U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Thursday, March 9, 2006

Grassley Continues Review of Medicare Quality Improvement Organizations

WASHINGTON – Sen. Chuck Grassley, chairman of the Committee on Finance, today continued his review of Medicare contractors known as Quality Improvement Organizations by asking the Centers for Medicare and Medicaid Services to respond to an Institute of Medicine Report on these organizations released today.

Grassley is concerned about the seeming lack of effectiveness and accountability by Quality Improvement Organizations, which have a major responsibility to investigate individual Medicare beneficiary complaints and appeals about the quality of doctor and hospital care.

The text of his letters today follows.

March 9, 2006

Via Electronic Transmission
The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator McClellan:

As Chairman of the Senate Committee on Finance (Committee), which has jurisdiction over the Medicare program, I am responsible for oversight of matters that affect the beneficiaries of federal health care programs. A number of allegations regarding Quality Improvement Organizations (QIO), which are charged with improving the quality of care provided to Medicare beneficiaries, were brought to my attention during the past several months, including but not limited to allegations of mismanagement of government funds and a lack of responsiveness to beneficiary complaints. As I outlined in correspondence to you dated March 3, 2006, the preliminary findings of my inquiry indicate a reason for concern about, among other things, the effectiveness of the QIOs.

Today, the Institute of Medicine (IOM) released a report on the QIOs mandated by Section 109 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Many of the findings

and recommendations confirm some of the problems my Committee staff identified in its ongoing review of documents and information related to the QIOs. As Chairman of the Committee, I request that the Centers for Medicare and Medicaid Services (CMS) describe in detail any actions it plans to take to address the issues and individual findings and recommendations presented in the IOM report by April 7, 2006. In particular, please respond specifically to the findings and recommendations outlined below. In addition, if CMS disagrees with, or wishes to expand upon, amend, or modify any of the IOM's findings please feel free to share your views regarding the future activities, operations, and structure of the QIOs.

QIO EFFECTIVENESS

On February 9, 2006, Secretary Michael Leavitt, Department of Health and Human Services (HHS), testified before the Committee on the President's fiscal year 2007 budget proposal and stated, among other things, that in assembling the HHS budget, he asked his colleagues to apply eight principles to every investment that the agency is making. One of those principles is looking for programs that can be measured. In particular, he testified, "If we cannot measure their benefit, I think there has to be some question asked about whether there is benefit." One of the repeated concerns about the QIOs is the lack of information about the effectiveness and quality of the services they provide. I am sure we both agree that ensuring an independent and rigorous evaluation of program effectiveness is critical to making significant financial investments of taxpayer funds.

The IOM recommends that a rigorous and extensive evaluation be conducted to assess the QIO program. The literature review conducted by the IOM revealed a lack of any conclusive evidence to determine the effectiveness of the QIOs in improving the quality of health care. Even when general improvements in quality are identified, it is not possible to determine the extent to which these improvements can be attributed to the QIOs' efforts. Furthermore, the IOM itself could not find conclusive evidence about which QIO intervention methods are most effective. The IOM report points to anecdotal evidence about the existence of "outstanding" and "mediocre" QIOs; however, based on the available QIO contractor performance data, IOM could not determine which QIOs belong in each category or whether there are significant differences in performance between QIOs.

In light of the fact that the IOM could not attribute the gradual improvements in quality of care to the QIOs, it recommends that CMS evaluate the QIO program as a whole, as well as evaluate the individual QIOs, and selected quality improvement interventions implemented by the QIOs. As noted in the current IOM report, the IOM has recommended in the past the need for documentation of the impact of QIOs and the need to evaluate the QIOs.[1] [2] Unfortunately, CMS did not implement these recommendations. Accordingly, please explain how CMS now plans to address the lack of conclusive evidence to determine the effectiveness of QIOs in improving the quality of health care. Additionally, please explain how CMS plans to address the lack of rigorous evaluations of the QIO program's impact on quality of health care. As Chairman of the Committee, as a U.S. Senator, and as a taxpayer, I believe it is imperative that CMS not let another decade go by before addressing this issue of QIO effectiveness, especially given the amount of taxpayer dollars consumed by the QIOs.

LIMITING QIO ROLE TO TECHNICAL ASSISTANCE

The IOM recommends that QIOs concentrate their resources and efforts solely on providing technical assistance to providers for performance measurement and quality improvement. To accomplish this,

the IOM also recommends that the responsibility for beneficiary complaints, appeals, and case reviews for payments be assigned to other entities such as fiscal intermediaries. IOM concluded this based on its finding that, currently, QIOs do not see the beneficiary as their primary customer. The IOM also concluded that a QIO's conflicting dual role of partner with providers on quality improvement and regulator on beneficiary complaints hinders its ability to perform both functions well. My Committee staff found information indicating that beneficiary complaints are not a high priority for QIOs even though it is one of their major functions. The number of beneficiary complaint cases completed by the QIOs, 2,891 between August 1, 2004, and August 30, 2005, appears disproportionately low considering there are 43 million Medicare beneficiaries.

In addition, the IOM found that the confidentiality protections afforded providers by the QIOs are not well suited to broader trends in the health care environment which emphasize transparency, public reporting, and consumer access. The IOM concluded that the current confidentiality restrictions constrain the use and sharing of data on quality improvement. My Committee staff identified a lack of responsiveness on the part of QIOs with regard to communicating with beneficiaries about the results of complaint reviews. Indeed, you may recall the *Washington Post* exposé on the QIOs this past summer. That exposé discussed a QIO's lack of responsiveness to David Shipp regarding the findings of a QIO investigation into the death of Mr. Shipp's wife; an investigation which was initiated by a complaint Mr. Shipp filed with the QIO. Mr. Shipp was forced to wait for the conclusion of legal proceedings, including an appeal by HHS of a ruling favorable to Mr. Shipp, just to learn what the QIO found with regard to his wife's death. Even the American Health Quality Association (AHQA) has now proposed changing the practice of withholding information about complaint reviews from complainants.

In light of the IOM's recommendation, coupled with AHQA's proposed changes to the practice of withholding information, I would appreciate knowing CMS's position on the IOM's recommendation to transfer beneficiary complaints, appeals, and case reviews to entities other than the QIOs. Regardless of CMS's preferred mechanism for conducting complaints, appeals, and case reviews, how will CMS ensure transparency and responsiveness to beneficiaries, who at this time are left in the dark?

DATA PROCESSING

The IOM concludes that the "Changing environment of health care, with the increased public reporting of performance measures and payment incentives for providers who meet certain quality standards, will create a growing demand from providers for technical assistance with the reporting of performance measures and analysis as well as with process and systems." The IOM recommended that the QIOs become an integral component of strategies for future performance measurement. The IOM believes the QIOs should help build provider capacity by providing instruction on how to collect, aggregate, and interpret data on quality measures, how to conduct root-cause analysis, and provide advice and guidance on how to bring about and sustain internal system design among other things. One IOM recommendation that is integral to this transformation is the revision of the QIO program's data handling practices. Data should be available to providers and the QIOs in a timely manner to improve services and measure performance. National reporting of performance measures, data aggregation, data analysis, and feedback are important components in the development of quality initiatives. The goal of integrating more care data from all providers and public and private payers to create records of patient data over time is also important as we move forward with greater transparency in the health care system. In light of IOM's recommendations in this area and CMS's

commitment to pay for performance as a strategy to improve quality, please explain how HHS and CMS plan to move forward with these recommendations regarding data processing and management on a national level. Please also outline what steps are being taken, if any, to allow and encourage the sharing of medical claims data when the sharing of the data is not precluded by the Health Insurance Portability and Accountability Act.

BOARD OF DIRECTORS: FUNCTIONS & STRUCTURE

The IOM recommended a number of changes to QIO board functions and structure. Specifically, the IOM called for implementing methods for periodically assessing the performance of individual board members and the boards as a whole, establishing a strong oversight role for the board, and ensuring transparency with regard to board member compensation. My Committee staff's review of the QIOs identified some problems with regard to board member compensation, contractual and other financial arrangements which give the appearance of conflicts of interest, and questionable expenditures by the QIOs. Steps taken to assess board member performance, strengthen the oversight role of QIO boards of directors, and increase transparency regarding board member and executive staff compensation arrangements would go a long way to addressing some of the problems that the IOM and my Committee staff found. Accordingly, please describe for the Committee, what actions CMS plans to take to address the issues raised by the IOM report regarding transparency and effectiveness of QIO boards of directors.

CONTRACT STRUCTURE

The IOM recommends further that CMS change the QIO contract structure to provide incentives for high performance and penalties for poor performance, and permit greater competition for new contracts. My inquiry revealed that there is very little, if any, competition for QIO contracts. Almost all QIO funding and contract renewals are contingent on a QIO's performance of the contract terms and not on performance relative to improving the quality of health care. As I suggested in my previous letter to CMS, dated March 3, 2006, perhaps it is time that CMS consider competing all QIO contracts in the future. Without introducing competition into the mix, CMS cannot ensure, in light of the wide and complex assortment of tasks performed by QIOs, that the executive branch is contracting with those entities best suited to perform the task at hand at the highest level for the American taxpayer.

RECENTLY PROPOSED GUIDELINES

Recently, AHQA formalized standards of business practices and accountability for the QIO community. Such guidelines are certainly a step in the right direction. Specifically, AHQA called upon the QIO community to adopt a "formal code of conduct." I understand that a good number of the QIOs have voluntarily agreed to adopt these guidelines addressing issues such as board/executive compensation, board structure, and travel policies. At the same time, it is indisputable that self-regulation, voluntary adoption, and public endorsement of high standards for QIO accountability are meaningless without consistent oversight and related accountability.

In closing, I would be remiss if I did not acknowledge that the QIO community does indeed have a function and a role to play in improving the quality of care provided to our Medicare beneficiaries. After all, there are thousands of individuals who are committed to improving the care in hospitals, nursing homes, physician practices, and home health care in all 50 states and the U.S. territories. At the same time, I do think it is high time to turn back the covers, to address the IOM's

recommendations, to re-examine the role and structure of the QIO community, and to force positive change for the future.

Thank you for your attention to this important matter. I would appreciate a response to my inquiries no later than April 7, 2006. Additionally, I propose that our respective staff join forces to address the critical issues and recommendations set forth by the IOM, as well as the findings of my Committee staff. Accordingly, please have your staff contact my office to schedule a meeting to occur no later than April 28, 2006, to discuss how to improve the QIO program.
Sincerely,
Charles E. Grassley
Chairman

(1) Institute of Medicine, *Medicare: A Strategy for Quality Assurance, Volume I*, Washington, DC: National Academy Press, 1990.
[2] Institute of Medicine, *An Assessment of the HCFA Evaluation Plan for the Medicare Peer Review Organization,* Washington, DC: National Academy Press, 1994.

March 9, 2006
Via Electronic Transmission
Harvey V. Fineberg, MD, PhD
President
Institute of Medicine
500 Fifth Street, NW
Washington, DC 20001

Dear Dr. Fineberg:

The Committee on Finance (Committee), which has exclusive jurisdiction over the Medicare program, has a responsibility to the millions of Americans served by this program to ensure that initiatives funded with Medicare dollars, such as the Medicare Quality Improvement Organization (QIO) program, achieve value for money spent.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed the Institute of Medicine (IOM) to conduct a study of the QIO program, including, among other things, evaluating the extent to which QIOs improve the quality of care for Medicare beneficiaries. Thank you for the report entitled, "Medicare's Quality Improvement Organization Program." I appreciate the IOM's intensive review and careful examination of the QIOs' activities, services, and operations.

Many of the IOM's findings regarding the beneficiary complaints process, board structure, contracting, and QIO effectiveness echo the concerns I raised about the program in my letter to the Centers for Medicare and Medicaid Services (CMS) last week. In particular, my Committee staff have heard from beneficiaries that are very dissatisfied with efforts by the QIOs on their behalf. It appears that the QIOs place a very low priority on their mandate to investigate and resolve beneficiary complaints against providers. Although the IOM did not have the opportunity to seek input from individual beneficiaries regarding the QIO program as part of its review, information obtained from other sources led the IOM to recognize that the QIOs are not effectively carrying out this portion of their mission and propose moving that function to a different set of organizations altogether. I commend the IOM for adding to the public discourse regarding the effectiveness of and

future role for the QIOs.

In closing, I forwarded a copy of IOM's report to CMS for consideration. In particular, I asked CMS to respond to specific issues, findings, and recommendations presented in the report. Thank you again for the IOM's input and recommendations on the QIO program.

Sincerely,

Charles E. Grassley
Chairman

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