November 14, 2011

Donald Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD  21244-8013

RE:  CLIA Program and HIPAA Privacy Rule; Patients’ Access to Test Reports, CMS-2319-P

Dear Dr. Berwick:

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the Department of Health and Human Services (HHS) Proposed Rule entitled CLIA Program and HIPAA Privacy Rule; Patients’ Access to Test Reports 76 Fed. Reg. 56712 (September 14, 2011). The AAMC represents all 135 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 125,000 faculty members, 75,000 medical students, and 106,000 resident physicians who deliver over one-fifth of all clinical care in the nation. For the reasons described below, the AAMC strongly opposes the proposed rule and urges that it be withdrawn; alternatively, the rule should be re-proposed with significant changes.

The AAMC fully supports providing patients with access to their own medical information. Yet, providing patients with information is empowering only when patients understand the impact that it may have on their health and the treatment options available. This is most true when the laboratory information involves abnormal test results for potentially life threatening conditions, such as HIV or Huntington’s disease. For example, physicians report that patients who learn that they carry the gene for Huntington’s disease have a high rate of suicide. These patients can benefit enormously from receiving test results from a health care professional who also can immediately make available psycho-social support and other information that will help the patient. A laboratory is not positioned—and may be prohibited by state law—from providing this type of support.

It also should be noted that if the changes to CLIA are finalized as proposed, CLIA will not be consistent with HIPAA which provides an exception for individual access if:

A licensed health care professional has determined, in the exercise of professional judgment, the access requested is reasonably likely to endanger the life or physical safety of the individual or another person. 42 CFR §164.524(3)(i).
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The CMS EHR Incentive Program contains a similar exception if, in the judgment of the eligible professional, “substantial harm may arise from the disclosure of particular information.” (75 Fed. Reg. 44358). This is not to suggest that laboratory results should be withheld from patients. Rather, ensuring that laboratory test results are provided during a discussion with a physician is the optimal way to allow patients to understand the results, the treatment options, and support mechanisms that are available.

At a minimum, if laboratories are to release test results directly to patients upon request, they should do so under similar limitations to those of HIPAA. However, laboratories do not interpret test results and in many, if not most, states are prohibited from doing so. Therefore, if HHS continues to believe that patients should have direct access to test results from laboratories the rule should be re-proposed. It should contain a method for distinguishing those tests to which patients could be given direct access from a laboratory—cholesterol tests, for example—and those which should be received from a physician—a cancer diagnosis, for instance.

Providing patients with the best care involves giving them information that they need to make decisions about their health care. Serious negative consequences may ensue when patients receive incomplete information, or when the information is best understood within a context that only a health care professional can provide. If the rule is not withdrawn, it should be significantly revised and re-proposed to allow for appropriate exceptions to direct patient access. Only in this way will revisions to CLIA support the goal of patient access to health information without having the potential of endangering the lives of certain patients.

If you need more information, please contact Ivy Baer at ibaer@aamc.org or 202-828-0499.

Sincerely,

Joanne M. Conroy, M.D.
Chief Health Care Officer
AAMC

cc: Ivy Baer, J.D.