statistical and research purposes related to evaluating and studying the operation and effectiveness of the Medicare program.

2. ''*Medicare Drug Data Processing System (DDPS),''* System No. 09–70–0553, last published at 73 FR 30943 (May 29, 2008). The primary purpose of this system is to collect, maintain, and process information on all Medicare covered, and as many non-covered drug events as possible, for people with Medicare who have enrolled into a Medicare Part D plan.

3. ''*Medicare Integrated Data Repository (IDR),''* System No. 09–70–0571, published at 71 FR 74915 (December 13, 2006). The primary purpose of this system is to establish an enterprise resource that provides one integrated view of all CMS data to administer the Medicare and Medicaid programs.

4. ''*Chronic Condition Data Repository (CCDR),''* System No. 09–70–0573, published at 71 FR 54495 (September 15, 2006). The purpose of this system is to collect and maintain a person-level view of identifiable data to establish a data repository to study chronically ill Medicare beneficiaries. This system utilizes data extraction tools to support accessing data by chronic conditions and processes complex customized research data requests related to chronic illnesses.

DATES: The Centers for Medicare & Medicaid Services (CMS) invites interested parties to submit written comments on the proposed system until November 16, 2011. As required by the Privacy Act (5 U.S.C. 552a(r)), CMS on October 17, 2011 sent a report of a new system of records to the Committee on Homeland Security and Governmental Affairs of the Senate, the Committee on Oversight and Government Reform of the House of Representatives, and the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB). The proposed action described in this notice is effective on November 26, 2011, unless CMS receives comments which result in a republication of the notice.

ADDRESSES: The public should address comments to: CMS Privacy Officer, Division of Information Security & Privacy Management, Enterprise Architecture and Strategy Group, Office of Information Services, CMS, Room N1–24–08, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., Eastern Time zone.

FOR FURTHER INFORMATION CONTACT: Chris Haffer, Ph.D., Program Manager, Data Development and Services Group, Center for Strategic Planning, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Mail-stop: C3–24–07, Baltimore, MD 21244–1850. *Office:* 410–786–8764, *Facsimile:* (410) 786–5515, *E-mail address: chris.haffer@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: The statute defines QEs as public or private entities that are determined by the Secretary to be qualified to use Medicare claims data to make such evaluations of provider/supplier performance, and that agree to meet specific requirements regarding the transparency of their methods and their use and protection of Medicare data. The statute requires that Medicare claims extracts be combined with other claims data, although the statute is not specific on what, or how much, other claims data should be combined with Medicare claims data. The statute requires that the only use of such data and the derived performance information about providers and suppliers be in reports in an aggregate form, released and made available to the public, after first making such reports available to any identified provider or supplier and affording an opportunity to appeal and correct errors. The statute also instructs the Secretary to take such actions as she deems necessary to protect the identity of individual beneficiaries, and authorizes her to establish additional requirements that she may specify for QEs to meet, such as ensuring the security of data. The Medicare claims extracts are to be made available to QEs at a fee equal to the cost of making such data available (the fees will be deposited into the Part B Trust Fund).

Dated: October 12, 2011.

Michelle Snyder,

Deputy Chief Operating Officer, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–27149 Filed 10–19–11; 8:45 am]

BILLING CODE 4120–03–P

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. 70, No. 249, pp. 77160–77161, dated December 29, 2005; Vol. 75, No. 56, pp. 14176—14178, dated March 24, 2010; and Vol. 76, No. 144, pp. 44933–44934, dated July 27, 2011) are amended to: (1) Realign the survey and certification function from the Center for Medicaid, CHIP and Survey & Certification to the Office of Clinical Standards and Quality (OCSQ) and to change the organizational title for the Center for Medicaid, CHIP and Survey & Certification to the Center for Medicaid and CHIP Services (CMCS), and (2) realign the governmental relations function from the Office of Legislation (OL) to CMCS. Part F, Sections FC.10 (Organization) and FC.20 (Functions) is revised as follows:

- Section FC. 10 (Organization):

Office of the Administrator (FC)
Office of Equal Opportunity and Civil Rights (FCA)
Office of Legislation (FCC)
Office of the Actuary (FCE)
Office of Strategic Operations and Regulatory Affairs (FCF)
Office of Clinical Standards and Quality (FCG)
Center for Medicare (FCH)
Center for Medicaid and CHIP Services (FCJ)
Center for Strategic Planning (FCK)
Center for Program Integrity (FCL)
Chief Operating Officer (FCM)
Office of Minority Health (FCN)
Center for Medicare and Medicaid Innovation (FCP)
Federal Coordinated Health Care Office (FCQ)
Center for Consumer Information and Insurance Oversight (FCR)
Office of Public Engagement (FCS)
Office of Communications (FCT)

- Section FC.20 (Functions):

Center for Medicaid and CHIP Services (FCJ)

- Serves as CMS' focal point for the formulation, coordination, integration, implementation, and evaluation of all national program policies and operations relating to the Medicaid and Children's Health Insurance Program (CHIP).
- In partnership with States, evaluates the success of State agencies in carrying out their responsibilities for effective State program administration and beneficiary protection, and, as necessary, assists States in correcting problems and improving the quality of their operations.
- Identifies and proposes modifications to Medicaid and CHIP program measures, regulations, laws and policies to reflect changes or trends

in the health care industry, program objectives, and the needs of Medicaid beneficiaries. Collaborates with OL on the development and advancement of new legislative initiatives and improvements.

• Serves as CMS' lead for management, oversight, budget and performance issues relating to Medicaid, CHIP, and the related interactions with the States.

• Coordinates with the Center for Program Integrity on the identification of program vulnerabilities and implementation of strategies to eliminate fraud, waste, and abuse.

• In conjunction with the Office of Public Engagement, oversees all CMS interactions and collaboration relating to Medicaid and CHIP with beneficiaries, States and territories and key stakeholders (e.g., health facilities and other health care providers, other Federal government entities, local governments) and communication and dissemination of policies, guidance and materials to same to understand their perspectives, support their efforts, and to drive best practices for beneficiaries, in States and throughout the health care industry.

• Develops and implements a comprehensive strategic plan, objectives and measures to carry out CMS' Medicaid and CHIP mission and goals and position the organization to meet future challenges with the Medicaid and CHIP programs.

Office of Clinical Standards and Quality (FCG)

• Serves as the focal point for all quality, clinical, medical science issues, survey and certification, and policies for CMS' programs. Provides leadership and coordination for the development and implementation of a cohesive, CMS-wide approach to measuring and promoting quality and leads CMS' priority-setting process for clinical quality improvement. Coordinates quality-related activities with outside organizations. Monitors quality of Medicare, Medicaid, and the Clinical Laboratory and Improvement Amendments (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, evaluates, adopts and supports performance measurement systems (i.e., quality measures) to evaluate care provided to CMS beneficiaries except for demonstration projects residing in other components.

• Assures that CMS' 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 for the Medicare, Medicaid, and CLIA programs.

• Oversees the planning, policy, 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 CLIA.

• Serves as CMS' lead for management, oversight, budget, and performance issues relating to the survey and certification program and the related interactions with the States.

• 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 Quality Improvement 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 coverage of new and established technologies and services and provides coverage recommendations to the CMS Administrator. Coordinates activities of CMS' 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.

Office of Legislation (FCC)

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

• Tracks, evaluates and develops provisions of annual legislative proposals for Medicare, Medicaid, CHIP, private health insurance programs, CLIA, Health Insurance Portability and Accountability Act and related statutes affecting health care financing, health insurance, quality, and access in concert with CMS 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 CMS in collaboration with the CMS Centers, Offices, and the Chief Operating Officer (COO).

• Participates with other CMS components in the development of CMS policy, including implementing regulations and administrative actions.

• Manages pro-actively CMS' response in times of heightened congressional oversight of CMS in collaboration with the Centers, Offices, and COO. 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 ASL's principal contact point on legislative and congressional relations.

• In collaboration with CMS Centers, Offices, and the COO, provides technical assistance, consultation and information services to congressional committees and individual members of Congress on the Medicare, Medicaid, CHIP, and private health insurance programs, new CMS initiatives, and pertinent legislation.

• In collaboration with the CMS Centers, Offices, and COO, provides technical, analytical, advisory, and information services to CMS' components, the Department, the White House, OMB, other government agencies, private organizations and the general public on CMS legislation.

• Tracks and reports on legislation relating to CMS programs and maintains legislative reference library.

• Coordinates CMS' participation in congressional hearings, including preparation of testimony and briefing materials, and covers all other congressional hearings on matters of interest to CMS except Appropriations Committee hearings specifically on the appropriation budget.

Authority: 44 U.S.C. 3101.

Dated: October 13, 2011.

Michelle Snyder,

Deputy Chief Operating Officer, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–27169 Filed 10–19–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0720]

International Conference on Harmonisation; E2B(R3) Electronic Transmission of Individual Case Safety Reports; Draft Guidance on Implementation; Data Elements and Message Specification; Appendix on Backwards and Forwards Compatibility; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs): Implementation Guide—Data Elements and Message Specification'' (the draft E2B(R3) implementation guidance) and an appendix to the draft guidance entitled ''ICSRs: Appendix to the Implementation Guide—Backwards and Forwards Compatibility'' (the draft BFC appendix). The draft E2B(R3) implementation guidance and draft BFC appendix were prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft E2B(R3) implementation guidance is intended to revise the standards for submission of ICSRs and improve the inherent quality of the data, enabling improved handling and analysis of ICSR reports. The draft BFC appendix describes the relationship between data elements from the 2001 ICH E2B guidance and draft E2B(R3) implementation guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on these draft documents before it begins work on the final versions of the documents, submit either electronic or written comments on the draft documents by January 18, 2011.

ADDRESSES: Submit written requests for single copies of the draft documents to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft documents may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft documents.

Submit electronic comments on the draft documents 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:

Regarding the guidance:

Krishna K. Chary, Center for Drug Evaluation and Research, Food and Drug Administration, 8201 Corporate Dr., suite 540, Landover, MD 20785, 240–487–7377, *fax:* 301–459–2285, *e-mail: krishna.Chary@fda.hhs.gov;* or

Deborah F. Yaplee, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3288, *fax:* 301–827–9434, *e-mail: deborah.yaplee@fda.hhs.gov.*

Regarding the ICH:

Michelle Limoli, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 3506, Silver Spring, MD 20993, 301–796–4600.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory Agencies.

The ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In June and July 2011, the ICH Steering Committee agreed that a draft guidance entitled ''E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs): Implementation Guide—Data Elements and Message Specification'' and a draft appendix entitled ''ICSRs: Appendix to the Implementation Guide—Backwards and Forwards Compatibility'' should be made available for public comment. The documents are the product of the E2B(R3) Expert Working Group of the ICH. Comments about these documents will be considered by FDA and the E2B(R3) Expert Working Group.

The key intention of the draft E2B(R3) implementation guidance is to revise the standards for submission of ICSRs and improve the inherent quality of the data, enabling improved handling and analysis of ICSRs. The draft E2B(R3) implementation guidance provides support for the implementation of software tools for creating, editing, sending, and receiving electronic ICSR messages. The draft E2B(R3) implementation guidance provides instruction for how pharmaceutical industries and regulatory authorities should use Part 2 of the International Organization for Standardization (ISO) ICSR standard to construct messages for exchanging pharmacovigilance information among themselves in ICH regions, and in other countries adopting ICH guidelines. The draft BFC appendix describes the relationship between data