



NQF Safe Practices and Related Processes

February 28, 2014

Overview

On January 9, 2014, the U.S. Department of Justice announced a \$40.1 million settlement with CareFusion Corp. based, in part, on its relationship with a former National Quality Forum (NQF) committee co-chair, Dr. Charles Denham. The settlement included allegations that Dr. Denham accepted \$11.6 million from CareFusion to promote one of its products, while he co-chaired the NQF Safe Practices Committee (2006, 2009, and 2010). NQF severed its relationship with Dr. Denham in 2010.

This settlement prompted a proactive, in-depth review by NQF of all of the processes related to the *Safe Practices for Better Healthcare, 2010 Update*.

In this review, NQF was guided by two important realities. First, the quality and patient safety communities must be constantly mindful of the ever-changing health-care climate; how consequential endorsement is; and the increasingly high stakes for quality measures and safe practices. Second, NQF must be ever vigilant in identifying conflicts of interest (COI) and maintaining rigorous, objective processes that ensure the integrity of quality measures and safe practices.

To that end, NQF is examining its work and policies in three critical areas: an audit of *Safe Practices for Better Healthcare, 2010 Update*; a review of NQF COI policies for its committee members, Board, and staff; and an examination of NQF's sponsorship guidelines.

I. Audit of Safe Practices for Better Healthcare, 2010 Update

First and foremost, NQF is committed to providing accurate, unbiased, expert recommendations to improve the health and safety of patients. Therefore, in light of the settlement findings, it was imperative that NQF examine *Safe Practices for Better Healthcare, 2010 Update* to ensure that the report's recommendations were not compromised and continue to provide accurate, current, and evidenced-based guidance for providers in the care of their patients.

On January 24, 2014, NQF initiated a multi-phased audit of the 2010 report with the goal of identifying required updates to the safe practices statements, the associated specifications, and relevant references.

NQF has assembled an expert committee to lead the audit. This slate is currently out for public comment. Proposed members of the committee include the following individuals:

David Bates, MD, MSc
Senior Vice President for Quality and Safety
Chief Quality Officer, Brigham and Women's Hospital

James Battles, PhD
Senior Advisor for Patient Safety, Center for Quality Improvement and Patient Safety
Agency for Healthcare Research and Quality (AHRQ), HHS

Jeff Hageman, MHS
Executive Secretary, Healthcare Infection Control Practices Advisory Committee
Centers for Disease Control and Prevention (CDC), HHS

David Hunt, MD
Medical Director, Patient Safety & Health IT Adoption
Office of the National Coordinator for HIT (ONC), HHS

Arthur Levin, MPH
Executive Director, Center for Medical Consumers

Gregg Meyer, MD
Chief Clinical Officer, Partners HealthCare

Patrick Romano, MD, MPH
Professor of General Medicine and Pediatrics
UC Davis Health System

Robert Wachter, MD
Professor and Associate Chairman, Department of Medicine
UCSF Medical Center

The audit comprises a three- step process:

- 1. Evidence Review:** NQF staff have already reviewed all of the 34 practices and the reference citations that were identified as supporting them in *Safe Practices for Better Healthcare, 2010 Update*. As part of this work, outdated and irrelevant references were recommended for deletion; current references were added; and other needed changes to the practices were identified. Additionally, recommendations for change have been made in terms of the "evidence" cited on the basis of relevance and quality of the evidentiary base. The staff paid particular attention to any safe practice that included the compound in question per the Denham case.

Staff are recommending substantive changes to several safe practices, including the practice related to prevention of Central Line-Associated Bloodstream Infections (CLABSI) to reflect updated guidelines and evidence. For evidence related to the safe practices featured in NQF's

2010 update, the staff review relied heavily on the March 2013 Agency for Healthcare Research and Quality (AHRQ) evidence report entitled, *Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*,¹ and the updated infection-related guidelines from the Centers for Disease Control and Prevention (CDC).

2. **Expert Review:** An advisory group composed of patient safety experts, including individuals who have been involved in safe practices work and key federal partners, will begin reviewing the safe practices as well as NQF staff recommendations on February 28th. They will determine any additional changes necessary to ensure that the safe practices are current, evidence- based and without bias.
3. **Member and Public Comment:** The draft audited report will be available for a two-week member and public comment period. To help facilitate NQF member and public comment, a table will be produced that highlights recommended changes to the report.

NQF expects that the report will be available for member and public comment by March 31, 2014. NQF leadership will then review the outcomes of the audit to help determine next steps for the *Safe Practices* work.

In 2009-2010, NQF convened an Evidence Task Force² to strengthen NQF's processes for evaluating the synthesis and scoring of evidence. The resulting changes to NQF's evaluation criteria significantly raised the rigor of NQF's evidence requirements related to measures. In addition, the Task Force recommended that these more rigorous requirements be applied to safe practices, preferably through a systematic review of the evidence (e.g., AHRQ and CDC systematic reviews). Given NQF's updated evidence requirements, the rigor of the evidence reviews for subsequent safe practice reports would need to be raised. Consequently, to update *Safe Practices for Better Healthcare, 2010 Update* – as opposed to the current audit – will require additional time, resources, and close collaboration with federal partners. If support is available, NQF is prepared to update the 2010 *Safe Practices for Better Healthcare* report.

II. Conflict of Interest

NQF has clear and comprehensive COI policies in place for its Board, committee members, and staff. NQF regularly examines its various COI policies to ensure that they are comprehensive and responsive to the changing environment. NQF updated its COI policy for the Board in 2010 and 2014; for committees in 2010 and 2013; and for staff in 2010.

As part of its longstanding process, all NQF Board members, committee members, and staff are required to complete a disclosure of interest form. Since 2010, all disclosure forms are reviewed by legal counsel and project staff. Board members are required to orally disclose information from their disclosure forms in a public meeting. The rationale for this requirement is to help create an environment where all are aware of each other's potential biases, and are prepared to respectfully question peers about perceived or potential conflicts as appropriate.

Committee member disclosure forms are also subject to a rigorous staff review by project staff and clinicians who are very familiar with the subject matter of a given committee. A disclosure analysis that

includes this topical expertise is more likely to identify gaps and inconsistencies in a nominee's disclosure form.

Committee members are also required to verbally disclose content from their disclosure forms that is relevant to the subject matter before a committee. This disclosure occurs at the first committee meeting for a new project and annually, thereafter, if the committee's work extends beyond 12 months. These verbal disclosures are recorded by oral and written transcripts, the latter of which is posted on the NQF web-site.

NQF believes that an oral disclosure requirement strikes a balance between the privacy of the individual serving and the need for the public and fellow committee or Board members to understand the activities and backgrounds of their colleagues. At the end of the oral disclosure, committee and Board members are invited to ask questions of each other or NQF's General Counsel based upon the oral disclosures. NQF also encourages committee members to speak up in real time if they believe that they have a conflict of interest or that another committee member may be conflicted or biased on a certain topic. NQF informs committee members that they may raise a concern openly in a meeting; speak to the co-chairs, who will consult NQF staff; or directly approach NQF staff.

It is important to note that written and oral disclosures for the Board and committee members are not limited to actual conflicts. The disclosure forms for Board and committee members elicit detailed information about professional activities, including consulting, speaking engagements, and grant activity. Board and committee members are required to share information relevant to the committee work they will be doing even if there is no conflict of interest.

Several recent enhancements to NQF's COI policies are worth noting:

1. *Committee COI Policy.* At the end of 2013, NQF revised its committee disclosure form with more specific questions designed to elicit detailed information needed for a thorough conflicts analysis. Committees that consider measures must now adhere to a two-step process. The first step is a general disclosure (described above), and the second step includes questions each member must address about involvement with measures under committee consideration. In addition, the updated COI policy provides specific guidance on the need for member recusal. Committee members identified as having a potential conflict of interest in relation to specific measures must recuse themselves from discussion, evaluation, and voting on those measures when seated on the Committee. These recusals will be noted on the NQF website. NQF is reviewing its committee COI Policy to see if additional improvements are needed.
2. *Board COI Policy.* In February 2014, the NQF Board took further steps to strengthen its own COI policy. This update includes:
 - Incorporation of the concept of perceived conflicts of interest and the process for how they would be addressed;
 - Explanation of the Board's ability to delegate to a subset of its members the authority to review in-depth and resolve conflicts of interest.

NQF Board members are in the process of updating their COI forms and oral disclosures; this process will be completed by March 26, 2014.

Given that even the best COI policies are made ineffective by a lack of transparency, as was brought home by the Denham case, COI policies must be implemented in a culture that encourages transparency and respectful questioning of colleagues should any concerns arise. NQF will continue to work to foster a strong culture of transparency across the organization and in all its work.

III. Sponsorship Guidelines

Most non-profit organizations, including NQF, rely on public, private, and philanthropic dollars to operate. Organizations must exercise care and transparency in managing any perceived or real conflicts of interest with their funders. At NQF, our sponsorship guidelines have established strict firewalls that prevent funders from influencing the work that we do.

NQF has continuously taken steps to ensure the integrity of its processes. After the conclusion of the *Safe Practices* work in 2010, NQF changed its guidelines to prohibit funders from serving on endorsement committees that they support financially. Further, NQF will not accept funds other than from government or philanthropic organizations for endorsement work. The NQF Board will review an updated sponsorship policy at its March 2014 meeting.

In Summary

The Denham case is a sobering reminder to NQF and the broader patient safety and quality communities of the imperative to constantly ensure that its processes are transparent and objective. This is important to assure the wider community and patients, in particular, that the measures NQF endorses and safe practices NQF recommends are evidence-based, unbiased and trustworthy.

As described above, NQF has undertaken a comprehensive, multi-pronged response that includes:

- An audit of the *Safe Practices for Better Healthcare, 2010 Update* (to be posted for member and public comment by March 31, 2014)
- An update of the Board Conflict of Interest Policy (completed February 2014)
- An update of all NQF Board members COI forms and oral disclosures (to be completed by March 26, 2014)
- An NQF Sponsorship Policy (to be presented to the Board on March 26, 2014)
- An update of the Committee COI Policy (completed on or before July 31, 2014)

NQF will continue to make every effort to keep its Board, members and external stakeholders fully informed about these important efforts; their implications for the organization and its work; and any additional steps necessary to further safeguard the integrity of NQF endorsement and selection processes.

For more information about the NQF audit of *Safe Practices for Better Healthcare, 2010 Update*: please contact us at safepactices@qualityforum.org.

¹ Agency for Healthcare Research and Quality (AHRQ). *Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices*. Rockville, MD: AHRQ Publication No. 13-E001-EF; 2013 Mar: 461-471. Available at <http://www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html>. Last accessed February 12, 2014.

² National Quality Forum (NQF). *Guidance for Evaluating the Evidence Related to the Focus of Quality Measurement and Importance to Measure and Report*. Washington, DC: NQF; January 2011. Available at http://www.qualityforum.org/Publications/2011/01/Evidence_Task_Force.aspx. Last accessed February 23, 2014.