New York State Bar Association

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Ronald F. Kennedy, *Director* • *Department of Governmental Relations* • (FAX) 518/487-5579

April 3, 2018

Stephanie Schulman, Ph.D., Director CLEP
New York State Department of Health
Wadsworth Center
P.O. Box 509, Empire State Plaza
Albany, NY 12201-0509

Re: Proposed Rule by the NYSBA Health Law Section

Dear Dr. Schulman,

The enclosed proposal, approved by the Association's Executive Committee on January 25, 2018, was developed by the Association's Health Law Section (the "Section"). More specifically, it was developed by the Section's Committee on Medical Research and Biotechnology chaired by Sam Servello and Alex Brownstein.

The New York State Department of Health ("DOH") is respectfully urged to consider promulgating the enclosed proposed rule.

The proposed rule would revise: *10 NYCRR 58.1.8: Results of tests to be reported only to physicians or other authorized persons.* This proposal would revise New York State regulations to allow research laboratories to disclose research findings that arise in an Institutional Review Board (IRB) approved study, and that may be clinically significant, to the health care provider designated by the study subject.

In preparing this proposal, input was invited from the members of our Section who are knowledgeable about issues which may arise upon its implementation. Concerns have been raised regarding a health care providers' ability to interpret research results and how information would flow between researchers, physicians and laboratories. Although treating providers are responsible for ordering tests for their patients, a Medical Doctor-Pathologist may be better trained to assess whether research data warrants clinical testing and whether an appropriate test is available. The development of guidance for stakeholders has been suggested by a number of our Section members. We believe these and other issues can be addressed while the DOH is processing its consideration of this proposal.

We welcome any questions you have as you consider this proposal.

Sincerely,

Ronald F. Kennedy

Enclosure: 1

CC: Mike Ryan, Ph.D., Director, Division of Laboratory Quality Certification
Jill Taylor, Ph.D. Director, Wadsworth Center
Anne Walsh, Ph.D., M.D., Director Medical Affairs, Wadsworth Center
Jonathan B. Karmel, Esq., Division of Legal Affairs

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Proposal in Relation to the Release of Subject-Identified Research Findings

NYSBA #33 April 2, 2018

Department of Health

PROPOSED RULE MAKING

Findings of Research Programs

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

***Proposed Action*:** Amendment of Part 58-1 of Title 10 NYCRR

***Statutory authority*:** New York State Public Health Law Article 5, §576.

Subject: Release of Subject-Identified Research Findings

Purpose: To allow research investigators possessing subject-identified, medically relevant research findings to disclose such findings to the subject's designated medical practitioner for purposes of referral for appropriate confirmatory analytical testing in a permitted clinical laboratory, using current approved test methods.

Substance of Proposed Rule: The proposed rule amends 10 NYCRR Part 58-1 by renumbering Section **1.8** as **1.8(a)** and adding a new section **1.8(b)** with the proposed language. The proposed rule codifies a process by which research investigators may report subject-identified research findings when such findings are deemed to represent significant health risks. The release of such information is done only with prior consent of the subject, and shall be used for referral of the subject/patient by an appropriate designated health care provider for confirmatory analytical testing in a permitted clinical laboratory, using current approved test methods.

Text of Proposed Rule:

1. Part 58-1.8 is renumbered as 58-1.8(a)

58-1.8(a)

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. 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.

2. Part 58-1.8(b) is added to read as follows:

58-1.8(b)

Results of tests conducted in the context of IRB approved research protocols by non-permitted research laboratories may be reported to the research subject's designated health care provider solely for the purpose of referral of the subject for confirmatory testing by a permitted laboratory using approved test methodology.

Regulatory Impact Statement

1. Statutory Authority

The authority for the promulgation of this regulation is contained in NYS PHL § 576 which sets forth the duties and powers of the Department to guide the practices of clinical laboratories. This section further includes the authority to adopt new regulations, as necessary, including regulation of laboratory reporting.

2. Legislative Objective

NYS Public Health Law Article 5, Title V provides for the regulation and licensure of clinical laboratories and blood banks to promote public health, safety, and welfare. Through these regulations, the Department ensures the proper performance of clinical laboratories and their directors through establishment of minimum acceptable standards. To ensure performance to these standards, it is necessary to adopt new regulations as previously uncontemplated issues arise. Section 580 specifically excludes research programs performing analysis solely for research purposes, where no individually identified subject's result is reported to that participant or to a health care provider, from the requirements of Article 5 Title V. However, in order for the research program to remain within the bounds of the research exclusion it is not possible for such entities to share possibly medically relevant individually identified findings with the research subject, even through their designated health care provider even where these findings could be of great immediate medical import for the subject. The proposed rule amendment is intended to create a permissive option for research entities to share possibly medically relevant findings with the research subject through their designated health care provider without the need to becoming certified as a clinical laboratory under NYS PHL Clinical Laboratory Evaluation Program.

The proposed rule establishes a process by which research programs may report the implications of research findings to pre-designated health care professionals in cases where research findings are medically relevant. Such communication would contain only the relevant information gleaned from research activities, and no actual sample analytical results. Additionally, such communications may be used only as an indicator that confirmatory testing is needed. Using this method, research programs would have a way to release medically relevant findings to subjects who want them, without having to fundamentally change their operating status and become a permitted clinical lab and to do so legally.

3. Needs and Benefits

The need for the proposed rule is two-fold. First, it allows a permissive option for those operating research programs faced with discovery of medically relevant research findings to share such findings with the predesignated health care provider for a research subject. This process will alleviate the medical-ethical dilemma of withholding potentially important findings in order to operate within the bounds of the research program statutory exemption from clinical laboratory permit requirements.

Second, analytical research findings have the ability to provide a significant amount of potentially relevant subject identified information which may be representative of serious health risks. These findings may be collected as a direct consequence of the research investigation or as incidental findings developed from the research methodology applied. Either type of finding may have high medical relevance to the subject and his designated practitioner. Sharing of such findings with the predesignated health care provider would empower subjects and their health care provider to make important medical decisions responsive to the findings by seeking confirmatory testing outside of the research program in a permitted clinical laboratory using current approved clinical laboratory test methods. Having this information available through the channel proposed by the new rule is in the interest of the public and optimized medicine.

Under current law, research programs operating without New York State permit are exempted from these permit standards only so long as the facilities perform their examinations without providing individually identified findings for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. The proposed rule would allow for such disclosures to take place solely for the purpose of referral for confirmatory clinical laboratory confirmation, while also allowing research programs to remain beyond the scope of clinical laboratory permit requirements. The proposed rule directly addresses this important need by creating a path for the research programs by which medically-relevant information may be shared while not defining them as a clinical laboratory.

4. Costs

Costs to regulated parties for the implementation of and continuing compliance with the rule.

For the research programs who would continue to be exempt from clinical laboratory permit requirements their cost considerations are minimal. The research programs are not expected to furnish samples, generate analytical reports, or perform any confirmatory analysis. Therefore, the main cost borne by the research programs would be the revision of the informed consent documents to include language regarding the ability of the subject to "opt-in" and designate a provider to receive notice of health related findings. As similar informed consent documents for research subjects already exist, such changes in language should impose no great financial burden on the research entities. Further costs could arise through the need to store and maintain subject-identified findings beyond normal research procedures. Research laboratories may also incur additional costs in their efforts to track and contact affected subjects and their designees. As the rule has no effect on the amount of testing performed by research programs, no additional costs may be expected relating to staffing, administration, and operation. The proposed rule allows research programs to create this option, but does not require them to do so.

Additional costs may be borne by the health care system at large. In any case where there is an increase in requested services, there is the potential for increased costs. With the probable increase in necessary confirmatory testing and office consultations, both physicians and permitted clinical laboratories will be confronted with some increase in the numbers of patients seeking services resulting in increased test referrals. As such services are generally offered on a fee basis the providers and permitted clinical laboratories are expected to recover the usual payment rates even if non-payment and low recovery rates for unpaid health care billings also plague the health care industry with medical debt recovery rates as low as 21.8 percent.[1]

Development of new approved testing methods for appropriate confirmatory testing of the research findings may result in some added costs for the reference clinical laboratories, but only if they choose to offer such added testing with the prospect of added revenue.No additional costs through applications, permits, licenses, or fees are contained in the proposed rule.

Costs to Department, State, and Local Government

There should be no significant cost to the Department, State or Local Governments. Any increased costs of these activities will not be borne by Government entities, but rather by the research programs and permitted clinical laboratories themselves.

The proposed regulation is an optional, permissive amendment merely allowing for sharing of subject identified potentially medically relevant research findings. A research program's nonparticipation is not tantamount to noncompliance, and will thus require no additional Government resources for enforcement of the proposed rule. Additionally, the proposed rule calls for no licensure, fees, or permitting which would require enforcement, thus further mitigating any increase in the need for Government resources.

[1] *Healthcare Collection Statistics,* ACA International (2016). *available at* http://www.acainternational.org/products-healthcare-collection-statistics-5434.aspx

5. Local Government Mandates

The proposed regulation imposes no mandates on Local Government.

6. Paperwork

Through implementation of the proposed rule, some additional paperwork may be generated by the regulated parties. The research programs will be providing documents relaying research findings to transmit this information between the research program and the designated health care provider. This will include some increase in paperwork for the participating research programs as correspondence for each subject requesting release of medically relevant findings. This increase in paperwork may be mitigated by the use of electronic methods for the delivery of information to subjects' designated practitioners.

Additionally, an increase in paperwork may be seen by the permitted clinical laboratories completing the confirmatory testing. Greater numbers of tests performed for confirmation of research findings would require additional documents, test requests, reports, and billing, but only if the clinical laboratory chooses to offer such testing. These materials would be created using existing laboratory management systems.

7. Duplication, Conflicts, Overlap

The proposed regulation attempts to accommodate the potential conflicts with NYS Public Health Law Article 5 Title V § 580 excluding facilities which perform laboratory tests solely for research purposes.

8. Alternatives

The foremost alternative to the proposed rule is to provide no exception for reporting of subject identified research findings. This choice is counter to public policy of effectively using and sharing potentially relevant medical information. A second alternative considered is requiring clinical laboratory permit compliance by all research programs that wish to report results. This method is severely burdensome, time consuming, and forces a large-scale change of the nature of research programs from their intended purpose. Such a drastic action is disproportional to the straightforward exception being sought by the proposed rule.

Presently, New York States provides an exemption allowing laboratories without NYS clinical laboratory permits, or permitted laboratories offering new unapproved tests methods to perform clinical testing.[2] Such exemptions are approved and governed by the Clinical Laboratory Evaluation Program (CLEP). Research laboratories may apply for single-test based on a number of factors including unavailability of clinical testing, continuity of care, and maintenance of sample integrity. The use of this "Restricted Laboratory Permit" exemption to New York State permitting is not a feasible alternative to the proposed regulation however, as such exemptions are issued solely on a case by case basis. It further requires that any laboratory applying for a Restricted Laboratory Permit be CLIA certified. It would also be impossible for research laboratories to ask prospectively for authorization to perform clinical testing prior to receiving subject samples. This system would therefore be overly burdensome on both the State and the laboratories themselves and is not a viable alternative to the proposed rule.

9. Federal Standard

[2] *New York State Non-Permitted Laboratory test Request Form Instructions,* New York State Department of Health, *available at* http://www.wadsworth.org/sites/default/files/WebDoc/1114528471/NPLInstructions2016.pdf.

No unified federal standard currently governs the release of medically relevant research results by entities not permitted as clinical laboratories, though there has been much debate on the topic. Responding to recent amendments to both HIPAA and CLIA, the Secretary's Advisory Committee on Human Research Protections of the HHS issued an advisory opinion in support of releasing research results. The Committee found "that researchers who identify clinically actionable information from the results of a research test conducted in a non-CLIA-certified laboratory [should] be able, without legal penalty, to refer a subject to a CLIA-certified laboratory for additional testing, to enable the subject to obtain such information through clinically reliable means."[3]

Echoing this idea, further federal support comes from the Centers for Disease Control (CDC) who outlined their criteria for returning individual results in population-based genetic research: "When the risks identified in the study are both valid and associated with a proven intervention for risk reduction, disclosure may be appropriate."[4] Though no official federal adoption of such measures has yet happened, it is clear that the proposed rule is in line with the evolving view of research laboratories' medical utility in relaying medically relevant findings.

10. Compliance Schedule

Affected research programs who choose to take advantage of this option will be able to comply with the rule as soon as informed consent documents are amended and methods by which designated physicians are notified have been developed and approved by the governing Institutional review Board. Presently, research programs are mandated by HHS Regulations to obtain informed consent prior to a subject's participation, so no new procedures will need to be established.[5] Given that research programs have authorized systems in place to collect and maintain Private Health Information (PHI) per their governing Institutional Review Board and Government guidelines, ready compliance should not be burdensome.[6]

Regulatory Flexibility Statement

1. Effect of Rule

The research programs who may consider participating in the option contemplated by the proposed rule are mainly large-scale research entities normally beyond the designation of small business.

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[3] *Attachment C: Return of Individual Results and Special Consideration of Issues Arising from Amendments of HIPAA and CLIA.* U.S. Department of Health & Human Services, (July 22, 2015), *available at* http://www.hhs.gov/ohrp/sachrp/commsec/attachmentc:letter9/28/15.html+&cd=1&hl=en&ct=clnk&gl=us.

[4] Susan M. Wolfe et al., *Managing Incidental Findings in Human Subjects Research,* 36 J. of Law, Med. (2008).

[5] HHS Protection of Human Subjects Regulations, 45 C.F.R. 46.116. *Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative…*

[6] HIPPA Privacy Rule, 45 CFR 164.508(a)(1). *Uses and disclosures for which an authorization is required.* ***(a) Standard: Authorizations for uses and disclosures (1) Authorization required: General rule.*** *Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.*

At this time, no affected programs are known to qualify as small businesses and thus there would be no direct effect.

However, other business may be affected by the proposed rule. Certain clinical laboratories qualifying as small businesses may be tasked with completing the confirmatory testing as required by a medically relevant research finding if they choose. This confirmatory testing would involve increased use of resources, personnel, and time. However, this increased testing may additionally lead to higher revenues for such clinical laboratories.

2. Compliance Requirements

There would be no compliance requirements under the proposed rule for research programs not qualifying as small businesses. Being a permissive regulation, those businesses indirectly affected by the rule's adoption, such as some clinical laboratories, have no affirmative steps needed to comply.

3. Professional Services

The adoption of the proposed rule should require no additional professional services.

4. Compliance Cost

The costs of compliance with the proposed rule are very minimal. For small businesses indirectly affected by the rule, namely clinical laboratories performing confirmatory testing, the costs may be counterbalanced by additional billings. Such costs may include increased testing, generation of reports, and resources expended coordinating with designated physicians. Through standard charges for such services, affected laboratories could experience a net positive effect from the increased confirmatory testing resultant of the rule.

5. Economic and Technological Feasibility

Businesses affected by the rule will be able to easily adapt to the proposed changes. Small business clinical laboratories conducting confirmatory testing will already have infrastructure in place to handle the processing of requests, communication with providers, and clinical testing. Although some new methods or technologies may need to be developed to handle requests originating at research programs for confirmatory testing in the permittedclinical laboratories, this is routine development for such laboratories if they choose to offer the relevant new tests.

6. Minimizing Adverse Impact

The proposed rule's potential for adverse economic impact on small business is very minor, and may be completely negated by the potential for increased revenues. As stated, small businesses likely to be affected are clinical laboratories taking on additional confirmatory testing. Though there are initial costs associated with higher volumes, the resultant increase in revenue will ultimately benefit the laboratory. Local governments will also see little impact from the proposed rule. With no need for enforcement of the rule, or the collection of fees or penalties, no additional government resources will be needed.

7. Small Business and Local Government Participation

Copies of the proposed rule will be published to the Department of State website, and will be open for comment when it is posted to the register.

Rural Area Flexibility Statement

1. Types and Estimated Number of Rural Areas

The proposed rule applies uniformly throughout the state. Rural areas will bear no greater consequence of the proposed change than any other area.

2. Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:

There will be no difference in the reporting, recordkeeping, or compliance subsequent to the rule change for rural areas. No additional professional services are expected to be needed for compliance with the proposed rule.

3. Costs

Costs to any business impacted by the proposed rule will not be different than those incurred by businesses in other areas of the state. These costs will be substantially the same as those outlined in the preceding *Regulatory Impact Analysis*, section 4.

4. Minimizing Adverse Impact

As no research programs are known to currently exist in rural areas, the adverse impact on any such rule making will be negligible. If an indirectly affected business, such as a clinical laboratory, is located rurally, the effects on such a laboratory would also be minimal. Such a laboratory would not be forced to alter its functioning in any way, or to adopt new methods or protocols. Rather, the greatest change would be the potential of increased business and greater revenue.

5. Rural Area Participation

Comments to the proposed rule will be welcomed and weighed from all parts of the state equally.

Job Impact Statement

1. Nature of Impact

The proposed rule should have no negative effect on jobs within the state. Rather, there may be a positive effect dependent on the volume of requests received for confirmatory testing. If the requests reach a great enough volume, it may eventually warrant more staff to manage their processing, testing, and administration.

Jobs within the research programs may also increase sufficient medically relevant research results are discovered. If a significant amount of resources are expended by such tasks as cataloging findings, maintaining affected subject information, and handling notification correspondence.

2. Categories and Numbers Affected

This proposed rule affects research programs and clinical laboratories. As this is a permissive regulation, the number of staff affected by the rule is dependent on elective participation of the affected entities.

3. Regions of Adverse Impact

Though no major adverse impact is expected, the areas most likely to suffer any impact would be those major metropolitan cities where most research programs are located. In New York State, these includes Buffalo, Rochester, Syracuse, Utica, Albany, and New York City.

4. Minimizing Adverse Impact

There are no adverse effects on existing jobs resultant of the proposed rule. The proposed rule will work to create new business through an increase in the number of tests performed at clinical laboratories while imposing a minimum burden on the researchers sharing the initial results. The regulation places no undue hardship on those participating in its directive as the framework for compliance with the rule presently exists within research laboratories and clinical laboratories.