

By direction of the Commission,
Commissioner Harbour recused.

Donald S. Clark,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office for Civil Rights; Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Chapter AT, Office for Civil Rights (OCR), as last amended at 65 FR 193279-81, dated April 11, 2000, is being amended to primarily realign the OCR Headquarters functions. The Changes are as follows:

I. Under Chapter AT, Office for Civil Rights (OCR), delete in its entirety and replace with the following:

AT.00 Mission

AT.10 Organization

AT.20 Functions

Section AT. Mission: OCR conducts public education, outreach, complaint investigation and resolution, and other compliance activities to prevent and eliminate discriminatory barriers, to ensure the privacy of protected health information, and to enhance access to HHS-funded programs. OCR's activities concentrate on ensuring integrity in the expenditure of Federal funds by making certain that such funds support programs that ensure access by intended recipients of services free from discrimination on the basis of race, national origin, disability, age, and gender; and by maintaining public trust and confidence that the health care system will maintain the privacy of protected health information while ensuring access to care. These OCR activities enhance the quality of services funded by the Department and the benefit of those services by working with covered entities to identify barriers and implement practices that can avoid potentially discriminatory impediments to quality services and protect the privacy of health information. The Department's goal of providing quality health and human services cannot be met when individuals do not receive these services as a result of practices that violate their fundamental rights of nondiscrimination or privacy.

Section AT.10 Organization: The Director of the Office for Civil Rights

reports to the Secretary and is responsible for overall coordination of the Department's civil rights and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule compliance and enforcement activities. The Director also serves as the Secretary's Special Assistant for Civil Rights. The Office is comprised of the following components:

- Office of the Director (ATA)
- Office of the Deputy Director for Civil Rights (ATB1)
- Office of the Deputy Director for Health Information Privacy (ATB2)
- Office of the Deputy Director for Management Operations (ATB3)
- Regional Offices for Civil Rights (ATD1 through ATDX)

Section AT.20 Functions: A. Office of the Director (ATA). As the Department's chief officer for the enforcement of civil rights and the HIPAA Privacy Rule, and as adviser to the Secretary on civil rights and the HIPAA Privacy Rule, the Director: Is responsible for the overall leadership and operations of the Office for Civil Rights; establishes policy and serves as adviser to the Secretary on civil rights issues and the HIPAA Privacy Rule, including intra-departmental activities aimed at incorporating civil rights and HIPAA Privacy Rule compliance into programs the Department administers and/or operates directly; represents the Secretary before Congress and the Executive Office of the President on matters relating to civil rights and the HIPAA Privacy Rule; sets overall direction and priorities of the Office through budget requests, strategic planning, and results-oriented operating and performance plans; maintains liaison with other Federal departments and agencies charged with civil rights enforcement responsibilities and compliance with the HIPAA Privacy Rule; coordinates with the White House on civil rights, the HIPAA Privacy Rule and related policies; maintains liaison with the Congress in coordination and consultation with the Assistant Secretary for Legislation; and determines policies and standards for civil rights and HIPAA Privacy Rule investigations, enforcement and voluntary compliance and outreach programs in coordination with the Secretary and other Federal agencies.

A Principal Deputy Director performs duties with the authority of the Director as delegated by the Director, assists in coordination and integration of the functions of all Deputy Directors, including cross-cutting activities such as media, public, and inter-

governmental relations, and acts for the Director in his/her absence.

B. Office of the Deputy Director for Civil Rights (ATB1). This office is headed by a Deputy Director who reports to the Director, OCR. The Deputy Director for Civil Rights oversees civil rights program operations, policy development, and public education and outreach activities nationwide.

The Office of the Deputy Director for Civil Rights includes operations, policy and public education and outreach functions that are managed through cross-functional teams that focus on: (1) Title VI of the Civil Rights Act of 1964, the Multi-Ethnic Placement Act (MEPA), Title VI and XVI of the Public Health Service Act (Hill-Burton Community Services Assurance provisions), Section 1808 of the Small Business and Job Protection Act, and Title IX; (2) Disability, Age and other nondiscrimination statutes and regulations; and (3) Medicare pre-grant certification reviews, program reporting, surveys and civil rights training.

These teams develop policy and assist in implementation of OCR's civil rights compliance and enforcement program; plan and coordinate OCR's high priority civil rights program initiatives; advise OCR staff nationwide on case development and quality; assist in developing negotiation, enforcement, and litigation strategies; identify training needs and design civil rights-specific training programs for OCR staff; review challenges to OCR civil rights findings; conduct policy and HHS program-related research; coordinate OCR's government-wide responsibilities for implementation of Age Discrimination Act requirements; develop civil rights surveys, and provide civil rights and program advice to OCR staff nationwide, other HHS components and external stakeholders.

Through the team structure, the Office of the Deputy Director for Civil Rights also provides technical assistance to and conducts pre-grant reviews of health care providers seeking Medicare certification and other program participation funded by the Department to determine their ability to comply with civil rights requirements; provides guidance and assistance to OCR Regional Offices to ensure uniform and efficient implementation of pre-grant processing policies and procedures; maintains civil rights assurance of compliance forms for permanent reference; and maintains liaison with and provides civil rights technical assistance and advisory services to HHS Operating Divisions (OPDIVS), as well as national advocacy, beneficiary, and

provider groups, and to other Federal departments and agencies with respect to civil rights outreach programs, initiatives, and mandates.

C. Office of the Deputy Director for Health Information Privacy (ATB2). This office is headed by a Deputy Director who reports to the Director, OCR. The Deputy Director for Health Information Privacy oversees HIPAA Privacy Rule program operations, policy development and administrative rule-making, public education and outreach activities nationwide and coordination of OCR nationwide Privacy Rule compliance activities and the application of policies to ensure consistency in interpretation and compliance enforcement.

The Office of the Deputy Director for Health Information Privacy includes operations, policy and public education and outreach functions that are managed through cross-functional teams.

These teams develop policy and assist in implementation of OCR's HIPAA Privacy Rule compliance and enforcement program; plan and coordinate OCR's high priority HIPAA Privacy Rule program initiatives; staff HIPAA and Privacy Rule intra- and inter-agency work groups; review challenges to OCR HIPAA Privacy Rule findings; conduct policy and HHS program-related research; advise OCR staff nationwide on case development and quality; assist in developing negotiation, enforcement, and litigation strategies; identify training needs and design HIPAA Privacy Rule-specific training programs for OCR staff; develop HIPAA Privacy Rule surveys; identify key issues and develop guidance to support public speaking requirements related to the HIPAA Privacy Rule; develop educational materials as well as other documentation to address public information requirements; and provide HIPAA Privacy Rule and program advice to OCR staff nationwide, other HHS components and external stakeholders.

D. Office of the Deputy Director for Management Operations (ATB3). This office is headed by a Deputy Director who reports directly to the Director, OCR. The Deputy Director coordinates the day-to-day operations of headquarters and the regions, overseeing management operations, management policy, administrative contacts, budget, information technology, program management data analysis and human resources activities, including OCR's internal coordination responsibilities.

The Deputy Director for Management Operations oversees performance

accountability and results management, resource planning, budget and performance integration, information technology, management policy and operations; and acts as senior advisor on matters that cross functional areas such as EEO, labor relations, etc.

The Deputy Director for Management Operations leads the Office for Civil Rights headquarters resource management functions as well as regional management operations. The Deputy is responsible for the development and implementation of OCR management strategies, business processes and standard operating procedures that fully support the attainment of OCR program goals and mission critical initiatives.

In coordination with the Deputy Director for Civil Rights and the Deputy Director for Health Information Privacy, the Office of the Deputy Director for Management Operations works to ensure fair, responsible and effective allocation of resources in order to achieve maximum benefit for the organization as a whole.

The Deputy Director, working through cross-functional teams, is responsible for performance accountability, results management, and quality assurance initiatives to maximize effectiveness and efficiency of OCR programs. The Deputy Director oversees the development of outcome-oriented management strategies and associated support systems such as performance program measurement and assessment systems, information resources systems and other program support systems.

The Deputy Director oversees the formulation and execution of OCR's annual budgets and financial operating plans and is responsible for ensuring that OCR effectively integrates its performance metrics and budget processes to support decision-making related to funding constraints and program results.

As part of the budget and performance integration and performance accountability functions, the deputy Director leads the development of data collection processes to ensure that OCR is able to measure its performance consistent with its commitments made as part of the Government Performance and Results Act; and directs the development and utilization of systems for the establishment and tracking of more effective benchmarks for performance and the cost effectiveness of OCR's results.

The Deputy Director for Management and Operations provides leadership to the OCR executive team for the development of the key management objectives that drive the continuous

improvement and updating of the OCR strategic vision and attendant organizational change requirements. This Deputy develops and implements action plans to ensure that OCR's management functions fully support its mission needs.

The Office of the Deputy Director for Management Operations includes responsibility for the following functions: (1) Budget and Performance Integration; (2) Performance Accountability and Results Measurement; (3) Management Policy; (4) Information Systems and Data Analysis; (5) Executive Secretariat and Program Support; and (6) Regional Operations. OCR Regional Managers report to the Deputy Director for Management Operations.

1. Budget and Performance Integration. Staff working on this function develop OCR's annual integrated budget and performance plan, incorporating a results, program quality and cost effectiveness focus into development and execution of integrated performance-based budgets and into the ongoing assessment and management of OCR's resource requirements.

2. Performance Accountability and Results Management. Staff working on this function oversee OCR's implementation of the performance objectives set in its annual integrated budget and performance plan. This includes establishing measures for organizational performance and setting regional and HQ component targets as a share of nationwide results-centered objectives. Staff working on this function monitor and report to the Director on accomplishments in meeting program results and program efficiency objectives.

The staff work on a day-to-day basis with regional offices in managing resources to achieve performance measures and provide assistance to the regions in accessing OCR Civil Rights and Privacy Rule policy and program operations technical assistance provided by staff of the Deputy Directors for Civil Rights and Health Information Privacy. Staff working on this function also ensure that all OCR staff performance plans incorporate the results and metrics set in the OCR integrated performance budget and in OCR leadership's performance contract and Senior Executive Service (SES) plans.

3. Management Policy. Staff working on this function serve collectively as OCR's internal consultant and source of expert technical assistance on: organizational development; strategic planning; standards of conduct and ethics (Deputy Ethics Officer);

management training; program and program support-related contracting; competitive sourcing (A-76); human capital management [e.g., staffing and workforce analysis, transition and succession planning, awards and special honors programs, support and advisory assistance to managers throughout OCR with liaison to the Rockville HR Center and other experts on sensitive personnel issues (EEO, labor and management relations, performance and conduct-based actions)]; delegations of authority; and internal controls. The Deputy Director for Management Operations leads, coordinates and administers OCR's ongoing implementation of the President's Management Agenda (PMA) objectives in: Strategic Management of Human Capital; Competitive Sourcing; Improved Financial Performance; Expanded E-Government; and Budget and Performance Integration. Staff working on this function work in coordination with others within the Office of the Deputy Director for Management Operations to monitor and manage the PMA objectives.

4. Information Resources and Data Analysis. Staff working on this function are led by OCR's Chief Information Officer (CIO) and are responsible for: information resources management policy; program systems development, maintenance and modification; operation of the Program Information Management System, OCR's workflow and document management system; the systems security of OCR's program systems; reporting on workload and related resource use; design and application of management data reports supportive of program operations and management; analysis of data in PIMS; statistical analysis in support of program management and compliance processing; maintenance and updating of OCR's website; coordination of OCR Paperwork Reduction Act and Government Paperwork Elimination Act clearance responsibilities working with program staff as appropriate; development of short- and long-term information resource management policy and plans; and liaison with HHS IRM resources, including the Information Technology Service Center (ITSC) and the OS and HHS Chief Information Officers.

5. Executive Secretariat and Program Support. Staff working on this function provide consolidated document, e-mail, telephonic, and TDD intake for OCR HQ and related scanning and entry and assignments to OCR managers for further staff assignments in PIMS (e.g., correspondence, complaints, and HQ outreach and public education projects). The staff respond to general and routine

correspondence using templates developed for this purpose and make referrals of correspondence that is not within OCR's nondiscrimination or Privacy Rule jurisdiction.

Staff working on this function also provide consolidated program support services (travel management, supply management, timekeeping, PowerPoint design, logistics liaison with OSEO, reports on phone center and toll-free line use and reference of calls to regional offices, and logistics support for OCR special projects and activities.

E. Regional Offices for Civil Rights (ATD1 through ATDX). The Regional Managers, Office for Civil Rights, report directly to the Deputy Director for Management Operations.

Within goals set by the Director, OCR and management policy and operational goals set by the Director for Management Operations, the Regional Manager in each of OCR's ten regions: develops and delivers a comprehensive regional enforcement and voluntary compliance program to carry out the office mission; manages staff and other resources allocated to the region; directs a program to meet OCR objectives in such areas as quantity, quality and timeliness of work products in investigations and voluntary compliance activities; serves as a resource to the HHS Regional Directors on civil rights and Privacy Rule matters; disseminates and implements OCR policies and procedures; establishes priorities for work assigned to the civil rights attorney in the regional attorney's office; determines compliance of recipients of Federal financial assistance with nondiscrimination regulations and of covered entities under the health Information Privacy Rule; initiates voluntary compliance; approves, disapproves, and monitors implementation of voluntary compliance and corrective plans; approves, disapproves, and monitors State agency Methods of Administration; determines the most effective enforcement method, including conciliation of differences between complainants and recipients; recommends to the Director administrative and/or judicial enforcement actions when voluntary compliance cannot be obtained; participates in headquarters policy and program development; prepares regional budget proposal and supporting resource and work measurement justification; implements final budget allotment for region; implements the part of annual integrated budget and performance plans and financial operating plans pertaining to the conduct of complaint investigations,

compliance, reviews, voluntary compliance activities, staff training and other regional office activities; coordinates with the Freedom of Information Officer and OCR headquarters on information requests and news media inquiries; establishes and maintains effective relations with offices of Governors, mayors, county officials, and other key State and local officials, and furnishes advice and assistance to them in civil rights and Privacy Rule matters; strives to develop mutually beneficial Federal-State-local partnerships; responds to Congressional inquiries as appropriate and in accordance with Office for Civil Rights protocol; implements court decisions as they pertain to OCR's program; and provides input into and implements OCR's affirmative action plan.

OCR's regional Program Information Management staff provide the Regional Manager with evaluative reports and advice concerning the Regional Office's achievement of its overall goals and objectives, specifically with regard to: The quantity of compliance activities completed; the completion of compliance actions within established time frames; and the achievement of change for beneficiaries. These staff also monitor regional attainment of integrated budget and performance objectives and targets set for the region; oversee regional resource planning; conduct regional data collections; provide for support services and computer input; assess and assist in meeting regional training needs; serve as liaison to OSEO and HR Center for services such as personnel, space and supply acquisition and utilization and maintenance; and directly provide support for OCR-managed systems and operations such as PIMS (workflow, document and correspondence control), office safety, and travel.

A. Investigative Functions—Under its enforcement authorities the Regional Office serves as a complaint intake unit. When complaints are received, the Office conducts complaint investigations of health and human services institutions to eliminate unlawful discrimination and ensure equal opportunity for the beneficiaries of Federal financial assistance provided by the Department of Health and Human Services; and the Office further seeks to ensure that covered entities are in compliance with the Privacy Rule implementing the health information privacy protections of the Health Insurance Accountability and Portability Act (HIPAA). In addition, the Office determines civil rights compliance by entities that receive federal financial assistance; advises the

Regional Manager on critical enforcement actions; provides assistance to recipients for corrective action; and monitors implementation of corrective plans; coordinates enforcement activities with OPDIV's regional officials, other Federal agencies and states and, as appropriate, with headquarters offices and divisions; solicits regional/area civil rights attorney's legal opinion on investigations as the Regional Manager deems appropriate; and processes all complaints received, including determination of jurisdiction and completeness.

B. Voluntary Compliance and Outreach Functions—OCR's Regional Office staff also: Conduct reviews to assist in identifying potential compliance problems; negotiate voluntary compliance with recipients of federal financial assistance, or with respect to the Privacy Rule, with entities that are covered by the Rule; advise the Regional Manager on critical compliance matters; coordinate voluntary compliance activities with OPDIVs and STAFFDIVs, regional officials, State, local and other Federal agencies and, as appropriate, headquarters offices and divisions; provide assistance and outreach services to recipients, covered entities, beneficiaries and organizations as requested or referred; establish and maintain effective relationships with the Offices of Governors, State and local officials in order to provide advice and assistance to them on civil rights matters; establish and maintain liaison with the HHS Regional Director in carrying out speaking engagements, media appearances and interviews.

Regions III and IX carry out OCR's functional responsibilities under an organization structure that includes field offices in Washington, DC and Los Angeles, CA respectively. In all regions, the management and supervisory structure consists of a Regional Manager and a Deputy Regional Manager.

II. Continuation of Policy: Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to the Office for Civil Rights heretofore issued and in effect prior to this reorganization are continued in full force and effect.

III. Delegation of Authority: All delegations and redelegations of authority made to officials and employees of the Office for Civil Rights will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

IV. Funds, Personnel and Equipment: Transfer of organizations and functions

affected by this reorganization shall be accompanied by direct and support funds, positions, personnel, records, equipment, supplies and other sources.

Dated: July 12, 2004.

Ed Sontag,

Assistant Secretary for Administration and Management.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Acting Assistant Secretary for Health have taken final action in the following case:

Nancy J. Strout, Ph.D., University of Southern Maine: Based on the report of an inquiry conducted by the University of Southern Maine (USM) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Nancy J. Strout, Ph.D., former interviewer, USM, engaged in scientific misconduct in research supported by Substance Abuse and Mental Health Services Administration (SAMSHA) cooperative agreement UD1 SM52362, "Maine evaluation of consumer-operated services."

Specifically, PHS found that the Respondent engaged in scientific misconduct by fabricating interview data for at least 50 interviews of human subjects enrolled in the Maine Evaluation of Consumer-Operated Services Project for mental health services, and possibly up to 150 interviews or more (based on calculations performed by USM), causing the project to nullify all 346 interviews due to her involvement at one or more stages with the subjects.

PHS also found that the Respondent is not presently responsible to be a steward of Federal funds because she falsified invoices for interviews and receipts for interview incentive payments in pursuit of a fraudulent scheme to obtain payment for services she did not render.

Dr. Strout has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed for a period of three (3) years, beginning on July 23, 2004:

(1) To exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in, nonprocurement programs of the United States Government as defined in the debarment regulations at 45 CFR Part 76; and

(2) To exclude herself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT:

Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (301) 443-5330.

Chris B. Pascal,

Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04287]

Purchase, Distribution and Tracking of Supplies to Support HIV/AIDS-Related Laboratory Services in the Republic of Uganda; Notice of Intent to Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2004 funds for a cooperative agreement program to The overall aim of this program is ensure a full-supply of laboratory reagents and materials for HIV-related laboratory services at all health center III (HC III) facilities and above, but excluding reference laboratories, to enable President's Emergency Plan for AIDS Relief (PEPFAR) goals of expanded HIV testing, care and treatment to be met. This program announcement (PA) is intended to complement PA # 04223, "Laboratory Service Strengthening at Health Centre IV and Above in the Republic of Uganda". The Catalog of Federal Domestic Assistance number for this program is 93.941.

B. Eligible Applicant

Assistance will be provided only to the National Medical Stores (NMS) of the Republic of Uganda.

NMS is the mandated institution in Uganda for the purchase and distribution of health-related commodities to government health facilities in Uganda. NMS has