Patient Access of Laboratory Test Results

Effective date: 12/23/15

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 576 and 587 of the Public Health Law, Sections 58-1.8, 58-8.4 and 34-2.11 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) are amended, to be effective upon publication of a Notice of Adoption in the State Register, as follows:

Section 58-1.8 is amended as follows:

58-1.8 Results of tests to be reported only to physicians or other authorized persons. No person shall report the result of any test, examination or analysis of a specimen submitted for evidence of human disease or medical condition except to a physician, his agent, or other person authorized by law to employ the results thereof in the conduct of his practice or in the fulfillment of his official duties. [Reports shall not be issued to the patients concerned except with the written consent of the physician or other authorized person, except that information concerning blood type and Rh factor may be provided in writing to the individual whose blood was tested without the consent of the individual's physician.] Upon request by a patient or the patient's personal representative, clinical laboratories may provide a patient access to

completed test reports that can be identified as belonging to that patient as provided in section 34-2.11 of this Title.

Section 58-1.9 is amended as follows:

58-1.9 Testing to be done on premises except in certain instances. All specimens accepted by a laboratory for specified tests shall be tested on its premises. However, specimens for infrequently performed tests or those not included within specialties or subspecialties stated on its permit or those requiring specialized equipment and skill may be forwarded to and accepted by another laboratory under permit issued by the commissioner or to a laboratory which is operated by a government agency or a nonprofit research institution or to any other laboratory approved by the department. The reports of the results of such tests shall be sent by the testing laboratory to the forwarding laboratory, except that the forwarding laboratory may authorize the testing laboratory to send the report [directly to the physician or other authorized person who requested the test] as provided in section 58-1.8 of this Part, in which event the testing laboratory shall send a duplicate of the said report to the forwarding laboratory. Where the results of a test have been reported to it by the testing laboratory, the forwarding laboratory shall send a transcript of such report [to the physician or other authorized person who requested the test] as provided in section 58-1.8 of this Part and shall indicate thereon the name of the laboratory actually performing the test. [In no event shall any report of the result of any test or transcript

thereof be sent to the patient concerned except with the written consent of the physician or other authorized person who requested the test.]

Subdivision (a) of section 58-8.4 is amended as follows:

(a) No clinical laboratory shall notify a physician or other person legally authorized to receive the result that an HIV test is positive solely on the basis of HIV antibody screening, except that a clinical laboratory may report a preliminary finding of HIV infection [pursuant to the written request of a physician or other person legally authorized to receive the test results] as provided in section 58-1.8 of this Part. Results for specimens found non-reactive by HIV antibody screening may be reported to the physician who ordered the testing or other person legally authorized to receive the result.

Subdivision (b) of section 34-2.11 is amended as follows:

(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:

(1) a clinical laboratory may communicate [to] in writing to the patient (by mail or electronically) an accurate and complete account of the result of the laboratory test along with information required to be included in a report of test results pursuant to Subpart 58-1 of this Title under the following circumstances:

[(i) the referring health services purveyor authorized by law to order and use the results of laboratory tests has provided affirmative written authorization (on paper or electronically), which specifically names the patient;]

[(ii)] (i) the laboratory test results have already been, or are simultaneously being communicated to the referring health services purveyor authorized by law to order and use the results of laboratory tests;

[(iii)] (ii) the clinical laboratory advises the patient that the referring health services purveyor authorized by law to order and use the results of laboratory tests has received or is receiving the test results;

[(iv)] (iii) the clinical laboratory shall include, in the communication to the patient, a clear statement, presented in a prominent manner, to the effect that the communication should not be viewed as medical advice and is not meant to replace direct communication with a physician or other health service purveyor;

[(v)] (iv) the clinical laboratory directs the patient's inquiries regarding the meaning or interpretation of the test results to the referring health services purveyor; and

[(vi)] (v) the communication to the patient does not include any information which would be consideration given for referral of specimens, including, but not limited to, medical advice specifically directed at the patient concerning the patient’s condition, including diagnosis or treatment of the patient’s condition.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) Sections 576 and 587 set forth the duties and powers of the department related to the operation of clinical laboratories and their business practices. PHL Sections 576 and 587 also include authority for the adoption of regulations guiding the operation of clinical laboratories and blood banks including, but not limited to, laboratory reporting.

Legislative Objectives:

The legislature enacted New York State PHL Article 5, Title V, to promote the public health, safety and welfare by requiring the licensure of clinical laboratories and blood banks, by establishing minimum qualifications for directors, and by requiring that the performance of all procedures employed by clinical laboratories and blood banks meet minimum standards accepted and approved by the department. PHL Sections 576 and 587 authorize the Department to promulgate regulations providing guidance relative to the proper operations of a clinical laboratory. Regulations reflect the complexity of laboratory test methods and cover all phases of laboratory testing, including the reporting of laboratory test results. PHL Article 5, Title VI relates to business practices, ethics and consumer protections.

10 NYCRR Subparts 58-1 (Clinical Laboratories), 58-8 (HIV Testing) and 34-2 (Laboratory Business Practices) currently state that laboratory test results cannot be reported directly to the patient unless written authorization is first provided by the

physician or authorized person. These requirements are described in 10 NYCRR § 58-1.8 (Results of tests to be reported only to physicians or other authorized persons); 10 NYCRR § 58-1.9 (Testing to be done on premises except in certain instances); 10 NYCRR § 58-8.4 (HIV results reporting requirements); and 10 NYCRR § 34-2.11 (Recall letters and reporting of test results).

Needs and Benefits:

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. On February 6, 2014, the Federal Department of Health and Human Services (HHS) published amendments to 42 CFR Part 493 and 45 CFR Part 164 that allow patients to access their test results directly from a laboratory (see http://www.gpo.gov/fdsys/pkg/FR-2014-02-06/pdf/2014-02280.pdf). The new Federal rule became effective on April 7, 2014, with a compliance date of October 6, 2014. Stakeholders who commented on the amendments felt that federal regulations were a barrier that prevented patients from having an active role in their personal health care decisions and that the amendments would empower patients to take an active role in managing their health and health care. While patients historically have had the right under the privacy regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA Privacy Rules) to access their own health records, the rule had excluded access to laboratory test results. The February 6th amendments removed the exclusion in 45 CFR §

164.524(a)(1) and amended CLIA regulations at 42 CFR § 493.1291(l) to specify that "Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient." Although the use of the word "may" in 42 CFR 493.1291(l) does not require a clinical laboratory to provide a patient access to their completed test report, HHS emphasized that it is important to read the amended CLIA regulation in concert with the changes to the HIPAA Privacy Rule at 45 CFR Part 164. When taken together, the amendments will require HIPAA covered laboratories to provide individuals, upon request, with access to their laboratory test reports. A laboratory, as a health care provider, is only a HIPAA covered entity if it conducts one or more covered transactions electronically, such as transmitting health care claims or equivalent encounter information to a health plan, requesting prior authorization from a health plan for a health care item or service it wishes to provide to an individual with coverage under the plan, or sending an eligibility inquiry to a health plan to confirm an individual's coverage under that plan. As described by HHS, these amendments will result in the preemption of a number of state laws that prohibit a laboratory from releasing a test report directly to the individual or that prohibit the release without the ordering provider's consent because the state laws now would be contrary to the access provision of the HIPAA Privacy Rule mandating direct access by the individual. Therefore, 10 NYCRR § 58-1.8, 10

NYCRR § 58-1.9, 10 NYCRR § 58-8.4 and 10 NYCRR § 34-2.11 are being amended to be consistent with the new federal rules.

Costs

Costs to Private Regulated Parties:

HHS indicated that data were not available to calculate the estimated costs and benefits that will result from their amendments. HHS provided an analysis of the potential impact based upon available information and certain assumptions. It was determined that impacted laboratories may require additional resources to ensure patients receive test reports when requested and patients will benefit from having direct access to their laboratory test results. It should be noted that HIPAA covered entities will already have procedures in place for responding to requests for records. Clinical laboratories will incur costs to implement processes to allow patients access to their test reports as a consequence of the amendments to the federal rules. Under HIPAA privacy rules, HIPAA covered entities will be allowed to impose on the individual a reasonable, cost-based fee for providing access to their test results, including the cost of supplies for and labor of copying the requested information. Although clinical laboratories will incur costs to implement processes to allow patients access to their test reports as a consequence of the amendments to the federal rules, the amendments to 10 NYCRR § 58-1.8, 10 NYCRR § 58-1.9, 10 NYCRR § 58-8.4 and 10 NYCRR § 34-2.11 are simply making the State regulations consistent with the new federal rules.

Costs for Implementation and Administration of the Rule:

Costs to State Government:

No new costs would be incurred by state government.

Costs to the Department:

No new costs would be incurred by the Department of Health.

Costs to Local Government:

To the extent that local governments operate clinical laboratories they may incur the same costs as private regulated parties.

Local Government Mandates:

The proposed regulation complies with federal policy and will impose new mandates on any clinical laboratory operated by a county, city, town or village government.

Paperwork:

There will be an increase in paperwork attributable to activities related to providing patients with direct access to test results. The increase will be dependent upon the number of requests received by a laboratory and if a laboratory uses paper- or electronic-based systems for the reporting of test results.

Duplication:

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

Alternative Approaches:

There are no viable alternatives to this regulatory proposal. This proposal conforms state regulations to federal regulations.

Federal Standards:

The amendments to 10 NYCRR § 58-1.8, § 58-8.4, and § 34-2.11 are being made to be consistent with recent changes in the Code of Federal Regulations (CFR), specifically 42 CFR Part 493 and 45 CFR Part 164. In the absence of these amendments, New York State regulations would be contrary to the access provision of the HIPAA Privacy Rule mandating direct access by the individual.

Compliance Schedule:

The amended regulations will become effective upon publication of a Notice of Adoption in the New York State Register. Clinical laboratories regulated by New York State (NYS) are aware of the amended federal rule which became effective on April 7, 2014. Clinical laboratories were also notified by the Department in February 2014 that steps would be taken to amend NYS regulations to be consistent with the Federal amendments. Consequently, regulated parties will be able to comply with changes to 10 NYCRR § 58-1.8 as of their effective date.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

In July 2014, the Department's Clinical Laboratory Evaluation Program (CLEP) issued permits to 933 clinical laboratories. Of these, 372 are located out of State and do not qualify as small businesses. Of the remaining 561 laboratories located in New York State, 51 are governmental laboratories, and 166 are estimated to be small businesses.

Compliance Requirements:

The proposed rules will not result in any additional burden beyond those that are incurred as a consequence of the changes to the federal rule. Impacted clinical laboratories that are small businesses or governmental laboratories will need to develop mechanisms to provide patients access to laboratory test results. HHS projected a laboratory would incur a one-time burden of 2 to 9 hours to identify the applicable legal obligations and to develop the processes and procedures for handling patient requests for access to test reports.

Professional Services:

The proposed rules will not result in any additional burden beyond those that are incurred as a consequence of the changes to the federal rule. HHS projected a laboratory would incur a one-time burden of 2 to 9 hours to identify the applicable legal obligations and to develop the processes and procedures for handling patient

requests for access to test reports. Additionally, HHS assumed an hourly rate for a management-level employee to be $50.06.

Compliance Costs:

The proposed rules will not result in any additional costs beyond those that are incurred as a consequence of the changes to the federal rule. HHS indicated that data were not available to calculate the estimated costs and benefits that will result from their amendments. HHS provided an analysis of the potential impact based upon available information and certain assumptions. It was determined that impacted laboratories may require additional resources to ensure patients receive test reports when requested and patients will benefit from having direct access to their laboratory test results. It should be noted that HIPAA covered entities will already have procedures in place for responding to requests for records and HIPAA privacy rules currently permit HIPAA covered entities to charge an individual reasonable cost-based fee for providing access to health information.

Economic and Technological Feasibility:

The proposed regulations will not present economic or technological difficulties to any small businesses and local governments affected by these amendments. The technical infrastructure for reporting laboratory test results is already in place.

Minimizing Adverse Impact:

The changes to the federal rules conflict with state regulations that prohibit a laboratory from releasing a test report directly to the individual or that prohibit the release without the ordering provider's consent. Therefore, the Department of Health did not consider alternate, less stringent compliance requirements, or regulatory exceptions for facilities operated as small businesses or by local government.

Small Business and Local Government Participation:

Clinical laboratories designated as a small business or governmental laboratories by New York State (NYS) are aware of the amended federal rule which became effective on April 7, 2014. Clinical laboratories were also notified by the Department in February 2014 that steps would be taken to amend NYS regulations to be consistent with the federal rules. Discussions on this topic have also been held with Greater New York Hospital Association and the College of American Pathologists.

RURAL AREA FLEXIBILITY ANALYSIS

Types and estimated numbers of rural areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (http://quickfacts.census.gov). Approximately 87 clinical laboratories are located in rural areas.

Allegany County
Cattaraugus County
Cayuga County
Chautauqua County
Chemung County
Chenango County
Clinton County
Columbia County
Cortland County
Delaware County
Essex County
Franklin County
Fulton County
Genesee County
Greene County
Hamilton County
Herkimer County
Jefferson County
Lewis County
Livingston County
Madison County
Montgomery County
Ontario County
Orleans County
Oswego County
Otsego County
Putnam County
Rensselaer County
Schenectady County
Schoharie County
Schuyler County
Seneca County
St. Lawrence County
Steuben County
Sullivan County
Tioga County
Tompkins County
Ulster County
Warren County
Washington County
Wayne County
Wyoming County
Yates County

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

Albany County	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	

Compliance Requirements:

The proposed rules will not result in any additional burden beyond those that are incurred as a consequence of the changes to the federal rule. Impacted clinical laboratories that are in rural areas will need to develop mechanisms to provide patients access to laboratory test results. HHS projected a laboratory would incur a one-time burden of 2 to 9 hours to identify the applicable legal obligations and to develop the processes and procedures for handling patient requests for access to test reports.

Professional Services:

The proposed rule will not result in any additional burden beyond those that are incurred as a consequence of the changes to the federal rule. HHS projected a laboratory would incur a one-time burden of 2 to 9 hours to identify the applicable legal obligations and to develop the processes and procedures for handling patient

requests for access to test reports. Additionally, HHS assumed an hourly rate for a management-level employee to be $50.06.

Compliance Costs:

The proposed rules will not result in any additional costs beyond those that are incurred as a consequence of the changes to the federal rule. HHS indicated that data were not available to calculate the estimated costs and benefits that will result from their amendments. HHS provided an analysis of the potential impact based upon available information and certain assumptions. It was determined that impacted laboratories may require additional resources to ensure patients receive test reports when requested and patients will benefit from having direct access to their laboratory test results. It should be noted that HIPAA covered entities will already have procedures in place for responding to requests for records and HIPAA privacy rules currently permit HIPAA covered entities to charge an individual reasonable cost-based fee for providing access to health information.

Minimizing Adverse Impact:

The changes to the federal rules conflict with state regulations that prohibit a laboratory from releasing a test report directly to the individual or that prohibit the release without the ordering provider's consent. Therefore, the Department of Health did not consider alternate, less stringent compliance requirements, or regulatory exceptions for rural facilities.

Opportunity for Rural Area Participation:

Clinical laboratories located in rural areas are aware of the amended federal rule which became effective on April 7, 2014. Clinical laboratories were also notified by the Department in February 2014 that steps would be taken to amend NYS regulations to be consistent with the Federal amendments. Discussions on this topic have also been held with Greater New York Hospital Association and the College of American Pathologists.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

Comment:

One comment generally supported the right of patients to access patient information but also expressed reservations about clinical laboratory test results being immediately available to patients prior to being seen or signed off by the ordering physician. The commenter thought this could be detrimental when the testing was for difficult or life-threatening diagnoses. The commenter asks that wording be included in the regulation to allow the physician who ordered the testing the opportunity to review the results prior to the patient having access to them. This would give the doctor the ability to speak to the patient and clarify what the test results mean before the patient sees the report.

Response:

The Federal Department of Health and Human Services (HHS) addressed this concern in responses to public comments received on the newly adopted federal rule. HHS emphasized that the rule does not alter the role of the ordering or treating provider in reporting and explaining test results to patients. HHS expects that patients will continue to obtain test results and advice about what those test results mean through their ordering or treating providers.

HHS also noted that under 45 CFR § 164.524(b)(2)(i), laboratories are not required to provide individuals with access to their laboratory test reports immediately; laboratories can wait up to 30 days. HHS believes 30 days is generally sufficient to allow the ordering

or treating provider to receive the test report in advance of the patient's receipt of the report, and to communicate the result to the patient, and counsel the patient as necessary with regard to the result. HHS emphasized that laboratories will not be responsible for providing interpretations of laboratory test results to patients.

Comment:

A comment requested information regarding how the proposed rule would be implemented given the requirements in PHL § 2781(5) for persons ordering HIV related tests to communicate test results to the subject of the test.

Response:

This regulation will have no effect on such requirements. Persons ordering HIV related tests will continue to be required to comply with PHL § 2781(5) in exactly the same manner.

Comment:

Some commenters requested that language be removed from 10 NYCRR § 34-2.11 that requires a clinical laboratory to direct patient inquiries regarding the meaning or interpretation of the test results to the referring health services purveyor, because this language prohibits a clinical laboratory pathologist from conferring with a patient on the interpretation of laboratory/pathology test results.

Response:

Removal of the language in 10 NYCRR § 34-2.11 is not consistent with the Department's goal of aligning its regulations with the federal requirements. Additionally, the requirement that a clinical laboratory direct patient inquiries regarding the meaning or interpretation of the test results to the referring health services purveyor applies to all clinical laboratory directors, including those individuals who are not pathologists. The Department of Health is planning on meeting with stakeholder groups to obtain additional feedback on conferrals between pathologists and patients.

Comment:

One comment generally supported the right of patients to access patient information but requested that language be removed from 10 NYCRR § 34-2.11 that requires a clinical laboratory to advise a patient that test results have already been, or are simultaneously being, communicated to the referring health services purveyor. The commenter stated that the current regulations would require a clinical lab to make customized statements on their reports for NYS patients indicating that that the provider has, or is receiving, results. This additional language on reports issued to NYS patients would be administratively burdensome and costly due to the need for additional programming of their reporting systems. They also stated that these requirements are of no therapeutic benefit to the patient.

Response:

The Department does not believe it is necessary to change the regulation as it does not specifically require that a statement be made on a patient report.