

(receipts from a person's own unincorporated business, professional enterprise, or partnership, after deductions for business expenses); net receipts from farm self employment (receipts from a farm which one operates as an owner, renter, or sharecropper, after deductions for farm operating expenses); regular payments from social security, railroad retirement, unemployment compensation, strike benefits from union funds, workers' compensation, veterans' payments, public assistance (including Aid to Families with Dependent Children, Supplemental Security Income, Emergency Assistance money payments, and non-Federally-funded General Assistance or General Relief money payments), and training stipends; alimony, child support, and military family allotments or other regular support from an absent family member or someone not living in the household; private pensions, government employee pensions (including military retirement pay), and regular insurance or annuity payments; college or university scholarships, grants, fellowships, and assistantships; and dividends, interest, net rental income, net royalties, periodic receipts from estates or trusts, and net gambling or lottery winnings.

For official statistical purposes, income does not include the following types of money received: capital gains; any assets drawn down as withdrawals from a bank, the sale of property, a house, or a car; or tax refunds, gifts, loans, lump-sum inheritances, one-time insurance payments, or compensation for injury. Also excluded are noncash benefits, such as the employer-paid or union-paid portion of health insurance or other employee fringe benefits, food or housing received in lieu of wages, the value of food and fuel produced and consumed on farms, the imputed value of rent from owner-occupied nonfarm or farm housing, and such Federal noncash benefit programs as Medicare, Medicaid, food stamps, school lunches, and housing assistance.

Dated: February 6, 1995.

**Donna E. Shalala,**

*Secretary of Health and Human Services.*  
[FR Doc. 95-3285 Filed 2-6-95; 8:45 am]

BILLING CODE 4150-04-P

## Food and Drug Administration

[Docket No. 91F-0324]

### Goodyear Tire & Rubber Co.; Filing of Food Additive Petition; Amendment; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of January 26, 1995 (60 FR 5184). The document amended the filing notice for a food additive petition filed by the Goodyear Tire & Rubber Co. to indicate that the petitioned additive, alkylthiophenolics, acid-catalyzed condensation reaction products of *p*-nonylphenol, formaldehyde, and 1-dodecanethiol, is also intended for use in pressure-sensitive adhesives. The document was published with some editorial errors. This document corrects those errors.

#### FOR FURTHER INFORMATION CONTACT:

Andrew Zajac, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3095.

In FR Doc. 95-2007, appearing on page 5184 in the **Federal Register** of Thursday, January 26, 1995, the following corrections are made:

On page 5184, in the second column, in the first full paragraph, in line 6, and in the third column, in line 13, the word "alkylthiophendics" is corrected to read "alkylthiophenolics".

Dated: February 3, 1995.

**Alan M. Rulis,**

*Acting Director, Office of Pre-market Approval, Center for Food Safety and Applied Nutrition.*

[FR Doc. 95-3300 Filed 2-8-95; 8:45 am]

BILLING CODE 4160-01-F

## Health Care Financing Administration

### Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB) for Clearance

**AGENCY:** Health Care Financing Administration, HHS.

The Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to OMB the following proposals for the collection of information in compliance with the Paperwork Reduction Act (Public Law 96-511).

1. *Type of Information Collection:* Reinstatement; *Type of Review*

*Requested:* Regular submission; *Title of Information Collection:* Provider Reimbursement Manual Sections 2721, 2722, and 2725; *Form No.:* HCFA-9044; *Use:* The requirements in the Manual describe justification for submitting an exception request to ESRD composite rates for outpatient dialysis services; *Respondents:* Business or other for profit, Federal agencies or employees/ Non-profit institutions and Small businesses or organizations; *Obligation to Respond:* Required to obtain or retain benefit; *Number of Respondents:* 400; *Total Annual Responses:* 400; *Total Annual Hours Requested:* 19,200.

2. *Type of Information Collection:* Reinstatement, with change, of a previously approved collection; *Type of Review Requested:* Regular submission; *Title of Information Collection:* Medicare Home Health Agency Conditions of Participation; *Form No.:* HCFA-R-39; *Use:* Home Health Agencies to participate in Medicare are required to maintain this information to show compliance with published health and safety; *Respondents:* State or local governments and Business or other for-profit; *Obligation to Respond:* Required to obtain or retain benefit; *Number of Respondents:* 8,039; *Total Annual Responses:* 8,039; *Total Annual Hours Requested:* 69,498.

*Additional Information or Comments:* Call the Reports Clearance Office on (410) 966-5536 for copies of the clearance request packages. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: February 3, 1995.

**Kathleen B. Larson,**

*Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.*

[FR Doc. 95-3286 Filed 2-8-95; 8:45 am]

BILLING CODE 4120-03-M

[HSQ-223-N]

### CLIA Program; Approval of the College of American Pathologists

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the approval of the College of American Pathologists (CAP) as an accrediting

organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have found that the accreditation process of this organization provides reasonable assurance that the laboratories accredited by it meet the conditions required by Federal law and regulations. Consequently, laboratories that voluntarily become accredited by CAP in lieu of receiving direct Federal oversight and continue to meet CAP requirements would meet the CLIA condition level requirements for laboratories and therefore are not subject to routine inspection by State survey agencies to determine their compliance with Federal requirements. They are, however, subject to validation and complaint investigation surveys.

**EFFECTIVE DATE:** This notice is effective for the period February 9, 1995 through December 31, 1998.

**FOR FURTHER INFORMATION CONTACT:** Val Coppola (410) 597-5906.

**SUPPLEMENTARY INFORMATION:**

**I. Background and Legislative Authority**

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578. CLIA replaced in its entirety section 353 of the Public Health Service Act (PHSA), as enacted by the Clinical Laboratories Improvement Act of 1967, and made every laboratory in the United States and its territories that tests human specimens for health reasons subject to the requirements established by HHS and Federal regulation whether or not it participates in the Medicare or Medicaid program and whether or not it tests specimens in interstate commerce. New section 353 requires HHS to establish certification requirements for any laboratory that performs tests on human specimens and certify through issuance of a certificate that those laboratories meet the certificate requirements established by HHS.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989, Public Law 101-239, amended the Social Security Act (the Act) to require that laboratories participating in the Medicare program meet the certificate requirements of section 353 of the PHSA. Subject to specified exceptions, laboratories must have a current unrevoked and unsuspended certificate to be eligible for reimbursement in the Medicare or Medicaid programs or both. Laboratories that are accredited by a private non-profit organization approved under section 353 of the PHSA will

automatically be eligible for Medicare and Medicaid participation as long as they meet applicable State requirements.

On February 28, 1992, we published several final rules in the **Federal Register** (57 FR 7002-7243) that implemented the amendments to section 353 of the PHSA. The technical and scientific portions of these rules were crafted by The Centers for Disease Control and Prevention (CDC) of the Public Health Service (PHS).

Specifically, regulations were established at 42 CFR part 493 that:

- Require laboratories to pay fees for issuance of registration certificates, certificates of waiver, certificates of accreditation, or other applicable certificates (in a subsequent rule published January 19, 1993, 58 FR 5215, we added "certificate for physician-performed microscopy procedures") and to fund activities to determine compliance with our performance requirements;

- Specify the performance requirements that apply to laboratories subject to CLIA (some of which were amended by the January 19, 1993 rule) and list requirements for laboratories performing certain limited testing to be eligible for a certificate of waiver; and
- Set forth the rules for the enforcement of CLIA requirements on laboratories that are found not to meet Federal requirements.

On July 31, 1992, HCFA issued additional final rules (57 FR 33992), under authority found in section 353(e)(2) of the PHSA, that establish that we may approve a private, nonprofit organization as an accreditation organization for clinical laboratories under the CLIA program if that organization's requirements for its accredited laboratories are equal to or more stringent than the applicable CLIA program requirements of part 493 of our regulations. Therefore, a laboratory accredited by an approved organization that meets and continues to meet all of the accreditation organization's requirements would meet CLIA condition level requirements if it were inspected against CLIA regulations. The regulations listed in subpart E of part 493 specify the requirements an accreditation organization must meet in order to be approved. We may approve an accreditation organization under § 493.501(d) of our regulations for a period not to exceed six years.

In general, the accreditation organization must:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by HCFA;

- Apply standards and criteria that are equal to or more stringent than those condition level requirements established by HHS when taken as a whole;

- Provide reasonable assurance that these standards and criteria are continually met by its accredited laboratories;

- Provide HCFA, within 30 days, with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked;

- Notify HCFA at least 30 days prior to changing its standards; and

- If HCFA withdraws its approval, notify its accredited laboratories of the withdrawal within 10 days of the withdrawal. A laboratory can be accredited if it meets the standards of an approved accreditation body and authorizes the accreditation body to submit to HCFA records and other information HCFA may require.

Along with requiring the promulgation of criteria for approving an accreditation body and for withdrawing such approval, CLIA regulations require HCFA to perform an annual evaluation by inspecting a sufficient number of laboratories accredited by an approved accreditation organization as well as by any other means that HCFA determines appropriate. Under section 353(o) of the PHSA, the Secretary may, by agreement, use the services or facilities of any other Federal, State or local public agency, or any private, nonprofit organization to conduct inspections of laboratories performing clinical testing on human specimens in the United States and its territories for the purpose of determining compliance with CLIA requirements.

**II. Notice of Approval of CAP as an Accrediting Organization**

In this notice, we approve CAP as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements. HCFA has examined the CAP application, in which it requested deemed status for all specialties and subspecialties, and all subsequent submissions against the requirements under subpart E of part 493 that an accreditation organization must meet in order to be granted approved status under CLIA. We have determined that CAP has complied with the applicable CLIA requirements as of February 9, 1995 and grant CAP approval as an accreditation organization under this Subpart through December 31, 1998 for all specialty/subspecialty areas.

As a result of this determination, any laboratory that is accredited by CAP

during this time period meets the CLIA requirements for laboratories found in part 493 of our regulations and, therefore, is not subject to routine inspection by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by HCFA, or by any other Federal or State or local public agency or nonprofit private organization which acts in conformance to an agreement with the Secretary.

### III. Evaluation of CAP

The following describes the process used to determine that CAP, as a private, nonprofit organization, provides reasonable assurance that those laboratories it accredits will meet the applicable requirements of the Federal law and regulations.

#### A. Requirements for Approving an Accreditation Organization Under CLIA

To determine whether HCFA should grant approval to CAP as a private, nonprofit organization for accrediting laboratories under CLIA, HCFA and CDC conducted a detailed and in-depth comparison of CAP's requirements for its laboratories to those of CLIA and evaluated whether CAP's standards are at least as stringent as the requirements of 42 CFR part 493 when taken as a whole. In summary, we evaluated whether CAP:

- Provides reasonable assurance to us that it requires the laboratories it accredits to meet requirements that are equal to or more stringent than the CLIA condition level requirements and would, therefore, meet the condition level requirements of CLIA if those laboratories had not been granted deemed status and had been inspected against condition level requirements; and
- Meets the requirements of § 493.506, which specify the Federal review and approval requirements of private, nonprofit accreditation organizations.

As specified in the regulations at § 493.506, our review of a private, nonprofit accreditation organization seeking deemed status under CLIA includes, but is not limited to, an evaluation of:

- Whether the organization's requirements for its accredited laboratories are equal to or more stringent than the condition level requirements of the CLIA regulations;
- The organization's inspection process to determine:

- The composition of the inspection teams, qualifications of the inspectors,

and the ability of the organization to provide continuing education and training to all of its inspectors;

- The comparability of the organization's full inspection and complaint inspection processes to those of HCFA, including but not limited to inspection frequency, and the ability to investigate and respond to complaints against its accredited laboratories;
- The organization's procedures for monitoring laboratories that it has found to be out of compliance with its requirements;
- The ability of the organization to provide HCFA with electronic data and reports that are necessary for effective validation and assessment of the organization's inspection process;
- The ability of the organization to provide HCFA with electronic data, related to the adverse actions resulting from unsuccessful proficiency testing (PT) participation in HCFA approved PT programs, as well as data related to the PT failures, within 30 days of the initiation of the action;
- The ability of the organization to provide HCFA with electronic data for all its accredited laboratories and the areas of specialty and subspecialty of testing;
- The adequacy of numbers of staff and other resources; and
- The organization's ability to provide adequate funding for performing the required inspections.
  - The organization's agreement with HCFA that requires it to:
    - Notify HCFA of any laboratory that has had its accreditation denied, limited, suspended, withdrawn, or revoked by the accreditation organization, or that has had any other adverse action taken against it by the accreditation organization within 30 days of the action taken;
    - Notify HCFA within 10 days of a deficiency identified in an accredited laboratory where the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public;
    - Notify HCFA of all newly accredited laboratories, or laboratories whose areas of specialty or subspecialty are revised, within 30 days;
    - Notify each laboratory accredited by the organization within 10 days of HCFA's withdrawal of recognition of the organization's approval as an accrediting organization under CLIA;
- Provide HCFA with inspection schedules, as requested, for the purpose of conducting onsite validation inspections;

- Provide HCFA, the State survey agency or other HCFA agent with any facility-specific data that includes, but is not limited to, PT results that constitute unsuccessful participation in HCFA approved PT programs and notification of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation;
- Provide HCFA with written notification at least 30 days in advance of the effective date of any proposed changes in its requirements; and
- Make available, on a reasonable basis, any laboratory's PT results upon the request by any person, with such explanatory information needed to assist in the interpretation of the results.

Laboratories that are accredited by a HCFA approved accreditation organization must:

- Authorize the organization to release to HCFA all records and information required by HCFA as required at § 493.501;
- Permit inspections as required by the CLIA regulations at 42 CFR part 493, subpart Q;
- Obtain a certificate of accreditation as required by § 493.632; and
- Pay the applicable fees as required by §§ 493.638 and 493.645.

#### B. Evaluation of the CAP Request for Approval as an Accreditation Organization Under CLIA

CAP has formally applied to HCFA for approval as an accreditation organization under CLIA for all specialties and subspecialties. We have evaluated the CAP application to determine equivalency with our implementing and enforcement regulations, and the deeming/exemption requirements of the CLIA rules. We also verified the organization's assurance that it requires the laboratories it accredits to be, and that the organization is, in compliance with the following subparts of 42 CFR part 493 as explained below:

#### Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

CAP has submitted a list of all specialties and subspecialties that it would accredit, a comparison of individual accreditation and condition level requirements, a description of its inspection process, PT monitoring process, and its data management and analysis system, a listing of the size, composition, education and experience of its inspection teams, its investigative

and complaint response procedures, its notification agreements with HCFA, its removal or withdrawal of laboratory accreditation procedures, its current list of accredited laboratories, and its announced or unannounced inspection process. We have determined that CAP has complied with the general requirements under § 493.501, the applicable parts of § 493.506, and the CLIA requirements for approval as an accreditation organization under various subparts of part 493.

Our evaluation identified areas of the CAP requirements that are more stringent than the CLIA requirements and apply to the laboratory as a whole. Rather than include them in the appropriate subparts multiple times, we list them here:

- CAP requires its accredited laboratories to possess documentation of all State laws and to follow them.
- CAP lists extensive requirements for the Laboratory Information System (LIS), which cover but are not limited to:
  - + The preservation, storage, and retrieval of laboratory and patient data;
  - + The review of LIS programs for appropriate content and testing before use when a new program is to be put in place or when changes are made to existing programming;
  - + The maintenance of the LIS facility, which must be clean, well ventilated, and at proper temperature and humidity;
  - + The protection of LIS against power interruptions and surges;
  - + The protection of the LIS, its data, patient information, and programs from unauthorized use;
  - + The entry of data and result reporting;
  - + The verification and maintenance of LIS hardware and software;
  - + The routine and emergency service and maintenance of the LIS; and
  - + An evaluation from the laboratory director of the LIS performance as it pertains to patient and clinician needs.
- + In addition, the LIS operators must have procedure manuals readily available, be adequately trained in LIS operation, and know what must be done to preserve data and equipment in emergency situations such as software or hardware failure or in the event of fire;
- CAP accredits laboratories that perform testing for any of the following areas and sets specific standards with which their accredited laboratories must comply:
  - + Athletic drug testing (for anabolic steroids, beta-blockers, cannabinoids, narcotics, and stimulants);
  - + Forensic urine drug testing;

- + Parentage testing; and
- + Reproductive laboratory testing (embryology and andrology).

**Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both**

The CAP requirements for proficiency testing (PT) are in conformance with the CLIA law, which states that standards shall require all laboratories be tested by PT for each examination for which PT is available. The CAP PT requirements are more stringent than the CLIA regulations at subpart I, which list specific tests for which the laboratory must participate in a HCFA approved PT program. CLIA exempts waived testing from PT, whereas CAP requires its accredited laboratories to participate in its HCFA approved PT program for all testing, including procedures waived under CLIA.

We have determined that the actions taken by CAP to correct unsatisfactory (one failure) and unsuccessful (2 in a row or 2 out of 3 failures) PT performance of its laboratories is equivalent to those of CLIA; in the cases of unsatisfactory performance and the CLIA phase-in allowances, CAP is more stringent. CAP has initiated an on-going electronic monitoring process that flags both unsatisfactory and unsuccessful results for all PT performance, both CLIA required analytes and all other testing for which PT is available and is required by CAP. CAP accredited laboratories are allowed 15 days to respond in writing to each unsatisfactory result, indicating how the problem was investigated, the cause of the problem, the specific corrective action that was taken to prevent recurrence, and evidence that the problem was successfully corrected.

CLIA regulations state that the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with an unsatisfactory score, take remedial action and document it. Unsuccessful PT performance, when identified by CAP, initiates immediate communication with the laboratory director. A written response must be submitted to CAP, explaining why the adverse results occurred, a description of the investigation of the problem and the actions taken to correct the problem. The laboratory must submit this information within ten working days. If, after review by CAP, it is determined that the laboratory's approach is scientifically valid and PT performance is within acceptable limits, no further action is taken. If the laboratory does not respond, fails to address the

problem seriously, or cannot bring performance into acceptable limits, the CAP would evaluate the situation and either request that the laboratory cease testing for the analyte or specialty or subspecialty in question, or, if warranted, revoke accreditation.

CLIA regulations allow a phase-in period for unsuccessful PT performance, which, for previously regulated laboratories (which includes most CAP accredited laboratories), impose no sanctions under § 493.803 (Condition: Successful Participation) until the end of 1994. As the phase-in period ends, the sanctions under CLIA and the actions taken by CAP become equivalent.

CAP also offers a voluntary continuing education and external quality assurance program for PAP smear cytology. The Interlaboratory Comparison Program in Cervicovaginal Cytopathology currently enrolls approximately 1,800 CAP accredited laboratories that perform cytology testing. The number of laboratories this program can enroll is dependent upon the availability of the referenced glass slide material (cervicovaginal smears). When CAP has sufficient quantities to accommodate all of its 2,600 accredited laboratories that perform gynecologic (GYN) cytology, it intends to offer this program as a cervicovaginal cytopathology pathology proficiency testing survey in which its accredited laboratories will be required to participate. Currently there is no HCFA approved cytology PT program capable of enrolling all CLIA certified laboratories that perform GYN cytology testing.

**Subpart J—Patient Test Management for Moderate or High Complexity Testing, or Both**

The CAP has expanded and in some cases revised its requirements to be equivalent to the CLIA requirements at §§ 493.1101 through 493.1111, on an overall basis. We have determined that CAP's requirements for an accredited laboratory to include on report forms the dates and times of specimen collection (when appropriate) and the release of the report are more stringent than the requirements under CLIA as well as their requirement that reports must be legible. The CAP also requires its accredited laboratories to use referral laboratories that are appropriately CLIA certified.

**Subpart K—Quality Control for Tests of Moderate or High Complexity, or Both**

The quality control (QC) requirements of CAP have been evaluated against the phased-in, complexity based

requirements of the CLIA regulations. We have determined that after the additions and revisions made by CAP, the QC requirements of CAP are more stringent than the CLIA requirements, when taken as a whole. Some specific requirements of QC that are more stringent are:

- The CAP does not allow a two year phase-in for QC requirements and requirements are effective without delay;
- The CAP imposes QC requirements equally upon all testing performed by their accredited laboratories, including CLIA's waived procedures. All testing is considered high complexity by CLIA definition;
- The CAP laboratory safety requirements are specific and detailed. Environmental safety requirements address electrical voltage, facility ventilation, lighting, temperature, humidity, and emergency power source and require remedial actions to be taken when necessary. CAP also has requirements in place for handling and disposal of biohazardous materials, fire safety and prevention of fire hazards, as well as all OSHA regulations as they pertain to the laboratory;
- The CAP requires procedure manuals to include the principle and clinical significance for each test, and the procedure manuals must also include documentation of initial and annual reviews;
- CAP accredited laboratories that rely on manufacturers' quality control of microbiological media must have a copy of the National Committee for Clinical Laboratory Standards Document M-22-A (Quality Assurance for Commercially Prepared Microbiological Culture Media) and provide documentation that its media supplier carries out the quality assurance guidelines enumerated in Document M-22-A;
- CLIA regulations allow cytology slide preparations made using automated, semi-automated, or other liquid-based slide preparations that cover half or less of a slide to be counted as one half slide for cytology workload purposes. This allows a maximum of 200 such preparations to be examined by an individual in a 24 hour period. The CAP does not recognize these preparations as half slides, but rather as full slides to be included in an individual's 100 slide, 24 hour maximum allowable workload;
- CAP requires its accredited laboratories to use the appropriate reagent grade water for the testing performed, stating which type of water (from type I through Type III) must be used in specific tests. Source water must also be evaluated for silicone levels;

- CAP accredited laboratories must verify all volumetric glassware and pipettes for accuracy and reproductability prior to use and recheck them periodically. These activities must be documented;
  - CAP accredited laboratories that perform maternal serum alpha-fetoprotein and amniotic fluid alpha-fetoprotein have specific requirements that must be met. These include a qualitative specimen evaluation, requesting and reporting information necessary for interpretation of results; i.e., gestational age, maternal birth date, race, maternal weight, insulin-dependent diabetes mellitus, multiple gestations, median ranges calculated and recalculated yearly, results reported in multiples of the mean, etc;
  - The CAP lists specific requirements for newer methodologies. Molecular pathology and flow cytometry standards are presented in separate checklists and immunohistochemistry has specific requirements within histology; and
  - CAP record retention requirements are the same or longer than those of CLIA.
- The CAP has made additions and revisions to its requirements to make them equivalent to the CLIA regulations. Some examples of these changes are:
- All reagents must be used within their indicated expiration date;
  - The laboratory must use components of reagent kits only with other kits of the same lot number, unless otherwise specified by the manufacturer;
  - Conforming revisions were made to the CAP standards for calibration and calibration;
  - Qualitative and quantitative test control procedure requirements were revised to specify the following more clearly:
    - + Control specimens must be tested in the same manner as patient specimens;
    - + Reagent performance and adequacy must be verified before placing the material in service. The results of the verification checks must be recorded; and
    - + Stains are checked for intended reactivity each day of use;
  - CAP has imposed a 100 slide maximum number of cytology slides that an individual may evaluate in a 24 hour period;
  - Records must be maintained of the number of cytology slides evaluated by each individual;
  - The technical supervisor in cytology (pathologist) must establish each individual's slide limit and reassess this limit every six months;
  - Also, in cytology, CAP requires a minimum of ten percent of negative

(GYN) cases be re-screened by a qualified individual and the results of these slides not be released until the rescreens are complete; and

- All previous negative cytology smears available within the past five years must be reviewed on a patient having a current positive smear.

#### **Subpart M—Personnel for Moderate and High Complexity Testing**

The Standards for Laboratory Accreditation of the CAP states at Standard I, Director and Personnel Requirements, under item D, Personnel, that all laboratory personnel must be in compliance with applicable federal, state, and local laws and regulations. This standard is implemented in the general laboratory requirement that there must be evidence in personnel records that all testing personnel have been evaluated against CLIA regulatory requirements for high complexity testing and that all individuals qualify. CAP has added requirements to all levels of laboratory personnel, most of which refer to the CLIA regulatory requirements. We have determined that the personnel requirements of the CAP are equal to or more stringent than the personnel requirements of CLIA.

#### **Subpart P—Quality Assurance for Moderate or High Complexity Testing or Both**

We have determined that CAP's requirements are equal to or more stringent than the CLIA requirements of this subpart. CAP has made revisions to its checklist requirements for quality assurance to equate to the CLIA requirements. CAP also offers an educational program, Q-Probes, to its accredited laboratories, which provides further information on quality assurance to the large, full service laboratories; this program allows peer review and comparisons between facilities.

#### **Subpart Q—Inspections**

We have determined that the CAP inspection requirements, taken as a whole, are equivalent to the CLIA inspection requirements. CAP has made some program modifications pertinent to its overall inspection process, specifically involving the training of all inspectors. CAP has initiated a Laboratory Accreditation Programs Inspector Training Seminars program. Two seminars in each of the 13 CAP regions are presented currently, with 60 such seminars to be presented nationally per year beginning in 1995. Training seminar participants include inspection team leaders and team members.

Another program modification addresses the gathering of information needed to investigate complaints. CAP has discontinued its practice of notifying the laboratory director of the specific reason for contact or inspection when a complaint investigation is in process.

The CAP will continue its policy of conducting announced biennial on-site inspections. An unannounced inspection would be performed when a complaint, lodged against a CAP accredited laboratory, indicates that severe and major problems exist within that laboratory that are likely to have serious and immediate effects on patient care.

Some areas of the CAP inspection process are more stringent than those of CLIA:

- CAP requires a mid-cycle self-inspection of all accredited laboratories. All requirements must be responded to in writing and the responses submitted to CAP within a specified timeframe; and
- A written evaluation of the inspection process and the inspectors must be completed after each on-site inspection of an accredited laboratory. The director of the inspected laboratory must submit this evaluation to the CAP within a specified timeframe.

#### **Subpart R—Enforcement Procedures for Laboratories**

CAP meets the requirements of subpart R to the extent that it applies to accreditation organizations. CAP policy stipulates the actions it takes when laboratories it accredits do not comply with its requirements and standards for accreditation. CAP will deny accreditation to a laboratory when appropriate and report the denial to HCFA within 30 days. CAP also provides an appeals process for laboratories that have had accreditation denied.

Some specific actions CAP takes in response to non-compliance or violation of its requirements or standards for accreditation include:

- When an accredited laboratory has been identified as having intentionally referred a PT specimen to another laboratory for analysis prior to the PT program end-date for receipt of results, the CAP laboratory will be denied accreditation and be ineligible for CAP accreditation for one year. This action is similar to the HCFA action of denial of certification for 1 year.
- When a CAP accredited laboratory participates unsuccessfully in PT for an analyte, subspecialty, and/or specialty, the laboratory must initiate corrective actions. It must submit to CAP

documentation of a detailed investigation of the problem causing the unsuccessful performance with a corrective action plan within ten working days. Specific educational activity or the retention of the services of a consultant may also be imposed. Failure to bring PT performance into acceptable limits or failure to address the PT problem seriously would cause CAP to request the laboratory to cease testing for the procedure(s) in question or, if warranted, revoke the laboratory's accreditation. This action is equal to the actions that HCFA may take under this subsection.

- When CAP becomes aware of a problem that is severe and extensive enough that it could cause a serious risk of harm (immediate jeopardy) situation in an accredited laboratory, an expedited evaluation is immediately undertaken by the Chair and Vice Chair of the Accreditation Committee, the regional Commissioner and the Director of the Laboratory Accreditation Program. If it is determined that an immediate jeopardy situation exists, the laboratory is required to remove the jeopardy situation immediately or accreditation would be revoked. An on-site focused re-inspection may be performed to verify that the immediate jeopardy no longer exists. These actions are similar to HCFA actions for immediate jeopardy.

- The CAP requires its accredited laboratories to correct all deficiencies within 30 days. CLIA deficiencies that are not condition level must be corrected in a timeframe that is acceptable to HCFA, but no longer than 12 months. CLIA deficiencies that are condition level but are not instances of immediate jeopardy must be corrected in an acceptable timeframe; however, HCFA may impose one or more alternate sanctions or a principal sanction to motivate laboratories to correct these deficiencies. The CAP timeframe for correction of deficiencies, when taken as a whole, is more stringent than CLIA.

We have determined that CAP's laboratory enforcement and policies are equivalent to the requirements of this subpart as they apply to accreditation organizations.

#### **IV. Federal Validation Inspections and Continuing Oversight**

The Federal validation inspections of CAP accredited laboratories, as specified in § 493.507, may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (called complaint inspections). The outcome of those validation inspections, performed

by HCFA, the State survey agency, or a HCFA agent, will be HCFA's principal means for verifying that the laboratories accredited by CAP remain in compliance with CLIA requirements. This Federal monitoring is an on-going process.

#### **V. Removal of Approval as an Accrediting Organization**

Our regulations at § 493.511 provide that the approval of an accreditation organization, such as that of CAP, may be removed by HCFA for cause, prior to the end of the effective date of approval. If validation inspection outcomes and the comparability or validation review produce findings as described at § 493.509(a), HCFA will conduct a review of an accreditation organization's program. A review is also conducted when the validation review findings, irrespective of the rate of disparity (as defined in § 493.2), indicate systemic problems in the organization's processes that provide evidence that the organization's requirements, taken as a whole, are no longer equivalent to the CLIA requirements, taken as a whole.

If it is determined that CAP has failed to adopt requirements that are equal to or more stringent than the CLIA requirements, or systemic problems exist in its inspection process, a probationary period, not to exceed one year, may be given to allow CAP to adopt comparable requirements. Based on an evaluation of any of the items stipulated at § 493.511(d), we will determine whether or not CAP retains its approved status as an accreditation organization under CLIA. If we deny approved status, an accreditation organization such as CAP may resubmit its application when it has revised its program to address the rationale for the denial, demonstrated that it can reasonably assure that its accredited laboratories meet CLIA condition level requirements, and resubmits its application for approval as an accreditation organization in its entirety. If, however, an accrediting organization requests reconsideration of an adverse determination in accordance with Subpart D of part 488 of our regulations, it may not submit a new application until a final reconsideration determination is issued.

Should circumstances result in CAP having its approval withdrawn, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

**Authority:** Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: January 17, 1995.

**Bruce C. Vladeck,**

*Administrator, Health Care Financing Administration.*

[FR Doc. 95-3165 Filed 2-8-95; 8:45 am]

BILLING CODE 4120-03-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

#### Program Exclusions: January 1995

**AGENCY:** Office of Inspector General, HHS.

**ACTION:** Notice of program exclusions.

During the month of January 1995, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all other Federal non-procurement programs.

Subject, city, State	Effective date
<b>Program-Related Convictions</b>	
Alexis, Peter, Dallas, TX .....	02/16/95
Alfonso, Leonard, Fairhaven, MA ..	02/13/95
B and L Transport, Inc., Milwaukee, WI .....	02/13/95
Battle, Robert Wayne, Dillard, GA ..	02/16/95
Becker, Donna C., Spokane, WA ..	02/16/95
Bhatt, Harshad, Manhassat, NY ...	02/13/95
Bronshiteyn, Boris, Lido Beach, NY .....	02/13/95
Brown, Ervin L., Spokane, WA .....	02/16/95
Brown, Eric P., Spokane, WA .....	02/16/95
Center Green Rest Home, Inc, Fairhaven, MA .....	02/13/95
Champion, Mackie, Blytheville, AR ..	02/16/95
Cole, Carl Edward, Granville, NY ..	02/16/95
Dunigan, James, Steele, MS .....	02/16/95
Fesler, Michael, Melbourne, AR ...	02/16/95

Subject, city, State	Effective date	Subject, city, State	Effective date
Gardners Grove Nursing Home, Fairhaven, MA .....	02/13/95	Egbuchunam, Maureen I, Irving, TX .....	02/16/95
Hadley, Arthur R, Richmond, CA ..	02/16/95	Evans, Billie Jean, Reyno, AR .....	02/08/95
Hamilton, Richard J, Woburn, MA ..	02/13/95	Ewing, Jon R, Quitman, AR .....	02/08/95
Hinton, Joseph L, Raymond, MS ..	02/16/95	Forbes, Janyce L, Saginaw, TX ...	02/08/95
Kelly, Michael, Brooklyn, NY .....	02/16/95	Grace, Shirlee J, Belton, TX .....	02/16/95
Melendez, Maria, M, Bronx, NY ...	02/13/95	Griffis, Michael S, Green Forest, AR .....	02/08/95
Murray, April B, Winthrop, ME .....	02/13/95	Hall, Gayla S, Mount Pleasant, TX ..	02/08/95
Newman, Donald Mark, Grady, AR .....	02/16/95	Hanus, Larry J, Waterloo, IA .....	02/13/95
Ortiz, Twila G, Hart, TX .....	02/08/95	Henningsgaard, Wayne, Stillwater, MN .....	02/13/95
Pelusi, Joseph F, Lynnfield, MA ...	02/13/95	Hobbs, William D, Frederick, OK ..	02/08/95
Pomonis, Nick S, Orange, TX .....	02/08/95	Jones, Z Joyce, Ft Worth, TX .....	02/16/95
Ruyle, David, Dania, FL .....	02/08/95	Klein, Cathy Marie, Columbia, CT ..	02/13/95
Schonbrun, David, Woodbridge, NY .....	02/16/95	Lanphere, Margaret Eleese, Krum, TX .....	02/08/95
Spielman, Michael, Hauppauge, NY .....	02/13/95	Loutfi, Yaser Hasan, Panama City, FL .....	02/12/95
Strogov, Emilia, Scotch Plains, NJ ..	02/16/95	Marang, Boitshoko, Detroit, MI .....	02/15/95
Thompson, Beverly K, Milwaukee, WI .....	02/13/95	Miller, Lynn J, Conway, AR .....	02/08/95
Weeks, Edward H, Bonney Lake, WA ..	02/16/95	Mills, Judy Y, Lexington, OK .....	02/08/95
Yellow Cab of Woburn, Inc, Woburn, MA .....	02/13/95	Morris, Sharon Ann, Springdale, AR .....	02/08/95
<b>Patient Abuse/Neglect Convictions</b>			
Anyakora, Peter, Baltimore, MD ...	02/13/95	Muhammad, Taalib-Din Iqbal, New York, NY .....	02/16/95
Bartholomew, Daryl, Denver, CO ..	02/15/95	Nyman, David W, Colorado Springs, CO .....	02/15/95
Brewer, Sherry Denise, Birmingham, AL .....	02/12/95	Oakley, Diane, Redbird, OK .....	02/08/95
Brown, Herman Jr, DeQueen, AR ..	02/08/95	Parker, Linda M, Hartford, CT .....	02/13/95
Cadiz, Pat, Danbury, TX .....	02/16/95	Raskiewicz, Edward B, Bridgeport, PA .....	02/13/95
Dickerson, Yulander, Talladega, AL .....	02/12/95	Reed, Guy D, Tulsa, OK .....	02/08/95
Gravdal, Georgene, Annandale, MN .....	02/13/95	Robinson, Taylor, Lexington, MA ..	02/13/95
Jasinski, Jeffrey R, West Seneca, NY .....	02/16/95	Samitier-Cardet, Richard, Miami, FL .....	02/12/95
Paul, Joyce Jean, Greenbrier, AR ..	02/08/95	Sands, Abel J, Oklahoma City, OK .....	02/08/95
Ross, Darryl, Donaldsonville, LA ..	02/08/95	Satterwhite, Linda L, Overton, TX ..	02/16/95
Siggers, Artedra, L, Ellisville, MS ..	02/08/95	Sears, Phyllis Lana, Little Rock, AR .....	02/16/95
Thatcher, James R, Chillicothe, OH .....	02/15/95	Sheehan, Timothy, Grand Rapids, MI .....	02/15/95
<b>Controlled Substance Convictions</b>			
Ekinci, Fevzi, Brooklyn, NY .....	02/13/95	Soss, Burton Jay, Melbourne, FL ..	02/12/95
Oliva, Phillip B, Boulder, CO .....	02/15/95	Thompson, Lewis E III, Little Rock, AR .....	02/08/95
Straw, Michael F, Denver, CO .....	02/15/95	Vaughans, Betty Jennell, Moss Point, MS .....	02/08/95
<b>License Revocation/Suspension</b>			
Altman, James Lloyd, Walterboro, SC .....	02/12/95	Welch, Susan E, Toronto, Ontario, CN .....	02/16/95
Amini, Mike, Jordan, UT .....	02/13/95	Willoughby, Deloris A, Crockett, TX .....	02/16/95
Baggett, Lynn D, Hugo, OK .....	02/08/95	Young, Henry A, Baltimore, MD ...	02/13/95
Bottles, Kurt D, Yukon, OK .....	02/08/95	Zatkowski, John R, Fairfield, CT ..	02/13/95
Boyd, Debra K, Belton, TX .....	02/16/95	<b>Federal/State Exclusion/Suspension</b>	
Buckner, John W, San Diego, CA ..	02/12/95	Anthony, Shirelle, New Orleans, LA .....	02/16/95
Busby, Theresa P, West Memphis, AR .....	02/08/95	Filoreto, Anthony R, West Hazelton, PA .....	02/13/95
Cash, Barbara Lynn, Fayetteville, AR .....	02/08/95	Torres, Pedro Luis, New Rochelle, NY .....	02/16/95
Chastan, Pamela S, Denison, TX ..	02/08/95	<b>Owned/Controlled by Convicted/Excluded</b>	
Cranford, Vanessa Lynne, Perryville, AR .....	02/08/95	Arora Clinics, Ltd, Grundy, VA .....	12/05/94
Daywood, Michael K, San Antonio, TX .....	02/08/95	Hinton Pharmacy, Raymond, MS ..	02/16/95
Deming, Robin, Southbury, CT .....	02/13/95	Medcare City Pharmacy, Clover, SC .....	02/12/95
DeVries, Edward J, Muskegon, MI ..	02/13/95	Medical Assistance SVC, Grady, AR .....	02/16/95
Edwards, Jerrie Dean, Little Rock, AR .....	02/08/95	Northeast Arkansas Ambulance, Blytheville, AR .....	02/16/95