(Pub. L. 109–417), the HPP is a cooperative agreement program funded and administered by the Assistant Secretary for Preparedness and Response (ASPR). Its purpose is to improve surge capacity and enhance community and hospital preparedness for public health emergencies.

Currently there are 62 awardees comprised of the 50 States; the District of Columbia; the three metropolitan areas of New York City, Los Angeles County and Chicago; the Commonwealths of Puerto Rico and the Northern Mariana Islands; the territories of American Samoa, Guam and the U.S. Virgin Islands; the Federated States of Micronesia; and the Republics of Palau and the Marshall Islands.

Since the inception of the program in 2002 awardees have received funding through a statutory formula that employs a base allocation with an adjustment for population. PAHPA amended section 319C–1 and 319C–2 of the PHS Act to add certain accountability provisions.

Consistent with those accountability provisions, this notice proposes to introduce a cost sharing requirement for the HPP program as a concrete way of solidifying collaboration between States and the Federal government in assuring this program will achieve enhanced sustainability in healthcare system preparedness during and after the project period has ended.

ASPR proposes that awardees will make available, either directly or through donations from public or private entities non-Federal contributions in an amount equal to five percent of the award amount in FY 2009 and ten percent of the award amount in FY 2010 and each successive year for the duration of the program. Non-Federal contributions would 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, would not be included in determining the amount of such non-Federal contributions.

The cost sharing requirement would apply to the entire award amount received by the State from the U.S. Department of Health and Human Services through the HPP.

The cost sharing requirement would be implemented as a term and condition of the HPP award.

Request for Comments: The ASPR invites public comment on this notice to add a cost sharing requirement to the HPP. You may submit comments in one of three ways (please choose only one of the ways listed):

- *E-mail*: CDR Melissa Sanders, *melissa.sanders@hhs.gov.*
- *Mail*: CDR Melissa Sanders, Team Leader, Healthcare Systems Preparedness Programs, HSS/OS/ASPR, 395 E Street, SW., 10th Floor, Suite 1075, Washington, DC 20201
- *Hand Delivery/Courier*: CDR Melissa Sanders, Team Leader, Healthcare Systems Preparedness Programs, HSS/OS/ASPR, 395 E Street., SW., 10th Floor, Suite 1075, Washington, DC 20201

Dated: May 9, 2008.

RADM W. Craig Vanderwagon,

Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services.

[FR Doc. E8–10970 Filed 5–15–08; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Program Reporting and Accountability Changes to the Hospital Preparedness Program (HPP)

AGENCY: Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, ASPR (HHS).

ACTION: Notification of intent to fund and information on: (1) Maintenance of Funding (MOF); (2) Evidenced-Based Benchmarks and Objective Standards; (3) Reporting; (4) Funding Formula; (5) Withholding; and (6) Maximum Carryover Amount.

The final FY 2008 Funding Opportunity Announcement (FOA) for the Hospital Preparedness Program (HPP) will be available in the coming weeks at *http://www.grants.gov*.

SUMMARY: The Department of Health and Human Services (HHS or the Department) is issuing in the third quarter of FY 2008 a Funding Opportunity Announcement (FOA) for the HPP, authorized under section 319C–2 of the Public Health Service (PHS) Act, as amended by the Pandemic and All-Hazards Preparedness Act (PAHPA) (Pub. L. 109–417). The Consolidated Appropriations Act, 2008, provides funding for these awards (Pub. L. 110–161). This **Federal Register** notice provides information concerning critical aspects of this program including:

- Program Background;
- Program Requirements:
  - Maintenance of Funding;
  - Evidenced Based Benchmarks and Objective Standards;
  - Reporting;
  - Funding Formula;
  - Withholding;
  - Maximum Carryover Amount;
- Important Dates.

FOR FURTHER INFORMATION CONTACT: CDR Melissa Sanders at (202) 245–0763, or *melissa.sanders@hhs.gov*.

SUPPLEMENTARY INFORMATION:

Program Background

Building on the lessons learned from the attacks of September 11th, 2001, and Hurricanes Katrina and Rita, 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. 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 HHS 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 Assistant Secretary for Preparedness and Response (ASPR); requiring the development and implementation of the National Health Security Strategy; and reauthorizing the Public Health and Emergency Preparedness (PHEP) cooperative agreements administered by the CDC and the HPP grants administered by the ASPR. In addition to reauthorizing these two cooperative agreement programs, PAHPA amended these grant programs to add certain new requirements that awardees must meet. The purpose of this notice is to notify HPP awardees about critical aspects and requirements of the HPP as amended by PAHPA.

Purpose: The purpose of the Hospital Preparedness Program (HPP) is to provide funding to improve surge capacity and realize the following preparedness goals:

- Integration: Ensuring the integration of public and private medical capabilities with public health and other first responder systems, including—

1. Periodically evaluating preparedness and response capabilities through drills and exercises; and

2. Integrating public and private sector public health and medical donations and volunteers.

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

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

2. Improving medical evacuation and fatality management capabilities.

3. Rapidly distributing and administering medical countermeasures, specifically to hospital based health care workers and their family members or partnership entities.

4. Utilizing effectively any available public and private mobile medical assets and integration of other Federal assets.

5. Protecting health care workers and health care first responders from workplace exposures during a public health emergency.

• At-Risk Individuals: Preparing for the medical needs of at-risk individuals in their community in the event of a public health emergency. Medical needs include behavioral health consisting of both mental health and substance abuse considerations. 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. Before, during and after an incident, members of at-risk populations may have additional needs in one or more of the following functional areas: maintaining independence, communications, transportation, supervision and medical care. In addition to those individuals specifically identified as at-risk in the above definition, individuals who may need additional response assistance should include those who:

1. Have disabilities;

2. Live in institutionalized settings;

3. Are from diverse cultures;

4. Have limited English proficiency or are non-English speaking;

5. Are transportation disadvantaged;

6. Have chronic medical disorders; and

7. Have pharmacologic dependency.

• Coordination: Minimizing duplication of, and ensuring coordination between, Federal, State, local, and tribal planning, preparedness, response and recovery activities (including the State Emergency Management Assistance Compact).

• 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: The following are eligible entities:

• A State;

• A political subdivision determined to be eligible for an award under section 319C–1 of the PHS Act; or

• A consortium of States.

Program Requirements

1. Maintenance of Funding (MOF)

Award recipients must maintain their health care preparedness expenditures at a level that is not less than the average of expenditures made during the preceding two year period (i.e., federal FY 2006 and FY 2007). The MOF requirement refers to the awardee's expenditures (i.e., state (or political subdivision) contributions for health care preparedness, not Federal dollars) and may include expenditures for surge capacity investments such as:

a. Beds;

b. Isolation;

c. Decontamination;

d. Personal Protective Equipment;

e. Pharmaceuticals;

f. Mobile Medical Assets;

g. Interoperable communications equipment;

h. Laboratory equipment and trainings.

2. Evidence-Based Benchmarks and Objective Standards

In accordance with section 319C–1(g) of the PHS Act, ASPR has established evidence-based benchmarks and targets to be achieved at the mid-year and end-of-year reporting times. Please see the FY08 HPP FOA for the specific benchmarks that awardees must achieve. As noted in more detail below, HPP awardees will have funds withheld from their FY 2009 awards if, when expending their FY 2008 HPP awards, they fail substantially to meet the benchmarks described in the FY 2008 HPP FOA.

3. Reporting

In order to ensure all awardees are able to demonstrate compliance with newly established benchmarks and other reporting requirements, HHS will require semi-annual reporting information. Please see the FY08 HPP FOA for actual reporting targets to be met.

4. Funding Formula

Per section 319C–2(j) of the PHS Act, funding for this mandatory cooperative agreement is determined in the same manner as amounts are determined for PHEP awardees under section 319C–1(i) of the PHS Act, via a statutory formula that employs a base allocation with an adjustment for population.

5. Withholding

The Secretary of HHS 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 HPP activities. The Secretary shall withhold funds beginning in FY 2009 from HPP awardees who fail substantially to meet the applicable benchmarks for the immediate preceding fiscal year and/or who fail to submit a Pandemic Influenza Plan. Thus, HPP awardees will have funds withheld from their FY 2009 awards if, when expending their FY 2008 HPP awards, they fail substantially to meet the benchmarks described in the FY 2008 FOA or to submit a Pandemic Influenza Plan. The amounts to be withheld are as follows:

(i) For the fiscal year immediately following a fiscal year in which an entity experienced a failure, an amount equal to 10 percent of the amount the entity was eligible to receive;

(ii) For the fiscal year immediately following two consecutive fiscal years in which an entity experienced a failure, an amount equal to 15 percent of the amount the entity was eligible to receive, taking into account the withholding of funds for the immediately preceding fiscal year;

(iii) For the fiscal year immediately following three consecutive fiscal years in which an entity experienced such a failure, an amount equal to 20 percent of the amount the entity was eligible to receive, taking into account the withholding of funds for the immediately preceding two fiscal years;

(iv) For the fiscal year immediately following four consecutive fiscal years in which an entity experienced such a failure, an amount equal to 25 percent of the amount the entity was eligible to receive, taking into account the withholding of funds for the three preceding fiscal years.

Each failure to meet the benchmarks for the immediately preceding fiscal year or to submit a Pandemic Influenza Plan will be treated as a separate failure for purposes of calculating amounts withheld. The Secretary is required to develop and implement a process to notify entities who have failed substantially to meet the evidence-based benchmarks or who have failed to submit a Pandemic Influenza Plan. HHS will notify awardees during the mid-

year reporting period that are determined to have failed to meet the benchmark targets that are described in the FOA. Awardees will have the opportunity to seek intensive technical assistance from project officers and be involved in the development of such technical assistance. Should awardees fail to correct their failures, they shall be subject to the withholding amounts described previously.

6. Maximum Carryover Amount

Per section 319C–1(j)(3) of the PHS Act the Secretary shall determine, for each fiscal year, the maximum percentage of unobligated funds that may be carried over to the succeeding fiscal year. If the percentage of unobligated funds exceeds the maximum percentage permitted, the awardee shall return that portion of the unobligated funds that exceeds the maximum amount permitted. Awardees may apply to the Secretary for a waiver of the maximum percentage amount by including an explanation why the requirement should not apply to the awardee and the steps the awardee will take to ensure that all funds will be expended appropriately. Further, the Secretary may waive or reduce the amount of carryover determined 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.

An awardee may not have more than 15% of the award available as unobligated funds at the time a carryover request is made, approximately 10 months into the budget cycle. Amounts in excess of 15% may result in repayment.

7. Important Dates

Anticipated Application Due Date: June 11, 2008.

Anticipated Award Date: August 1, 2008

Dated: May 9, 2008.

RADM W. Craig Vanderwagon,

Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services.

ASPR Hospital Preparedness Program (HPP) Cooperative Agreement

Enforcement Actions and Disputes

I. Purpose

Sections 319C–1 and C–2 of the Public Health Service (PHS), as amended by the Pandemic and All-Hazards Preparedness Act (PAHPA), include certain accountability and compliance requirements that grantees must meet, including achievement of evidence-based benchmarks, audit requirements, and maximum carryover amounts. This document provides information about enforcement actions associated with these requirements, and appeal processes in the event there is a dispute. This document addresses requirements and enforcement actions specifically outlined in section 319C–1 and C–2 of the PHS. It is not intended to cover all requirements that grantees must meet pursuant to grant laws, regulations, Departmental grants policy, and terms and conditions of the award. Grant laws, regulations, and Departmental grants policies apply to these grants to the extent they are consistent with section 319C–1 and C–2 of the PHS Act.

II. Abbreviations, Acronyms and Definitions

A. For the purpose of this document, the following abbreviations and acronyms apply:

1. ARC—Agency Review Committee.
2. ASPR—Assistant Secretary for Preparedness and Response.
3. CGMO—Chief Grants Management Officer.
4. DAB—Departmental Appeals Board.
5. GMO—Grants Management Officer.
6. GMS—Grants Management Specialist.
7. HHS—Department of Health and Human Services.
8. HPP—Hospital Preparedness Program.
9. IDDA—Intra-Departmental Delegation of Authority (IDDA).
10. NoA—Notice of Award.
11. OPHS—Office of Public Health and Science.
12. PHEP—Public Health Emergency Preparedness.
13. PO—Project Officer.

B. For the purpose of this document, the following definitions apply:

1. HHS Department Appeals Board (DAB)—The administrative board responsible for resolving certain disputes arising under HHS assistance programs. The DAB provides an impartial adjudicatory hearing process for appealing certain final written decisions by GMOs. The DAB's jurisdiction is specified in 45 CFR Part 16, ''Procedures for HHS Grant Appeals Board.''

2. Agency Review Committee (ARC)—Committee comprised of awarding agency members who review awardee appeals to adverse determinations made by grant officials. A minimum of three appointed core members, one of whom will be designated a chairperson by the ASPR. Others may be designated as determined by the chairperson. Members of the ARC may not be from the branch or program whose adverse determination is being appealed.

3. Recipient—The organization that receives a grant or cooperative agreement award from an awarding agency, and is responsible and accountable for using the funds provided, and for the performance of the grant-supported project or activity. The recipient is the entire legal entity, even if a particular component is designated in the NoA. The term includes ''awardee/grantee.''

4. Corrective action—Action taken by the awardee that corrects identified deficiencies or produces recommended improvements.

5. Enforcement—Actions taken to compel the observance of policies, regulations, and laws governing the administration of an assistance program. Such actions are generally the result of a recipient's failure to comply with the terms and conditions of an award. These failures may cause an awarding agency to take one or more actions, depending on the severity and duration of the non-compliance. The awarding agency generally will afford the recipient an opportunity to correct the deficiencies before taking enforcement action, unless public health or welfare concerns require immediate action. However, even if an awardee is taking corrective action, the awarding agency may take proactive steps to protect the Federal government's interests, including placing special conditions on awards, or may take action designed to prevent future non-compliance, such as closer monitoring.

6. Termination—The permanent withdrawal by the awarding agency of an awardee's authority to obligate previously awarded grant funds before that authority would otherwise expire, including the voluntary relinquishment of that authority by the recipient.

7. Disallowance—A determination denying payment of an amount claimed under an award, or requiring return of funds or off-set of funds already received.

8. Void—A determination that an award is invalid because the award was not authorized by statute or regulation, or because it was fraudulently obtained.

9. Withholding of funds—An action taken by an awarding agency to withhold or reduce support within a previously approved or subsequent budget period. Withholding may occur for the following justifiable reasons: (1) An awardee is delinquent in submitting required reports; (2) adequate Federal funds are not available to support the project; (3) an awardee fails to show satisfactory progress in achieving the objectives of the project, e.g.,

performance measures/benchmarks and/or excessive carryover; (4) an awardee fails to meet the terms of a previous award; (5) an awardee's management practices fail to provide adequate stewardship of Federal funds; (6) any reason which would indicate that continued funding would not be in the best interests of the Government.

10. Offset—The withholding of funds from an award recipient in order to compensate for costs owed the awarding agency.

11. Repayment of funds—Funds for payment of a debt determined to be owed to the Federal Government. Repayment of funds cannot come from other Federally-sponsored programs.

12. Terms and conditions of award—All requirements imposed on a recipient by the Federal awarding agency, whether by statute, regulation, or within the grant award document itself. The terms of award may include both standard and special provisions, appearing on each NoA that are considered necessary to attain the objectives of the grant; facilitate post award administration of the grant, conserve grant funds, or otherwise protect the Federal government's interests.

13. Performance measures/benchmarks—The use of statistical evidence to determine progress toward specific defined objectives. These are leading indicators that will allow a national ''snapshot'' to show how preparedness and response activities, and the associated resources, aid in improving the public health system.

14. Excessive Carryover—Unobligated funds of a recipient that exceed the established maximum percentage of 15% of the award, as reported on a Financial Status Report (SF–269) at the time a carryover request is made, approximately 10 months into the 12 month budget cycle. The threshold amount includes direct and indirect costs.

15. Outlays or Expenditures—The charges made to the Federally-sponsored project or program. They may be reported on a cash or accrual basis. For reports prepared on a cash basis, outlays are the sum of cash disbursements for direct charges for goods and services, the amount of indirect expense charged, the value of third party in-kind contributions applied and the amount of cash advances and payments made to sub-awardees. For reports prepared on an accrual basis, outlays are the sum of cash reimbursements for direct charges for goods and services, the amount of indirect expense incurred, the value of in-kind contributions applied, and the net increase (or decrease) in the amounts owed by the recipient for goods and other property received, for services performed by employees, contractors, sub-awardees and other payees and other amounts becoming owed under programs for which no current services or performance are required.

16. Audits—A systematic review or appraisal made to determine whether internal accounting and other control systems provide reasonable assurance of financial operations are properly conducted; financial reports are timely, fair, and accurate; the entity has complied with applicable laws, regulations, and terms and conditions of award; resources are managed and used economically and efficiently; desired results and objectives are being achieved effectively.

17. Failure—Noncompliance with any or all of the provisions of the NoA which include but not limited to various laws, regulations, assurances, terms, or conditions applicable to the grant or cooperative agreement.

18. Matching or Cost Sharing—The value of third-party in-kind contributions and the portion of the costs of a federally assisted project or program not borne by the Federal Government. Costs used to satisfy matching or cost-sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.

III. Background

PAHPA amended section 319C–2 of the PHS Act, and authorizes the Assistant Secretary for Preparedness and Response (ASPR) to award cooperative agreements to eligible entities to enable such entities to improve surge capacity and enhance community and hospital preparedness for public health emergencies. Funding for these awards is provided by the Consolidated Appropriations Act of 2008 (Public Law 110–161).

Grantees must meet certain statutory accountability and compliance requirements. Sections 319C–1 and C–2 of the PHS Act require the Department to take certain enforcement actions if grantees fail to meet these requirements. More specifically, this document addresses the following enforcement actions required by the statute: (1) Beginning in fiscal year 2009, withholding a statutorily-mandated percentage of the award if an awardee fails substantially to meet established benchmarks and performance measures for the immediately preceeding fiscal year or fails to submit a satisfactory pandemic flu plan to the Department; (2) repayment of any funds that exceed the maximum percentage of an award that an entity may carryover to the succeeding fiscal year; and (3) repayment or future withholding or offset as a result of a disallowance decision if an audit shows that funds have not been spent in accordance with section 319C–2 of the PHS Act .

IV. Enforcement Actions and Disputes

A. Withholding for Failure To Meet Established Benchmarks and Performance Measures or To Submit a Satisfactory Pandemic Influenza Plan

1. Beginning with the distribution of FY 2009 funding, awardees that fail substantially to meet performance measures/benchmarks for the immediately preceding fiscal year and/or who fail to submit a pandemic influenza plan to CDC as part of their application for PHEP funds, may have funds withheld from their FY 2009 and subsequent award amounts. An awardee that fails to correct such noncompliance shall be subject to withholding in the following amounts:

- For the fiscal year immediately following a fiscal year in which the awardee has failed substantially to meet performance measures/benchmarks or who has failed to submit a satisfactory pandemic influenza plan; an amount equal to 10 percent of funding the awardee was eligible to receive.
- For the fiscal year immediately following two consecutive fiscal years in which an awardee experienced such a failure, an amount equal to 15 percent of funding the awardee was eligible to receive, taking into account the withholding of funds for the immediately preceding fiscal year.
- For the fiscal year immediately following three consecutive fiscal years in which an awardee experienced such a failure, an amount equal to 20 percent of funding the awardee was eligible to receive, taking into account the withholding of funds for the immediately preceding fiscal years.
- For the fiscal year immediately following four consecutive fiscal years in which an entity experienced such a failure, an amount equal to 25 percent of funding the awardee was eligible to receive for such a fiscal year, taking into account the withholding of funds for the immediately preceding fiscal year.

Please note that HHS is required to treat each failure to substantially meet all the benchmarks and each failure to submit a satisfactory pandemic influenza plan as a separate withholding action. For example, an awardee failing substantially to meet benchmarks/performance measures and who fails to

submit a satisfactory pandemic influenza plan could have 10% withheld for each failure for a total of 20% for the first year this happens. If this situation remained unchanged, HHS would then be required to assess 15% for each failure for a total of 30% for the second year this happens. Alternatively, if one of the two failures are corrected in the second year but one remained, HHS is required to withhold 15% of the second year funding.

2. Technical Assistance and Notification of Failures

ASPR may, in coordination with the CGMO and in accordance with established Departmental grants policy, provide to an awardee, upon request, technical assistance in meeting benchmarks/performance measures and submitting a satisfactory pandemic influenza plan. In addition, as described below, ASPR will notify awardees that are determined to have failed substantially to meet benchmarks/performance measures and/or who have failed to submit a satisfactory pandemic influenza plan and give them an opportunity to correct such noncompliance. Entities who fail to correct such noncompliance will be subject to withholding as described in the paragraph above.

The awardee shall submit the required progress report on or before the specified due date according to the terms and conditions of the NoA. The Project Officer shall, within 15 days of receipt of the required progress report, assess performance, provide technical assistance to the awardee as required, and issue a written letter acknowledging completion of assessment and that the assessment has been forwarded to the GMO. Upon determination that the awardee has failed to comply with the terms and conditions of a grant or cooperative agreement, the Project Officer (PO) shall issue a written recommendation and provide a complete documentation package to the Grants Management Officer (GMO) based on the review and monitoring of the awardee.

Within 15 days of receipt of the recommendation from the PO, the GMO shall issue an initial failure notification to the awardee in writing. This document will provide compliance requirements as submitted by the PO and will include the total amount of Federal funds which will be withheld or reduced in the subsequent fiscal year due to noncompliance, absent corrective action by the awardee that is satisfactory to the GMO. The document will specify that the GMO will take such other remedies as may be legally available and appropriate in the circumstances, such as withholding of Federal funds.

The awardee must provide a proposed Corrective Action Plan (CAP) in writing to the GMO, within 15 days of receipt of the initial failure notification.. The GMO will forward a copy to the PO. The awardee may request technical assistance at this time.

Within 15 days of receipt of the proposed CAP, the PO will assess the remedies and provide a recommendation to the GMO. If the GMO finds the corrective action measures satisfactory, the GMO shall, within 15 days of receipt of the PO's assessment, provide notification to the awardee of the awarding agency's intent to rescind the initial failure notification. If in the GMO's judgment the awardee has still failed to comply with the terms and conditions of a grant or cooperative agreement, the GMO shall issue a final failure notification and provide information about the appeal process to include applicable timelines in writing. The GMO will concurrently issue his/her decision to the awardee and the Agency Review Committee (ARC).

3. Dispute Process

The ASPR has established an ARC for the purpose of providing awardees a fair and flexible process to appeal certain enforcement actions such as a final decision to withhold funds due to a failure to meet benchmarks/performance measures and/or to submit a satisfactory pandemic influenza plan. The ARC consists of three regular members: ASPR Principal Deputy (Director); OPEO (Director); and Resource Planning and Evaluation (Director). The ASPR Principal Deputy, Director, or designee, shall be the chairperson for the ARC. The ARC may consult with subject matter experts within the Department as necessary (i.e., attorneys, Branch Chiefs, Team Leaders, Project Officer/Public Health Advisors, etc.) Members of the ARC may not be from the branch or program whose adverse determination is being appealed.

If the awardee chooses to appeal the GMO decision, the awardee must do so directly to the ARC within ten days of receipt of the GMO's final failure notification. The Notice of Appeal shall include: (1) a detailed description of the reason for appeal including supporting documentation and (2) a description of how the enforcement action impacts the affected organization. The awardee should be aware that they bear the burden of proof to the extent of the type of modification or reversal of the GMO's decision they seek and the necessity for modification or reversal.

Within ten days of receipt of the awardee's notice of appeal, the GMO will (1) Brief the ARC on the issues of the case, (2) submit any relevant documentation supporting the decision, and (3) provide a written statement responding to the notice of appeal.

Within ten days of receipt of the brief and documentation submitted by the GMO, the ARC will acknowledge, in writing, the notice of appeal to the awardee and the GMO. The ARC will review the relevant information, within seven days of providing written notification to awardee and GMO, and use one or a combination of the following methods for dispute resolution:

(a) Documentation Review—an independent evaluation of documents to verify compliance with laws, regulations, or policies;

(b) Conference—allow parties an opportunity to make an oral presentation to clarify issues, question both parties to obtain a clear understanding of the facts, and provide recommendations for resolution. Telephone conferences are acceptable.

Based on the outcome of the review or conference, the ARC will decide on the resolution of an issue within seven days. The ARC may decide that the Department should waive or reduce the withholding as described above for a single entity or for all entities in a fiscal year, if the ARC reviews and determines that mitigating conditions exist that justify the waiver or reduction. The ARC will notify the GMO, PO, and the awardee, in writing, of their final decision that the Department should waive or withhold federal funds.

If the ARC's final decision is to for the Department to waive the federal funds to be withheld or withhold Federal funds for the subsequent fiscal year, the GMO shall issue, in writing, a final decision to the awardee within ten days from the receipt of the ARC's final decision.

Funds that are withheld for failure to substantially meet benchmarks/performance measures and/or to submit a satisfactory pandemic influenza plan will be reallocated so that the Secretary may make awards under section 319C–2 to entities described in subsection (b)(1) of that section (i.e., Healthcare Facility Partnership grants).

4. Responsibilities

A. PO/Public Health Advisor shall:

1. During the corrective action phase, provide technical assistance to the awardee to meet the requirement.

2. If determined the awardee will not meet the requirement, the PO shall issue a written recommendation to the GMO

based on the review and monitoring of awardee progress.

3. Provide a timely documentation package to the GMO regarding a decision to withhold or reduce cooperative agreement funds.

B. GMO shall:

1. Rescind initial failure notification or issue a final failure notification and provide the awarding agency's process for appeal to include applicable timelines, in writing, to the awardee and provide a copy to ARC.

2. Brief ARC on issues pertaining to disputes.

3. Prepare and submit a complete documentation package to the ARC regarding a decision to withhold or reduce cooperative agreement funds.

C. ARC shall:

1. Establish regular committee members and consult with subject matter experts in the Department as necessary.

2. Receive initial Notice of Appeal.

3. Send acknowledgements to the awardee and GMO.

4. Review disputes by documentation or conference.

5. Provide recommendations and facilitate disputes to preclude further action.

6. Provide the ARC decisions on appeals.

D. Awardee or Complainant shall:

1. Remedy non-compliance issues during the corrective action phase. If the GMO determines that corrective actions have not been adequate, the awardee may submit a written request for review.

2. If awardee disputes the GMO's final decision, submit dispute to ARC after Failure Notification is received from the agency awarding office. The dispute must contain the following:

A. A detailed description of the reason for dispute including supporting documentation and

B. A description of how the enforcement action impacts the affected organization.

B. Repayment of Any Funds That Exceed the Maximum Percentage of an Award That an Entity May Carry Over to the Succeeding Fiscal Year

1. For each fiscal year, ASPR, in consultation with the States and political subdivisions, will determine the maximum percentage amount of an award that an awardee may carry over to the succeeding fiscal year. This percentage amount will be listed in the funding opportunity announcement (FOA). For fiscal year 2008 awards, this maximum percentage amount that an awardee may carry over is 15%. For each fiscal year, if the percentage amount of an award unobligated by an awardee exceeds the maximum percentage permitted (i.e., 15% for FY 2008 awards), the awardee shall repay the portion of the unobligated amount that exceeds the maximum amount permitted to be carried over to the succeeding fiscal year.

2. Notification of Failure

Upon determination that the awardee has exceeded the maximum percentage permitted, the GMO shall issue an initial failure notification to the awardee in writing. Such documentation will specify that the GMO will take such remedies as may be legally available and appropriate in the circumstances, such as requiring repayment of the portion of the unobligated amount that exceeds the maximum amount permitted to be carried over to the succeeding fiscal year.

The awardee must provide a proposed Corrective Action Plan (CAP) in writing to the GMO, within 15 days of receipt of the initial failure notification.. The GMO will provide a copy to the PO. The awardee may request technical assistance at this time.

Within 15 days of receipt of the proposed CAP, the PO will assess the remedies and provide a recommendation to the GMO. The GMO shall, within 15 days of receipt of the PO's assessment, provide notification to the awardee of the awarding agency's intent to rescind the initial failure notification. If the awardee has still failed to comply with the terms and conditions of a grant or cooperative agreement, the GMO shall issue a final failure notification in writing and provide information about the appeal process and application for waiver of repayment to include applicable timelines. The GMO will concurrently issue his/her decision to the awardee and the Agency Review Committee (ARC).

3. Dispute Process

If the awardee chooses to appeal the GMO decision, the awardee must do so directly to the ARC within ten days of receipt of the GMO's final failure notification. The Notice of Appeal shall include: (1) A detailed description of the reason for appeal including supporting documentation; (2) a description of how the enforcement action impacts the affected organization; and (3) request for a waiver of repayment that includes an explanation why such requirement (for maximum percentage of carryover amount) should not apply to the awardee and the steps taken by the awardee to ensure that all HPP funds will be expended appropriately. The awardee should be aware that they bear the burden of proof to the extent of the type of modification or reversal of the GMO's decision they seek and the modification or reversal.

Within ten days of receipt of the awardee's notice of appeal, the GMO will (1) Brief the ARC on the issues of the case, (2) submit any relevant documentation supporting the decision, and (3) provide a written statement responding to the notice of appeal.

Within ten days of receipt of the brief and documentation submitted by the GMO, the ARC will acknowledge, in writing, the notice of appeal to the awardee and the GMO.

The ARC will review the relevant information, within seven days, and use one or a combination of the following methods for dispute resolution:

(a) Documentation Review—an independent evaluation of documents to verify compliance with laws, regulations, or policies;

(b) Conference—allow parties an opportunity to make an oral presentation to clarify issues, question both parties to obtain a clear understanding of the facts, and provide recommendations for resolution. Telephone conferences are acceptable.

The ARC may decide that the Department should waive or reduce the amount to be repaid for a single entity or for all entities in a fiscal year, if the ARC reviews and determines that mitigating conditions exist that justify the waiver or reduction. The ARC will notify the GMO, PO, and the awardee, in writing, of their final decision that the Department should waive or require repayment of the portion of the unobligated amount of HPP funds that exceeds the maximum amount permitted to be carried over to the succeeding fiscal year.

If the ARC's final decision is to waive or to require repayment of the portion of the unobligated amount of HPP funds that exceeds the maximum amount permitted to be carried over to the succeeding fiscal year, the GMO shall issue a final decision in writing to the awardee within ten days from the receipt of the ARC's final decision.

Funds that are repaid to ASPR will be reallocated so that the Secretary may make awards under section 319C–2 to entities described in subsection (b)(1) of that section (i.e., Healthcare Facility Partnership grants).

4. Responsibilities

A. PO/Public Health Advisor shall:

1. If determined the awardee has exceeded the maximum carryover percentage, the PO shall issue a written recommendation to the GMO based on

the review and monitoring of awardee progress.

2. Provide a timely documentation package to the GMO regarding a decision to repay unobligated HPP funds that exceed the maximum carryover percentage.

B. GMO shall:

1. Rescind initial failure notification or issue a final failure notification and provide the awarding agency's process for appeal to include applicable timelines, in writing, to the awardee and provide a copy to ARC.

2. Brief ARC on issues pertaining to disputes.

3. Prepare and submit a complete documentation package to the ARC regarding a decision to repay.

C. ARC shall:

1. Establish regular committee members and consult with subject matter experts in the Department, as necessary.

2. Receive initial Notice of Appeals.

3. Send acknowledgements to the awardee and GMO.

4. Review disputes by documentation or conference.

5. Provide recommendations and facilitate disputes to preclude further action.

6. Provide the ARC decisions on appeals.

D. Awardee or Complainant shall:

1. Remedy non-compliance issues during the corrective action phase. If the GMO determines that corrective actions have not been adequate, the awardee may submit a written request for review.

2. If awardee disputes the GMO's final decisions, submit dispute to ARC after Failure Notification is received from the agency awarding office as described in the NoA. The dispute must contain the following:

A. A detailed description of the reason for dispute including supporting documentation;

B. A description of how the enforcement action impacts the affected organization; and

C. Request for a waiver of repayment that includes an explanation why such requirement (for maximum percentage of carryover amount) should not apply to the awardee and the steps taken by the awardee to ensure that all HPP funds will be expended appropriately.

C. Repayment or Future Withholding or Offset as a Result of a Disallowance Decision if an Audit Shows That Funds Have Not Been Spent in Accordance With Section 319C–2 of the PHS Act

1. Awardees shall, not less often than once every 2 years, audit their expenditures from HPP funds received. Such audits shall be conducted by an entity independent of the agency administering the HPP program in accordance with the Comptroller General's standards for auditing governmental organizations, programs, activities, and functions and generally accepted auditing standards. Within 30 days following completion of each audit report, awardees should submit a copy of that audit report to ASPR.

Awardees shall repay to the United States amounts found not to have been expended in accordance with section 319C–2 of the PHS Act. If such repayment is not made, ASPR may offset such amounts against the amount of any allotment to which the awardee is or may become entitled under section 319C–2 or may otherwise recover such amount. ASPR may withhold payment of funds to any awardee which is not using its allotment under section 319C–2 in accordance with such section. ASPR may withhold such funds until it finds that the reason for the withholding has been removed and there is reasonable assurance that it will not recur.

2. Disallowance notification

Upon determination as a result of audit findings that the awardee has not expended funds in accordance with section 319C–2, the GMO shall issue a disallowance notification to the awardee for the portion of funds not expended in accordance with section 319C–2 and require repayment of those funds to the United States.

3. Dispute process

HHS has established a DAB for the purpose of providing awardees a fair and flexible process to appeal certain written final decisions involving grant and cooperative agreement programs administered by agencies of HHS. This document notifies HPP awardees that an opportunity exists to appeal a disallowance enforcement action to the DAB. If the awardee chooses to appeal a final disallowance decision by the GMO, the awardee must do so directly to the DAB within thirty days of receipt of the GMO's final disallowance notification. The Notice of Appeal shall include: (1) A copy of the final decision, (2) a statement of the amount in dispute in the appeal, and (3) a brief statement of why the decision is wrong. More details about the DAB's procedures may be found at 45 CFR part 16.

V. References

A. Code of Federal Regulations (CFR)

- 45 CFR Part 16 and Appendix A, Procedures of the Departmental Grants Appeal Board.
- 45 CFR Part 74 and Appendix E, Uniform Administrative Requirements for Awards and Sub-awards to Institutions of Higher Education, Hospitals, Other Nonprofit organizations, and commercial organizations.
- 45 CFR Part 92, Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments.

B. OMB Circulars

- A–87, Cost Principles for State, Local and Indian Tribal Governments.
- A–102, Grants and Cooperative Agreements with State and Local Governments.
- A–110, Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations.
- A–133, Audits of States, Local Governments, and Non-Profit Organizations Requirements.

C. HHS Grants Policy Statement, January 1, 2007

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–08–08BD]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c)