Board of Governors of the Federal Reserve System, April 22, 1998.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 98–11193 Filed 4–27–98; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

TIME AND DATE: 11:00 a.m., Monday, May 4, 1998.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any matters carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Joseph R. Coyne, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.bog.frb.fed.us for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: April 24, 1998.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 98–11452 Filed 4–24–98; 3:59 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities: Submission for OMB Review; Comment Request

The Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

1. HHS Procurement-Solicitations and Contracts—Extension—0990–0115—This clearance request covers general information collection requirements of the procurement process such as technical proposals and statements of work.—*Respondents:* State or local governments, businesses or other for-profit, non-profit institutions, small businesses; *Annual Number of Respondents:* 5,660; *Frequency of Response:* one time; *Average Burden per Response:* 253.41 hours; *Estimated Annual Burden:* 1,434,300 hours.

OMB Desk Officer: Allison Eydt.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690–6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street N.W., Washington, D.C. 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue S.W., Washington, DC, 20201. Written comments should be received within 30 days of this notice.

Dated: April 10, 1998.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 98–11178 Filed 4–27–98; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Vaccine Program Office Meetings

The National Vaccine Program Office, Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: National Vaccine Advisory Committee (NVAC) Immunization Registries Workgroup on Ensuring Provider Participation.

Time and date: 8:30 a.m.–12:30 p.m., May 13, 1998.

Name: NVAC Immunization Registries Workgroup on Resource Issues.

Time and date: 1:30 p.m.–5:30 p.m., May 13, 1998.

Name: NVAC Immunization Registries Workgroup on Privacy and Confidentiality.

Time and date: 8:30 a.m.–12:30 p.m., May 14, 1998.

Name: NVAC Immunization Registries Workgroup on Technological and Operational Challenges.

Time and date: 1:30 p.m.–5:30 p.m., May 14, 1998.

Place: Omni Shoreham Hotel, Ambassador Ballroom, 2500 Calvert Street, NW., Washington, DC, telephone (202) 234–0700.

Status: Open to the public, limited only by space availability. The meeting room accommodates approximately 200 people.

Purpose: During a White House Ceremony on July 23, 1997, the President directed the Secretary of Health and Human Services (HHS) to work with the States on integrated immunization registries. As a result, NVAC has formed workgroups, staffed by the National Immunization Program (NIP), that will gather information for development of a National Immunization Registry Plan of Action.

To assist in the formulation of a work plan, a series of public meetings relating to (1) privacy and confidentiality; (2) resource issues; (3) technological and operational challenges; and (4) ensuring provider participation, will be held throughout the Nation. These meetings will provide an opportunity for input from all partners which include state and local public health agencies, professional organizations of private health agencies, managed care organizations (MCOs), employer-funded health care plans, vaccine manufacturers and developers, vendors and developers of medical information systems, information standards development organizations, parents, social welfare agencies, law enforcement agencies, legislators, privacy and consumer interest groups, and other representatives of the public at large.

For each meeting, the Workgroup is inviting experts to address the four specific issues outlined above. Expert speakers are being asked to respond to the questions outlined below in writing, make brief oral presentations, and to respond to additional questions from the Workgroup.

Members of the public who wish to provide comments may do so in the form of written statements, to be received by the completion of the last meeting, addressed as follows: NIP/CDC, Data Management Division, 1600 Clifton Road, NE., M/S E–62, Atlanta, Georgia, 30333.

There will be a period of time during the agenda for members of the public to make oral statements, not exceeding 3 minutes in length, on the issues being considered by the Workgroup. Members of the public who wish to speak are asked to place their names on a list at the registration table on the day of the meeting. The number of speakers will be limited by the time available and speakers will be heard once in the order in which they place their names on the list. Written comments are encouraged; please provide 20 copies.

Based on the outcome of these meetings, a National Immunization Registry Plan of Action will be developed and proposed to NVAC for their deliberation and approval. This plan will identify registry barriers and solutions, strategies to build a registry network, resource requirements and commitments, and a target date for network completion.

Matters to be discussed: Agenda items will include an overview of the Initiative on Immunization Registries and current immunization registry efforts and testimonies by organizational representatives on the following issues relevant to immunization registries: privacy and confidentiality, resources, technological and operational challenges, and ensuring provider participation.

Agenda items are subject to change as priorities dictate.

Resource Issues Questions To Be Considered

1. What approaches have been successful in securing funding to support registries?
2. What approaches to secure funding have been tried but failed?
3. What cost-sharing arrangements would your organization view as reasonable and fair to ensure long-term sustainability of a registry?
4. Would you be willing to share costs through a fee-for-service arrangement and how much would you be willing to pay?
5. Would you be willing to support a vaccine surcharge and at what rate?
6. What types of resources and/or in-kind support do you receive and from whom?
7. What types of resources and/or in-kind support do you provide?
8. What types of resources are you willing and able to provide over the short-term and/or long-term to ensure registry sustainability?
9. Are you willing to provide resources or in-kind support toward linking your existing registries with state and local registries?
10. What are the costs of implementing/operating an immunization registry?
11. What are the costs of not having an immunization registry (e.g., looking up immunization histories, generating school immunization records, etc.)?
12. How should immunization registries be integrated with larger patient information systems and how should their component costs be ascertained?
13. Do you feel there is a need for the Federal Government to provide leadership in developing state and community-based immunization registries? What should the role of the Federal Government be in this effort?

Technological and Operational Questions To Be Considered

1. How can universal, interactive, real-time, secure immunization record exchange between immunization providers be implemented?
2. How does your system implement record exchange?

A. Can a provider get an up-to-date immunization history for a patient sitting in his or her office?

B. How is this function implemented?

3. How can it be assured that the most complete and up-to-date copy of an immunization record is always retrieved by a requesting provider?
4. How does your system identify the definitive record?
5. How can existing practice management systems achieve connectivity with immunization registries efficiently, without dual systems, redundant processes, and multiple interfaces?
6. What software systems can your system interface with?
7. How are connections between your system and existing systems implemented?
8. How can registries be used to measure immunization rates, accurately and routinely, at county, state, and national levels, without counting any individual more than once?
9. How can the functionality of immunization registries be standardized without compromising registries' ability to customize and extend that functionality?
10. What immunization registry functions should be standardized?
11. Who should provide leadership in such a standardization effort?
12. How will/should standards be implemented in immunization registries?
13. How can the cost of operating immunization registries be reduced to a level at which immunization providers themselves would be willing to support them? [crossover with cost issue]
14. What sorts of inter-organizational arrangements and legal structures need to be in place to provide an environment in which immunization registry data can flow as needed? [crossover with privacy & confidentiality issue]
15. Do you feel that there is a need for the Federal Government to provide leadership in developing state and community-based immunization registries? What should the role of the Federal Government be in this effort?
16. How can duplication of records be minimized?
17. How can existing billing/encounter information systems be modified to provide appropriate immunization registry functions?
18. How can immunization registries be broadened to provide other important functions in patient monitoring (*e.g.,* well-child assessments, metabolic/hearing screening, etc.)?
19. What mechanisms are needed to detect and prevent unauthorized access to registry data?
20. What data capture technology (*e.g.,* bar codes, voice recognition, etc.) can minimize the negative impact on workflow?
21. What techniques (*e.g.,* standard knowledge representation such as Arden Syntax) can be used to disseminate vaccination guidelines to individual registries quickly and with a minimum of new programming required to update automated reminder/recall and forecasting based on the guidelines?

Privacy and Confidentiality Questions To Be Considered

Terminology: Privacy—The right of an individual to limit access by others to some aspect of the person. Confidentiality—The treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Individually identifiable information—Information that can reasonably be used to identify an individual (by name or by inference).

1. Should immunization data have different privacy requirements than the rest of the medical record?
2. How can the disclosure and re-disclosure of immunization information be controlled through policies, procedures, and legislation?
3. Should consent to participate be implied or required? In what form?
4. Should different levels of disclosure be possible? What levels should be available to what groups?
5. Who should have access to immunization registry data?
6. What information should be disclosed to an immunization registry?
7. What other uses can immunization registry data have?
8. Would ability to produce a legal record be a desirable function for the registry?
9. What fair information practices should be implemented (e.g., ability to correct the record, notice of being put in registry to parent)?
10. How long should information be kept in a registry?
11. How will privacy issues affect the following groups: parents, immigrants, religious groups, HIV-positive and other immunocompromised health conditions, law enforcement, victims of domestic violence, and custodial parents?
12. How should registries ensure that privacy policies are followed?
13. Do you have any comment or recommendation for NVAC/CDC/HHS related to the implementation of the network of state and community-based registries and do you have any concerns?
14. Do you feel there is a need for the Federal Government to provide leadership in developing state and community-based immunization registries? What should the role of the Federal Government be in this effort?
15. Given the mandate of Health Insurance Portability and Accountability Act to create a unique health identifier, how should that goal be achieved while minimizing the probability of inappropriate use of the identifier?
16. What steps can be taken to prevent unauthorized re-disclosure of information already provided to an organization or person?
17. What legal barriers exist which prevent data sharing by MCOs and how can they be obviated?
18. What mechanism should be available to allow parents to opt out of the registry?
19. What agency/organization should be responsible for maintaining registry information?
20. How should consent for inclusion in an immunization registry be obtained? Should it be implicit or explicit?
21. What information should be included in an immunization registry?
22. Should registries include (and release) information on contraindications, adverse events, etc.?
23. Who should have access to immunization registry data and how can restricted access be assured?
24. What information should be available to persons other than the client/patient and the direct health care provider (e.g., schools)?
25. What is the best way to protect privacy and ensure confidentiality within a registry?

26. How should individuals/parents have access to registry information on themselves/their children?

27. Should data maintained in a state and community-based immunization registry be considered public information?

28. Would national privacy and confidentiality standards help ensure that data maintained in an immunization registry is protected?

Ensuring Provider Participation Questions To Be Considered

1. What type of resources (e.g., hardware, staff, etc.) are needed for you (provider/organization) to participate in a computerized registry?

2. What are the cost-related barriers that keep you (provider/organization) from participating in an immunization registry?

3. What cost should providers be responsible for, pertaining to participation in immunization registry systems?

4. What are the cost savings you would anticipate as a result of participating in a computerized registry (e.g., increased return visit form reminders, less personnel paperwork for preschool exams, etc.)?

5. How much time would you be willing to invest per patient visit (e.g., additional 1, 5, 7, 10 minutes) in the overall success of an immunization registry?

6. What type of user support would be needed in order for you (provider/organization) to participate in an immunization registry?

7. How would you (provider/organization) encourage providers and consumers in your community to participate in an immunization registry?

8. What community support would be necessary for you to participate in the immunization registry?

9. What benefits/value (e.g., immunization reminders, quick access to immunization histories, etc.) would a registry provide that would encourage your (provider/organization) participation?

10. What incentives should be offered to providers/organizations to participate in an immunization registry?

11. What barriers have you (provider/organization) encountered that have prevented you from participating in an immunization registry?

12. Is provider liability (e.g, disclosure of sensitive patient information) a barrier to participating in an immunization registry? Why?

13. How would an immunization registry impact your practice/organization?

14. Do you currently share immunization data with other providers electronically? For what purpose (e.g., billing, share group data, etc.)?

15. How (e.g., electronic record, paper record) is medical information maintained in your practice/organization?

16. Who should retain ownership of immunization records as they are distributed throughout an immunization registry?

17. How would you (provider/organization) use the data maintained in an immunization registry?

18. What type of quality control process would you (provider/organization) perform to ensure the accuracy and completeness of the immunization data entered into an immunization registry?

19. What type of security policies and procedures need to be in place for you to be confident that data are secure?

20. What functions should a registry perform in your office in order for you (provider/organization) to participate?

21. Do you have any advice or recommendations for NVAC/CDC/HHS related to the implementation of the network of state and community-based registries and do you have any concerns?

22. Do you feel that there is a need for the Federal Government to provide leadership in developing state and community-based immunization registries? What should the role of the Federal Government be in this effort?

23. Have you received training on the use and maintenance of computerized medical information? Do you feel this training is needed to fully support the development and maintenance of immunization registries?

Contact Person for More Information: Robb Linkins, M.P.H., Ph.D., Chief, Systems Development Branch, Data Management Division, NIP, CDC, 1600 Clifton Road, NE, M/S E–62, Atlanta, GA 30333, telephone (404) 639–8728, e-mail rxl3@cdc.gov.

Dated: April 22, 1998.

Joseph E. Salter,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–11185 Filed 4–27–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D–0349]

Draft Guidance for Industry on SUPAC–IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''SUPAC–IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum.'' This draft guidance is intended to provide insight and recommendations to pharmaceutical sponsors of new drug applications (NDA's) and abbreviated new drug applications (ANDA's) who wish to change equipment during the postapproval period.

DATES: Written comments may be submitted on the draft guidance document by June 29, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm.'' Written requests for single copies of the draft guidance for industry should be submitted to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John L. Smith, Center for Drug Evaluation and Research (HFD–590), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2175.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''SUPAC–IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum.'' This draft guidance is intended to provide recommendations to pharmaceutical manufacturers using CDER'S Guidance for Industry on ''Immediate Release Solid Oral Dosage Forms, Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation'' (SUPAC–IR), which published in November 1995, and CDER's Guidance for Industry ''SUPAC–MR: Modified Release Solid Oral Dosage Forms Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation,'' which published in September 1997.

This draft guidance is a revision of the guidance entitled ''SUPAC–IR: Immediate Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum'' that published in October 1997, and the draft guidance is intended to supersede the previously published guidance. The draft guidance includes information on equipment used to manufacture modified release solid oral dosage form products as well as immediate release solid oral dosage form products and may be used to determine what documentation should be submitted to FDA regarding equipment changes made in accordance with the recommendations in sections V and VI.A of the SUPAC–IR guidance