



***BEYOND QIO:***  
**MODELING A MEDICARE BENEFICIARY COMPLAINT  
PROCESS FOR QUALITY OF CARE**

**Elements and Considerations for Developing a Medicare Beneficiary  
Complaint Process to Address Quality of Care Concerns:  
The Medical Perspective**

Peter A. Hollmann, MD\*

**ABSTRACT**

The Centers for Medicare & Medicaid Services (CMS) contracts with Quality Improvement Organizations (QIOs) for services, including the review of beneficiary complaints about quality of care. Among other substantial studies, a recent (2006) Institute of Medicine (IoM) report, *Medicare's Quality Improvement Organization Program: Maximizing Potential*, challenged CMS to move the review of the beneficiary complaint process from the QIOs. This paper takes the perspective of a physician in assessing attributes of a more ideal process, regardless of the ultimate entity selected to perform the review function. It uses the attributes delineated by a 2001 report from the Department of Health and Human Services Office of the Inspector General (OIG) as a basis of analysis and comment. The paper concludes that the complaint-review process is complex and challenging, while retaining its primary obligation of maintaining beneficiary and societal trust through responsiveness, transparency, and assurances of minimal standards of provider competency. Secondary roles relate to quality and safety improvement and improving provider competency. The quality and value of the review process is only partly determined by the designation of a review entity. Processes that foster communication, disclosure, self-assessment, problem identification, and root-cause analysis are also desirable. This paper is one of two commissioned by the Center for Medicare Advocacy, Inc., to examine the history of the complaint review process and assesses the potential for alternative structural and procedural mechanisms of review. The objective is to stimulate and inform discussion regarding alternatives to the current beneficiary complaint review system. It is written with the assumption that the QIOs will not perform beneficiary complaint review.

---

\* Geriatrician and Assistant Clinical Professor in Family Medicine, Brown University Medical School, Providence, RI; Medical Director, Blue Cross & Blue Shield of Rhode Island

# **Elements and Considerations for Developing a Medicare Beneficiary Complaint Process to Address Quality of Care Concerns: The Medical Perspective**

## **INTRODUCTION**

This paper seeks to assess the challenges that the Centers for Medicare & Medicaid Services (CMS) contracted Quality Improvement Organizations (QIO) have faced. The purpose here is to review those assessments to highlight effective or ineffective performance for the purpose of defining necessary attributes for a better organizational structure and processes, not to assess the QIOs. Other evaluations<sup>1,2</sup> have sought to evaluate performance of the QIOs and their predecessor Peer Review Organizations (PROs).

This paper takes a medical perspective in addressing these issues. It is a companion to another paper that relies upon the skills and insights of the legal perspective. That paper also provides additional background regarding the history of the QIO process and analyzes specific alternative entities in more detail. The set of papers does consider existing entities. State survey agencies and physician licensure boards are primary candidates. An entirely new organization is felt to likely increase fragmentation and duplication. But, the focus of this paper is more on an ideal process that may be considered regardless of the ultimate review entity. It is likely that some potential entities would have a greater or lesser capacity to implement such goals.

A fundamental operating assumption in this writing is that the QIOs, in keeping with the recommendations of the Institute of Medicine (IoM),<sup>3</sup> will not perform complaint review. It endeavors to answer whether better performance is possible, whether any entity may be able to perform more effectively, and what will be lost and gained if beneficiary complaint review is not a core QIO function. A further question is how to describe the skills and processes that need to be in place for adequate complaint review and response, what new relationships will be required, and what systemic, rather than organizational, changes may be necessary for improvement.

This paper is written with the premise that while the beneficiary complaint process ideally achieves many laudable goals, it is not successful if the beneficiary does not feel the complaint itself was addressed in a generally adequate, fair, and open manner. The purpose of these papers is to stimulate and inform discussion regarding impending policy decisions about the beneficiary complaint process. It is a prelude to a summary of the discussion and not a draft proposal to resolve the debate.

---

<sup>1</sup> “The Medicare Beneficiary Complaint Process: A Rusty Safety Valve,” OIG OEI-01-00-00060 (August 2001) (hereinafter “2001 OIG Report”).

<sup>2</sup> “Medicare’s Quality Improvement Organization Program: Maximizing Potential,” Institute of Medicine, 2006 (hereinafter “2006 IoM Report”).

<sup>3</sup> *Id.* at 112.

It may be presumed, but it should be disclosed, that a physician would bring certain biases to such a review. The “medical perspective” is really that of a physician and although it may be shared by organizational entities such as hospitals, nursing facilities, equipment providers and others, that is not certain.

## **DISCUSSION**

### **The Interplay of Complaints and Quality**

Perhaps the greatest bias a physician brings to this discussion concerns how complaints are perceived in the larger context of quality, quality measurement, and quality improvement. Complaints review is reminiscent of the past QIO focus of reviewing records and finding something that was “wrong” and then beginning an investigation.

This methodology was rejected as inefficient, if not detrimental, in improving the quality of care. It contrasts to the current approach of defining certain measures, seeking continuous performance improvement and support of an infrastructure transformation designed to improve quality and efficiency. Complaints are “anecdotes” as compared to designed studies powered to achieve statistical relevance. Complaints are fundamentally reactive and not preventive. Complaints may create an awareness of a need for a process or structural change warranting a quality improvement approach, just as a medical observation may be the start of a future randomized controlled trial. This is the principle of sentinel event review. But healthcare providers would not want to see the current direction of quality improvement and infrastructure support being replaced with the former approach that was accepted as inefficient, ineffective, and potentially adversarial.<sup>4,5</sup>

Patient satisfaction is important. Outside of care undertaken primarily to control contagion or otherwise protect the public, the individual patient’s health goal is the primary purpose for care. A patient who is dissatisfied is less likely to follow recommended care or may become a risk management concern. Healthcare providers, nonetheless, generally place a greater emphasis on technical quality than on patient satisfaction. This is professionalism greater than hubris. In other words, a hallmark of professionalism is defining standards and quality. While patient perspectives are respected and germane, satisfaction alone is an insufficient attribute to define quality. Many patients are very satisfied with care that physicians regard as unscientific and with provider types that physicians would only begrudgingly consider healthcare professionals.

Complaints are even a poor quantitative methodology for measuring satisfaction. At best, a pattern of complaints does identify persons with poor communication skills who are higher than average risk management concerns. While physicians view complaints as

---

<sup>4</sup> Bhatia, AJ, Blackstock, S, et al. “Evolution of Quality Review Programs for Medicare: Quality Assurance to Quality Improvement.” 2000. *Health Care Financing Review*, 22(1): 69-74.

<sup>5</sup> 2001 OIG Report at Appendix B (citing American College of Physicians-American Society of Internal Medicine letter to OIG, March 7, 2001).

relevant and as needing to be addressed, they would also view complaint management as having only limited potential to achieve greater goals than resolving the complaint.

It should be noted that there is no suggestion that complaint review replace quality improvement activities. To the contrary, the suggestion to remove the review from the QIO is to allow the QIO to focus on quality improvement. Additionally, there is no statement of expanding processes to find problems and problem providers. Rather, this is about defining a process of handling a complaint that was presented to Medicare by a beneficiary. While physicians recognize that most opportunities to improve care, safety, and outcomes are the result of suboptimal systems of care and are not the result of individual competence, they likewise know that there are problem providers or providers that need to be directed to improvement. While most complaints are not about and do not identify such providers, some do.

Finally, a physician's ears may have trouble in fully appreciating the seemingly obvious phonetic differences between "complaint" and "lawsuit." This problem is addressed in greater detail below.

### **A Focus on Quality Improvement Elements**

The 2001 landmark publication on healthcare quality, *Crossing the Quality Chasm*,<sup>6</sup> proposed six specific aims for quality improvement. Health-care should be: safe, timely, effective, efficient, equitable, and patient-centered ("STEEEP"). When it is not, healthcare professionals and organizations should seek to change processes and systems to improve healthcare quality. Such care is the goal of all healthcare providers and is reasonably accepted as a shared goal with individual patients and society. Failure to attain such goals may be a cause of patient complaint.

At a minimum, a beneficiary complaint reflects a failure to achieve the *patient-centered* goals of "providing care that is respectful and responsive to individual preferences, needs, and values and of ensuring that patient values guide all clinical decisions."<sup>7</sup> Healthcare providers have had to confront and acknowledge widely-accepted reports that there are many opportunities to improve in matters of safety<sup>8</sup> and in the processes of prevention and treatment.<sup>9</sup>

It is no reach to expect that there may be complaints in need of action. However, complaint management is extraordinarily complex. It requires skills in dealing with emotions of fear and anger; in understanding settings of care as diverse as the pharmacy and the nursing home; in evaluating care provided by an array of medical specialties; in handling multiple simultaneous issues;<sup>10</sup> in finding the sentinel event or near-miss needle

---

<sup>6</sup> Institute of Medicine, "Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century," 2001.

<sup>7</sup> *Id.*

<sup>8</sup> Institute of Medicine, "To Err is Human: Building a Safer Health System," Kohn, LT, Corrigan, JM, and Donaldson, MS, eds., 2000 (hereinafter "2000 IoM Report").

<sup>9</sup> McGlynn, EA, Asch, SM, et al. "The Quality of Health Care Delivered to Adults in the United States." 2003. *New England Journal of Medicine*, 348(26): 2635-2645.

<sup>10</sup> 2001 OIG Report.

in the complaint haystack; in judging fairly, without being judgmental and being a pioneer in the developing quality improvement and transparency movements. All this takes place under a cloud of concerns over litigation and privacy.

It is no wonder that there have been complaints about the process of complaint review for Medicare beneficiaries. Just as healthcare quality can be evaluated using its ability to attain the goals of STEEEP care, so do we seek a complaint review process that is STEEEP. It should be:

**Safe-** Matters requiring urgent resolution for patient safety and well-being must be addressed promptly by engagement in advance of extensive investigation; healthcare providers should not be harmed unless they are the rare incompetent or malicious provider.

**Timely-** The process should be thorough, but advance with sufficient speed so that the complainant appreciates the possibility of positive change being effected without delay and does not feel defeated or ignored.

**Effective-** Complainants should feel their complaints have been addressed, quality should improve in measurable ways, there should be provider remediation, and providers beyond remediation should be removed.

**Efficient-** The assessment process, corrective action evaluation, monitoring of improvements and fair hearing activity consumes resources that would otherwise be used for quality improvement, patient care or competing social needs such as education; unnecessary duplication of efforts by different entities should be eliminated.

**Equitable-** The process should be balanced, favoring no one party, producing neither winners nor losers, but rather promoting conflict resolution and performance improvement.

**Patient-centered-** All providers of healthcare ultimately desire the patient to receive a respectful acknowledgement of their concerns, even when there is disagreement. A process that is not understood or transparent to the patient will promote dissatisfaction and mistrust.

The 2006 IoM report, *Medicare's Quality Improvement Organization Program: Maximizing Potential*, concludes that beneficiary complaint management may hinder the QIOs in their primary mission to provide quality improvement technical support. It suggests that removing complaint management from QIO responsibility would allow the QIO to maintain the current focus and allow another entity to place the beneficiary as the primary client. In 2001, the Department of Health and Human Services Office of the Inspector General (OIG) evaluated the performance of the PROs in the area of

beneficiary complaint review. The OIG labeled the system a “rusty safety valve.” It used an evaluation template that was accepted by CMS and which remains useful today. The 2006 IoM report does note some measured improvement in beneficiary satisfaction regarding the process,<sup>11</sup> but based its recommendation to remove beneficiary complaint review from the QIOs as a matter of role clarity. However, the OIG commentary is useful to consider when reviewing the desired attributes of an alternative entity and therefore is considered below.

These two major assessments of the QIO program and the QIO management of beneficiary complaints are used as a starting point in commentary about several attributes of complaint management. They are important documents that have been the subject of substantial public comment and CMS review. The assessment template will serve as the outline for discussing a more ideal process and some consideration of alternate entities. For ease of presentation, we will label the beneficiary complaint review organization a “CRO.” This is not to suggest that any more acronyms are needed in Medicare, nor that a new entity is required and that a CRO function could not be fulfilled by an existing entity such as a professional licensure board.

The OIG report identified eight key attributes: accessibility, investigative capacity, interventions and follow-through, quality improvement orientation, responsiveness, timeliness, objectivity, and public accountability. These attributes are quite similar to using STEEEP as a manner of assessment. They are chosen as they have been accepted by CMS and widely considered. Each attribute is introduced using the OIG summary language followed immediately by a discussion which, except as noted, is not a representation of the OIG or IoM report conclusions. (To make the transition most apparent, quotation marks and italics are used for the OIG portion.)

### *Accessibility*

*“Accessibility requires that complainants be aware of the system and find it easy to use.”*

Phone line access and answer accuracy have been stated concerns by the OIG and IoM.<sup>12,13</sup> Accessibility may also be considered to involve convenience and the level of psychological barriers. Entities that frequently interact with the beneficiary are likely to be better known and more natural contacts than the QIO. Providers are the party with whom beneficiaries most frequently interact and, therefore, would be the most natural entity point for complaints, based upon familiarity alone. Providers can be expected to report complaints when identified as such. Often complaints are most quickly resolved when brought to the provider’s attention. Alternate dispute mechanisms for complaint and personal injury litigation or risk management propose using self-reporting mechanisms.<sup>14</sup>

---

<sup>11</sup> 2006 IoM Report.

<sup>12</sup> *Id.*

<sup>13</sup> 2001 OIG Report.

<sup>14</sup> Mello, M, Studdert, D, et al. “Health Courts” and Accountability for Patient Safety. 2006. *The Millbank Quarterly*, 84(3): 459-492 (hereinafter “Mello 2006”).

Many states require institutional provider reporting of specified events to regulators. Further, provider reports can come with the provider's assessment of the issue(s), identified opportunities for improvement and, when appropriate, a corrective action and quality monitoring plan. Providers may even solicit satisfaction results with standardized surveys and in doing so, elicit complaints. However, a system solely reliant upon self-reporting would have obvious limitations. This is especially problematic if providers perceive self-reporting as associated with adverse "report card" or regulatory events.

*Provider notice of non-coverage* - Providers also issue many notices as required by Medicare. Hospital admissions, home care service terminations, and skilled nursing facility terminations are among the services where a beneficiary is notified of appeal rights related to coverage of services. The notice provides an opportunity to inform the reader of complaint rights as well. A drawback may be that such notices do have an appropriately "legalese" format, which may create a barrier to conveying an open or "welcoming" process. It should not be the case that any format appear pejorative to the provider, but provider-issued notices remain an opportunity to communicate beneficiary rights to complain.

Medicare Advantage plans have frequent interaction with beneficiaries and have extensive customer services systems. Approximately 16 percent of Medicare beneficiaries are in such plans.<sup>15</sup> They do evaluate and handle complaints about providers and about their own performance. Part D plans also would be expected to be similarly structured. These organizations' efforts should be integrated into any process.

*State licensure or survey authority* - While beneficiaries would infrequently interact with a state licensure or survey authority, the beneficiaries are likely to be aware of such entities and the possibility of filing a complaint. For example, many facilities must post information about consumer protection rights and contacts. Media often use information from the survey and licensure entities or are critical of them for failing to protect the public. In either case, it contributes to recognition. Ease of communication with these organizations would be expected to vary by state.

*Perceptions of consequence* - Beneficiaries may also be reluctant to complain about any but the most serious matters if by lodging a complaint with a regulator the beneficiary felt it would be defacto perceived as being a statement that the professional or provider organization should receive licensure sanction. Some beneficiaries or their heirs may seek a pound of flesh, but many wish to continue relationships. Regulatory agencies are expanding their options to respond to issues. In doing so they are generally creating options that are less draconian and more oriented toward prevention and quality improvement. This allows them to more effectively be positioned with providers as protecting the profession or industry.

---

<sup>15</sup> Kaiser Family Foundation, "Medicare at a Glance – Fact Sheet." Webpage accessed July 2006. <http://www.kff.org/medicare/1066.cfm>.

*Improvement not punishment* - The provider community and public may also see the evolving regulator as being part of a cooperative enterprise to improve and not just punish. It is somewhat ironic that regulatory authorities are seeking to adopt some of the changes the QIOs adopted over a decade ago that are creating conflicts of interest for the QIO evaluation of complaints. While it is doubtful the regulator would ever be perceived or seek to be perceived as primarily an “assistant in performance improvement,” it is likely that psychological barriers for the public to report complaints can be lowered.

*Measuring access* - Improved accessibility, by removal of psychological barriers, may not be easily measured in regular reports. The concern remains for those who never make contact. However, basic measures such as calls blocked and answer times are metrics that call centers easily handle and monitor, often in real time. They are obvious performance monitoring candidates for any CRO that performs complaint review. Specific methods of public notice of call centers or other communication options, a requirement for a toll free number and multi-lingual options, can be specified.

*Form of complaints (oral or written)* - Complaints should be accepted orally or in writing. In most instances, a written confirmation will be required so that the complainant is aware of the CRO’s understanding of the complaint. The CRO can assist the complainant in the process of presenting a written or oral complaint. In doing so, the CRO will be able to convert all oral complaints into written ones, if the beneficiary is willing to sign and return a summary prepared by the CRO on his or her behalf. The interaction will also help clarify the complaint or help the beneficiary re-direct it, if the complaint is not about a qualifying matter (e.g., a benefits coverage issue only). Complaints will be received from the beneficiary, his or her representative, providers and others. These should all be accepted, but the specifics of investigation, follow-up and response will vary depending upon the beneficiary or the legal representative giving consent.

In summary, CMS can create contractual performance specifications for any CRO. Regulatory agencies appear to be good candidates for a CRO, but they may need to address fears of beneficiaries that complaints will result in undue severe action so as to minimize beneficiary reluctance to file complaints that the beneficiary perceives as only rising to the level of identification of an opportunity for improvement, not sanction. Complaints reviewed by any entity, e.g., a Medicare Advantage plan should be sent with a summary to the CRO.

### ***Investigative Capacity***

*“Investigative capacity indicates that appropriate experts, resources and methods are available to assess complaints and determine if they are part of an underlying problem.”*

*Qualifications of reviewers* - Appropriate expertise requires a wide range of professionals. Ideally reviews are not performed simply by physicians. In many cases there would need to be expertise in facilities issues such as staffing patterns. The best healthcare is provided by teams that work together effectively. The same may be said for quality

review. Furthermore, many complaints actually are multiple complaints and may include more than one provider type. Care transitions and care coordination are points where some of the most significant lapses in quality occur and would be expected to be common sources of complaint.

It is generally accepted that quality of care is reviewed by a physician of a like specialty that treats the disorder in question. Standards of care may be national, but there is some practice variation in the treatment of most conditions that is acceptable and may vary by community when there is a lack of evidence-based standards. Community resources and culture also affect care. It is anticipated that many, if not most, complaints would involve judgments using *implicit standards of care* and not explicit standards that are based upon evidence from well-designed research. Reviewers should avoid apparent conflict by reviewing care of associates or competitors. Therefore, there is need to balance local knowledge with potential conflicts of interest. Access to expert medical reviewers may require a large pool of physicians that exceeds local capacity. Such expertise can be costly.

*Knowledge of the complaint review process is paramount* - The true expertise needed is not subspecialty medical knowledge in most cases. The expertise required is in complaint review. The volume of complaints must be matched with personnel in a manner that not only allows timely review, but also sufficient volume to attain expertise. One method to both increase reviewer volume and facilitate pattern recognition is to select a review organization that reviews complaints regardless of whether the complainant is a Medicare beneficiary, privately-insured, Medicaid beneficiary, or uninsured.

Triage is required very early in the process. Triage requires a high level of expertise. Each case may not require medical records review by consultants. Many complaints would not be expected to be substantiated or refuted in any record. It may be prudent to typically review records, but these do not necessarily need to be reviewed by a consultant sub-specialist expert in all cases. The review coordinator needs to be able to make such judgments. When specialty expertise is required, the expert should confer with a complaint manager or have known complaint management expertise so that the task is completed in a useful manner. Consultants are to provide consultation regarding specific questions, usually about standards of care and not how to best conduct reviews. While consultants may identify key issues, not otherwise recognized, they are advisors and the process should not be delegated to them. Consultants needed would include a wide range of professionals such as pharmacists, clinical laboratory directors, durable medical equipment and prosthetics suppliers, and nursing home administrators.

The complainant should be contacted early in the process when possible. A written acknowledgement that reiterates the complaint and that it will be reviewed is useful and should be retained, but oral contact and discussion convey a personal approach. They allow the issues to be clarified and can help set appropriate expectations.

*Capacity to investigate* - Investigative capacity should also include an ability to promptly visit a facility or meet with providers. This could be achieved directly by the CRO or by

the CRO having a relationship with state inspectors/regulators. In some instances, it is hard to imagine any CRO matching the expertise of local regulators at knowing how or what to look for. For example, nursing home inspection teams are experts at the task of inspecting nursing homes. Even a geriatrician or nurse, who once was a nursing home nursing director and is now part of a beneficiary complaint review team, would be less experienced than most state inspection team members. Local regulators may also have considerable familiarity with certain providers and some familiarity with all members of a provider type (e.g., nursing homes).

*Due process* - The QIOs have devoted detailed consideration of the investigative process. Because of concerns about fairness and labeling providers, there has been an intense emphasis on the review methodology with a careful multi-step record review. This due process needs to be balanced with resolution needs. Alternatives such as mediation may be appropriate relatively early and without extensive record review. Some more immediate problems could likely be resolved by adopting an intervention, rather than post hoc review strategy. Medical care requires empiric treatment from time to time. During the treatment process greater details are learned and skilled clinicians respond to the information. This type of expertise and judgment are needed by the complaint resolution specialists, who need to know what minimal facts are necessary and when treatment of the problem is needed. There are risks to such an approach and it will be important to gather data on the risks and benefits if the approach is taken.

*Clinical observation skills* - Another critical clinical skill is learning how to identify the warning signs of an impending major problem. It is insufficient to recognize whether the care could have been better or not. The critical judgment is whether some event or complaint is a red flag. It is simply impractical to consider that when any error occurs, a sample review of a clinician's care will be undertaken to see if there is a pattern of problems. This may rarely be required, but there could never be enough resources to be so thorough in following up on all confirmed complaints.

It is important to acknowledge that the severity of provider impact is likely to affect investigation method and cost. If the system is one of providers seeing a complaint as an opportunity to improve care or satisfaction, the investigation is more easily completed. However, when a complaint leads to *contested* conclusions that have substantial sanction implication, the matter is different. For example, state physician licensure boards reported costs of investigating and processing contested serious complaints warranting sanction through hearings to conclusion to be in the \$100,000 range.<sup>16</sup>

In summary, the CRO will need to have some local presence directly or through relationships that will need to be cultivated. The CRO or CROs will need to coordinate activities that typically require multiple disciplines, cross various settings of care, and involve institutions and professionals. The progress CMS and the QIOs have made in sharing and standardizing best practices should continue. The best investigative process

---

<sup>16</sup> Department of Health and Human Services, "State Discipline of Physicians: Assessing State Medical Boards through Case Studies," R. Bovbjerg, P. Aliaga, and J. Gittler, February 2006 ("2006 DHHS Board Study").

is not yet known and continuous improvement should be a goal. The CRO can be most effective in gaining review expertise, gaining knowledge about providers, and changing provider performance if the jurisdiction of complaint management includes complaints outside of Medicare.

### ***Interventions and Follow-through***

*“Interventions and follow-through [are when] substantiated complaints result in appropriate corrective action and monitoring assures compliance.”*

*Referral of complaints to other agencies* - The OIG and IoM noted that few referrals to other agencies occurred. This appeared to be cited as a failing. Most complaints are not substantiated as quality problems by QIOs.<sup>17,18</sup> Most complaints to physician licensure boards are not about confirmed quality of care matters.<sup>19,20</sup> Different complaint reviewers may see different types of complaints. There would be expected selection biases depending on a host of factors, such as ease of filing a complaint. For example, a medical licensure authority may see more serious confirmed complaints than the risk management or patient advocate office of a hospital that reviews complaints made by the hospital’s patients. However, it has been my experience in reviewing quality of care complaints made to Blue Cross and Blue Shield of Rhode Island over many years that the majority do not represent serious problems that require structural or process changes. Almost none has ever required a referral to a licensure agency. Among the most serious issues over the years have been prescription dispensing errors, an area where many safety interventions are extant. Therefore, if referrals are only made when sanction is felt likely to be required, a small number would be expected. If referrals were to be made in all cases when the QIO could not do an investigation or simply in all cases so the agency database had all complaints recorded, larger numbers would be expected. The latter case has never appeared to be the expectation.

*Importance of inter-agency relationships* - There are times when there is a need to work with a provider to create corrective actions and to monitor the implementation of such actions. This capacity ideally would reside with the CRO so that a hand-off to another organization is not required. Even organizational providers may lack an ability to assess a problem and define and measure the effectiveness of improvements. Some providers may even need consultation on basic standards of practice. However, in some cases there may be matters of technical expertise requiring enlisting the QIO in the role of consultant that the IoM continues to expect. In others, the matter is sufficiently serious that referral to a regulator is appropriate, either because of the potential for sanction or because of the nature of the complaint (e.g., boundary violations-sexual misconduct). There should be a relationship with regulators and a culture in the processes that allow regulators to be informed of significant issues even when there is no expectation of sanction. There is a need for policing and sanctions, but measuring the success of the complaint process by

---

<sup>17</sup> 2006 IoM Report.

<sup>18</sup> 2001 OIG Report.

<sup>19</sup> 2006 DHHS Board Study.

<sup>20</sup> Personal Communication, Rhode Island Board of Medical Licensure and Discipline.

counting sanctions is unlikely to be useful. Furthermore, should providers sense that such a metric is used to evaluate the CRO, there will be a poisoning of the provider/CRO relationship that will limit any efficacy of the CRO.

In summary, the CRO should have capacity to assist and monitor basic provider-specific quality improvement and corrective actions. The CRO should have a working relationship with regulators that involves routine contact and collaboration. The QIO should remain a resource for technical assistance. Sanction count should not be used as a measure of CRO efficacy.

### ***Quality Improvement Orientation***

*“Quality improvement orientation [is when] complaints guide quality improvement efforts.”*

It was noted that few projects came from complaints. This would be expected. Complaints should be *one* source of information that is used in guiding quality improvement efforts. They would be unlikely to guide the majority of quality improvement efforts. Quality improvement efforts are more effectively determined by a process that defines important conditions or processes where there are measured gaps in care.

*Use of complaint information* - Complaint information may be able to be used in a manner similar to that of a sentinel events registry. At present, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is home for a sentinel events review process and database. The basic steps are defining what gets reported, requiring an analysis of the event and a description of the change in systems or processes to come with the report, and sharing information nationally so that there is a greater knowledge of such events and prevention strategies. Sentinel events are specific events that should never occur, or are very unusual, and events that result in serious harm to patients or could have resulted in serious harm, the “near-hit.” Examples are wrong-site surgery and delay in treatment. Sentinel events are those that signal a need for immediate investigation and response.<sup>21</sup>

*Self-reported data* – JCAHO-accredited providers are expected to self-report these events. They must perform the root cause analysis. Over time this helps organizations develop analytical skills and allows them to share and implement best practices. JCAHO-accredited organizations already have made a significant commitment to quality improvement and performance measurement or they could not be accredited. Therefore, they have a level of sophistication that may not be present in all providers such as physician offices. Hospitals are the predominant JCAHO-accredited organizations. Many of the most serious events would be expected to occur in hospitals or result in hospitalization, but not all. Approximately 600 events per year are reported to the

---

<sup>21</sup> Joint Commission on Accreditation of Healthcare Organizations, “Policy on Sentinel Events.” Webpage accessed 11/28/06, [http://www.jointcommission.org/SentinelEvents/PolicyandProcedures/se\\_pp.htm](http://www.jointcommission.org/SentinelEvents/PolicyandProcedures/se_pp.htm).

JCAHO and roughly two-thirds are self-reported. Complaints were the source of 12.1 percent of the sentinel events reported from 1995 through 2005.<sup>22</sup>

It is possible that the number of individual quality improvement activities was not counted in the OIG assessment. A monitored plan of correction is a distinct activity appropriately considered follow-through and would not be counted as a “quality improvement project,” which would more likely be a statewide activity.

*Use of a voluntary reporting system* - The IoM considered a voluntary reporting system modeled after the Aviation Safety Reporting System in the 2000 report *To Err is Human*. This consideration related to a system for reporting, tracking and analyzing *errors*, not *complaints*. The IoM stopped short of recommending such a system for several reasons including the existence of other agencies/systems, cost, complexity, and lack of knowledge as to what type of system would be most effective. Particularly relevant to the consideration of a national complaint tracking and analysis system was the concern that no single group was likely to have the expertise required to analyze such a diverse set of issues. The potential for “mini-systems” that are targeted to selected areas was suggested as an alternative.<sup>23</sup>

CMS maintains the Case Review Information System (CRIS) so that the QIOs can track and report case review activities. Neither the IoM report nor the Secretary of Health and Human Services Michael O. Leavitt’s response to Congress regarding the report indicated the CRIS system is used to define methods to prevent complaints or errors. Timeliness and satisfaction statistics with the QIO investigation are utilized. Ideally, a complaint tracking system is a source of data that is used by expert groups that are convened to analyze the data so as to design quality improvement activities and improvement interventions.

*Complaints and quality improvement* - The review of complaints is not antithetical to a quality improvement orientation because it does have the potential to provide useful information and stimulate providers to improve, when appropriate. Most healthcare organizations and professionals are oriented towards quality. Even when they resist measurement or deflect criticism, there is a competitive pride and patient orientation. There is a need for removal, required remediation, or sanction in rare instances. The conflict the IoM cited as applicable to the QIO is inevitable for all potential CRO organizations. The transition from quality improvement partner to regulator dispensing sanction is a gray scale. Even criminal justice systems have prevention and rehabilitation goals and activities. The manner of review and the ability to align public and provider goals, while reserving the right to take forceful action, is important.

In summary, the CRO has a primary goal to resolve complaints. It can also have a quality improvement orientation. The CRO should, at a minimum, engage in sentinel events registry activities and contribute to a national database that is available for experts to analyze.

---

<sup>22</sup> March 2006, *Joint Commission Perspectives*, 26(3): 8.

<sup>23</sup> 2000 IoM Report.

## ***Responsiveness***

*“Responsiveness [is when] responses to complaints are regular, substantive and clear.”*

This would generally be expected to require that the reviewer restate the complaint, indicate that it was investigated, briefly outline the investigative process, and provide a conclusion as to whether the complaint is substantiated or not. Additionally, when there is a substantiated complaint, there should be a statement that interventions will or have occurred to prevent such future events. When a complaint cannot be substantiated, there should be an indication that serious consideration occurred nonetheless.

*Confidentiality and beneficiary satisfaction* - Confidentiality provisions, especially regarding provider consent to release of identifying information and case review details, have been cited as a source of creating an apparently “secretive” and non-substantive report. The level of frustration with the responses has been reported in the media<sup>24</sup> and has resulted in consumer rights litigation.<sup>25</sup>

In all cases of complaint review, QIOs survey beneficiaries on their satisfaction with the complaint review process. CMS case-review statistics from April 2003 to July 2004 indicate that 93.4 percent of respondents are satisfied or very satisfied with the process overall. There was a 93 percent satisfaction with the response. However, only 39 percent were satisfied with the review outcome. Analysis of the data comparing April to June 2003, as compared to April to June 2004, indicated that satisfaction with the outcomes increased from 39 to 60 percent.<sup>26</sup>

In general and not specific to the QIO data, complaints about physicians may be about personal interactions, service issues such as office wait times, administrative matters such as billing, non-preventable events such as an adverse drug reaction, or more serious events involving medical errors. (The current process limits investigations to those that are determined to be about quality of care and can be evaluated through record review.)

*Communication with beneficiaries about errors* - There is more literature on patient and physician expectations and responses regarding medical error than about complaints. However, there are inferences that may reasonably be made regarding complaints and potential lessons from the information regarding communications surrounding errors. (Presumably it is not even inference if the complaint involves an alleged error.) Patients want the complaint to be respectfully acknowledged. Some evaluation of the causes of the event(s) that relate to the complaint is expected. This is especially true of more serious matters, as one of the most consistent concerns is to prevent a bad event from

---

<sup>24</sup> Gaul, GM. “Once Health Regulators Now Partners,” July 26, 2005. *Washington Post*, A1 (hereinafter “Gaul 2005”).

<sup>25</sup> Public Citizen, Inc. v. Department of Health and Human Services and Centers for Medicare and Medicaid Services, 357 U.S. App. D.C. 1 (2003) (affirming Public Citizen, Inc. v. Department of Health and Human Services, et al., 151 F. Supp. 2d 64 (2001 U.S. Dist. LEXIS 10087)).

<sup>26</sup> 2006 IoM Report.

occurring to another patient.<sup>27,28</sup> The expectation is for what is effectively a sentinel event analysis, i.e., what was the root cause and what will be changed quickly to prevent a recurrence. An apology is generally expected, but is insufficient. The explanation of the event is of greater importance. Complainants may still indicate that they will seek legal advice or compensation.<sup>29</sup> However, resorting to a lawsuit is often cited as being more likely when there is a lack of information and a response about the event of concern, thus potentially creating an appearance of a cover-up.<sup>30</sup>

The same literature notes that physicians have considerable difficulty in dealing with disclosure of medical error. There may be significant emotional distress and guilt without a support system in place to help the physician. There may be fear of a lawsuit or loss of reputation in the patient and provider communities. There is conflict created by knowing that ethical obligations require truth telling<sup>31</sup> and yet, disclosure may result in such fears coming to fruition. To make matters worse, there has been a history of potentially misguided advice from peers, hospital administrators, risk managers, and others to keep quiet. The result is variability, emotional turmoil and, too often, destruction of a salvageable doctor-patient relationship. There is a movement that aligns ethical canon, error prevention processes, and legal risk management. It involves analysis, apology, and open disclosure. It typically also involves compensation offers early on when there has been error or negligence. This disclosure and settlement methodology is supported by an organization known as “Sorry Works.”

The University of Michigan uses such a program<sup>32</sup> and summarizes it in three points:

1. We will seek to compensate quickly and fairly when our unreasonable medical care causes patient injuries.
2. We will defend our staff and institution vigorously when our care was reasonable or when we did not cause a patient injury.
3. We will seek to learn from our mistakes and our patients’ experiences.

Such approaches appear to reduce liability costs overall by reducing legal defense costs and by creating a climate of fair and reasonable settlement. However, the reduction of overall costs is unproven and even considered implausible by some experts.<sup>33</sup> Some states have enacted legislation to support such programs or to eliminate the use of apologies as admissions of guilt in subsequent litigation.

---

<sup>27</sup> Gallagher, TH, Waterman, A, et al. “Patients’ and Physicians’ Attitudes Regarding the Disclosure of Medical Errors.” 2003. *Journal of the American Medical Association*, 289(8): 1001-1007.

<sup>28</sup> Friele, RD and Sluijs, EM. “Patient Expectations of Fair Complaint Handling in Hospitals: Empirical Data.” 2006. *BMC Health Services Research*, Aug 18; 6: 106.

<sup>29</sup> Mazor, KM, et al. “Health Plan Members’ Views about Disclosure of Medical Errors.” 2004. *Annals of Internal Medicine*, 140: 409-418.

<sup>30</sup> Weber, DO. “Who’s Sorry Now?” 2006. *The Physician Executive*, March-April 2006: 6.

<sup>31</sup> American Medical Association, “Code of Ethics,” 2006.

<sup>32</sup> Wojcieszak, D, Banja, J, and Houk, C. “The Sorry Works! Coalition: Making the Case for Full Disclosure.” 2006. *Joint Commission Journal on Quality and Patient Safety*, 32(6): 344-350.

<sup>33</sup> Studdert, D, Mello, M, and Brennan, T. “Medical Malpractice.” 2004. *New England Journal of Medicine*, 350(3): 283-292 (hereinafter “Studdert 2004”).

These points are germane to the complaint management process by a CRO for several reasons. First, the concern about confidentiality and provider consent for release of information may actually be counter-productive to the provider interests. It is a source of frustration to the complainant, which only increases the risk of suit for the provider. While some institutions have well developed programs and protocols, most providers do not address complaints in such an effective manner. The physician office has very limited resources to implement such a program and physicians lack experience in resolving such matters.

*Managing complaint information: A need for facilitation and training* - The CRO could be an effective source of on-the-spot training for the physician or other providers as a complaint is managed. This would involve establishing a relationship with the providers and often with risk management or claims staff at liability insurance companies. If a major pillar of making disclosure meaningful in cases of improper care is an offer of compensation, the CRO would not be able to directly address that issue. However, a skilled complaint review staff potentially could provide support and education for the provider, making it more feasible for the provider to effectively interact with the complainant. In turn, the complainant is more likely to feel the complaint is being effectively addressed when the provider, not a third party, directly responds in a facilitated manner that creates a greater comfort level for all the parties.

The QIOs have created mediation processes for these reasons. However, the current complexity of the process limits its use and effectiveness. Mediation by the QIO has also been limited to cases where the care either was acceptable or simply may have been reasonably expected to be better, without significant adverse patient effect. Therefore, substantial evaluation must occur before mediation is offered. Cases of care being grossly or flagrantly unacceptable or care that failed to follow accepted guidelines or usual practice were not eligible for mediation.<sup>34</sup> One can understand that other interventions, such as immediate referral to regulatory agencies, may be needed in some or most cases of care being *flagrantly* outside the norm. But, even these cases and certainly cases of care simply outside of accepted guidelines are the type of instances that an expanded “Sorry Works”-like intervention could address.

Both sides must agree to the mediation. There are protections for the provider regarding use of the mediation should litigation be pursued by the patient. Despite the limitations and resulting infrequent use of the process, the QIOs do appear to view mediation as promising and capable of resolving many complaints which they see largely resulting from failed communication.<sup>35</sup> Providers are presently allowed to resolve complaints on their own and the QIO evaluates resolution with the complainant. These provider sponsored methods do not have the protected information provisions of mediation, unless state law so affords this.

---

<sup>34</sup> 2006 IoM Report

<sup>35</sup> Qualidigm (The Connecticut QIO), “Mediation Resource Packet for Physicians/Providers,” October 2003.

The QIOs possess technical capacity in event analysis that could be of great assistance to the providers who must not simply apologize, but analyze, and as appropriate, correct processes. This consultative capacity should not be lost.

A more streamlined and easily utilized facilitated complaint resolution and apology system is potentially very responsive to the complainant. Equally important, it creates a quality improvement educational opportunity for providers with every complaint management event. This is needed as many providers simply lack the skills to effectively address complaints and as a result avoid the very actions that may resolve the problems most effectively.

*The importance of disclosure* - Responsiveness and transparency are closely linked as complainants will not consider their complaint addressed if there is insufficient disclosure of what was assessed and changed. However, this is not to state that all details of each complaint review should necessarily be available to the complainant. For example, a case that is assessed by a medical expert may have detailed consultative comments by that expert for the review agent to use along with other important pieces of information. The complainant should receive a clear summary of the ultimate synthesis and conclusions with sufficient detail to understand what was found and what, if any, changes are to be made as a result. The expert consultant review need not be disclosed to achieve this result. Protecting such detail may facilitate a more forthright analysis and should not constitute secrecy. Beneficiaries also need to have the right to confidentiality when requested. In such cases, the review agency must consider what can be done to investigate a complaint anonymously and explain in a non-coercive manner that the review may be less responsive as a result.

In complaints about failure to meet standards of care, the medical records may be assessed and conclusions drawn. While there may be divided expert opinion on some matters, the process can lead to a determination that the care was appropriate or not. This is relatively factual. The facts may be inconsistent with the complainant's belief or be difficult to convey to the persons with even above average medical literacy, but a conclusion is drawn. The CRO may be limited to evaluating such complaints.

*Improving beneficiary satisfaction* - Many complaints are about issues such as personal interactions where the provider may have been completely unaware of an offense. Complaints may be delayed and providers may be unable to recall details or they may be about office staff persons where the physician can investigate, but may remain uncertain as to what occurred. A significant number of conclusions will be that there can be no determination of what actually occurred. Review agents need to be able to indicate this in a manner that acknowledges and respects the beneficiary concern. Often, the provider can be coached into being helpful by also acknowledging the concern in a positive manner. These types of complaints ideally are included in those subject to review as they provide an opportunity to respond to beneficiaries and educate providers.

However, on some occasions, there will be vehement dispute of the facts and beneficiary satisfaction with the review outcome would be unlikely. The ceiling of satisfaction with

the outcome of any review process is not established. As noted above, the current satisfaction with review outcome is 60 percent and rising. It is not possible to ever be 100 percent, but the ceiling is not yet known. Only measurement of the effects of efforts to steadily increase it will define the point of plateau. The continuing collection of satisfaction information is important. If the review agent or processes are changed, it is even more critical to gather data in a method that allows comparisons to be made over time and across agents.

Responsiveness is at the root of access. Failure to properly respond to complaints will result in psychological barriers, therefore it is critical that the intake of complaints and output is respectful of the complainant's need for information and the expected limitations in addressing that need are clear.

In summary, the review process can be substantive while respecting beneficiary and limited provider confidentiality needs. Sufficient information is disclosed to provide transparency and satisfaction. There should be continued exploration of alternate methods of resolution, especially those that promote a culture of prompt disclosure, problem evaluation, and quality improvement interventions. The CRO should possess triage and coaching skills to facilitate such methods. Beneficiary and provider satisfaction with the process should be continuously measured.

### ***Timeliness***

*“Timeliness [is when] each step is completed within a reasonable timeframe, and mechanisms exist to deal with emergent complaints in an expedited manner.”*

*Timely complaint responses* - The OIG report noted that timeframes were often exceeded and media noted the long timeframes as being a source of frustration.<sup>36,37</sup> CMS has shortened timeframes and made timeliness a major factor in assessing performance on the task of case review.<sup>38</sup> Timeframes for completion or intermediate action must be consistent with the nature and severity of the complaint. Successful identification of complaints requiring immediate action requires skill in identifying such issues or protocols that specify emergent matters. Meeting timeframe goals requires a tracking database and sufficient personnel. In general, timeliness is one of the most measurable and therefore potentially improved attributes. Improvements have occurred. Part of the difficulty in timeliness does relate to medical record review requests. Delays in providers processing such requests can be problematic.

Traditionally, record review has been followed by a provider opportunity to supply additional information and respond. Then a re-review with this information occurs. It may be that a process can remain fair and considerate of providers while being somewhat more efficient. For example, if complaint resolution is viewed as important, records should be received promptly. The record is not subject to change and should be available

---

<sup>36</sup> 2001 OIG Report.

<sup>37</sup> Gaul 2005.

<sup>38</sup> 2006 IoM Report.

when requested. Providers may be asked to respond to the complaint at the same time they supply the records so that some steps are combined. Some providers may already take such actions. As providers realize that promptness affects the complainant's further actions, the responsiveness will likely improve. A balance between speed and allowing a careful investigation can be struck.

*Timeliness and resource utilization* - Included in tracking data on timeliness should be some tracking of resource utilization in the process. As noted in the previous section regarding investigative capacity, the triage function is critical. This function should identify the case that is amenable to immediate resolution of the complaint or is a sentinel event requiring urgent review and potential inspection of a facility or other provider intervention. An example of the former would be contacting a durable medical equipment provider to resolve a complaint about delayed and pending equipment delivery. An example of the latter would be a report suggesting unsafe conditions in a facility.

Timeliness standards and tracking mitigate adverse effects of complaint review being a secondary function of an organization, because the statistics shine a light on performance. However, complaint review as a priority function will most increase the likelihood that sufficient resources and attention are devoted to the process.

In summary, complaint review must be a priority function of any CRO. There need to be sufficient resources devoted to the process to allow timely response. Alternate dispute resolution may be able to expedite timeframes. In some cases, the power to sanction or subpoena may promote speedy information collection.

### ***Objectivity***

*“Objectivity [is when] the review process is unbiased, balancing the rights of each party.”*

The PRO was credited with doing a good job in this area in 2001 and the IoM in 2006 reached the same conclusion. The credibility of any review agent will depend upon its reputation for being balanced and fair.

*Creating Consistency* - Defined processes help promote implementation in an objective manner, allow all parties to be informed of the procedures, and create an opportunity for public comment on the processes. They also promote consistent application of review principles. Given the importance of the skills of personnel in managing complaints and the potential diversity of experts, all CROs should perform inter-rater reliability analyses. If review is delegated to multiple agencies, such as physician review to medical boards and facility review to other agencies, it will be even more important for CMS to have established processes that must be followed, including provisions for self and/or external assessment of reliability, consistency, and competency of review. Consolidation of complaint management into regional agencies might reduce the complexity of a monitoring program for CMS, but it would not eliminate the need for it.

In summary, the CRO should utilize an operations manual and promote the development of objective standards by professionals and institutions. The CRO must rigorously self-assess the quality of its review. Failure to be respected for being objective will result in providers or beneficiaries or both not utilizing and accepting the process.

### ***Public accountability***

*“Public accountability [is when] complaint information is made available to the public.”*

There would seem to be little controversy at the extremes of information release: release of summary statistics on the number and nature of complaints without provider-identifying information is acceptable; release of patient-identifying information is not. Transparency is important for the complaint resolution process to be effective and credible. While transparency is most critical in case-specific communication to the complainant (responsiveness), the public trust requires some greater public information be available than just summary statistics.

*The Need for Adequate and Sufficient Information* - Addressing the need for sufficient information to foster trust in the process seems the salient point. Currently, healthcare providers are being beset with many matters related to transparency. Provider report cards, so-called “pay for performance” initiatives, and efficiency ratings are being promoted or implemented by employer groups, payers, and the government. This has the potential to promote better and more coherent measurement; engage providers and consumers in improving care, improving self-care, and more wisely consuming resources; and improve the way we communicate and explain the reality of care structure, process, and outcomes. It is also filled with controversy and a dearth of facts about the use, utility, and harm from such data release. Years ago medical licensure boards created controversy when they indicated sanctions would be posted on consumer-oriented websites created by the boards. This type of disclosure does not seem to engender any controversy today.

Medicare provides information on selected provider types. While such information likely does stimulate provider attention to improvement, it works best when the design of the disclosure process includes the providers and there is an agreed-upon measurement methodology.<sup>39</sup> There are legitimate concerns that in some performance reporting systems, providers of vulnerable populations will appear deficient by virtue of caring for persons who have greater challenges in following recommended testing and treatment or who have more co-morbid conditions, i.e., the report card will not be case-mix adjusted. There are also other provider concerns that more likely reflect the transient fear seen in previous introductions of new reporting schemata. In fact, if complaints were a highly sensitive system for recording opportunities for improving care and communication, it is hard to imagine any provider not having multiple complaints filed daily.

---

<sup>39</sup> Mehrotra, A, Bodenheimer, T, and Dudley, RA. “Employers’ Efforts To Measure And Improve Hospital Quality: Determinants of Success.” 2003. *Health Affairs*, 22(2): 60-71.

In summary, the provider-specific data is rather unlikely to be damaging to the provider or highly useful to the public. However, until such data are provided, their absence creates a perception of important missing information and secrecy. What is necessary is an imperative to provide a degree of transparency. Once the directive is established, then the parties can be convened to design a fair and effective process. The initial process can then be monitored and improved. The design of the methodology of publicly reporting complaint data should take place in a coordinated manner with the extensive activities related to performance measurement and reporting that are ongoing nationally.

### **Litigation and Effects on Complaint Review**

Assessments of the QIOs have not devoted major attention to the effects of the American tort system. This may be because there is limited data on actual effects. However, perception is relevant. Physicians generally regard the tort system as unfair and wasteful of resources. It is important that they do not equate the CRO process with the tort process. Myths abound on both consumer advocate and provider sides. Facts suggest that most negligent events do not result in litigation or compensation. A significant minority of suits occur when there has been no negligence. Only half of the expenses of the litigation and compensation reach the plaintiff.<sup>40,41</sup> Accordingly, either “side” can claim legitimacy for the position that the system fails them. Complaints unfortunately have an air of pending suit. This creates an atmosphere that is too often protective of information. The culture of punishment, which is how a provider may perceive litigation, is one of silence and is antithetical to a culture of safety and openness.<sup>42</sup> This is the likely basis of confidentiality concerns regarding the CRO response. However, the QIO must already report a conclusion as to whether the care was acceptable or not, even if certain details must be omitted without physician consent. Given that substantive conclusions are already required to be reported to the beneficiary, a wiser course for providers to pursue is to promote disclosure. Alternative dispute resolution mechanisms should be pursued to more fully reap the benefits of early disclosure.

It is relevant to consider the potential conflicts of regulatory agencies becoming CROs. These agencies have both public and confidential activities and documentation. If they become CROs, they may need additional procedures to segregate CRO information from other activities that may involve sanction and their current duties. In effect, they may need to formally partition reviews and complainant responses depending upon the origin of the complaint, even while a single agent review is promoting access, efficiency and pattern analysis goals. Should it be concluded that licensure boards and state survey agencies are appropriate replacement CROs, the best mechanism to accomplish the potentially required “firewalls” must be evaluated by those with appropriate expertise.

---

<sup>40</sup> Bovbjerg, R and Berenson. R. “Surmounting Myths and Mindsets in Medical Malpractice.” *The Urban Institute Health Policy Brief*, October 2005.

<sup>41</sup> Studdert 2004.

<sup>42</sup> Mello 2006.

## CONCLUSION

### Characteristics of a New Entity and Promoting System Changes

It is not expected that any existing entity currently has the capacity to implement the beneficiary complaint process in a manner described above. The QIO has been attempting to meet many of the stated goals and has been improving by some measures in doing so. Other entities such as state professional licensure authorities, state ombudsman programs, and state survey agencies have considerable experience, but would require additional resources, linkages, and authority to achieve the goals. While they may be more beneficiary-focused, they too have multiple audiences and must be effective partners with the provider community. It is expected that using an existing organization with modification will be more cost-efficient than creating completely new entities. We suggest key characteristics of a CRO and certain system changes to facilitate improved complaint management.

The key characteristics include:

1. The entity is well-known to the public and ideally has regular contact with the public.
2. The CRO is able to establish a good working relationship with the provider community by use of both authority and leadership, enabling it to be respected as a provider partner and resource capable of changing provider attitude and behavior.
3. The CRO has the capacity to approach problems with multiple disciplines or is part of a closely coordinated set of entities with expertise in select disciplines (e.g., physicians, hospitals, nursing homes, pharmacies, home care, dialysis, durable medical equipment, Medicare Advantage plans).
4. Expert consultants are used wisely and only as consultants and the entity has access to a wide range of experts.
5. The CRO with CMS is capable of creating a defined review process, monitoring its consistent application, and continuously improving reliability.
6. The CRO is an expert in complaint management.
7. The CRO can evaluate complaints regardless of the insurance coverage or beneficiary status of the complainant.
8. There is local capacity to perform site visits and inspections.
9. The CRO has the capacity to teach the basics of quality improvement and sentinel event root cause analysis and is linked to the QIO when there is an identified need for the type of more sophisticated technical assistance than the QIO is able to provide.
10. The entity is able to regularly confer with the regulators and not just in cases of extreme outliers or providers requiring sanction. (Or the entity is the regulator.)

11. The CRO is able to participate in a national registry that, at a minimum, includes tracking of those instances of confirmed significant quality lapses and sentinel events. (The entity is not expected to have capacity to conduct analysis of such data, as it would be expected that CMS would convene expert review panels for such analysis. The CRO should be able to recognize local patterns, however.)
12. There should be a capacity to case manage complaints early in the process, including coaching providers on complaint management and disclosure/apology principles. The CRO should be capable of establishing relationships with risk managers and professional liability carriers.

System issues include change or recognition of the need to continue the growth of evolving processes.

1. A more extensive system of provider self-reporting should be established.
2. There needs to be support and resource allocation to analyze a complaint database or databases by expert panels.
3. Regulation and statute should support a case management approach with early intervention processes, including recognition of the potential value of apology/disclosure programs.
4. Certain details of the review should be peer review-protected information.
5. CMS should be supported in its continued refinement of oversight activities and performance standards. Included should be assessments of cost and efficiency of the processes.
6. Public reporting should be developed in conjunction with other current activities regarding performance measurement and reporting.
7. Efforts should continue to coordinate all parties that perform complaint review so as to avoid duplication and waste, reduce hassle for the provider, avoid the potential for different reviewers to reach divergent results, and reduce the chance that with more than one agency involved, cracks are created through which complaints may fall.

### **Developing Consensus Regarding Complaint Review**

The creation of a new process and organization for beneficiary complaint review will require a national dialogue among the many parties with interests and knowledge, such as beneficiary and provider groups and quality improvement organizations. It is hoped that these papers will stimulate the dialogue and further the discussion.