System No.	Title	System manager
09–70–0063	Evaluation of the Medicaid Demonstration for Improving Access to Care for Substance Abusing Pregnant Women.	HHS/CMS/ORDI
09–70–0066	Evaluation of and External Quality Assurance for the Community Nursing Organization Demonstration	HHS/CMS/ORDI

Dated: September 27, 2005.

Charlene Brown,

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

[FR Doc. 05–19906 Filed 10–5–05; 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: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

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 SOR titled ''Medicare Care Management Performance Demonstration (MCMP),'' System No. 09–70–0562. MCMP demonstration tests a payment methodology for physician practices that combines Medicare fee-for-service payments with performance-based payments for improvements in information technology systems, patient education, care management, and quality of care. Improvements in these areas are expected to generate savings to the Medicare program to offset the costs of the performance payments. Mandated by Section 649 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the MCMP Demonstration seeks to provide incentives for physicians to adopt and integrate information technology systems into their practices, and to improve quality as defined by key measurable outcomes.

The primary purpose of the system is to establish a pay-for-performance three year pilot with physicians to promote the adoption and use of health information technology to improve the quality of patient care for chronically ill Medicare patients. Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) assist another Federal or state agency with information to 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) assist 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 constituent requests made to a congressional representative; (5) support litigation involving the agency; and (6) combat fraud and abuse in certain 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.

EFFECTIVE DATES: CMS filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on September 27, 2005. In any event, we will not disclose any information under a routine use until 40 days after publication. 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: CMS Privacy Officer, Division of Privacy Compliance Data Development, CMS, 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 zone.

FOR FURTHER INFORMATION CONTACT: Jody Blatt, Research Analyst, Division of Payment Policy, Medicare Demonstration Programs Group, Office of Research Development and Information, CMS, Mail Stop C4–17–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. The telephone number is (410) 786–6921 or e-mail *jody.blatt@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 649 of (MMA) requires the Secretary of Health and Human Services to ''establish a pay-for-performance demonstration program with physicians to meet the needs of eligible beneficiaries through the adoption and use of health information technology and evidence-based outcomes measures.'' The resulting demonstration, known as MCMP Demonstration, provides incentives to primary care physician practices for (1) clinical systems, which encompasses the implementation and use of information technology, patient education, and care management, and (2) clinical quality, which encompasses using evidence-based outcome measures. The objectives of the demonstration are to: (1) Promote continuity of care, (2) stabilize medical conditions, (3) reduce adverse health outcomes, and (4) prevent or minimize acute episodes of chronic conditions that require an emergency room visit or hospitalization.

In the demonstration, payments will be made to physician practices that meet or exceed performance standards established by CMS. There will be two categories of performance payments. One payment will be made for clinical systems based on the number of patients who are Medicare beneficiaries with a chronic condition; and the other will be made for clinical quality based on the number of beneficiaries with the specific diseases of diabetes, congestive heart failure, or coronary artery disease. Payment for clinical quality will also be made for meeting standards on various screening measures. Payments can vary based on performance.

The three year demonstration project will be launched in four states, with up to 2,800 physicians from solo and small to medium-sized group practices participating, including practices in both urban and rural areas. The project is expected to become operational in 2006, with physicians being paid in 2006, 2007, and 2008. It will operate in the same four states as initiated the Doctor's Office Quality—Information Technology project (California, Utah,

Arkansas, and Massachusetts), thus allowing the Quality Improvement Organizations (QIOs) in those states to provide support to participating physicians.

I. Description of the New System of Records

A. Statutory and Regulatory Basis for System

The authority for maintenance of this system is given under the provisions of Section 649 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108–173).

B. Collection and Maintenance of Data in the System

This system will maintain individually identifiable data collected on the Medicare expenditures of beneficiaries assigned to the participating physician practices. The data will consist of clinical quality measures collected from the individual physician practices participating in the demonstration. The collected information will contain: provider name, unique provider identification number, unique demonstration practice identification number, beneficiary health insurance claim number, and whether the beneficiary received the services described by the clinical measure and was counted in either the numerator and/or the denominator of the performance measure calculation for the physician.

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 MCMP 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 MCMP. 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 data on Medicare expenditures of the beneficiaries assigned to participating physician practices that is relevant to calculating physician based performance on clinical quality measures and making performance payments to participating physician practices.

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 information 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 individually 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. Entities Who May Receive Disclosures Under Routine Use

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 or consultants who have been engaged by the agency to assist in the performance of a service related to this system 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 or consultant 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 or consultant from using or disclosing the information for any purpose other than that described in the contract and requires the contractor or consultant 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 Medicare 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 MCMP information in order to support evaluations and monitoring of Medicare 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 MCMP data will provide for research or in support of evaluation projects, a broader, longitudinal, national perspective of the status of Medicare beneficiaries. CMS anticipates that many researchers will have legitimate requests to use these data in projects that could ultimately improve the care provided to Medicare beneficiaries and the policy that governs the care.

4. To a member of Congress or to a congressional staff member in response to an inquiry of the congressional office made at the written request of the constituent about whom the record is maintained.

Beneficiaries sometimes request the help of a member of Congress in resolving an issue relating to a matter before CMS. The member of Congress then writes CMS, and CMS must be able

to give sufficient information to be responsive to the inquiry.

5. 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.

6. 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 or abuse in such program.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual relationship or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud and abuse.

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

7. 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 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 or abuse in such programs.

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

B. Additional Provisions Affecting Routine Use Disclosures

This system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 Code of Federal Regulation Parts 160 and 164, 65 Fed. Reg. 82462 (12–28–00), Subparts A and E. Disclosures of PHI 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.''

In addition, our policy will be to prohibit release even of not directly identifiable information, 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 who are familiar with the enrollees 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 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 include 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 New System 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.

CMS will take precautionary measures (see item IV. above) 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 is maintained in the 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 maintaining this system.

Dated: September 27, 2005.

Charlene Brown,

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

System No.: 09–70–0562

SYSTEM NAME:

''Medicare Care Management Performance Demonstration (MCMP)'' HHS/CMS/ORDI.

SECURITY CLASSIFICATION:

Level 3 Privacy Act Sensitive.

SYSTEM LOCATION:

This system is maintained at the Centers for Medicare & Medicaid

Services (CMS) Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850, and CMS contractors and agents at various locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The data will be maintained on individual physicians participating in the demonstration. In order to collect this data and use it to determine incentive payments to physicians, the system will also maintain individually identifiable information on Medicare beneficiaries assigned to physicians participating in the demonstration.

CATEGORIES OF RECORDS IN THE SYSTEM:

The data will consist of clinical quality measures collected from physician participating in the demonstration. The collected information will contain provider name, unique provider identification number, unique demonstration practice identification number, beneficiary health insurance claim number (HICN), beneficiary demographic and diagnostic information relevant to the measure, and whether the beneficiary received the services described by the clinical measure and was counted in either the numerator and/or the denominator of the performance measure calculation for the physician.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authority for maintenance of this system is given under the provisions of Section 649 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173).

PURPOSE(S) OF THE SYSTEM:

The primary purpose of the system is to establish a pay-for-performance three year pilot with physicians to promote the adoption and use of health information technology to improve the quality of patient care for chronically ill Medicare patients. Information retrieved from this system will also be disclosed to: (1) Support regulatory, reimbursement, and policy functions performed within the agency or by a contractor or consultant; (2) assist another Federal or state agency with information to 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) assist 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 constituent requests made to a congressional representative; (5) support litigation involving the agency; and (6) combat fraud and abuse in certain health benefits programs.

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

A. Entities Who May Receive Disclosures Under Routine Use

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 or consultants who have been engaged by the agency to assist in the performance of a service related to this system 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 Medicare 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 a member of Congress or to a congressional staff member in response to an inquiry of the congressional office made at the written request of the constituent about whom the record is maintained.

5. 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.

6. 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 or abuse in such program.

7. 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 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 or abuse in such programs.

B. Additional Provisions Affecting Routine Use Disclosures

This system contains Protected Health Information (PHI) as defined by Department of Health and Human Services (HHS) regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 Code of Federal Regulations (CFR) Parts 160 and 164, 65 FR 82462 (12–28–00), Subparts A and E. Disclosures of PHI 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.''

In addition, our policy will be to prohibit release even of not directly identifiable information, 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 who are familiar with the enrollees 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 magnetic media.

RETRIEVABILITY:

Information collected will be retrieved by the name or other identifying information of the participating provider, and may also be retrievable by HICN at the individual beneficiary record 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 include 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. Office of Management and Budget 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:

CMS will retain identifiable information maintained in the MCMP system of records for a period of 6 years. Data residing with the designated claims payment contractor shall be returned to CMS at the end of the project, with all data then being the responsibility of CMS for adequate storage and security. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from the DOJ.

SYSTEM MANAGER AND ADDRESS:

Director, Medicare Demonstration Program Group, Office of Research Development and Information, CMS, 7500 Security Boulevard, Mail stop C4–17–27, Baltimore, Maryland, 21244–1850.

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, provider identification number, and the patient's medical record number.

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).

RECORD SOURCE CATEGORIES:

Information maintained in this system will be collected from physicians volunteering to participate in the MCMP Demonstration. Additional data will be collected from Medicare claims payment records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05–19907 Filed 10–5–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The Essentials of Food and Drug Administration Device Regulations: A Primer for Manufacturers and Suppliers; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Philadelphia District, in cooperation with AdvaMed's Medical Technology Learning Institute, is announcing a public workshop on FDA device regulations. This 1 1/2-day public workshop for start up and small device manufacturers and their suppliers will include both industry and FDA perspectives and a question and answer period.

Date and Time: The public workshop will be held on Tuesday, October 11, 2005, from 8:30 a.m. to 5:30 p.m. and Wednesday, October 12, 2005, from 8:30 a.m. to 12 noon.

Location: The public workshop will be held at The Wyndham Philadelphia at Franklin Plaza, 17th and Race St., Philadelphia, PA 19103, 215–448–2000. For further hotel information and driving directions, go to *http://www.wyndham.com/hotels/PHLFP*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Contact:

For FDA: Judy Summers-Gates, Food and Drug Administration, rm. 900, U.S. Customhouse, 200 Chestnut St., Philadelphia, PA 19106, 215–717–3008, FAX: 215–597–4660, e-mail: *judith.summers-gates@fda.gov*.

For AdvaMed: Krystine McGrath, 202–434–7237, FAX: 202–783–8750, *kmcgrath@advamed.org*; or Dia Black, 202–434–7231, FAX: 202–783–8750, e-mail: *dblack@avamed.org*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), and the registration fee of $350 per person to the AdvaMed contacts (see *Contact*). The registration fee for FDA employees is waived. To register via the Internet go to *http://www.advamed.org/philadelphia*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)