



UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

MANPOWER AND WELFARE
DIVISION

NOV 14 1973



Mr. James B. Cardwell
Commissioner of Social Security
Department of Health, Education, and
Welfare

Dear Mr. Cardwell:

We are performing a survey of the manner in which independent laboratories are regulated and reimbursed under four federally funded health programs--Medicare, Medicaid, the Federal Employees Health Benefits Program, and the Civilian Health and Medical Program of the Uniformed Services. During the survey, we noted that there are considerable delays by the Bureau of Health Insurance (BHI) headquarters in acting on recommendations from BHI regional offices that independent laboratories' certification for participation under Medicare be terminated (decertified), either entirely or for certain laboratory specialties.

To help assure the health and safety of Medicare patients who obtain laboratory services, laboratories must be certified by BHI to be eligible to participate under Medicare. Under agreements entered into with the Secretary of HEW pursuant to title XVIII of the Social Security Act, State agencies determine whether independent laboratories meet the conditions for participation under Medicare. On the basis of determinations by State agencies that independent laboratories meet the conditions for participation, the BHI regional offices send the laboratories a written notice of certification.

The State agencies also resurvey laboratories to ascertain continued compliance with requirements for participating in Medicare. When a State agency determines that a laboratory certified to participate under Medicare is out of compliance with requirements for such participation to such an extent that the laboratory should be decertified, the State agency recommends decertification to the BHI regional office. Such recommendations are to be made by the State agency if a laboratory

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- is not licensed in a State in which licensing is required,
- does not meet standards determined by the Secretary of HEW to be necessary to assure the health and safety of individuals for which laboratory tests are performed,
- has deficiencies of such character that seriously limit its capacity to render adequate service; and there is no early prospect as determined by discussion with the laboratory that such deficiencies will be corrected, or
- is not making progress toward correcting significant deficiencies that were noted when the laboratory was initially certified.

The State Operations Manual states that the BHI regional office is to review the State agencies' recommendations for decertification of laboratories. If the regional office concurs with the State agency, the regional office forwards the recommendation for decertification to the BHI headquarters for review and approval and notifies the laboratory that the State has recommended decertification and that the recommendation has been forwarded to BHI headquarters. At BHI headquarters, processing of the recommendations for decertification begins in the Hospital and Independent Laboratory Section, Division of State Operations. We noted that there are considerable delays before the Hospital and Independent Laboratory Section begins processing recommendations to decertify laboratories.

Since inception of Medicare, 34 independent laboratories have been decertified. For some of these laboratories, there was considerable time from receipt by BHI headquarters of the recommendation to decertify and the decertification. As of October 15, 1973, there were 13 recommendations for decertification pending in BHI headquarters. Although the recommendations had been at BHI headquarters for as long as 9 months, an official of the Hospital and Independent Laboratory Section told us that processing had been started on only 1 of the 13 recommendations as of October 15, 1973. The first of the 13 recommendations was received by BHI headquarters on January 8, 1973, and no recommendation to decertify a laboratory received since that date has been processed by the Hospital and Independent Laboratory Section.

An official of the Hospital and Independent Laboratory Section told us that there was not sufficient time to work on the recommendations for decertification of laboratories because of the time required to perform other duties, such as developing and revising regulations pertaining to independent laboratories, responding to inquiries from the regional offices concerning policy and other matters, and coordinating activities with other governmental agencies. The length of time that each of the 13 recommendations for decertification had been in BHI headquarters as of October 15, 1973, is shown below.

<u>Laboratory name and location</u>	<u>Date received at the Hospital and Independent Laboratory Section, BHI</u>	<u>Number of months held at BHI</u>
Rupp Clinic Laboratories, Sand Springs, Oklahoma	January 8, 1973	9
W. J. Pierce, M.D. Laboratory, Bruceville, Indiana	January 18, 1973	9
University District Medical Laboratories, Seattle, Washington	February 5, 1973	8
Multiphasic Medical Laboratory, Los Angeles, California	February 21, 1973	8
Solano Laboratories, Inc. San Francisco, California	March 15, 1973	7
Mayfair X-Ray and Laboratory, Las Vegas, Nevada	April 13, 1973	6
Golden Gate Medical Group Laboratory, Pacifica, California	April 17, 1973	6
Almont Medical Services, Inc., Almont, Michigan	June 15, 1973	4
Physician's Clinical Laboratory, Colorado Springs, Colorado	August 13, 1973	2
Jeffery Clinical Laboratory, Inc., Chicago, Illinois	August 30, 1973	1½
Doctors Clinical Laboratory, Toledo, Ohio	August 31, 1973	1½
Dalton Clinical Laboratory, Lakewood, Colorado	September 5, 1973	1
Westside Clinical Laboratory Chicago, Illinois	September 13, 1973	1

Information in BHI files indicates that laboratories recommended for decertification may be significantly deficient--yet the laboratories continue to be eligible for participation under Medicare. For example, the recommendation for the decertification of the Multiphasic Medical Laboratory states that the laboratory

- is not participating in approved proficiency testing,
- is employing unqualified personnel,
- does not have written policies, practices, and procedures,
- is deficient in quality control,
- is not maintaining notebooks of current laboratory methods,
- is not adequately sterilizing equipment, and
- is examining specimens without the request of a licensed physician.

The recommendation for the decertification of this laboratory was received by BHI headquarters on February 21, 1973.

The W. J. Pierce, M.D. Laboratory was recommended for decertification because the laboratory would not permit the State agency personnel access to resurvey the laboratory. The recommendation for decertification of this laboratory was received by BHI headquarters on January 18, 1973.

The recommendation for the decertification of the University District Medical Laboratories states that the laboratory

- is not participating in a proficiency testing program approved by the State,
- does not have a quality control program on a continuous basis,
- does not routinely check equipment,
- does not have adequate equipment for certain tests which the laboratory is authorized to perform, and
- has glassware washing and bacteriology work done off the premises.

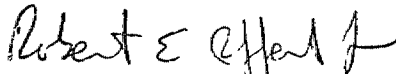
The recommendation for the decertification of this laboratory was received by BHI headquarters on February 5, 1973.

We suggest that BHI act promptly on the recommendation for decertification of laboratories that are currently in BHI headquarters. Also, we suggest that action be taken to ensure that future recommendations by State agencies for decertification of laboratories are processed in a timely manner. If the workload will not permit the BHI headquarters staff to process the recommendations in a timely manner, it may be appropriate to delegate the authority to decertify laboratories to the BHI regional offices. In this regard, we are aware of SSA's current Decentralization Plan which, we understand, includes a proposal for delegating authority to decertify independent laboratories to the BHI regional offices.

We would appreciate your comments on this matter and advice as to any actions taken.

Because laboratories certified for participation under Medicare are eligible to participate under Medicaid, a copy of this letter report is being sent to the Administrator, Social and Rehabilitation Service. Copies also are being sent to the Assistant Secretary, Comptroller, and the Director of the HEW Audit Agency.

Sincerely yours,


Robert E. Iffert, Jr.
Assistant Director