DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Personalized Healthcare Workgroup Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the 16th meeting of the American Health Information Community Personalized Healthcare Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.).

DATES: June 10, 2008, from 1 p.m. to 4 p.m. [Eastern Time].

ADDRESSES: Mary C. Switzer Building (330 C Street, SW., Washington, DC 20201), Conference Room 1114. Please bring photo ID for entry to a Federal building.

FOR FURTHER INFORMATION CONTACT: *http://www.hhs.gov/healthit/ahic/healthcare/*.

SUPPLEMENTARY INFORMATION: The Workgroup will discuss possible common data standards to incorporate interoperable, clinically useful genetic/genomic information and analytical tools into Electronic Health Records (EHRs) to support clinical decision-making for the clinician and consumer.

The meeting will be available via Web cast. For additional information, go to: *http://www.hhs.gov/healthit/ahic/healthcare/phc_instruct.html*.

Dated: May 19, 2008.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. E8–11773 Filed 5–23–08; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

Pursuant to Pub. L. 92–463, notice is hereby given of the sixteenth meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 8:30 a.m. to approximately 11:30 a.m. on Monday, July 7, 2008, and 8 a.m. to approximately 5 p.m. on Tuesday, July 8, 2008, at the Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. The meeting will be open to the public with attendance limited to space available. The meeting also will be Web cast.

The meeting will involve an exploration of the issues associated with the marketing of personalized genomic information and services directly to consumers. The Committee will hear presentations about these services, including the specificity of information being provided and plans for helping consumers interpret and utilize the results for healthcare decisionmaking, consumer perspectives, the state of the underlying science, and public policy considerations. As part of this exploration, the Committee will adjourn for the afternoon of July 7 to participate in a workshop sponsored by Secretary Leavitt's Personalized Health Care Initiative on Understanding the Needs of Consumers in the Use of Genomic-Based Health Information Services. The Committee also will review a proposed action plan for addressing issues associated with the genetics education and training of health professionals and move into the second stage of its priority setting process.

As always, the Committee welcomes hearing from anyone wishing to provide public comment on any issue related to genetics, health and society. Individuals who would like to provide public comment should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301–496–9838 or e-mail at *carrs@od.nih.gov*. The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892. Anyone planning to attend the meeting who is in need of special assistance, such as sign language interpretation or other reasonable accommodations, is also asked to contact the Executive Secretary.

Under authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic and genomic technologies and, as warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the Web cast, will be available at the following Web site: *http://www4.od.nih.gov/oba/sacghs.htm*.

Dated: May 16, 2008.

Jennifer Spaeth,

Director, NIH Office of Federal Advisory Committee Policy.

[FR Doc. E8–11798 Filed 5–23–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Department of Health and Human Services Implementation of New Authorities for the Public Health Emergency Preparedness Cooperative Agreement

AGENCY: Department of Health and Human Services, Centers for Disease Control and Prevention, Coordinating Office for Terrorism Preparedness and Emergency Response, Division of State and Local Readiness.

ACTION: Notification of intent to implement: (1) Maintenance of funding (MOF); (2) nonfederal matching requirements; (3) evidence-based benchmarks and objective standards; (4) maximum amount of carryover; (5) pandemic influenza operations plans criteria; (6) audit requirements; and (7) withholding and repayment guidelines. Links to the Interim Progress Report (IPR) for Budget Period 9 (BP9) of the Public Health Emergency Preparedness (PHEP) program are provided for informational purposes only.

SUMMARY: The Department of Health and Human Services (HHS or the Department), Centers for Disease Control and Prevention (CDC), will issue an Interim Progress Report (IPR) for the PHEP cooperative agreement program in the third quarter of Fiscal Year (FY) 2008, as authorized under section 319C–1 of the Public Health Service (PHS) Act, as amended by the Pandemic and All-Hazards Preparedness Act (PAHPA) (Pub. L. 109–417) (42 U.S.C. 247d–3a). The Consolidated Appropriations Act, 2008, (H.R. 2764) provided funding for these awards. This notice provides information to facilitate the critical aspects of the program, including:

- Background of the program;
- Current requirements for awardees:
  - MOF;
- Future requirements of awardees:
  - Nonfederal matching requirements—reduced or no award provided;
  - Evidence-based benchmarks and objective standards—substantial failure results in withholding of funds;

○ Maximum amount of carryover—exceeding the limit results in repayment of funds;

○ Pandemic influenza planning documents—failure to submit a sufficient operations plan results in withholding of funds;

○ Audit requirements—failure results in repayment of funds;

- Electronic submission;
- Important dates;
- Reporting;
- PHEP IPR for BP9 (*http://www.emergency.cdc.gov/*);
- Withholding and Repayment Guidance (Attachment).

FOR FURTHER INFORMATION CONTACT: Donna Knutson at (404) 639–7530, or e-mail at [*dbk2@cdc.gov*].

SUPPLEMENTARY INFORMATION:

Background of the Program

Building on the lessons learned from the attacks of September 11, 2001, and Hurricanes Katrina and Rita in 2005, the PAHPA was enacted in December 2006 to improve the Nation's public health and medical preparedness and response capabilities for emergencies, whether deliberate, accidental, or natural. The PAHPA amended and added new sections to the PHS Act. Examples of these changes include identifying the Secretary of Health and Human Services as the lead official for all Federal public health and medical responses to public health emergencies and other incidents covered by the National Response Framework; establishing the position of the Assistant Secretary for Preparedness and Response (ASPR), who will lead and coordinate HHS preparedness and response activities, advise the Secretary of Health and Human Services during an emergency, and lead the coordination of emergency preparedness and response efforts between HHS and other Federal agencies; consolidating Federal public health and medical response programs under the renamed ASPR; requiring the development and implementation of the National Health Security Strategy; and reauthorizing the PHEP cooperative agreements administered by CDC and the Hospital Preparedness Program (HPP) cooperative agreements administered by ASPR. In addition to reauthorizing these two cooperative agreement programs, the PAHPA added new requirements that awardees must meet. The purpose of this notice is to notify PHEP awardees about critical aspects and requirements of the PHEP cooperative agreements, as amended by PAHPA. The Secretary of Health and Human Services is required under section 319C–1(g) of the PHS Act to develop and require application of measurable benchmarks and objective standards that measure levels of preparedness with respect to PHEP activities. The Secretary of Health and Human Services must withhold funds beginning in FY 2009 from PHEP awardees who fail substantially to meet the applicable benchmarks or objective standards for the immediately preceding fiscal year and/or who fail to submit a sufficient pandemic influenza operations plan. Thus, PHEP awardees will have funds withheld from their FY 2009 awards (as described in the attached withholding guidance) if, when expending their FY 2008 PHEP awards, they fail substantially to meet the benchmarks and objective standards described in the FY 2008 (BP9) IPR or to submit a sufficient pandemic influenza operations plan. The Secretary of Health and Human Services is required to develop and implement a process to notify entities who have failed substantially to meet the evidence-based benchmarks and objective standards or who have failed to submit a sufficient pandemic influenza operations plan. The process must provide awardees with the opportunity to correct their noncompliance.

Purpose: The purpose of the PHEP cooperative agreement program is to provide funding to improve and upgrade state and local public health jurisdictions' preparedness and response to bioterrorism, outbreaks of infectious diseases, and other public health threats and emergencies, utilizing the following goals:

1. Integration—integrating public health and public and private medical capabilities with other first responder systems including through—

i. The periodic evaluation of Federal, State, local, and tribal preparedness and response capabilities through drills and exercises; and

ii. The integration of public and private sector public health and medical donations and volunteers.

2. Public health—developing and sustaining Federal, State, local, and tribal essential public health security capabilities, including the following—

i. Disease situational awareness domestically and abroad, including detection, identification, and investigation.

ii. Disease containment including capabilities for isolation, quarantine, social distancing, and decontamination.

iii. Risk communication and public preparedness.

iv. Rapid distribution and administration of medical countermeasures.

3. Medical—increasing the preparedness, response capabilities, and surge capacity of hospitals, other healthcare facilities (including mental health facilities), and trauma care and emergency medical service systems, with respect to public health emergencies, which shall include developing plans for the following—

i. Strengthening public health emergency medical management and treatment capabilities.

ii. Medical evacuation and fatality management.

iii. Rapid distribution and administration of medical countermeasures.

iv. Effective utilization of any available public and private mobile medical assets and integration of other Federal assets.

v. Protecting healthcare workers and healthcare first responders from workplace exposures during a public health emergency.

4. At-risk individuals—

i. Taking into account the public health and medical needs of at-risk individuals in the event of a public health emergency.

ii. For purposes of these awards, the term ''at-risk individuals'' means children, pregnant women, senior citizens, and other individuals who have special needs in the event of a public health emergency, as determined by the Secretary of Health and Human Services (see the IPR for BP9 for updated definition).

5. Coordination—minimizing duplication of, and ensuring coordination between, Federal, State, local, and tribal planning, preparedness, and response activities (including Emergency Management Assistance Compact). Such planning shall be consistent with the National Response Framework, or any successor plan, and National Incident Management Systems and the National Preparedness Goal.

6. Continuity of operations—maintaining vital public health and medical services to allow for optimal Federal, State, local, and tribal operations in the event of a public health emergency.

Eligibility: Since the funding opportunity represents the fourth year of a five-year cooperative agreement, eligibility is limited to those currently funded through PHEP Program Announcement AA154 and authorized under 42 U.S.C. 247d–3a. Eligible applicants are the health departments of States or their bona fide agents, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American

Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau, and the official public health agencies of New York City, New York; Los Angeles County, California; and Chicago, Illinois.

Current Requirements of Awardees

Maintenance of Funding (MOF)

MOF is defined as ensuring that the amount contributed by the entity that receives the award to support public health security does not fall below the average of the amount provided annually during the previous two years. This definition includes:

1. Appropriations specifically designed to support public health emergency preparedness as expended by the entity receiving the award; and

2. Funds not specifically allocated for public health emergency preparedness activities but which support public health emergency preparedness activities, such as personnel assigned to public health emergency preparedness responsibilities or supplies or equipment purchased for public health emergency preparedness from general funds or other lines within the operating budget of the entity receiving the award.

The definition of expenditures does not include one-time expenses to support public health preparedness and response, such as purchases of antiviral drugs. Awardees will be required to document the required MOF as part of the IPR for BP9. According to Public Law 109–417, any funds withheld from the PHEP cooperative agreement program or the Hospital Preparedness Program will be reallocated to the Healthcare Facilities Partnership program in the same state.

Future Awardee Requirements

Matching Requirements

PHEP cooperative agreement funding must be matched by nonfederal contributions beginning with the distribution of federal FY 2009 funds (Budget Period 10). Nonfederal contributions (match) may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the federal government, or services assisted or subsidized to any significant extent by the federal government, may not be included in determining the amount of such nonfederal contributions. Awardees will be required to provide matching funds as described:

i. For FY 2009, not less than 5% of such costs ($1 for each $20 of federal funds provided in the cooperative agreement); and

ii. For any subsequent fiscal year of such cooperative agreement, not less than 10% of such costs ($1 for each $10 of federal funds provided in the cooperative agreement).

Please refer to 45 CFR 92.24 for match requirements, including descriptions of acceptable match resources. Documentation of match must follow procedures for generally accepted accounting practices and meet audit requirements. Beginning with federal FY 2009, the Secretary of Health and Human Services may not make an award to an entity eligible for PHEP funds unless the eligible entity agrees to make available nonfederal contributions as described above. CDC will require each eligible entity to include in its FY 2008 (BP9) mid-year progress report a plan describing the methods and sources of match that the eligible entity agrees to pursue in FY 2009.

Evidence-Based Benchmarks and Objective Standards

In accordance with section 319C–1(g)(1), CDC has established the following evidence-based benchmarks and objective standards. Substantial failure to meet these benchmarks and standards will result in withholding of funds for the FY 2009 budget year (BP10). The following benchmarks and standards also appear in the PHEP IPR for BP9:

1. *Demonstrated capability to notify primary, secondary, and tertiary staff to cover all incident management functional roles during a complex incident.*

To provide an effective and coordinated response to a complex incident, a public health department must maintain a current roster of pre-identified staff available to fill core Incident Command System (ICS) functional roles. During an incident that lasts more than 12 hours, secondary and tertiary staff may be called upon to fill ICS roles, and thus the health department must maintain a roster of all staff qualified for those roles. Testing the staff notification system is critical for an efficient response, especially when the notification is unannounced and occurs outside of regular business hours.

a. Confirm the accuracy of the primary, secondary, and tertiary contact information for all eight ICS functional roles at least once every six months.

b. Test the notification system twice a year, with at least one test being unannounced and occurring outside of regular hours. The test can be a drill or an exercise, or it may be demonstrated by a response to a real incident.

Guidance on the numerator, denominator, and scoring methodology to determine how results will factor in to a withholding penalty for this measure will be available by May 15, 2008.

2. *Demonstrated capability to receive, stage, store, distribute, and dispense material during a public health emergency.*

Health departments must be able to provide countermeasures to 100% of their identified population within 48 hours after the decision to do so. To be able to achieve this standard, health departments must maintain the capability to plan and execute the receipt, staging, storage, distribution, and dispensing of material during a public health emergency.

a. Obtain a score of 69 or higher on the Division of Strategic National Stockpile (DSNS) State Technical Assistance Review by December 31, 2008.

b. Each planning/local jurisdiction within each Cities Readiness Initiative (CRI) metropolitan statistical area conducts a minimum of three DSNS drills by August 10, 2009.

c. To comply with the PAHPA legislation and for purposes of guiding funding decisions for 2009, the planning/local jurisdiction(s) that comprises the 25% most populous within a CRI MSA conducts at least one of the three DSNS drills prior to December 31, 2008 (with the remaining two drills conducted by August 10, 2009).

These drills may include any three of the following: staff call down, site activation, facility set-up, pick-list generation, dispensing, and/or modeling of throughput. Guidance on the numerator, denominator, and scoring methodology to determine how results will factor in to a withholding penalty for this measure will be available by May 15, 2008.

Maximum Amount of Carryover

CDC shall determine the maximum percentage amount of an award that an awardee may carry over to the succeeding fiscal year. Unjustifiable unobligated balances will be determined by using the awardee's spend plan and financial status and progress/performance reports. (See the Withholding and Repayment Guidance for additional information).

To provide effective program management, an awardee must be able to develop and execute spend plans, make procurements and let contracts on schedule, and otherwise assure the

infrastructure capacity to support the attainment of programmatic objectives. One outcome of an effective management infrastructure is the full expenditure of funds awarded in the budget period.

CDC recognizes that there may be justifiable causes (e.g., state hiring freezes, inefficiencies on the part of the awarding agency) or unjustifiable causes (e.g., ineffective management infrastructure at the state level, irregularities in contracting or payment of debt) for dollars to remain unobligated at the end of the budget period even after a robust execution of plans. Therefore, the awardee must immediately communicate with CDC any events occurring between the scheduled spend plan and progress/performance report date which have significant impact upon the cooperative agreement.

CDC will make available by May 15, 2008, additional guidance regarding spend plan and progress/performance reports to determine how results will factor into a repayment penalty for this measure.

Pandemic Influenza Plans

State pandemic influenza operations plans must meet national standards. On June 16, 2008, awardees will submit a second version of their pandemic influenza operations plans based on guidance provided by HHS on March 13, 2008. Two scores (Comprehensiveness and Operational Readiness) for each of the seven elements in the ''Health and Medical'' category will be used by CDC to determine the extent to which criteria have been met, as follows:

Comprehensiveness Score:
- No Major Gaps
- A Few Major Gaps
- Many Major Gaps
- Inadequate Preparedness

Operational Readiness Score:
- Substantial Evidence of Operational Readiness
- Significant Evidence of Operational Readiness
- Little Evidence of Operational Readiness

Failure to meet accepted criteria for pandemic influenza operations planning will result in the withholding of funds for the FY 2009 budget period. Guidance on the numerator, denominator, and scoring methodology for this measure will be available by May 15, 2008.

Audit Requirements

Each entity receiving funds shall, not less than once every two years, audit its expenditures from amounts received from the PHEP cooperative agreement. Such audits shall be conducted by an entity independent of the agency administering the PHEP cooperative agreement in accordance with Office of Management and Budget (OMB) Circular A–133, Audits of States, Local Governments, and Non-Profit Organizations.

Audit reports must be submitted to CDC. Failure to conduct an audit or expenditures made not in accordance with PHEP cooperative agreement guidance and grants management policy may result in a requirement to repay funds to the Federal treasury or the withholding of future funds.

Electronic Submission

Given the technical capabilities necessary to carry out and document the activities required under this program, HHS is announcing the funding opportunity on the grants.gov Web site at *http://www.grants.gov*. Detailed instructions for submitting the combined IPR and application for funding will be available through a download in the Preparedness Emergency Response System for Oversight, Reporting, and Management Services (PERFORMS) at *https://sdn/cdc/gov*.

Important PHEP Dates

- Anticipated application due date: June 27, 2008.
- Anticipated award date: August 11, 2008.

Reporting

Please refer to the PHEP IPR for actual reporting dates and requirements.

Withholding and Repayment Guidance

The Withholding and Repayment Guidance is provided in its entirety for review as an attachment. (See attachment below.)

Dated: May 20, 2008.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention, Department of Health and Human Services.

Attachment

CDC Public Health Emergency Preparedness Cooperative Agreement Withholding and Repayment Guidance

Procedural Consideration

This standard operating procedure (SOP) describes procedures CDC will use to implement withholding or repayment actions in connection with the Public Health Emergency Preparedness (PHEP) cooperative agreement program.

A. Pandemic and All-Hazards Preparedness Act (PAHPA) requirements for the PHEP Cooperative Agreement. The PAHPA requires the withholding of amounts from entities that fail to achieve benchmarks and objective standards or to submit an acceptable pandemic influenza operations plan, beginning with Fiscal Year 2009 and in each succeeding fiscal year:

Benchmarks and Statewide Pandemic Influenza Operations Plan

(1) Enforcement Condition: Awardees substantially fail to meet evidence-based benchmarks and objective standards and/or fail to prepare and submit an acceptable pandemic influenza operations plan.

Please note 319C–1(g)(6)(B) Separate Accounting: Each failure described under A(1) shall be treated as a separate failure for purposes of calculating amounts withheld under A(2). For example, a failure to achieve applicable benchmarks as a whole will count as one failure and a failure to submit a pandemic influenza operations plan will count as a second failure.

(2) Enforcement Action:
- Withhold funds—Fiscal Year 2008 is for the purpose of evaluation to determine the amount to be withheld from the year immediately following year of failure. Additionally, each failure is to be treated as a separate failure for the purposes of the penalties described below:
- Initial failure—withholding in an amount equal to 10% of funding per failure.
- Two consecutive years of failure—withholding in an amount equal to 15% of funding per failure.
- Three consecutive years of failure—withholding in an amount equal to 20% of funding per failure.
- Four consecutive years of failure—withholding in an amount equal to 25% of funding per failure.
- Reallocation of amount withheld—According to Pub. L. 109–417, any funds withheld from the PHEP or the Hospital Preparedness Program will be reallocated to the Healthcare Facilities Partnership program in the same state.
- Preference in reallocation—According to Pub. L. 109–417, any funds withheld from the PHEP or the Hospital Preparedness Program will be reallocated to the Healthcare Facilities Partnership program in the same state.

Waive or Reduce: The Secretary of Health and Human Services may waive or reduce the withholding as described above for a single entity or for all entities in a fiscal year, if the Secretary determines that mitigating conditions

exist that justify the waiver or reduction.

Audit Implementation

(1) Enforcement Condition: Awardees who fail to submit the required audit or spend amounts in noncompliance.

(2) Enforcement Action: Grants Management Officer disallows costs and requests payment via standard audit disallowance process or temporarily withholds funds pending corrective action.

Adjudication: Enforcement will be in accordance with 45 Code of Federal Regulation (CFR), part 16.

Carryover

(1) Enforcement Condition: For each fiscal year, the percentage amount of an award unexpended by an awardee exceeds the maximum percentage permitted by the Secretary.

(2) Enforcement Action: Awardees shall return to the Secretary the portion of the unexpended amount that exceeds the maximum permitted to be carried over. According to Public Law 109–417, any funds withheld from the PHEP or the Hospital Preparedness Program will be reallocated to the Healthcare Facilities Partnership program in the same state.

Waive or Reduce: The awardee may request a waiver of the maximum percentage amount or the Secretary may waive or reduce the withholding as described above for a single entity or for all entities in a fiscal year, if the Secretary determines that mitigating conditions exist that justify the waiver or reduction. The Secretary will make a decision after reviewing the awardee's request for waiver.

The Department of Health and Human Services (HHS) permits grantees to appeal to the Departmental Appeal Board (DAB) certain post-award adverse administrative decisions made by HHS officials (see 45 CFR part 16). CDC has established a first-level grant appeal procedure that must be exhausted before an appeal may be filed with the DAB (see 42 CFR part 50.404). CDC will assume jurisdiction for any of the above adverse determinations.

[FR Doc. E8–11718 Filed 5–23–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0298]

Reportable Food Registry as Required by the Food and Drug Administration Amendments Act of 2007; Announcement of Delay in Implementation and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; delay in implementation and request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a delay in the implementation of the Reportable Food Registry (the Registry) of the Food and Drug Administration Amendments Act of 2007 (FDAAA). FDA intends to implement the FDAAA requirement to establish an electronic portal for reportable food by utilizing the business enterprise system currently under development by the agency. This system will be easy to use and the most efficient and cost effective for both users and the agency. FDA expects that the agency's business enterprise system will be operational in spring 2009. FDA acknowledges that the prohibited act provisions relating to the Registry will not apply until such time as FDA establishes the electronic portal to implement the Registry. In conjunction with this delay announcement, FDA is requesting comments on certain aspects of the Registry provisions.

DATES: Submit written or electronic comments by August 11, 2008.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Faye Feldstein, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2428.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, the President signed FDAAA into law (Public Law 110–85). Section 1005 of FDAAA amends the Federal Food, Drug, and Cosmetic Act (the act) by creating a new section 417 (21 U.S.C. 350f). Section 417 of the act requires the Secretary of Health and Human Services (the Secretary) to establish within FDA a Reportable Food Registry (the Registry); the Registry is to be established not later than 1 year after the date of enactment (i.e., by September 27, 2008). The Congressionally-identified purpose of the Registry is to provide a ''reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health'' (121 Stat. 965). The Secretary has delegated to the Commissioner of Food and Drugs the responsibility for administering the act, including section 417 of the act.

To further the development of the Registry, section 417 of the act requires FDA to establish, also within 1 year after the date of enactment (i.e., by September 27, 2008), an electronic portal (the Reportable Food electronic portal) by which instances of reportable food may be submitted to FDA by responsible parties or public health officials.

Section 417(a)(1) of the act defines ''responsible party'' as a person that submits the registration under section 415(a) of the act (21 U.S.C. 350d) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held. Persons who are authorized to submit a facility registration under section 415 of the act are the owner, operator, or agent in charge of a domestic or foreign facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States. Section 417(a)(2) of the act defines a ''reportable food'' as an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

Under section 417(d) of the act, a responsible party is required to submit a report to FDA through the Reportable Food electronic portal as soon as practicable, but in no case later than 24 hours after the responsible party determines that an article of food is a reportable food. Federal, State, and local public health officials may voluntarily submit such reports to FDA through the electronic portal under section 417(d)(3) of the act. Section 417(e) of the act specifies 11 data elements that are required in the initial report or in a subsequent report to FDA; such reports are to be submitted via the Reportable Food electronic portal. Examples of required data elements include the following: (1) The registration numbers