

keeping informed and working together; (7) FDA conduct of clinical investigator inspections; (8) meetings with FDA: why, when, and how; (9) investigator initiated research; (10) medical device aspects of clinical research; (11) working with FDA's Center for Biologics Evaluation and Research; and (12) The inspection is over—what happens next? What are the possible FDA compliance actions?

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) as an outreach activity by Government agencies to small businesses.

Dated: March 19, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 75 FR 10296, dated March 5, 2010) is amended to reflect the establishment of the Office of the Associate Director for Policy.

Section C–B, Organization and Functions, is hereby amended as follows: Delete in their entirety the title and functional statements for the CDC Washington Office (CAQ) and insert the following:

*Office of the Associate Director for Policy (CAQ).* The mission of CDCs Office of the Associate Director for Policy (OADP) is to bring about policies that result in demonstrable improvements in public health-globally and at the federal, state, and local levels.

In carrying out its mission, OADP: (1) Provides advice to CDC leadership in developing agency policy and legislative strategies; (2) creates and maintains partnerships to implement policy and legislative strategies; (3) implements key policies to improve public health; (4) ensures the agency's scientific credibility, reputation, and needs are respected and supported by policy makers and stakeholders.

*Office of the Director (CAQ1).* (1) Provides strategic advice to CDC leadership on overall agency direction and priorities, and drives CDC towards actions to reduce leading preventable causes of morbidity and mortality; (2) ensures organizational effectiveness in policy or strategy across the agency; (3) ensures capacity throughout CDC for policy and strategy; (4) leads the development and management of policy agendas with federal agencies and other organizations; (5) establishes strategy and maintains relations with key organizations and individuals working on public health policies or legislation.

*Office of Prevention through Healthcare (CAQ 12).* (1) Uses policy tools to gain the maximum preventive benefit from the clinical system and to integrate clinical care with community health interventions; (2) draws upon expertise and functional roles resident in other units of the Office of the Associate Director for Policy as well as from across CDC to apply that expertise and functionality to advancing prevention through healthcare; (3) crafts a coordinated agency response to implementing provisions of health reform legislation once it is enacted.

*Policy Research, Analysis, and Development Office (CAQB).* (1) Identifies and assists CDC leadership in establishing policy at multiple levels (federal, state, local, global and in the private sector); (2) conducts policy analysis (including regulatory, legal, economic); (3) develops and implements strategies (including regulatory, legal, economic) to deliver on policy priorities; (4) coordinates agency work with the healthcare system and other health-related organizations to advance CDCs policy agenda within the healthcare sector; (5) develops expertise in programs, regulations, and initiatives of other agencies that may provide opportunity for health impact; (6) builds relations with government agencies and other organizations to advance policy agendas, with a special emphasis on state and local agencies; (7) monitors and evaluates impact of policy implementation priorities; (8) identifies and assesses policy best practices and helps diffuse and replicate those practices; (9) leads the strengthening

and development of policy capacity and talent within CDC, as well as within the larger public health community; (10) leads the development and implementation of CDCs health policy research agenda; (11) ensures CDC operates in an integrated, consistent manner in policy-related activities; (12) leverages relationships with think tanks, policy consultancies, and academic institutions; (13) manages selected partner cooperative agreements and contracts that focus on policy; and (14) develops an agency-wide strategy related to advancing policy for partner relations that are managed elsewhere in CDC.

*CDC Washington Office (CAQC).* (1) Directs and manages CDC interactions with Congress; (2) leads the development and oversees the execution of appropriations strategies; (3) develops and executes legislative strategies; (4) builds Congressional relations; (5) tracks and analyzes legislation; (6) develops strategy and leads response efforts for Congressional oversight; (7) builds relations with government agencies and other organizations to advance policy agendas, with an emphasis on federal agencies; (8) protects and advances the agency's reputation, scientific credibility, and interests; (9) informs CDC leadership of current developments and provides insight into the Washington policy environment; (10) coordinates District of Columbia-area assignees and helps maximize their impact in supporting the agency's strategies and priorities.

Dated: March 11, 2010.

**William P. Nichols,**

*Acting Chief Operating Officer, Centers for Disease Control and Prevention.*

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### Centers for Disease Control and Prevention

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