

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions, and Delegations of Authority; Office of the Deputy Assistant Secretary for Administration

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: Statement of Organizations, Functions, and Delegations of Authority.

The Administration for Children and Families (ACF) has reorganized the Office of the Deputy Assistant Secretary for Administration (ODASA). This reorganization renames the Office of Management Resources (OMR) to the Office of Workforce Planning and Development. In addition, it realigns the ethics, facilities, security and travel functions formerly located in OMR to the Immediate Office of the Deputy Assistant Secretary for Administration.

FOR FURTHER INFORMATION CONTACT:

Jason Donaldson, Deputy Assistant Secretary for Administration, 901 D Street SW., Washington, DC 20447, (202) 401-9238.

This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF) as follows: Chapter KP, Office of the Deputy Assistant Secretary for Administration, (ODASA), as last amended, 71 FR 59117-59123, October 6, 2006.

I. Under Chapter KP, Office of the Deputy Assistant Secretary for Administration, KP.00 Mission, delete in its entirety and replace with the following:

KP.00 Mission. The Deputy Assistant Secretary for Administration serves as principal advisor to the Assistant Secretary for Children and Families on all aspects of personnel administration and management; information resource management; financial management activities; grants policy and overseeing the issuance of grants; procurement issues; the ethics program; staff development and training activities; organizational development and organizational analysis; administrative services; facilities management; and State systems policy. The Deputy Assistant Secretary for Administration oversees the ACF Equal Employment Opportunity and Civil Rights program and all administrative special initiative activities for ACF.

II. Under Chapter KP, Office of the Deputy Assistant Secretary for Administration, KP.10 Organization, delete in its entirety and replace with the following:

KP.10 Organization. The Office of the Deputy Assistant Secretary for Administration is headed by the Deputy Assistant Secretary who reports to the Assistant Secretary for Children and Families. The Office is organized as follows:

Immediate Office of the Deputy Assistant Secretary for Administration (KPA)
Office of Information Services (KPB)
Office of Financial Services (KPC)
Office of Workforce Planning and Development (KPD)
Office of Grants Management (KPG)
Grants Management Regional Units (KPGDI-X)

III. Under Chapter KP, Office of the Deputy Assistant Secretary for Administration, KP.20 Functions, paragraph A, delete in its entirety and replace with the following:

KP.20 Functions. A. The Immediate Office of the Deputy Assistant Secretary for Administration (ODASA) directs and coordinates all administrative activities for the Administration for Children and Families (ACF). The Deputy Assistant Secretary for Administration serves as ACF's: Chief Financial Officer; Chief Grants Management Officer; Federal Manager's Financial Integrity Act (FMFIA) Management Control Officer; Principal Information Resource Management Official serving as Chief Information Officer; Deputy Ethics Counselor; Personnel Security Representative; and Reports Clearance Officer. The Deputy Assistant Secretary for Administration serves as the ACF liaison to the Office of the General Counsel, and as appropriate, initiates action in securing resolution of legal matters relating to management of the agency, and represents the Assistant Secretary on all administrative litigation matters.

The Deputy Assistant Secretary for Administration represents the Assistant Secretary in HHS and with other Federal agencies and task forces in defining objectives and priorities, and in coordinating activities associated with Federal reform initiatives. ODASA provides leadership of assigned ACF special initiatives arising from Departmental, Federal and non-Federal directives to improve service delivery to customers.

The Deputy Assistant Secretary for Administration provides day-to-day executive leadership and direction to the Immediate Office of the Deputy

Assistant Secretary, Office of Information Services, Office of Financial Services, Office of Workforce Planning and Development, and the Office of Grants Management. The Immediate Office of the Deputy Assistant Secretary for Administration consists of the Deputy Director, Chief of Staff, and the Management Operations Team (formerly referred to as the Administrative Team), the Budget Team, Facilities Team, and Ethics Team.

The Management Operations Team coordinates human capital management needs within ODASA. The Team provides leadership, guidance, oversight and liaison functions for ODASA personnel related issues and activities as well as other administrative functions within ODASA. The Management Operations Team coordinates with the Office of Workforce Planning and Development to provide ODASA staff with a full array of personnel services, including position management, performance management, employee recognition, staffing, recruitment, employee and labor relations, employee worklife, payroll liaison, staff development, training services, and special hiring and placement programs. The Team develops and implements ACF travel policies and procedures consistent with Federal requirements. The Team provides technical assistance and oversight; coordinates ACF's use of the Travel Management System; manages employee participation in the Travel Charge Card program, and coordinates Travel Management Center services for ACF. It purchases and tracks common use supplies, stationery and publications. It plans and manages reprographic services.

The Budget Team manages the formulation and execution of ODASA's Federal administration budget and assigned ACF program and common expense budgets. The Budget Team maintains budgetary controls on ODASA accounts, reconciling accounting reports and invoices, and monitoring all spending. The Team develops, defends and executes the assigned funds for rent, repair and alterations, facilities activities, telecommunication, information technology, personnel services and training. The Team also controls ODASA's credit card for small purchases.

The Facilities Team is responsible for planning, managing, and directing ACF's facility, safety, security, and emergency management programs. The Team serves as the lead for ACF in coordination and liaison with Departmental, GSA and other Federal agencies on implementation of Federal

facility and security directives. The Facilities Team serves as lead and coordinator for all tenant matters in ACF Headquarter locations. The Team coordinates facility activities for ACF's regional offices. The Team is responsible for planning and executing ACF's environmental health program, and ensuring that appropriate occupational health and safety plans are in place. The Team is responsible for issuing, managing and controlling badge and cardkey systems to control access to agency space for security purposes. The Team provides, prepares, coordinates, and disseminates information, policy and procedural guidance on administrative and materiel management issues on an agency-wide basis. It directs and/or coordinates management initiatives to improve ACF administrative and materiel management services with the goal of continually improving services while containing costs. The Team establishes and manages contracts and/or blanket purchase agreements for administrative support and materiel management services, including space design, building alteration and repair, reprographics, moving, labor, property management and inventory, systems furniture acquisitions and assembly, and fleet management. The Team provides management and oversight of ACF mail delivery services and activities, including Federal and contractor postal services nationwide, covering all classes of U.S. Postal Service mail, priority and express mail services, and courier services, etc. The Team plans, manages/operates employee transportation programs, including shuttle service and fleet management; employee and visitor parking. The Team directs all activities associated with the ACF Master Housing Plan, including coordination and development of the agency long-range space budget; planning, budgeting, identification, solicitation, acceptance and utilization of office and special purpose space, repairs, and alterations; serving as principal liaison with GSA and other Federal agencies, building managers and materiel engineers, architects and commercial representatives, for space acquisitions, negotiation of lease terms, dealing with sensitive issues such as handicapped barriers, and space shortages. It develops and maintains space floor plans and inventories, directory boards, and locator signs. The Team serves as principal liaison with private and/or Federal building managers for all administrative services and materiel management activities. The Team

develops and implements policies and procedures for the ACF Personal Property Management program, including managing the ACF Personal Property Inventory, and other personal property activities.

The Ethics Team manages the agency-wide ethics program and ensures that the agency and ACF employees are in compliance with the Executive Branch Standards of Ethical Conduct, the HHS Supplemental Standards of Ethical Conduct, the criminal conflict of interest statutes, and other ethics related laws and regulations. The Agency-wide ethics program includes the public financial disclosure reporting system, confidential financial disclosure reporting system, outside activity prior approval and annual report process, non-federal source cash or in-kind travel reimbursement, procurement integrity enforcement, standards of ethical conduct determinations, conflicts resolution, advisory committees ethics program, advice and counsel, education and training, and enforcement. The Ethics Team Officer reports directly to the DASA, who serves as the Deputy Ethics Counselor.

IV. Under Chapter KP, Office of the Deputy Assistant Secretary for Administration, KP.20 Functions, paragraph D, delete in its entirety and replace with the following:

D. The Office of Workforce Planning and Development (OWPD) advises the Deputy Assistant Secretary for Administration on human resource management, and organizational and employee development activities for ACF. OWPD provides leadership, direction and oversight for human resource management services provided to ACF through a contract and supplemental memoranda of understanding (MOUs) with the Program Support Center (PSC). OWPD, in collaboration and coordination with the PSC, provides advice and assistance to ACF managers in their personnel management activities, including recruitment, selection, position management, performance management, designated performance and incentive awards and employee assistance programs and other services to ACF employees. OWPD provides management, direction and oversight of the following personnel administrative services: the exercise of appointing authority, position classification, awards authorization, performance management evaluation, personnel action processing and recordkeeping, merit promotion, special hiring, and placement programs. OWPD serves as liaison between ACF, the Department, and the Office of Personnel

Management. It provides technical advice and assistance on personnel policy, regulations, and laws. OWPD formulates and interprets policies pertaining to existing personnel administration and management matters and formulates and interprets new human resource programs and strategies. The Office, in collaboration and coordination with the PSC, provides oversight and management advisory services on all ACF employee relations issues. The Office plans and coordinates ACF employee relations and labor relations activities, including the application and interpretation of the Federal Labor Management Relations Program collective bargaining agreements, disciplinary and adverse action regulations and appeals. The Office participates in the formulation and implementation of policies, practices and matters affecting bargaining unit employees' working conditions by assuring management's compliance with the Federal Labor Relations Program (5 U.S.C. Chapter 71). The Office maintains oversight, leadership and direction of the labor-management and employee relations services provided under contract with the PSC.

OWPD is responsible for formulation, planning, analysis and development of ACF human resource policies and programs, workforce planning, and liaison functions to the Department on ACF payroll matters. The Office formulates and oversees the implementation of ACF-wide policies, regulations and procedures concerning all aspects of the Senior Executive Service (SES), and SES-equivalent recruitment, staffing, position establishment, compensation, award, performance management and related personnel areas. The Office manages the ACF SES performance recognition systems and provides services for functions of the Executive Secretary to the Executive Resources Board and the Performance Review Board. OWPD coordinates Schedule C and executive personnel activity with the Office of the Secretary and is the focal point for data, reports and analyses relating to Schedule C, SES and Executive-level personnel. OWPD advises the Deputy Assistant Secretary for Administration on organizational analysis and development including: delegations of authority; planning for new organizational elements; and planning, organizing and performing studies, analyses and evaluations related to structural, functional and organizational issues, problems, and policies to ensure organizational effectiveness. The Office

administers ACF's system for review, approval and documentation of delegations of authority. The Office provides technical assistance and guidance to ACF offices on intra-component organizational proposals and is responsible for development and/or review of inter-component organizational proposals. The Office develops policies and procedures for implementing organizational development activities and provides leadership of assigned ACF special initiatives arising from Departmental, Federal and non-Federal directives to improve service delivery to customers and to enhance employee work environment. The Office manages and coordinates designated incentive awards programs. The Office develops training policies and plans for ACF. It provides leadership in directing and managing Agency-wide staff development and training activities for ACF. OWPD is responsible for the functional management of all information technology and software training, common needs training, and management training in the Agency, including policy development, guidance, technical assistance, and evaluation of all aspects of career employee, supervisory, management and executive training. The Office provides leadership in managing/overseeing and monitoring the ACF Training Resource Center and the Computer Training and Information Centers. The Office develops and manages the consolidated training budget for the Agency.

Dated: October 25, 2011.

George H. Sheldon,

Acting Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0771]

Draft Blueprint for Prescriber Education for Long-Acting/Extended-Release Opioid Class-Wide Risk Evaluation and Mitigation Strategy; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Blueprint for Prescriber Education for

the Long-Acting/Extended-Release Opioid Class-Wide REMS" (Blueprint). The draft Blueprint contains core messages intended for use by continuing education (CE) providers to develop educational materials to train prescribers of long-acting and extended-release opioids under the required risk evaluation and mitigation strategy (REMS) for these products (Opioid REMS). FDA seeks stakeholder input on the document. After comments are received, FDA will revise the Blueprint as appropriate, incorporate it into the Opioid REMS when it is approved, and post it on FDA's Web site for use by CE providers.

DATES: Submit either electronic or written comments on the draft Blueprint by December 7, 2011.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft Blueprint. Submit electronic comments on the draft Blueprint to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Michie I. Hunt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6153, Silver Spring, MD 20993-0002, (301) 796-3504.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration Amendments Act of 2007 (FDAAA) gave FDA the authority to require manufacturers to develop and implement a REMS when necessary to ensure the benefits of a drug or biological product outweigh its risks.

A. REMS for Long-Acting and Extended-Release Opioids

On February 6, 2009, FDA sent letters to manufacturers of certain opioid drug products indicating that these drugs will be required to have a REMS to ensure that the benefits of the drugs continue to outweigh the risks.¹ The affected opioid drugs include long-acting and extended-release brand name and generic products and are formulated with the active ingredients buprenorphine, fentanyl, hydromorphone, methadone, morphine,

oxycodone, oxymorphone, and tapentadol. After sending the letters, FDA held a series of meetings with stakeholders and convened an advisory committee to obtain input on the appropriate elements of the Opioid REMS.

On April 19, 2011, in conjunction with the Office of National Drug Control Policy (ONDCP) release of the Obama Administration's *Epidemic: Responding to America's Prescription Drug Abuse Crisis*—a comprehensive action plan to address the national prescription drug abuse epidemic, FDA issued letters to application holders directing them to submit a REMS within 120 days and describing the elements that needed to be included in the REMS (REMS notification letters). The central component of the Opioid REMS program is an education program for prescribers (e.g., physicians, nurse practitioners, physician assistants) and patients.

B. REMS Prescriber Education

In the REMS notification letters, FDA provided an outline of the required prescriber education. The outline specified that the education must include information on weighing the risks and benefits of opioid therapy, choosing patients appropriately, managing and monitoring patients, and counseling patients on the safe use of these drugs. In addition, the education must include information on how to recognize evidence of, and the potential for, opioid misuse, abuse, and addiction. The REMS notification letters stated that although there is no mandatory requirement that prescribers take the course as a precondition to dispensing the medication to patients, application holders will be required to establish goals for the number of prescribers trained, collect the information about the number of prescribers who took the courses, and report the information to FDA as part of periodic required assessments.

C. CE Providers Will Conduct Prescriber Education

The REMS notification letter expressed FDA's expectation that the training would be conducted by accredited, independent continuing education providers. FDA later elaborated on its vision for prescriber education stating that we expect the CE training to be provided without cost to the healthcare professionals and that sponsors would offer unrestricted grants to accredited CE providers to develop CE for the appropriate prescriber

¹ See the Opioid REMS Meeting Invitation Template at <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM163652.pdf> and the Opioids Products Chart at <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163654.htm>.