

and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

Records will be retained for a period of 10 years after the demonstration and evaluation project has completed. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

SYSTEM MANAGER AND ADDRESS

Director, Division of Advocacy and Special Initiatives, Disabled and Elderly Health Programs Group, Center for Medicaid and State Operations, Mail Stop S2-14-26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1849.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), HICN, and/or SSN (furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with

Department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORDS SOURCE CATEGORIES:

Data will be collected from Medicaid administrative and claims records, and from grantee progress reports.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E7-24786 Filed 12-20-07; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers For Medicare & Medicaid Services

Privacy Act of 1974; Report of a New System of Records

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice of a New System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system titled, "Home and Community-Based Alternatives (CBA) to Psychiatric Residential Treatment Facilities (PRTF) Demonstration (CBA-PRTF), System No. 09-70-0594." The demonstration, created by section 6063 of the Deficit Reduction Act of 2005 (Pub. L. 109-171), allows up to 10 states (as defined for purposes of title XIX of the Social Security Act (the Act)) to provide home and community-based services to youth as alternatives to PRTFs. The purpose of the demonstration is to test the effectiveness in improving or maintaining a child's functional level and cost effectiveness of providing coverage of home and community-based alternatives to psychiatric residential treatment for children enrolled in the Medicaid program under title XIX of the Act.

The purpose of this system is to collect and maintain individually identifiable information on Medicaid recipients, and providers of services who voluntarily participate in the

national evaluation of the CBA-PRTF. Information retrieved from this system may be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor, grantee, or consultant; (2) assist another Federal or state agency with information to contribute to the accuracy of CMS's proper payment of Medicaid benefits, enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) support an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects; (4) support litigation involving the agency; and (5) combat fraud, waste, and abuse in certain Federally-funded health benefits programs. We have provided background information about the new system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See "Effective Dates" section for comment period. **DATES:** *Effective Date:* CMS filed a new SOR report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on *December 14, 2007*. To ensure that all parties have adequate time in which to comment, the new system will become effective 30 days from the publication of the notice, or 40 days from the date it was submitted to OMB and the Congress, whichever is later. We may defer implementation of this system or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comments to the CMS Privacy Officer, Division of Privacy Compliance, Enterprise Architecture and Strategy Group, Mail-stop N2-04-27, 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.

FOR FURTHER INFORMATION CONTACT: Effie Shockley, Division of Advocacy and Special Initiatives, Disabled and Elderly Health Programs Group, Center for Medicaid and State Operations, Mail Stop S2-14-26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1849. She can be reached by telephone at 410-786-8639, or via e-mail at Effie.Shockley@cms.hhs.gov.

SUPPLEMENTARY INFORMATION: The demonstration, created by section 6063 of the Deficit Reduction Act of 2005 (Pub. L. 109-171), allows up to 10 states (as defined for purposes of title XIX of the Act) to provide home and community-based services to youth as alternatives to PRTFs. The purpose of the demonstration is to test the effectiveness in improving or maintaining a child's functional level and cost effectiveness of providing coverage of home and community-based alternatives to psychiatric residential treatment for children enrolled in the Medicaid program under title XIX of the Act. Participating states will acquire approved functional outcomes on participants across the following life domains: community living, school functioning, juvenile justice, family functioning, alcohol and other drug use, mental health, social support, program satisfaction and environmental variables. The overall evaluation must directly address the two primary questions posed in the statutes: Does the provision of home and community-based services to youth under this demonstration (1) result in the maintenance or improvement in a child's functional status; and (2) on average, cost no more than anticipated aggregate PRTF expenditures in the absence of the demonstration?

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for SOR

The statutory authority for this system is given under Section 6063 of the Deficit Reduction Act of 2005.

B. Collection and Maintenance of Data in the System

This system will collect and maintain individually identifiable and other data collected on Medicaid recipients, and providers of services who voluntarily participate in the national evaluation of the CBA-PRTF. The collected information will include, but is not limited to: name, address, telephone number, health insurance claims number, race/ethnicity, gender, date of birth, patient medical charts, physician

records, community living, school functioning, juvenile justice activity, alcohol and other drug use, mental health, social support, family functioning outcomes, program satisfaction and changes in the patient's environment.

II. Agency Policies, Procedures, and Restrictions on the Routine Use

A. The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a "routine use." The Government will only release CBA-PRTF information that can be associated with an individual as provided for under "Section III. Proposed Routine Use Disclosures of Data in the System." Both identifiable and non-identifiable data may be disclosed under a routine use. We will only collect the minimum personal data necessary to achieve the purpose of CBA-PRTF.

CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. Disclosure of information from the system will be approved only to the extent necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected; e.g., to collect and maintain individually identifiable information on Medicaid recipients, and providers of services who voluntarily participate in the national evaluation of the CBA-PRTF.
2. Determines that:
 - a. The purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;
 - b. The purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and
 - c. There is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).
3. Requires the information recipient to:
 - a. Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;
 - b. Remove or destroy, at the earliest time, all patient-identifiable information; and
 - c. Agree to not use or disclose the information for any purpose other than

the stated purpose under which the information was disclosed.

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a "routine use." The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors, consultants or grantees, who have been engaged by the agency to assist in the performance of a service related to this collection and who need to have access to the records in order to perform the activity.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing CMS function relating to purposes for this system.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor, consultant or grantee whatever information is necessary for the contractor or consultant to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor, consultant or grantee from using or disclosing the information for any purpose other than that described in the contract and requires the contractor, consultant or grantee to return or destroy all information at the completion of the contract.

2. To another Federal or state agency to:

- a. Contribute to the accuracy of CMS's proper payment of Medicaid benefits;
- b. Enable such agency to administer a Federal health benefits program, or, as necessary, to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; and/or
- c. Assist Federal/state Medicaid programs within the state.

Other Federal or state agencies, in their administration of a Federal health program, may require CBA-PRTF information in order to support evaluations and monitoring of Medicaid claims information of beneficiaries,

including proper reimbursement for services provided.

3. To an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.

The CBA-PRTF data will provide for research or support of evaluation projects and a broader, longitudinal, national perspective of the status of Medicaid beneficiaries. CMS anticipates that researchers may have legitimate requests to use these data in projects that could ultimately improve the care provided to Medicaid beneficiaries and the policies that govern their care.

4. To the Department of Justice (DOJ), court or adjudicatory body when:

a. The agency or any component thereof, or

b. Any employee of the agency in his or her official capacity, or

c. Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. The United States Government, is a party to litigation or has an interest in such litigation, and, by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

Whenever CMS is involved in litigation, and occasionally when another party is involved in litigation and CMS policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court or adjudicatory body involved.

5. To a CMS contractor (including, but not necessarily limited to, fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, and abuse in such program.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual, grantee, cooperative agreement or consultant relationship with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud, waste, and abuse. CMS occasionally contracts out certain of its functions or

makes grants or cooperative agreements when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor, grantee, consultant or other legal agent whatever information is necessary for the agent to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the agent from using or disclosing the information for any purpose other than that described in the contract and requiring the agent to return or destroy all information.

6. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste, or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such programs.

Other agencies may require CBA-PRTF information for the purpose of combating fraud, waste, and abuse in such Federally-funded programs.

B. Additional Provisions Affecting Routine Use Disclosures

To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation "Standards for Privacy of Individually Identifiable Health Information" (45 CFR Parts 160 and 164, Subparts A and E) 65 Fed. Reg. 82462 (12-28-00). Disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the "Standards for Privacy of Individually Identifiable Health Information." (See 45 CFR 164.512(a) (1)).

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals could, because of the small size, use this information to deduce the identity of the beneficiary).

IV. Safeguards

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security

requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effects of The Proposed System of Records on Individual Rights

CMS proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system will be subject to the authorized releases in accordance with the routine uses identified in this system of records.

CMS will take precautionary measures to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights of patients whose data are maintained in this system. CMS will collect only that information necessary to perform the system's functions. In addition, CMS will make disclosure from the proposed system only with consent of the subject individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act. CMS, therefore, does not anticipate an unfavorable effect on individual privacy as a result of information relating to individuals.

Dated: December 7, 2007.

Charlene Frizzera,

Chief Operating Officer, Centers for Medicare & Medicaid Services.

SYSTEM NO. 09-70-0594

SYSTEM NAME:

• “Home and Community-Based Alternatives (CBA) to Psychiatric Residential Treatment Facilities (PRTF) Demonstration (CBA-PRTF),” HHS/CMS/CMM.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive Data.

SYSTEM LOCATION:

Centers for Medicare & Medicaid Services (CMS) Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244-1850 and at various co-locations of CMS agents.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system will collect and maintain individually identifiable and other data collected on Medicaid recipients, and providers of services who voluntarily participate in the national evaluation of the CBA-PRTF.

CATEGORIES OF RECORDS IN THE SYSTEM:

The collected information will include, but is not limited to: name, address, telephone number, health insurance claims number (HICN), race/ethnicity, gender, date of birth, patient medical charts, physician records, community living, school functioning, juvenile justice activity, alcohol and other drug use, mental health, social support, family functioning outcomes, program satisfaction and changes in the patient’s environment.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The statutory authority for this system is given under Section 6063 of the Deficit Reduction Act of 2005.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to collect and maintain individually identifiable information on Medicaid recipients, and providers of services who voluntarily participate in the national evaluation of the CBA-PRTF. Information retrieved from this system may be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor, grantee, or consultant; (2) assist another Federal or state agency with information to contribute to the accuracy of CMS’s proper payment of Medicaid benefits, enable such agency to administer a

Federal health benefits program, or to enable such agency to fulfill a requirement of Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; (3) support an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects; (4) support litigation involving the agency; and (5) combat fraud, waste, and abuse in certain Federally-funded health benefits programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

A. The Privacy Act allows us to disclose information without an individual’s consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a “routine use.” The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To agency contractors, consultants or grantees, who have been engaged by the agency to assist in the performance of a service related to this collection and who need to have access to the records in order to perform the activity.
2. To another Federal or state agency to:
 - a. contribute to the accuracy of CMS’s proper payment of Medicaid benefits;
 - b. enable such agency to administer a Federal health benefits program, or, as necessary, to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds; and/or
 - c. assist Federal/state Medicaid programs within the state.
3. To an individual or organization for a research project or in support of an evaluation project related to the prevention of disease or disability, the restoration or maintenance of health, or payment related projects.
4. To the Department of Justice (DOJ), court or adjudicatory body when:
 - a. the agency or any component thereof, or
 - b. any employee of the agency in his or her official capacity, or
 - c. any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee, or
 - d. the United States Government, is a party to litigation or has an interest in

such litigation, and, by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

5. To a CMS contractor (including, but not necessarily limited to, fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, and abuse in such program.

6. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste, or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such programs.

B. Additional Provisions Affecting Routine Use Disclosures. To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation “Standards for Privacy of Individually Identifiable Health Information” (45 CFR Parts 160 and 164, Subparts A and E) 65 Fed. Reg. 82462 (12-28-00). Disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the “Standards for Privacy of Individually Identifiable Health Information.” (See 45 CFR 164.512(a)(1)).

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals could, because of the small size, use this information to deduce the identity of the beneficiary).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**STORAGE:**

All records are stored on electronic media.

RETRIEVABILITY:

The collected data are retrieved by the name or other identifying information of the participating provider or beneficiary, and may be retrieved by a distinct identifier such as the HICN, at the individual beneficiary level.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002; the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

Records will be retained for a period of 10 years after the demonstration and evaluation project has completed. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

SYSTEM MANAGER AND ADDRESS:

Director, Division of Advocacy and Special Initiatives, Disabled and Elderly Health Programs Group, Center for Medicaid and State Operations, Mail Stop S2-14-26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1849.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), HICN, and/or SSN (furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5 (a) (2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORDS SOURCE CATEGORIES:

Data will be collected from Medicaid administrative and claims records, patient medical charts, and physician records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E7-24788 Filed 12-20-07; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 20, 2008, from 8 a.m. to 5 p.m.

Location: National Labor College, Lane Kirkland Center, Solidarity Hall, 10000 New Hampshire Avenue, Silver Spring, MD, 301-431-6400.

Contact Person: Teresa A. Watkins, Center for Drug Evaluation and Research, HFD-21, Food and Drug Administration, 5630 Fishers Lane (for express delivery, 5630 Fishers Lane, Rm. 1093) Rockville, MD 20857, 301-827-7001, fax: 301-827-6776, e-mail: teresa.watkins@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512545. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the new drug application (NDA) 22-150, icatibant solution for injection (proposed tradename FIRAZYR), by Jerini, for the proposed indication of treatment of attacks of hereditary angioedema.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 5, 2008. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1:30 p.m. Those desiring to make formal oral presentations