

Cronin, Chairperson, Advisory Panel on Medicare Education; Joyce Dubow, M.U.P., Senior Policy Advisor, Public Policy Institute, AARP; Jennie Chin Hansen, Executive Director, On Lok Senior Health Services; Elmer Huerta, M.D., M.P.H., Director, Cancer Risk and Assessment Center, Washington Hospital Center; Bonita Kallestad, J.D., M.S., Mid Minnesota Legal Assistance; Steven Larsen, J.D., M.A., Maryland Insurance Commissioner, Maryland Insurance Administration; Brian Lindberg, M.M.H.S., Executive Director, Consumer Coalition for Quality Health Care; Heidi Margulis, B.A., Vice President, Government Affairs, Humana, Inc.; Patricia Neuman, Sc.D., Director, Medicare Policy Project, Henry J. Kaiser Family Foundation; Elena Rios, M.D., M.S.P.H., President, National Hispanic Medical Association; Samuel Simmons, B.A., President and CEO, The National Caucus and Center on Black Aged, Inc.; Nina Weinberg, M.A., President, National Health Council; and Edward Zesk, B.A., Executive Director, Aging 2000.

The agenda for the February 14, 2002 meeting will include the following:

- A recap of the previous (October 25, 2001) meeting;
- CMS update/issues;
- Update on the Fall Medicare Ad Campaign;
- Update on the State Health Insurance Assistance Program;
- Medicare Education Research Update;
- APME Annual Report;
- Public comment.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should contact Ms. Caliman by 12 noon, Thursday, February 7, 2002. In conjunction, a written copy of the oral presentation should also be submitted to Ms. Caliman by 12 noon, Thursday, February 7, 2002. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to Ms. Caliman by 12 noon, Thursday, February 7, 2002. The meeting is open to the public, but attendance is limited to the space available. Individuals requiring sign language interpretation for the hearing impaired or other special accommodation should contact Ms. Caliman at least 15 days before the meeting.

(Section 222 of the Public Health Service Act (42 USC 217a) and section 10(a) of Public Law 92-463 (5 U.S.C. App. 2, section 10(a) and 41 CFR 102-3))

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital

Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 14, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02-1687 Filed 1-18-02; 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. 66, No. 177, pp. 47497-47499 dated September 12, 2001) is amended to reflect changes to the Press Office and the Center for Medicaid and State Operations (CMSO). Specifically, the Press Office will be retitled as the Public Affairs Office (PAO) and the Intergovernmental and Tribal Affairs Group (ITAG) will be transferred from CMSO. The transfer of ITAG from CMSO to PAO will strengthen and improve the coordination of responses to the press, and local/national media, while integrating the State, local government, and tribal affairs programs into the PAO media relations and communications activities.

The specific amendments to part F are described below:

- Section F.10. (Organization) is amended to read as follows:
 1. Public Affairs 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 Press Office and the Center for Medicaid and State Operations. The new functional statements read as follows:

1. Public Affairs Office (FAC)

- Serves as the focal point for the Agency to the news media and provides leadership for the Agency in the area of intergovernmental affairs. Advises the Administrator and other Agency components in all activities related to the media and on matters which affect other units and levels of government.
- Coordinates CMS activities with the Office of the Assistant Secretary for Public Affairs and the Secretary's intergovernmental affairs officials.
- Serves as senior counsel to the Administrator in all activities related to the media. Provides consultation, advice, and training to the Agency's senior staff with respect to relations with the news media.
- Develops and executes strategies to further the Agency's relationship and dealings with the media. Maintains a broad based knowledge of the Agency's structure, responsibilities, mission, goals, programs, and initiatives in order to provide or arrange for rapid and accurate response to news media needs.
- Prepares and edits appropriate materials about the Agency, its policies, actions and findings, and provides them to the public through the print and broadcast media. Develops and directs media relations strategies for the Agency.
- Responds to inquiries from a broad variety of news media, including major newspapers, national television and radio networks, national news magazines, local newspapers and radio and television stations, publications directed toward the Agency's beneficiary populations, and newsletters serving the health care industry.
- Manages press inquiries, coordinates sensitive press issues, and develops policies and procedures for how press and media inquiries are handled.
- Arranges formal interviews for journalists with the Agency's Administrator or other appropriate senior Agency staff; identifies for interviewees the issues to be addressed, and prepares or obtains background materials as needed.
- For significant Agency initiatives, issues media advisories and arranges press conferences as appropriate; coordinates material and personnel as necessary.

- Serves as liaison with the Department of Health and Human Services and White House press offices.
- Serves as focal point for all Agency interactions with Native American and Alaskan Native tribes.
- Coordinates State program issues/concerns (i.e., waiver reviews, Medigap, Medicare-Select, survey and certification, Clinical Laboratory Improvement Act (CLIA), tribal affairs) with program staff and regional offices.
- Serves as coordinator of State health care policy and as liaison between CMS and State and local officials, and individual lobbyists representing State and local officials and advocate groups.
- Serves as coordinator of tribal affairs issues and liaison between CMS and State and local officials representing tribal affairs groups.
- Responsible for handling highly sensitive and complex correspondence from and to State and local elected officials. Reviews proposed regulations affecting States.
- Coordinates roll-out of waivers or other significant announcements relating to States.

10. Center for Medicaid and State Operations (FAS)

- Serves as the focal point for all Agency interactions with States and local governments (including the Territories).
- Develops national Medicaid policies and procedures which support and assure effective State program administration and beneficiary protection. In partnership with the States, evaluates the success of State agencies in carrying out their responsibilities and, as necessary, assists the States in correcting problems and improving the quality of their operations.
- Develops, interprets, and applies specific laws, regulations, and policies that directly govern the financial operation and management of the Medicaid program and the related interactions with the States and regional offices.
- Develops national policies and procedures to support and assure appropriate State implementation of the rules and processes governing group and individual health insurance markets and the sale of health insurance policies that supplement Medicare coverage.
- In coordination with other components, develops, implements, evaluates and refines standardized provider performance measures used within provider certification programs. Supports States in their use of standardized measures for provider

feedback and quality improvement activities. Develops, implements and supports the data collection and analysis systems needed by States to administer the certification program.

- Reviews, approves and conducts oversight of Medicaid managed care waiver programs. Provides assistance to States and external customers on all Medicaid managed care issues.
- Develops national policies and procedures on Medicaid automated claims/encounter processing and information retrieval systems such as the Medicaid Management Information System (MMIS) and integrated eligibility determination systems.
- In coordination with the Office of Financial Management, directs, coordinates, and monitors program integrity efforts and activities by States and regions. Works with the Office of Financial Management to provide input in the development of program integrity policy.
- Through administration of the home and community based services program and policy collaboration with other Agency components and the States, promotes the appropriate choice and continuity of quality services available to frail elderly, disabled and chronically ill beneficiaries.
- Develops and tests new and innovative methods to improve the Medicaid program through demonstrations and best practices including managing review, approval, and oversight of the Section 1115 demonstrations.

- Directs the planning, coordination, and implementation of the survey, certification, and enforcement programs for all Medicare and Medicaid providers and suppliers, and for laboratories under the auspices of the Clinical Laboratory Improvement Act (CLIA). Reviews and approves applications by States for "exemption" from CLIA and applications from private accreditation organizations for deeming authority. Develops assessment techniques and protocols for periodically evaluating the performance of these entities. Monitors the performance of proficiency testing programs under the auspices of CLIA.

Dated: January 2, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02-1064 Filed 1-24-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0399]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Rapid Response Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by February 25, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Rapid Response Surveys (OMB Control No. 0910-0457)—Extension

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries, and malfunctions, and user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health, or gross deception of the consumer. Section 903(d)(2) of the act (21 U.S.C. 393(d)(2)) authorizes the