



**DEPARTMENT OF HEALTH & HUMAN SERVICES**  
**Health Care Financing Administration**

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**Center for Medicaid and State Operations**  
**7500 Security Boulevard**  
**Baltimore, MD 21244-1850**

July  
6, 2000

Dear State Medicaid Director:

This letter provides guidance on the development of immunization registries as a component of the Medicaid Management Information System (MMIS) to ensure all children receive their immunizations on time to live happy, healthy lives. HCFA strongly supports State efforts to ensure that children and adults are immunized based on the standards and recommendations of the Advisory Committee on Immunization Practices. Immunization registries can be a valuable tool in tracking immunization rates.

Under certain conditions, enhanced Federal financial participation (FFP) is available at 90 percent for the design, development, and installation, and 75 percent FFP for the operation of State MMIS systems. These enhanced rates are available for immunization registries that are components of the State MMIS to the extent that the registry serves Medicaid program beneficiaries and meets the specifications set forth in the attachments to this letter. In States where the Immunization Registry is developed, owned, and operated by a public health or other non-Medicaid agency, FFP is available at 50 percent for State's costs associated with Medicaid eligible children.

**BACKGROUND**

In response to a request by the U.S. Senate Appropriations Committee in 1998, the Institute of Medicine of the National Academy of Sciences recently completed a study, *Calling the Shots: Immunization Finance Policies and Practices*.<sup>1</sup> The Study Committee cited much progress with immunization efforts and describes the overall approach as being highly decentralized and shaped by local circumstances, resources, and needs as well as by national goals and policies.

In spite of record levels of immunization achieved across the country since 1993, certain problems have persisted with the immunization delivery system:

- ! The need to sustain and document high levels of immunization coverage for a growing number of vaccines delivered within multiple health settings;

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- ! Persistent racial and ethnic disparities in childhood levels of immunization coverage;
- ! Mortality and morbidity from preventable infectious diseases; and
- Gaps and inconsistencies from State to State in the coordination, support, and documentation of immunization efforts.

In recent years, the country has seen immunization rates increase as more and more children are receiving their scheduled immunizations on time. This news is encouraging, but low immunization rates, particularly among Medicaid-eligible children, remain. Over 60 percent of all children who do not receive timely and complete immunizations come from poor areas, and many of them are Medicaid beneficiaries. Most health providers have difficulty tracking the immunization history of children for a variety of reasons, such as frequent moves and lack of a consistent medical home. One highly effective way to address this problem is through the development, installation, and use of immunization registries.

### WHAT IS AN IMMUNIZATION REGISTRY?

An immunization registry is a confidential, population-based, computerized information system that contains information about immunizations and children. Information in the registry can be used to determine individual vaccine needs and remind parents when their child is due for a vaccine. Providers can access the registry to determine which vaccines their patients need and bring them back to the clinic or office when immunizations are due.

Because confidentiality of Medicaid data is an important issue, we would like to remind you of discussion on this topic contained in our October 22, 1998, State Medicaid Director letter, **Facilitating Collaborations for Data Sharing between State Medicaid and Health Agencies.** In the Model Medicaid Data Sharing Agreement attached to that letter and co-signed by the

Administrators of HCFA and HRSA, as well as the Director of the Centers for Disease Control and Prevention, we reference Section 1902 (a)(7) of the Social Security Act (as amended) which provides for safeguards in this area. In addition, regulations at 42 CFR 431.302 are also cited and specify the purposes directly related to State plan administration.

### MEDICAID'S ROLE

In recent months, we have been working closely with the Centers for Disease Control and Prevention, as well as the Health Resources and Services Administration, to develop an initiative

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to promote State use of the Medicaid MMIS to support immunization reporting efforts. We believe it should be an integral part of the Medicaid program.

Enclosed is a template for a Planning Advance Planning Document (APD) designed to expedite Federal approval for FFP to support immunization registries. We have also enclosed an APD Guidance Document (which provides detail on the Registry APD process as well as the functional requirements), and a matrix highlighting the mandatory functional requirements required for registries to receive Medicaid funds. States are required to allocate costs among Federal and State programs according to the principles contained in OMB Circular A-87 in accordance with relative benefits received.

If your staff has any questions regarding the enclosed documentation, please have them contact your MMIS representative in your Regional Office, or Jason Goldwater on my staff at (410) 786-0476.

By supporting immunization registries, whether within the MMIS, or developed and maintained by other State agencies (for which 50 percent FFP is available to the extent that the activity can be allocated to the Medicaid program), we can make great strides in improving the health status of our beneficiaries.

I am sure you will agree with me that immunization registries warrant serious attention and your support. I look forward to working with you on this endeavor.

Sincerely,

Timothy M. Westmoreland

Enclosures

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cc:

All HCFA Regional Administrators

All HCFA Associate Regional Administrators  
for Medicaid and State Operations

Lee Partridge  
Director, Health Policy Unit  
American Public Human Services Association

Joy Wilson  
Director, Health Committee  
National Conference of State Legislatures

Matt Salo  
Director of Health Legislation  
National Governors Association

Walter A. Orenstein, M.D.  
Director, National Immunization Program  
Centers for Disease Control and Prevention

Claude E. Fox, M.D., M.P.H.  
Administrator  
Health Resources and Services Administration

Claire Hannan  
Association of State and Territorial Health Officials

Bill Watson  
All Kids Count

Amy Pisani  
Every Child by Two

Paula Soper  
American Immunization Registry Association

Page 5 - State Medicaid Director

Laurel Woods  
Association of Immunization Managers

Director  
Partnership for Prevention



U.S. Department of  
Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

***Health Care Financing***  
Administration (HCFA)  
Medicaid  
***Action Transmittal***

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Action Transmittal #: DSS-CMSO-AT-00-001

Issuance Date: July 6, 2000

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TO: State Agencies Administering  
or Supervising the Administration of Title XIX of the Social  
Security Act, State Departments of Public Health and other  
interested parties administering or supervising Statewide  
Immunization programs.

**SUBJECT:** Automation of an Immunization Registry

**KEY WORDS:** Statewide Automated Immunization Registry System (SAIRS)

**ORIGINATORS:** Center for Medicaid and State Operations  
Data and Systems Group  
Division of State Systems

**RELATED REFERENCES:** Title XIX of the Social Security Act, §1903 (a)(3)(A)(i) and (7) of the Social Security Act , 42 CFR Part 433, Subpart A, §433.10, §433.15, §433.35, Public Health 42 CFR, Subpart C, and , §432.50 (b)(3), Public Welfare 45 CFR, Part 74, Part 95, Subparts F and G, (references OMB Circular A-87 “Cost Principles for State, Local and Indian Tribal Governments.

**PURPOSE:** This Action Transmittal (AT) provides system guidance and identifies the system requirements for States pursuing the development of a Statewide Automated Immunization Registry System under Title XIX for Mechanized Claims Processing and Information Retrieval Systems. It is intended to establish policy and supplement the intent of CFR 42 in the development of a Medicaid Management Information System (MMIS) as interpreted through regulation, and to provide technical assistance to States in the design, development and implementation of an Immunization Registry.

**CONTENT:** This Action Transmittal contains five major sections:

- Part I contains a background section which discusses the authorizing legislation, and the implementing regulations, which support an Immunization Registry. (Page 1)
- Part II includes more specific agency policies related to Immunization Registry planning, development and implementation. (Page 2)
- Part III contains detailed information on allowable costs, exemptions, the Planning Advance Planning Document (APD) and cost allocation methodologies. (Page 4)

- Part IV includes information on the degree of functionality for the Immunization Registry and its interfaces. (Page 10)
- Part V contains the functional requirements for the Immunization Registry and general program guidance. (Page 12)

**SUPERSEDED**

**MATERIAL:**

None

**EFFECTIVE DATE:**

Immediately

**INQUIRIES TO:**

HCFA Regional Administrators

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Timothy M. Westmoreland  
Director  
Center for Medicaid and State Operations

Attachment

## **Part I – Background**

Effective statewide-automated capability to support the administration of services offered through immunization registries is essential to enable improvements in Medicaid program administration and service delivery. 1996, President Clinton urged that 90 percent of all 12 to 23-month-old children be fully up-to-date for their recommended immunizations by the turn of the century. While the nation is making considerable progress towards reaching that goal new approaches are needed to overcome deficiencies in current immunization information handling practices. Current challenges include:

- (1) Incomplete records due to fragmentation of health care delivery. This is often seen in the movement of “at-risk” children from public providers to Medicaid managed care or in the movement of children on or off the Medicaid rolls, or simply when children receive immunizations from different providers. Such movement may hinder the ability of providers and parents to assess immunization needs as well as the ability of third-party payers to validate the quality of services their customers receive.
- (2) Antiquated methods resulting in large and cumbersome files of paper records. Such files may not allow rapid access to immunization histories, even in one physical location.
- (3) Errors or difficulties in assessing immunization needs due to the increasing complexity and continuously improving immunization schedule.

To sustain high coverage rates for future generations, current efforts should be aimed at permanently resolving these deficiencies. Immunization registries or electronic immunization information systems can meet this need. A stable infrastructure based on electronic systems (immunization registries) would help a State Medicaid Agency by providing an accurate count of the number of Medicaid beneficiaries, from the age of

0-18, that are being vaccinated. The immunization information would be an accessible and integral component of patient data, which could then be utilized for quality assessment measures (i.e. HEDIS), amongst other things. Additionally, this would also take the form of an assessment tool to rapidly and continually monitor immunization coverage rates and identify special needs that may require a concentration of resources.

## **Funding**

The applicable regulation for the Title XIX program is contained in 42 CFR Part 433 at 433.15 Subpart.A. It provides for Federal financial participation (FFP) in State expenditures for Statewide planning, design, development and installation (DDI) for mechanized claims processing and information retrieval systems, namely Medicaid Management Information Systems (MMIS). FFP is available at the

90 percent rate for DDI [pursuant to Section 1903(a)(3)(A)(i) and 42 CFR 432.50(b)(3)] and FFP is available at the 75 percent rate for the continued operation of such systems approved by HCFA. (Section 1903(a)(3)(B); 42 CFR 432.50(b)(2).) Additionally, funding for all other activities for the proper and efficient administration of the State plan are funded at a 50 percent rate (section 1903(a)(7) and 45 CFR 433.15 9a)(7), and to build interfaces from other data systems which:

- meet the requirements imposed by regulation promulgated pursuant to Section 1903 (Section 4753 of Public Law 105-33) and 1903 (a)(3) of 15 A.
- meet the functional requirements identified in this guidance document; and
- to the extent practicable, are capable of interfacing with State data collection systems that collect information regarding immunization histories of children.

Whether or not enhanced match is available for the development, design, installation and operation of an automated immunization registry depends upon an analysis of the registry's relationship to the MMIS, as explained in this Action Transmittal.

## ***Part II – Immunization Registry Policies***

This section addresses more specific agency policies related to Immunization Registry planning, development and implementation.

### **A. Eligibility for Enhanced Funding under Title XIX**

Medicaid is authorized as a part of Title XIX of the Social Security Act, and provides funds to all States, and the District of Columbia. Insular areas are not included in Title XIX, and Puerto Rico is subject to a financial cap in the Social Security Act, which precludes it from claiming additional funds. The 50 States and the District of Columbia are the only jurisdictions eligible to receive enhanced funding under these provisions.

Title XIX funds may be “passed through” by States to entities with which they have agreements to perform some or all of the functions of the State Title XIX agency. Expenditures for such purposes are eligible for reimbursement under Title XIX as if they were expended by the State agency itself. The claims are submitted to HCFA only by the State, not by any entity with which the State has an agreement. Typically, these entities are Indian Tribes and private, non-profit social service agencies. Expenditures under Title XIX may be claimed for the eligible State agency and for entities with which it has agreements, so long as the claims are for otherwise allowable costs.

## ***B. Statewide System***

A Statewide system must operate uniformly as a single system (including the application software) throughout the State and must encompass all political subdivisions that administer programs provided under Title XIX.

In some cases, a Statewide system may interface with another system(s) to perform required functions (e.g., a State Bureau of Vital Statistics to provide birth data). The APD must include a narrative to describe how the Immunization Registry will link to other systems to meet the functionality required.

## **C. Efficient, Economical and Effective Administration of Title XIX State Plans**

In consideration of demonstrated economic benefits, a State may propose an alternate design to that which is described in this Action Transmittal. By clearly documenting the potential savings, the State may propose a design which links an Immunization Registry type system existing in a large urban area to a new Statewide system. Based on our review of the documentation, which should be included in the State's Implementation Advance Planning Document (APD), HCFA will determine if the alternative design meets the efficient, effective and economical requirements of the Title XIX regulations.

## ***D. Use of Equipment***

Equipment may only be funded with Title XIX funds if it is for full time use by State agency employees responsible for providing Title XIX services offered by the designated State agency. Tribal employees, volunteers, and contract or private employees that replace or supplement designated State agency's employees for the provision of these services are, for the purpose of funding the cost of equipment installed for their use, considered State agency employees.

## ***E. Use of System/Application***

Within legal parameters, the State agency may allow non-State agency staff (e.g., service providers, non-State agency staff who provide State agency services) to have access to and utilize the statewide application. The application may not be modified to meet the unique needs of such users. Expenditures for any additional functions, processes, reports, data elements or requirements must be allocated to and supported by the non-State agency user.

As with any system access, the State should take necessary precautions to comply with the safeguarding of data and confidentiality provisions addressed elsewhere in this transmittal. Use agreements with any third parties are encouraged at the State's option. Use of the system for purposes other than those

related to the Title XIX program should comply with applicable State and Federal Law.

## ***F. System Reviews – Certification***

Regional office staff will conduct a certification review to validate that a State's SAIRS meets minimal requirements for approval. The purpose for this certification process is to assure that all of the functional requirements have been met, according to the terms of the State's approved APD.

## **Part III – Allowable Costs, Exemptions, Planning Advance Planning Document and Cost Allocation**

This section contains detailed information on allowable costs (at both the enhanced and regular matching rates) and additional guidance in the areas of exemptions, minimum requirements for a Planning Advance Planning Document and cost allocation. (An overview of the minimum requirements for the planning APD is in Appendix A.)

### **A. Allowable Costs**

In order to ascertain whether or not an enhanced match can be applied to an immunization registry, a determination must be made as to whether the registry could be part of the MMIS. Section 1903 (a)(3) of the Act refers to these systems as including an "information retrieval" element. The regulation defining the systems further states that they are to be used "to retrieve and produce service utilization and management information required by the Medicaid single State agency and Federal Government for program administration..." (42 C.F.R. § 433.111 (b)). If the immunization Registry, is developed as part of the MMIS, then the system is an information retrieval mechanism within the definition of the MMIS.

HCFA has determined that Federal financial support of these registries is in the best interest of the Medicaid program. Therefore, the analysis is whether under each of the following scenarios below the Immunization Registry, as proposed, would reside in, and be a part of, a State's MMIS, thereby qualifying for the enhanced match provided in 1903 (a)(3) of the Act. If the registry exists independent of the State's MMIS, HCFA assumed that the registry is an administrative cost, the Medicaid match would be made pursuant to § 1903 (a)(7) and matched at 50%.

In addition, there must be an allocation of costs between Medicaid and non-Medicaid sources in order to maintain consistency with past HCFA and Departmental policies. OMB Circular A-87, "Cost Principles for State, Local, and Indian Tribal Governments," sets forth certain requirements regarding allocation. The Circular states that, to be claimed under a Federal grant program, a cost must be "allowable" and among the factors determining whether it is allowable are whether it is ' necessary and

reasonable” and whether it is “allocable” (OMB Circular A-87 at 9-10). The Circular further states that “a cost is allocable to a particular cost objective if the goods or services involved are chargeable or assignable to such cost objective in accordance with relative benefits received.” (Id. at 11).

- a. Example 1 - The Immunization Registry is built as part of the State’s current MMIS reporting system. Ownership and operation of the registry is by the State Medicaid Agency. The registry would include both Medicaid and non-Medicaid beneficiaries. Based on 1903(a)(3)(A)(I) of the Act, an enhanced rate of 90% is permissible for the costs allocable to Medicaid for the design, development, and installation of a registry under this scenario. Under § 1903(a)(3)(B) of the Act, the application of the 75% enhanced rate is permissible for the costs allocable to Medicaid for the operation and maintenance of a registry under this scenario.
- b. Example 2 - The Immunization Registry is built and owned by the State’s Department of Public Health, or a Department similar in kind, and is completely separate from the State’s MMIS reporting system. The registry includes both Medicaid and non-Medicaid beneficiaries. The outlay of funds in this case is deemed necessary “for the proper and efficient administration of the State plan.” Section 1903(a)(7) would allow Federal financial participation at the 50% match for the design, development and installation as well as the continued operation of the Registry.
- c. Example 3 - the Immunization Registry is built and owned by the State’s Department of Public Health, or a Department similar in kind, and includes only non-Medicaid beneficiaries. An interface is constructed to connect the registry with the State’s MMIS reporting system so as to include Medicaid beneficiaries. Additional development within the Registry would be needed to increase its capacity to include the additional Medicaid population, as well as to add functionality needed to support the Medicaid program. To the extent that the interface is outside of the MMIS, a 50% match for its design, development and installation and continued operation would be appropriate based on § 1903(a)(7) of the Act. Additionally, development on the Immunization Registry to increase its capacity in addition to its operation would also be eligible for the 50% match.
- d. Example 4 - the Immunization Registry may be located anywhere (other than the State’s MMIS reporting system) and includes both Medicaid and non-Medicaid beneficiaries. As outlined above and based on § 1903(a)(7) of the Act, a 50% match for the design, development and installation and the continued operation of the Registry is appropriate.

## **B. Exemptions**

There are cases where a State has already designed, developed and installed an Immunization Registry, and funding has already been approved by HCFA at either the enhanced rate or the regular Federal match rate. In these instances, States will not have to submit an Advance Planning Document to maintain their funding. However, if at any time a State decides to add additional functionality, or change the design and/or specifications of its existing registry, the State must request funding through HCFA (according to 45 CRF, Part 95). The Immunization Registry must meet the functional specifications contained in Part V.

### **C. Confidentiality**

Federal statutes and regulations allow, and in many instances require, designated State agencies to disclose confidential information to other State Agencies for the purpose of administering other Federal programs. To the extent that these registries are maintained as part of the Medicaid program, the information collected would be confidential information subject to the confidentiality provisions of 42 C.F.R. Part 431, Subpart F. Under current policy, such information could not be disclosed for non-beneficiaries, because such disclosure would not be consistent with “plan administration” as set forth in 42 C.F.R. §431.302. In addition, Section 1902(a)(7) of the Act requires that the State restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the medical assistance plan.

### ***D. Planning Advance Planning Document (APD)***

The Planning APD is a brief document prepared and submitted to HCFA prior to initiating Planning Phase activities. The purpose is not to provide needs and plans in detail, but to develop a high-level management statement of vision, needs, objectives, plans, and estimated costs. The focus is on describing how planning will be accomplished and demonstrating that the State has established a plan that is reasonable for the level of effort of the project. Planning APDs that meet the standards for approval detailed below will be approved within 60 days. The Planning APD has four sections: Statement of Need, Project Management Plan, Planning Project Budget and Estimate of Total Project Cost.

## 1. Statement of Need

This section of the Planning APD should set forth the State's information and services, "vision," including the scope and the objectives of the planned information system and its interrelationships with other systems (if known). In addition, the needs statement should define the system requirements in terms of problems and needs listed. The State must address five distinct issues relating to the need for an Immunization Registry at an enhanced rate. Those issues can be broken down into the following:

- Statement of "Vision" – The State must demonstrate that the development of an immunization registry would reduce the overall incidence of vaccine-preventable disease by giving providers and the State a high-quality, confidential, flexible and expendable tool. It would ensure age appropriate immunization for all children with the most efficient expenditure of the program and its resources.
- System interrelationships – The State must demonstrate how the immunization registry would interact with data systems so as to would populate the registry on a continual cycle. It must also demonstrate that interaction between the registry and the Medicaid program that would allow for the entire population of Medicaid eligible children to be included. Appendix A gives an indication of the types of interrelationships imagined. If those in the State differ, an explanation of those differences must be included.
- Problems of deficiencies in existing system - The State must identify whether a registry currently exists and any deficiencies in that system that may warrant the procurement of a new system.
- New or changed program requirements – The functional requirements detailed in Part IV of the Guidance Document must be addressed in the development of a registry. Any differences must be explained.
- Opportunities for economy or efficiency – If a State can demonstrate that their registry is compliant with the functional requirements of Part IV, then HCFA will determine that the registry has sufficient opportunities for both economy and efficiency.

## **2. Project Management Plan**

The project management plan summarizes how the State will plan to implement its Immunization Registry. The State's planning project organization are briefly described. At this point in the project, all that is required is that the State identify key players in the planning phase, such as the project manager and other key planning staff by name and title. This information can be depicted in an organization chart. The Project Management Plan for planning describes how and when the activities for the Planning Phase will be conducted and schedules milestones for completion of key events. The State must identify the following components of a project management plan:

- Planning Project Organization – The State must detail those individuals, from both the State and a potential contractor(s) that would be responsible for the development and implementation of the registry. Furthermore, the responsibilities and relationships must also be highlighted, with an organizational chart and an accompanying narrative.
- Planning activities, products and deliverables – The State must detail, in one page or less, the planning activities mentioned in the APD, the products that would come from the development and implementation phases, and a schedule of deliverables they intend on adhering to.
- Commitment to conduct analysis and JAD (Joint Application Design Sessions with Users) – Each State must check off whether they intend to do any of the following types of analysis:
  1. Requirements Analyses – the resources and time needed to develop and implement an immunization registry.
  2. Feasibility study – an analysis done by the State in order to determine the necessity of developing a registry
  3. Alternatives analysis – examining the potentiality of developing alternate systems, our utilizing previously implemented technology within the status quo to accomplish the goals of a registry.
  4. Cost/benefit analysis – analyzing the initial and long-term costs during the development and implementation of the registry and comparing them to the cost benefits a registry would provide over a certain period of time.
  5. JAD (joint application design sessions with users) – whether a State will participate with users of a registry in its initial design phase.
  6. Functional specification – a detailed analysis of the functionality of the registry being developed and whether it is consistent with HCFA's functional requirements.
  7. Systems design – an analysis of how the registry would be developed, what technology would be employed, how it would be populated and how it would serve the Medicaid community.
- Re-Inventing the Wheel – a State must explain if they have given any consideration to transferring an existing module that would have the functionality of a registry. If it is deemed that

such a transfer would be non-beneficial, than an explanation justifying the new procurement must be included.

- State/contractor needs – The State should summarize, in one page or less, the resource needs for the development and implementation phases.
- Planning project procurement activities and schedule – In one page or less, the State must provide detail regarding the acquisition of the registry technology in addition to its development and implementation target date.
- Requirements and evaluation plan – A State must also describe its requirements for acquiring and developing a registry, in addition to a comprehensive evaluation plan to ensure that all functional requirements have been met.
- Restrictions on work – If any exist, an explanation must be attached
- Testing plans of interfaces – A description of testing plans and methodologies regarding interfaces to the MMIS, as well as other secondary systems (i.e., EPSDT, WIC, etc.), needs to be added, as well as a summary of a testing schedule.

### **3. Planning Project Budget**

This section describes the resource needs that funding supports during the Planning Phase that may be requested by the State. These needs may relate to State and contractor staff costs, computer time, hardware and commercially available software, travel space, supplies, telephones, photocopying and so forth. This section of the APD also provides the budget and the cost allocation to be used during the Planning Phase. States must address costs in a planning APD by categories, cost elements and amounts.

#### ***a. Anticipated FFP***

States must include information on the Federal Financial Participation (FFP) that they anticipate based upon the scenario that is most appropriate (see above, “Allowable Costs”).

#### ***b. Anticipated State Costs***

A State must include documentation that anticipates all costs that would be included in both the development and implementation of the registry, as well as a breakdown of projected costs by fiscal quarter and summarized by fiscal year.

### **4. Total Project Cost**

The total cost of the immunization registry project must be included, and contain the State and Federal cost distributions.

#### ***D. Cost Allocation***

A State must include in its planning APD a proposed methodology for allocating costs when the registry includes programs other than those carried out by Title XIX. This section gives general guidance in developing and applying this cost allocation methodology.

##### **A. Immunization Registry Planning, Development and Installation**

States use a range of factors when developing a cost allocation methodology for a system project. Often, factors considered in cost allocation methodologies take different forms such as: analyzing system data elements; evaluating the specific functions to be programmed into the system; examining the populations to be served; projecting the level of effort in the design or programming activity and examining equipment utilization statistics measured on past projects with a similar size and scope. Since there is no preferred or best method, it is the State's responsibility to develop a methodology using factors that they believe accurately reflects Federal and State program shares to appropriately and equitably allocate project costs, and to describe this methodology as part of the APD submitted for approval.

Regardless of what factors are considered in a State's methodology, the following guidance shall apply:

1. If a factor exclusively benefits the programs funded under Title XIX, then the cost may be directly charged in full to Title XIX, with a 90% enhanced match expected.
2. If a factor is necessary for and primarily benefits the programs under Title XIX:
  - a. And without further modification it benefits Medicaid programs (e.g., EPSDT), the cost may be charged in full to Title XIX.
3. If a factor supports but does not exclusively or primarily benefit the programs under Title XIX, the cost must be allocated among all benefiting programs.

4. If a factor exclusively benefits any other single program, the cost must be “direct-charged” in full to that program at the appropriate FFP rate.

**B. Immunization Registry Equipment**

Equipment acquired solely to support the activities of contract staff administering the Immunization Registry under the approved State plan may be charged to Title XIX. Equipment which is acquired to support other individuals or programs must either be direct-charged to the other agency or program, or allocated among all appropriate funding sources, dependent upon whether the equipment is used partially for the program under Title XIX. If equipment costs are to be partially allocated to Title XIX based on the fact that its use is shared among various programs, the State must propose a cost allocation methodology that accurately reflects its proper usage.

**C. Central Data Processing Facilities**

In States where the agency acquires resources from a central data processing (CDP) facility, costs at the applicable matching rate must be charged in accordance with a HCFA approved cost allocation plan, normally based on the percentage of use by each agency utilizing the equipment. Equipment acquired for, or dedicated solely to, the operation and support of the Immunization Registry, consistent with the cost allocation principles outlined above, may be charged to Title XIX at the applicable FFP rate.

**Part IV – Degree of Functionality and Interfaces**

***A. Degree of Functionality***

At a minimum, a State’s immunization registry must include the functionality described in Part V. Additional functionality, beyond what is defined in this guidance document, may be funded at the enhanced rate if the State can demonstrate that it will provide more efficient, economical and effective administration of an immunization program administered under Title XIX. Further, to be eligible for enhanced funding, the added feature may not duplicate functionality included in an existing system to which an interface is required. The justification and request to fund additional functionality at the enhanced rate must be included and approved in a State’s APD

In order for HCFA to provide funding for an immunization registry, the planning APD must address two basic categories:

- Core Attributes
- Interface Requirements

Both the core attributes and the interface requirements represent mandatory elements of an Immunization Registry. Some optional attributes have been added which a State may want to implement. Those optional features would be funded at the appropriate enhanced rate. An overview of the minimum functional requirements is in Appendix B.

## **B. Interfaces**

The interfaces are critical to the overall effectiveness of an Immunization Registry. Its functionality would be hindered and ineffective if an interface did not exist between the Immunization Registry and a State's Medicaid Management Information System (MMIS). This becomes apparent when such a registry is outside the domain of a Medicaid Department. An interface becomes essential in populating the registry with Medicaid beneficiaries as part of a State's total population. Enhanced Title XIX funding may not be used to design, develop, modify or install other systems, nor is FFP available to develop functionality in an Immunization Registry when it duplicates functionality in other State systems for which an interface is required. For example, Title XIX eligibility must be determined through an existing Title XIX system.

Funding for the optional interfaces is contingent on the overall cost effectiveness of the State's design and the appropriate use of automation. For interfaces to entities that may operate several independent systems (e.g., public health clinics, health information systems) that State may develop a standard interface for the exchange of information. To the extent that such an interface is cost effective, the Medicaid part of it may be funded with enhanced funds. As with the limits on duplicative functionality, HCFA will not fund the development of multiple interfaces to common entities. For example, an Immunization Registry, which proposes multiple interfaces to public health clinics, will not be cost effective. Development of a single, comprehensive Immunization Registry interface that can accommodate the necessary exchange of data between the Immunization Registry and multiple entities would be acceptable and eligible for enhanced funding.

## **Part V:**

### **STATEWIDE AUTOMATED IMMUNIZATION REGISTRY SYSTEM PROGRAM/SYSTEM FUNCTIONS AND GUIDANCE**

#### ***A. Core Requirements***

Functions with an asterisk (\*) are those that have been determined to be critical functions in meeting the minimum requirements of an automated Immunization Registry and should be met as part of the Medicaid Management Information System (MMIS) or through an automated interface. An underlined “may” is an optional function that may be added and for which enhanced funding would be approved.

##### ***1. Identifiable Information***

This function consists of information used to identify Medicaid-eligible children, demographic and vaccine-related information.

###### **A. Medicaid Information\***

1. Medicaid Identifier\* - The automated Immunization Registry must contain fields that can accommodate the child’s Medicaid Identification number.
2. Demographic Information\* - The automated Immunization Registry must contain fields for the Child’s first, last and middle names, birth date, sex, birth State/county, race/ethnicity and a guardian’s first, last and middle names. Additionally, optional fields may be added from the Health Level-7 (HL-7) Code Set.
3. Eligibility Information – The automated Immunization Registry may contain fields for time periods of Medicaid eligibility.
4. Primary Provider/Medical Home – The automated Immunization Registry may contain fields that identify the Primary Care Provider/Medical Home for a Medicaid child.

###### **B. Vaccination Information\***

1. Vaccination Information\* - The automated Immunization Registry must contain fields for the type of vaccinations given and date of administration.
2. Identify Provider\* – To the extent possible, the automated Immunization Registry must identify the provider who administers a specific vaccination to a child.

3. Lot Information – The automated Immunization Registry may contain fields for a vaccination manufacturer and lot number.

## 2. Case Management

This function entails the enrollment of Medicaid children within the automated Immunization Registry, the types of functionality needed to support this population, and the management of delivery of the services provided by this automated support.

### A. Enrollment\*

1. Enroll children at birth\* - The automated Immunization Registry must establish a registry record for children no more than 6 weeks after birth or six weeks after they have otherwise been entered into the state's information management system(s) and maintain them within the system until they reach the age of 18. At that time, in accordance with State and local statutes and laws, the child's records may be expunged from the Immunization Registry. Additionally, the Registry must identify the following:
  - Adoptions; record information about adoptive services, including the adoptive parents information within the parameter of State law.
  - Deaths; record information about a Medicaid child's death before the age of 18.
2. Maintain Individuals in the system for life – The system may maintain the individuals in the automated Immunization Registry until date of death.
3. Record and Track visits of family members/household – The automated Immunization Registry may record and track visits of all family members/household.

### B. Case Review/Evaluation\*

1. Contraindications/Exemptions\* - The automated Immunization Registry must contain information on contradictions and personal and/or philosophical exemptions.
2. Reminder/Recall\* - The automated Immunization Registry must generate an alert for guardians of Medicaid children as to the need for a series of vaccinations. Such information would be garnered from the immunization history of each child. This level of functionality would require that the name and address fields on the immunization record be completed.
3. Provider Access\* - To the extent possible, the automated Immunization Registry must be

accessible by all providers in their place of practice. The Registry must enable providers access to vaccination histories at the time of a scheduled encounter to determine the vaccinations needed.

4. Adverse Event - The automated Immunization Registry may enable vaccine-associated adverse event reporting.

### C. Monitoring Service\*

1. Needs Assessments\* - The automated Immunization Registry must automatically determine the immunization(s) needed, in compliance with current recommendations from the Centers for Disease Control and Prevention, when an individual presents for a vaccination.
2. Coverage/Community-Based Assessments\* - The automated Immunization Registry must be capable of automating and managing community-based coverage assessments. The registry must have an automated function to measure immunization coverage (% of children “age-appropriately” immunized) as of a given date for an individual provider’s practice, for the registry’s entire catchment area, and for subgroups within a practice of the catchment area (e.g., children of a certain age). “Age-appropriate” should be defined according to current CDC recommendations implemented in the registry’s algorithm.
3. Surveillance of Reportable Diseases - The automated Immunization Registry may allow for surveillance of vaccine-preventable diseases.

## 3. Resource Management

This function supports the maintenance of monitoring of information on Medicaid children within the automated Immunization Registry

### A. Provider Support\*

1. Submission of Information\* - The automated Immunization Registry must have the ability to receive and process immunization information within one month of a vaccine administration.
2. Flexibility\* - The automated Immunization Registry must be flexible enough to add/delete vaccines as new vaccinations are added to the recommended schedule and others are removed.
3. Data Requirements\* - The automated Immunization Registry must have the capability to use the HL-7 defined code set for exchanging information.
4. GIS Analysis - The Immunization Registry may enable analysis through Geographic Information

Systems (GIS).

5. Platforms for Non-Immunization Programs – The Immunization Registry may have a computer platform for non-immunization programs and/or systems.

## B. Resource Support\*

1. Consolidation of Information\* - The automated Immunization Registry must consolidate immunization records from multiple sources. Such functionality would also include de-duplication and quality checks.
2. Data Backup and Recovery\*- The automated Immunization Registry must be backed up regularly and backup media must be stored in a separate location.
3. Inventory Reporting – The automated Immunization Registry may allow for automated vaccine inventory reporting.
4. Vaccine Inventory – The automated Immunization Registry may manage vaccine inventories and generates reports on management and wastage.

## B. Interfaces

### 1. REQUIRED INTERFACES\*

- If an immunization registry is developed as part of a State's MMIS, then it must interface with a Statewide system that, at a minimum, exchanges data on a weekly basis. To the extent that such a Statewide system exists, it must integrate the entire population of children from age 0 to 18 that can be immunized along with all Medicaid children. Ideally, the interface would represent real-time, on-line data exchange.
- If the registry is built outside of a State's MMIS, then an interface that, at a minimum, would exchange data on a weekly basis, must be constructed to link the MMIS with the automated Immunization Registry. This must be done to fully populate the registry with Medicaid children in order to provide immunization rates. Ideally, the interface would represent real-time, on-line data exchange.

### 2. OPTIONAL INTERFACES

- Additionally, to the extent possible, the State Registry may provide for interfaces with other systems within the State, such as:

- a. Child Welfare (SACWIS)
- b. Women, Infants and Children (WIC)
- c. Early Periodic Screening, Diagnosis and Treatment (EPSDT) Program
- d. Bureau of Vital and Health Statistics
- e. Children's Health Insurance Program (S-CHIP)
- f. Public Health Clinics
- g. Health Information Systems (HIS)
- h. Vaccine Management System (VACMAN) (CDC)
- i. Other

# PLANNING APD CHECKLIST

## *Immunization Registries (Medicaid)*

A Planning APD is a very brief document (6-10 pages) prepared and submitted *prior to initiating* Planning Phase activities. It is used to secure Federal financial participation (FFP) for the State. It is a plan to plan. The purpose is not to provide needs and plans in detail but to develop a high-level management statement of vision, needs, objectives, plans, and estimated costs. The focus is on describing how planning will be accomplished and demonstrating that the State has established a plan that is reasonable for the level of effort of the project. Planning APDs that meet the standards for approval shown in the following two pages will be approved within 60 days. The Planning APD has four sections: 1. Statement of Need 2. Project Management Plan for planning 3. Planning project budget, and 4. Estimated of total project costs.

Section	Content	Description of Minimum Requirements
<p><b>Statement of Need</b></p> <p>This section of the Planning APD should set forth the State's information and objectives "vision,"<sup>1</sup> including scope and objectives of planned information system and its interrelationships with other systems (if known). In addition, the needs statement should define the system requirements in terms of problems and needs listed in next column.</p>	<p>✓ Statement of "Vision"</p>	<p>Reduce incidence of vaccine-preventable disease by giving providers and the State a high-quality, confidential, flexible and expendable tool. It ensures age-appropriate immunization for all children with the most efficient expenditure of program, resources.</p> <p style="text-align: center;">Yes                  No</p>
	<p>✓ System interrelationships</p>	<p>Include a diagram of the system interrelationships</p>
	<p>✓ Problems or deficiencies in existing system</p>	<p>Does an immunization registry already exist in your State?</p> <p style="text-align: center;">Yes                  No</p>
	<p>✓ New or changed program requirements</p>	<p>See attached CDC Minimum criteria. Explain any differences.</p>

<sup>1</sup> "Vision" means the State planners' view of future program needs and the systems architecture necessary to support those needs.

	✓ Opportunities for economy or efficiency	HCFA will assume the immunization registry has sufficient opportunities for both economy and efficiency provided that the CDC minimum criteria are addressed.																												
<p><b>Project Management Plan</b></p> <p>Project Management Plan summarizes how the State will plan.</p> <p>State's planning project organization is briefly described. At this point in the project, all that is required is for the State identify key players in the planning phase, such as the project manager and other key planning staff name and title. This information can be depicted in organization chart.</p> <p>Project Management Plan for planning describes when and when the activities in the Planning Phase will be conducted and schedules milestones for completion of events.</p>	✓ Planning project organization (State and contractor) – people, responsibilities and relationships	Provide descriptive one page chart and one page of accompanying narrative.																												
	✓ Planning activities, products and deliverables	Briefly summarize in one page or less.																												
	✓ Commitment to conduct analyses and JAD sessions	<table border="0"> <tr> <td>Requirements analysis</td> <td>Yes</td> </tr> <tr> <td>No</td> <td></td> </tr> <tr> <td>Feasibility study</td> <td>Yes</td> </tr> <tr> <td>No</td> <td></td> </tr> <tr> <td>Alternatives analysis</td> <td>Yes</td> </tr> <tr> <td>No</td> <td></td> </tr> <tr> <td>Cost/benefit analysis</td> <td>Yes</td> </tr> <tr> <td>No</td> <td></td> </tr> <tr> <td>JAD (joint application design sessions with users)</td> <td>Yes</td> </tr> <tr> <td>No</td> <td></td> </tr> <tr> <td>Functional specification</td> <td>Yes</td> </tr> <tr> <td>No</td> <td></td> </tr> <tr> <td>Systems design</td> <td>Yes</td> </tr> <tr> <td>No</td> <td></td> </tr> </table>	Requirements analysis	Yes	No		Feasibility study	Yes	No		Alternatives analysis	Yes	No		Cost/benefit analysis	Yes	No		JAD (joint application design sessions with users)	Yes	No		Functional specification	Yes	No		Systems design	Yes	No	
	Requirements analysis	Yes																												
	No																													
	Feasibility study	Yes																												
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No																														
Functional specification	Yes																													
No																														
Systems design	Yes																													
No																														
✓ Re-inventing the Wheel	What consideration has been given to transferring an existing module? Explain.																													
✓ State/contractor needs	Briefly summarize in one page or less.																													
✓ Planning project procurement activities and schedule	Briefly summarize in one page or less.																													
✓ Requirements and evaluation plan	Briefly summarize in one page or less.																													
✓ Restrictions on work?	None If any, explain																													
✓ Testing plans of interfaces	Describe plans and provide summary of testing schedule.																													

Section	Content	Description of Minimum Requirements
<p><b>Planning Project Budget</b></p> <p>This section succinctly describes in narrative form the source needs for which planning support during the Planning Phase may be requested by the State. These needs may relate to fee and contractor staff costs, computer time, software and commercially available software, travel, postage, supplies, telephones, photocopying, and so forth.</p> <p>This section of the APD also provides the budget and the cost allocation to be used during the Planning Phase.</p>	<p>✓ By categories, cost elements and amounts</p>	<p>Show cost allocation among users</p> <p>Anticipated FFP (90%, 75% and 50%)</p> <p>Anticipated State costs</p> <p>Projected costs by fiscal quarter + summarized by fiscal year, including planning project total, and program totals.</p>
<p><b>Total Project Cost</b></p> <p>This section provides a gross estimate of total project costs for the entire system acquisition — including planning and implementation. This information is very preliminary and will be updated in the implementation APD.</p>	<p>✓ Estimated project costs</p>	<p>State and Federal shares, cost distribution</p>

## MANDATORY FUNCTIONAL REQUIREMENTS

### Medicaid Immunization Registries

<u>Category</u>	<u>Section</u>	<u>Content</u>	<u>Description</u>
Core Requirements	<i>Identifiable Information</i>	Medicaid Information	<p>The Immunization Registry must contain a field for a child's Medicaid Identification Number</p> <p>The Immunization Registry must contain fields for the Child's first, last and middle names, birth date, sex, birth State/county, race/ethnicity and</p>

date, sex, birth State/county, race/ethnicity and guardian's first, last and middle names.

Vaccination Information The Immunization Registry must contain fields for the vaccination and date of administration

To the extent possible, the Immunization Registry must identify the provider who administers specific vaccination to a child

The Immunization Registry must establish a registry record for children no more than 6 weeks after birth and keep them within the system until they reach the age of 18. At that time, in accordance with State and local statutes and laws, the child's records may need to be expunged from the Immunization Registry. Additionally, the Registry must identify the following:

*Case Management*

Enrollment

a. Adoptions; records information about adoption services, including the guardian's information within the parameter of State law.

b. Deaths; record information about a Medicaid child's death before the age of 18.

The Immunization Registry must contain information on contraindications and personal and/or philosophical exemptions.

**Core Requirements (continued)**

*Case Management (continued)*

The Immunization Registry must automate a reminder/recall service that alerts guardians of Medicaid children as to the need for a series of vaccinations. Such information would be garnered from the immunization history of each child. This level of functionality would require that the name and address fields on the immunization record be completed.

Case Review/Evaluation

To the extent possible, the Immunization Registry must be accessible by all providers in their place of practice. The Registry must enable provider access to vaccination histories at the time of a scheduled encounter to determine the vaccinations needed.

		Monitoring Service	<p>The Immunization Registry must automatically determine the immunization(s) needed, compliance with current recommendations for the Centers for Disease Control and Prevention, when an individual presents for a vaccination.</p>
			<p>The Immunization Registry must be capable of automating and managing community-coverage assessments.</p>
			<p>The Immunization Registry must have the ability to receive and process immunization information within one month of a vaccine administration</p>
	<i>Resource Management</i>	Provider Support	<p>The Immunization Registry must be flexible enough to add/delete vaccines as new vaccinations are added to the recommended schedule and others are removed.</p>
		Provider Support	<p>The Immunization Registry must have the capability to use the HL-7 defined code set for exchanging information</p>
<b>Core Requirements (continued)</b>	<i>Resource Management (continued)</i>	Resource Support	<p>The Immunization Registry must consolidate immunization records from multiple sources. Such functionality would also include deduplication and quality checks.</p>
			<p>The Immunization Registry must be backed up regularly and backup media must be stored in a separate location.</p>
<b>Interface Requirements</b>			<p>If an Immunization Registry is constructed as part of a State's MMIS, then it must have an interface with a Statewide system that, at a minimum, exchanges data on a weekly basis. To the extent that such a Statewide system exists, it must integrate the entire population of children from age 0 to 18 that can be immunized along with Medicaid children.</p>
		Mandatory Interfaces	<p>If the Immunization Registry is built outside of a State's MMIS, then an interface that, at a minimum, would exchange data weekly basis must be constructed to link the MMIS with the Immunization Registry. This must be done to fully populate the registry with Medicaid children in order to provide immunization rates.</p>

**Interface Requirements**

Optional Interfaces

Additionally, to the extent possible, the State Registry may also decide to interface or intergrate with one or more of the following:

- a. Child Welfare (SACWIS)
- b. Women, Infants and Children (WIC)
- c. Early Periodic Screening, Diagnosis and Treatment (EPSDT) Program
- d. Bureau of Vital and Health Statistics
- e. Children's Health Insurance Program, (S CHIP)
- f. Public Health Clinics
- g. Health Information Systems (HIS)
- h. Vaccine Management System (VACMAN) (CDC)
- i. Others

Optional Interfaces  
(continued)

