

1997 LABORATORY REGISTRY

Once a year the Health Care Financing Administration makes available to physicians and to the general public specific information (including information provided to HCFA by the Office of Inspector General) that is useful in evaluating the performance of laboratories. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) and implementing regulations at 42 CFR 493.1850 require that this listing include 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 reasons for the adverse actions.
- (3) A list of persons who have been convicted of violating CLIA requirements, as specified in section 353(I) 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;
 - (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- (5) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.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 Section 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.

Civil settlements reached with clinical laboratories are also noted.

The Laboratory Registry is compiled for the calendar year preceding the date the information is made available and also contains corrections of any erroneous statements or information that appeared in the previous registry.

A final section includes other specific information that may be useful in evaluating the performance of laboratories, as specified in 493 CFR 1850(a). It also includes information provided by CLIA exempt states.

Contacts:

Sheila Ward, E-mail, sward@cms.hhs.gov

Jim Cometa, E-mail, jcometa@cms.hhs.gov

1997 LABORATORY REGISTRY

(as required by Section 353(n) of the Public Health Service Act)

Activity January 1, 1997 through December 31, 1997

1. LABORATORIES SUBJECT TO CLIA THAT HAVE BEEN CONVICTED, UNDER FEDERAL OR STATE LAWS RELATING TO FRAUD AND ABUSE, FALSE BILLING, OR KICKBACKS.

The following was supplied by the Office of Inspector General:

Allied Clinical Laboratories, Inc.

2515 Park Plaza

Nashville, Tennessee

EKG Unlimited, Inc.,

3710 Rawlins -- Suite 110

Dallas, Texas

2. LABORATORIES THAT HAVE HAD THEIR CLIA CERTIFICATES SUSPENDED, LIMITED, OR REVOKED, AND THE REASON FOR THE ADVERSE ACTION. (Medicare cancellation, a principal sanction, has been included in this category.)

Eugene M. Tachuk, M.D.

1679 Main Street, Suite A

El Cajon, California 92021

CLIA #05D0566311

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certificate.

EFFECTIVE DATE: March 19, 1997 (Medicare cancellation/CLIA suspension)

REASON: Immediate and serious threat to the health and safety of patients found during State Agency complaint survey. Alternative sanctions were also imposed.

STATUS: Hearing request filed May 19, 1997; hearing held December 8, 1997. The hearing request was withdrawn on the second day of the hearing and the Administrative Law Judge dismissed case, which resulted in sanction becoming final. Revocation of CLIA certification pending.

Eugene R. Pocock, M.D., Director

Watson Medical Laboratories, Inc.

4835 N. Hallmark Parkway

San Bernardino, California 92407

CLIA #05D0575066

SANCTION: Revocation of CLIA certification.

EFFECTIVE DATE: June 5, 1997

REASON: Immediate and serious threat to the health and safety of patients found during State Agency complaint survey.

STATUS: Hearing request filed September 13, 1996 was withdrawn February 27, 1997. Case was dismissed by the Administrative Law Judge and sanction became final. Suspension of the laboratory's CLIA certificate and cancellation of approval to receive Medicare payment for all laboratory services previously effectuated September 16, 1996.

Williams Bio Medical Laboratory

Corliss Shelton, M.D., Director

500 West Willow Street

Long Beach, California 90806

CLIA #05D0642670

SANCTION: Revocation of CLIA certification.

EFFECTIVE DATE: August 5, 1997

REASON: Failure to correct cited deficiencies within 12 months after State Agency survey in August 1994.

STATUS: Hearing request was filed December 2, 1995. The Administrative Law Judge upheld sanction in decision dated August 5, 1997. Cancellation of the laboratory's approval to receive Medicare payment for all laboratory services was previously effectuated December 18, 1995.

Awad S. Anthony, M.D.

dba California Medical Associates Laboratory

2775 West Pico Boulevard

Los Angeles, California 90006

CLIA #05D0711870

SANCTION: Suspension of CLIA certification.

EFFECTIVE DATE: June 12, 1997

REASON: Condition level non-compliance, including immediate and serious threat to the health and safety of patients.

STATUS: Hearing request filed May 14, 1996. The Administrative Law Judge upheld sanction in decision dated May 30, 1997. Cancellation of approval to receive Medicare payment for all laboratory services was previously effectuated April 1, 1996.

Paul C. Boynton, M.D., Director

Clinical Laboratory of Hemet

850 East Latham Avenue, Suite A

Hemet, California 92543

CLIA #05D0863964

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services and revocation of CLIA certificate.

EFFECTIVE DATE: March 18, 1997 (Medicare cancellation)

May 2, 1997 (Revocation)

REASON: Improper referral of proficiency testing to another laboratory found as a result of a State Agency survey.

Ahsan Qazi, M.D., Director

Qazi Medical Group

264 N. Highland Springs Avenue #2A

Banning, California 92220

CLIA #05D0865163

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services and revocation of CLIA certificate.

EFFECTIVE DATE: December 19, 1997 (Medicare cancellation)

REASON: Due to revocation effective October 31, 1997 of Draw One Arterial Laboratory Inc. in Riverside, CA. CLIA regulations prohibit the owner, operator or director of a laboratory from owning, operating or directing another laboratory for a period of two years from the date of revocation. Ahsan Qazi, M.D., was the director of Draw One Arterial Laboratory Inc. at the time its CLIA certification was revoked.

STATUS: Hearing filed December 10, 1997.

Ivan Serdar, M.D., Director

BCL Clinical Labs

13140 Telegraph Road, Unit A6

Santa Fe Springs, California 90670

CLIA #05D0868130

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certificate.

EFFECTIVE DATE: January 29, 1997 (Medicare cancellation/CLIA suspension)

March 29, 1997 (Revocation)

REASON: Immediate and serious threat to the health and safety of patients found during State Agency complaint survey of December 19, 1996. Alternative sanctions were also imposed.

Andrew T. Trapalis, M.D., Director

Metro Medical Clinic

10259 Folsom Blvd., Suite B

Rancho Cordova, California 95670

CLIA #05D0869566

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certificate.

EFFECTIVE DATE: September 7, 1997 (Medicare cancellation and suspension)

November 1, 1997 (Revocation)

REASON: Failure to provide an acceptable plan of correction for deficiencies found during State Agency survey, which was initiated when it was reported that the laboratory had been performing high complexity testing without proper CLIA certification. The survey found that the laboratory was performing HIV testing without the required state licensure. Alternative sanctions were also imposed.

Ahsan Qazi, M.D., Director

Draw One Arterial Laboratory Inc.

12155 Magnolia Avenue, Suite 3B

Riverside, California 92503

CLIA #05D0872676

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certificate.

EFFECTIVE Date: September 19, 1997 (Medicare cancellation and suspension)

October 31, 1997 (Revocation)

REASON: Immediate and serious threat to the health and safety of patients found during State Agency complaint survey. Alternative sanctions were also imposed.

STATUS: Hearing request filed.

Editha Bernardo / Ernesto Niebres, Owners

Ace Medilab Services

1110 Artesia Blvd., Suite J

Cerritos, California 90703

CLIA #05D0888693

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certificate.

EFFECTIVE DATE: November 21, 1997 (Medicare cancellation and suspension)

REASON: Immediate and serious threat to the health and safety of patients found during State Agency complaint survey. The laboratory was operating without a qualified director since May 1996. Alternative sanctions were also imposed.

STATUS: CLIA certification revoked.

Joaquin Jimenez, Owner

Pulmonary Testing Services

671 South Mollison Avenue, Suite F

El Cajon, California 92020

CLIA #05D0908427

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certificate.

EFFECTIVE DATE: October 26, 1997 (Medicare cancellation and suspension)

December 12, 1997 (Revocation)

REASON: Immediate and serious threat to the health and safety of patients found during State Agency complaint survey. The laboratory was operating without a director. Alternative sanctions were also imposed.

Andrew T. Trapalis, M.D., Director

Metron Medical Group

aka Watt Avenue Medical Clinic

3428 Watt Avenue

Sacramento, California 95821

CLIA #05D0913047

SANCTION: Cancellation of approval to receive Medicare payment for the specialty of hematology; CLIA limitation in the area of hematology.

EFFECTIVE DATE: April 20, 1997

REASON: Failure to provide an acceptable plan of correction for deficiencies found during State Agency survey. Alternative sanctions were also imposed.

STATUS: Revocation of CLIA certification pending due to the revocation effective November 1, 1997 of Metro Medical Clinic in Rancho Cordova. CLIA regulations prohibit the owner, operator or director of a laboratory from owning, operating or directing another laboratory for a period of two years from the date of revocation. Both Metron Medical Group and Metro Medical Clinic are owned by Andrew T. Trapalis, M.D.

Andrew T. Trapalis, M.D., Director

Metron Medical Group #2

601 Court Street

Jackson, California 95642

CLIA #05D0928575

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services.

EFFECTIVE DATE: December 2, 1997 (Medicare cancellation)

REASON: Due to the revocation effective November 1, 1997 of Metro Medical Clinic in Rancho Cordova. CLIA regulations prohibit the owner or operator including director of a laboratory with a revoked CLIA regulations prohibit the owner, operator or director of a laboratory from owning, operating or directing another laboratory for a period of two years from the date of revocation. Both Metron Medical Group #2 and Metro Medical Clinic are owned by

Andrew T. Trapalis, M.D.

STATUS: CLIA certification revoked.

Robert C. Jacobs, M.D.

4545 E. 9th Avenue

Denver, Colorado 80220

CLIA #06D0920836

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services and limitation of certification in the area of hematology.

EFFECTIVE DATE: October 31, 1997

REASON: Proficiency testing failure in hematology.

STATUS: Certificate limited for hematology.

Foster Ian Phillips, M.D.

40 Hart Street

New Britain, Connecticut 06062

CLIA #07D0708740

SANCTION: Revocation of CLIA certification.

EFFECTIVE DATE: December 1, 1997

REASON: Condition level non-compliance.

Luis L. Ragunton, M.D.

98-1079 Moanalua Road #440

Aiea, Hawaii 96701

CLIA #12D0706947

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certification.

EFFECTIVE DATE: November 10, 1997 (Medicare cancellation and suspension)

December 26, 1997 (Revocation)

REASON: Failure to submit an acceptable plan of correction for deficiencies cited at the May 9, 1997 survey of the laboratory.

Edward O. Leonard, Ph.D., Director

Mahendra Patel - Manager/General Supervisor

Delm Medical Laboratory

1812 Broadway

Melrose Park, Illinois 60160-2039

CLIA #14D0416374

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, limitation of CLIA certification in cytology, limitation of Medicare approval in cytology, suspension and revocation of CLIA certification.

EFFECTIVE DATE: May 12, 1997 through August 13, 1997 (Limitation of CLIA certificate and limitation of Medicare approval in the cytology subspecialty area).

August 14, 1997 (Medicare cancellation and CLIA suspension)

September 28, 1997 (Revocation)

REASON: Immediate jeopardy conditions were found in the cytology subspecialty area, in addition to other condition level non-compliance. The laboratory failed to submit an acceptable plan of correction.

STATUS: Laboratory closed.

Ara M. Minasian, Director

Avenue Medical Laboratory

16234 South Louis Avenue

South Holland, Illinois 60473-2260

CLIA #14D0420452

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, and suspension of CLIA certification.

EFFECTIVE DATE: December 20, 1997

REASON: Laboratory failed to submit an acceptable plan of correction for condition level non-compliance.

STATUS: Revocation of CLIA certification pending hearing decision.

Nafees W. Qadri, M.D., Director

Northshore Clinical Laboratories, Inc.

2353 West Birchwood Avenue

Chicago, Illinois 60645-1738

CLIA #14D0426602

SANCTION: Cancellation of approval to receive Medicare payment and limitation of CLIA certification in cytology.

EFFECTIVE DATE: June 26, 1997

REASON: Condition level non-compliance. Conditions present cytology subspecialty area caused immediate jeopardy to patients.

C. R. Carmichael, M.D., Director

803A Americana Drive

Troy, Illinois 62294-2037

CLIA #14D0434521

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certification.

EFFECTIVE DATE: December 10, 1997 (Medicare cancellation and CLIA suspension)

REASON: Laboratory failed to submit a plan of correction.

STATUS: CLIA certification revoked.

K. Michael Baker, M.D., Director

Bandy's Pharmacy, Inc.

1413 West Whittaker

P. O. Box 546

Salem, Illinois 62881-0546

CLIA #14D0894753

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certification.

EFFECTIVE DATE: September 18, 1997 (Medicare cancellation and CLIA suspension)

November 1, 1997 (Revocation)

REASON: Condition level non-compliance. Laboratory failed to submit a plan of correction.

Anne E. Niedenthal, M.D., Director

L G M LLC

1625 Sheridan Road

Wilmette, Illinois 60091

CLIA #14D0907974

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certification.

EFFECTIVE DATE: April 24, 1997 (Medicare cancellation and suspension)

June 3, 1997 (Revocation of CLIA certificate).

REASON: Laboratory failed to submit a plan of correction.

Ward General Practice Clinic

10514 Jefferson Highway

River Ridge, Louisiana 70123

CLIA #19D0897371

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services.

EFFECTIVE DATE: March 2, 1997

REASON: Lab director owned another CLIA laboratory that had its certification revoked.

STATUS: Hearing request filed.

Leon W. Berube, M.D.

97 Old Route 5

Mechanicsville, Maryland 20659

CLIA #21D0209627

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, and revocation of CLIA certification.

EFFECTIVE DATE: April 17, 1997 (Medicare cancellation of Medicare)

June 2, 1997 (Revocation)

REASON: Condition level non-compliance and failure to submit acceptable plan of correction.

Surendra D. Morjaria, M.D.

3000 Manchester Road

Manchester, Maryland 21102

CLIA #21D0215440

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, and suspension of CLIA certification.

EFFECTIVE DATE: April 2, 1997

REASON: Condition level non-compliance and failure to submit an acceptable plan of correction.

STATUS: Compliance with CLIA conditions achieved. Re-certification to certificate of waiver issued at the request of laboratory.

Laurie B. Glanz, Director

35 Church

Mount Clemens, Michigan 48043-2331

CLIA #23D0363658

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certification.

EFFECTIVE DATE: January 28, 1997 (Medicare cancellation/CLIA suspension).

March 9, 1997 (Revocation)

REASON: Failure to submit a plan of correction and to pay CLIA fees.

Lonnie Joe Jr., M.D., Director

15901 West Nine Mile Road, Suite 400

Southfield, Michigan 48075-4883

CLIA #23D0364884

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certification.

EFFECTIVE DATE: May 13, 1997 (Medicare cancellation/CLIA suspension)

June 27, 1997 (Revocation)

REASON: Condition level non-compliance causing immediate jeopardy to the health and safety of the laboratory's patients.

Ronald Hines, M.D., Director

Allied Medical Laboratory, Inc.

G-8445 South Saginaw

Grand Blanc, Michigan 48439

CLIA #23D0373014

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certification.

EFFECTIVE DATE: September 2, 1966 (Medicare cancellation)

September 2, 1996 - November 30, 1997 (Suspension)

December 1, 1997 (Revocation)

REASON: Condition level non-compliance.

STATUS: Hearing request filed October 8, 1996. On December 1, 1997, the Administrative Law Judge dismissed the case because of the laboratory's failure to participate in the hearing proceedings.

Thabet R. Abbarah, M.D., Director

4000 Highland Road, Suite 115

Waterford, Michigan 48328-2163

CLIA #23D0692131

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certification.

EFFECTIVE DATE: September 18, 1997 (Medicare cancellation/CLIA suspension)

November 1, 1997 (Revocation)

REASON: Condition level non-compliance. Laboratory failed to submit a plan of correction.

Burton J. Bacher, M.D., Director

Drs. Bacher, Isaacs, Tabbilos

25779 Kelly Road

Roseville, Michigan 48066-4973

CLIA #23D0700737

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services and suspension of CLIA certification.

EFFECTIVE DATE: December 30, 1996 - June 22, 1997 (Medicare cancellation).

March 18 - June 22, 1997 (Suspension)

REASON: Condition level non-compliance.

STATUS: Agreement negotiated in lieu of a hearing determination. As part of the agreement, the March 18, 1997 revocation, in place before the hearing request was filed, was rescinded and categorized as a suspension. Effective June 23, 1997, the laboratory was authorized to perform only those tests approved under a Provider-Performed

Microscopy Procedures certificate for at least a two year period from the effective date of suspension.

Cesar A. Sturla, M.D., Director

Cascade Laboratory

(Formerly known as, Livonia Internal Medicine Associates)

20311 Farmington Road

Livonia, Michigan 48152-1411

CLIA #23D0860681

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services and suspension of CLIA certification.

EFFECTIVE DATE: May 15 1997 - June 9, 1997

REASON: Condition level non-compliance causing immediate jeopardy to the health and safety of the laboratory's patients. Laboratory failed to submit an acceptable plan of correction.

STATUS: Cancellation of Medicare payment and suspension of CLIA certificate lifted on June 10, 1997. Laboratory submitted an acceptable plan of correction and supporting evidence to confirm compliance. On June 26, 1997 a directed plan of correction was imposed to assure compliance with applicable CLIA requirements.

Arnold J. Taft, Ph.D.

Citilab, Inc.

333 Broad Street

Elizabeth, New Jersey 07208

CLIA #31D0900247

SANCTION: Suspension of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certification.

EFFECTIVE DATE: May 2, 1997 (Medicare suspension/CLIA suspension)

July 7, 1997 (Revocation)

REASON: Condition level non-compliance causing immediate jeopardy to the health and safety of the laboratory's patients. Laboratory obtained and tested blood samples from unknown and/or unidentified sources and assigned the results obtained to real patients.

STATUS: Laboratory closed.

Richard Gordon, M.D.

American Women's Center

157 South Main Street

Phillipsburg, New Jersey 08865

CLIA #31D0914104

SANCTION: Revocation of CLIA certification.

EFFECTIVE DATE: September 10, 1997

REASON: Failure to submit an acceptable plan of correction.

Richard Gordon, M.D.

American Women's Center

34 East Jersey Street

Elizabeth, New Jersey 07201

CLIA #31D0914105

SANCTION: Revocation of CLIA certification.

EFFECTIVE DATE: September 10, 1997

REASON: Failure to submit an acceptable plan of correction.

Richard Gordon, M.D.

American Women's Center

1 Alpha Avenue, Suite 27

Voorhees, New Jersey 08043

CLIA #31D0914106

SANCTION: Revocation of CLIA certification.

EFFECTIVE DATE: September 10, 1997

REASON: Failure to submit an acceptable plan of correction.

Hobart C. Price, M.D.

119-06 Guy R. Brewer Blvd.

Jamaica, New York 11434

CLIA # 33D0152534

SANCTION: Revocation of CLIA certification.

EFFECTIVE DATE: August 1, 1997

REASON: Failure to submit an acceptable plan of correction.

Owen J. O'Neill, M.D.

311 North Street

White Plains, New York 10605

CLIA #33D0662988

SANCTION: Revocation of CLIA certification.

EFFECTIVE DATE: August 15, 1997

REASON: Failure to submit an acceptable Plan of Correction

Joseph Putignano, M.D.

Gramatan Urology

26 Fondfield Road West

Bronxville, New York 10708

CLIA #33D0863122

SANCTION: Revocation of CLIA certification.

EFFECTIVE DATE: August 1, 1997

REASON: Failure to submit an acceptable plan of correction.

Wilfred L. Anderson, M.D., Director

5 Severance Circle #818

Cleveland, Ohio 44118-1513

CLIA #36D0336888

SANCTION: Revocation of CLIA certification.

EFFECTIVE DATE: January 23, 1997 (Revocation of CLIA certificate).

REASON: Condition level non-compliance.

STATUS: Laboratory's certification had been suspended and Medicare authorization cancelled effective December 14, 1996.

Charles S. Johnson, M.D., Director

2020 West 3rd Street

Dayton, Ohio 45417-2540

CLIA #36D0890424

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certification.

EFFECTIVE DATE: August 31, 1997 (Medicare cancellation/CLIA suspension)

October 14, 1997 (Revocation)

REASON: Validation survey found condition level non-compliance. Laboratory failed to submit a plan of correction.

Frank Abbati, M.D., Director

3100 West Central Avenue, Suite 114

Toledo, Ohio 43606

CLIA #36D033116

SANCTION: Accreditation organization imposed action of cease testing for problem analyte(s).

EFFECTIVE DATE: November 3, 1997

REASON: Repeated unsuccessful proficiency testing.

STATUS: Laboratory has failed to remit cease testing agreement to accreditation organization.

Hunter Clinic

901 S.W. 33rd Street

Oklahoma City, Oklahoma 73109

CLIA #37D0470540

SANCTION: Revocation of CLIA certification.

EFFECTIVE DATE: April 10, 1997 (Revocation)

REASON: Intentional referral of proficiency testing specimens to another laboratory.

Laboratorio Clinico Bacteriologico Del Oeste

27 Brau Street

Cabo Rojo, Puerto Rico 00603

CLIA #40D0876005

SANCTION: Suspension of CLIA certification.

EFFECTIVE DATE: November 14, 1997

REASON: Condition level non-compliance.

STATUS: Re-certified after submission of documentation supporting the correction of the deficiencies cited.

Warner B. Massey M.D., Pathology Services

119 E. Houston Street

Tyler, Texas 75702

CLIA #45D0659703

SANCTION: Revocation of CLIA certification.

EFFECTIVE DATE: August 29, 1997

REASON: Condition level non-compliance causing immediate and serious threat to the health and safety of patients.

Ban Laboratories

P.O. Box 150247

Dallas, Texas 75315

CLIA #45D0683772

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certification.

EFFECTIVE DATE: April 15, 1997 (Medicare cancellation)

April 15, 1997 (Suspension)

REASON: Condition level non-compliance. Immediate and serious threat to the health and safety of patients was found during a complaint investigation. .

STATUS: Revocation of CLIA certification pending hearing.

Professional Labs

1130 Pecan, Suite 2

McAllen, Texas 78501

CLIA #45D0914232

SANCTION: Revocation of CLIA certification.

EFFECTIVE DATE: January 25, 1997

REASON: Laboratory did not adhere to alternative sanction imposed in 1996.

IHC Health Center - Ephraim

525 N. Main

Ephraim, Utah 84627

CLIA #46D0662411

SANCTION: Cancellation of approval to receive Medicare payment and limitation of CLIA certification for endocrinology, hematology and sodium.

EFFECTIVE DATE: March 10, 1997 (endocrinology)

October 31, 1997 (hematology and sodium)

REASON: Proficiency testing failure in endocrinology, hematology and sodium.

Ronald J. Payne, M.D., FACP

550 E. 1400 N #B

Logan, Utah 84321

CLIA #46D0678580

SANCTION: Suspension of approval to receive Medicare/Medicaid payment and suspension of CLIA certification.

EFFECTIVE DATE: May 30, 1997

REASON: Failure to submit an acceptable Plan of Correction

STATUS: Reinstated October 1, 1997.

Howard Levine, Director

Women's Health Care Center

1833 Harvard Avenue

Seattle, Washington 98122-2229

CLIA #50D0863424

SANCTION: Limitation of State license.

EFFECTIVE DATE: May 10, 1997

REASON: Condition equivalent non-compliance in proficiency testing, quality control and quality assurance.

Clarence G. Novotny, M.D., Director

Healthcare Center

15425 North Greenway-Hayden Loop, Suite A-300

Scottsdale, Arizona 85260

CLIA #52D0395068

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services and revocation of CLIA certification.

EFFECTIVE DATE: December 31, 1996 (Medicare cancellation)

March 21, 1997 (Revocation)

REASON: Performing moderate complexity testing after CLIA certificate had been terminated on December 31, 1996, per the laboratory's request; history of condition level non-compliance; and failure to correct deficiencies cited during past surveys.

Nina B. Vicente, M.D., Director

Vicente Office Lab

2040 West Wisconsin Avenue #419

Milwaukee, Wisconsin 53233 - 2012

CLIA #52D0865925

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services and suspension of CLIA certification. .

EFFECTIVE DATE: February 19-April 14, 1997.

REASON: Laboratory failed to submit a plan of correction.

STATUS: An acceptable plan of correction and supporting evidence to confirm correction of deficiencies was submitted on April 15, 1997.

3. A LIST OF PERSONS CONVICTED OF VIOLATING CLIA REQUIREMENTS AS SPECIFIED IN SECTION 353(L) OF THE PUBLIC HEALTH SERVICEACT, WITH THE CIRCUMSTANCES OF EACH CASE AND THE PENALTIES IMPOSED:

None

4. A LIST OF LABORATORIES ON WHICH ALTERNATIVE SANCTIONS HAVE BEEN IMPOSED, SHOWING--

(I) THE EFFECTIVE DATE OF THE SANCTIONS:

(iii) 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 THE COMPLIANCE;

Eugene M. Tachuk, M.D.

1679 Main Street, Suite A

El Cajon, California 92021

CLIA #05D0566311

SANCTION: Civil Money Penalty, \$9,150

Directed Portion of a Plan of Correction

EFFECTIVE DATE: March 16, 1997 through March 18, 1997 at \$3,050 per day.

REASON: Immediate and serious threat to the health and safety of patients found during State agency complaint survey. The laboratory's CLIA certificate was suspended March 19, 1997 and later revoked.

Ivan Serdar, M.D., Director

BCL Clinical Labs

13140 Telegraph Road, Unit A6

Santa Fe Springs, California 90670

CLIA #05D0868130

SANCTION: Civil Money Penalty, \$20,000

Directed Portion of a Plan of Correction

EFFECTIVE DATE: January 27, 1997 through January 28, 1997 at \$10,000 per day.

REASON: Immediate and serious threat to the health and safety of patients found during State agency complaint survey. The laboratory's CLIA certificate was subsequently suspended January 29, 1997 and revoked March 29, 1997.

Andrew T. Trapalis, M.D., Director

Metro Medical Clinic

10259 Folsom Blvd., Suite B

Rancho, Cordova, California 95670

CLIA #05D0869566

SANCTION: Civil Money Penalty, \$9,000

Directed Portion of a Plan of Correction

EFFECTIVE DATE: September 4 - September 6, 1997 for three days at \$3,000 per day.

REASON: Failure to provide an acceptable plan of correction for deficiencies found during State agency survey initiated when it was reported that the laboratory had been performing high complexity testing without proper CLIA certification. The laboratory's CLIA certificate was subsequently revoked.

Ahsan Qazi, M.D., Director

Draw One Arterial Laboratory, Inc.

12155 Magnolia Avenue, Suite 3B

Riverside, California 92503

CLIA #05D0872626

SANCTION: Civil Money Penalty, \$30,000

Directed Portion of a Plan of Correction

EFFECTIVE DATE: September 16 - September 18, 1997 for three days at \$10,000 per day.

REASON: Immediate and serious threat to the health and safety of patients found during State agency complaint survey. The laboratory's CLIA certificate was subsequently suspended on September 19 and revoked on October 31, 1997.

Joaquin Jimenez, Owner

Pulmonary Testing Services

671 South Mollison Avenue, Suite F

El Cajon, California 92020

CLIA #05D0908427

SANCTION: Civil Money Penalty, \$30,000

Directed Portion of a Plan of Correction

EFFECTIVE DATE: October 23 - October 25, 1997 for three days at \$10,000 per day

REASON: Immediate and serious threat to the health and safety of patients found during State agency complaint survey. The laboratory's CLIA certificate was subsequently suspended on October 26 and revoked December 12, 1997.

Andrew T. Trapalis, M.D., Director

Metron Medical Group

(aka Watt Avenue Medical Clinic)

3428 Watt Avenue

Sacramento, California 95821

CLIA #05D0913047

SANCTION: Civil Money Penalty, \$3,000

Directed Plan of Correction

State On-site Monitoring

EFFECTIVE DATE: April 1, 1997 for one day (Civil Money Penalty)

April 20, 1997 (Directed Plan of Correction; State On-site Monitoring)

REASON: Failure to provide an acceptable plan of correction for deficiencies found during State agency survey. The laboratory's CLIA certificate was subsequently revoked.

Edward O. Leonard, Ph.D., Director

Mahendra Patel, Manager/General Supervisor

Delm Medical Laboratory

1812 Broadway

Melrose Park, Illinois 60160-2039

CLIA #14D0416374

SANCTION: Directed Plan of Correction

Directed Portion of a Plan of Correction.

EFFECTIVE DATE: May 12, 1997

REASON: Condition level non-compliance in the cytology subspecialty area resulting in immediate jeopardy to the laboratory's patients. Laboratory failed to submit a plan of correction.

STATUS: Laboratory closed without notice. CLIA certification revoked September 28, 1997.

Dr. Nafees W. Qadri, Director

Northshore Clinical Laboratories, Inc.

2353 West Birchwood Avenue

Chicago, Illinois 60645-1738

CLIA #14D0426602

SANCTION: Directed Plan of Correction

Directed Portion of a Plan of Correction.

EFFECTIVE DATE: June 26, 1997

REASON: Condition level non-compliance in the cytology subspecialty area resulting in immediate jeopardy to the laboratory's patients.

STATUS: Laboratory ceased testing in the cytology subspecialty area. Limitation of laboratory's CLIA certificate in the cytology subspecialty was imposed on June 26, 1997.

Dr. John Passmann, M.D.

Doctor's Hospital of Hyde Park, Inc.

5800 South Stony Island

Chicago, Illinois 60637

CLIA #14D0710677

SANCTION: Directed Plan of Correction

EFFECTIVE DATE: July 15, 1996 - January 7, 1997

REASON: Laboratory failed to demonstrate that it was capable of preventing recurring deficiencies. The deficiencies impacted the laboratory's ability to ensure accurate and reliable test results.

STATUS: The laboratory was found in compliance with the directed plan of correction during follow-up survey.

Lonnie Joe Jr., M.D., Director

15901 West Nine Mile Road, Suite 400

Southfield, Michigan 48075-4883

CLIA #23D0364884

SANCTION: Directed Portion of a Plan of Correction.

EFFECTIVE DATE: May 13, 1997

REASON: Condition level non-compliance resulting in immediate jeopardy to the health and safety of the laboratory's patients.

STATUS: Certification revoked June 27, 1997.

Cesar A. Sturla, M.D., Director

Cascade Laboratory

(Formerly, Livonia Internal Medicine Associates)

20311 Farmington Road

Livonia, Michigan 48152 - 1411

CLIA #23D0860681

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: June 26 - December 18, 1997

REASON: Condition level non-compliance resulting in immediate jeopardy to the health and safety of the laboratory's patients. Laboratory submitted revised plan of correction and supporting evidence to confirm compliance.

Edward Mason, M.D.

Ban Laboratories

4248 Fitzhugh, Suite A

P.O Box 150247

Dallas, Texas 75210

CLIA #45D0914232

SANCTION: Directed Portion of a Plan of Correction

EFFECTIVE DATE: April 15, 1997

REASON: Condition level non-compliance resulting in immediate jeopardy to the health and safety of the laboratory's patients, discovered during a state agency complaint survey.

STATUS: Pending hearing decision.

Professional Labs

1130 Pecan, Suite 2

McAllen, Texas 78501

CLIA #45D0914232

[This listing contains additional information to the 1996 Laboratory Registry entry for this laboratory.]

SANCTION Civil Monetary Penalty, \$20,800

Directed Portion of a Plan of Correction.

EFFECTIVE DATE: May 18, 1996 (Civil Monetary Penalty)

June 19, 1996 (Directed Portion of a Plan of Correction)

REASON: Condition level non-compliance resulting in immediate jeopardy to the health and safety of the laboratory's patients.

STATUS: The laboratory has withdrawn from the CLIA program. CLIA certification subsequently revoked.

James Redd, Director

Blanding Urgent Care Center

930 N. 400 W

Blanding, Utah 84511-3418

CLIA #46D0525318

[This listing contains additional information to the 1995 Laboratory Registry entry for this laboratory.]

SANCTION: Suspension of approval to receive Medicare payment.

EFFECTIVE DATE: August 15, 1995

REASON: Improper referral of proficiency testing samples.

(5) A LIST OF LABORATORIES WHOSE ACCREDITATION HAS BEEN WITHDRAWN OR REVOKED AND THE REASONS FOR THE WITHDRAWAL OR REVOCATION:

Blount Memorial Hospital

1000 Lincoln Avenue

P.O. Box 1000

Oneonta, Alabama 35121

CLIA #01D0300297

SANCTION: Denial of Accreditation

EFFECTIVE DATE: January 23, 1997

REASON: Failure to respond to Proficiency Testing Exception Summaries, excessive number of phase II deficiencies, and an increasing number of recurring deficiencies.

STATUS: The laboratory did not file an appeal to the denial decision.

Eugene M. Tachuk, M.D.

Eugene M. Tachuk, M.D. & Medical Corp.

1679 East Main Street, Suite 104

El Cajon, California 92021-5212

CLIA #05D0566311

SANCTION: Denial of Accreditation

EFFECTIVE DATE: April 11, 1997

REASON: Failure to adhere to accreditation organization imposed required improvements. Deliberate disregard for accreditation organization's policy. CLIA certification subsequently revoked.

Anthony Dean, M.D.

5575 Wilas Positas Blvd. #260

Pleasanton, California 94588

CLIA #05D0655976

SANCTION: Accreditation Withdrawn

EFFECTIVE DATE: February 4, 1997

REASON: Failure to complete the survey process by not responding to a plan of correction for cited deficiencies.

Sang K. Lee, M.D.

5150 Graves Avenue, Suite 4

San Jose, California 95129-5004

CLIA #05D0608698

SANCTION: Denial of Accreditation

EFFECTIVE DATE: April 11, 1997

REASON: Failure to meet accreditation organization requirements. The laboratory later changed CLIA certification to waived testing only.

Vernon G. Allport, M.D.

Allergy Diagnostic Lab

854 Farmington Avenue

W. Hartford, Connecticut 06119-2181

CLIA #07D0094939

SANCTION: Denial of Accreditation

EFFECTIVE DATE: December 3, 1997

REASON: Failure to remit "Agreement to Plan of Required Improvement" to accreditation organization.

Kenneth Blau, M.D.

Women's Health Associates

27 Hospital Avenue, Suite 305

Danbury, Connecticut 06810-5954

CLIA #07D0100948

SANCTION: Denial of Accreditation

EFFECTIVE DATE: July 23, 1997

REASON: Failure to remit "Agreement to Plan of Required Improvement" to accreditation organization.

Continental Medical Laboratory, Inc.

Central Laboratory Inc.

7515 West Oakland Park Boulevard

Lauderhill, Florida 33319

CLIA #10D0645378

SANCTION: Revocation of Accreditation

EFFECTIVE DATE: November 13, 1997

REASON: Failure to enroll in required proficiency testing after repeated requests for compliance.

STATUS: The laboratory did not file an appeal to the denial decision.

Arnold Markowitz, M.D., Director

2112 Cass Lake Road

Keego Harbor, Michigan 48320-1272

CLIA #23D0371712

SANCTION: Denial of Accreditation

EFFECTIVE DATE: September 27, 1997

REASON: Disregard of accreditation organization's policies, and failure to adhere to required improvements.

STATUS: Laboratory was subsequently surveyed by State agency. Condition level non-compliance found. Further CLIA action pending.

Accumed Diagnostic Laboratory

187 Livingston Avenue

New Brunswick, New Jersey 08901

CLIA #31D0125729

ACTION: Accreditation Withdrawal

EFFECTIVE DATE: June 19, 1997

REASON: Accreditation organization recommended withdrawal from the accreditation program after numerous deficiencies were identified at the initial inspection.

Andrew Blank, M.D.

Sunset Road Medical Associates

911 Sunset Road

Burlington, New Jersey 08016-2250

CLIA #31D0685438

SANCTION: Denial of Accreditation

EFFECTIVE DATE: April 11, 1997

REASON: Failure to remit "Agreement to Plan of Required Improvement" to accreditation organization.

Robert DeMartin, M.D.

Laurel Avenue & Highway 35

Sea Girt, New Jersey 08750

CLIA #31D0709295

SANCTION: Denial of Accreditation

EFFECTIVE DATE: June 17, 1997

REASON: Failure to remit "Agreement to Plan of Required Improvement" to accreditation organization.

Michael L. Greenberg, M.D.

Hematology Associates

5 East 98th Street 10th Floor

New York, New York 10029-6501

CLIA #33D0133300

SANCTION: Denial of Accreditation

EFFECTIVE DATE: December 3, 1997

REASON: Failure to remit "Agreement to Plan of Required Improvement" to accreditation organization.

Jay B. Adlersberg, M.D.

220 E. 69th Street

New York, New York 10021-5737

CLIA #33D0671333

SANCTION: Denial of Accreditation

EFFECTIVE DATE: December 3, 1997

REASON: Failure to adhere to accreditation organization's required improvements.

Robert Weiner, M.D.

Family Medical Diagnostics

2381 Ralph Avenue

Brooklyn, New York 11234-5516

CLIA #33D0714652

SANCTION: Denial of Accreditation

EFFECTIVE DATE: May 19, 1997

REASON: Failure to remit "Agreement to Plan of Required Improvement" to accreditation organization.

Ernest J. Simak, M.D., Director

Northern Ohio Medical Services, Inc.

6803 Mayfield Road, Suite 412

Mayfield Heights, Ohio 44124-2214

CLIA #36D0664985

SANCTION: Accreditation withdrawn

EFFECTIVE DATE: May 9, 1997

REASON: Disregard of accreditation organization's standards and policy. The laboratory failed to respond to repeated requests for action to correct the deficiencies in accordance with the laboratory's post-survey Plan of Required Improvement.

STATUS: Laboratory currently has a certificate of waiver.

Dr. Jose Ramos Lebron Hospital

P.O. Box 1283

Fajardo, Puerto Rico 00738

CLIA #40D0658081

ACTION: Non-accreditation

EFFECTIVE DATE: September 4, 1997

REASON: Due to the accreditation organization's policy of accrediting the organization as a whole, the laboratory services were also non-accredited because of problems with the hospital services only. Laboratory met requirements for accreditation under other circumstances.

Columbia Medical Center at Terrell

1551 Highway 34 South

Terrell, Texas 75160

CLIA #45D0478792

SANCTION: Denial of Accreditation

EFFECTIVE DATE: December 16, 1997

REASON: Failure to demonstrate compliance with Standards for Laboratory Directorship and Quality Control.

STATUS: Laboratory appealed the denial decision. Denial was upheld.

Hermann Hospital/University of Texas

Houston Fertility Lab

6431 Fannin MSB R3 512

Houston, Texas 77030

CLIA #45D0699586

ACTION: Accreditation withdrawn

EFFECTIVE DATE: November 25, 1997

REASON: Accreditation organization recommended a focused reinspection due to a high number of deficiencies at the initial inspection. The laboratory withdrew from accreditation program.

Sara Apsley-Ambriz, CO

4127 E. South Cross, #4

San Antonio, Texas 78222

CLIA #45D0725916

ACTION: Denial of Accreditation

EFFECTIVE DATE: April 11, 1997

REASON: Failure to remit "Agreement to Plan of Required Improvement" to accreditation organization after repeated requests.

Algianon M. Jeffero, M.D.

2929 Calder Street, Suite 312

Beaumont, Texas 77702

CLIA #45D0873156

ACTION: Accreditation withdrawn

EFFECTIVE DATE : January 10, 1997

Centro de Salud Familiar La Fe

700 South Ochoa

El Paso, Texas 79901

CLIA #45D0880844

ACTION: Laboratory ceased testing all analytes

EFFECTIVE DATE: November 7, 1997

REASON: Laboratory ceased all testing due to repeated failure to perform required proficiency testing.

STATUS: After successful performance of two cycles of proficiency testing for all analytes provided, laboratory testing was reinstated.

James S. Cook, M.D.

Health South Medical Bldg. 1

7670 E. Parnam Road Suite 100

Richmond, Virginia 23294

CLIA #49D0227487

SANCTION: Denial of Accreditation

EFFECTIVE DATE: June 17, 1997

REASON: Failure to adhere to accreditation organization's required improvements.

Ulysses D, Agas, M.D.

Ulysses D. Agas, M.D., Inc.

557 Main Street

Logan, West Virginia 25601-3809

CLIA #51D0234840

SANCTION: Denial of Accreditation

EFFECTIVE DATE: July 23, 1997

REASON: Deliberate disregard for accreditation organization's policies and failure to adhere to accreditation organization's required improvements.

(6) ALL APPEALS AND HEARING DECISIONS:

Eugene M. Tachuk, M.D.

1679 Main Street, Suite A

El Cajon, California 92021

CLIA #05D0566311

SANCTION: Medicare cancellation and certificate suspension/revocation.

REASON: On May 19, 1997 hearing filed to appeal determination to suspend and revoke the laboratory's CLIA certificate, cancel Medicare payments, and assess a Civil Money Penalty of \$9,150, due to failure to correct deficiencies which resulted in the finding of immediate jeopardy to patient health and safety. The hearing was held on December 8, 1997 but was withdrawn on the second day of the hearing. Administrative Law Judge dismissed the case, resulting in sanctions becoming final.

Williams Bio Medical Laboratory

500 West Willow Street

Long Beach, California 90806

CLIA #05D0642670

SANCTION: Medicare cancellation.

REASON: Hearing request filed December 2, 1995. The Administrative Law Judge upheld sanction determination in decision dated August 5, 1997. Cancellation of the laboratory's approval to receive Medicare payment for all laboratory services was previously effectuated December 18, 1995.

Awad S. Anthony, M.D.

California Medical Associates Laboratory

2775 West Pico Boulevard

Los Angeles, California 90006

CLIA #05D0711870

SANCTION: Suspension of CLIA certification.

REASON: Condition level non-compliance resulting in immediate jeopardy to the health and safety of patients was found during initial survey. Hearing request filed May 14, 1996. The Administrative Law Judge upheld sanction determination in decision dated May 30, 1997.

STATUS: CLIA certification revoked.

Ward General Practice Clinic

10541 Jefferson Hwy.

River Ridge, Louisiana 70123

CLIA #19D0897371

SANCTION: Medicare cancellation

HEARING DECISION: The laboratory withdrew appeal September 26, 1997. Administrative Law Judge dismissed the case..

STATUS: CLIA certification revoked.

Ronald Hines, M.D., Director

Alexis J. Pittman, President

Allied Medical laboratory

G-8445 Saginaw

Grand Blanc, Michigan 48439

CLIA #23D0373014

SANCTION: Medicare cancellation and certificate suspension/revocation

HEARING DECISION: Hearing request filed on September 20, 1996. Hearing request dismissed by the Administrative Law Judge on December 1, 1997 because of the laboratory's failure to participate in the hearing proceedings. Revocation of the laboratory's CLIA certificate became effective on December 1, 1997.

Drs. Bacher, Isaacs, Tabbilos

25779 Kelly Road

Roseville, Michigan 48066-4973

CLIA #23D0700737

SANCTION: Revocation of certification and proposed revocation of two other laboratories owned and/or operated by owners/operators of laboratory.

HEARING DECISION: Hearing request filed April 30, 1997. Settlement agreement negotiated. Hearing dismissed and laboratory recertified for Provider Performed Microscopy Procedures (PPMP) testing, effective June 23, 1997. The March 18, 1997 revocation was rescinded, and the sanction in place on March 18, 1997 categorized as a suspension. The laboratory agreed not to test outside of the PPMP certification or seek certification for more comprehensive testing for two years, beginning March 18, 1997. The proposed certification revocations of the two other laboratories owned/operated by the owner/operator of the laboratory were rescinded.

Thyroid Specialty Laboratory

2900 Lemay Ferry Road, Suite 14

Saint Louis, Missouri 63125

CLIA #26D0710182

SANCTION: Medicare cancellation and revocation of certification

HEARING DECISION: Appeal filed June 28, 1996 and hearing held February 13, 1997. Hearing decision issued October 21, 1997 upheld revocation due to improper referral of proficiency testing to another laboratory.

(7) A LIST OF LABORATORIES AGAINST WHICH HCFA HAS BROUGHT SUIT UNDER SECTION 493.1846 AND THE REASONS FOR THOSE ACTIONS:

None

(8) A LIST OF LABORATORIES THAT HAVE BEEN EXCLUDED FROM PARTICIPATION IN MEDICARE OR MEDICAID AND THE REASONS FOR THE EXCLUSION. (The following listing include settlements and are based in part on information supplied by the HHS, Office of Inspector General.)

R & M Laboratory

1990 SW First Street

Miami, Florida 33135

CLIA #10D0670960

Permanent, beginning July 29, 1997

Doctors Clinic Laboratory

4325 Alby Road

Alton, Illinois, 62002

CLIA #14D0715183 Provider #14847

Four years beginning August 18, 1997

Finlay Medical Laboratory

4912 Bergenline Avenue

West New York, New Jersey 07093

CLIA #31D0107778

Indefinite, beginning December 18, 1997

Specialty Clinical Laboratories

40 Paterson Street

P.O. Box 480

New Brunswick, New Jersey 08903

CLIA #31D0858841

Indefinite, beginning October 5, 1997

Williams Clinical Laboratory

404 11th Street SW

Birmingham, Alabama 35211

Provider #54265

10 years, beginning November 20, 1997

Yang Laboratories

7837 10th Avenue/South Street

St. Petersburg, Florida 33707

10 years, beginning April 3, 1997

Franklin Laboratories, Inc.,

4343 W. Flagler Street

Miami, Florida

50 years, beginning July 17, 1997

C & S Laboratory, Inc.,

15801 SW 137th Avenue

Miami, Florida 33177

Provider #L8565

10 years, beginning November 20, 1997

Advanced Medical Diagnostic

135 Front Street

Indianola, Mississippi 38751

Permanent, beginning September 9, 1997

Precise Medical Laboratories

40 Paterson Street

New Brunswick, New Jersey 08903

Five years, beginning October 6, 1997

SETTLEMENTS:

Smith-Kline Beecham Clinical Laboratories

1201 South Collegeville Rd.

Collegeville, Pennsylvania 19426

(multiple-locations)

SmithKline Beecham Clinical Laboratories, Inc. (SBCL) reached a civil settlement in February of 1997 with the United States government in the amount of \$325 million to resolve the government's civil and administrative claims against the company for the filing of false claims to Medicare and other governmental payers during a seven-year period from 1989 to 1996. SBCL is a national chain of clinical laboratories with its headquarters in Collegeville, PA. This settlement was a result of four years of investigation, first by an interagency task force in San Diego, California, and since early 1994, by a task force of law enforcement agencies in Philadelphia. The civil settlement addressed the following types of alleged false or fraudulent claims: add-on test, tests not performed, code jamming, kickbacks, dialysis testing and additional indices. The settlement requires SBCL to undertake and maintain a comprehensive compliance program negotiated with the Office of the Inspector General (OIG) to ensure that the complained of practices, or other false claims, do not recur. OIG will monitor compliance. This civil settlement resolves claims filed by private persons, known as relators, who brought suit under the False Claims Act against SBCL. .

Physician Clinical Laboratories

3301 "C" Street, Suite 100E

Sacramento, California 95816

(19 locations)

Physician Clinical Laboratories (PCL), located in Sacramento, California, agreed in October of 1997 to pay the United States \$2 million to settle allegations filed in a civil suit that it had over billed Medicare and CHAMPUS for blood and urine testing. PCL did not admit in its settlement that it had engaged in any illegal or improper conduct. This case was handled by the U.S. Attorney's Office for the Eastern District of California.

The company filed for bankruptcy, reorganized and is now doing business as Bio-Cypher Laboratories.

9. CORRECTIONS OF ANY ERRONEOUS STATEMENTS OR INFORMATION THAT APPEARED IN THE 1996 REGISTRY:

Category 1, Laboratory Convictions

Roche Biomedical

1447 York Ct.

Burlington, NC 27215-2230

Delete

Category 1, Individual Convictions

Graham-Massey Analytical Lab

a/k/a Massey Analytical Lab

a/k/a Massey Medical Lab

2212 Main Street

Bridgeport, CT 06606

CLIA #07D0686807

Correct to read:

Massey Analytical Labs., Inc.

2212/2214 Main Street

Bridgeport, CT 06606

CLIA #07D0686807

EFFECTIVE DATE: August 3, 1996

Correct to read:

EFFECTIVE DATE: August 13, 1996

Delete

last sentence of explanation under "REASON:".

10. OTHER ACTIONS

This section includes other specific information that may be useful in evaluating the performance of laboratories, as specified in 493 CFR 1850(a). It also includes information provided by CLIA exempt states.

Bio-Mechanics Clinic

20 South Main

Aberdeen, Idaho 83210

CLIA #13D0922898

ACTION: Withdrawal from CLIA certification when informed that their testing was high complexity and the naturopaths involved did not qualify as clinical consultants.

EFFECTIVE DATE: June 3, 1997

Natural Health Center

3249 Indian Springs Road

American Falls, Idaho 83211-5507

CLIA #13D0927129

ACTION: Withdrawal from CLIA certification when informed that their testing was high complexity and the naturopaths involved did not qualify as clinical consultants.

EFFECTIVE DATE: August 26, 1997

Bio-Logix

810 North Henry #230

Post Falls, Idaho 83854

CLIA #13D0927135

ACTION: Lab withdrawal from CLIA certification when informed that their testing was high complexity and the naturopaths involved did not qualify as clinical consultants.

EFFECTIVE DATE: June 3, 1997

Care Corner Laboratory

1151 May Street

Hood River, Oregon 97031-1526

CLIA #38D0622007

ACTION: Voluntary withdrawal of the specialty of hematology due to unacceptable proficiency testing on one test. Laboratory licensure downgraded to Provider Performed Microscopy Procedures level of complexity.

EFFECTIVE DATE: February 28, 1997

David Spiro, M.D., Director

Coastal Pediatrics Association

775 SW 9th Annex A

Newport, Oregon 97365-4850

CLIA #38D0626212

ACTION: Voluntary downgrade from high to moderate complexity testing level of licensure because of condition equivalent deficiencies in quality control and proficiency test performance in the specialty of microbiology.

EFFECTIVE DATE: November 1997

Virginia Shepard, M.D., Director

Yamhill County Public Health

412 North Ford Street

Meminnville, Oregon 97128

CLIA #38D0662712

ACTION: Voluntary downgrade from moderate to Provider Performed Microscopy Procedures complexity testing level of licensure because of condition equivalent deficiency for failure to meet director qualifications.

EFFECTIVE DATE: December 1997

Steven Wells, M.D., Director

Klamath County Health Service

403 Pine Street

Klamath Falls, Oregon 97601-6035

CLIA #38D0896636

ACTION: Voluntary downgrade from moderate to waived complexity testing level of licensure based on condition equivalent deficiencies for failure to meet director qualification.

EFFECTIVE DATE: September 1997

Diagnos-Techs

6620 South 192nd Place #J104

Kent, Washington 98032-2102

CLIA #50D0630141

ACTION: Laboratory corrected condition equivalent deficiencies in quality assurance, quality control and management practices.

EFFECTIVE DATE: August 5, 1997

STATUS: Verified date of compliance - October 20, 1997

Eugene Schneider, Director

Meridian Valley Clinical Laboratory

515 West Harrison Street

Kent, Washington, 98032

CLIA #50D0630590

ACTION: Discontinued serum magnesium testing based on proficiency testing performance.

EFFECTIVE DATE: August 15, 1997

Robert L. & Laura C. Perry, D.O

12610 Des Moines Memorial Drive

Seattle, Washington 98168-2270

CLIA #50D0633420

ACTION: Discontinued automated differentials testing based on proficiency testing performance.

EFFECTIVE DATE: December 21, 1997

Doctors Clinic/Central Pediatrics

9615 Levin Road, NW #101

Silverdale, Washington 98383-9406

CLIA #5OD0860394

ACTION: Discontinued automated differentials testing based on proficiency testing performance.

EFFECTIVE DATE: May 7, 1997