



February 11, 2014

Nirav R. Shah, M.D., M.P.H.
New York State Department of Health
Corning Tower
Empire State Plaza,
Albany, NY 12237

Re: Request for Revision of Regulation 10 NYCRR 34-2.11 (v)

Dear Commissioner Shah:

I am writing you 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 clinical 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.

As you know, the promulgation of new federal regulations revising the application of the Health Insurance Portability and Accountability Act (HIPAA) of 1986 and Clinical Laboratory Improvement Amendments of 1988 (CLIA) will preempt state laws and regulations that impede direct patient access to their laboratory test results from the clinical laboratory. Thus, New York regulations impeding patient access are voided and will likely require revision. The purpose of this correspondence is to request additional revisions and updates to 10 NYCRR § 34-2.1.

Specifically, we are requesting repeal of the New York State regulation (10 NYCRR § 34-2.1(v)) that prohibits patient contact with the pathologist medical director of the laboratory providing their diagnosis, in furtherance of the implementation of federal preemption. The regulation states that: "the clinical laboratory directs the patient's inquiries regarding the meaning or interpretation of the test results to the referring health services purveyor" (10 NYCRR § 34-2.11(v)). This regulation constitutes a legal impediment to physician pathologist's ability, in their capacity as laboratory medical directors, to confer with patients regarding their test results and reports to which patients are now entitled, under federal law, to receive directly from the laboratory.

This legal impediment is based upon an anachronistic practice paradigm that has placed New York patients at a significant medical disadvantage compared with patients in other states who are able, without state legal constraint, to seek and receive pathologist medical input on their diagnosis, prognosis and even course of therapy. There is no sound medical reason for placing any such legal barrier, as currently exists in New York, between pathologists, as physicians and laboratory directors, and their patients.

Moreover, we do not believe the underlying rationale and assumptions regarding medical practice of pathology, upon which this regulation are presumably based, are grounded in appropriate, modern medical practice or New York State case law. New York States courts have categorically affirmed that pathologists have a duty of care to **their** patients and not to the clinicians who order tests.

College of American Pathologists

"Here, in sharp contrast, the diagnoses of the pathologists **were provided for the exclusive, direct benefit of the patient, to whom the pathologist clearly owed a duty**. While the surgeon may have reasonably relied upon the pathologists' final, unanimous conclusion of malignancy, unlike the investors and other plaintiffs in the commercial negligent misrepresentation cases, **the opinions of the pathologists were not rendered to benefit the surgeon, but the patient**. Accordingly, not only has the surgeon failed to cite any precedents permitting recovery on a theory of negligent misrepresentation as between medical care providers, his reliance upon the aforementioned distinguishable commercial negligent misrepresentation cases is seriously misplaced." (*Megally v. LaPorta* 253 A.D. 2d 35,679 N.Y.S. 2d 649; 1998) (emphasis added)

"The courts in this State have consistently rejected attempts to expand the scope of physicians' duty of care to third persons outside of the physician-patient relationship. (*Purdy v Public Adm'r of County of Westchester*, *supra*; *Eiseman v State of New York*, 70 NY2d 175, *supra*; *Hecht v Kaplan*, 221 AD2d 100; *Adams v Elgart*, 213 AD2d 436, *supra*; *Ellis v Peter*, 211 AD2d 353; *Sorgente v Richmond Mem. Hosp.*, 142 Misc 2d 870.) This court now declines to extend a physician's duty of care to encompass other physicians. If such a departure is to occur, it awaits the actions of appellate courts or the Legislature." (*Megally v. LaPorta*, 172 Misc. 2d 958:658 N.Y.S. 2d 570; 1997)

It should also be noted that this regulation in New York, that denies patient consultation with their diagnosing pathologist, appears to be unique among the states, as we know of no other regulation or law in the nation that establishes such a fundamental and substantial legal impediment to physician pathologists in their practice of medicine as it relates to patient conferral.

Moreover, as medical science advances and molecular and genetic testing become prosaic practices, pathologist conferral with patients on interpretation of complex medical test results will have greater importance and medical need. Thus, the continued existence of this anachronistic regulation will be a clear detriment to patient care and will deny patients access to physician pathologist expertise in the interpretation of their test results. For these reasons, the College of American Pathologists (CAP) and the New York State Society of Pathologists (NYSSPATH) urge that this regulation be voided to allow for direct pathologist-patient contact.

If further information is needed, please feel free to contact Barry R. Ziman, Director of Legislation and Political Action, College of American Pathologists, bziman@cap.org, 202-354-7117. Thank you for your courtesies and consideration of this request.

Sincerely,



Gene N. Herbek, MD, FCAP
President

cc: Jill Taylor, Ph.D, Director, Wadsworth, New York State Department of Health
Michael Ryan, Director, Division of Laboratory Quality, Department of Health
Rana Samuel, MD, FCAP, President, New York State Society of Pathologists
Kathryn Knight, MD, FCAP, Chair CAP Federal and State Affairs Committee