



AMERICAN COLLEGE OF PHYSICIANS  
INTERNAL MEDICINE | *Doctors for Adults*

November 14, 2011

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

Dear Dr. Berwick:

The American College of Physicians, representing over 132,000 internists and medical students who specialize in the primary and comprehensive care of adolescents and adults, is pleased to offer the following comments re proposed rule: "*CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports*", 45 CFR Part 164 [CMS-2319-P]

This proposed rule would amend the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to specify that, upon a patient's (or their authorized representative's) request, the laboratory may provide access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient. The proposed rule retains all other currently existing provisions that provide for release of test reports. This proposed rule would also amend the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to provide individuals the right to receive their test reports directly from laboratories.

The College understands that this proposed rule applies to both CLIA and CLIA-Exempt laboratories. Furthermore, under this proposed rule, the patient (or authorized representative) must specifically request to receive their test results directly from the laboratory; that the laboratory must provide this information in the form or format requested (e.g. electronically) by the individual, but only if the laboratory can readily produce these results in such form or format; that the laboratory can charge a reasonable, cost-based fee to provide this information; and that this provision would pre-empt any contrary provision of state law.

The proposed changes are broadly consistent with College policy that promotes the transparency of a patient's healthcare information. These changes also allow patients to have increased control over their personal health information, will facilitate their ability to receive this information in a timelier manner, and, in general, appropriately reinforce

patients' active participation in their healthcare. Thus, the College is in support of these proposed changes.

While supportive of this proposed rule, the College strongly believes in the value that physicians and other healthcare professionals bring to the interpretation of laboratory test results in support of healthcare decisions in collaboration with patients. Laboratory results reviewed by patients in isolation can lead to misinterpretation - both unwarranted concerns and inappropriate reassurances. Furthermore, laboratory data are only part of the information physicians and other healthcare professionals use to make treatment and diagnostic recommendations.

As a result of these concerns, the College strongly recommends that all directly accessed laboratory reports include a standard statement that provides general guidance and encourages patients to review the results with the ordering physician or healthcare professional. The following is an example of such a possible standard statement, which should be written in plain language and in a manner consistent with nationally recognized health literacy guidelines:

*Note: Lab test results are reported as a positive or negative, or more often they show whether or not your results fall within a normal range. Normal values vary from person to person and normal test results may not exclude a health problem. Abnormal values also don't always indicate the presence of disease. Some laboratory tests are precise, reliable indicators of specific health problems, while others only provide more general information about your health condition. These laboratory results are just part of the information you and your physician/other health care professional (add name and phone number, according to the laboratory's records) should use to make decisions about your health care. If you do not have a follow-up appointment with your physician in the near future, you should contact him/her if you have any questions about this report or your treatment plan.*

The College appreciates this opportunity to comment on this important proposed rule. Please contact Neil Kirschner on our staff at 202 261-4535 or [nkirschner@acponline.org](mailto:nkirschner@acponline.org) if you have any questions regarding this submission.

Respectively,



Don Hatton, MD, MACP  
Chair, Medical Practice and Quality Committee