

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]

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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

also transfers the Quality Measurement and Health Assessment Group from the Office of Clinical Standards and Quality to the Center for Beneficiary Choices.

The specific amendments to part F are described below:

- Section F.10. (Organization) is amended to read as follows:

1. Press Office (FAC)
2. Center for Beneficiary Choices (FAE)
3. Office of Legislation (FAF)
4. Center for Medicare Management (FAH)
5. Office of Equal Opportunity and Civil Rights (FAJ)
6. Office of Strategic Planning (FAK)
7. Office of Communications and Operations Support (FAL)
8. Office of Clinical Standards and Quality (FAM)
9. Office of the Actuary (FAN)
10. Center for Medicaid and State Operations (FAS)
11. Northeastern Consortium (FAU)
12. Southern Consortium (FAV)
13. Midwestern Consortium (FAW)
14. Western Consortium (FAX)
15. Office of Internal Customer Support (FBA)
16. Office of Information Services (FBB)
17. Office of Financial Management (FBC)

- Section F.20. (Functions) is amended by deleting the functional statements in their entirety for the Center for Beneficiary Services, Center for Health Plans and Providers, and the Quality Measurement and Health Assessment Group within the Office of Clinical Standards and Quality. The new functional statements read as follows:

2. Center for Beneficiary Choices (FAE)

- Serves as the focal point for all Agency interactions with beneficiaries, their families, care givers, health care providers, and others operating on their behalf concerning improving beneficiary ability to make informed decisions about their health and about program benefits administered by the Agency. These activities include strategic and implementation planning, execution, assessment, and communications.

- Assesses beneficiary and other consumer needs, develops and oversees activities targeted to meet these needs, and documents and disseminates results of these activities. These activities focus on Agency beneficiary service goals and objectives and include: development of baseline and ongoing monitoring information concerning populations affected by Agency programs; development of performance measures and assessment programs; design and implementation of beneficiary services

initiatives; development of communications channels and feedback mechanisms within the Agency and between the Agency and its beneficiaries and their representatives; and close collaboration with other Federal and state agencies and other stakeholders with a shared interest in better serving our beneficiaries.

- Develops national policy for all Medicare Parts A, B, and C beneficiary eligibility, enrollment, and entitlement; rights and protections; dispute resolution process; as well as policy for managed care enrollment and disenrollment to ensure the effective administration of the Medicare program, including the development of related legislative proposals.

- Oversees the development of privacy and confidentiality policies pertaining to the collection, use, and release of individually identifiable data.

- Coordinates beneficiary centered information, education, and service initiatives.
- Develops and tests new and innovative methods to improve beneficiary aspects of health care delivery systems through Title XVIII, XIX, and XXI demonstrations and other creative approaches to meeting the needs of Agency beneficiaries.

- Ensures that, in coordination with other Centers and Offices, the activities of Medicare contractors, including managed care plans, agents, and state agencies, meet the Agency's requirements on matters concerning beneficiaries and other consumers.

- Plans and administers the contracts and grants related to beneficiary and customer service, including the State Health Insurance Assistance Program grants.

- Formulates strategies to advance overall beneficiary communications goals and coordinates the design and publication process for all beneficiary centered information, education, and service initiatives.

- Builds a range of partnerships with other national organizations for effective consumer outreach, awareness, and education efforts in support of Agency programs.

- Serves as the focal point for all Agency interactions with managed health care organizations for issues relating to Agency programs, policy, and operations.

- Develops national policies and procedures related to the development, qualification, and compliance of health maintenance organizations, competitive medical plans and other health care delivery systems and purchasing arrangements (such as prospective pay, case management, differential payment,

selective contracting, etc.) necessary to ensure the effective administration of the Agency's programs, including the development of statutory proposals.

- Handles all phases of contracts with managed health care organizations eligible to provide care to Medicare beneficiaries.

- Coordinates the administration of individual benefits to ensure appropriate focus on long-term care, where applicable, and assumes responsibility for the operational and demonstration efforts related to the payment aspects of long-term care and post-acute care services.

- Designs and conducts payment, purchasing, and benefits demonstrations.

4. Center for Medicare Management (FAH)

- Serves as the focal point for all Agency interactions with health care providers, intermediaries, and carriers for issues relating to Agency fee-for-service (FFS) policies and operations.

- Monitors providers' and other entities' conformance with quality standards (other than those directly related to survey and certification); policies related to scope of benefits; and other statutory, regulatory, and contractual provisions.

- Based on program data, develops payment mechanisms, administrative mechanisms, and regulations to ensure that CMS is purchasing medically necessary services under FFS.

- Writes payment and benefit-related instructions for Medicare contractors.

- Defines the scope of Medicare benefits and develops national FFS payment policies, as necessary, to ensure the effective administration of the Agency's programs, including the development of related statutory proposals.

- Develops Agency medical coding policies related to FFS payments.

- Provides administrative support to the Practicing Physician Advisory Council.

- Coordinates provider, physician, and contractor centered information, education, and service initiatives.
- Serves as the CMS lead for Medicare carrier and fiscal intermediary (FI) management, oversight, budget, and performance issues.

- Functions as CMS liaison for all Medicare carrier and FI program issues and, in close collaboration with the regional offices and other CMS components, coordinates the agency-wide contractor activities.

- Manages contractor instructions, workload, and change management process.

- Collaborates with other CMS components to establish ongoing performance expectations for Medicare contractors (carriers and FIs) consistent with the agency's goals; interprets, evaluates, and provides information on Medicare contractors in terms of ongoing compliance with performance requirements and expectations; evaluates compliance with issued instructions; evaluates contractor-specific performance and/or integrity issues; and evaluates/monitors corrective action, if necessary.

- Manages, monitors, and provides oversight of contractor (carriers and FIs) transition activities including replacement of departing contractors and the resulting transfer of workload, functional realignments, and geographic workload carveouts.

- Maintains and provides accurate contractor specific information.

Develops and implements long-term FFS contractor strategy, tactical plans, and other planning documents.

- Serves as lead on current/proposed legislation in order to determine impact on provider and contractor operations.

- Develops national policy and implementation of all Medicare Part A, Part B, and Part C premium billing and collection activities and coordination of benefits to assure effective administration of FFS aspects of the Medicare program.

Dated: September 6, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01-22821 Filed 9-11-01; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

Endangered Species

The public is invited to comment on the following application(s) for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*). Written data, comments, or requests for copies of these complete applications should be submitted to the Director (address below) and must be received within 30 days of the date of this notice.

Applicant: The Dallas World Aquarium, Dallas, TX, PRT-043800.

The applicant requests a permit to import 1.1 captive held giant river otter,

Pteronura brasiliensis, currently being held in Venezuela, for the purpose of enhancement of the survival of the species through captive propagation and conservation education.

Applicant: Edward E. Seager, Bedford, PA, PRT-047589.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Richard M. Welch, Mechanicsville, TX, PRT-047505.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Patrick B. Sands, Dallas, TX, PRT-047504.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

The U.S. Fish and Wildlife Service has information collection approval from OMB through March 31, 2004, OMB Control Number 1018-0093. Federal Agencies may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a current valid OMB control number.

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203, telephone 703/358-2104 or fax 703/358-2281.

Dated: August 31, 2001.

Monica Farris,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. 01-22902 Filed 9-11-01; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Outer Continental Shelf (OCS), Central and Western Gulf of Mexico, Oil and Gas Lease Sales for Years 2002-2007

AGENCY: Minerals Management Service, Interior.

ACTION: Call for information and nominations, Notice of intent to prepare an environmental impact statement.

SUMMARY: MMS proposes to adopt a multisale process for the Central and Western Gulf of Mexico (GOM) sales in the 2002-2007 OCS Oil and Gas Leasing Program. This single multisale process will cover all proposed sales in both planning areas. The Call, the initial step in the process, will cover ten sales—five Central GOM sales and five Western GOM sales. There will also be complete National Environmental Policy Act, OCS Lands Act, and Coastal Zone Management Act coverage for each sale. We propose to prepare an Environmental Assessment for Sale 184, Western GOM, tiering off the previous multisale EIS for Western GOM Sales. We propose to prepare one multisale EIS for the remaining nine Central and Western GOM sales in the 2002-2007 OCS Leasing Program.

DATES: Nominations and comments must be received no later than October 12, 2001.

FOR FURTHER INFORMATION CONTACT: For information on the Call for Information and Nominations, please contact Ms. Jane Burrell Johnson, Minerals Management Service, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123-2394, telephone (504) 736-2811. For information on the Notice of Intent to Prepare an EIS, please contact, Mr. Joseph Christopher, Minerals Management Service, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123-2394, telephone (504) 736-2788.

SUPPLEMENTARY INFORMATION: In 1996, MMS adopted multisale processes for sales in the Central and Western GOM. The multisale process for each planning area incorporated prelease planning and analysis steps for all sales proposed in the 1997-2002 OCS Oil and Gas Leasing Program (except for the first sale in the Western GOM, which was covered in a previous Call and EIS). MMS proposes to adopt a similar process for the Central and Western GOM sales in the 2002-2007 OCS Oil and Gas Leasing Program. For the Proposed 5-Year Program, a single multisale process will cover all proposed sales in both planning areas.