AMERICAN CLINICAL LABORATORY ASSOCIATION

February 2, 2021

The Honorable Andrew M. Cuomo
Governor of New York State
New York State Capitol Building
Albany, New York 12224

Governor Cuomo:

I am writing in regard to the recent New York State Executive Order 202.82 ("Executive Order" or "Order") issued on December 13, 2020. The American Clinical Laboratory Association (ACLA) is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA members are at the forefront of driving diagnostic innovation to meet the country's evolving health care needs and provide vital clinical laboratory tests that identify and prevent infectious, acute, and chronic disease. ACLA members also have been a vital component of the response to the COVID-19 pandemic, having performed nearly 100 million COVID-19 diagnostic tests to date.

ACLA understands New York State's desire to improve access to patient data to inform COVID-19 public health efforts, better understand health disparities in infection and mortality rates, and track outbreaks, and ACLA members have been responding to those needs throughout the pandemic. As you know, ACLA members that are conducting COVID-19 testing in New York State already report test results and other required patient information through ECLRS as required by the June 29, 2020 "Interim Guidance for Laboratory Reporting of COVID-19 Test Results and Data Collection." However, questions about the scope and interpretation of the Executive Order have made it difficult for ACLA members to assess its applicability and the resources that may be needed to comply with any new obligations it may validly impose.

The provisions of the Executive Order at issue are as follows:

> IN ADDITION, by virtue of the authority vested in me by Section 29-a of Article 2-B of the Executive Law to issue any directive during a disaster emergency necessary to cope with the disaster, I hereby issue the following directives for the period from the date of this Executive Order through January 12, 2021:
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> Within 60 days of this Order, all clinical laboratories permitted by the Department of Health pursuant to Article 5, Title 5 of the Public Health Law, and having more than 25 employees, must become qualified entity participants and connect to the SHIN-NY through a qualified entity, and must allow private and secure bi-directional access to patient information by other qualified entity participants authorized by law to access such patient information, pursuant to Part 300 of Title 10 of the NYCRR.

The first issue, given the directive's internal inconsistency and lack of conformity to the requirements of the Section of the Executive Law under which it is said to be authorized, is whether it is applicable at all. The internal inconsistency is that, by its own terms, the directive is effective only from the date of the Order, December

13, 2020, to January 12, 2021; yet it purports to direct clinical laboratories to take actions within 60 days of the Order – by February 11 – at which time the Order itself would have expired. The effective period of the Order is governed by NY CLS Exec § 29-a(2)(a), which expressly provides that no directive shall be made for a period in excess of thirty days. There is an exception for an extension of a suspension of a statute, local law, ordinance, or orders, rules or regulations or parts thereof for additional periods not to exceed thirty days each, but that exception is not applicable here because this provision is a directive, not a suspension. For this reason, the provisions of the Executive Order at issue on their face appear to be invalid and inapplicable. If the State disagrees, we would appreciate an explanation of the basis for the Order's validity and applicability given these irregularities.

This issue is particularly important given the nature of the activity purporting to be required. Establishing an interface with a health information exchange can be a time-consuming and expensive process, and is typically pursued only for the purpose of a permanent connectivity arrangement. However, as noted above, the Section of the Executive Law under which the Order is said to be authorized envisions only temporary directives. Besides its questionable legal validity in this instance, implementation of a long-term arrangement within the 60 days envisioned is infeasible and use of an emergency directive inappropriate as a matter of public policy.

The second issue, assuming the Order is valid and applicable, is the scope of information to which it applies. The Order references "patient information" without defining that term within the Order, which has led to questions about its scope. The Order references Part 300 of Title 10 of the NYCRR, and the term "patient information" is defined in 10 NYCRR § 300.1(g) as "health information that is created or received by a qualified entity participant and relates to the past, present, or future physical or mental health or condition of an individual or the provision of health care to an individual, and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual." However, by its own terms, the Order was issued by virtue of authority to issue directives "*during a disaster emergency necessary to cope with the disaster*," and NY CLS Exec § 29-a(2)(b) expressly prohibits directives that are not reasonably necessary to aid the disaster effort. Therefore, since a broader interpretation of "patient information" to include information other than COVID-19-related information would be inconsistent with the authority under which the Order was issued, ACLA interprets the reference to "patient information" in the Order to refer solely to COVID-19 related patient information for New York residents. If the State disagrees, we would appreciate an explanation of the basis for its position and a clarification of the scope of information to which the Order relates, consistent with cited authority.

The third issue, assuming the Order is valid and applicable, is what is meant by the requirement to "allow private and secure bi-directional access to patient information by other qualified entity participants authorized by law to access such patient information, pursuant to Part 300 of Title 10 of the NYCRR." In the lab context, a bi-directional interface typically means an interface that enables the transmission of test results from the lab's information system to the ordering provider, and the transmission of test orders from the provider to the lab. But what appears to have occurred here is the inappropriate transposition to labs of electronic health record information exchange requirements more applicable to hospitals and other health care providers.

Under 10 NYCRR § 300.6 (a), hospitals and other healthcare facilities (other than clinical laboratories) who utilize certified electronic health record technology under the Federal Health Information Technology for Economic and Clinical Health (HITECH) Act were made subject to the following pertinent requirements:

> …must become qualified entity participants in order to connect to the SHIN-NY through a qualified entity, and must allow private and secure bi-directional access to patient information by

> other qualified entity participants authorized by law to access such patient information. Bi-directional access means that a qualified entity participant has the technical capacity to upload its patient information to the qualified entity so that it is accessible to other qualified entity participants authorized to access the patient information and that the qualified entity participant has the technical capacity to access the patient information of other qualified entity participants from the qualified entity when authorized to do so.

Clinical laboratories do not utilize certified electronic health record technology under the HITECH Act because their laboratory information systems are not included within the scope of such technology, and they do not create and maintain "electronic health records" in the same sense that hospitals and other healthcare providers do. The "bi-directional access" referred to in Part 300 of Title 10 of the NYCRR refers to the ability of hospitals and healthcare providers to upload to and receive from a qualified entity patient information from their respective certified electronic health record systems; using the same language in the context of the Order's directive to labs does not make sense.

It is also important to note that the regulatory requirement to which hospitals and other healthcare providers are subject in 10 NYCRR § 300.6 (a) provided for one to two years for implementation after a notice and comment rulemaking procedure; the Order is purporting to require labs to adopt the same requirement in the midst of a pandemic within the space of 60 days, without prior notice or opportunity to comment. We therefore ask the State to clarify exactly what kind of interface it expects laboratories to build, with reference to its specific expected functionality and with attention to the limitations of the authority by which the Order was issued.

The fourth issue, assuming the Order is valid and applicable, is whether it applies to reference laboratories. As you know, clinical laboratories in New York State may send specimens to reference laboratories, which then run the test and report results to the referring laboratory. It is our interpretation that reference laboratories are not subject to this Executive Order, and to the extent that it is applicable at all, it would only apply to the laboratory that receives the test order from and reports the test result to the patient's health care provider.

Finally, we also have concerns that the Executive Order's requirements for laboratories to provide patient information to SHIN-NY through qualified entities are duplicative of current laboratory reporting to New York's Electronic Clinical Laboratory Reporting System (ECLRS). To require simultaneous reporting of the same information to SHIN-NY places unreasonable and unnecessary additional strain on laboratories that are already investing unprecedented resources in the COVID-19 response. Furthermore, duplicative reporting may cause confusion at a time when access to accurate and reliable data on COVID-19 testing and cases are crucial to our public health response. If it is not the State's intent to create duplicative reporting requirements, please clarify which of the purported requirements of the Order, or the ECLRS requirements, will no longer apply going forward. Should the purported requirements of the Order apply, it is important to note that laboratories may result interim, final, amended, and/or corrected results, causing multiple results with different status to the provider's electronic health record system and therefore, to health information exchanges. Having multiple deliveries of the same data carries with it the additional risk of data breach.

As you work to address these questions and concerns, we ask that you suspend the provisions of the Executive Order at issue and any attempt to enforce them until the validity of the Order's application is explained, the scope of its requirements are clarified, and labs have been given a reasonable time to respond and take the actions necessary to comply. Given the tremendous pressure that laboratories currently face in the

COVID-19 pandemic and our outstanding questions regarding the Executive Order's requirements, the current February 11, 2021 deadline is not feasible.

Thank you for consideration of our concerns and your prompt responses to our questions. ACLA looks forward to continuing to partner with you to combat COVID-19 and maintain access to critical testing in New York and to addressing the above concerns with you.

Sincerely,

Julie Khani, President
American Clinical Laboratory Association

cc: Howard A. Zucker, Commissioner of Health