practitioner Requests

Between August 1, 2008—the start of the 9th SOW—and December 31, 2009, QIOs completed 4,500 complaint reviews. As part of those 4,500 reviews, QIOs made 2,768 requests for practitioner consent to disclosure, and 52 percent (1,449) of those practitioners consented.[18] This means that in almost half of the cases involving specific practitioners, the beneficiaries received less information about the outcome of their complaint (e.g., no summary of their medical record) than in cases that had practitioner consent. This consent rate is higher than the rate found in our 2001 report, which found that QIOs obtained practitioner consent in only 21 percent of complaints when a quality-of-care concern was confirmed and in 42 percent of complaints when no concern was confirmed.[19]

Of the 120 Total Responses we Reviewed, 116 Met Requirements

<u>One hundred and eighteen responses stated whether care met professional standards</u>. Both the 2003 court decision and CMS require all QIO final responses, regardless of whether the practitioner consented to disclosure, to state whether the care under review met professional

[18] Not all beneficiary complaint reviews involve a specific practitioner. Some concern only a facility; in these cases the QIO would not need to seek practitioner consent for disclosure. Conversely, some complaints may involve more than one practitioner; in these cases, the QIO must seek consent from each involved practitioner.

[19] OIG, *The Medicare Beneficiary Complaint Process: A Rusty Safety Valve*, OEI-01-00-00060, August 2001.

standards. In meeting this criterion, 118 of 120 responses we reviewed stated that care met "professionally recognized standards of care" or that care "was appropriate."

The two responses that did not meet this requirement each concerned complaints in which the practitioner did not consent to disclosure, and both came from the same QIO. Each response stated only that the QIO completed the review and would take appropriate action if warranted, omitting any mention of the QIO's findings. This means that for these two complaints, the beneficiaries who complained did not learn whether the care they received met professional standards of quality.

All 60 responses with consent for disclosure contained a summary of the medical record. Each of the 60 responses for which the practitioner consented to disclosure contained a summary of the beneficiary's care as noted in the medical record. This summary typically included any tests given, their results, and the course of treatment.

All but 2 of the 60 responses with consent for disclosure described the corrective action taken in response to a confirmed quality-of-care concern. Responses that met the criterion for a description of the corrective action listed specific actions that the QIO took. For example, these responses stated that the QIO required the provider or practitioner to complete a quality improvement plan, or that the QIO's physician reviewer recommended alternative approaches to future care designed to address the quality-of-care concern. Of the two responses that did not meet this criterion, one stated that the QIO would work with the practitioner to improve future care, and the other stated only that "appropriate action will be taken."

Six of the sixty responses in which the practitioner declined to consent to disclosure provided more information than CMS requires. Each of these six responses included information describing corrective actions taken in response to a confirmed quality-of-care concern. In these cases, a typical response required the practitioner to complete a quality improvement plan. When the practitioner does not consent to disclosure, CMS does not require QIOs to include information regarding the corrective actions the QIO took. We spoke with staff at the QIO that sent three of these six responses. According to staff, the involved practitioners had not objected to including that information.

CONCLUSION

Our review showed that most QIO responses to complainants are meeting the terms of both the court decision and CMS criteria regarding professional standards, as well as CMS's additional criteria. However, QIOs do not obtain consent for disclosure from almost half of the practitioners involved (Medicare regulations allow practitioners to decline consent). As similarly identified in previous OIG reports, requiring practitioner consent remains a barrier to providing beneficiaries with more complete information about their complaints.

Our review also showed that 6 of the 60 responses exceeded CMS's criteria by including information on corrective actions even when the practitioner did not consent to disclosure. The fact that at least one QIO is already providing such a response to beneficiaries without adverse consequences suggests that disclosure might not impose an undue burden on practitioners and that other QIOs could make the complaint process more transparent to all beneficiaries. Responses providing information on corrective actions taken would likely provide some assurance to beneficiaries that their complaints and any underlying problems identified were being addressed.

This report is being issued directly in final form because it contains no recommendations. If you have comments or questions about this report, please provide them within 60 days. Please refer to report number OEI-01-09-00620 in all correspondence.