DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BOARD OF HEALTH

NOTICE OF INTENTION TO AMEND ARTICLE 13
OF THE NEW YORK CITY HEALTH CODE

NOTICE OF PUBLIC HEARING

In compliance with Section 1043(b) of the New York City Charter and pursuant to the authority granted to the Board of Health by Section 558 of said Charter, notice is hereby given of the proposed amendments of Article 13 of the New York City Health Code.

NOTICE IS HEREBY GIVEN THAT THE DEPARTMENT WILL HOLD A PUBLIC HEARING ON THE PROPOSAL ON AUGUST 16, 2005 FROM 10AM TO 12PM IN THE THIRD FLOOR BOARDROOM, ROOM 330 AT 125 WORTH STREET, NEW YORK, NEW YORK 10013.

PERSONS INTERESTED IN PRE-REGISTERING TO SPEAK SHOULD NOTIFY, IN WRITING, RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013; (212) 788-5010 BY AUGUST 15, 2005. PLEASE INCLUDE A TELEPHONE NUMBER WHERE, IF NECESSARY, YOU MAY BE REACHED DURING NORMAL WORKING HOURS. SPEAKERS WILL BE LIMITED TO FIVE (5) MINUTES.

PERSONS WHO REQUEST THAT A SIGN LANGUAGE INTERPRETER OR OTHER FORM OF REASONABLE ACCOMMODATION FOR A DISABILITY BE PROVIDED AT THE HEARING ARE ASKED TO NOTIFY RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013; (212) 788-5010 BY AUGUST 2, 2005.

REGISTRATION WILL BE ACCEPTED AT THE DOOR UNTIL 10A.M. HOWEVER, PREFERENCE WILL BE GIVEN TO THOSE WHO PREREGISTER.

WRITTEN COMMENTS REGARDING THE PROPOSAL MUST BE SUBMITTED TO RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013, OR BY EMAIL TO THIS ADDRESS, RESOLUTIONCOMMENTS@HEALTH.NYC.GOV OR BY FAX ADDRESSED TO RENA BRYANT AT (212) 788-4315, ON OR BEFORE AUGUST 16, 2005.

WRITTEN COMMENTS RECEIVED BY THE SECRETARY TO THE BOARD OF HEALTH AND A TRANSCRIPT OF THE PUBLIC HEARING WILL BE AVAILABLE FOR PUBLIC INSPECTION WITHIN A REASONABLE TIME AFTER RECEIPT, BETWEEN THE HOURS OF 9:00 A.M. AND 5:00 P.M., AT THE OFFICE OF THE SECRETARY.

STATUTORY AUTHORITY

These amendments to the New York City Health Code ("Health Code") are promulgated pursuant to Sections 556, 558 and 1043 of the New York City Charter ("Charter"). Section 556 of the Charter grants the Department of Health and Mental Hygiene ("Department") jurisdiction to regulate matters affecting health in the City of New York. Specifically, Section 556(c)(2) and (4) of the Charter specifically empower the Department to supervise the reporting and control of chronic diseases, and to regulate clinical laboratories as authorized by Section 580(3) of the New York State Public health Law, respectively. Section 558(b) and (c) of the Charter empower the Board of Health to amend the Health Code and to include in the Health Code all matters to which the Department's authority extends. Section 1043 of the Charter grants the Department of Health rule making powers. In addition, Public Health Law Section 580 (3)(a) authorizes the Department to, "enact or enforce additional laws, codes or regulations affecting clinical laboratories… related to the control, prevention or reporting of diseases or medical conditions…"

STATEMENT OF BASIS AND PURPOSE

The New York City Department of Health and Mental Hygiene ("Department") is required by law to protect and promote the health of all New Yorkers. This requirement includes the prevention and control of chronic disease as well as communicable disease. The Bureau of Chronic Disease Prevention and Control, in the Division of Health Promotion and Disease Prevention, oversees the Diabetes Prevention and Control Program. Diabetes, a life-long disease, has recently become epidemic in New York City (NYC) and is a major public health problem. The prevalence of diabetes in NYC has doubled in the past ten years. The NYC 2003 Community Health Survey (CHS) estimates that 9% (530,000) of adult New Yorkers and 20% of adults over 65 have diagnosed diabetes. People may have diabetes an average of 4-7 years before being diagnosed, and it is estimated that another 265,000 may have diabetes and not yet know it. Diabetes is now the fourth leading cause of death in New York City, moving up from 6th in 2002. This epidemic condition requires similar or greater urgency in public health response to that traditionally accorded to infectious disease monitoring and control.

For infectious and non-infectious health conditions, including blood lead levels and communicable diseases, laboratory-based reporting has proven to be an efficient and reliable way to collect surveillance data. Other sources of surveillance data include New York State chronic disease registries, such as for cancer and the dementias, which are populated by case reports from clinicians. Of historical interest, Dr. Hermann Biggs, a prominent figure in public health, instituted a practice of requiring doctors to report all cases of tuberculosis (TB) to the city, provided free testing in the Department of Health laboratory and introduced methods for follow-up care in the 1890s. His approach provided the guideline to address the TB epidemic with the emergence of drug resistant forms of TB in NYC in the 1990s.

The laboratory reporting of Hemoglobin A1C (A1C), a measure of blood

glucose control reflecting average blood sugar levels over the past 3 months, can be used for public health surveillance and monitoring of trends of blood sugar control in people with diabetes. Evaluating these trends can be used to:

- Plan programs in the Diabetes Prevention and Control Program,
- Measure outcomes of diabetes care, and thereby
    - Direct more efficient interventions to health care institutions, health care providers and people with diabetes.

For example, the A1C registry can be used by the Department to report a roster of patients to clinicians, stratified by patient A1C levels, highlighting patients under poor control (e.g., A1C>9.0%) who may need intensified follow-up and therapy. The registry can also be used to direct resources to people with diabetes under poor control. This intervention approach has been used by the National Institute of Health funded Vermont Diabetes Information System (VDIS). The VDIS is a regional registry-based decision support and reminder system, targeted to primary care providers and their patients with diabetes. The registry is populated automatically by electronically submitted test results, including A1C, from clinical laboratories across Vermont. These results are reported back to clinicians daily and quarterly, and to patients when they have elevated values or are overdue for testing. The system is a promising approach to utilizing a registry to improve quality of care and clinical outcomes by focusing the attention of primary care providers on a population approach to delivering care.

The Department, consistent with the position of the national American Diabetes Association, recommends that people with diabetes have their A1C measured every 3-6 months. The goal for A1C is less than 7.0%, which is considered "good" blood sugar control (average blood sugar of 170 mg/dL). Despite many cost-effective treatments, diabetes care in the US remains sub-optimal. The 1999/2000 National Health and Nutrition Examination Survey (NHANES) estimates that only 37% of US adults with diabetes have an A1C <7.0% and 20% have an A1C >9.0% ("poor" blood sugar control). In New York State, 31% of diabetic patients in commercial managed care and 42% in Medicaid Managed Care have an A1C >9.0%.

There is strong evidence that with tight blood sugar control (A1C <7.0%), the small blood vessel complications (eye disease, kidney disease and peripheral nerve disorders) of diabetes can be reduced by over 25%. For every drop of 1% (e.g., from 9% to 8%), there is a 35% reduction in small blood vessel complications. Keeping the average blood sugar (A1C) under 7.0% can prevent many diabetes-related complications and deaths.

The Department is proposing an amendment to Article 13 of the NYC Health Code to address this epidemic. Amendment of current law to include the reporting of A1C will advance the public health approach to surveillance and management of the epidemic of diabetes. The reporting of all A1C test results is important for program planning, education, outreach, disease management and surveillance purposes. The Department proposes stringent confidentiality requirements that would prevent the sharing of diabetes diagnoses with anyone other than the patient or the treating medical providers. In the case of a minor, this information could be disclosed to the minor's parent or legal guardian. This information therefore, could not be used,

for example, to make it more difficult for persons with diabetes to obtain or renew a driver's license, health insurance, life insurance, etc.

The Department proposes that laboratories be mandated to report blood tests identified by the following terms:

a) For A1C and/or the appropriate LOINC codes (www.loinc.org).
Synonyms/Inclusions:

- HgbA1c
- HgbA1c by HPLC
- HbA1c
- Glycohemoglobin A1C
- Gycolhaemoglobin
- Glycohemoglobin
- Glycated Hgb
- Glyco-Hb
- GHb
- Ghb

Exclusions:

- Hgb
- Hemoglobin
- Hb
- Hb without reference to glycated or glycosylated or A1C
- Glycohemoglobin total

The Department proposes that all laboratories that report through the Electronic Clinical Laboratory Reporting System (ECLRS) via file upload method be required to report A1C in an electronic format defined by the Department's Bureau of Integrated Data Systems in cooperation with the Diabetes Prevention and Control Program. The provision of this data should represent a minor burden on laboratories already participating in electronic reporting, requiring minimal one-time programming changes in order to submit the additional tests.

The creation of a clinical laboratory based A1C registry is a promising approach to guide the Department in achieving the goal of preventing diabetes-related complications and death by the improvement of blood glucose control in New Yorkers with diabetes. In addition, the Department proposes to amend Section 13.03(a)(1) of the Health Code regarding what information must be reported by clinical laboratories for any and all reportable conditions. Specifically, the Department is proposing to require the reporting of the date of birth and address of the person from whom the specimen was taken. These elements are already required by the New York State Department of Health to be reported by laboratories to public health authorities. [*See* Laboratory Reporting of Communicable Diseases 2004, issued by New York State Department of Health].

For more information about diabetes and this proposal, see
http://www.nyc.gov/html/doh/downloads/pdf/diabetes/diabetes-presentation-a1c-registry.pdf

The proposal is as follows:

Note - matter in brackets [ ] to be deleted
matter underlined is new

RESOLVED, that subsection (a) of Section 13.03 of the New York City Health Code as last amended by resolution, on the --------date----------, be and the same hereby is amended, to be printed together with explanatory notes, to read as follows:

§13.03 Report of positive findings.

(a) The director of a clinical laboratory shall report to the Department within 24 hours all laboratory findings which indicate the presumptive presence of any disease required to be reported by §11.03 of this Code. Reports shall state the particulars required by §11.05 and shall include:

(1) The full name of the person from whom the specimen was taken, [and, if known,] the date of birth and address of such person.

…

Notes: Paragraph (1) of subsection (a) was amended on --------date--------, to require the reporting of the date of birth and address of the person from whom the specimen was taken.

RESOLVED, that Article 13 of the New York City Health Code as last amended by resolution, on the --------date--------, be and the same hereby is amended to create a new section, Section 13.04 Reporting of Hemoglobin A1C, to be printed together with explanatory notes, to read as follows:

§ 13.04. Reporting of Hemoglobin A1C.

(a) All clinical laboratories, as defined under §13.01 of this Article, that report laboratory test results electronically to the Department and which use a file up-load method, shall electronically report to the Department all laboratory results for Hemoglobin A1C tests, as defined in subsection (b) of this section, within 24 hours.

(b) The "Hemoglobin A1C" laboratory test represents an index of blood glucose control measuring average blood sugar over the past 90 days, and shall mean the following for the purposes of this section: HgbA1c; HgbA1c by HPLC; HbA1c; Glycohemoglobin A1C; Gycolhaemoglobin; Glycohemoglobin; Glycated Hgb; Glyco-Hb; GHb; Ghb. As defined in this section, "Hemoglobin A1C" shall not mean the following: Hgb; Hemoglobin; Hb; Hb without reference to glycated or glycosylated or A1C; or Glycohemoglobin total.

(c) Reports required by subsection (a) shall contain the information required in Section 13.03 (a) (1) through (6) of this Article.

(d) Hemoglobin A1C test results and other identifying information reported to the Department pursuant to this section shall be confidential and shall not be disclosed to any person other than the individual who is the subject of the report or to such person's treating medical providers. If the subject of the report is a minor, information can be disclosed to the subject's parent or legal guardian.

Notes: Section 13.04 is new and was added on --------date--------, to require clinical laboratories that report to the Department electronically and which use a file upload method to report to the Department electronically A1C test results. Further this section provides for strict confidentiality protection for the information reported to the Department pursuant to this section.