



Centers for Disease Control and Prevention: Section 317 Immunization Program

A. Funding Table

(Dollars in millions)

Program/ Project/Activity	Total Appropriated	FY 2009 Actual Obligations	FY 2010 Estimated Obligations
Vaccine purchase and grantee operations	250	127.4	122.6
Innovative Immunization and Reimbursement Initiatives	18	6.7	11.3
National communication campaign and provider education	9	3.7	5.3
Strengthening the evidence base	21.5	16.4	5.1
Management and oversight	1.5	0.2	1.3
Total	300	154.4	145.6

B. Objectives

The American Recovery and Reinvestment Act appropriated to the Department of Health and Human Services Office of the Secretary \$300 million and specified that these funds be transferred to the Centers for Disease Control and Prevention (CDC) for its Section 317 Immunization program (Section 317). The Section 317 Program funds 64 immunization programs that include all 50 states, Washington DC, 5 urban areas, the U.S. Territories, and selected Pacific Island nations. The majority of Section 317 program funds are dedicated to routine childhood programs, with a small portion remaining for adolescent and adult immunization programs. Most children served with Section 317-funded vaccines are under-insured or their parents cannot afford the out-of-pocket costs required to fully vaccinate their children. The Recovery Act program funds will expand access to vaccines and vaccination services by making more vaccines available, increase national public awareness and knowledge about the benefits and risks of vaccines and vaccine-preventable diseases, and strengthen the evidence base for vaccination policies and programs.

Public Benefits

This investment will expand access to vaccines and vaccination services by:

- Making recommended vaccines available in all states through the existing network of private and public immunization providers and supporting and expanding the network of providers as needed;
- Expanding access to the childhood vaccine series and influenza vaccines through using innovative vaccine delivery strategies;



- Providing grants to immunization programs to conduct needs assessments and develop plans that will enable health departments to bill private insurance for immunization services provided to insurance plan members;
- Increasing national public awareness and knowledge about the benefits and risks of vaccines and vaccine-preventable diseases;
- Enhancing assessments of vaccine coverage, vaccine impact, vaccine effectiveness and vaccine adverse events.

C. Activities

Below is a list of activities to be performed, including project scope for each:

Reaching more children and adults: Provides additional vaccine and the means for administering this vaccine through Section 317 grantees and their community partners:

- Vaccine purchase: procurement of additional vaccines for children and adults
- Grant supplements: assistance funding to 64 immunization programs that include all 50 states, Washington DC, 5 urban areas, the U.S. Territories, and selected Pacific Island nations to support programs operations

Innovative initiatives for improving reimbursement and enhancing electronic immunization data exchange:

Time-limited projects to develop demonstrate how innovative approaches can successfully and measurably deliver more vaccine to selected target groups, and enhance the interoperability of electronic immunization data exchange between Electronic Health Record (EHR) systems and immunization registries (IR) and to develop specifications to harmonize clinical decision support algorithms. Partnerships will engage national interests such as Medicare, Medicaid and CHIP in assisting with these efforts and forging other important partnerships at the state and local levels with health agencies, healthcare providers, professional organizations, insurers, employers, and other community leaders:

- Improving Reimbursement: Competitive awards to immunization programs for planning grants to develop appropriate mechanisms to bill private health insurance for immunization services provided to plan members.
- Electronic Health Record (EHR) Systems and Immunization Registries (IR): Competitive awards to current immunization grantees to enhance interoperability of electronic immunization data exchange between Electronic Health Record (EHR) systems and immunization registries (IR) and to develop specifications to harmonize clinical decision support algorithms.

National communication campaign and provider education: Purposes include: 1) increase public awareness of vaccine-preventable diseases and CDC's immunization recommendations for Americans of all ages, 2) enhance knowledge among immunization providers about CDC's immunization recommendations, and 3) engage the American public on questions related to U.S. immunization policy:

- Communication and education activities: raise awareness of vaccine availability as well as address public questions about vaccine benefits and risks. Includes the development and provision of training and education resources and tools that increase knowledge of complex immunization schedules and recommendations.



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Strengthening the evidence base: Time-limited assessments of vaccine-preventable disease burden trends and vaccine effectiveness, filling selected gaps in current vaccination coverage assessment capability, upgrading the current sentinel immunization registries allowing for more rapid monitoring of vaccination trends, improving existing systems for monitoring vaccine safety, and conducting short term training courses for state health laboratories.

D. Characteristics

Spend Plan Category	Type of Award	Total Funding Amount	Methodology for Award Selection	Recipients
Vaccine purchase and operations	Grants and contracts	\$250,000,000	Supplement to existing funding announcements, new and existing contracts	Official state or local health department
Innovative Immunization and Reimbursement Initiatives *	Grants and Contracts	\$18,000,000	New competitive funding opportunity, announcement supplement to existing funding announcements, new and existing contracts	Official state or local health department
National Communication Campaign and Provider Education	Grants and contracts	\$9,000,000	New competitive funding opportunity, announcement supplement to existing funding announcements, new and existing contracts	Official state or local health departments, Contractors, and national non-profit organizations
Strengthening the Evidence Base	Grants and Contracts	\$21,500,000	New competitive funding opportunity, announcement supplement to existing funding announcements, new and existing contracts	Official state or local health departments, Contractors, and national non-profit organizations
Management and Oversight	Other	\$1,500,000	Other	Other
Total		\$300,000,000		

E. Delivery Schedule

Major Milestones	Expected Completion Date
Vaccine Ordering and Forecasting Applications sent to grantees to complete vaccine spend plans	May 2009
Publication of funding opportunity announcement for 50 States,	May 2009



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Major Milestones	Expected Completion Date
Washington DC, 5 urban areas, and selected Pacific Island Nations program operations grants	
Publication of funding opportunity announcement Innovative Immunization and Reimbursement Initiatives	June 2009
Finalize State vaccine purchase levels	May 2009
Awards for funding opportunity announcement for 50 States, Washington DC, 5 urban areas, and selected Pacific Island Nations program operations grants	September 2009
Awards for innovative immunization and reimbursement initiatives to bill private health insurance for immunization services to increase total vaccine availability under Section 317	September 2009
Awards for strengthening the evidence base projects	September 2009
Publication of funding opportunity announcement for innovative initiatives to enhance the interoperability of electronic immunization data exchange between Electronic Health Records (EHR) systems and immunization registries	May 2010
Awards for public communication and engagement activities and provider outreach	April 2009 – September 2010
All National Communications Campaign and Provider Education awards will be completed	June 2010
Awards for innovative initiatives to enhance the interoperability of electronic immunization data exchange between Electronic Health Records (EHR) systems and immunization registries	August 2010
All Reaching More operations grants have been awarded to states and all vaccine purchases are on schedule.	August 2010
Innovative Immunization and Reimbursement Initiatives- fourteen (14) grants have been awarded funds for the reimbursement initiatives and awards to grantees to enhance immunization registry and electronic health records linkages are planned for August.	August 2010
All Strengthening the Evidence Base awards will be completed	August 2010

F. Environmental Review Compliance

The CDC grants and contracts addressed in this program are subject to a National Environmental Policy Act (NEPA) categorical exclusion promulgated by HHS [65 FR 10229 (2/25/2000); HHS GAM Part 30-20-40, B.2. (e), (g), (i), (j)] and additional NEPA review is not required. Categorical exclusions and other environmental reviews are documented in writing and reported on the Section 1609(c) report.

G. Measures

Table 1A: ARRA Measures—Type, Polarity, Target, and Frequency

Measure and Explanation	Type	Polarity	Target	Frequency
ARRA-funded vaccine doses providers will administer to	Outcome	Positive	FY09-Q4: 20% FY10-Q1: 40%	Quarterly



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Table 1A: ARRA Measures—Type, Polarity, Target, and Frequency

Measure and Explanation	Type	Polarity	Target	Frequency
children (0-18 years) Explanation: Cumulative number of doses of ARRA-funded vaccine ordered by public and private providers for administration to children. Immunization providers are allowed to order only as much vaccine as they intend to administer.			FY10-Q2: 50% FY10-Q3: 60% FY10-Q4: 95% FY11-Q1: 100% FY11-Q2: 100%	
ARRA-funded vaccine doses providers will administer to adults (19 years and older) Explanation: Cumulative number of doses of ARRA-funded vaccine ordered by public and private providers for administration to adults. Immunization providers are allowed to order only as much vaccine as they intend to administer.	Outcome	Positive	FY09-Q4: 20% FY10-Q1: 40% FY10-Q2: 50% FY10-Q3: 60% FY10-Q4: 95% FY11-Q1: 100% FY11-Q2: 100%	Quarterly
% recipients on track with meeting project-specific milestones.	Output	Positive	FY10-Q1: 70% FY10-Q2: 80% FY10-Q3: 80% FY10-Q4: 90%	Quarterly

Table 2A: ARRA Measures—Data Source, Validation, and Reporting

Measure	Data Source and Validation	Reporting System	How Reported to Public
ARRA-funded vaccine doses providers will administer to children (0-18 years)	Source: CDC's Vaccine Central Distribution Ordering and Shipment Data Warehouse Validation: Vaccine orders are submitted by recipients to CDC's Vaccine Management system based on actual vaccine orders they have received from providers. These data are compared against shipping data of the centralized distributor to ensure that ordered doses were	Extracted by Program staff from Data Warehouse, compiled and reported up. No grantee reporting required.	Compiled monthly, but will be reported up quarterly to CDC/FMO and then to designated website(s)
ARRA-funded vaccine doses providers will administer to adults (19 years and older)			



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Table 2A: ARRA Measures—Data Source, Validation, and Reporting

Measure	Data Source and Validation	Reporting System	How Reported to Public
	actually shipped.		
Percentage of recipients on track with meeting project-specific milestones	Source: Recipient progress on project-specific milestone checklist Validation: Project Officer review of progress reports + routine TA with grantees will help with report preparation and prior report follow up. Failure to meet reporting requirements will be elevated to supervisory authorities for troubleshooting.	Recipient will develop milestones/checklist in their proposal and complete checklist as part of their progress reporting. PO will assess progress per checklist against targets for progress.	Compiled monthly, but will be reported up quarterly to CDC/FMO and then to designated website(s)



Performance Reporting

Outcome / Achievement	Units	Type	9/30/09	12/31/09	3/31/10	6/30/10	9/30/10	12/31/10	3/31/11	6/30/11	9/30/11	Program End
ARRA-funded vaccine doses providers will administer to children (0-18 years)	%	Projected	20%	40%	50%	60%	95%	100%	100%			100%
		Actual	-	37%	53%							
ARRA-funded vaccine doses providers will administer to adults (19 years and older)	%	Projected	20%	40%	50%	60%	95%	100%	100%			100%
		Actual	-	45%	53%							
% of recipients on track with meeting project-specific milestones	%	Projected	-	70%	80%	80%	90%					90%
		Actual	-	86%	88%							



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H. Monitoring and Evaluation

All Recovery Act programs are assessed for risk to ensure that appropriate internal controls are in place throughout the entire life cycle of the program. These assessments are conducted by operating components to comply with the statutory requirements of the Federal Manager's Financial Integrity Act and the Improper Payments Information Act as well as OMB Circular A-123, "Management's Responsibility for Internal Control" (including Appendices A, B, and C).

CDC's risk management process fits within the overall governance structure established at HHS to address Recovery Act program risks. The HHS Risk Management and Financial Oversight Board provides executive leadership and establishes accountability for the risk assessment process related to internal controls over financial reporting, and the HHS Senior Assessment Team ensures that risk assessment objectives are clearly communicated throughout the Department. CDC's Senior Assessment Team carries out comprehensive annual assessments of its Recovery Act programs to identify risks and develop strategies to address them, including those associated with selecting recipients, awarding and overseeing funds, and achieving program goals. It meets at least quarterly to monitor and assess the effectiveness of mitigation strategies and identify emerging risks.

In addition, CDC will present its high level risks to the Recovery Act Implementation Team. Chaired by the Deputy Secretary and comprised of senior policy officials from throughout the Department, the Implementation Team convenes monthly to monitor progress in carrying out Recovery Act programs and address the obstacles and risks that could impact on their success.

Understanding that funds allocated as part of Recovery Act require additional accountability, CDC has established a centralized oversight function, for agency-wide Recovery Act Coordination (RAC), to oversee and coordinate all Recovery Act-funded activities. Quarterly reviews of Recovery Act programs will be conducted by RAC in collaboration with CDC's Financial Management Office (FMO) and Procurement and Grant's Office (PGO), as well as program managers. Potential risks associated with executing Recovery Act funds have been identified and appropriate mitigation strategies have been instituted to ensure Recovery Act funding is effectively and efficiently utilized to achieve program goals. In addition, assurance of adequate staffing levels within FMO, PGO, and within the program has been addressed to provide appropriate oversight and monitoring of recipient activity.

To ensure Recovery Act grantee accountability and performance and to minimize risks associated with the misuse of Recovery Act funds, CDC will perform the following contract and grant management activities for Recovery Act-funded contractors and grantees:

- Coordinate with the Office of the Inspector General (OIG) to ensure that Recipient Capability Assessments are conducted on funded organizations as needed;
- Ensure ongoing technical assistance is provided to contractors and grantees who need assistance in meeting administrative and program requirements;



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- Monitor the receipt of financial reports, and review those reports for the purpose of monitoring compliance with financial requirements;
- Monitor the receipt of recipient progress reports, and review those reports for the purpose of monitoring compliance with program requirements;
- Conduct vigorous post-award monitoring to include site visits to grantees;
- Ensure the unique identification of Recovery Act funds in contractual and grant agreements, to include the use of unique Recovery Act CFDA numbers for grants;
- Refer all known instances of suspected fraud, waste, or abuse to the OIG;
- Ensure that timely enforcement actions are taken on any non-performing contractor or grantee;
- Take appropriate enforcement action, such as the disallowance of costs, the recovery of funds, the referral of suspected fraud to the OIG, the implementation of administrative corrective actions by the contractor or grantee, or the termination of funding if CDC determines that a contractor or grantee has misused Recovery Act funds, CDC will; and
- Support the oversight of the Recovery Accountability and Transparency Board, the OIG, and General Accounting Office, to include taking timely action on inquires and recommendations.

In accordance with current practice for the Section 317 Immunization Grant Program, there will be frequent communication between grant and contract recipients and program staff, including regular conference calls. Program staff will ensure site visits are conducted according to Recovery Act requirements, and that technical assistance is provided. Recipients may be allowed to charge increased administrative costs to support the frequent and extensive reporting required by the Recovery Act. Allowable and unallowable expenditures will be clearly communicated to recipients and appropriate penalties for misappropriation or misuse of funds will be enforced. The Office of Management and Budget (OMB) Circular A-133, "Audits of States, Local Governments and Non profit Organizations" will set the administrative requirements for these entities. OMB Circular A-87, "Cost Principles for State, Local and Indian Tribal Governments" will set the Federal principles for determining allowable costs.

Development and submission of grantee plans and quarterly updates on progress towards measures and targets will enhance recipient accountability. Specific financial and program performance measures and the frequency for their reporting have been enumerated regarding measures. These indicators will serve as an evaluation of progress in deploying funds and achieving the intended outcomes. Lack of progress will serve as a warning for early intervention to ensure timely mitigation of issues. Monthly and quarterly reporting by recipients will be monitored by project and contract officers and failures to adhere to performance measures will be elevated to supervisory authorities immediately for troubleshooting.

I. Transparency

CDC is open and transparent in all of its contracting and grant competitions and regulations depending on what is appropriate for Section 317 program activities that involve spending of Recovery Act funding consistent with statutory and OMB guidance and published on



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grants.gov and fbo.gov. CDC ensures that recipient reports required by Section 1512 of the Recovery Act are submitted and reviewed for material omissions and significant errors that would mislead or confuse the public. CDC informs recipients of their reporting obligation through standard terms and conditions, grant announcements, contract solicitations, and other program guidance. In addition, CDC provides key award information to recipients and other technical assistance to grantees and contractors and fully utilizes Project Officers to ensure compliance with reporting requirements.

CDC will provide technical assistance to grantees and contractors and fully utilize Project Officers to ensure compliance with reporting requirements. CDC will ensure recipient cost and performance requirements are reported on a quarterly basis. All awards issued with Recovery Act will have special accounting numbers and codes to track the funds and awards.

Recipients will report economic indicators of job creation and/or preservation on a quarterly basis directly to a central reporting system in accordance with the provisions of Section 1512. These data will be available at the recipient level. All other indicators will be collected from existing databases, collated by the program staff and then reported to CDC RAC. The customary process for reporting progress on these measures to the Department of Health and Human Services (HHS) and the OMB will be employed. These measures will be reported in aggregate, however the recipient-by-recipient performance on which they are based will be available from the program and its project officers. A CDC point of contact has been established for federalreporting.gov and recovery.gov to receive and answer public inquiries regarding programmatic efforts with Recovery Act funds.

CDC shall ensure merit-based decision-making for Recovery Act grant and contract awards by:

- Promoting competition to the maximum extent practicable;
- Considering the weighting of selection criteria to favor applicants with demonstrated ability to deliver performance;
- Using award methods that allow grantees and contractors to commence activities as quickly as possible;
- Ensuring that receipt of funds is contingent on grantees and contractors agreeing to meet Recovery Act reporting requirements;
- Adapting current applicant evaluation and review processes to reflect Recovery Act needs; and
- Pursuing efforts to overcome impediments to Recovery Act awards.

CDC grant announcements and contract solicitations involving Recovery Act funds shall contain transparent merit-based selection criteria that allow CDC to evaluate an applicant's demonstrated or potential ability to:

- Deliver programmatic results;
- Create economic stimulus, to include the number of jobs created or saved in relation to Federal dollars obligated;
- Achieve long-term public health benefits; and



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- Satisfy Recovery Act transparency and accountability objectives, to include all reporting requirements.

CDC shall avoid the funding of imprudent projects by:

- Exercising the formal approval of Agency, Program and Spend Plans;
- Identifying measurable Program and Recovery Act outcomes;
- Reviewing proposed activities and expenditures for imprudent projects; and
- Making the timely obligation of funds.

J. Accountability

To ensure that managers are held to high standards of accountability in achieving program goals under the Recovery Act, CDC will build on and strengthen existing processes. Senior CDC Section 317 program officials will meet regularly with senior Department officials to ensure that projects are meeting their program goals, assessing and mitigating risks, ensuring transparency, and incorporating corrective actions. The personnel performance appraisal system will also incorporate Recovery Act program stewardship responsibilities for program and business function managers.

Centers for Disease Control and Prevention

The 317 program has developed a CDC-approved Program Implementation Plan containing management and oversight processes. Additionally, a point of contact has been established for Recovery.gov to receive and answer public inquiry regarding programmatic efforts with Recovery Act funds.

CDC will conduct quarterly reviews between Division Directors/Management Officials and project officers prior to the end of the quarter to evaluate progress to date and discuss grantee performance. This information will be provided to the National Center and ultimately CDC's Recovery Act Coordination unit for review. Additionally, National Center and Division Directors will have accountability and performance measurement objectives included in performance plans. Annual reviews will be conducted with CDC leadership to ensure programmatic objectives and grantee accountability measures are being executed and achieved as stated.

K. Barriers to Effective Implementation

Circumstances that could impede the effective implementation of Recovery Act activities have been evaluated. In each of these circumstances, CDC has developed a strategy to identify and take actions to mediate appropriately.

1. **Some state legislatures may not be in session full time. Passage of state appropriations may not coincide with the timing of implementation of Recovery Act funds, potentially causing a delay in programmatic activities.** CDC monitors program activities to determine if this becomes a factor with effective program implementation. If program activities are impeded, program staff will elevate concerns through CDC management to determine the appropriate course of action.



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2. **Some states have implemented hiring freezes due to the current economic environment. This may inhibit the ability of CDC to efficiently execute Recovery Act funded activities.** CDC monitors program activities to determine if this becomes a factor with effective program implementation. If program activities are impeded, program staff will elevate concerns through CDC management to determine the appropriate course of action.

L. Federal Infrastructure

Not applicable.

Summary of Significant Changes:

- Updated **Public Benefits** and **Activities** section to align with February 2010 spend plan that was approved by OMB.
- Updated **Characteristics** section with additional details in the Type of Award and Recipients column.
- Updated the **Delivery Schedule** with revised completion dates and added the following:
 - Publication and award date for Innovative Initiatives/Electronic Health NOFA
 - Projected award date for National Communication Campaign and Provider Education
- **Measures** – revised targets in child/adult vaccine doses measures based on ARRA-funded vaccine purchase patterns.
- Updated mitigation strategy for each risk identified in the **Barriers to Effective Implementation** section



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Appendix A – Additional Information

Does this program align with an existing PART program? Yes

PART Program Code #: 10000250

Does this program align with an existing CFDA program? Yes

CFDA #: 93.712 ARRA Immunization

Related Programs:

93.268 Immunization Grants

93.185 Immunization Research, Demonstration, Public Information and Education-
Training

and Clinical Skills Improvement Projects

93.283 Centers for Disease Control and Prevention – Investigations and Technical
Assistance

93.217 Family Planning Services

93.185 Varicella Active Surveillance Project