



STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower

The Governor Nelson A. Rockefeller Empire State Plaza

Albany, New York 12237

Antonia C. Novello, M.D., M.P.H., Dr. P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

July 23, 2003

Christopher M. Peters
Project Executive, Public Health/Bio-surveillance
Cerner Corporation
Attn: Leslie Woodward
2800 Rockcreek Parkway
Kansas City, MO 64117-2551

Re: DOH GC Opinion No. 03-02
Laboratory Use of Contractor to Report Certain
Cases

Dear Mr. Peters:

This responds to your letter of June 3, 2003 which requested on behalf of Cerner Corporation an opinion as to whether New York State licensed laboratories may use contractors to fulfill their responsibilities to report cases of communicable disease, HIV/AIDS, sexually transmissible disease and tuberculosis to the Department of Health. The Department of Health has created the Electronic Clinical Laboratory Reporting System ("ECLRS") to facilitate laboratory reporting and Department analysis of data. As I understand it Cerner Corporation ("Cerner") wishes to market a system under which it will access certain laboratory data, including test results and patient specific information, process the data, and send reports of cases of the above diseases electronically to the Department of Health. Data will be stored and transmitted over secure systems. This will be a system under which data will be collected and routed to the Department for Cerner customers; Cerner will not be a preferred or the exclusive New York State vendor for ECLRS reporting, nor will Cerner be considered an approved vendor by virtue of this letter. It is my opinion that a laboratory may use a contractor to make such reports on its behalf provided the contractor meets all requirements of, and is certified to participate in, the ECLRS system. However, the laboratory, and not its contractor, will be held responsible by the Department for assuring that reporting is accomplished as required by law, including that data are reported accurately and timely and confidentiality is maintained. Finally, any transfer of personally identifiable information must be accomplished in accordance with the provisions of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) ("HIPAA") and its implementing regulations (45 CFR Parts 160 and 164).

Discussion

Christopher M. Peters
July 23, 2003
Page 2

Laboratories are required to report cases of communicable disease to the State Department of Health by Public Health Law § 2102(1). Communicable diseases are listed in 10 NYCRR §2.1 and include tuberculosis and certain sexually transmitted diseases. Laboratories are required to report initial determinations or diagnoses of HIV infection, HIV related illness and AIDS to the State Department of Health by Public Health Law § 2130 and 10 NYCRR § 63.4. Public Health Law § 577(1)(b) requires that clinical laboratories restrict access to laboratory reports to those authorized by law to receive them. In addition, the confidentiality of HIV/AIDS information must be maintained as required by Public Health Law §§ 2134, 2782 and 10 NYCRR § 63.6. The Department does not consider a laboratory's use of contractors providing services such as those described above to be "disclosure" for purposes of these provisions so long as (1) the confidentiality of the information during transmission from the laboratory to the contractor is assured; and (2) the information is not disclosed by the contractor except to the Department of Health for this purpose or as otherwise allowed by law.

Laboratory regulations at 10 NYCRR § 58-1.8 provide that the results of any test, examination or analysis of a specimen submitted for evidence of human disease or medical condition may not be reported 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. The Department does not interpret this to prevent laboratory use of a contractor in lieu of an employee to make its required reports to the State Department of Health, provided that the contractor complies with the laboratory's requirements for accuracy and timeliness of reports, maintaining confidentiality of the information and compliance with the requirements of the ECLRS system. Whether or not a contractor is used, the Department will hold the laboratory responsible for assuring compliance with all such requirements. Therefore use of redundant electronic or paper back up systems in either the laboratory or the contractor is recommended. Laboratories are also advised to assure compliance with HIPAA in any such arrangements into which they enter.

Finally it should be understood that the Department is not hereby agreeing to a preferential or exclusive vendor arrangement for Cerner Corporation or any other vendor or laboratory. Nor may Cerner represent that this opinion in any way constitutes the Department's endorsement of Cerner's system. ECLRS will continue to accept reports from Cerner customers as well as other vendors and laboratories through any of several methods, provided they meet the same requirements and are approved for participation in the ECLRS system.

Christopher M. Peters
July 23, 2003
Page 3

These conclusions are based on the facts set forth herein and any change in those facts might result in a change of the conclusion.

Very truly yours,

Donald P. Berens, Jr.
General Counsel