



# COLLEGE of AMERICAN PATHOLOGISTS

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July 13, 2015

Ms. Katherine Ceroalo  
New York State Department of Health  
Bureau of House Counsel, Regulatory Affairs Unit  
Corning Tower Building, Rm. 2438  
Empire State Plaza  
Albany, New York 12237

*Re: Amendments of Parts 58 and 34 of Title 10 NYCRR (Patient Access of Laboratory Test Results)*

Dear Ms. Ceroala:

I am writing to provide comments regarding the above referenced regulation on behalf of the College of American Pathologists (CAP) and the New York State Society of Pathologists (NYSSPATH). The CAP is a national medical specialty society representing nearly 18,000 physicians who practice laboratory medicine and anatomic pathology in community hospitals, independent clinical laboratories, academic medical centers and federal and state health facilities. The New York State Society of Pathologists is a state medical specialty society representing many practicing pathologists in New York.

The proposed regulation maintains the following language at 10 NYCRR § 34-2.11:

b) A clinical laboratory shall not communicate to a patient of a referring health services purveyor the results of a clinical laboratory test, including, but not limited to, a Pap smear.

This language should be deleted as it directly conflicts with the purpose of the rule change, for conformance with federal law authorizing the communication of test results to the patient directly from the clinical laboratory. Of further concern, the proposed rule maintains a prohibition on the clinical laboratory and pathologist, as the director of the clinical laboratory, responding to patient inquiries on test results that the patient may now directly access from the laboratory. Of specific concern, 10 NYCRR § 34-2.11(b)(1)(iv) states:

iv) the clinical laboratory directs the patient's inquiries regarding the meaning or interpretation of the test results to the referring health services purveyor

This language should also be deleted. Both the CAP and NYSSPATH have noted in several communications to the Department that this continued prohibition, as stipulated in this regulation, adversely impacts patient care and is counter to the legal and ethical obligations of the pathologist physician to fully participate in the care of his or her patients.



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(See: attached CAP correspondence to Commissioner Nirav R. Shah, February 11, 2014 and to Commissioner Zucker, October 21, 2014). It is our position that New York State pathologists are licensed physicians of the state who are morally obligated to communicate with their patients. This obligation is concordant with federal regulation. It should also be aligned with New York State regulation.

We again urge that this provision be rescinded, for the many reasons contained in the attached prior correspondence, and given the fact that the retention of 10 NYCRR § 34-2.11(b)(1)(iv) is antithetical to the proposed regulation's "needs and benefits" as asseverated by the Department in the June 17, 2015 notice of proposed rulemaking:

The right to access personal health information, including laboratory results, is a powerful tool towards allowing patients to track their health progress, become engaged decision makers with the guidance of health care professionals and comply with important treatment plans.

In light of this acknowledgment by the Department, and in light of the changes now being proposed to this regulation, as compelled under federal law, continued New York regulatory impediments to patient conferrals with his or her pathologist, regarding the meaning or medical interpretation of test results, are untenable and should not be maintained under the proposed revisions of this regulation.

Thank you for your courtesies in consideration of our comments.

Sincerely,

Gene Herbek, MD, FCAP  
President

Attachments:

Correspondence of College of American Pathologists, Gene Herbek, MD to NYS Department of Health Commissioner Nirav R. Shah, February 11, 2014.

Correspondence of College of American Pathologists, Gene Herbek, MD to NYS Department of Health Commissioner Howard Zucker, MD, JD, October 21, 2014

*Sent via email REGSQNA@health.ny.gov and first class mail.*

cc: Michael P. Ryan, Director, Division of Laboratory Quality, NYS Health Dept.  
Mary Fowkes, MD, President, New York State Society of Pathologists  
Barry R. Ziman, CAP Director, Legislation and Political Action