Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 586 and 587 of the Public Health Law, Section 34-2.11(b) of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is amended, to be effective upon publication of a Notice of Adoption in the State Register, to read as follows:

§ 34-2.11 Recall letters and reporting of test results.

(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. A clinical laboratory shall not prepare such communication for the health services purveyor to send, or otherwise facilitate the preparation or sending of such communication by the health services purveyor. Such communication or its facilitation shall be deemed consideration given for referral of specimens for performance of clinical laboratory services and is prohibited, except that:

* * *

(2) nothing in this subdivision shall prohibit a licensed physician from communicating with a patient:

(i) when requested by the referring health services purveyor;

(ii) when requested by the patient; or

(iii) when the referring health services purveyor, or other health services purveyor responsible for using the test results, cannot be reached and a critical value needs to be communicated to the patient.

Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) sections 586 and 587 set forth the duties and powers of the department related to clinical laboratory business practices. PHL sections 586(3) and 587(6) specifically authorize the Department to adopt regulations pertaining to clinical laboratory business practices.

Legislative Objectives:

The legislature enacted PHL sections 586 and 587 to prevent health services purveyors from splitting fees with clinical laboratories and to prevent payment for referrals. The Public Health and Health Planning Council and the Commissioner of Health are authorized to adopt and amend regulations necessary to effectuate the provisions and purpose of PHL sections 586 and 587. This proposed regulation is consistent with the legislative objective, as it will clarify for physicians and clinical laboratories allowable business practices.

Needs and Benefits:

Subpart 34-2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) regulates the business practices of clinical laboratories. These regulations prohibit certain practices by clinical laboratories and health services purveyors. The intent of these regulations is to mitigate improper business practices that could, among other things, result in kickbacks to laboratories from hospitals, physicians, and other health services purveyors for the referral of patients or specimens.

Section 34-2.11 prohibits certain communications between a clinical laboratory and a patient of a referring health services purveyor to prevent kickbacks or other payments from being given for the referral of laboratory services. To prevent such kickbacks, section 34-2.11(b)(1)(iv) requires clinical laboratories to direct a patient's inquiries regarding the meaning or interpretation of test results to the referring health services purveyor.

Direct communication between pathologists and patients regarding test results is not always needed but in some instances, direct communication is crucial to providing safe, high quality, patient centered care. Traditionally, pathologists communicate with health care providers to help interpret test results or to guide further management of a patient. However, there are instances when patients may wish to obtain information from a pathologist concerning their test results. Pathologists may also need to communicate test results to a patient when a critical value is obtained by the testing laboratory, especially if the pathologist cannot reach the ordering physician, or other health services purveyor responsible for using the test results. Under these circumstances, a licensed physician working at the laboratory should be able to reach out to the patient to ensure that a critical value is communicated. The proposed regulation will add affirmative language to Section 34-2.11 to provide that, under specific circumstances, a licensed physician employed by a clinical laboratory may discuss the meaning and interpretation of test results directly with patients.

Costs:

Costs to Regulated Parties:

The new language allows, but does not require, licensed physicians to discuss the meaning and interpretation of test results with patients. The proposed regulation will not impose costs on regulated parties.

Costs to the Agency, State and Local Governments:

The proposed regulation will not impose additional costs on the New York State Department of Health or local governments.

Local Government Mandates:

The proposed regulation imposes no new mandates on any county, city, town or village government.

Paperwork:

The proposed regulation does not mandate new paperwork requirements. However, laboratory physicians should document all communications with patients.

Duplication:

These rules do not duplicate any other law, rule or regulation.

Alternative Approaches:

One alternative is to not amend the regulation. However, this would prevent clinical laboratory physicians from communicating with their patients the meaning or interpretation of test results. The Department recognizes the importance of a pathologist-patient relationship as part of the spectrum of physician-patient relationships and its role in ensuring the delivery of safe, high quality, patient centered health care. Therefore, the Department rejected this alternative.

Federal Standards:

The proposed regulation does not exceed any minimum standards of the federal government.

Compliance Schedule:

The proposed regulation is permissive. Accordingly, regulated parties do not need to take any action to come into compliance.

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Statement in Lieu of

Regulatory Flexibility Analysis

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

Rural Area Flexibility Analysis

No Rural Area Flexibility Analysis is required pursuant to section 202-bb(4)(a) of the State Administration Procedure Act (SAPA). It is apparent from the nature of the proposed regulation that it will not impose any adverse impact on rural areas, and the rule does not impose any new reporting, recordkeeping or other compliance requirements on public or private entities in rural areas.

Statement in Lieu of Job Impact Statement

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed regulation, that it will not have an adverse impact on jobs and employment opportunities.