NEW YORK STATE CLINICAL LABORATORY ASSOCIATION, INC.

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SAGE COMMISSION PROPOSAL

Prepared: February 23, 2012

Submitted by: The New York State Clinical Laboratory Association, Inc. (NYSCLA)

Supported by: The Healthcare Association of New York State (HANYS), the American Clinical Laboratory Association (ACLA), the New York State Society of Pathologists (NYSSPATH), the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA).

Background: The SAGE Commission's overall goal is to modernize and right-size government to make it more efficient, effective and accountable. This proposal advances this goal by seeking to eliminate duplicative state government activities, streamline clinical laboratory oversight, and encourage New York businesses to continue their investment in New York.

Supporting Attachments: A letter from The Joint Commission (TJC) and a letter from the College of American Pathologists (CAP) provide their perspectives on how a public-private partnership model in which private accreditation agencies, working in conjunction with state and federal governmental agencies, can result in a reduction in duplicative and redundant inspections and proficiency testing for medical laboratories. The process they describe has successfully interfaced with the oversight activities of state licensing agencies in other states to allow for a more effective use of limited state resources in the oversight of medical laboratories.

Note: The version of this proposal that was submitted through the SAGE Commission website was not able to include the supporting attachments described above. These attachments will be submitted separately to the SAGE Commission.

PROPOSAL SUMMARY

Eliminate redundant inspections and proficiency testing conducted at clinical laboratories by the New York State Department of Health, Clinical Laboratory Evaluation Program (CLEP) and improve the timeliness of CLEP's review process for new or modified test methods.

DESCRIPTION OF INEFFICIENCIES

Since 1965, regulatory oversight of clinical laboratories in New York State has been conducted by the New York State Department of Health, the New York City Department of Health, or both. In 1993, oversight of clinical laboratories by the New York City Department of Health was eliminated, and this function is now performed by the New York State Department of Health (DOH).

In 1988, the federal government enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) that created a national regulatory and oversight program for clinical laboratories, whether located in hospitals, outside of hospitals (referred to as independent laboratories), or in physician offices. The intent of CLIA was to establish consistent laboratory standards for all laboratories no matter where they are located and to protect the public in all 50 states. The Centers for Medicare & Medicaid Services (CMS) has the responsibility for implementing the CLIA Program and regulates all laboratory testing (except research) performed on humans in the United States. CMS does this by designating state agencies to conduct inspections, as needed, and to monitor the inspections and proficiency testing of laboratories that are performed by approved accreditation organizations. Fees are collected by CMS from the laboratories to conduct this oversight, and the states are paid by CMS for their efforts.[1]

Many laboratories in New York located both in hospitals and outside of hospitals choose for various reasons to be inspected by national accreditation organizations such as the College of American Pathologists (CAP) and The Joint Commission (TJC). CMS approves such organizations to conduct laboratory inspections and accepts their findings. CMS also approves proficiency testing programs, such as the ones offered by CAP and the American Association of Bioanalysts (AAB). CLEP, however, does not accept any of the inspections or proficiency testing conducted by CAP, AAB, TJC, or any other CMS approved entity. This means that the 900 clinical laboratories doing business in New York State that are subject to CLEP and that are also inspected by CAP, TJC, or any other entity or which participate in a proficiency testing program approved by CMS are *also* required by CLEP to undergo identical inspections and proficiency testing by the New York State DOH, CLEP. This results in time-consuming and expensive, redundant laboratory inspections and proficiency testing of all hospital and independent clinical laboratories that are licensed to do business in New York State.[2]

Contrary to the national standards and practices required by CLIA and in effect in every other state in the United States, CLEP will not accept the proficiency testing or inspections that are performed by CMS approved entities. CLEP recognizes only the proficiency testing and inspections that it performs, creating extreme duplications of effort that are not required for a public health purpose. This redundant oversight program conducted by the New York State DOH, CLEP, is hugely expensive, costing many times more than the cost incurred by any other state. For example, the CLEP annual budget is approximately $20-million for the oversight of approximately 900 laboratories. The oversight program in Florida, which includes approximately 10,000 laboratories and which recognizes proficiency testing and inspections performed by CMS approved entities, costs approximately $2-million. All of the costs of the CLEP oversight program in New York are passed on to the clinical laboratories operating in New York State, creating an unnecessary, job-killing financial burden on New York State laboratories which results in added healthcare costs for patients, physicians, and payors as well as laboratories.[3]

Another area of inefficiency is the review by CLEP of laboratory developed tests (LDT's) and modified FDA cleared or approved tests. As part of its oversight function, CLEP reviews the appropriateness of new laboratory developed testing methods or kits that have not been approved by the Food and Drug Administration. Until these test methods are approved by CLEP, the test may not be performed on New York State residents. Unfortunately, it is not uncommon for the review of a new testing method to be stretched out over a period of a year and a half to two years. The tests being developed are generally innovative, cutting-edge procedures. By the time a new test is approved, that test, itself, may have become obsolete. Because of the unreasonably delayed approval time of LDT's, New York State residents cannot benefit from legitimate advances in laboratory science, and laboratories operating in New York State are placed at a competitive disadvantage to laboratories that may be allowed to conduct these tests for patients residing in other states. There are laboratories within New York State that have simply ceased conducting research on new testing methods because it is not financially feasible for them to acquire and maintain the necessary instrumentation during a two-year waiting period. This should be contrasted with the current CLIA process for allowing new test methods. For laboratories subject to rigorous CLIA oversight, such as the 7,800 practitioner office laboratories located in New York State and the laboratories located in all other states, there is no prior approval process necessary to offer a LDT.

PROPOSAL

1. CLEP should recognize inspections and proficiency testing performed by any CMS approved accreditation agency. There is no data indicating that the redundant inspections and proficiency testing by CLEP make laboratories operating in New York State any safer than the laboratories operating in the other 49 states. All states, including New York, are required to operate in accordance with the CLIA standards. These are the national standards, and the vast majority of states achieve compliance through a system that does not result in redundant inspections and proficiency testing. If CLEP recognized inspections and proficiency testing performed by CMS approved agencies, laboratories operating in New York State would no longer be subject to redundant inspections and testing. CLEP must become more business friendly instead of being business averse. This is what is done in other states. Laboratories could still choose to undergo inspections and proficiency testing by CLEP should they not have arrangements with other CMS approved agencies. In fact, this is the oversight system currently used for all laboratories in New York located in the 7,800 offices of physicians and other practitioners, many of whom perform the same complex tests performed by the hospital and independent clinical laboratories. There is no justification for having an oversight system for one laboratory that is different from that for another laboratory if they are performing the same test.

2. CLEP should continue to issue permits to all laboratories operating in New York State. The results of the inspections and proficiency testing conducted by CMS approved entities should automatically be conveyed to CLEP so that permits could be issued to laboratories as may be appropriate. If a laboratory is not performing satisfactorily for any reason, that laboratory would continue to be subject to increased oversight and sanctions by CLEP, as is now the case.

3. The cost savings to CLEP resulting from the elimination of the redundant inspections and proficiency testing that it currently conducts should be used to lower the extraordinarily high annual assessments charged to hospital and independent laboratories performing testing for

New York patients. The annual assessment is determined by the allowable costs incurred by CLEP, so if those costs decrease, the annual assessment should automatically decrease.

4. Many new tests developed in a laboratory setting have provided major healthcare breakthroughs, especially in the areas of cancer and infectious disease. The oversight process for reviewing these new test methods, including modified FDA cleared or approved tests, tests designated for research use only (RUO) or investigational use only (IUO), and other laboratory developed tests, should include a delicate balancing of relevant considerations. Oversight must be conducted in such a way as to allow patients to receive the benefits of innovative diagnostic tests in a timely manner. Those tests, however, must be accurate and reliable. CLEP must have a reasonable, predictable, and timely regulatory policy for ensuring the accuracy and reliability of these test methods.

It is our understanding that CLEP is already in the process of improving the review process by establishing a mechanism for conditional approval once a submitted validation package has been reviewed for completeness and has been confirmed to be complete (the "package received" stage). This process, which we support if appropriately implemented, will allow conditionally approved tests to be made available for patient care pending final review and approval. However, due to variations in submission volumes, delays could still occur. If additional resources are demonstrated by CLEP to be necessary to allow it to conduct its review in an efficient manner and in accordance with a defined timeline, consideration should be given to developing a reasonable schedule of processing fees that would be charged to those laboratories needing to have a new test method reviewed. A new processing fee should only be considered if the current annual assessment has been reduced as a result of savings stemming from the elimination of redundancies in proficiency testing and inspections as previously discussed. Those laboratories that do not develop new test methods should not be asked to pay this processing fee or to contribute to the resources needed for the review system. An oversight system developed along these principles would encourage innovation, improve patient outcomes, ensure patient safety, and may help reduce health care costs.

NOTE: The coalition supporting this Proposal had wanted to discuss with CLEP the recommendations contained in the Proposal with a view to arriving at consensus recommendations. Conversations did commence with CLEP, but there was not sufficient time to complete the discussions before it became necessary to submit this Proposal.

Respectfully submitted,

Tom Rafalsky

Thomas R. Rafalsky
President, NYSCLA

[1] CLIA allows states that have regulatory programs in place to become "exempt" from CLIA and to continue those programs as long as the regulations of the state program are equal to or more stringent than the CLIA requirements. Only two states, New York and Washington, have such "exempt status." New York applied for, and received, "exempt status" from CMS under CLIA based upon the State's claim that its regulations were equal to or more stringent than the CLIA requirements. It should be noted, however, that the State applied for "exempt status" only for the 500 or so independent laboratories and hospital laboratories physically located in New York State, so those are the only laboratories in New York over which CLEP has direct oversight responsibility as a result of New York's CLIA exempt status. CLEP also exercises oversight over approximately 400 hospital and independent laboratories located outside of New York State, but that oversight authority does not stem from New York's CLIA exempt status. (It should be noted that there are approximately 2,800 "limited" labs doing simple tests that fall under the jurisdiction of CLEP, but they are not subject to routine inspections and proficiency testing so are not pertinent to this Proposal.) There are also approximately 7,800 laboratories in New York State operated by licensed practitioners, such as physicians, osteopaths, dentists, midwives, nurse practitioners, and podiatrists that do not have "exempt status" and fall outside of CLEP's jurisdiction. Even though many of these practitioner laboratories perform the same tests as the 900 hospital and independent clinical laboratories mentioned earlier, they are not issued permits by CLEP, and they are not subject to the oversight of CLEP. They are all subject to CLIA, and DOH, not CLEP, has been designated by CMS as the CLIA state agency to exercise general oversight over these labs. DOH, not CLEP, is paid by CMS for its oversight activities.

[2] Washington State, the only other state besides New York that is "exempt" from CLIA (see endnote 1), does not conduct its own proficiency testing. It utilizes CLIA approved organizations to conduct such testing. Washington State also accepts the results of inspections conducted by TJC and CAP, all of which makes the Washington State program much more cost-effective and business friendly and less redundant than New York's.

[3] CMS even requires New York State to pay a fee of several hundred thousand dollars each year for the privilege of maintaining its exempt status, a cost that is passed on to New York State's laboratories. On the other hand, CMS pays approximately $1-million a year to DOH as the designated CLIA agency exercising oversight over the 7,800 or so laboratories operated by physicians and other providers in New York State that are not exempt from CLIA.

The Joint Commission

February 21, 2012

Thomas R. Rafalsky
President
New York State Clinical Laboratory Association, Inc.
394 Waverly Avenue
Brooklyn, NY 11238

Dear Mr. Rafalsky,

Several New York-based health care associations, including the New York State Clinical Laboratory Association and the Healthcare Association of New York State have asked The Joint Commission to provide its perspective on how private accreditation of medical laboratories, working in conjunction with state and federal governmental agencies, can result in a reduction in duplicative and redundant inspections. As the nation's oldest and largest accrediting organization, The Joint Commission welcomes this opportunity to describe a public-private partnership model that has effectively achieved this goal for every type of health care organization, in every state. In New York State alone, The Joint Commission has entered into collaborative agreements with the New York State Department of Health and the New York State Office of Mental Health such that those state agencies rely upon Joint Commission accreditation surveys of hospitals, ambulatory surgery centers and inpatient psychiatric units in lieu of conducting routine licensure inspections. This reliance on accreditation for the routine evaluation of high risk settings such as hospitals and psychiatric units has resulted in a more effective use of the limited state resources devoted to oversight of those facilities.

Founded in 1951, The Joint Commission is a private, non-profit accrediting organization that develops evidence-based standards and safety goals, and conducts surveys to determine compliance with those standards. Today, The Joint Commission accredits more than 19,500 health care organizations in the United States. This includes 1,650 clinical laboratories covering over 2,500 CLIA certificates. Over 75 organizations in New York State have licensed laboratories accredited by The Joint Commission.

The Centers for Medicare & Medicaid Services recognize The Joint Commission's Laboratory Accreditation Program as meeting the requirements of CLIA. CLIA regulations require that all laboratories be surveyed on a two-year cycle. CLIA regulations also require that there be an on-site survey by an approved agency such as The Joint Commission, for all tests of moderate or high complexity. Joint Commission standards and CLIA regulations also require that a laboratory be enrolled in a CMS-approved proficiency testing program for all regulated tests conducted by the lab. Annually, laboratories must report verification of annual enrollment in a proficiency testing program to The Joint Commission. CLIA requires that a laboratory's proficiency testing results be monitored on an ongoing basis by The Joint Commission.

In addition to the federal recognition and reliance of The Joint Commission's Laboratory Accreditation Program, eight states with laboratory licensure requirements above and beyond the CLIA requirements have regulatory language permitting the use of Joint Commission accreditation in lieu of the state licensure inspection. In these states, The Joint Commission works closely with the state licensing agency to ensure effective and efficient oversight of clinical laboratories. While these states delegate the responsibility of conducting routine surveys to accrediting agencies, they do not forgo the obligation or ability to effectively monitor the laboratories to which they issue a license. On the contrary, The Joint Commission's experience has been that the oversight of laboratories is only strengthened when states rely on accreditation for the routine inspections. First of all, state licensing agencies typically receive the accreditation reports which contain specific information on the level of compliance with important safety-related standards and processes. In addition, states that no longer perform routine inspections of clinical laboratories have found that they have more time to focus their limited resources on high priority issues. For example, states can devote more time and energy to investigating serious complaints and adverse events, and monitoring laboratories that are not already reviewed regularly by accrediting agencies. It is also important to remember that licensing agencies in all the states that recognize accreditation retain their authority to perform licensure inspections whenever they have information suggesting that patient safety may be jeopardized in one of their licensed laboratories.

The Joint Commission takes seriously its role in the public-private partnership which exists whenever a state relies upon accreditation in its licensure oversight process. For example, The Joint Commission routinely shares its unannounced survey dates with the responsible state agency to keep them apprised of survey activity involving their licensed laboratories. In addition, The Joint Commission will proactively share information on serious complaints it receives, in the event the state licensing agency wishes to conduct a coordinated survey/inspection. Whenever The Joint Commission issues a "cease testing notice" due to proficiency testing failure or makes an "immediate threat to life" declaration as a result of serious conditions at an accredited laboratory, the state licensing agency is immediately notified of the situation. Finally, The Joint Commission can make laboratory-specific accreditation reports and related information available to state authorities 24/7 through a password-protected internet-based portal.

I trust that this overview of the Joint Commission accreditation process and how it can interface with the oversight activities of state licensing agencies proves helpful as stakeholders consider mechanisms to reduce duplicative inspections and improve monitoring of clinical laboratories in New York State. Please rest assured that The Joint Commission stands ready to work with provider associations, the Governor's Office and the state licensing agency to ensure effective, coordinated oversight of our accredited laboratories. Please contact me at (630) 792-5260 or mcrafton@jointcommission.org with any questions.

Sincerely,

Mark A. Crafton

Mark A. Crafton, MPA, MT(ASCP)
Executive Director, State & External Relations
Division of Business Development, Government & External Relations

February 15, 2012

Mr. Thomas Rafalsky
President, New York State Clinical Laboratory Association
394 Waverly Avenue
Brooklyn, New York 11238

Dear Mr. Rafalsky:

I am writing on behalf of the College of American Pathologists (CAP) in support of New York State governmental efforts to recognize both the accreditation of clinical laboratories and the proficiency testing of facilities conducted by non-profit entities that are deemed by the Federal Centers for Medicare and Medicaid Services (CMS) for these purposes.

It is the position of the CAP that New York State recognition of CAP accreditation can obviate State routine inspections of CAP accredited laboratories and thereby mitigate the resource and personnel burden on these facilities resulting from the conduct of dual inspections. In addition, State recognition of CAP proficiency testing will promote efficiency and cost savings by eliminating the requirement for these laboratories to conduct duplicative proficiency testing.

Currently, twelve (12) states (AZ,CA, FL, GA, KY, ME, MD, NV, PA, WV, WA, WY) with laboratory licensure requirements have provisions in law that permit State recognition of clinical laboratory accreditation, including use of the accreditation inspection report in lieu of the routine state inspection. The CAP supports efforts to provide for State recognition of clinical laboratory accreditation and our organization has cooperated and coordinated with State oversight entities to secure formal recognition through harmonization of our requirements.

We look forward to securing New York State recognition of both our proficiency testing and accreditation programs. This would advance our mutual goal of providing an efficient and harmonious oversight process that will ensure the highest quality standards for clinical laboratories in New York. Thank you for your efforts in promoting this process.

Sincerely,

Kathryn T. Knight, MD, FCAP

Kathryn Knight, MD, FCAP
Chair, Federal and State Affairs Committee

CC: David Michael Crossland, MD, FCAP, President, New York State Society of Pathologists
Vernon A. Pilon MD, FCAP, State Issue Advisor, New York State Society of Pathologists