Dated: February 28, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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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. 72, No. 248, pp. 73847–73850, dated Friday, December 28, 2007) is amended to reflect updates to the functions for the Center for Beneficiary Choices and the Office of E-Health Standards and Services.

Part F. is described below:

• Section F. 20. (Functions) reads as follows:

Center for Beneficiary Choices (FAE)

• Serves as Medicare Beneficiary Ombudsman, as well 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's 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, C and D beneficiary eligibility, enrollment, entitlement; premium billing and collection; coordination of benefits; rights and protections; dispute resolution process; as well as policy for managed care enrollment and disenrollment to assure the effective administration of the Medicare program, including the development of related legislative proposals.

• 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.

• Assures, 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 assure 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 assure appropriate focus on long term care, where applicable, and assumes responsibility for the operational efforts related to the payment aspects of long term care and post-acute care services.

• Serves as the focal point for all Agency interactions with employers, employees, retirees and others operating on their behalf pertaining to issues related to Agency policies and operations concerning employer sponsored prescription drug coverage for their retirees.

• 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.

• Primarily responsible for all operations related to Medicare Prescription Drug Plans and Medicare Advantage Prescription Drug (Part D) plans.

• Performs activities related to the Medicare Parts A & B processes (42 CFR part 405, subparts G and H), part C (42 CFR part 422, subpart M), part D (42 CFR part 423, subpart M) and the PACE program for claims-related hearings, appeals, grievances and other dispute resolution processes that are beneficiary-centered.

• Develops, evaluates, and reviews regulations, guidelines, and instructions required for the dissemination of appeals policies to Medicare beneficiaries, Medicare contractors, Medicare Advantage (MA) plans, Prescription Drug Plans (PDPs), CMS regional offices, beneficiary advocacy groups and other interested parties.

Office of E-Health Standards and Services (FHA)

• Develops and coordinates implementation of a comprehensive e-health strategy for CMS. Coordinates and supports internal and external technical activities related to e-health services and ensures that individual initiatives tie to the overall agency and Federal
e-health goals strategies.

• Promotes and leverages innovative component initiatives. Facilitates cross-component awareness of various e-health projects.

• Develops regulations and guidance materials, and provides technical assistance on the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), including transactions, code sets, identifiers, and security.

• Develops and implements the enforcement program for HIPAA

Administrative Simplification provisions.

• Develops and implements an outreach program for HIPAA Administrative Simplification provisions. Formulates and coordinates a public relations campaign, prepares and delivers presentations and speeches, responds to inquiries on HIPAA issues, and maintains liaison with industry representatives.

• Adopts and maintains messaging and vocabulary standards supporting electronic prescribing under Medicare Part D.

• Serves as agency point of reference on Federal and private sector e-health initiatives. Works with Federal departments and agencies to identify and adopt universal messaging and clinical health data standards, and represents CMS and HHS in national projects supporting the national health enterprise architecture and the national health information infrastructure.

• Coordinates and provides guidance on legislative and regulatory issues related to e-health standards and services.

• Collaborates with HHS on policy issues related to e-health standards, and serves as the central point of contact for the Office of the National Coordinator for Health Information Technology.

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

Dated: October 19, 2007.

Karen Pelham O'Steen,

Director, Office of Operations Management, Centers for Medicare & Medicaid Services.

Editorial Note: This document was received at the Office of the Federal Register on Tuesday, March 4, 2008.

[FR Doc. E8–4585 Filed 3–6–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0146]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements for Collection of Data Relating to the Prevention of Medical Gas Mix-ups at Health Care Facilities-Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on measures, taken by certain health care medical facilities that use medical oxygen, to present mix-ups with other gases.

DATES: Submit written or electronic comments on the collection of information by May 6, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Requirements for Collection of Data Relating to the Prevention of Medical Gas Mix-ups at Health Care Facilities-Survey—(OMB Control Number 0910–0548)—Extension

FDA has received four reports of medical gas mix-ups occurring during the past 9 years. These reports were received from hospitals and nursing homes and involved 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but who were actually receiving a different gas (e.g., nitrogen, argon) that had been mistakenly connected to the facility's oxygen supply system. In 2001, FDA published guidance making recommendations to help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mix-ups and alerting these facilities to the hazards. This survey is intended to assess the degree of facilities' compliance with safety measures to prevent mix-ups, to determine if further steps are warranted to ensure the safety of patients.

FDA estimates the burden of this collection of information as follows: