

§ 493.1850

laboratory, would constitute a significant hazard to the public health, HCFA may bring suit in a U.S. District Court to enjoin continuation of the specific activity that is causing the hazard or to enjoin the continued operation of the laboratory if HCFA deems it necessary. Upon proper showing, the court shall issue a temporary injunction or restraining order without bond against continuation of the activity.

§ 493.1850 Laboratory registry.

(a) Once a year HCFA makes available to physicians and to the general public specific information (including information provided to HCFA by the OIG) that is useful in evaluating the performance of laboratories, including the following:

(1) A list of laboratories that have been convicted, under Federal or State laws relating to fraud and abuse, false billing, or kickbacks.

(2) A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reason for the adverse actions.

(3) A list of persons who have been convicted of violating CLIA requirements, as specified in section 353(1) of the PHS Act, together with the circumstances of each case and the penalties imposed.

(4) A list of laboratories on which alternative sanctions have been imposed, showing—

(i) The effective date of the sanctions;

(ii) The reasons for imposing them;

(iii) Any corrective action taken by the laboratory; and

(iv) If the laboratory has achieved compliance, the verified date of compliance.

(5) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.

(6) All appeals and hearing decisions.

(7) A list of laboratories against which HCFA has brought suit under § 493.1846 and the reasons for those actions.

(8) A list of laboratories that have been excluded from participation in Medicare or Medicaid and the reasons for the exclusion.

42 CFR Ch. IV (10–1–99 Edition)

(b) The laboratory registry is compiled for the calendar year preceding the date the information is made available and includes appropriate explanatory information to aid in the interpretation of the data. It also contains corrections of any erroneous statements or information that appeared in the previous registry.

Subpart S [Reserved]

Subpart T—Consultations

SOURCE: 57 FR 7185, Feb. 28, 1992, unless otherwise noted.

§ 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

(a) HHS will establish a Clinical Laboratory Improvement Advisory Committee to advise and make recommendations on technical and scientific aspects of the provisions of this part 493.

(b) The Clinical Laboratory Improvement Advisory Committee will be comprised of individuals involved in the provision of laboratory services, utilization of laboratory services, development of laboratory testing or methodology, and others as approved by HHS.

(c) HHS will designate specialized subcommittees as necessary.

(d) The Clinical Laboratory Improvement Advisory Committee or any designated subcommittees will meet as needed, but not less than once each year.

(e) The Clinical Laboratory Improvement Advisory Committee or subcommittee, at the request of HHS, will review and make recommendations concerning:

(1) Criteria for categorizing tests and examinations of moderate complexity (including the subcategory) and high complexity;

(2) Determination of waived tests;

(3) Personnel standards;

(4) Patient test management, quality control, quality assurance standards;

(5) Proficiency testing standards;

(6) Applicability to the standards of new technology; and

(7) Other issues relevant to part 493, if requested by HHS.