Centers for Innovation in Advanced Development and Manufacturing
Request for Proposal
Fact Sheet

The U.S. Department of Health and Human Services issued a request for proposals (RFP) today for one or more Centers for Innovation in Advanced Development and Manufacturing (Solicitation Number: HHS 11-100-SOL00011). The RFP supports the Administration's approach to enhancing the nation's preparedness for catastrophic events.

HHS articulates a four-part need in this RFP:

- U.S.-based Centers for Innovation in Advanced Development and Manufacturing (the "Centers") as public-private partnerships
- Greater assistance in the development and manufacture of CBRN medical countermeasure (MCM) product candidates
- Secure, robust, & nimble domestic vaccine and other biopharmaceutical manufacturing surge capacity in an emergency
- Training of next generation of operators with workforce development training programs.

The requirements for these Centers come directly from the August 2010 *HHS Public Health Emergency Medical Countermeasure Review*.

Secretary Sebelius requested the comprehensive review in December 2009 when the department encountered challenges with the 2009 H1N1 pandemic flu vaccine, highlighting the need for a modernized countermeasure production process. The review covered the steps involved in the research, development, and FDA approval of medications, vaccines, and medical equipment and supplies for a health emergency.

The review was informed by recommendations from the President's Council on Science and Technology [PCAST] report of August 2010 which evaluated influenza vaccine technologies and capabilities in the United States. The HHS review resulted in recommendations including in a focused set of initiatives such as the Centers for Innovation in Advanced Development and Manufacturing.

In releasing the draft solicitation for this program in September 2010 for public engagement and comment, HHS drew on more than a decade of examination, analysis, and reports on domestic manufacturing facilities, as well as department experience in public-private partnership with manufacturing facilities.

HHS/BARDA manufacturing infrastructure building for medical countermeasures has a successful track record, including its original egg supply contract for pandemic influenza

preparedness in 2004, retrofitting U.S.-based manufacturing facilities in 2007, and construction of the first cell-based influenza vaccine manufacturing facility in the U.S. in 2009.
The Centers for Innovation in Advanced Development and Manufacturing are expected to help bolster the nation's existing manufacturing surge capacity with more rapid, nimble, and flexible manufacturing of vaccines for pandemic influenza and provide a readiness posture to produce other products in an emergency to known and unknown threats.

HHS efforts to establish Centers for Innovation in Advanced Development and Manufacturing, in conjunction with the Department of Defense efforts to establish a center, represent a national strategy. That strategy includes facilitating the development and availability of medical countermeasures for chemical, biological, radiological and nuclear emergencies, as well as increasing domestic vaccine manufacturing capabilities in an emergency. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), including HHS and DoD, will coordinate the prioritization, assignment, and oversight of product development and manufacturing at these centers. HHS will oversee the HHS centers.

Today's RFP to establish capabilities for advanced development and manufacturing supports the Administration's approach to enhancing the nation's preparedness for catastrophic events, as Federal Emergency Management Administrator Craig Fugate explained in testimony March 30 before the House Committee on Transportation & Infrastructure.

Program Objectives

1. **Establish Center Facilities**
    - Construction of new or retrofit existing facilities in the U.S. utilize state-of-the art flexible manufacturing approaches for platform vaccine and biopharmaceutical product technologies
    - Facility design, construction, commissioning, and validation are cost-shared between HHS and Offeror(s).
    - The Centers will be operated and maintained for no more than 25 years.

2. **Provide ADM Core Services for CBRN MCMs**
    - Provide primarily, on a routine basis, core services that include the advanced development and manufacturing of chemical, biological, radiological, and nuclear (CBRN) medical countermeasures.
    - Offeror must provide at least 6 months of core services per annum.
    - The U.S. government will pay operational & maintenance costs for services rendered with 6 months/annum.
    - Specific activities supported at these centers
        i. Upstream & downstream process development, optimization, scale up, and validation
        ii. Manufacturing process validation
        iii. Product formulation chemistry
        iv. Lot release & clinical testing assay development, optimization, and validation
        v. Quality systems (Control & Assurance – GMP & GLP compliance)
        vi. Regulatory affairs (IND, EUA, BLA, NDA submissions & strategy)
        vii. Clinical investigational lot manufacturing (pilot scale)
        viii. Commercial scale manufacturing
        ix. Program management

3. **Provide Emergency Flexible Vaccine Manufacturing for Pan Flu and Other Threats**
    - Provide rapid & nimble commercial scale manufacturing surge capabilities for vaccine & biological product production in an emergency
    - Manufacturing facilities will utilize state-of-the-art flexible and innovative manufacturing processes combined with new cell, recombinant & molecular platform technologies
    - Produce vaccines & biologicals for pandemic influenza, emerging infectious diseases, & other unknown threats

- Pandemic influenza vaccine manufacturing capacity should be at least 50 million doses within four (4) months and first dose available within 12 weeks on pandemic onset
- Pandemic vaccine candidates will be assigned to Centers based on technology capabilities at contract awarding or afterwards

4. **Workforce Development Training Program**
    - Establish a workforce development training program to enhance and maintain the U.S.-based personnel ability to produce these medical countermeasures
    - Bring technology and innovation into the American job market is a critical element of these Centers
    - Training programs will need to align with FDA training requirements and current best practices in commercial industry
    - Partnership with accredited U.S.-based universities will be a pre-requisite for these programs

Mandatory Criteria

- <u>FDA Licensure of a Biopharmaceutical Product within the Last Ten (10) Years</u>
  Offeror must have sponsored successfully BLA or NDA leading to production of a FDA licensed biopharmaceutical product in last ten (10) years

- <u>U.S. Biopharmaceutical Manufacturing commitment</u>
  Written evidence of a firm commitment that the Offeror shall initiate the establishment, and maintain, the necessary facilities in the U.S. or its territories [U.S.-based] for core advanced development and multi-purpose manufacturing services throughout the amortized lifetime of the facility(s).

- <u>Cost Sharing</u>
  Offeror Minimum: 51% of the total cost of new construction of US Facility
  25% of the total cost to retrofit an existing US facility

- <u>Surge Manufacturing Capacity of Vaccines for Pandemic Influenza Vaccine & Other Threats</u>
  Offeror Minimum: 50 million finished doses within four (4) months of delivery order receipt

- <u>Training</u>
  Offeror shall provide written evidence of a firm commitment to supply biopharmaceutical-oriented workforce development that is aligned with current regulatory guidelines via training programs with U.S.-based, accredited academic institutions or other industry recognized U.S.-based organizations that specialize in this area.

Key Program Concerns

- Procurement process is full and open competition

- Public-private partnerships will establish new or retrofit existing U.S.-based biopharmaceutical facilities (Multiple awards anticipated)
    - Solicitation will include a Statement of Objectives (rather than a Statement of Work) to encourage innovative proposals to the Government's requirement

- After contract awarding, USG-supported pandemic influenza vaccine candidates will be assigned to the most compatible Center [for Offerors without a pandemic influenza vaccine partner]
    - Providing routine advance development core services for CBRN MCMs is the primary work of the Centers, not development of influenza vaccines.

- Contract awards will support annual Facility Readiness Reimbursements to offset operating costs of facilities for six (6) months each year, if necessary.

- Centers are not required to manufacture commercial products; however, the facilities must meet FDA requirements and provide commercial-scale capacity

HHS & DoD Centers Comparison

The scale of manufacturing at the HHS Centers will be larger than the DoD Center to accommodate the larger civilian population needs.

The focus of core services for the HHS Centers is the advanced development and manufacturing of CBRN medical countermeasures, whereas the DoD Center will focus on adaptable technology innovation in biopharmaceutical MCM expression and manufacturing systems to meet DoD requirements.

In an emergency both HHS and DoD Centers will focus on rapid, flexible, and nimble technologies scalable for large product production.

HHS Centers will provide workforce development programs with academic institutions for product development and manufacturing, whereas the DoD Center will serve as residence for in-house science & technology, advanced development and regulatory science workforce development.

Program Next Steps

Proposal submission
Offerors will have a 90-day period in which to submit their proposal to the Contracting Officer

Pre-proposal Conferences
During the proposal preparation timeframe, HHS/AMCG will hold two (2) pre-proposal conferences

First: on or about 30 days after release of the RFP
Second: on or about 30 days after the first pre-proposal conference.

Contract Awards
Awarding of multiple contracts is anticipated by the early 2012 pending results of technical evaluations and contract negotiations.