

DEPARTMENT OF HEALTH AND HUMAN SERVICES

REGION 1
JOHN F. KENNEDY FEDERAL BUILDING
GOVERNMENT CENTER
BOSTON, MASSACHUSETTS 02203

OFFICE OF THE
REGIONAL DIRECTOR

OCT 28 1982

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COMMISSIONER
Health & Hospitals

Robert Healy
Manager
City of Cambridge
795 Massachusetts Avenue
Cambridge, Massachusetts 02139

Dear Mr. Healy:

Enclosed for your information is a copy of a letter from the Associate Regional Administrator of the Division of Health Standards and Quality, of the Health Care Financing Administration, to Cambridge Diagnostics, Inc., 359 Allston Street, Cambridge, Massachusetts. This letter notifies Cambridge Diagnostics, Inc. that the Health Care Financing Administration has determined that the laboratory is no longer approved as a supplier of services under the Medicare program. This determination will preclude Medicare reimbursement for clinical laboratory testing services.

In the event that corrective action is accomplished, the laboratory may again request approval for participation in the Medicare program. Since Medicaid program requirements parallel those of Medicare and since Cambridge Diagnostics, Inc. is also a certified provider of services in the Medicaid program, Medicaid officials will be notified of this action.

This same information is being provided to Senator Kennedy, Senator Tsongas, Congressman O'Neill and Governor King.

Sincerely yours,

Nancy L. Harris
for Clairia P. Monier
Regional Director

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

HEALTH CARE FINANCING
ADMINISTRATION
Division of Health Standards & Quality

Region I
John F. Kennedy Federal Bldg.
Government Center
Boston MA 02203

October 28, 1982

Laxman Desai, D.Sc.
Director
Cambridge Diagnostics, Inc.
359 Allston Street
Cambridge, Massachusetts 02139

Dear Dr. Desai:

This is to inform you that a thorough review of your laboratory's compliance with the conditions for coverage of its services under Medicare (Title XVIII of the Social Security Act) as prescribed in the regulations has led to a determination on the part of the Health Care Financing Administration that Cambridge Diagnostics, Inc., does not meet the requirements for participation as a supplier of independent laboratory services in the Health Insurance for the Aged and Disabled Program (Medicare).

Continued participation in the Medicare program on the part of an independent laboratory is contingent upon that laboratory meeting the provisions of sections 1861(s)(10) and (11) of Title XVIII of the Social Security Act and the regulations issued pursuant thereto by the Secretary of Health and Human Services.

Based on the survey conducted on March 19, 1982 by the Massachusetts State agency, a joint Federal/State visit conducted on April 8, 1982, and a State follow-up visit conducted on September 1, 1982 following full consideration of the information you presented at a meeting with members of the Health Care Financing Administration on May 25, 1982, we have determined that Cambridge Diagnostics, Inc., is not in compliance with the Conditions for Coverage 42 CFR 405.1312, Director; 42 CFR 405.1313, Supervision; 42 CFR 405.1316, Management; and 42 CFR 405.1317, Quality Control. You have been previously provided with a written copy of the findings of the March 19 and April 8, 1982 on-site surveys and are herewith being provided with a copy of the findings from the September 1, 1982 revisit, the deficiencies found at the time of those visits being the basis for our decertification action.

Specifically, with regard to Condition for Coverage 405.1312 (Director), the director does not adequately administer the technical and scientific operations of the laboratory, including assurance of proper performance and validation of all procedures in use, assurance of proper evaluation of all critical operating characteristics for each piece of equipment in the laboratory, assessment of the quality of work performed in all laboratory specialties to assure accuracy and the reporting out of results of tests performed.

With regard to Condition for Coverage 405.1313 (Supervision), as evidenced by the nature and number of deficiencies identified in the areas of Management and Quality Control, neither technical nor general supervision is adequate to provide assistance on specific testing, on quality control procedures, advice in and monitoring of problem areas, and in the day-to-day supervision of the laboratory operations.

With regard to Condition for Coverage 405.1316 (Management), the record keeping system of the laboratory is not adequate in that the procedure manuals, accession records, work sheets and final reports are not consistently and completely maintained.

With regard to Condition for Coverage 405.1317 (Quality Control), quality control practices, including use of standards and controls, preventive maintenance, and review of test results, are not adequate to assure that all tests performed and reported out are reliable and accurate.

Cambridge Diagnostics, Inc., has failed to comply with the regulations contained in the Conditions for Coverage of Services of Independent Laboratories in the areas of Director, Supervision, Management and Quality Control (42 CFR 405.1312, 42 CFR 405.1313, 42 CFR 405.1316, and 42 CFR 405.1317) and has failed to attain compliance with those regulations as evidenced by the presence during the September 1, 1982 on-site follow-up of the same deficiencies which were cited during the March 19 and April 8, 1982 survey. The appearance of the deficiencies in the areas of Management and Quality Control demonstrates that the technical and administrative expertise required to appropriately maintain a clinical laboratory are not being exercised at Cambridge Diagnostics, Inc.. Based on the seriousness of the deficient condition of the laboratory which has existed since March 19, 1982, there is no reason to believe that corrective action will be implemented within a reasonable period of time or if compliance is attained that it will be maintained. It is necessary, therefore, that we withdraw approval of the clinical services provided by Cambridge Diagnostics, Inc. to be effective November 12, 1982. We will arrange to publish a notice in the newspapers serving the area in which your laboratory is located. Our decision and the reasons for this action will also be made known to the professional users of your services.

If you believe that this determination is not correct, you may request a hearing before an administrative law judge of the Bureau of Hearings and Appeals. If you desire a hearing, you must file a written request for one not later than 60 days from the date this letter is received by the laboratory. Such a request should be made to the Health Care Financing Administration, Bureau of Program Operations, Office of Standards and Performance Evaluation, Division of Reimbursement, Recovery, and Reconsideration Evaluation Reconsideration Evaluation Branch P.O. Box 770 Baltimore, Maryland 21203 Attention: Hearing Control (PPH Unit).

The request for a hearing should contain a statement as to the specific issues or findings of fact and conclusions of law with which you disagree and the basis for your contention that such issues and/or findings and conclusions are incorrect (42 CFR 405.1531(b)). Evidence and arguments may be presented at the hearing where you may be represented by counsel.

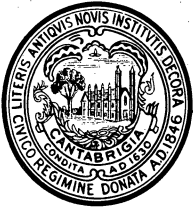
Sincerely yours,

Lawrence W. Osborn, M.D.
Associate Regional Administrator

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OFFICE OF THE
CITY MANAGER



The Cambridge Hospital

Affiliated with
Harvard Medical School



November 1, 1982

Mr. Robert Healy
City Manager
City Hall
Cambridge, MA

Dear Mr. Healy:

The Cambridge City Council at its October 18, 1982 meeting asked you certain questions relating to Cambridge Diagnostics, Inc., a private laboratory located on Allston Street in Cambridge (Council order attached).

Private, free-standing (non-hospital affiliated) clinical laboratories doing business in Massachusetts are, by law, licensed by the Commonwealth's Department of Public Health and regularly surveyed by representatives of that agency's clinical laboratory licensing division. In addition, private laboratories which perform tests for Medicare recipients must meet federal Medicare standards and are, therefore, subject to federal survey as well. In addition, the College of American Pathologists (CAP) and other recognized nongovernmental, voluntary accreditation groups establish standards and weigh surveyed laboratories against those standards; many private laboratories elect to undergo the accreditation process to demonstrate to their customers that they meet an acknowledged high standard of quality.

In light of these multiple layers of expert and in many cases legally mandated oversight, the role of the City in relation to deficiencies in operational procedures of private laboratories ought to be coordinative in nature. Since the City has no means to evaluate private laboratories' technical performance and no explicit legal authority to do so, and since other public and private agencies are by law required to serve this function, the City, through its Commissioner of Health and Hospitals, can only monitor whether or not such private laboratories are properly licensed.

Cambridge Diagnostics, Inc. is and has been licensed by the Commonwealth as a clinical laboratory; the City can take no action against a properly licensed laboratory based on allegations of improper laboratory procedure other than continue to monitor its licensed standing and cooperate with the licensing authority's investigation. This we have been and will continue to do.

The Council order also asks about relationships between the Cambridge Hospital and Cambridge Diagnostics, Inc. From July 1, 1979 through June 30, 1980

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OFFICE OF THE
CITY MANAGER

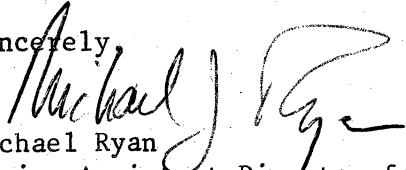
Cambridge Diagnostics performed selected referral laboratory work, almost exclusively toxicology and drug level analyses, under a contract with the Cambridge Hospital. In June of 1980 a request for competitive proposals for this referral work was sent to six potential bidders. Bioran Medical Laboratory on Massachusetts Ave. in Cambridge, was subsequently awarded a contract for referral toxicology. Cambridge Diagnostics has done no work since that time for the Cambridge Hospital.

In January of 1982 the Hospital entered into a personal service contract with Laxman S. DeSai, formerly known to the Hospital as a principle in Cambridge Diagnostics, Inc. Under the terms of that contract Dr. DeSai served as the Hospital laboratory's Clinical Chemist supervising all work in the chemistry area of the laboratory and, in particular, performing on-site toxicological testing which in other circumstances would have been sent to a referral laboratory. Dr. DeSai agreed in the contract "To be available to the Hospital on a twenty-four hour basis and establish a regular schedule of in-hospital work hours that sum to a full time appointment." As a prerequisite to entering into this agreement the Hospital required Dr. DeSai to waive any claim against the Hospital for compensation for billing losses previously alleged by him to have arisen from the Hospital's July 1, 1979-June 30, 1980 agreement with Cambridge Diagnostics, Inc. Dr. DeSai, in signing the letter waiving such claims, presented himself as a principle owner of Cambridge Diagnostics, Inc.

In April of 1982 an inquiry by a Massachusetts Department of Public Health Laboratory Inspector began to raise some questions about Dr. DeSai's continuing operational responsibilities with Cambridge Diagnostics, Inc. In June of 1982 Dr. DeSai terminated his employment relationship with the Cambridge Hospital effective July 1, 1982 due to protracted difficulties in divesting himself of his Cambridge Diagnostic responsibilities.

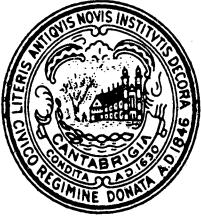
To the best of my knowledge, the above represents the full extent of any relationships between the City, the Cambridge Hospital, or any of its officials or employees, and Cambridge Diagnostics, Inc. or any of its principles or employees.

Sincerely,


Michael Ryan
Senior Assistant Director for
Cambridge Hospital

cc: Dr. Chalfen

MR/ab



CITY OF CAMBRIDGE

CAMBRIDGE, MASSACHUSETTS 02139
Tel. 498-9011

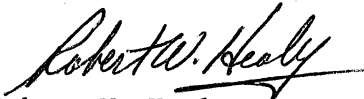
EXECUTIVE DEPARTMENT
ROBERT W. HEALY
City Manager

November 8, 1982

To the Honorable, the City Council:

With respect to Awaiting Report Item No. 20 relative to Cambridge Diagnostics, Inc. of Allston Street, enclosed please find copies of communications from the Department of Health and Human Services and from the Cambridge Hospital.

Very truly yours,


Robert W. Healy
City Manager

RWH/mbf
Encs.

Agenda Item Number Three *S-688*

Re: response to Awaiting Report Item No. 21
regarding Cambridge Diagnostics, Inc., of
Allston St.

*copy sent to the City Manager
11/9/82*

In City Council,

November 8, 1982

11/8/82

*Not
Placed on File -
Deferred Back to
Cmcr - Motion of C. Duchay*