CALIFORNIA HOSPITAL ASSOCIATION

*Providing Leadership in Health Policy and Advocacy*

April 4, 2011

Donald Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

***RE: Medicare and Medicaid Programs; Patient Notification of Right to Access State Survey Agencies and Medicare Beneficiary Notification of the Right to Access Quality Improvement Organizations (QIOs) [CMS-3225-P]***

Dear Dr. Berwick:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association is pleased to offer the following comments in response to the Centers for Medicare & Medicaid Services' (CMS) Patient Notification of Right to Access State Survey Agencies and Medicare Beneficiary Notification of the Right to Access Quality Improvement Organizations (QIOs) [CMS-3225-P] proposed rule.

Providing safe, high–quality, efficient care is our highest priority. Further, critically evaluating and addressing every patient complaint that raises even the smallest concern or calls into question the quality of care provided is critically important to establishing internal quality-improvement programs, as well as ensuring appropriate oversight and compliance with the Medicare Conditions of Participation (CoP). CHA believes that adequate patient notification about how one would raise concerns and/or complaints is an important part of how hospitals and other providers identify areas of improvement and is something we consider of utmost importance.

However, with that being said**, CMS proposed modifications to the Medicare CoPs, as outlined in this proposed rule, would make an already complex and paper-driven documentation process more cumbersome. Further, it ignores the current patient-complaint protocols already in place by health care provider and supplier organizations around the country. The proposed rule would unnecessarily add significant administrative costs to our health care system; create undue administrative burden on providers without improving the quality of patient care; and further confuse patients.**

**We strongly urge CMS to reconsider its policies outlined in the proposed rule for the reasons outlined below**. Further, CHA would like to work with CMS on a number of issues related to the Medicare CoPs so we may address additional areas of concern. As you are aware, the Medicare CoPs have not been systematically reviewed and updated since 1986, and in many ways do not reflect the way health care is currently delivered or will be delivered in the next three to five years.

**CMS RATIONAL FOR PROPOSED CHANGES IN MEDICARE COPS**

In the proposed rule, CMS highlights the 2006 Institute of Medicine (IOM) report to Congress that made several recommendations for improvements to the Quality Improvement Organization (QIO) program. The IOM report noted that the QIOs review very few beneficiary complaints. CMS further states that "we believe that a factor contributing to the low volume of beneficiary complaints is that beneficiaries are unaware of their right to voice complaints to the QIO of their state."

Section 482.13(a)(1) of the Code of Federal Regulations (CFR), in the Medicare and Medicaid CoPs, requires that hospitals must protect and promote each patient's rights. Further, Section 482.13(a)(2) states the hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. *The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization.*

The interpretive guidelines for Section 482.13(a)(2) go on to note the following:

> This regulation requires coordination between the hospital's existing mechanisms for utilization review notice and referral to QIOs for Medicare beneficiary concerns (See 42 CFR Part 489.27). This requirement does not mandate that the hospital automatically refer each Medicare beneficiary's grievance to the QIO; however, the hospital must inform all beneficiaries of this right, and comply with his or her request if the beneficiary asks for QIO review. (Interpretive Guidelines §482.13(a)(2))

**The low utilization rate of QIO reviews are likely more of an indication of the robust customer service and patient advocate offices currently in place in many provider settings than a lack of patient access and information for submitting complaints. These departments and their dedicated staff are critical components in improving quality, patient safety and patient satisfaction, and handle a significant number of patient complaints as required under the Medicare CoPs.** CMS provides no documentation of the number of patient complaints successfully addressed internally by the hospital or successfully addressed by other entities, including The Joint Commission or State Survey Agencies. In our view, CMS has not provided sufficient evidence or rational for why the proposed policy would adequately address the concerns raised by the IOM or improve the quality of care. We urge CMS to reconsider.

In addition to the March 2006 IOM report, criticisms of QIOs' complaint processes had been made as early as 1990 by an earlier IOM report, *Medicare: A Strategy for Quality Assurance* (1990), as well as by the Office of the Inspector General (OIG) in the Department of Health and Human Services in two reports, *The Beneficiary Complaint Process of the Medicare PROs* (1995) and *The Medicare Beneficiary Complaint Process: A Rusty Safety Valve* (2001). These reports were largely consistent in their criticisms of QIOs' performance in handling beneficiaries' complaints about quality of care**.** In light of these documented challenges, CHA does not

agree with CMS' approach to shifting additional responsibilities in the area of patient complaints until such time as the deficiencies in these reports have been adequately addressed.

In addition, the President's fiscal year (FY) 2012 budget proposes to "eliminate the conflict of interest between beneficiary protection and quality improvement activities for QIOs" and would essentially eliminate the budget for QIOs for patient complaint review. **CHA urges CMS to put forward an overarching plan for the coordination of the Medicare beneficiary complaint process and to align that plan with the current direction being set forth by the Administration.**

**SPECIFIC PROVISIONS IN PROPOSED RULE**

CMS proposes to amend relevant CoPs or Conditions for Coverage to require that Medicare beneficiaries be informed by written notice of their right to voice concerns about the quality of care they are receiving (or have received) to the QIO in the state where services are being (or have been) provided. As part of the written notice, the provider or supplier would be required to provide the name, telephone number, e-mail address and mailing address of the QIO. CMS proposes the provider or supplier would also be required to document that it presented such written notice to the beneficiary or the beneficiary's representative or a surrogate selected by the beneficiary, such as a family member or friend of the beneficiary. In addition, the proposed rule states that "[w]here necessary for compliance with Title VI of the Civil Rights Act of 1964, providers and suppliers should provide written translations for limited English proficient persons, particularly for languages that are commonly used by non-English-speaking beneficiaries, such as Spanish." Finally, CMS proposes that this written documentation be included in the medical record.

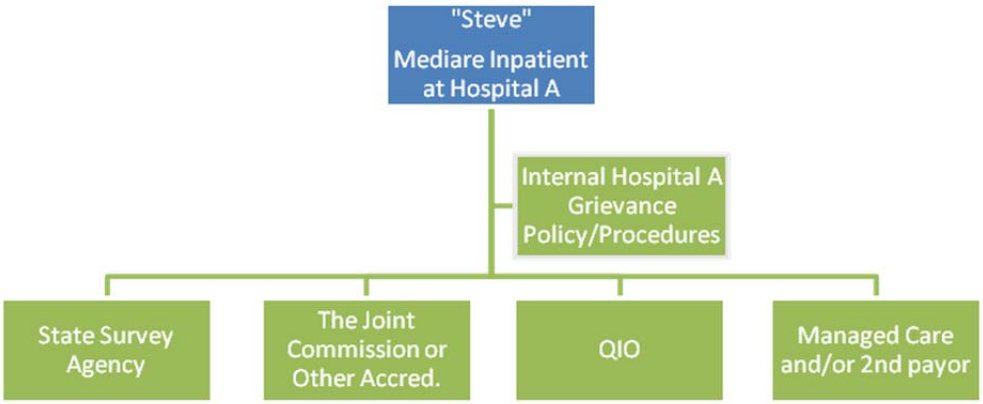
It is our understanding that the proposed rule would not require use of a specific format for providing the written notice; however, CMS mentions the use of the approved federal "Important Message from Medicare" (IM) notice as an example to develop written notices to avoid spending time on re-creating a similar document. Further, according to the CMS Interpretive Guidelines, the IM is a standardized, Office of Management and Budget-approved form and cannot be altered from its original format. The IM is to be signed and dated by the patient to acknowledge receipt. (Interpretive Guidelines §482.13(a)(1)).

**We ask CMS to further clarify its proposal. The IM already provides information to patients upon admission to a hospital regarding their rights and specifically provides information about the role of QIOs. In addition, hospitals provide information regarding how to contact the QIO as part of the CoP-required grievance policies as noted above. This proposal would create a redundant transfer of information separate from existing documentation, and at the same time encourages the patient to go directly to the QIO before seeking to resolve issues internally — a process we believe is working. Finally, the added burden of providing documentation in the medical record is burdensome and would require additional training and documentation changes. For these reasons, CHA does not support the additional requirement of providing redundant QIO information to patients at this time.**

CHA agrees that patients should have access to the necessary information to voice their concerns or complaints. Figure 1 illustrates the pathways in which a patient would be able to voice a

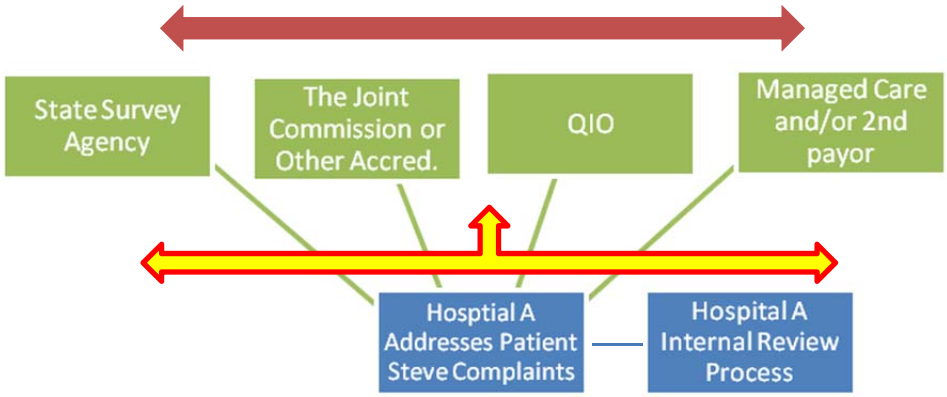
complaint should this policy proceed. In this figure, the patient has at a minimum three or perhaps four different organizations in which to issue a formal complaint in a hospital. The criteria for review of patient complaints, as well as the response times, vary between contractors. Further, the OIG found that the QIOs do not provide complainants with meaningful, substantive responses to their complaints

**Figure 1: Patient Options for Filing Complaints**




While we agree that patients should be informed on now to take action, this information is already shared in multiple places (including in the hospital orientation packet for inpatients and outpatients) and is likely to confuse patients. Further, the likely result is that a patient will call all of the agencies to issue his or her complaint resulting in the complexity illustrated in Figure 2.

**Figure 2: Hospital Management of Patient Complaints**




Medicare does not currently have a national clearinghouse from which to monitor and adequately address beneficiary complaints, let alone all patient complaints. Instead it relies on multiple contractors to address beneficiary concerns. Each organization noted in Figure 2 that has some level of responsibility for reviewing patient complaints, yet each has different processes and criteria for responding to such complaints. Currently, the CoPs only require the hospital and the QIO to collaborate on addressing a patient complaint (Section 482.13(a)(2)) and this is a secondary step following the hospital being the first point of contact for the patient. The downstream effect of

this lack of coordination and collaboration among contractors that results in increased costs to the health care system and much of this cost is borne by the provider in responding to multiple agency requests for information regarding the same patient complaint. In many instances providers have told CHA that by the time they are notified by external organizations of a complaint, it has been resolved internally or is already well underway. The lack of coordination and collaboration results in patient frustration and takes providers away from addressing the potential areas for improvement that were likely the root cause of such a complaint.

CMS proposes to require seven out of the 10 providers/suppliers to inform *all* patients, including Medicare beneficiaries, of state survey agency contact information (mailing address, e-mail address and telephone number) to facilitate filing complaints with such agencies.

**CHA supports state survey agency contact information being made available to *all* patients to facilitate filing complaints. In California, skilled-nursing facilities are required to provide this information and it has become standardized practice for others. With that said, we would encourage CMS to proceed only after a systematic process for coordination between state survey agencies, The Joint Commission and other accrediting bodies, including state medical boards, is developed. This process would ensure that the patients' needs are addressed appropriately and that patient experience and quality of care can be improved. CHA urges CMS to consider a national patient complaint clearinghouse similar to the national recovery audit contractor claims clearinghouse to help eliminate the duplicative investigations and multiple requests of the hospitals to provide information on the same complaint.**

CMS would then have access to national data on all patient complaints and could measure the performance of its contractors in addressing these important issues.

**SPECIFIC COMMENTS REGARDING OTHER SETTINGS**

CHA is very concerned about the CMS proposed policy to extend the patient notification policies to patients who receive care in the outpatient setting (including short-term acute-care hospitals, as well as Critical Access Hospitals), specifically for patients who utilize hospital-based outpatient clinics and rural health clinics. Much of the care provided in these settings is similar to the care provided in a physician office setting. Patients routinely visit these clinics for primary and urgent care while others also receive treatment for chemotherapy, etc., requiring multiple visits. **To provide patient notification at *every visit* and to provide documentation in the Medical record is unreasonable. Further, the added cost of such a policy is not adequately addressed in the CMS impact analysis. The administrative burden of tracking every notification in this setting does not make sense, and we urge CMS to reconsider.**

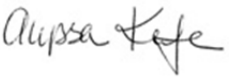
**FUTURE PROPOSALS UNDER CONSIDERATION**

While we appreciate CMS' consideration of additional proposals for future consideration, including whether the proposed QIO-related notice should *also* be given at the end of a Medicare beneficiary's treatment, service or hospitalization, or alternatively, whether the proposed QIO notice should be given upon completion of treatment or discharge (in addition to the notification upon admission) only if the Medicare beneficiary has experienced an adverse event, CHA opposes any

additional expansion of patient notification until such time as systematic process is developed by which to coordinate

We appreciate the opportunity to provide you with our thoughts on many of the topics outlined in the proposed rule. If you have any questions, please do not hesitate to contact me at (202) 244-4688 or akeefe@calhospital.org.

Sincerely,



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