Trans#	Acquiring	Acquired	Entities
20012272	Pegasus Partners II, L.P	Golden Books Family Entertainment, Inc., debtor-in-possession.	Golden Books Family Entertainment, Inc., debtor-in-possession.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Parcellena P. Fielding, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, room 303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 01–22856 Filed 9–11–01; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the U.S. Department of Health and Human Services announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS).

Times and Dates: 9:00 a.m.—5:30 p.m., September 24, 2001, 9:00 a.m.—4:00 p.m., September 25, 2001.

Place: Conference Room 705A, Hubert H. Humphrey Building, 200 Independence Avenue S.W., Washington D.C. 20201.

Status: Open.

Purpose: The National Committee on Vital and Health Statistics is scheduled to meet on September 24–25, 2001. The NCVHS is the Department's statutory public advisory body on health data, statistics, and health information policy. In addition, the Committee advises HHS on the implementation of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPPA). The meeting will focus on a variety of health data policy and privacy issues. Department officials will update the Committee on recent activities of the HHS Data Council and the status of HHS activities in implementing the administrative simplification provisions of HIPAA. A briefing from the HHS Deputy Chief Information Officer is planned, and GAO staff will brief the Committee on confidentiality practices and issues in record linkage for research purposes.

The Committee is also expected to discuss and take action on recommendations to HHS from the Privacy and Confidentiality Subcommittee relating to the implementation of the HIPAA Health Information Privacy regulation, following a subcommittee public hearing on the subject in August. Subcommittee breakout sessions also are planned.

All topics are tentative and subject to change. Prior to the meeting, please check the NCVHS web site, where a detailed agenda will be posted when available.

FOR FURTHER INFORMATION CONTACT: Substantive information as well as summaries of NCVHS meetings and a roster of committee members may be obtained by visiting the NCVHS website (http://ncvhs.hhs.gov) where an agenda for the meeting will be posted when available. Additional information may be obtained by calling James Scanlon, NCVHS Executive Staff Director, Office of the Assistant Secretary for Planning and Evaluation, DHHS, Room 440–D. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, telephone (202) 690–7100, or Marjorie S. Greenberg, Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458–4245.

Note: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, individuals without a government identification card may need to have the guard call for an escort to the meeting room.

Dated: September 4, 2001.

James Scanlon,

Director, Division of Data Policy.

[FR Doc. 01–22820 Filed 9–11–01; 8:45 am]

BILLING CODE 4151–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2119–N]

Medicare, Medicaid, and CLIA Programs; Continuance of the Approval of the College of American Pathologists as a CLIA Accreditation Organization

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the continuance of the approval of the College of American Pathologists (CAP) as an accreditation organization for laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). We found that the accreditation process of this organization provides reasonable assurance that the laboratories accredited by it meet the conditions required by CLIA statute and regulations. Consequently, laboratories that voluntarily become accredited by CAP in lieu of 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 CLIA requirements. However, they are subject to Federal validation and complaint investigation surveys.

EFFECTIVE DATE: This notice is effective for the period September 12, 2001 through September 30, 2007.

FOR FURTHER INFORMATION CONTACT: Val Coppola, (410) 786–3531.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On July 31, 1992, we published a final rule in the **Federal Register** (57 FR 33992) that implemented section 353(e)(2) of the Public Health Service Act. Under this rule CMS may approve a private, nonprofit organization to accredit clinical laboratories (that is, an approved accreditation organization) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) if the organization meets certain requirements. An organization's requirements for accredited laboratories must be equal to, or more stringent than, the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). A laboratory accredited by an approved accreditation organization that meets and continues to meet all of the accreditation organization's requirements would be considered to meet CLIA condition level requirements as if it was inspected against CLIA regulations. The regulations in 42 CFR part 493, subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specify the requirements an accreditation organization must meet in order to be approved. CMS approves an accreditation organization for a period not to exceed 6 years.

In general, an approved accreditation organization must, among other conditions and requirements:

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by CMS.
- Apply standards and criteria that are equal to, or more stringent than, those condition level requirements established by CMS when taken as a whole.
- Provide reasonable assurance that these standards and criteria are continuously met by its accredited laboratories.
- Provide CMS with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked within 30 days of the action taken.
- Notify CMS in writing at least 30 days before the effective date of any proposed change in its standards.
- Notify the accredited laboratories of CMS's decision to withdraw its approval within 10 days of the withdrawal. A laboratory can be accredited if, among other things, it meets the standards of an approved accreditation organization and authorizes the accreditation body to submit records and other information to CMS as required.

In addition to requiring the promulgation of criteria for approving and withdrawing the approval of an accreditation body, CLIA requires CMS to perform an annual evaluation by inspecting a sufficient number of laboratories accredited by an accreditation organization, as well as, by any other means that CMS determines appropriate.

I. Notice of Continued Approval of CAP as an Accreditation Organization

In this notice, we approve CAP as an organization that may continue to accredit laboratories for purposes of establishing their compliance with CLIA. The Centers for Disease Control and Prevention and CMS (hereinafter referred to as ''we'') have examined the CAP application and all subsequent submissions to determine equivalency with the requirements under 42 CFR part 493, subpart E that an accreditation organization must meet to be granted approved status under CLIA. We have determined that CAP has complied with the applicable CLIA requirements and grant CAP approval as an accreditation organization under 42 CFR part 493, subpart E, September 12, 2001 through September 30, 2007, for all specialty and subspecialty areas under CLIA.

As a result of this determination, any laboratory that is accredited by CAP during this time period for an approved specialty or subspecialty is deemed to meet the applicable CLIA condition level requirements for laboratories found in 42 CFR part 493 and, therefore, is not subject to routine inspection by a State survey agency to determine compliance with CLIA requirements. However, the accredited laboratory is subject to validation and complaint investigation surveys performed by CMS, or any other Federal, State, local public agency, or nonprofit organization under 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 the laboratories it accredits will meet the applicable requirements of CLIA.

A. Requirements for Approving an Accreditation Organization Under CLIA

To determine whether CMS should grant approval to CAP as a private, nonprofit organization for accrediting laboratories under CLIA for all requested specialty, and subspecialty areas of human specimen testing, we conducted a detailed and in-depth comparison of CAP's laboratory requirements to CLIA laboratory requirements. Our evaluation determined whether CAP meets the following requirements:

- 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 (for the requested specialties and subspecialties) 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.
- Meets the applicable requirements of 42 CFR part 493, subpart E.

As specified in the regulations of 42 CFR part 493, subpart E, our review of a private, nonprofit accreditation organization seeking approved status under CLIA, includes, but is not limited to, an evaluation of the following:

- 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.

—Comparability of the organization's full inspection and complaint inspection requirements to the Federal requirements including, but not limited to inspection frequency, and the ability to investigate and respond to complaints against its accredited laboratories.

—Organization's procedures for monitoring laboratories that are out of compliance with its requirements.

—Organization's ability to provide CMS with electronic data and reports that are necessary for effective validation and assessment of the organization's inspection process.

—Organization's ability to provide CMS with electronic data related to the adverse actions resulting from unsuccessful proficiency testing (PT) participation in CMS-approved PT programs, as well as, data related to the PT failures, within 30 days of the initiation of the action.

—Ability of the organization to provide CMS with electronic data for all its accredited laboratories, and the areas of specialty and subspecialty testing.

—Adequate numbers of staff and other resources.

—Organization's ability to provide adequate funding for performing the required inspections.

- The organization's agreement with CMS that requires it, among other things, to meet the following requirements:

—Notify CMS of any laboratory that has had its accreditation denied, limited, suspended, withdrawn, or revoked by the accreditation organization, or any other adverse action taken against it by the accreditation organization within 30 days of such action.

—Notify CMS within 10 days of a deficiency identified in an accredited laboratory if the deficiency poses an immediate jeopardy to the patients of the laboratory or a hazard to the general public.

—Notify CMS 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 CMS's withdrawal of approval of the organization as an accreditation organization.

—Provide CMS with inspection schedules as requested, for the purpose of conducting onsite validation inspections.

—Provide our agent, the State survey agency, or CMS with any facility-specific data that includes, but is not limited to, PT results that constitute unsuccessful participation in an approved PT program and notification

of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation.

—Provide CMS with written notification at least 30 days in advance of the effective date of any proposed changes in its requirements.

—Provide upon the request by anyone, on a reasonable basis (and subject to applicable State law concerning disclosure of confidential information), any laboratory's PT results with the explanatory information needed to assist in the interpretation of the results.

Laboratories that are accredited by an approved accreditation organization, among other things must comply with the following requirements:

• Authorize the organization to release to CMS all records and information required.

• Permit inspections as required by the CLIA regulations at 42 CFR part 493, subpart Q (Inspection).

• Obtain a certificate of accreditation as required by § 493.55 (Application for registration certificate and certificate of accreditation).

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

CMS has examined CAP's assurance that it requires the laboratories it accredits to be, and that the organization is in compliance with the following subparts of part 493:

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

CAP has requested continued approval to accredit all specialties and subspecialties, and has submitted the following:

• Description of its inspection process, policies, PT monitoring process, and data management and analysis system.

• List of its inspection team size, composition, and education and experience.

• Investigative and complaint response procedures.

• CMS's notification agreements.

• Procedures for the removal or withdrawal of accreditation from a laboratory.

• Current list of accredited laboratories with announced or unannounced inspection process.

We have determined that CAP has complied with the requirements under CLIA for approval as an accreditation organization under this subpart.

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 the directors of its accredited laboratories to sign an attestation that their laboratory(ies) are in compliance with all applicable Federal, State, and local laws.

• CAP lists extensive requirements for the Laboratory Information System (LIS) that include but, are not limited to the following areas:

—Preservation, storage, and retrieval of laboratory and patient data.

—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.

—Maintenance of the LIS facility (must be clean, well ventilated, and at proper temperature and humidity).

—Protection of LIS against power interruptions and surges.

—Readily available procedure manuals for LIS operators, adequately trained operators that know how to preserve data and equipment in emergency situations (for example, fire, software or hardware failure).

—Protection of the LIS, its data, patient information, and programs from unauthorized use.

—Entry of data and result reporting.

—Verification and maintenance of LIS hardware and software.

—Routine and emergency service and maintenance of the LIS.

—Evaluation from the laboratory director of the LIS performance as it pertains to patient and clinician needs.

• CAP accredits laboratories that perform testing for any of the following areas and sets specific standards with which accredited laboratories must comply:

—Athletic drug testing (for anabolic steroids, beta-blackers, cannabinoids, narcotics, and stimulants).

—Forensic urine drug testing.

—Parentage testing.

—Reproductive laboratory testing (embryology).

2. Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

The CAP requirements for PT are in conformance with the CLIA statute that states the standards accreditation organizations must 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 in Subpart I that lists specific tests in which the laboratory must enroll and participate in a CMS-approved PT program. CLIA exempts waived testing from PT, whereas CAP requires its accredited laboratories to participate in a CMS-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) PT performance are equivalent to those of CLIA and that the actions taken to correct unsuccessful (2 in a row or 2 out of 3 failures) PT performance of its laboratories are more stringent than those of CLIA. CAP utilizes 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. The response must indicate 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 that is necessary to correct problems associated with an unsatisfactory score, take remedial action, and document all steps taken.

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 problem, and the actions taken to correct the problem. The laboratory must submit this information within 10 working days. If, after review by CAP, it is determined that the laboratory's subsequent PT performance is within acceptable limits, no further action is taken. If the laboratory does not respond, fails to seriously address the problem, or cannot bring performance into acceptable limits, the CAP would evaluate the situation and either request that the laboratory cease testing for the analyte, specialty, or subspecialty in question, or, if warranted, revoke accreditation.

CLIA regulations allow a laboratory to undertake training of its personnel or to obtain technical assistance or both, when the initial unsuccessful PT performance occurs instead of imposing alternative or principal sanctions.

CAP also requires its accredited laboratories performing GYN cytology to participate in its external quality assurance program for PAP smear cytology. The Interlaboratory Comparison Program in Cervicovaginal Cytopathology currently enrolls all of CAP's 2,793 accredited laboratories that perform GYN cytology. This program is a cervicovaginal cytopathology proficiency testing survey, in which all CAP accredited laboratories are required to participate. Currently there is no CMS-approved cytology PT program capable of enrolling all CLIA certified laboratories that perform GYN cytology testing.

3. Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity or Any Combination of These Tests

The CAP requirements are equivalent to the CLIA requirements at §§ 493.1101 through 493.1111. We have determined that CAP's requirements for an accredited laboratory include on report forms the dates and times of specimen collection (when appropriate), is more stringent than the requirements under CLIA.

4. Subpart K—Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests

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 the QC requirements of CAP are more stringent than the CLIA requirements, when taken as a whole. Some specific areas of QC that are more stringent are as follows:

• The CAP laboratory safety requirements are specific and detailed.

—Environmental safety requirements address electrical voltage, facility ventilation, lighting, temperature, humidity, emergency power source, and require remedial actions to be taken when necessary.

—Requirements are in place for handling and disposal of biohazardous materials, fire safety and prevention of fire hazards, and OSHA regulations related to laboratories.

• The CAP requires procedure manuals to include the principal and clinical significance for each test, and their procedure manuals must include documentation of initial and annual reviews.

• 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 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 also must be evaluated for silicone levels.

• CAP accredited laboratories must verify all volumetric glassware and pipettes for accuracy and reproductability before use, and must 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, for example, 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.

• 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.

• CAP retention requirements are the same or longer than those of CLIA.

5. Subpart M—Personnel for Moderate and High Complexity (Including the Subcategory) 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 holds all technical personnel in its accredited laboratories to the CLIA high complexity personnel requirements. Therefore, we have determined that the personnel requirements of the CAP are more stringent than the personnel requirements of CLIA, when taken as a whole.

6. Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests

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

7. Subpart Q—Inspection

We have determined that the CAP inspection requirements, taken as a whole, are equivalent to the CLIA inspection requirements. CAP has continued its Laboratory Accreditation Programs Inspection Training Seminars program. In the year 2000, there were 8 regional training programs held (hosting 747 participants) and 13 national training programs (hosting 433 participants) with 12 ad hoc training sessions presentations. In addition, 4 audio training conferences were held in which 6,351 inspection team leaders and team members participated.

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

CAP requires a mid-cycle self-inspection of all accredited laboratories. All requirements for the mid-cycle self-inspection must be responded to in writing, and the responses must be submitted to CAP within a specified timeframe. CLIA regulations do not have this requirement.

8. Subpart R—Enforcement Procedures

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. As demonstrated during its first period of approval, CAP denies accreditation to a laboratory when appropriate, and reports the denial to CMS within 30 days. CAP also provides an appeal 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 is identified as having intentionally referred a PT specimen to another laboratory for analysis, the CAP laboratory will be denied accreditation and be ineligible for CAP accreditation for 1 year. This action is similar to the CMS action of denial of certification for 1 year.

• When a CAP accredited laboratory participates unsuccessfully in PT for an analyte, subspecialty, or specialty, the laboratory must initiate corrective actions. The laboratory must submit to CAP documentation of a detailed investigation of the problem causing the unsuccessful performance with a corrective action plan within 10 working days. Specific educational activity or the retention of the services of a consultant may be imposed. Failure to bring PT performance into acceptable limits or failure to seriously address the PT problem 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 equivalent to the actions that CMS may take under this section.

• When CAP becomes aware of a problem in an accredited laboratory that is so severe and extensive that it could cause a serious risk of harm (immediate jeopardy) situation, 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 CMS 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 CMS, but no longer than 12 months. CLIA deficiencies that are condition level that are not considered immediate jeopardy must be corrected in an acceptable timeframe; however, CMS 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 may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (complaint inspections). The outcome of those validation inspections, performed by our agent, the State survey agency, or us, will be CMS's principal means for verifying that the laboratories accredited by CAP remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may remove the approval of an accreditation organization (for example, CAP) for cause, before the end of the effective date of approval. If validation inspection outcomes, and the comparability, or validation review produce findings as described in § 493.573 (Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure program), CMS will conduct a review of an approved accreditation organization's program. In addition, we will conduct a review, when the validation review findings, irrespective of the rate of disparity (as defined in § 493.2), indicate systematic 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 CMS determines that CAP has failed to adopt or maintain requirements that are equal to, or more stringent than, the CLIA requirements, or systematic problems exist, CMS may give a probationary period, not to exceed 1 year, to CAP to adopt equal, or more stringent requirements. CMS will determine whether CAP retains its approved status as an accreditation organization under CLIA. If approved status is withdrawn, an accreditation organization such as CAP may resubmit its application to CMS if it revises its program to address the rationale for the denial, demonstrates 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. However, if an approved accreditation organization requests reconsideration of an adverse determination in accordance with subpart D (Reconsideration of Adverse Determinations—Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs) of part 488 (Survey, Certification, and Enforcement Procedures) of our regulations, it may not submit a new application until CMS issues a final reconsideration determination. If circumstances result in CAP having its approval withdrawn, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

Federalism

We have reviewed this notice under the threshold criteria of Executive Order 13132, Federalism, and have determined that this notice will not have any negative impact on the rights, roles, and responsibilities of State, local, or tribal governments.

OMB Review

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: July 18, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–22822 Filed 9–11–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), (**Federal Register**, Vol. 62, No. 85, pp. 24120–24126 dated Friday, May 2, 1997) is amended to reflect changes to the organizational structure of CMS by replacing the Center for Beneficiary Services and the Center for Health Plans and Providers with the Center for Beneficiary Choices and the Center for Medicare Management. Also, it transfers managed care audit responsibility from the Office of Financial Management to the Center for Beneficiary Choices, and