

Miami, FL 33126, Officers: Rossin V. Garcia, Vice President (Qualifying Individual), Manuel Garcia, President.

Dated: December 23, 2005.

Bryant L. VanBrakle,
Secretary.

[FR Doc. E5-8009 Filed 12-28-05; 8:45 am]

BILLING CODE 6730-01-P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-XXXX]

National Capital Region (NCR), Office of Childcare Services; Information Collection; General Services Administration (GSA) Child Care Specialist Feedback Form

AGENCY: NCR Office of Childcare Services, Public Buildings Service (PBS), GSA.

ACTION: Notice of request for comments regarding a request for a new OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration has submitted to the Office of Management and Budget (OMB) a request to review and approve a new information collection requirement. This information will be used to assess satisfaction with services delivered by staff from the Office of Child Care Services. The respondents are current users of the Office of Child Care Services. A request for public comments was published at 70 FR 56167, September 26, 2005. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

DATES: Submit comments on or before: January 30, 2006.

FOR FURTHER INFORMATION CONTACT: Leo G. Bonner, Regional Child Care Coordinator, Office of Child Care Services, at telephone (202) 401-7403 or via e-mail to leo.bonner@gsa.gov.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Ms. Jeanette Thornton, GSA Desk Officer, OMB, Room 10236, NEOB,

Washington, DC 20503, and a copy to the Regulatory Secretariat (VIR), General Services Administration, Room 4035, 1800 F Street, NW., Washington, DC 20405. Please cite OMB Control No. 3090-XXXX, General Services Administration (GSA) Child Care Specialist Feedback Form, in all correspondence.

SUPPLEMENTARY INFORMATION:

A. Purpose

This information will be used to assess consumer satisfaction with services delivered by staff from the Office of Child Care services.

B. Annual Reporting Burden

Respondents: 144.

Responses Per Respondent: 1.

Hours Per Response: .083 (5 minutes).

Total Burden Hours: 12.

Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (VIR), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 208-7312. Please cite OMB Control No. 3090-XXXX, General Services Administration (GSA) Child Care Specialist Feedback Form, in all correspondence.

Dated: November 30, 2005

Michael W. Carleton,

Chief Information Officer.

[FR Doc. E5-8001 Filed 12-28-05; 8:45 am]

BILLING CODE 6820-A4-S

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. 62, No. 85, pp. 24120-24126, dated Friday, May 2, 1997, as amended thereafter) is being republished to reflect the current organizational structure of CMS in relation to meeting the Department's goal of having no more than four management levels in the Agency and to also exercise leadership in implementing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

Part F is described below:

• Section F.10. (Organization) reads as follows:

1. Office of External Affairs (FAC)
2. Center for Beneficiary Choices (FAE)
3. Office of Legislation (FAF)
4. Center for Medicare Management (FAH)
5. Office of Equal Opportunity and Civil Rights (FAJ)
6. Office of Research, Development, and Information (FAK)
7. Office of Clinical Standards and Quality (FAM)
8. Office of the Actuary (FAN)
9. Center for Medicaid and State Operations (FAS)
10. Office of the Boston Regional Administrator (FAU1)
11. Office of the New York Regional Administrator (FAU2)
12. Office of the Philadelphia Regional Administrator (FAU3)
13. Office of the Atlanta Regional Administrator (FAV4)
14. Office of the Chicago Regional Administrator (FAV5)
15. Office of the Dallas Regional Administrator (FAV6)
16. Office of the Kansas City Regional Administrator (FAV7)
17. Office of the Denver Regional Administrator (FAX8)
18. Office of the San Francisco Regional Administrator (FAX9)
19. Office of the Seattle Regional Administrator (FAXX)
20. Office of Operations Management (FAY)
21. Office of Information Services (FBB)
22. Office of Financial Management (FBC)
23. Office of Strategic Operations and Regulatory Affairs (FGA)
24. Office of E-Health Standards and Services (FHA)
25. Office of Acquisition and Grants Management (FKA)
26. Office of Policy (FLA)

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

1. Office of External Affairs (FAC)

• Serves as the focal point for the Agency to the news media and provides leadership for the Agency in the area of intergovernmental affairs. Advises the Administrator and other Agency components in all activities related to the media and on matters that affect other units and levels of government.

• Coordinates CMS activities with the Office of the Assistant Secretary for Public Affairs and the Secretary's intergovernmental affairs officials.

• Serves as senior counsel to the Administrator in all activities related to the media. Provides consultation, advice, and training to the Agency's

senior staff with respect to relations with the news media.

- Develops and executes strategies to further the Agency's relationship and dealings with the media. Maintains a broad based knowledge of the Agency's structure, responsibilities, mission, goals, programs, and initiatives in order to provide or arrange for rapid and accurate response to news media needs.

- Prepares and edits appropriate materials about the Agency, its policies, actions and findings, and provides them to the public through the print and broadcast media. Develops and directs media relations strategies for the Agency.

- Responds to inquiries from a broad variety of news media, including major newspapers, national television and radio networks, national news magazines, local newspapers and radio and television stations, publications directed toward the Agency's beneficiary populations, and newsletters serving the health care industry.

- Manages press inquiries, coordinates sensitive press issues, and develops policies and procedures for how press and media inquiries are handled.

- Arranges formal interviews for journalists with the Agency's Administrator or other appropriate senior Agency staff; identifies for interviewees the issues to be addressed, and prepares or obtains background materials as needed.

- For significant Agency initiatives, issues media advisories and arranges press conferences as appropriate; coordinates material and personnel as necessary.

- Serves as liaison with the Department of Health and Human Services and White House press offices.

2. 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.

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

- 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 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 plans, Prescription Drug Plans, CMS regional offices, beneficiary advocacy groups and other interested parties.

3. Office of Legislation (FAF)

- Provides leadership and executive direction within the Agency for legislative planning to address the Administration's agenda.

- Tracks, evaluates and develops provisions of annual legislative

proposals for Medicare, Medicaid, Clinical Laboratory Improvement Act, Health Insurance Portability and Accountability Act and related statutes affecting health care financing quality and access in concert with HCFA components, the Department and the Office of Management and Budget.

- Advances the legislative policy process through analysis, review and development of health care initiatives and issues.
- Develops the long-range legislative plans for the Agency in collaboration with the CMS Centers and Offices.
- Participates with other CMS components in the development of Agency policy, including implementing regulations and administrative actions.
- Manages pro-actively the Agency's response in times of heightened congressional oversight of CMS in collaboration with the Centers and Offices. Manages, coordinates and develops policies for responding to congressional inquiries.
- Coordinates activities with the Office of the Assistant Secretary for Legislation (ASL) and serves as the ASLs principal contact point on legislative and congressional relations.
- In collaboration with CMS Centers and Offices, provides technical assistance, consultation and information services to congressional committees and individual members of Congress on the Medicare and Medicaid programs, new CMS initiatives and pertinent legislation.
- In collaboration with the CMS Centers and Offices, provides technical, analytical, advisory and information services to the Agency's components, the Department, the White House, OMB, other government agencies, private organizations and the general public on Agency legislation.
- Tracks and reports on legislation relating to CMS programs and maintains legislative reference library.
- Coordinates the Agency's participation in congressional hearings, including preparation of testimony and briefing materials, and covers all other congressional hearings on matters of interest to the Agency except Appropriations Committee hearings specifically on the appropriation budget.

4. Center for Medicare Management (FAH)

- Serves as the focal point for all Agency interactions with health care providers, intermediaries and carriers for issues relating to Agency fee-for-service policies and operations.
- Monitors providers' and other entities' conformance with quality

standards (other than those directly related to survey and certification); policies related to scope of benefits; and other statutory, regulatory, and contractual provisions.

- Based on program data, develops payment mechanisms, administrative mechanisms, and regulations to ensure that CMS is purchasing medically necessary services under fee-for-service.
- Writes payment and benefit-related instructions for Medicare contractors.
- Defines the scope of Medicare benefits and develops national fee-for-service payment policies, as necessary, to assure the effective administration of the Agency's programs, including the development of related statutory proposals.
- Develops Agency medical coding policies related to fee-for-service payments.
- Provides administrative support to the Practicing Physician Advisory Council.
- Coordinates provider, physician and contractor centered information, education, and service initiatives.
- Serves as the CMS lead for Medicare carrier and fiscal intermediary management, oversight, budget, and performance issues.
- Functions as CMS liaison for all Medicare carrier and fiscal intermediary program issues and, in close collaboration with the regional offices and other CMS components, coordinates the agency-wide contractor activities.
- Manages contractor instructions, workload, and change management process.
- Collaborates with other CMS components to establish ongoing performance expectations for Medicare contractors (carriers and fiscal intermediaries) consistent with the agency's goals; interprets, evaluates, and provides information on Medicare contractors in terms of ongoing compliance with performance requirements and expectations; evaluates compliance with issued instructions; evaluates contractor-specific performance and/or integrity issues; and evaluates/monitors corrective action, if necessary.
- Manages, monitors, and provides oversight of contractor (carriers and fiscal intermediaries) transition activities including replacement of departing contractors and the resulting transfer of workload, functional realignments, and geographic workload carveouts.
- Maintains and provides accurate contractor specific information. Develops and implements long-term fee-for-service contractor strategy, tactical plans, and other planning documents.

- Serves as lead on current/proposed legislation in order to determine impact on provider and contractor operations.

- Develops national policy and implementation of all Medicare Part A, Part B, and Part C premium billing and collection activities and coordination of benefits to assure effective administration of fee-for-service aspects of the Medicare program.

5. Office of Equal Opportunity & Civil Rights (FAJ)

- Provides agency-wide leadership and advice on issues of diversity, civil rights, and promotion of a supportive work environment for Agency employees.
 - Develops, implements and manages affirmative employment programs. Provides principal advisory, advocacy, and liaison services for the Administrator to Agency leadership and employees concerning equality in employment related issues to ensure a diverse workforce.
 - Develops Equal Employment Opportunity (EEO) and civil rights compliance policy for the Agency. Assesses the Agency's compliance with applicable civil rights statutes, executive orders, regulations, policies, and programs.
 - Identifies policy and operational issues and proposes solutions for resolving these issues in partnership with management, Office of the General Counsel, and other organizational entities.
 - Receives and evaluates complaints for procedural sufficiency; investigates, adjudicates and resolves such complaints.
 - Promotes the representation of minority groups, women, and individuals with disabilities through community outreach and other activities.
 - Resolves informal discrimination complaints by means of EEO counseling and/or Alternative Dispute Resolution.
 - Develops and analyzes data for internal and external reports reflecting the diversity of the Agency workforce and fairness in employment related actions. Makes recommendations to management on changes needed to ensure equal employment opportunity in every respect.
 - Serves as the internal advocate for civil rights and related principles. Provides training, seminars, and technical guidance to Agency staff.
- #### **6. Office of Research, Development & Information (FAK)**
- Provides analytic support and information to the Administrator and

the Executive Council needed to establish Agency goals and directions.

- Performs environmental scanning, identifying, evaluating, and reporting emerging trends in health care delivery and financing and their interactions with Agency programs.
- Manages strategic, crosscutting initiatives.
- Designs and conducts research and evaluations of health care programs, studying their impacts on beneficiaries, providers, plans, States and other partners and customers, designing and assessing potential improvements, and developing new measurement tools.
- Coordinates all Agency demonstration activities, including development of the research and demonstration annual plan, evaluation of all Agency demonstrations, and assistance to other components in the design of demonstrations and studies.
- Manages assigned demonstrations, including Federal review, approval, and oversight; coordinates and participates with departmental components in experimental health care delivery projects.
- Develops research, demonstration, and other publications and papers related to health care issues.
- Designs and conducts payment, purchasing, and benefits demonstrations.

7. Office of Clinical Standards & Quality (FAM)

- Serves as the focal point for all quality, clinical and medical science issues and policies for the Agency's programs. Provides leadership and coordination for the development and implementation of a cohesive, agency-wide approach to measuring and promoting quality and leads the Agency's priority-setting process for clinical quality improvement. Coordinates quality-related activities with outside organizations. Monitors quality of Medicare, Medicaid, and CLIA. Evaluates the success of interventions.
- Identifies and develops best practices and techniques in quality improvement; implementation of these techniques will be overseen by appropriate components. Develops and collaborates on demonstration projects to test and promote quality measurement and improvement.
- Develops, tests and evaluates, adopts and supports performance measurement systems (quality indicators) to evaluate care provided to CMS beneficiaries except for demonstration projects residing in other components.

- Assures that the Agency's quality-related activities (survey and certification, technical assistance, beneficiary information, payment policies and provider/plan incentives) are fully and effectively integrated. Carries out the Health Care Quality Improvement Program (HCQIP) for the Medicare, Medicaid, and CLIA programs.
 - Leads in the specification and operational refinement of an integrated CMS quality information system, which includes tools for measuring the coordination of care between health care settings; analyzes data supplied by that system to identify opportunities to improve care and assess success of improvement interventions.
 - Develops requirements of participation for providers and plans in the Medicare, Medicaid, and CLIA programs. Revises requirements based on statutory change and input from other components.
 - Operates the Medicare Peer Review Organization and End Stage Renal Disease Network program in conjunction with regional offices, providing policies and procedures, contract design, program coordination, and leadership in selected projects.
 - Identifies, prioritizes and develops content for clinical and health related aspects of CMS' Consumer Information Strategy; collaborates with other components to develop comparative provider and plan performance information for consumer choices.
 - Prepares the scientific, clinical, and procedural basis for and recommends to the Administrator decisions regarding coverage of new and established technologies and services. Coordinates activities of the Agency's Technology Advisory Committee and maintains liaison with other departmental components regarding the safety and effectiveness of technologies and services; prepares the scientific and clinical basis for, and recommends approaches to, quality-related medical review activities of carriers and payment policies.
- #### **8. Office of the Actuary (FAN)**
- Conducts and directs the actuarial program for CMS and directs the development of and methodologies for macroeconomic analysis of health care financing issues.
 - Performs actuarial, economic and demographic studies to estimate CMS program expenditures under current law and under proposed modifications to current law.
 - Provides program estimates for use in the President's budget and for reports required by Congress.

- Studies questions concerned with financing present and future health programs, evaluates operations of the Federal Hospital Insurance Trust Fund and Supplementary Medical Insurance Trust Fund and performs microanalyses for the purpose of assessing the impact of various health care financing factors upon the costs of Federal programs.
- Estimates the financial effects of proposals to create national health insurance systems or other national or incremental health insurance reform.
- Develops and conducts studies to estimate and project national and area health expenditures.
- Develops, maintains, and updates provider market basket input price indexes and the Medicare Economic Index.
- Analyzes data on physicians' costs and charges to develop payment indices and monitors expansion of service and inflation of costs in the health care sector.
- Performs actuarial reviews and audits of employee benefit expenses charged to Medicare by fiscal intermediaries and carriers.
- Publishes cost projections and economic analyses, and provides actuarial, technical advice and consultation to CMS components, governmental components, Congress, and outside organizations.

9. Center for Medicaid and State Operations (FAS)

- Serves as the focal point for all Centers for Medicare & Medicaid Services activities relating to Medicaid, the State Children's Health Insurance Program, the Clinical Laboratory Improvement Act, the survey and certification of health facilities and all interactions with States and local governments (including the Territories).
- Develops national Medicaid policies and procedures which support and assure effective State program administration and beneficiary protection. In partnership with States, evaluates the success of State agencies in carrying out their responsibilities and, as necessary, assists States in correcting problems and improving the quality of their operations.
- Develops, interprets, and applies specific laws, regulations, and policies that directly govern the financial operation and management of the Medicaid program and the related interactions with States and regional offices.
- In coordination with other components, develops, implements, evaluates and refines standardized provider performance measures used within provider certification programs.

Supports States in their use of standardized measures for provider feedback and quality improvement activities. Develops, implements and supports the data collection and analysis systems needed by States to administer the certification program.

- Reviews, approves and conducts oversight of Medicaid managed care waiver programs. Provides assistance to States and external customers on all Medicaid managed care issues.

- Develops national policies and procedures on Medicaid automated claims/encounter processing and information retrieval systems such as the Medicaid Management Information System (MMIS) and integrated eligibility determination systems.

- In coordination with the Office of Financial Management (OFM), directs, coordinates, and monitors program integrity efforts and activities by States and regions. Works with OFM to provide input in the development of program integrity policy.

- Through administration of the home and community-based services program and policy collaboration with other Agency components and the States, promotes the appropriate choice and continuity of quality services available to frail elderly, disabled and chronically ill beneficiaries.

- Develops and tests new and innovative methods to improve the Medicaid program through demonstrations and best practices including managing review, approval, and oversight of the Section 1115 demonstrations.

- Directs the planning, coordination, and implementation of the survey, certification, and enforcement programs for all Medicare and Medicaid providers and suppliers, and for laboratories under the auspices of the Clinical Laboratory Improvement Act (CLIA). Reviews and approves applications by States for "exemption" from CLIA and applications from private accreditation organizations for deeming authority. Develops assessment techniques and protocols for periodically evaluating the performance of these entities. Monitors the performance of proficiency testing programs under the auspices of CLIA.

10. Office of the Boston Regional Administrator (FAU1)

- Assures the effective administration of CMS programs and implements national policy at the regional level.

- Develops policy, participates in the formulation of new policy and recommends changes in existing national policy for CMS programs.

- Monitors the regional administrative budget, including

oversight of the regional travel funding allocation.

- Manages procurement and contracting activities, and personnel administration for the region.

- Serves as principal CMS contact for professional and provider/supplier organizations in the region's service area.

- Oversees workplanning, facilities and property management, labor-management relations, and staff training for the region.

- Initiates and directs the implementation of special regional and national projects.

- Assures effective relationships within the region with State and local governments, beneficiaries and their representatives, and the media.

- Coordinates with the DHHS Regional Director to assure effective relationships with Congressional representatives and State and local governments.

11. Office of the New York Regional Administrator (FAU2)

- Assures the effective administration of CMS programs and implements national policy at the regional level.

- Develops policy, participates in the formulation of new policy and recommends changes in existing national policy for CMS programs.

- Monitors the regional administrative budget, including oversight of the regional travel funding allocation.

- Manages procurement and contracting activities, automated data processing/local area network systems, and personnel administration for the region.

- Serves as principal CMS contact for professional and provider/supplier organizations in the region's service area.

- Oversees workplanning, facilities and property management, labor-management relations, and staff training for the region.

- Initiates and directs the implementation of special regional and national projects.

- Assures effective relationships within the region with State and local governments, beneficiaries and their representatives, and the media.

- Coordinates with the Department of Health and Human Services' Regional Director to assure effective relationships with Congressional representatives and State and local governments.

12. Office of the Philadelphia Regional Administrator (FAU3)

- Assures the effective administration of CMS programs and implements national policy at the regional level.

- Develops new policies and recommends changes in existing national policies for CMS programs.

- Monitors the regional administrative budget, including oversight of the regional travel funding allocation.

- Manages procurement and contracting activities and personnel administration for the region.

- Serves as principal CMS contact for professional and provider/supplier organizations in the region's service area.

- Oversees work planning, facilities and property management, labor-management relations, and staff training for the region.

- Initiates and directs the implementation of special regional and national projects. Assures effective relationships within the region with State and local governments, beneficiaries and their representatives, and the media.

- Coordinates with the Department of Health and Human Services' Regional Director to ensure effective relationships with elected officials as well as State and local governments.

13. Office of the Atlanta Regional Administrator (FAV4)

- Directs the planning, coordination, and implementation of the programs under Titles XI, XVIII, and XIX of the Social Security Act and related statutes within the Agency's regional/field offices that comprise the Atlanta and Dallas Regional Offices.

- Provides executive leadership and direction to the Agency's Regional Administrator(s) in the Atlanta and Dallas Regional Offices.

- Assures that the Agency's programs are carried out in the most effective and efficient manner within the Atlanta and Dallas Regional Offices, and that they are coordinated both at the Atlanta and Dallas level and with the Agency's headquarters' offices.

- Provides an Atlanta and Dallas perspective to the Agency's Administrator and other members of the Executive Council in such activities as strategic planning, determining the effectiveness of the Agency's programs and policies, budget formulation and execution, legislation, and administrative management.

- Assures that the Agency's national policies, programs and special initiatives are implemented effectively throughout the Atlanta and Dallas Regional Offices. Conducts local projects to improve the quality of medical care provided to beneficiaries and to control fraud, abuse and waste in the Agency's programs.

- Evaluates progress in the administration of the Agency's programs in the Atlanta and Dallas Regional Offices, ensuring that required actions are taken to direct or redirect efforts and/or resources to achieve program objectives.

- Working with the Regional Administrator(s) in the Atlanta and Dallas Regional Offices and the Agency's headquarters' leadership, assures that the information needs of the Medicare and Medicaid beneficiaries are fully understood and met, to the maximum degree possible. In association with other Agency components, maintains an understanding of the health care market that is operating in the Atlanta and Dallas Regional Offices in order to allow the Agency to adapt to changes in that market when appropriate.

- Assures that the Regional Administrator(s) in the Atlanta and Dallas Regional Offices fully coordinate the Agency's programs with other Health and Human Services' components, other Federal agencies, the Agency's contractors, State and local governments, professional associations, other interested groups, and the Agency's beneficiaries and/or representatives in their respective region.

- Working with the Agency's headquarters, manages the Atlanta and Dallas' administrative budget, to include the planning and allocation of resources to the regional offices comprising the Atlanta and Dallas Regional Offices.

- Provides executive leadership and guidance on behalf of the Atlanta and Dallas Regional Administrator to CMS components at the regional level.

- Serves on the Atlanta and Dallas Leadership Council, which sets the overall direction for the Atlanta and Dallas Regional Offices, and implements the Council's directions within the Region's service area.

- Effectively implements national policy, programs, and special initiatives at the regional level. Conducts local projects to improve the quality of medical care provided to beneficiaries and to control fraud, abuse, and waste in the Agency's programs.

- Assures that the information needs of the Medicare and Medicaid beneficiaries are fully understood and met, to the maximum degree possible. In association with other Agency components, maintains an understanding of the health care market that is operating in the Region in order to allow the Agency to adapt to changes in that market when appropriate.

- Participates in the formulation of new policy and recommends changes in

existing national policy for CMS programs.

- Develops and implements a professional relations program within the Region for all CMS programs and serves as the principal CMS contact for all professional organizations such as hospital and medical associations.

- Fully coordinates the Agency's programs with other Health and Human Services' components including the Department's Regional Director, other Federal agencies, the Agency's contractors, State and local governments, professional associations, other interested groups, and the Agency's beneficiaries and/or representatives in the Region.

- Manages procurement and contracting activities, ADP/LAN systems, and personnel actions for the Region.

- Provides regional perspective to the Administrator and the Executive Council.

- Monitors the regional administrative budget, including oversight of the regional travel funding allocation.

14. Office of the Chicago Regional Administrator (FAW5)

- Serves as the principal office for Regional operations of CMS.

- Directs the administration of all CMS programs within the region.

- Sets the overall direction for the Chicago and Kansas City Regional Offices through the Midwest Consortium Advisory Board, and implements Board directions within the Region's service area.

- Monitors the Regional administrative budget, including oversight of the Regional travel funding allocation.

- Manages procurement and contracting activities, ADP/LAN systems, and personnel actions for the Region.

- Serves as principal CMS contact for professional and provider/supplier organizations in the Region's service area.

- Oversees work planning, facilities and property management, labor-management relations, merit promotion principles, EEO, and staff training for the Region.

- Coordinates environmental scanning and strategic planning for the Region. Pursues activities which enable the Regional staff to become knowledgeable regarding developments and trends in health care delivery within the States they serve.

- Serves as focal point among Regional Office components for special

initiatives and broad cross-cutting issues.

15. Office of the Dallas Regional Administrator (FAV6)

- Provides executive leadership and guidance on behalf of the Atlanta and Dallas Regional Administrators to CMS components at the regional level.

- Serves on the Atlanta and Dallas Leadership Council, which sets the overall direction for the Regions, and implements the Council's directions within the Region's service area.

- Effectively implements national policy, programs, and special initiatives at the regional level. Conducts local projects to improve the quality of medical care provided to beneficiaries and to control fraud, abuse, and waste in the Agency's programs.

- Assures that the information needs of the Medicare and Medicaid beneficiaries are fully understood and met, to the maximum degree possible. In association with other Agency components, maintains an understanding of the health care market that is operating in the Region in order to allow the Agency to adapt to changes in that market when appropriate.

- Participates in the formulation of new policy and recommends changes in existing national policy for CMS programs.

- Develops and implements a professional relations program within the Region for all CMS programs and serves as the principal CMS contact for all professional organizations such as hospital and medical associations.

- Fully coordinates the Agency's programs with other Health and Human Services' components including the Department's Regional Director, other Federal agencies, the Agency's contractors, State and local governments, professional associations, other interested groups, and the Agency's beneficiaries and/or representatives in the Region.

- Manages procurement and contracting activities, ADP/LAN systems, and personnel actions for the Region.

- Provides regional perspective to the Administrator and the Executive Council.

- Monitors the regional administrative budget, including oversight of the regional travel funding allocation.

16. Office of the Kansas City Regional Administrator (FAW7)

- Serves as the principal official for regional operations of CMS and directs the administration of all CMS programs within the region.

- Directs the Consortium Survey and Certification and Consortium Contractor Management organizations.

- Monitors the regional administrative budget, including oversight of the regional travel funding allocation.

- Develops and implements a media relations plan to market CMS programs to the diverse populations of the region.

- Manages procurement and contracting activities, ADP/LAN systems, and personnel actions for the Region.

- Oversees work planning, facilities and property management, labor-management relations, merit promotion principles, EEO and staff training for the region.

- Coordinates environmental scanning and strategic planning for the region. Pursues activities which enable the Chicago and Kansas City regional staff to become knowledgeable regarding developments and trends in health care delivery within the states they serve.

- Serves as the focal point among regional office components for special initiatives and broad cross-cutting issues.

- Manages and executes the Health Insurance Portability and Accountability Act's insurance portability enforcement process for the nation.

17. Office of the Denver Regional Administrator (FAX8)

- The Office of the Regional Administrator directs the operations of programs administered by the CMS, including Medicare, Medicaid, Clinical Laboratory Improvement Act, and Health Insurance Portability and Accountability Act, in a distinct geographic area and provides executive leadership to regional office staff on behalf of the CMS Administrator.

- Develops and implements an outreach plan which includes media relations, community participation, speeches and presentations, and local Congressional office liaison, to market CMS programs to the diverse populations of the region.

- Manages the human and dollar resources of the regional office in an efficient and effective manner including work planning, facilities and property management, human resource management (recruitment, retention, training, development and performance management), and labor-management relations.

- Coordinates with the Department's Regional Director to assure effective relations with State and local governments and with other Departmental programs and offices.

- Evaluates diverse needs of constituents in the region and advises policy makers so that such needs are considered by CMS in national policy development.

- Develops expert opinion to advise national policy makers on concerns of American Indians and Alaska Natives as they relate to programs administered by HHS.

18. Office of the San Francisco Regional Administrator (FAX9)

- The Office of the Regional Administrator directs the operations of programs administered by the CMS, including Medicare, Medicaid, Clinical Laboratory Improvement Act, and Health Insurance Portability and Accountability Act, in a distinct geographic area and provides executive leadership to regional office staff on behalf of the CMS Administrator.

- Develops and implements an outreach plan which includes media relations, community participation, speeches and presentations, and local Congressional office liaison, to market CMS programs to the diverse populations of the region.

- Manages the human and dollar resources of the regional office in an efficient and effective manner including work planning, facilities and property management, human resource management (recruitment, retention, training, development and performance management), and labor-management relations.

- Coordinates with the Department's Regional Director to assure effective relations with State and local governments and with other Departmental programs and offices.

- Evaluates diverse needs of constituents in the region and advises policy makers so that such needs are considered by CMS in national policy development.

19. Office of the Seattle Regional Administrator (FAXX)

- The Office of the Regional Administrator directs the operations of programs administered by the CMS, including Medicare, Medicaid, Clinical Laboratory Improvement Act, and Health Insurance Portability and Accountability Act, in a distinct geographic area and provides executive leadership to regional office staff on behalf of the CMS Administrator.

- Develops and implements an outreach plan which includes media relations, community participation, speeches and presentations, and local Congressional office liaison, to market CMS programs to the diverse populations of the region.

- Manages the human and dollar resources of the regional office in an efficient and effective manner including work planning, facilities and property management, human resource management (recruitment, retention, training, development and performance management), and labor-management relations.

- Coordinates with the Department's Regional Director to assure effective relations with State and local governments and with other Departmental programs and offices.

- Evaluates diverse needs of constituents in the region and advises policy makers so that such needs are considered by CMS in national policy development.

- Designs and implements health care quality improvement projects and manages contracts of peer review organizations to improve health care quality in 13 Western States.

20. Office of Operations Management (FAY)

- Prepares and presents recommendations to the Administrator, Deputy Administrator, Chief Operating Officer and other high-level CMS and Department officials on planning, leadership, implementation and policy issues concerning modifications to existing and proposed operating policies that will improve the administration and operations of programs and the Agency as a whole.

- Provides consulting services internally to Agency management and staff to identify processes that need improvement, to develop improvement strategies, and to monitor processes and improvements over time. Participates in agency-wide initiatives to streamline operations, improve accountability and performance, and implement management best practices.

- Promotes project planning principles throughout the Agency and provides technical guidance to the Agency on project planning and management techniques. Prepares and presents recommendations to senior officials regarding major projects.

- Promotes and teaches risk assessment methods to business owners throughout CMS. Promotes awareness of the importance of risk analysis as a component of business planning and trains CMS staff in specific techniques and their applicability in particular situations.

- Identifies operational vulnerabilities within CMS and develops and executes an operational review plan for each fiscal year, subject to approval by the Deputy

Administrator, Chief Operating Officer and other senior leadership of CMS.

- Plans and conducts targeted internal audits and makes recommendations to strengthen internal audits and improve the operations of the Agency.

- Serves as the Agency focal point for emergency preparedness.

- Provides the Agency's internal customers (employees) with support in human resource management, procurement management, and logistics. Includes planning, organizing, coordinating, and evaluating needed activities in each area.

- Manages and directs the Agency's ethics and management programs; provides policy direction, coordination and support for administrative services including space, property, records, printing and facilities management, safety and security, and a centralized customer service desk.

- Provides administrative support functions for the Commissioned Corps.

- Develops and maintains administrative systems for ethics, awards, procurement, and property management.

- Provides staff support to the Provider Reimbursement Review Board (PRRB) and the Medicare Geographic Review Board (MGCRB).

- Conducts Medicare and Medicaid Hearings on behalf of the Secretary or the Administrator that are not within the jurisdiction of the Department Appeals Board, the Social Security Administration's Office of Hearings and Appeals, the PRRB, the MGCRB, or the States.

21. Office of Information Services (FBB)

- Serves as the focal point for the responsibilities of the Agency's Chief Information Officer in planning, organizing, and coordinating the activities required to maintain an agency-wide Information Resources Management (IRM) program.

- Ensures the effective management of the Agency's information technology, and information systems and resources (e.g., implementation and administration of a change management process).

- Provides workstation, server, and local area network support for CMS-wide activities. Works with customer components to develop requirements, needs and cost benefit analysis in support of the LAN infrastructure including hardware, software and office automation services.

- Serves as the lead for developing and enforcing the Agency's information architecture, policies, standards, and

practices in all areas of information technology.

- Develops and maintains enterprise-wide central databases, statistical files, and general access paths, ensuring the quality of information maintained in these data sources.

- Directs Medicare claims payment systems activities, including CWF operation, as well as systems conversion activities.

- Develops ADP standards and policies for use by internal CMS staff and contractor agents in such areas as applications development and use of the infrastructure resources.

- Manages and directs the operation of CMS hardware infrastructure, including the Agency's Data Center, data communications networks, enterprise infrastructure, voice/data switch, audio conferencing and other data centers supporting CMS programs.

- Leads the coordination, development, implementation and maintenance of health care information standards in the health care industry.

- Provides Medicare and Medicaid information to the public, within the parameters imposed by the Privacy Act.

- Performs information collection analyses as necessary to satisfy the requirements of the Paperwork Reduction Act.

- Directs CMS' ADP systems security program with respect to data, hardware, and software.

- Directs and advises the Administrator, senior staff, and components on the requirements, policies, and administration of the Privacy Act.

22. Office of Financial Management (FBC)

- Serves as the Chief Financial Officer and Comptroller for the Agency.

- Formulates, presents and executes all Agency budget accounts; develops outlay plans and tracks contract and grant award amounts; acts as liaison with the Congressional Budget Office (CBO) on budget estimates; reviews demonstration waivers (except 1115) for revenue neutrality. Is responsible for ensuring that the budget is formulated in accordance with the Agency's strategic plan and the GPRAs goals and performance measures.

- Acts as liaison with ASMB, OMB, and the Congressional appropriations committees for all matters concerning the Agency's operating budget.

- Manages the Medicare financial management system, the Medicare contractors' budgets, Peer Review Organizations' budgets, research budgets, managed care payments, the issuance of State Medicaid grants, and

the funding of the State survey/certification and the CLIA programs. Is responsible for all Agency disbursements.

- Performs cash management activities and establishes and maintains systems to control the obligation of funds and ensure that the Anti-Deficiency Act is not violated.

- Performs the Agency's debt management activities (e.g., accounts receivable, user fees, penalties, disallowances).

- Reconciles all Agency financial data and prepares external reports to other agencies such as HHS, Treasury, OMB, Internal Revenue Service, General Services Administration, related to the Agency's obligations, expenditures, prompt payment activities, debt and cash management, and other administrative functions.

- Has overall responsibility for the fiscal integrity of all Agency programs. Develops and performs all benefit integrity policy and operations in coordination with other Agency components. Manages the Medicare program integrity contractors authorized by the HIPAA and managed care financial audit and enforcement functions. In coordination with the Center for Medicaid and State Operations, develops Medicaid program integrity policy; and monitors Medicaid program integrity activities.

- Working with other CMS components, develops Agency policies governing both Medicare Secondary Payer and Medicaid Third Party Liability.

- Develops and implements all civil money penalty policies in all programs.

- Prepares financial statements for *Federal Managers Financial Integrity Act* and GPRAs.

23. Office of Strategic Operations & Regulatory Affairs (FGA)

- Manages the Agency's decision-making and regulatory process.

- Serves in a neutral broker coordination role which includes: Scheduling meetings and briefings for the Administrator and coordinating communications between and among central and regional offices to ensure that emerging issues are identified early, all concerned components are directly and fully involved in policy development/decision making, and that all points of view are presented.

- Provides leadership, direction, and advocacy, on behalf of top CMS officials in connection with official policy matters for presentation to the Administrator and Deputy Administrator/ Chief Operating Officer to insure that all points of view and

program interests of concern to the Administrator and Deputy Administrator/Chief Operating Officer are developed and properly presented for consideration. Reviews policy statements by component Directors and others to anticipate potential problems or inconsistencies with views of the Administrator, Deputy Administrator/Chief Operating Officer, and the Administration. Assists in resolving these matters to the satisfaction of the Agency and top management.

- Manages meeting requests for or on behalf of the Administrator, and Deputy Administrator/Chief Operating Officer. Coordinates the preparation of briefing materials for the Administrator, Deputy Administrator/Chief Operating Officer, and the Department in advance of the Administrator and Deputy Administrator/Chief Operating Officer's participation in meetings, appointments with major groups, etc. Works with CMS components to assure that appropriate briefing materials are presented to Senior Leadership. Senior officials in CMS and the Department, as well as officials of other Federal agencies, State and local governments, and outside interest groups attend these meetings.

- Coordinates the preparation of manuals and other policy instructions to ensure accurate and consistent implementation of the Agency's programs.

- Manages the Agency's system for developing, clearing and tracking regulations, setting regulation priorities and corresponding work agendas; coordinates the review of regulations received for concurrence from departmental and other government agencies, and develops routine and special reports on the Agency's regulatory activities.

- Manages the regulations development process to ensure timely decision making by the Administrator and Deputy Administrator/Chief Operating Officer on CMS regulations.

- Provides leadership and management of the Agency's Executive Correspondence system. Operates the agency-wide correspondence tracking and control system and provides guidance and technical assistance on standards for content of correspondence and memoranda.

- Manages the agency-wide clearance system to ensure appropriate involvement from Agency components and serves as a primary focal point for liaison with the Executive Secretariat in the Office of the Secretary.

- Provides management and administrative support to the Office of the Attorney Advisor and staff.

- Acts as audit liaison with the General Accounting Office (GAO) and the HHS Office of Inspector General (OIG).

- Monitors and coordinates major CMS legislative initiatives such as tracking the status of the Agency's implementation of Balance Budget Act, Balanced Budget Refinement Act, and the Benefits Improvement and Protection Act provisions.

- Coordinates and prepares the advance planning reports for the Secretary and the Administrator (Secretary's Forecast Report).

- Acts as the liaison with the Office of the Secretary for Reports to the Congress and maintains a tracking system to monitor status. Also serves as the CMS liaison with the Small Business Administration's Office of the National Ombudsman.

- Develops standard processes for all CMS FACA committees and provides operational and logistical support to CMS components for conferences and on all matters relating to Federal Advisory Committees.

- Conducts activities necessary to the receipt, management, response, and reporting requirements of the Department under the Freedom of Information Act (FOIA) regarding all requests received by CMS.

- Maintains a log of all FOIA requests received by the central office, refers requests to the appropriate components within headquarters, the regions or among carriers and intermediaries for the collection of the documents requested. Makes recommendations and prepares replies to requesters, including denials of information as permitted under FOIA, and drafts briefing materials and responses in connection with appeals of denial decisions.

- Directs the maintaining and amending of CMS-wide records for confidentiality and disclosure to the Privacy Act to include: Planning, organizing, initiating and controlling privacy matching assignments.

- Provides direct services and develops policy, standards, and procedures for CMS' records, management and vital records program for all CMS Central and Regional Offices.

24. 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.

25. Office of Acquisition & Grants Management (FKA)

- Serves as the Agency's Head of the Contracting Activity. Plans, organizes, coordinates and manages the activities required to maintain an agency-wide acquisition program.

- Serves as the Agency's Chief Grants Management Official, with responsibility for all CMS discretionary grants.

- Ensures the effective management of the Agency's acquisition and grant resources.

- Serves as the lead for developing and overseeing the Agency's acquisition planning efforts.

- Develops policy and procedures for use by acquisition staff and internal CMS staff necessary to maintain

efficient and effective acquisition and grant programs.

- Advises and assists the Administrator, senior staff, and Agency components on acquisition and grant related issues.

- Plans, develops, and interprets comprehensive policies, procedures, regulations, and directives for CMS acquisition functions.

- Represents CMS at departmental acquisition and grant forums and functions, such as the Executive Council on Acquisition and the Executive Council for Grants Administration Policy.

- Serves as the CMS contact point with HHS and other Federal agencies relative to grant and cooperative agreement policy matters.

- Coordinates and/or conducts training for contracts and grant personnel, as well as project officers in CMS components.

- Develops agency-specific procurement guidelines for the utilization of small and disadvantaged business concerns in achieving an equitable percentage of CMS' contracting requirements.

- Provides cost/price analyses and evaluations required for the review, negotiation, award, administration, and closeout of grants and contracts. Provides support for field audit capability during the pre-award and closeout phases of contract and grant activities.

- Develops and maintains the OAGM automated procurement management system. Manages procurement information activities (i.e., collecting, reporting, and analyzing procurement data).

26. Office of Policy (FLA)

- Assists the Policy Council with immediate/rapid response on timely issues and transform concepts into institutionalized processes.

- Assists the MMA Council as requested to develop, implement, and coordinate a policy process for the agency for key major cross-cutting and policy issues resulting from MMA legislation and subsequent issues.

- Advises the Administrator on medical technical innovation and health information technology matters.

- Plans and develops future CMS program policy. Assists OL in the development of legislative strategies by providing analytic support for legislative options and proposals. Conducts legislative, economic, and policy analyses related to the overall structure of health care financing. Translates research findings into policy applications.

- Performs environmental scanning, identifying, evaluating, and reporting emerging trends to health care delivery and financing. Works with Agency components and outside organizations to obtain relevant information on emerging trends. Analyzes trends for their interactions with Agency programs and implications for future policy development and planning. Identifies emerging trends and policy issues that would benefit the Office of Research, Development, and Information's research, evaluation, and survey enterprises.

- Conducts management and development of the long-term strategic plan for the Agency. Provides analytic support and information to the Administrator and Senior Leadership needed to establish the Agency's goals and directions. Conducts special studies and analyses concerning Agency-wide planning issues.

- Provides data analyses, graphics presentations, briefing materials, and analyses on short notice to support the immediate needs of the Administrator and Senior Leadership.

- Manages strategic, cross-cutting initiatives as assigned by the Office of the Administrator.

- Facilitates policy development by providing analytic liaison with other components in HHS and elsewhere in the Administration.

- Serves as CMS' contact for international visitors. Responds to requests from intergovernmental agencies and the international community for information related to the United States health care system.

Dated: December 20, 2005.

Karen Pelham O'Steen,

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

[FR Doc. E5-8073 Filed 12-28-05; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction

Program (the Site Tours Program). The purpose of this notice is to invite pharmaceutical companies interested in participating in this program to contact CDER.

DATES: Pharmaceutical companies may submit proposed agendas to the agency by February 27, 2006.

FOR FURTHER INFORMATION CONTACT: Beth Duvall-Miller, Office of New Drugs (HFD-020), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 22, rm. 6466, Silver Spring, MD 20903, 301-796-0700, FAX: 301-796-9858.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, the Center has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) First hand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. Regulatory Project Management Site Tours and Regulatory Interaction Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and