AMA
AMERICAN
MEDICAL
ASSOCIATION

Michael D. Maves, MD, MBA, Executive Vice President, CEO

March 8, 2011

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Hospital Inpatient Value-Based Purchasing Program; Proposed Rule; 76 *Fed. Reg.* 2454 (Jan. 13, 2011).

Dear Administrator Berwick:

The American Medical Association (AMA) appreciates the opportunity to provide our views concerning certain regulatory revisions in the Center for Medicare and Medicaid Services' (CMS) proposed rule on the Hospital Inpatient Value-Based Purchasing Program. **In the rule, CMS proposes to lift certain regulatory restrictions regarding Quality Improvement Organizations' (QIOs) ability to disclose information to CMS, including patient-, physician-, and other provider-specific information. The AMA urges CMS not to implement this proposal. We have strong concerns that lifting these confidentiality restrictions, thereby granting CMS open access to confidential information about patients, physicians, and other providers, will undermine the QIO program and quality improvement goals overall.**

CMS' proposal stands in stark contrast to Congress' original intent in establishing the QIO confidentiality provisions. Congress makes clear under section 1160 of the Social Security Act that QIOs are not federal agencies for purposes of the Freedom of Information Act (FOIA) and that QIO-acquired data shall be held in confidence and shall not be disclosed to any person. This statute allows exceptions "in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care."

CMS regulations have long upheld the obligations to protect the confidentiality of QIO information, including the specific stipulation that CMS itself does not have access to certain QIO information. The purpose of ensuring that QIO information is not subject to FOIA is to encourage physician and other provider participation in QIOs. As CMS states in the proposed rule, these restrictions were considered necessary to obtain the frank and open communication needed to improve the quality of health care. These restrictions, in turn, support QIO efforts in promoting the effectiveness, efficiency, economy, and quality of care delivered to Medicare beneficiaries.

American Medical Association 515 N. State St. Chicago IL 60654
phone: (312) 464-5000 fax: (312) 464-4184 www.ama-assn.org

The AMA is concerned that if these restrictions are lifted, QIO information would be subject to FOIA, which would include releasing confidential patient- physician-, and provider-specific information to the general public that Congress never intended to become public. This result would strike down the fundamental intent of the statute, *i.e.*, to maintain the confidentiality of the QIO-acquired data and restrict it from FOIA-availability, and render the statute meaningless. Although the statute provides the Secretary with limited authority to establish exceptions to the strong confidentiality requirements written into the statute, this exception mandates that the Secretary "assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care." **If CMS moves forward with this proposal, this statutory threshold for meeting the exception would not be met because releasing confidential data to the public could result in serious unintended adverse consequences for patients, physicians, and other providers.** Specifically, it could compromise patient confidentiality (even where patient identifiers are stripped) and also unfairly damage the professional reputation of physicians. The latter could be particularly significant in underserved communities where physicians are caring for vulnerable populations with numerous risk factors and present with more acute and previously untreated conditions.

Further, although CMS states that technological-driven circumstances have changed since the QIO confidentiality restrictions were put in place in 1985, the AMA does not believe anything has changed to nullify the need for "frank and open communication" to support the effectiveness of QIOs. Protecting the confidentiality of patient-, physician-, and provider-specific information remains of the utmost importance, as confirmed by Congress when it enacted section 1160 of the Social Security Act.

These confidentiality safeguards are also a critical component for alleviating physicians' concerns over potential liability exposure and ensuring the effectiveness of QIOs to improve quality of care. The AMA believes CMS' proposal to remove these safeguards would derail the trust that is built into the QIO program and will discourage disclosure and open communication within the QIO program, which will adversely impact a QIO's ability to effectively carry out its quality improvement activities. **Accordingly, the AMA strongly urges CMS not to make the proposed changes to the QIO regulations.**

CMS also requests comments on whether confidential QIO information should be made available to researchers. As we stated above, this would undermine the QIO program and discourage disclosure and open communication within the QIO program. **We urge CMS not to allow the disclosure of QIO information to researchers.**

Sincerely,

Michael D. Maves, MD, MBA