

NEW YORK
state department of
HEALTH

Howard A. Zucker, M.D., J.D.
Acting Commissioner of Health

Sue Kelly
Executive Deputy Commissioner

May 6, 2014

Gene N. Herbek, MD, FCAP
College of American Pathologists
325 Waukegan Road
Northfield, IL 60093

Dear Dr. Herbek,

I am writing in response to your letter regarding New York State (NYS) laboratory business practice regulations that instruct the clinical laboratory to direct a patient's inquiries regarding the meaning or interpretation of the test results to the referring health services purveyor. You indicated that 10 NYCRR § 34-2.11(b)(1)(v) constitutes a legal impediment to physician pathologists' ability, in their capacity as laboratory medical directors, to confer with patients regarding their test results and reports. Additionally, you requested that 10 NYCRR § 34-2.11(b)(1)(v) be repealed in furtherance of the recently amended federal regulations which give patients a right to access completed laboratory test results directly from clinical laboratories.

The February 6, 2014 amendments to 42 CFR Part 493 and 45 CFR Part 164 give patients a right to access medical records directly from clinical laboratories, including completed laboratory test reports. This federal rule will allow an individual or an individual's personal representative to request and receive completed test reports directly from a laboratory that is a HIPAA covered entity. It should be noted that the Department of Health and Human Services provides clarification that the final federal rule does not require that laboratories interpret test results for patients and that laboratories may continue to refer patients with questions about the test results back to their ordering or treating providers (see Federal Register Vol. 79, No. 25, p. 7293). Currently, NYS regulation 10 NYCRR § 58-1.8 does not allow a laboratory that tests samples originating from NYS to release laboratory results directly to a patient unless written consent is first provided by the physician or other authorized person. Consistent with the amended federal rule, the NYS Department of Health intends to repeal 10 NYCRR § 58-1.8 and to allow laboratories to provide patients with access to test reports without any consent from the practitioner who ordered the test.

Section 34-2.11 of NYS laboratory business practice regulations (10 NYCRR subpart 34-2) describes requirements that clinical laboratories must meet for recall letters and reporting of test results. This section also contains language regarding a patient's access to laboratory test results and amendments will be required to be consistent with the federal rule. 10 NYCRR § 34-2.11(b)(1)(v), which you have requested to be repealed, instructs the clinical laboratory to direct a patient's inquiries regarding the meaning or interpretation of the test results to the referring health services purveyor. This regulation does not prohibit clinical laboratories from providing patients with test results; it prohibits clinical laboratories from providing patients with the meaning or interpretation of the test results. This regulation is based on Public Health Law

§ 587, which prohibits clinical laboratories from giving any form of consideration for referrals. A clinical laboratory that provides a patient with the meaning or interpretation of the test results is discharging the ordering physician's responsibilities and such discharge is of decided benefit to the physician, precluding the practitioner from incurring expenses or expending time.

Traditionally, the physician, as part of the physician/patient relationship, explains test results and their implications, tracks patient medical history, and arranges for follow-up care. However, care coordination teams are being implemented to improve the quality of patient care and the cost effectiveness of health care. I would be interested to learn if there are models for this interdisciplinary approach to health care that involve pathologists.

Sincerely,

A handwritten signature in black ink that reads "Howard Zucker, M.D." The signature is written in a cursive style with a large, stylized 'Z'.

Howard A. Zucker, M.D., J.D.
Acting Commissioner of Health