



**American Hospital
Association**

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Submitted electronically

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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 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed regulation on beneficiary notification of the right to access Quality Improvement Organizations (QIOs).

As detailed in our comments, we have concerns with CMS' duplicative proposals to require hospitals to give patients the contact information for filing complaints with both state survey agencies and QIOs. We are also concerned that these notices are required to be given to **every** Medicare patient.

EXISTING POLICY

Section 482.13(a)(1) of the code of federal regulations (CFR), in the Medicare and Medicaid Conditions of Participation (CoPs), requires that hospitals must protect and promote each patient's rights. These regulations require hospitals to establish a process for prompt resolution of patient grievances and to inform each patient of whom to contact to file a grievance. Further, the interpretive guidance that accompanies the regulations encourages hospitals to provide patients with a phone number and address for filing a grievance with the state agency. These regulations do not apply to Critical Access Hospitals (CAHs).



Section 482.13(a)(2) requires a hospital's governing body to approve and be responsible for the effective operation of the grievance process and review, and to resolve the grievances filed. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate QIO. Further, the interpretive guidance encourages hospitals to have procedures for referring Medicare patients' concerns to the QIOs.

Section 482.13(a)(2)(ii) requires a hospital, in its resolution of a grievance, to provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process and the date of completion.

In preparing our comments, we spoke with several hospitals to understand how the current policy works in practice. The CMS requirements for handling beneficiary complaints are only part of the picture. Hospitals also must comply with requirements from their state department of health, their accrediting agency and each health plan that services their geographic area. Each of these entities also requires a grievance resolution process. As a separate requirement outside of the patient's rights CoP requirements, section 1866(a)(1)(M) of the *Social Security Act* (SSA) requires hospitals to provide beneficiaries with a notice of the following rights:

- (i) the individual's rights to benefits for inpatient hospital services and for post-hospital services under this title, (ii) the circumstances under which such an individual will and will not be liable for charges for continued stay in the hospital, (iii) the individual's right to appeal denials of benefits for continued inpatient hospital services, including the practical steps to initiate such an appeal, and (iv) the individual's liability for payment for services if such a denial of benefits is upheld on appeal.

To implement section 1866(a)(1)(M) of the SSA, CMS (November 27, 2006) finalized the *Notification of Hospital Discharge Appeal Rights* (71 FR 68708), which required hospitals to provide an "Important Message from Medicare"¹ (IM) notice to all beneficiaries within two days of admission. Rather than address quality of care concerns, the required IM notice primarily addresses a beneficiary's right to appeal a planned discharge date.

PROPOSALS

CMS proposes to require hospitals to provide patients with written notification of the address and telephone number of the state survey agency to which they should report complaints. This expands the current requirement to provide this information to Medicare patients who choose to file a complaint. CMS has not previously required that this information be provided in written form. Rather, the existing CoP allows each hospital the ability to define its own

¹ http://www.cms.gov/BNI/12_HospitalDischargeAppealNotices.asp#TopOfPage

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process for notifying beneficiaries of their rights. The existing standard is working well; therefore, **we do not support CMS' proposal to require hospitals to provide every beneficiary with a written form containing the address and telephone number of the state survey agency.**

In addition to requiring written notice of the state survey agency address and telephone number, CMS proposes requiring hospitals to provide patients with the address and telephone number of the QIO (in the state where services are or were provided) to report complaints. **We do not support CMS' proposal to require hospitals to provide every beneficiary with a written form containing the address and telephone number of the state QIO.** This proposal would result in a duplication of effort. We do not understand why CMS would want to build multiple mechanisms for tracking the same complaint.

We are also puzzled as to why CMS has explicitly built notification of QIO contact information in to this process. QIO contact information is distributed to all Medicare beneficiaries through the IM notification described above. The first page of the IM includes the name of the QIO for the state and the telephone number for the QIO. It is completely duplicative to require hospitals to provide this information in the existing IM and to create an additional form for beneficiaries.

Beyond the requirement to provide QIO contact information to beneficiaries, CMS also proposes to require that the hospital document in the beneficiary's record that it has presented the QIO information to the beneficiary. **We do not support this overly burdensome requirement.** This proposal would require additional training in order to alter the current documentation process. We ask that CMS provide justification as to why this documentation and subsequent training are necessary.

CMS proposes to require CAHs to provide patients with the mailing address, electronic mail address and telephone number of the state survey agency if the patient wishes to report complaints. This proposal would result in a new subparagraph, section 485.627(c) of the CFR. **We support CMS' proposal to require CAHs to provide patients with the contact information of the state survey agency if a beneficiary chooses to file a complaint.** We believe beneficiaries should be afforded the same patient rights in CAHs that they are afforded in larger acute care hospitals as it pertains to filing complaints. Further, CMS also proposes to require CAHs to provide patients with written notification of address and telephone number of the state survey agency to report complaints. **We do not support this proposal.** Finally, CMS proposes to require CAHs to provide patients with the address and telephone number of the QIO to report complaints, which **we do not support.**

In addition to the concerns listed above, we are concerned with the impact this new requirement will have on beneficiaries. Multiple entities, such as state departments of health and accrediting organizations, also require a hospital to provide the contact information to beneficiaries. We are concerned that this information, coupled with the proposed CMS requirements, will only serve to further confuse beneficiaries. When beneficiaries are

presented with multiple parties to contact, they may be unsure as to whom the appropriate contact party should be. In many cases, beneficiaries will choose to contact all of the parties listed. When this occurs, an audit is started by several different agencies for the same compliant. This in turn makes the burden placed on hospitals three to four times greater than it needs to be. **Rather than require hospitals to provide beneficiaries with another contact for filing complaints, we urge CMS to work with all parties who require complaint notification to build the capacity for a centralized tracking system that allows multiple parties access.** Further, only one entity should take the lead for establishing an investigation for a beneficiary complaint.

FURTHER CLARIFICATION

We ask for further clarification regarding CMS' intention to require beneficiary notification of patient rights for outpatient services. CMS did not explicitly propose application of these changes to outpatient services. However, CMS proposes (75 FR 5762) the following:

Proposed § 482.13(a)(1)(ii) would require that at the time of the inpatient admission or *outpatient service*, the hospital must inform all Medicare beneficiaries by written notice of their right to file a written complaint with the QIO in the state where services are being or were provided about the quality of care they are receiving or have received.

We ask that CMS clarify that this was an error in drafting this proposed regulation, as CMS does not have the statutory authority to apply inpatient CoPs to outpatient departments. Further, we are confident that this extension was unintended extension because CMS did not include a burden estimate for providing notifications to outpatient beneficiaries.

BURDEN

We are concerned with the assumptions that CMS has made about the burden associated with each of its proposals. CMS estimates that development of a standard written notice for information on state survey agencies would impose a one-time, one-hour burden for hospitals. However, CMS did not account for the time necessary to discuss this proposed change with each hospital's governing body, which is a requirement. **We ask that CMS re-estimate the burden associated with the state agency notification proposal to account for the time associated with discussing the change with the hospital's board of directors.**

CMS estimates that development of a standard written notice for information on QIOs and documentation of receipt in the medical record would impose a one-time, two-hour burden for hospitals. However, CMS did not account for the time necessary to train professionals for the new documentation procedures. **We ask that CMS re-estimate the burden associated with**

the QIO medical record documentation proposal to account for the time associated with training professionals.

CMS estimates hospitals will distribute 1,107,852 notices per year. We are puzzled as to where this number came from. CMS proposes that a notice must be given to **every** Medicare beneficiary. According to CMS' website, in calendar year 2009, there were 6,942,420 inpatient discharges.² **We ask that CMS re-estimate the burden associated with distributing written notifications for 6,942,420 beneficiaries, rather than 1,107,852 beneficiaries.**

CMS estimates that development of a standard written notice for contact information for state survey agencies and QIOs and documentation of the receipt of this information in the medical record would impose a one-time, two-hour burden for CAHs. However, CMS did not account for the time necessary to discuss this proposed change with each CAH's governing body and to train professionals for the new documentation procedures. Further, unlike acute care hospitals, CAHs may not have prior experience with beneficiary notification because there is no requirement in the current CAH CoPs. **We ask that CMS re-estimate the burden associated with the providing notification and medical record documentation proposals to account for the time associated with discussing the change with the CAH's board of directors and with training professionals.**

CMS also did not account for the time associated with discussing the changes with boards of directors and training professionals for all of the other provider categories, including ambulatory surgical centers, hospices, long-term acute care facilities, home health agencies, comprehensive rehabilitation agencies, rural health clinics and federally qualified health centers. We ask that CMS re-estimate the burden associated with providing notification and medical record documentation proposals to account for the time associated with discussing the changes with boards of directors and training professionals for each of these provider types. Further, we ask that CMS re-estimate the burden associated with distributing written notifications for the total number of beneficiaries treated in each facility type listed for the most recent year of data available.

CMS includes a burden estimate for providers. However, the agency failed to capture the burden associated with implementing the proposed changes for non-providers. Specifically, CMS did not account for the burden that will be placed on both state survey agencies and QIOs. With increased notification, it is very likely that the number of complaints will increase. This will directly affect the resources needed by state survey agencies and QIOs to respond to inquiries. In addition, when changes are made to CoPs, additional changes must be made to the standards for accrediting agencies and the non-state surveying process that audits compliance. **We request that CMS add a burden estimate for state survey agencies, QIOs, accrediting organizations and non-state surveyors.** Because CMS has under-estimated the burden associated in several key areas, we believe that the overall

² http://www.cms.gov/Medicare/MedicareStatSupp/09_2010.asp#TopOfPage

regulatory impact analysis will exceed \$100 million and **we therefore request that CMS prepare a full regulatory impact analysis for this proposed regulation.**

ADDITIONAL CONCERNS

In addition to the specific concerns raised above, the president's Fiscal Year (FY) 2012 budget proposes to completely eliminate the QIO budget for tracking beneficiary complaints. This proposal attempts to "eliminate the conflict of interest between beneficiary protection and quality improvement activities for QIOs." We are puzzled these two conflicting proposals in this area. Furthermore, the FY 2012 budget also proposes to reduce the funding available for the QIO program by: (1) reducing the geographic scope of QIO contracts to achieve greater efficiency; (2) expanding the pool of contractors eligible for QIO funds; and (3) aligning QIO termination procedures with the Federal Acquisition Regulations.

In addition to the concerns raised in the president's budget with the QIO program, the Medicare Payment Advisory Commission (MedPAC) also has been critical of the QIO program's ability to handle beneficiary complaints. During the February 2011 MedPAC Commissioners meeting, the following was discussed:

A third barrier is the requirement that QIOs also perform regulatory oversight as well as field and investigate beneficiary complaints. This dual role creates some problems. First, to our point here on competition, it restricts the type of organization that will compete to be a QIO. Second, which is not directly on point but still very important, it creates a conflict of interest that can hamper the effectiveness of technical assistance agents. It's hard to be a trusted consultant to the provider when you also may be called upon to investigate them. And it's hard to advocate for the patient when you are trying to earn the trust of the provider. And, also, we may be creating a fragmented system for capturing beneficiary complaints -- and really all patient complaints -- by having so many different organizations handle the complaints, and this can mean that we're missing patterns of problems that could help target our resources on our surveys more effectively. Currently complaints are fielded by 41 QIOs, state health agencies, state medical boards, accrediting agencies, and maybe there's even more. Creating a single entry point for complaints may be a far more effective way to use this information. Our recommendation here, though, speaks to the competition angle here and removing barriers. So the Draft Recommendation 3 here reads: The Congress should authorize the Secretary to define technical assistance agents so that a variety can compete to assist providers and to provide community-level quality improvement. The Congress should remove requirements that the agents be physician-sponsored, serve a specific state, and have regulatory responsibilities. Again, we envision this to be a budget-neutral recommendation and also that it would result in improved quality of care for patients. This recommendation very much echoes several of the IOM recommendations made in 2006, and also in the FY2012 President's budget are similar proposals, although they are scored as small or

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as savers. And to be clear, this means that the regulatory responsibilities, including beneficiary complaints, would not just disappear. They would be designated for another agency to perform.

For some time, we have expressed our concerns with the process for updating the CoPs and the companion interpretive guidance for surveyors. We have requested that CMS update the CoPs to ensure they are consistent with the latest research on what contributes to safer, higher quality of care. The CoPs have not been updated since 1986 and, therefore, do not reflect the way health care is currently delivered. This proposed regulation addresses one of our concerns. However, it is not responsive to changes we have requested to the remainder of the CoPs and implementation and audit of the CoPs. We have asked that the process used to provide interpretive guidance, once a CoP change is finalized, be conducted in an open and transparent way that allows for a dialogue with the public.

Subsequently, we have requested that the process used to train and provide instructions to the surveyors who are responsible for auditing compliance also be conducted in an open and transparent way.

We appreciate the opportunity to comment on the proposed regulation on beneficiary notification of the right to access QIOs. If you have any questions, please contact me or Lisa Grabert, senior associate director of policy, at (202) 626-2305 or lgrabert@aha.org.

Sincerely,

Rick Pollack
Executive Vice President