

August 16, 2005



American  
Clinical Laboratory  
Association

**BY FAX**

Ms. Rena Bryant  
Secretary to the New York City Board of Health  
Department of Health and Mental Hygiene  
125 Worth Street  
CN-31  
New York, NY 10013

**Re: Notice of Intention to Amend Article 13, Sections 13.03(a)(1)  
and 13.04 of the New York City Health Code**

Dear Ms. Bryant:

The American Clinical Laboratory Association (“ACLA”) is pleased to have this opportunity to submit our comments with regard to the proposed amendments to Sections 13.03(a)(1) and 13.04 of the New York City Health Code (the “Code”). ACLA is an association representing independent clinical laboratories throughout the country, including local, regional, and national laboratories. Many ACLA members furnish services to residents of the New York metropolitan area; therefore, they will be directly affected by these new requirements.

The proposed amendments to Article 13 will dramatically increase the reporting responsibilities of clinical laboratories by requiring them to try to obtain information to which they may not have ready or easy access and will significantly impair the privacy rights of patients and their physicians by requiring the reporting of certain test results to the New York City Department of Health and Mental Hygiene (the “Department”). Based on the Department’s proposed changes, clinical laboratories would be required to report to the Department: (i) the demographic information for *all* persons whose test results indicate the presumptive presence of any reportable condition specified in the Code, regardless of whether the laboratory possesses the information or has access to it; and (ii) electronically, all laboratory test results for Hemoglobin A1C (“A1C”) within 24 hours to the Department. ACLA is extremely concerned by these proposed changes and we have presented our concerns below.

**1. The Removal of the Qualifier “If Known” in Section 13.03 is Unfair**

The removal of the “if known” language from the reporting requirement in Section 13.03(a)(1) would alter the meaning in such a way that the provision would be extremely difficult for clinical laboratories to comply with for several reasons. While laboratories are currently required to report information to the Department within 24 hours for certain diseases, where that information is known to the laboratory, the new language removes the “if known” qualifier. The intent of the change appears to be to impose this reporting requirement on the laboratory, even if it does not possess the required information or have access to it. Therefore, the first objection to this language is that it imposes an impossible-to-meet obligation on laboratories; namely, it literally requires the laboratory to report information, even if the

laboratory does not know the information and is unable to report it. Such an obligation is clearly unfair and unreasonable.

Second, clinical laboratories are frequently not in the position to acquire all of the necessary demographic information (i.e. full name, date of birth, and address) that would be required for all patients covered by the requirement. As indirect treatment providers, clinical laboratories usually do not see the patient, and therefore, may not have an opportunity to obtain directly from the patient the information that is supposed to be reported. Following up with the patient is not an option because the missing information makes such direct follow-up impossible. In contrast, because physicians and other facility providers are able to have face-to-interactions with their patients, they are in a better position to obtain demographic information from patients. Providers who have direct contact with patients are better suited to collect full names, dates of birth, and addresses, as well as contact patients on the occasions where such information is missing. It is often difficult for the laboratory to obtain the required demographic information from the provider's office, especially in time to meet the 24-hour reporting requirement because of the competing demands on the provider's office. Thus, it would be preferable for the Department to obtain this information directly from the provider's office.

Additionally, the burden of this change would be significant. In a survey of ACLA member laboratories, members reported that they currently report an average of 720 specimen records per day under the current requirements. If only 10 percent of these records are missing demographic information, that is 72 specimen records per day (or 360 per business week), which must be followed up with the physician. That may not seem like much until it is recalled that each one requires a laboratory employee to telephone or contact the physician to obtain the required information. Moreover, the proposed reporting of A1C test results, as discussed below, for member laboratories would amount to an average of 2101 additional specimen reports per day. If 10 percent of these records are missing any demographic information, then 210 additional reports would need to be followed up with the physician, which only further demonstrates the burden that this requirement would impose on these laboratories.

Finally, clinical laboratories should not be required to bear the costs associated with such increased reporting responsibilities, especially the added costs associated with tracking down and verifying missing information. This will obviously be a manual and labor-intensive process, the costs of which will eventually be imposed on the health care payors.

## **2. The Reporting of Hemoglobin A1C Test Results in Section 13.04 is Unreasonable and Unnecessary**

The requirement that clinical laboratories report all A1C test results to the Department within 24 hours is an unreasonable and unnecessary expansion of the Code. Infectious diseases, such as tuberculosis ("TB") and HIV, are often monitored and controlled to curb the incidence and prevalence of infectious diseases, which would result in a serious threat to the public's health. Diabetes, however, is a chronic disease, which cannot be equated with the danger posed by the spread of a communicable disease. The testing of A1C levels reflects the "average blood sugar levels over the past 3 months ..." and, according to the Department, "... can be used for public health surveillance and [the] monitoring of trends of blood sugar control in people with

diabetes.” While we recognize that diabetes is a significant problem today, the testing of A1C levels does not affect the spread of diabetes because it is a chronic condition. Therefore, although ACLA appreciates the Department’s laudable goal of monitoring the prevalence of diabetes, the public health need for this type of reporting is far less clear than for other infectious conditions.

a. *Legal Implications Regarding a Patient’s Right to Privacy*

The mandatory reporting of A1C test results raises significant legal implications as to a patient’s constitutional right to privacy. The Supreme Court has recognized that the “zone of privacy” involves two types of privacy interests, which include the “individual interest in avoiding disclosure of personal matters, and another is the interest in independence in making certain kinds of important decisions.” *Whalen v. Roe*, 429 U.S. 589, 599 ( 1977). The Supreme Court has also observed that it is the role of courts to review legislative action “enacted to protect the public health, the public morals or the public safety, [that] has no real or substantial relation to those objects, or is, beyond all question, a plain, palpable invasion of rights secured by the [Constitution]....” *Jacobson v. Massachusetts*, 197 U.S. 11, 31 (1905). Since then, lower courts have interpreted this standard and stated that although a patient’s right to privacy in their medical information and records is not absolute, “[t]he court must determine whether the societal interest in disclosure outweighs the privacy interest involved. To avoid a constitutional violation, the government must show a *compelling* state interest in breaching that privacy.” *Doe v. Borough of Barrington*, 729 F. Supp. 376, 385 (1990) (emphasis added).

It is clear then that the Department must demonstrate more than a mere concern for the increase in prevalence rates of diabetes to mandate the reporting of A1C test results. As reflected by the privacy interests recognized by the Court, the right of patients to determine whether their A1C test results are disclosed to the Department is a right that should be recognized and protected. While the invasion may be easily defended in the case of a public health threat, such as presented by infectious or communicable diseases, no such threat exists here. Moreover, as patients are made aware that their test results would be disclosed to the Department, patients may be more reluctant to undergo testing, which is vital to the management of their diabetic condition. This of course, would be the complete opposite intent and goal of the Department.

b. *Intrusion on the Physician-Patient Relationship*

ACLA strongly believes that the reporting requirement intrudes inappropriately on the physician-patient relationship. The proper care of diabetic patients is the responsibility of the treating physician. Reporting A1C levels to the Department will not assist the physician in managing that responsibility. The management of diabetes requires significant patient involvement and motivation, which is rarely dictated by providers and, therefore, most certainly not by the Department. The assessment of diabetic control involves a host of factors, which affect A1C levels, such as body weight, body type, ethnicity, and diabetic complications. Because laboratories are typically not aware of such other factors, it would be inappropriate for the Department to evaluate a patient’s blood sugar control based on A1C levels alone. How then will the Department determine which physicians to contact and how will the Department regulate

those physicians whose patients do not take the necessary steps to reduce their A1C levels? Is it really reasonable to expect that the Department will intervene whenever a laboratory reports that a patient's A1C levels are above 9.0%, presumably indicating that the patient is under "poor" blood sugar control? These unanswered questions are an important element in determining whether the Department's proposed requirements are necessary.

*c. Reporting Requirements will be Burdensome on the Department and Clinical Laboratories*

It is difficult to understand how the Department will be able to monitor and analyze the tremendous amount of information that it will be receiving. For example, according to the proposal, there are an estimated 530,000 New York residents diagnosed with diabetes. Based on the general standard of care as provided under Medicare requirements, on average, diabetics have their A1C tested 4 times a year. National Coverage Determination Manual, 100-3, § 190.2. That means that there will be over 2 million laboratory test results reported to the Department each year, within 24 hours of being completed. With all due respect, given the incredible demands already imposed on the Department, ACLA finds it difficult to believe that the Department will be able to collate this information, analyze its impact, determine which patients and physicians require follow up, and then respond in any coherent or comprehensive fashion. Moreover, recent studies have demonstrated the difficulties in achieving desirable goals of glycemic management, in spite of comprehensive, intensive therapy, and motivation.<sup>1</sup> ACLA strongly believes that laboratories should not bear the burdens associated with the proposed reporting requirement if such reporting is proven to be futile. Indeed, it would appear to be far more productive to take the cost of implementing this program and use the funds to expand the Department's public education campaign targeted at patients and physicians that addresses the importance of A1C testing.

*d. Implications Under the Health Insurance Portability and Accountability Act ("HIPAA")*

Generally, a permitted public health disclosure under HIPAA is one where a covered entity may disclose protected health information to a public health authority in an effort to prevent or control disease. 45 C.F.R. § 164.512(b)(1)(i) (2004). However, the reporting of A1C levels for the prevention and control of diabetes is contrary to the "spirit" of HIPAA. The public health disclosure provision is intended to allow public health authorities to combat diseases that threaten the public's health. Although diabetes poses a public health concern, ACLA does not believe that a chronic disease, such as diabetes, meets the public health threat for which this narrow HIPAA exception was drafted.

Further, some reporting issues – and therefore, some HIPAA issues – are almost certain to occur. For example, the reporting requirements only apply to patients who are residents of the

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<sup>1</sup> Richard S. Beaser, et al., *Dyslipidemia and Diabetes: Reducing Macrovascular Risk – Diabetes, the Metabolic Syndrome, and Vascular Health: Clinical Interrelationships – Impact of Multifactorial Intervention* (CME) (Jan. 26, 2005) (finding that after a multifactorial intervention of 160 Type 2 diabetic subjects less than 20% achieved normal A1C levels below 6.5%); see also Richard S. Beaser, et al., *Dyslipidemia and Diabetes: Reducing Macrovascular Risk – Dyslipidemia: Etiology and Treatment Strategies* (CME) (Jan. 26, 2005).

five boroughs of New York. However, it is sometimes difficult for a laboratory to know for certain where a patient resides, especially given the fact that requisitions may not include a patient's home address. In that case, the laboratory may inadvertently report to the Department test results based on the location of the ordering provider's office for individuals who are not residents of New York. As a result, clinical laboratories could be subject to allegations of HIPAA violations for disclosing protected health information not subject to the Department's proposed requirement.

### **3. Conclusion**

In sum, while ACLA supports the Department's effort to address the prevention and control of chronic diseases, such as diabetes, we strongly encourage the Department to reevaluate its proposed changes. The "if known" language should not be removed from Section 13.03(a)(1) as it is extremely difficult for clinical laboratories to consistently provide demographic information when it is often not provided by providers. In addition, ACLA does not support the reporting of all A1C test results because it does not serve the purpose for which it is intended, and may result in adverse HIPAA, legal, privacy, and cost implications for clinical laboratories. These implications would eventually affect patients as they would become more reluctant to undergo testing, which would only worsen the public health problem that the Department is intending to ameliorate.

ACLA is pleased to have the opportunity to respond to the proposed amendments to Article 3 of the Code. We look forward to working with the Department as it continues to develop the appropriate solution to this problem. If you have any further questions or comments, do not hesitate to contact us.

Sincerely,

JoAnne Glisson  
Senior Vice President