

Nevertheless, the Commission believes it is primarily small businesses that will benefit from the publication of the policy because they, unlike larger businesses, may be unaware that self-reporting and seeking a one-time reprieve from relabeling is an option. For that reason, the Commission has used Section 223 of SBREFA as a model. Section 223 of SBREFA requires that agencies establish policies to reduce or waive penalties for small entities in appropriate circumstances. The primary goal of this provision is to foster a more cooperative, less threatening regulatory environment for small entities. Although the Commission has already established the policies required by SBREFA, it believes that the proposed corporate leniency policy for violations of the Textile and Wool Rules will also foster a more cooperative, less threatening regulatory environment for small entities. In addition, the Commission believes that the informal policy developed by Commission staff has resulted in more compliance with the Textile and Wool Rules because it has encouraged self-reporting of violations and subsequent reform of internal company policies to avoid future violations. The Commission believes that the policy announced today will also result in more compliance with those rules for the same reason.

IV. Request for Comments

Members of the public are invited to comment on any issues or concerns that they believe are relevant or appropriate to the policies described above. The Commission requests that factual data upon which the comments are based be submitted with the comments. In this section, the Commission identifies specific issues on which it solicits public comments. This list is designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted.

Questions

(1) Should the Commission revise in any way the corporate leniency policy that it has announced? (e.g., should the policy be revised to include other possible violations, such as catalog disclosure requirements?) If so, please provide specific suggestions.

(2) How would the revisions affect the benefits provided by the policy?

(3) Are any of the criteria that the Commission has used in establishing the leniency policy inappropriate? If so, please explain.

(4) Are there any other criteria that the Commission should use? If so, please elaborate.

Such comments may be filed until December 31, 2002.

Authority: 38 Stat. 717, as amended, 15 U.S.C. 41 *et seq.*; 15 U.S.C. 68 *et seq.*; 15 U.S.C. 70 *et seq.*

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Public Health Emergency Preparedness; Office of Public Health and Science; Statement of Organization, Functions and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS) is being amended at Chapter AA, Immediate Office of the Secretary, Chapter AN, "Office of the Assistant Secretary for Public Health Emergency Preparedness (OASPHEP)"; Chapter AB, Deputy Secretary, Chapter ABC as last amended at 66 FR 40288, dated August 2, 2001; and Chapter AC, the "Office of Public Health and Science (OPHS)" as last amended at 67 FR 48903-48905, dated 7/26/2002; and ACK "Office of the Surgeon General (OSG)," OPHS, as last amended at 60 FR 56606-06, dated November 9, 1995. This organizational change is primarily to realign the functions of the OASPHEP to more clearly delineate responsibilities for the various activities associated with emergency preparedness and response. The changes are as follows:

I. Under Part A, Chapter AN, "Office of the Assistant Secretary for Public Health Emergency Preparedness," delete in its entirety and replace with the following:

Office of the Assistant Secretary for Public Health Emergency Preparedness (AN)

AN.00 Mission

AN.10 Organization

AN.20 Functions

Section AN.00 Mission. On behalf of the Secretary, the Office of the Assistant Secretary for Public Health Emergency Preparedness (OASPHEP) directs and coordinates HHS-wide efforts with

respect to preparedness for and response to bioterrorism and other public health emergencies. OASPHEP will direct the National Disaster Medical System (NDMS) and any other emergency response activities within the Department of Health and Human Services that are related to bioterrorism and other public health emergencies. OASPHEP is responsible for ensuring a "One-Department" approach to developing such preparedness and response capabilities and directs and coordinates relevant activities of the OPDIVs.

Section AN.10 Organization. The Office of the Assistant Secretary for Public Health Emergency Preparedness (OASPHEP) is headed by an Assistant Secretary for Public Health Emergency Preparedness (ASPHEP), who reports directly to the Secretary, and includes the following components:

- Immediate Office of the ASPHEP (ANA)
- Office of Research and Development Coordination (ANB)
- Office of Emergency Response (ANC)
- Office of Planning and Emergency Response Coordination (ANE)
- Office of State and Local Preparedness (ANF)

Section AN.20 Functions

1. *Immediate Office of the Assistant Secretary for Public Health and Emergency Preparedness (ANA).* The Immediate Office of the ASPHEP provides executive and administrative direction to OASPHEP components. The ASPHEP is the principal advisor to the Secretary on matters relating to bioterrorism and other public health emergencies. The ASPHEP coordinates interagency interfaces between HHS and other Departments, agencies, offices of the United States and state and local entities with responsibility for emergency preparedness and direct activities relating to protecting the civilian population from acts of bioterrorism and other public health emergencies. The ASPHEP provides the necessary leadership and coordinates activities for emergency preparedness matters internal to the Office of the Secretary's components and represents the HHS in working closely with the **Federal Emergency Management Agency** and other Federal departments and agencies. OASPHEP acts as the lead Federal agency for Emergency Support Function #8 within the Federal Response Plan.

2. *Office of Research and Development Coordination (ANB).* The Office of Research and Development Coordination (ORDC) is headed by a Director and is responsible for research

and development toward new vaccines, diagnostics, and drugs related to the pathogenic organisms most likely to be used in a terrorist attack on the U.S. homeland. A key function of ORDC is to direct and coordinate activities related to the development of vaccines and other pharmaceuticals to be included in the National Pharmaceutical Stockpile. ORDC supports the ASPHEP by working with all scientific agencies of the Department, including the National Institutes of Health (NIH), the Centers of Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), as well as other governmental, private, and non-profit scientific entities.

3. *Office of Emergency Response (ANC)*. The Office of Emergency Response (OER) is responsible for supporting the interdepartmental NDMS Senior Policy Group and Directorate Staff; enrolling Disaster Medical Assistance Teams (DMAT), Disaster Mortuary Operational Response Teams (DMORT), National Medical Response Teams (NMRT), Veterinary Medical Assistant Teams (VMAT), International Medical Surgical Response Teams (IMSURT) and specialty team volunteers; maintaining the national NDMS data base; and supporting NDMS personnel requirements during training exercises and deployments; credentialing for NDMS team members; developing and implementing policies, procedures, and guidance for NDMS; developing and coordinating of web-based training and development and implementation of field training for NDMS; overseeing Federal Coordinating Centers; facilitating hospital claims processing; interfacing with and supporting the Metropolitan Medical Response Systems localities; and development of the yearly NDMS conference.

a. *The Division of Emergency Response Operations (ANC1)*: The Division of Emergency Response Operations (DERO) is responsible for developing national DMATs, DMORTs, NMRTs, VMATs, IMSURTs, and specialty teams capable of dealing with health and medical consequences of natural and man-made disasters, and terrorist incidents involving mass casualties, improving the communications infrastructure to support NDMS field response resources, especially for mass casualty incidents; maintaining the equipment required for emergency responses; and managing the Emergency Operations Center.

1. *National Disaster Medical System (NDMS) Branch (ANC11)*: NDMS Branch is responsible for supporting the interdepartmental NDMS Senior Policy

Group and Directorate Staff; enrolling Disaster Medical Assistance Teams (DMAT), Disaster Mortuary Operational Response Teams (DMORT), National Medical Response Teams (NMRT), Veterinary Medical Assistant Teams (VMAT), International Medical Surgical Response Teams (IMSURT) and specialty team volunteers; maintaining the national NDMS data base; supporting NDMS personnel requirements during training exercises and deployments; credentialing for NDMS team members; developing and implementing policies, procedures, and guidance for NDMS; developing overall coordination of web-based training and development and implementation of field training for NDMS; overseeing Federal Coordinating Centers; facilitating hospital claims processing; and development of the yearly NDMS conference, including the award ceremony.

2. *The Field Operations Branch (ANC12)*: The Field Operations Branch (FOB) is responsible for developing national DMATs, DMORTs, NMRTs, VMATs, IMSURTs, and specialty teams capable of dealing with health and medical consequences of natural and man-made disasters and terrorist incidents involving mass casualties; improving the communications infrastructure to support NDMS field response resources, especially for mass casualty incidents; maintaining the equipment required for emergency response; managing the Emergency Operations Center during emergencies; working with the Department of Veterans Affairs to achieve appropriate pharmaceutical availability, especially for mass casualty incidents; and establishing Management Support Teams at the site of emergencies.

b. *The Division of Administration and Support (ANC2)*. The Division of Administration and Support (DAS) is responsible for OER budget execution and formulation, personnel and procurement actions, and other administrative activities. To accomplish these tasks, DAS works with the OASPHOP Operations Officer; and the Office of the Secretary Executive Office (OSEO) and OER program managers to develop solutions to administrative related problems and to develop more effective and efficient administrative support for accomplishing OER activities. DAS also provides staff support for the OASPHOP Operations Officer in coordinating cross-cutting activities.

4. *Office of Planning and Emergency Response Coordination (ANE)*. The Office of Planning and Emergency Response Coordination (OPERC) is

headed by a Director, who reports to the ASPHEP and is responsible for ensuring that the ASPHEP has in place the systems and processes necessary to coordinate the HHS response to bioterrorism and other public health emergencies. OPERC represents the ASPHEP in the planning and execution of activities to support the Continuity of Government in times of crisis. Key functions of OPERC include: (1) Development and direction of the Secretary's Command Center; (2) implementation and management of the Secretary's Emergency Response Teams; (3) development of the HHS Continuity of Operations Plan (COOP) and coordination of its execution whenever required; (4) direction and coordination of HHS activities under the Federal Response Plan (especially Emergency Support Function #8); (5) liaison with the OASPHOP Office of Emergency Response (OER); (6) primary HHS liaison with emergency response entities elsewhere within HHS (especially CDC and FDA), within other Departments and Agencies (especially the Office of Homeland Security, the Department of Justice, the Department of State, and the Federal Emergency Management Agency), and within other Nations and multi-national organizations such as the World Health Organization; (7) planning, development, and implementation of exercises and other tools for assessing the readiness of HHS emergency response entities; and (8) professional education and training of OPERC personnel and response staff.

a. *The Readiness Enhancement and Assessment Program (ANE1)*. The Readiness Enhancement and Assessment Program (REAP) is responsible for evaluating the response capabilities of the Department, through its many operational assets (e.g., the National Medical Disaster System, the Commissioned Corps Readiness Force, and the Epidemic Intelligence Service). Through this analysis, REAP will recommend and implement necessary changes to operational plans, Departmental functions and policy guidance. The REAP will design, implement and analyze internal and external exercises, both functional and command post. REAP supports the Director OPERC and the ASPHEP by providing analytical analysis of plans, operations and exercises, making recommendations for future improvements.

b. *The Secretary's Emergency Response Team Office (ANE2)*. The Secretary's Emergency Response Team (SERT) Office is responsible for coordinating health activities between

state or local government officials involved on site with emergency incidents and the Secretary of Health and Human Services or his representative. The SERT will design, roster, equip, train and exercise a rapidly deployable group of personnel to support the combined local, state and national response to public health emergencies. The SERT will provide on-site policy guidance and communications linkages between field operations and the ASPHEP.

c. *Secretary's Command Center (ANE3)*. The Secretary's Command Center (SCC) is responsible for coordinating all information received by the HHS related to public health emergencies. The SCC shall monitor both internal and external information sources and communicate relevant information directly to the ASPHEP or the Secretary. The SCC will serve as the single point of contact for all public health emergencies providing 24 hour staffing, 7 days a week, 365 days a year. During emergencies, the SCC shall serve as the focal point for liaison activities within HHS.

5. *Office of State and Local Preparedness (ANF)*. The Office of State and Local Preparedness (OSLP) is headed by a Director, who reports to the ASPHEP and is responsible for directing and coordinating the activities of HHS Operating and Staff Divisions with respect to enhancing state and local preparedness for bioterrorism and other public health emergencies. OSLP takes the lead in developing policies, plans and strategies that are intended to strengthen and upgrade State and local public health and medical capacities to respond to bioterrorism. OSLP is also responsible for ensuring stewardship of the federal investment in State and local preparedness and provides oversight, in collaboration with the Operating Divisions. Such oversight will include financial auditing, project monitoring and readiness assessment.

II. Under Part A, Chapter AB, Deputy Secretary," add the following new component "Security Clearance and Drug Testing Office (ABE):"

Security Clearance and Drug Testing Office (ABE). The Security Clearance and Drug Testing Office (SCDTO) reports directly to the Deputy Secretary and receives operational oversight from OASPHEP. (1) provides Department-wide guidance for policy, oversight, and operations of personnel security; classified information; and telecommunication security; and (2) coordinates the Department's drug-free workplace program, which includes scheduling drug and alcohol testing.

III. Under Part A, Chapter AC, "Office of Public Health and Science," add the following new paragraph at the end of Section AC.20 Functions, Paragraph K, "Office of the Surgeon General (ACK)".

The Commissioned Corps Readiness Force (CCRF) is responsible for developing, commanding, deploying and coordinating a specialized cadre of U.S. Public Health Service (PHS) officers uniquely qualified by education and skills, who can be mobilized in times of extraordinary need during disaster, strife, or other public health emergencies. In coordination with the Assistant Secretary for Public Health and Emergency Preparedness (ASPHEP), the CCRF will respond to domestic or international requests to provide leadership and expertise by directing, enhancing, and supporting the services of the PHS and other HHS Operating Divisions, other U.S. government agencies or other responders.

IV. *Continuation of Policy*: Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to the functions contained in this reorganization, heretofore issued and in effect prior to the date of this reorganization, are continued in full force and effect.

V. *Delegations of Authority*: All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

VI. *Funds, Personnel and Equipment*: Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies and other resources.

Dated: November 21, 2002.

Ed Sontag,

Assistant Secretary for Administration and Management.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifiers: CMS-R-5, CMS-R-96, CMS-209]

Agency Information Collection Activities: Proposed Collection; Comment Request

Agency: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

(1) *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Physician Certifications/Recertifications in Skilled Nursing Facilities (SNFs) Manual Instructions and Supporting Regulations in 42 CFR Section 424.20; *Form No.*: CMS-R-5 (OMB# 0938-0454); *Use*: This information collection requires SNFs to keep record of physician certifications and recertifications of information such as the need for care and services, estimated duration of the SNF stay, and plan for home care.; *Frequency*: On occasion; *Affected Public*: State, local or tribal government, individuals or households, business or other for-profit, not-for-profit institutions; *Number of Respondents*: 2,068,716; *Total Annual Responses*: 883,838; *Total Annual Hours*: 441,793.

(2) *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Emergency and Foreign Hospital Services-Beneficiary Statement in Canadian Travel Claims and Supporting Regulations in 42 CFR, Section 424.123; *Form No.*: CMS-R-96 (OMB# 0938-0484); *Use*: Payment may be made for certain part A inpatient hospital services and part B outpatient hospital services provided in a non-participating U.S. or foreign hospital when services are necessary to prevent the death or serious impairment of the health of the individual. This statement must be submitted by the beneficiary to support their claim for payment.; *Frequency*: On occasion; *Affected Public*: Individuals or households; *Number of Respondents*: 1,100; *Total*