AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

November 9, 2011

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS–2319–P
P.O. Box 8010
Baltimore, MD 21244–8010

Re: Clinical Laboratory Improvement Amendments and Health Insurance Portability and Accountability Act Privacy Rule; Patients' Access to Test Reports

Dear Dr. Berwick:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 100,300 family physicians and medical students nationwide, I write in response to the Centers for Medicare & Medicaid Services' (CMS) proposed Clinical Laboratory Improvement Amendments (CLIA) and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule; Patients' Access to Test Reports as published in the September 14, 2011 *Federal Register*.

This rule proposes to amend CLIA regulations to specify that, upon a patient's request, the laboratory may provide access to completed test reports. In addition, this rule also proposes to amend the HIPAA privacy rule to provide individuals the right to receive their test reports directly from laboratories by removing the exceptions for CLIA-certified laboratories and CLIA-exempt laboratories from the provision that provides individuals with the right of access to their protected health information.

The AAFP supports these proposals despite a concern over possible instances in which a patient is not able to comprehend the test reports. Laboratory results are an integral part of the physician's diagnosis process and interpreting the results is the responsibility of the ordering physician. The majority of patients are not trained to interpret their results. However, the AAFP believes that all patients have the right to access their personal health information as doing so is more patient-centered since access to these results increases the patient's level of engagement and responsibility.

As a way to minimize potential patient confusion, the AAFP suggests working with the physician, beneficiary, and clinical laboratory community to develop a standardized statement that would be provided with the lab results to the patient. This statement should include an explanation that the clinical lab results are subject to a physician's interpretation and also include contact information regarding the physician who ordered the tests. The AAFP also suggests that CMS develop a guide for Medicare beneficiaries that provides an overview of commonly ordered clinical lab services. The AAFP remains committed to assisting CMS with both of these suggestions.

2021 Massachusetts Ave., N.W. • Washington, DC 20036-1011 • 888.794.7481 • 202.232.9033 • Fax: 202.232.9044 • capitol@aafp.org

We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have or clarifications you might need. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,

Roland A. Goertz, MD, MBA, FAAFP
Board Chair