Immunization Information System Collaboration with Vaccines For Children Program and Grantee Immunization Programs

Recommendations of the
American Immunization Registry Association (AIRA)
Modeling of Immunization Registry Operations Work Group (MIROW)

April 14, 2011

Suggested citation:
AIRA Modeling of Immunization Registry Operations Work Group (eds). Immunization Information System Collaboration with Vaccines For Children Program and Grantee Immunization Programs. Atlanta, GA: American Immunization Registry Association. April, 2011.

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Acknowledgments

Members of the Modeling of Immunization Registry Operations Work Group (MIROW) appreciate and acknowledge the following:

- External reviewers of the recommendations document for their willingness to read and constructively critique the Work Group's materials. Their efforts benefited this document significantly:
  - **Dr. Noam H. Arzt**
  - **Nathan Bunker**
  - **Nathan Crawford**
  - **Nancy Fasano**
  - **Dr. Janet L. Fath**
  - **Michael K. Flynn**
  - **Christy Gray, Crista Sullivan, Dr. Sandra Sommer, and Dr. Archer Redmond**
  - **Therese Hoyle**
  - **Shirley Huie and Angel Aponte**
  - **Mary Beth Kurilo, Lydia M. Luther, and Lorraine Duncan**
  - **Dr. Marlene M. Lugg**
  - **Susan Salkowitz**
  - **Ray Seggelke**
  - **Elizabeth Sobczyk**
  - **Linda Stevens**
  - **Pejman Talebian**
  - **Cecile M. Town**

- Facilitation support provided during the modeling sessions in Atlanta, Georgia (June 15-17, 2010) by the team from Advanced Strategies, Inc. —**Kahil Branton, Gail DeCosta,** and **Charles West.**

- Editorial support—**Tiffany Bailey** and **Kondra Williams**, Technical Writers-Editors at the Centers for Disease Control and Prevention (CDC).

- Administrative support of the AIRA staff—**Angelica Velez** and **Ina Kichen**—in organization of modeling sessions.

- Contributions of the following organizations in providing materials on IIS-VFC/Grantee immunization program collaboration issues that helped in framing the topic and preparing for the modeling sessions:
  - **CHILD Profile — Washington State Immunization Registry**
  - **Kansas Immunization Registry — KSWebIZ**
  - **Michigan Care Improvement Registry**
  - **Pennsylvania Statewide Immunization Information System**
  - **Vermont Immunization Registry**
  - **HP Enterprise Services — Immunization Solution Services**

Executive Summary

Background

The Modeling of Immunization Registry Operations Work Group (MIROW) was formed in 2005 by the American Immunization Registry Association (AIRA) in partnership with the National Center for Immunization and Respiratory Diseases (NCIRD) at the Centers for Disease Control and Prevention (CDC) to develop a best practices guidebook for immunization information systems (IISs). This document is one chapter of the guidebook. It provides consensus-based best practice recommendations for IIS to support operations of the federal Vaccines for Children (VFC) program, immunization programs of CDC grantees, and provider organizations, with a focus on resolving and tracking VFC eligibility status for patients.

The federal VFC program requires that participating provider organizations screen patients for VFC eligibility and report certain eligibility-related information that, among other things, is used to determine needs for vaccine ordering. Grantees also may require provider organizations to screen patients for grantee vaccine program eligibility. Some grantees do not currently use IIS to support the federal VFC or grantee vaccine programs. Among grantees that use IIS to support the VFC and grantee vaccine programs, there is variation in resolving and tracking patients' eligibility status and in the collection and reporting of data used to estimate the amount of vaccine that provider organizations will administer. IIS data capture is based on both direct user interface for provider organizations and electronic transfer from other data sources, such as electronic medical record (EMR) and electronic health record (EHR) systems.

The IIS application is the base for handling eligibility-related activities such as screening patients, validating recorded information, and providing aggregated reports to support the needs of provider organizations and vaccine programs. The goal of this guide is to provide a set of common guidelines to assist IIS with aligning operational practices and processes by adhering to recommended best practices.

Benefits of IIS-VFC/Grantee vaccine program collaboration

Adoption of these best practice guidelines will:

- Encourage use of IIS to support VFC and grantee vaccine programs
- Reduce the reporting burden on provider organizations since their reporting to IIS will result in providing aggregated data for VFC and grantee vaccine programs (provider organizations also need to record information as required for clinical records)
- Provide standard practices to capture VFC and grantee vaccine program eligibility status for patients that can be referenced as requirements when developing IIS applications (direct data entry) and EMR/EHR systems (for electronic transfer to IIS)
- Ensure that eligibility status data are comparable across all grantees and all provider organizations
- Improve data quality for the VFC and grantee vaccine programs

Highlights of Recommendations

The guidelines provide best practices to use IIS as a base for handling eligibility-related activities – such as screening for eligibilities, validating recorded information, and providing aggregated reports to support the needs of provider organizations and grantee vaccine programs.

During the first step of the process, the provider organization screens the patient for VFC eligibility, grantee program eligibility, and private coverage. The provider organization selects between available program eligibilities and private coverage, taking into consideration, among other factors, eligibility of needed vaccines. Eligibility screening scenarios, presented in decision tables, and associated explanatory notes provide logic to support the determination of patient eligibility. Examples of business rules (BR) related to patients' screening include:

- Information needed for patient eligibility screening (BR602)
- Age criteria for patient participation in the vaccine program (BR601)
- How often to screen (BR603)
- How to resolve dual-coverage issues (e.g., a patient has private insurance and Medicaid) (BR609)

During a subsequent step of the process the provider organization validates and records the vaccination event information in the IIS or reports it via a third party application. Examples of business rules related to validating and recording eligibilities include:

- Screening data should be documented/recorded electronically (BR611)
- Vaccination Events should be recorded after the vaccine has been administered (BR612)
- Provider organization should report patient's eligibility to IIS for every vaccination event/dose administered (BR613)
- Patient's eligibility data items that provider organizations should report to the IIS are:
    - Minimum Set (Good Practice, BR614). A single data item/element from the following list:
        - Medicaid
        - American Indian and Alaska Native (AI/AN)
        - Uninsured
        - Underinsured – Federally Qualified Health Center (FQHC), Rural Health Center (RHC), and Provider Organizations with Delegated Authority only
        - Grantee eligible (various degree of granularity, grantee-specific)
        - Private coverage (Private insurance or out-of pocket pay) = VFC Ineligible
    - Expanded Set (Best Practice, BR615). An applicable valid combination of data items/elements from the list above. Example of a valid combination of reported eligibility data items would include Medicaid and AI/AN, which should be resolved as VFC eligible. Example of an invalid combination would include Medicaid and Uninsured.
- Single eligibility/coverage status should be assigned to a patient for every vaccination event/dose administered (BR608) and the hierarchy of choices for patient's eligibility or coverage is, in general (BR607):
    - Private insurance coverage
    - VFC program eligibility
    - Grantee program eligibility

In addition to business rules that provide specific process-related requirements, this guideline contains ***general recommendations*** (GR) for IIS functionality and various operations aspects of IIS-VFC/grantee immunization program collaboration. Examples of general recommendations are:

- Both the provider organization and the IIS must validate eligibility data. The provider organization and the IIS should validate vaccination event information at the time of recording the vaccination and by routinely running reports (e.g., monthly reports, GR602). The IIS application should have functionality to validate data reported by a provider organization at both the data element and aggregated level, as well as data aggregated for all or selected subsets of provider organizations (GR603).
- IIS application should have reports available to support the needs of vaccine programs and provider organizations, e.g., needs for the detailed analysis by the vaccine program of provider organization practices (GR605). Contents of several reports are discussed in Chapter 5: Provider Organization Profile Report, Provider Organization Profile Report (aggregated), Doses Administered Report, Patient Detailed Lists Reports, Vaccine Accountability Reports, Quality Assurance Reports, Pockets of Need Report, and Provider Coverage Report.

In addition to decision tables, business rules, and general recommendations, this guide documents a process model (diagrams and description) and a domain model (agreed upon terms and definitions). The guide also contains considerations for implementation of the best practice guidelines, HL7 considerations, an example of a paper based eligibility assessment tool that can be used by provider organizations, and a list of selected peer-reviewed literature references.

Conclusion

The National Vaccine Advisory Committee (NVAC) has included a recommendation to "Promote the adoption of a guidebook and best practices for IIS as stated by the CDC/NIP and AIRA/MIROW workgroup to adopt consistent operational guidance and quality control procedures that ensure good data quality." This best practices guide is one example of addressing the NVAC recommendation. It will assist IIS to align practices through adherence to a set of common recommendation and guidelines. As a result, IIS will be able to better serve the needs of vaccine programs and provider organizations.

Chapter 1: Introduction

About the MIROW IIS-VFC/Grantee Immunization Program Collaboration Project
The Modeling of Immunization Registry Operations Work Group (MIROW) of the American Immunization Registry Association (AIRA) was formed in partnership with the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention to develop a topic-by-topic best practice guidebook for various aspects of the functionality of immunization information systems (IISs). Since 2005, MIROW has developed several operational guidelines for the following IIS functional areas: Reminder/Recall, Incoming Data Quality Assurance, Vaccination Level Deduplication, Patient Immunization Status, and IIS-Vaccine Adverse Event Reporting System Collaboration.

The MIROW Web page at http://www.immregistries.org/pubs/mirow.phtml contains complete recommendations documents for previous topics and abridged mini-guides. "Evaluating IIS Best Practice Operational Guidelines: Emerging Trends and Challenges," a presentation delivered at the 44th National Immunization Conference, also describes MIROW's efforts. The presentation can be accessed at http://cdc.confex.com/cdc/nic2010/webprogram/Paper22530.html.

The current report represents MIROW's efforts to develop best practice recommendations for the topic of IIS collaboration with Vaccines for Children (VFC) Program and Grantee Immunization Programs. The development process consisted of a preliminary phase that included Web-based teleconferences held March–June 2010, face-to-face meetings held June 15–17, 2010 in Atlanta, Georgia, and post-meeting activities to finalize the recommendations**.**

About this document
This document provides consensus-based best practice recommendations for IIS to support operations of the federal VFC Program, Immunization Programs of Grantees, and Provider Organizations, especially for resolving and tracking VFC eligibility status for Patients.

The following assumptions reflect MIROW's approach to the development of business rules, general recommendations, and associated best practices presented in this document:

- The focus should be on recommendations and business rules that have the greatest potential for providing value and use across all IISs.
- The business rules represent an attempt to balance ideal possible practices with pragmatic considerations of what will be possible to implement in an IIS.
- Each IIS will tweak the implementation of business rules (and associated best practices) based on its resources, goals, need, and unique implementation concerns.
- The set of business rules and general recommendations presented here is not exhaustive. Individual IISs may choose to implement additional rules based on its unique requirements and insights.
- The developed business rules and associated best practices will need to change and evolve over time as business requirements change.

Implementation/technology independence
Developed best practice recommendations are intended to be at the business/operational level and, as a result, independent from particular IIS implementations and technology solutions. This

reflects the industry-wide strategic approach to capture and maintain business knowledge, requirements, and policies/constraints independently of implementation architecture and technical solutions. As a result, developed best practice recommendations will be able to support the wide variety of IIS implementation strategies on different technological platforms.

Intended audience

This guide is designed to be read by programmatic, technical and operational personnel involved in creating or maintaining an IIS, as well as personnel of the VFC and Grantee Vaccine Programs. The guide intends to bridge the gap between IIS technical and program staff, as well as between the staff of IISs and VFC/ Grantees Vaccine Programs. Bridging these gaps will help create mutual understanding of the issue of IIS collaboration with VFC Program and Grantee Vaccine Program and target actions to address these recommendations.

Intended use

This guide contains a set of recommended operational best practices (including a set of principles and business rules to follow) that are intended for use as a basis for requirements in IIS applications and operations. In addition, this guide can be used by IIS for staff training, operational documentation, and communication purposes, as well as provide guidance for vendors and users of EMR/EHR applications.

The implementation of developed best practice recommendations will vary based on the IIS and EMR/EHR vendors' technology, application architecture, and specifics of a particular IIS. Also, resource constraints, or required changes to existing functionality, may result in ***incremental adoption*** of these guidelines.

The approach used and results presented are relevant for and can be utilized beyond immunization information systems, e.g., for developing and documenting best practices and operational requirements for domain-specific applications in public health, health care, and other areas.

Work Group approach

The Work Group used business engineering and facilitation techniques to analyze IIS processes and develop recommendations. It utilized a pragmatic results-oriented approach that has been effective for modeling of IIS and cancer registration operations. Initial ***preparatory off-line work*** (assembling pertinent materials, producing preparatory notes, analysis of processes and development of preliminary drafts) was performed by a group of business analysts and subject matter experts (SMEs). During a subsequent ***face-to-face facilitated modeling session*** held on June 15-17, 2010 in Atlanta, Georgia a full work group of SMEs used preparatory materials as a framing and scoping resource and began development and formulation of consensus-based recommendations. The ***post-session work*** was aimed at finalizing the development of recommendations. The work group was divided into two small groups of SMEs, each addressing a set of remaining tasks during a series of teleconferences. Additional teleconferences were dedicated to progress reviews of small groups by the full group of SMEs. The work group aimed for a consensus among SMEs regarding developed best practice recommendations which did not reflect 100% agreement, but rather meant ***"I can live with that and support it."*** While the first part ("can live with that") allowed the group to focus on achieving a consensus in principle,

avoiding prolonged discussions on minor features (when at least no one disagrees strongly enough to veto the agreement), the second part ("support it") provided a due diligence check to ensure that there are no serious disagreements left among the experts and assurance that experts agreed enough with the recommendation to stand behind it and support it.

Scope

A ***primary focus*** for the MIROW IIS-VFC/Grantee Immunization Program collaboration topic is resolving and tracking the VFC Program and Grantee Vaccine Program ***eligibility status for a Patient*** , which is based on the VFC and Grantee policies and Patient's insurance coverage.

Patient's eligibility tracking is considered in the context of Provider Organizations recording (reporting) eligibility information in IIS, that, in turn, maintains and aggregates eligibility information and provides reports to support needs of the VFC Program, Grantee Vaccine Program, and Provider Organizations.

Concepts that are related to and support the determination of Patient's eligibility include (see Appendix A for definitions and the discussion – pp. 64-66, 77)

- Vaccine Eligibility – based on Advisory Committee on Immunization Practices (ACIP) recommendations and Grantee policies (e.g., VFC Select state)
- Vaccination Event Eligibility – based on agreement (match) between Patient Eligibility and Vaccine Eligibility
- Provider Organization characteristics, such as the organization VFC enrollment status and facility type

Figure 1 below illustrates the scope in a context of immunization operations. Figure 2 presents essence of the scope with a simplified process sketch. Figure 3 illustrates the scope with a use case diagram.

At the time of development of these guidelines it is not possible to foresee the exact impact of health care reform on VFC and Grantee Vaccine Program policies related to the eligibility of a Patient for publicly-purchased Vaccines. However, it is possible that the number of Patients in both the Underinsured and Uninsured categories will be reduced. The majority of best practice recommendations presented in this guideline will still be applicable and the document can be modified by users as necessary to reflect the impact of health care reform.

Detailed focus statement can be found in the Appendix E of this document.

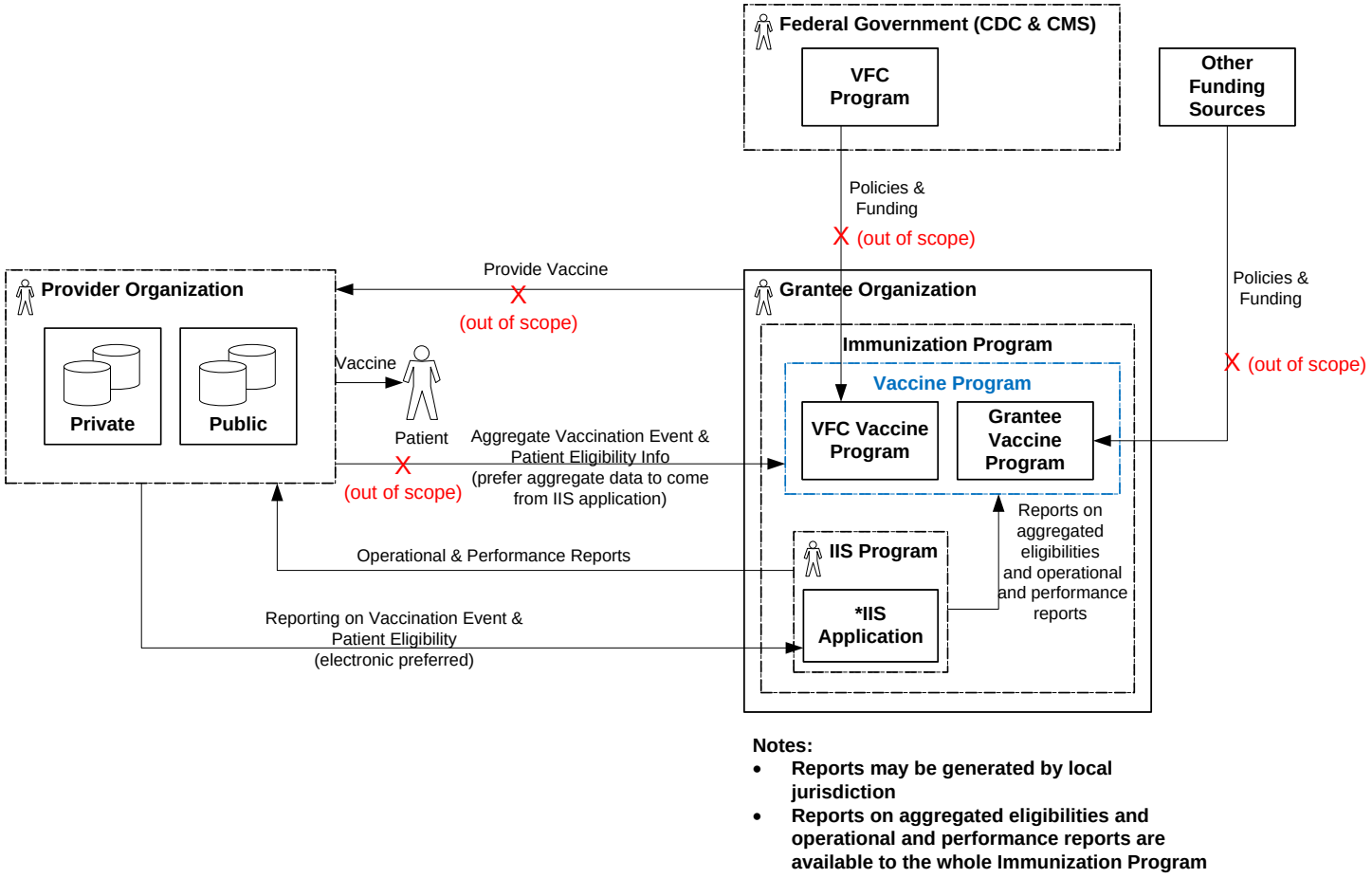

Figure 1. Context diagram: scope in context of immunization operations

Notes:

- While policies and funding aspects of the federal component of the VFC Program are out of scope for this effort, it should be noted that federal guidelines have been used by the MIROW experts in their decision-making.
- Abbreviations: CDC = Centers for Disease Control and Prevention; CMS = Centers for Medicare & Medicaid Services; IIS = Immunization Information System; VFC = Vaccines for Children Program.

- Provider Organization screens (evaluates) and reports eligibilities to IIS – for every dose administered (*in scope*)
- IIS provides reports on dose administered and associated eligibilities (aggregated over a period of time) to Vaccine Program (*in scope*)
- Vaccine Program utilizes aggregated eligibilities information from IIS to, among other things, balance accounting for funding sources (*out of scope*)
- Reporting of the aggregated information from Provider Organization directly to Vaccine Program is *out of scope* and not shown on this sketch
- Note: completeness of reporting from all Provider Organizations is crucial to enable IIS support of Vaccine Programs and Provider Organizations with quality data for reporting purposes

Figure 2. Essence of the scope – a simplified sketch

Eligibility versus Funding Source

- Provider Organization evaluates and reports eligibilities. Patient Eligibility indicates who should pay for a vaccine.
- Vaccine Program manages funding sources. Funding source indicates who actually pays for a vaccine.
- Vaccine Program utilizes aggregated eligibilities information to balance accounting for funding sources.
- See Appendix A, pp. 66-68 for a detailed discussion

Revision date: 04-11-2011

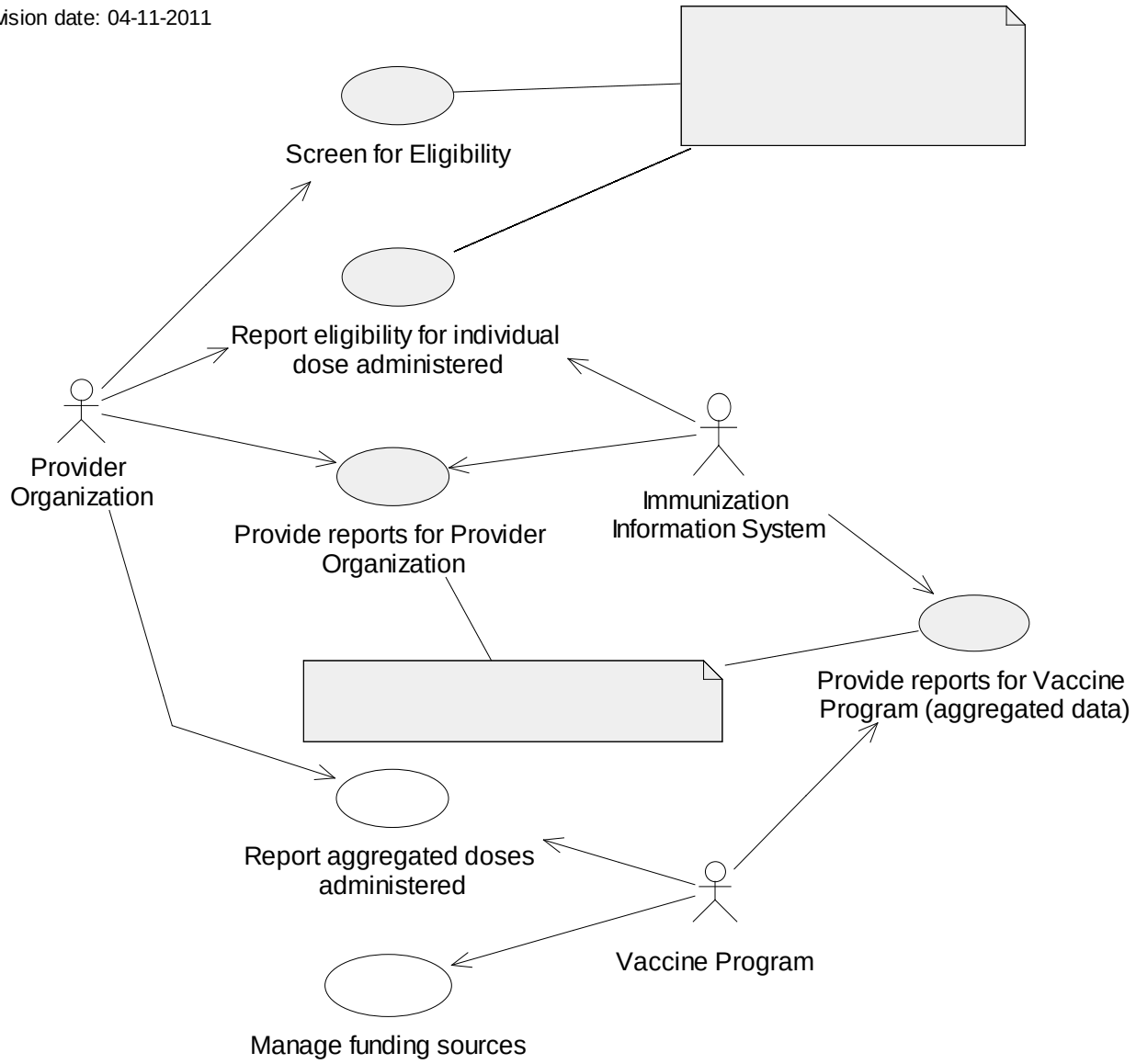

Figure 3. Scope illustrated with a use case diagram

- Provider Organization assigns and reports Patient Eligibility to
  - IIS (for every dose administered), *this is in-scope*
  - Vaccine Program (aggregated over a period of time), *this is out of scope*. It means that direct reporting from Provider Organization to Vaccine Program is out of scope for this topic (reporting to IIS is in-scope)
- IIS provides reports to Vaccine Program on doses administered and associated eligibility information (aggregated over a period of time), *this is in-scope*
- IIS provides reports to Provider Organizations (see Chapter 5) – this is *in-scope*
- Vaccine Program utilizes aggregated eligibility information from IIS (*this is in-scope*) and/or from Provider Organization (*this is out of scope*) to balance accounting for funding sources (*this is out of scope*)

Chapter 2: Process Model

This chapter describes an eligibility screening and reporting process that utilizes an immunization information system (IIS). Definitions of eligibility categories for Patient, Vaccine, Vaccination Event, as well as definitions of other terms used in describing and discussing various aspects of the process are presented in Appendix A (pp. 64-66, 74, 77).

The process includes two main components:

1) Provider screening a Patient for Vaccine Program eligibilities and private coverage, selecting between available choices or their valid combinations, and recording eligibility information in an IIS (or reporting this eligibility information to IIS via a third party application, such as electronic medical record (EMR) and electronic health record (EHR) systems using Health Level Seven (HL7) messaging – see appendix C "HL7 Considerations" – or other types of standard messages and formats).
2) IIS aggregating Patients' eligibility information to support generation of the Provider Organization Profile Report and other reports requested by the Vaccine Program, Provider Organization, and/or IIS itself on behalf of the Provider Organization.

Process activities and associated materials for the first component are described in this chapter, Chapter 3 "Eligibility Screening Scenarios," and Chapter 4 "Business Rules," Appendix B "Partitioned Decision Tables and Associated Screening Process," Appendix C "HL7 Considerations," and Appendix D "Paper-Based Eligibility Assessment Tool." Process activities for the second component are described in this chapter, Chapter 5 "IIS Reports to Support Needs of VFC/Grantee Immunization Programs and Provider Organizations," and Chapter 6 "General Recommendations."

A simplified diagram in Fig. 4 illustrates the general approach and main process activities. Provider Organization screens a Patient for Vaccines for Children (VFC) Program eligibility, Grantee Vaccine Program eligibility, and private coverage (private health insurance or out-of-pocket pay) and selects between available program eligibilities and private coverage. If VFC Program eligibility or Grantee Vaccine Program eligibility is selected, the Vaccine should be administered from a public stock. If Private Coverage is selected, the Vaccine should be administered from a private stock. Information for each Vaccination Event is recorded in (reported to) IIS by the Provider Organization. IIS collects and aggregates reported (recorded) information for Patients' eligibilities. Therefore, the need for Provider Organizations to provide a separate report to the Grantee Vaccine Program is eliminated. This helps to reduce the burden of VFC Program and Grantee Program reporting requirements for Provider Organizations and increase reliability and accuracy of the information for the Grantee Vaccine Programs. IIS provides a facility to generate various aggregated reports on doses administered. As a logical conclusion of the process, the Grantee Vaccine Program utilizes IIS-based reports' information on aggregated eligibilities and coverage to balance accounting among funding sources.

A process overview diagram in Fig. 5 illustrates a separation of concerns and responsibilities between Provider Organization, IIS, and Vaccine Program. The IIS Application is shown at the bottom of Fig. 5 as a base for handling eligibility-related activities such as screening for eligibilities, validating recorded information, and providing aggregated reports to support the

needs of Provider Organizations and Grantee Vaccine Programs. Table 1 contains description of the activities/steps depicted in Fig. 5.

The presented process is not prescriptive regarding the sequence of screening for Patient's eligibilities and coverage. A variety of screening sequences could be employed by Provider Organizations, depending on such factors as established office workflows, proportion of Patients with private coverage, type of practice, and many others. The key element is to satisfy screening requirements of VFC and Grantee Immunization Programs. The Modeling of Immunization Registry Operations Work Group (MIROW) panel of experts recommends a screening sequence described in detail in Appendix B and by business rule (BR) BR604.

Eligibility screening scenarios presented in decision tables (Table 2, Tables 9-B2, 11-B4, 13-B6) and notes for associated scenarios (Table 3 and Tables 10-B3, 12-B5, 14-B7) provide logic to support the determination of Patient's eligibility.

Only eligibility data items for a Patient are recorded in (reported to) the IIS. Such data items include (see BR614 and BR615):

- Medicaid
- American Indian/Alaska Native (AI/AN)
- Uninsured
- Underinsured – Federally Qualified Health Center (FQHC), Rural Health Center (RHC), and Delegated Authority Provider Organizations only
- Grantee Vaccine Program eligible (various degree of granularity, Grantee-specific)
- Private coverage (Private insurance or out-of-pocket pay) = VFC Ineligible

Based on the eligibility data items recorded/reported, the IIS Application deduces Patient's eligibility status. For example, if Medicaid and AI/AN are reported, the IIS Application will conclude that the Patient is VFC eligible and if Private coverage is reported, the IIS Application will conclude that the Patient is VFC ineligible.

Figure 4. Simplified process diagram

Note: In many cases the Provider Organization does not know if private insurance actually covers a Vaccine until months after the administration of the Vaccine (see BR610)

Eligibility versus Coverage

- Eligibility describes an association with the public Vaccine Program, e.g., Patient is ***eligible*** for the VFC Program
- Coverage describes an association with the private insurance, e.g., Patient is ***covered*** by private insurance.
- Dual coverage describes a situation when Patient is eligible for the VFC Program and also has private insurance coverage.
- See Appendix A, pp. 64-66 for a detailed discussion

Revision date 04-13-2011

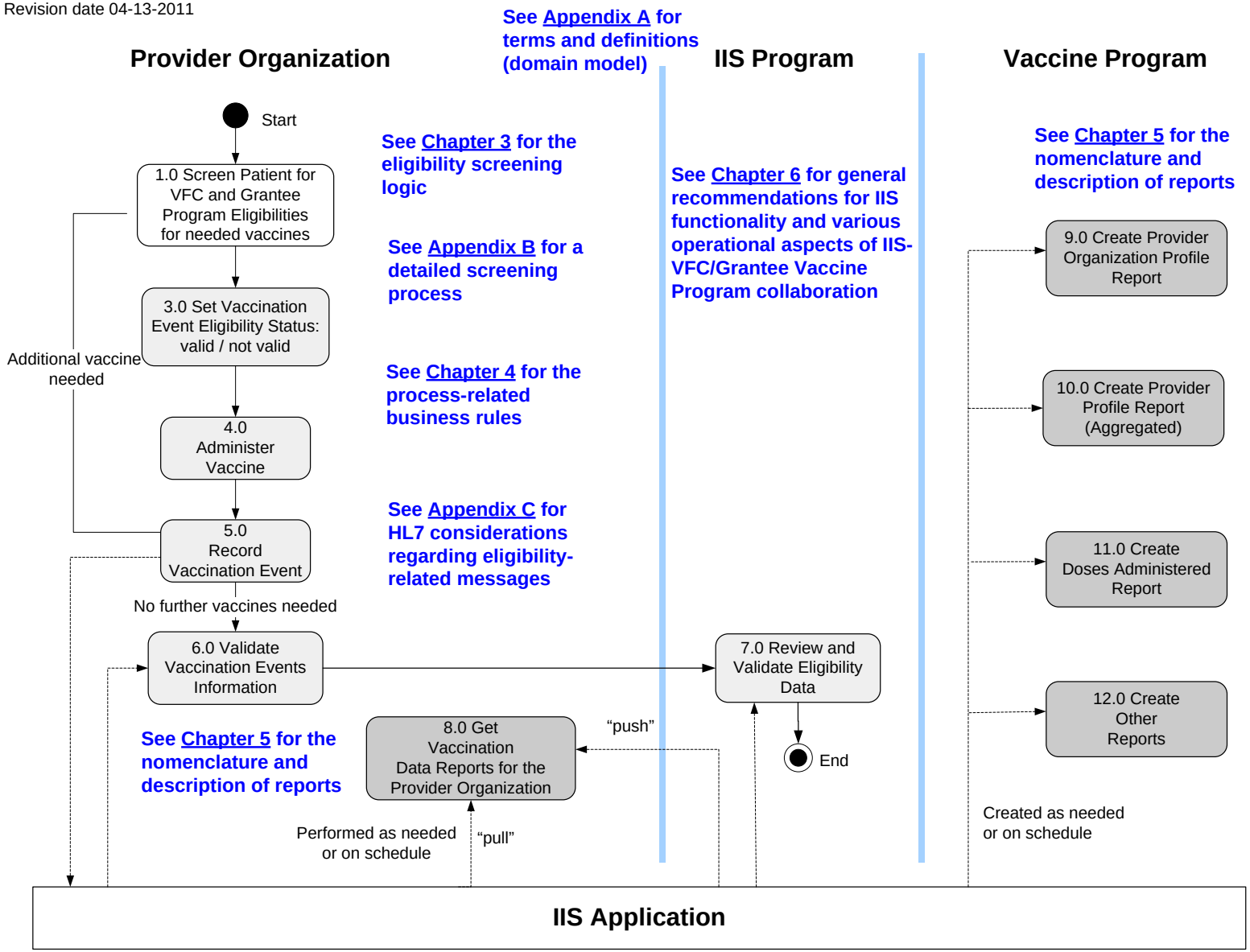

Figure 5. Process overview diagram

Note: See Appendix B, Fig. 8-B1 and Fig. 9-B2 for the activity 1.0 detailed logic and for the activity 2.0

Table 1. Process Description
(see Fig. 5)

ID	Name	Business Rules (BRs) and General Recommendations (GRs)	Role	Description/Notes/ Issues/Inputs/Outputs

1.0	Screen Patient for VFC and Grantee Program Eligibilities	BR601
		BR602
		BR603
		BR604
		BR605
		BR606
		BR607
		BR608
		BR609
		BR610
			Provider Organization	• During this step the Provider
				  o Screens Patient for VFC Program Eligibility, Grantee Program Eligibility, and private coverage
				  o Selects between available program eligibilities and private coverage
				  o Determines eligibility of needed Vaccine(s) for selected Vaccine Program (based on Vaccine Type and Vaccine Program policies)
				• Input: Screening data, i.e. data gathered in order to conduct the Vaccine Program eligibility screening.
				• Possible outcomes (for each Vaccination Event):
				  o Patient Eligibility
				  ➢ VFC-eligible (Medicaid, AI/AN, Uninsured, Underinsured eligibility categories), or
				  ➢ Private Coverage (i.e., VFC-ineligible), or
				  ➢ Grantee-eligible
				  o Vaccine Eligibility (based on Vaccine Type):
				  ➢ Vaccine is eligible for the VFC Program, or
				  ➢ Vaccine is ineligible for the VFC Program (Private Coverage), or
				  ➢ Vaccine is eligible for the Grantee Program
				• See Appendix B, Table 8-B1 for the description of a specific screening logic (activities 1.1 – 1.5)
				• In states with a universal purchase policy, the Patient will always be eligible for the VFC Program or Grantee Program. In states with a universal select purchase policy, the Patient will be eligible for the majority of the Vaccines.
				  o See Appendix A, Table 7-A2 for a description of various Vaccine purchasing schemes.

ID	Name	Business Rules (BRs) and General Recommendations (GRs)	Role	Description/Notes/ Issues/Inputs/Outputs
2.0				• See Appendix B, Table 8-B1 and Figure 9-B2.
3.0	Set Vaccination Event Eligibility status		Provider Organization	• Input: Patient Eligibility, Vaccine Eligibility - for VFC and Grantee Vaccine Programs • Possible outcomes: o Vaccination Event Eligibility status set for "valid" (if the Patient and Vaccine have been deemed eligible for the same Vaccine Program). o Vaccination Event Eligibility status set for "not valid" (if Patient is not eligible for VFC or Grantee Vaccine Programs or if Provider chose not to use the VFC Vaccine – Vaccine has Private coverage) • Vaccination Event Eligibility indicates a validity of the match between Patient Eligibility and Vaccine Eligibility (which is based on Vaccine Type). Example: Patient is VFC eligible, needed Vaccine is VFC eligible. Then the Vaccination Event is valid (eligible). See Appendix A, p. 66 for a detailed explanation • Provider uses a concept of Vaccination Event Eligibility to confirm a match between Patient Eligibility and eligibility of a Vaccine that is going be administered. The Vaccination Event Eligibility is not recorded by Provider Organization in IIS or messaged
4.0	Administer Vaccine	BR608	Provider Organization	• Administer a Vaccine from the appropriate stock, either public or private.
5.0	Record Vaccination Event Information	GR601 GR602 BR611 BR612 BR613 BR614 BR615	Provider Organization	• This includes recording the eligibility status for a Patient in the IIS Application for every Vaccination Event (dose administered) • Vaccine Eligibility and Vaccination Event Eligibility (valid/invalid) are not recorded in or reported to IIS, but rather serve to support validations of dose administered by Provider Organizations and IIS. See Appendix A for a detailed explanation • Patient's eligibility information can be recorded directly in the IIS application or reported via the third party application using HL7 messaging (see appendix C) or

ID	Name	Business Rules (BRs) and General Recommendations (GRs)	Role	Description/Notes/ Issues/Inputs/Outputs
				other types of messages and formats. • Patient VFC Eligibility Status can be deduced by the IIS Application based on the data items reported (see notes for BR615) • Input: Data items for Patient's Eligibility (see BR614 and BR615) • Output: Eligibility information within the Patient's record for a Vaccination Event • Information should be stored within the IIS Application but there are multiple acceptable methods (e.g. EMR/EHR, paper) for getting it there. • The information can be validated by IIS Application at the time that it is recorded.
6.0	Validate Vaccination Event Information	GR602	Provider Organization	• Ensure that the individual Vaccination Event's information is correct (based on completeness and accuracy) o See GR602 for potential validation examples • Review the IIS record to be sure that the information recorded is what was intended
7.0	Validate Eligibility Data	BR614 BR615 GR602 GR603 GR604	IIS Program	• Review the information for completeness and accuracy. • Compare Patient Eligibility with eligibility of administered Vaccine Type (i.e., confirm Vaccination Event Eligibility – see step 3.0)

8.0	Get Vaccination Data Reports For the Provider Organization	BR616
		BR617
		GR605
		GR606
		GR609
			Provider Organization and/or IIS Program	• See Chapter 5 for the nomenclature and description of reports that support needs of Provider Organizations:
				  o Provider Organization Profile Report
				  o Provider Organization Profile Report (Aggregated)
				  o Doses Administered Reports
				  o Patient Detailed List Reports
				  o Vaccine Accountability Reports: (i.e. inventory tracking)
				  o Quality Assurance Reports
				  ➢ Data Completeness reports
				  ➢ Accuracy reports

ID	Name	Business Rules (BRs) and General Recommendations (GRs)	Role	Description/Notes/ Issues/Inputs/Outputs
				➢ Timeliness reports o Pockets of Need Report o Provider Coverage Report • IIS push out reports to Provider Organizations or Provider Organization pulls these reports.
9.0	Create Provider Organization Profile Report	BR616 BR617 GR605 GR606 GR609	Vaccine Program	• See Chapter 5 for the description of this report
10.0	Create Provider Profile Report (Aggregated)	BR616 BR617 GR605 GR606 GR609	Vaccine Program	• See Chapter 5 for the description of this report
11.0	Create Doses Administered Report	BR616 BR617 GR605 GR606 GR609	Vaccine Program	• See Chapter 5 for the description of this report
12.0	Create Other Reports	BR616 BR617 GR605 GR606 GR609	Vaccine Program	• See Chapter 5 for the nomenclature and description of these “other” reports: o Patient Detailed List Report o Vaccine Accountability Reports: (i.e. inventory tracking) o Quality Assurance Reports (Data Completeness Reports, Accuracy Reports, Timeliness Reports) o Pockets of Need Report o Provider Coverage Report

Chapter 3: Eligibility Screening Scenarios

This chapter contains eligibility screening scenarios for a Patient (for a process description refer to Chapter 2, Table 1, step 1.0 and Table 8-B1, steps 1.2, 1.3, and 1.4). Materials are organized in two tables: Table 2 is a decision table which contains the screening logic for 26 scenarios; Table 3 contains explanatory notes for each scenario. These scenarios cover all possible combinations of conditions for the VFC Program eligibility and Private coverage; specific conditions and scenarios for the Grantee Program eligibility should be developed locally by each Grantee. The Vaccine Eligibility (i.e., determination if needed Vaccines are eligible to be administered under the VFC or Grantee Program) is not reflected in these scenarios - it is assumed that needed Vaccines are eligible for these programs. The actual recording/reporting of the eligibility information for a Patient takes place later in the process, after the Vaccination Event eligibility is validated (to make sure that needed Vaccine Eligibility is matching Patient Eligibility – see Table 1, steps 3.0 and 5.0).

Decision table 2- together with business rules described in Chapter 4 - can support a variety of eligibility screening processes. In order to support a particular process sequence, presented in Appendix B, this table 2 has been partitioned in three tables: 9-B2, 11-B4, and 13-B6. Top rows of these tables contain cross-references that allow the reader to trace the logic for each scenario.

Table 2. Decision Table: Screening a Patient for VFC and Grantee Vaccine Program Eligibilities and Private Coverage.

SCENARIOS Numbers	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**
Partitioned Table 9-B2 (step 1.2) Reference	1	4	4	4	4	4	2	3	3	5	6	6	6	6	6	6	8	7	7	7	7	7	7	7	na	na
Partitioned Table 11-B4 (step 1.3) Reference	na	9	9	6	13	12	na	9	9	na	10	11	13	12	7	8	na	1	2	2	3	4	4	5	na	na
Partitioned Table 13-B6 (step 1.4) Reference	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	3	1	na	3	1	na	1	2,3
CONDITIONS																										
Reached 19th birthday: Y/N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	Y
Medicaid: Y/N	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	-	-
American Indian or Alaska Native: Y/N	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	N	N	N	N	-	-
Patient has private health insurance: Y/N	N	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	-	-
Private insurance covers needed Vaccine: Y/N	–	Y	Y	N	Y	Y	-	Y	Y	-	Y	Y	Y	Y	N	N	-	N	N	N	Y	Y	Y	Y	-	-
Private insurance Vaccine cap reached: Y/N	–	Y	Y	-	N	N	-	Y	Y	-	Y	Y	N	N	-	-	-	-	-	-	Y	Y	Y	N	-	-
Patient at Provider Organization (Facility) Type: (R)HC or (F)QHC or (D)elegated Authority	–	N	Y	-	N	N	-	N	Y	-	Y	N	-	-	Y	N	-	Y	N	N	Y	N	N	-	-	-
Choose to use VFC: Y/N	–	-	-	-	Y	N	-	-	-	-	-	-	Y	N	-	-	-	-	-	-	-	-	-	-	-	-
VFC & Underinsured , or VFC & Underinsured Select, or Universal, or Universal Select State, or Other – meaning not VFC Only: Y/N	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	N	Y	-	N	Y	-	-	-
Meets Grantee Program eligibility criteria: Y/N	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Y	-	-	Y	-	Y	N
ACTIONS																										
General VFC Eligibility Status																										
1. Record Patient VFC eligible	X	X	X	X	X		X	X	X	X	X	X	X		X	X	X	X			X					
2. Record Patient VFC ineligible (or Private coverage)						X								X					X	X		X	X	X	X	X
VFC Eligibility Criteria																										
3. Check “Medicaid”	X	X	X	X	X		X	X	X																	
4. Check “American Indian or Alaska Native”							X	X	X	X	X	X	X		X	X										
5. Check “Uninsured”										X							X									
6. Check “Underinsured”											X				X			X			X					
General Grantee (State) Eligibility Status																										
7. Record Patient Grantee Program eligible																				X			X		X	
8. Record Patient Grantee Program ineligible																			X			X				X

Abbreviations: “Y” = Yes, “N” = No, dash “-“means that it does not matter for the outcome of a scenario if it is “Y” or “N”, “X” points to actions that should be taken for this scenario, and blank indicates actions that are not applicable for this scenario.

Table 3. Scenario Notes for Decision Table 2.

SC	Scenario Notes	BRs GRs
1.	Patient has Medicaid and does not meet any other VFC eligibility criteria.	
2.	In this scenario, a Patient has Medicaid and private insurance. Private insurance has reached its Vaccine cap, but the Patient is not at a FQHC, RHC, or Delegated Authority Provider Organization. Therefore, Patient's eligibility for VFC is due to Medicaid. VFC Program should pay for the vaccination and Medicaid should pay for the administration fee.	BR605
3.	A Patient has Medicaid and also meets the criteria for underinsured (because Vaccine cap has been reached). However, because Medicaid is considered public insurance, only the Medicaid eligibility category is recorded (a Patient with Medicaid cannot be marked "Underinsured").	BR605
4.	A Patient has Medicaid and also meets the criteria for underinsured (because insurance does not cover the needed Vaccine). However, because Medicaid is considered public insurance, only the Medicaid eligibility category is recorded (a Patient with Medicaid cannot be marked "Underinsured").	BR605
5.	Patient has dual coverage – both Medicaid and private insurance. Provider chooses to use the Patient's VFC eligibility.	BR607 BR608 BR609 BR610
6.	Patient has dual coverage – both Medicaid and private insurance. Provider chooses to use the private insurance. Therefore, Patient is documented as VFC Ineligible (or Private coverage), although in fact the Patient is VFC eligible. The reason for this is that single eligibility/coverage status should be assigned to a Patient (BR608). Also, the reimbursement to the Provider may be greater through the private payer.	BR608 BR607 BR609 BR610
7.	Patient is American Indian or Alaska Native (AI/AN) and also has Medicaid.	BR614 BR615
8.	Patient is AI/AN and has Medicaid. Patient also has private insurance which has reached its cap, but Patient is not at a FQHC, RHC, or Delegated Authority Provider Organization (so they do not meet the criteria for Underinsured).	BR605 BR614 BR615
9.	Patient is AI/AN and has Medicaid. Patient also has private insurance which has reached its cap and they are at a FQHC, RHC, or Delegated Authority Provider Organization. But because Medicaid is considered public insurance, Patient will not be documented as Underinsured – even though Patient otherwise meet the criteria for Underinsured.	BR605 BR614 BR615
10.	Patient is AI/AN and is also Uninsured.	BR614 BR615

SC	Scenario Notes	BRs GRs
11.	Patient is AI/AN, has private insurance which has reached its cap and they are at a FQHC, RHC, or Delegated Authority Provider Organization. They will be documented as both AI/AN and "Underinsured".	BR605 BR614 BR615
12.	Patient is AI/AN, has private insurance which has reached its cap but Patient is not at a FQHC, RHC, or Delegated Authority Provider Organization. Patient will be documented as AI/AN.	BR605 BR614 BR615
13.	Patient is AI/AN and also has private insurance coverage for the needed Vaccine. In this scenario, the Provider chooses to use the Patient's VFC eligibility.	BR607 BR609 BR614 BR615
14.	Patient is AI/AN and also has private insurance coverage for the needed Vaccine. In this scenario, the Provider chooses to use the Patient's private insurance. Patient is therefore documented as Ineligible for VFC, although in fact the Patient is eligible.	BR607 BR609 BR614 BR615
15.	Patient is AI/AN and also meets the criteria for Underinsured. The Provider should document both eligibility criteria.	BR614 BR615
16.	Patient is AI/AN and does not meet the criteria for Underinsured. The Provider should document Patient as AI/AN.	BR605 BR614 BR615
17.	Patient does not have Medicaid, is not AI/AN, and does not have a private health insurance. Therefore, Patient should be documented as Uninsured (VFC eligible).	BR606
18.	Patient's private insurance does not cover the Vaccine needed and Patient is at a qualifying Provider Organization. Patient has no other basis for VFC eligibility, therefore Patient is VFC eligible due to being Underinsured.	BR605
19.	Patient's private insurance does not cover the Vaccine needed, but Patient is not at a qualifying Provider Organization (not at FQHC, RHC, or Delegated Authority Provider Organization). Therefore Patient is not eligible for VFC for the specific Vaccine needed. Also, Patient is in a state that has VFC Only purchase policy and, therefore, Patient is ineligible for a Grantee Vaccine Program.	GR607 BR605
20.	Patient's private insurance does not cover the Vaccine needed and Patient is not at a qualifying Provider (not at FQHC, RHC, or Delegated Authority Provider Organization). Therefore Patient is not eligible for VFC for the specific Vaccine needed. A Patient is in a state that has a Vaccine purchase policy in addition to VFC (VFC & Underinsured, or VFC & Underinsured Select, or Universal, or Universal Select State, or Other – meaning not VFC Only) and meets a Grantee Vaccine Program eligibility criteria. Therefore, Patient is eligible for the Grantee Vaccine Program.	
21.	Patient's private insurance does cover the Vaccine needed but Patient's Vaccine cap has	BR605

SC	Scenario Notes	BRs GRs
	been reached. Patient meets no other criteria for VFC eligibility, and is at a qualifying Provider Organization (FQHC, RHC, or Delegated Authority Provider Organization). Therefore Patient is VFC eligible due to being "Underinsured."	
22.	Patient's private insurance does cover the Vaccine needed, but the Vaccine cap has been reached. Patient is not at a qualifying Provider Organization (not at FQHC, RHC, or Delegated Authority Provider Organization) and, therefore, Patient is not eligible for VFC for the specific Vaccine needed. Also, Patient is not in a VFC Only state and, therefore, is ineligible for a Grantee Vaccine Program.	GR607 BR605
23.	Patient's private insurance does cover the Vaccine needed, but the Vaccine cap has been reached. Patient is not at a qualifying Provider Organization and therefore Patient is not eligible for VFC for the specific Vaccine needed. A Patient is in a State that has a Vaccine purchase policy in addition to VFC (VFC & Underinsured, or VFC & Underinsured Select, or Universal, or Universal Select State, or Other – meaning not VFC Only) and meets Grantee Program eligibility criteria. Therefore, Patient is eligible for the Grantee Program.	BR605
24.	Patient has private insurance which covers the specific Vaccine being evaluated (although it may not cover other needed Vaccines).	BR614 BR615
25.	Patient reached the 19th birthday and, therefore, is not eligible for the VFC Program. Patient meets Grantee Vaccine Program criteria, and, therefore, is eligible for the Grantee Vaccine Program.	BR601
26.	Patient reached the 19th birthday and, therefore, is not eligible for the VFC Program. Patient does not meet Grantee Vaccine Program criteria, and, therefore, is not eligible for the Grantee Vaccine Program.	BR601

Chapter 4: Business Rules

This chapter contains process-related business rules. Business rules represent specific requirements regarding how the business should operate based on the laws, policies, regulations, and chosen business/operational style.

Business rules are arranged in Table 4 in the following order:

- BR601: Age Criteria
- BR602: What information is needed for Patient's eligibility screening
- BR603: How often to screen
- BR604: Patient Eligibility screening sequence
- BR605: Underinsured vs. Medicaid and Provider Organization type
- BR606: Uninsured vs. Medicaid
- BR607: Hierarchy of choices for Patient's eligibility/coverage
- BR608: Single eligibility/coverage status
- BR609: How to deal with dual-coverage
- BR610: Private insurance - dealing with unknown
- BR611: What format to use
- BR612: When to record
- BR613: How often to report Patient's eligibility
- BR614: What information to report (minimum set)
- BR615: What information to report (expanded set)
- BR616: How to count VFC eligible Patients for the Vaccination Encounter (visit)
- BR617: How to count VFC eligible Patients for a year

Table 4. Business Rules

	BR ID	Principle/Business Rule Statement	Remarks
1	BR601	**Age Criteria** The Patient has to fit the age criteria of the Vaccine Program.	• E.g., for the VFC Program a Patient has to be less than 19 years old

2	BR602	**What information is needed for Patient's eligibility screening**
		
		Information needed for determination of Patient's eligibilities include:
		• Vaccination Encounter (screening for full VFC Program eligibility):
		  o Immunization history (if child needs vaccination)
		  o Patient Date of Birth (DOB)
		  o Patient health insurance plan (Medicaid and/or private insurance)
		  o AI/AN status
		  o Grantee Vaccine Programs available
		  o Facility Type (see VFC Enrollment entity in the Domain Model – Appendix A)
		• Vaccination Event (screening for Conditional VFC Program eligibility, dual coverage, and Grantee Program eligibility):
		  o Outcome of the Vaccination encounter screening
		  o Vaccine needed
		  o Vaccine Eligibility
			• Screening for the Vaccination Event means screening for a specific Vaccine - this is what changes compare to screening for the Vaccination Encounter
			  o Vaccination Encounter (visit) may include many Vaccination Events; see Appendix A for definitions.
			• Facility Type indicates the level of services covered by the VFC Program. Accordingly, for the purposes of screening for and documenting eligibilities, the type of Provider Organization should be recorded at the specific site/facility. See Appendix A, Table 6-A1, VFC Enrollment and Provider Organization entities: some IIS set up a Provider Organization for every site/facility; for the purposes of this project a site/facility has the same definition as a Provider Organization.
			• See Appendix A, pp. 65, 74-75 for definitions of Patient Full and Conditional VFC Program eligibility.

	BR ID	Principle/Business Rule Statement	Remarks
3	BR603	**How often to screen** • Screening the Patient for full VFC Program eligibility (no private coverage and Medicaid, AI/AN, Uninsured) - should be done for each Vaccination Encounter. • Screening the Patient, who has private health insurance, for conditional VFC Program eligibility (Underinsured), and dual coverage should be done for each Vaccination Event • Screening for the Grantee Vaccine Program eligibility the Patient who is o VFC ineligible and does not have private insurance coverage for a Vaccine, or o over 19 years old should be done once per Vaccination Event or once per Vaccination Encounter (driven by the Grantee Vaccine Program rules)	• See BR613 for a guideline on how often to report Patient's eligibility - once per Vaccination Event (dose administered). • According to VFC guidelines, screening must be done once per Vaccination Encounter. • Conditional VFC Program eligibility – Patient is eligible for a specific Vaccine (applicable for Underinsured category). o See Appendix A, pp. 65, 74-75 for definitions of Patient Full and Conditional VFC Program eligibility. • Dual coverage – Patient has private insurance which covers the Vaccine and also has either Medicaid or is AI/AN. o In the dual-coverage situation, see BR604 and BR609 for a decision-making logic on whether to use public Vaccine or private Vaccine • Example. A Patient could be VFC eligible for the ACIP recommended Vaccine, but VFC ineligible for the travel Vaccine (e.g. typhoid). However, the Patient may be eligible for the travel Vaccine via a Grantee Vaccine Program. • Screening data must be documented every time the screening process is conducted. • The screening documentation may be outside of the IIS. • The VFC requirement is that all children must be screened. • According to VFC guidelines, initial screening must be documented and as long as the Patient's eligibility status doesn't change, verbal screening at subsequent encounters is sufficient. • Record has to reflect screening for the date of vaccination. • Patient's VFC eligibility should always be documented, even if the Grantee Vaccine Program eligibility will apply instead (i.e., VFC-ineligible). • In states with a universal purchase policy, screening for VFC eligibility is still required, so that Grantee can determine which Patients were not VFC-eligible. This allows the Grantee Vaccine Program to use aggregated eligibility data to reconcile balance sheets for funding sources.

	BR ID	Principle/Business Rule Statement	Remarks
4	BR604	**Patient Eligibility screening sequence** The sequence of Vaccine Program eligibility screenings for Patient under age of 19 should be: • Screening for full VFC Program eligibility (for all VFC Vaccines) • Screening for conditional eligibility and dual-coverage (for specific Vaccine) – if necessary • Screening for Grantee Program eligibility – if applicable	• There is a common practice among many private Providers (who can't administer a Vaccine to underinsured children and who see primarily privately insured Patients) to screen for private insurance coverage, and, if Patient has private insurance, record Patient as VFC Ineligible, and not conduct a further VFC screening for Medicaid and AI/AN. While this is an acceptable practice, the best practice would be to screen Patient for both – private insurance coverage and VFC eligibility – and then, in dual-coverage situations, select (under certain guidelines) what coverage/eligibility to use. o See Appendix B for a detailed discussion of a screening sequence described in this business rule BR604. • For a given Vaccination Encounter, if a Patient has been found to be "fully" eligible for all VFC Program Vaccines (by virtue of having Medicaid, being AI/AN or being totally uninsured), then there is no need to rescreen the Patient for each Vaccine needed. • However, Patients with private insurance need an additional screening for each Vaccine to determine if the Patient's private insurance covers the Vaccine. • Some Provider Organizations add VFC eligibility screening to the insurance screening workflow, which is conducted before the Patient is seen. When a Patient's insurance status changes, so does the VFC eligibility status. The Provider still gets to choose what the Patient's VFC eligibility is at the dose administered level, but the value is defaulted to whatever value they chose during the insurance screening stage. • Screening for Grantee Program eligibility is necessary only when Patient is not eligible for the VFC Program and Vaccine is not covered by the Patient's insurance. • For private Provider Organizations that are not enrolled in VFC Program the screening sequence includes screening for a private coverage and for Grantee Program eligibility.
5	BR605	**Underinsured vs. Medicaid and Provider Organization type** If the Patient:	• FQHC and RHC Provider Organizations can delegate authority to non-FQHC and non-RHC Provider Organizations. • Delegation of authority is a contractual agreement defined by the FQHC/RHC and the Grantee.

	BR ID	Principle/Business Rule Statement	Remarks
		• does not have Medicaid, and • has private insurance, and • private insurance coverage does not include Vaccines, or • private insurance covers only selected Vaccines, or • private insurance cap for Vaccine coverage has been reached, and • is receiving care at a FQHC, RHC, or Delegated Authority Provider Organization then the Patient is eligible for VFC ("Underinsured") ***Therefore, Patient cannot be Underinsured if he/she has Medicaid.***	• Also, the Patient cannot be classified as Uninsured if he/she has Medicaid (see BR606). • Underinsured does not include the Patient being unable to pay the co-pay or deductible.
6	BR606	**Uninsured vs. Medicaid** If the Patient does not have Medicaid and any private insurance, then the Patient is eligible for VFC ("Uninsured") ***Therefore, Patient cannot be Uninsured if he/she has Medicaid.***	• Private insurance is any insurance other than Medicaid. o Some state insurance plans (e.g., Child Health Plan and Child Health Plan Plus) are expansions of Medicaid and some (e.g., in Michigan) are considered private. • Medicaid is the payer of last resort. Medicaid is always secondary insurance to private insurance.
7	BR607	**Hierarchy of choices for Patient's eligibility/coverage** In general, the hierarchy of eligibility/coverage choices for the Patient under age of 19 years old	• If a Patient has a private insurance and Medicaid (dual-coverage), the Patient can receive either VFC Vaccine or private insurance Vaccine at the Providers/Patients discretion. If the child receives VFC Vaccine, the Provider Organization bills Medicaid for the regional administration fee, Medicaid pays the fee to the Provider Organization and then bills the private insurance company to recoup the fee to the

	BR ID	Principle/Business Rule Statement	Remarks

		should be:
		• Private Insurance coverage
		• VFC Program eligibility (for all program Vaccines or for a specific Vaccine)
		• Grantee Program eligibility
		
		Accordingly, in general,
		• Private insurance coverage should be selected over VFC Program eligibility and Grantee Vaccine Program eligibility.
		• VFC Program eligibility should be selected over Grantee Vaccine Program eligibility.
			extent that is financially feasible for the Medicaid agency to do so.
			• When a Patient is eligible for publicly-purchased Vaccines (VFC or/and Grantee Program) and has private insurance coverage for immunizations (i.e., a dual-coverage situation), the Provider Organization should also take under consideration which option results in the least out of pocket costs for the Patient (i.e., use of public or private Vaccine)
			  o Dual-coverage: VFC eligible (Medicaid and/or AI/AN) and Private insurance → the selection should be made by a Provider based on the best financial interest of a Patient.
			• Use of the private insurance coverage leaves more public funds available for Patients without private insurance.
			• There is no reason to use state funds instead of VFC funds.
			  o State funds are limited and should be used sparingly, with the focus on Patients who are not eligible for other vaccination choices.
			• There are certain types of state defined incidents (e.g. pandemics) in which this does not apply. In a public health emergency eligibilities might not be assessed.
			• See BR604 for the sequence of screening for eligibilities and coverage.

8	BR608	**Single eligibility/coverage status** Single eligibility/coverage status should be assigned to a Patient for every Vaccination Event (dose administered): • VFC Program eligible • Grantee Program eligible • Private Coverage (Private insurance or out-of-pocket pay)	• There is no need to differentiate between Private insurance coverage and Out-of-pocket pay: it is sufficient for IIS/Vaccine Program to know that Patient was vaccinated from the Provider Organization's privately purchased Vaccine inventory (i.e., VFC ineligible). • For VFC Program eligible and Grantee Program eligible Patients Vaccine should be administered from the publicly-purchased inventory. For Patients with Private Coverage Vaccine should be administered from the privately-purchased inventory. See Fig. 4 - Simplified process diagram. • See also BR613.
9	BR609	**How to deal with dual-coverage** For a VFC eligible Patient who has private	• This describes the scenarios 5, 13 and 6, 14 in the decision table 2 and scenarios 12, 13 in the decision table 11-B4. • VFC recommendation: Medicaid is the payer of last resort. Medicaid should always

	BR ID	Principle/Business Rule Statement	Remarks
		insurance and Medicaid as a secondary insurance (i.e., a dual-coverage situation), the Provider Organization has two options: • Indicate the Patient has private insurance coverage and not VFC eligible, and use private Vaccine • Indicate that Patient is VFC eligible and use public Vaccine According with BR607, the first option should be selected.	be a secondary insurance to private insurance.
10	BR610	**Private insurance - dealing with unknown** • If at the time of Vaccination Encounter details of private insurance coverage are unknown (i.e. if cap has been reached, is Vaccine covered or not), Provider Organization should assume that private insurance covers needed Vaccines. • If later this assumption turns out to be wrong (e.g., claim has been rejected), then Provider Organization has to change/update Patient Eligibility status in IIS to reflect reality and also deal with Vaccine borrowing requirements.	• Private insurance coverage/cap in many cases is not known to the Provider Organization until after a submission to the private insurance. The Provider Organization does not know if private insurance actually pays for a Vaccine until months after the administration of the Vaccine. • Vaccine borrowing - VFC Operations manual (See [2.8] VFC: Frequently Asked Questions): If the primary insurance is billed first and the insurance denies the claim, the Provider could replace the private stock Vaccine used with VFC Vaccine and then bill the maximum regional charge for the Vaccine administration fee to Medicaid. The Medicaid agency should bypass their cost avoidance edit allowing the claim to be considered for payment. o See also general recommendation GR608 for a discussion of borrowing. • The Provider Organization must not change information about which specific Vaccine (lot #) was given. • It is a challenge to get a Provider Organization to go back into Patient's record and IIS to change Patient VFC eligibility status. • When Provider Organization is not FQHC, RHC, or an entity with Delegated Authority, and the Provider Organization learns later that the Patient is underinsured (i.e. claim rejected two months later), the Provider Organization should not change the information in IIS because the VFC Vaccine cannot be used in any case (see SC2 in the partitioned Decision Table 11-B4).

	BR ID	Principle/Business Rule Statement	Remarks
11	BR611	**What format to use** Screening data should be documented/ recorded electronically.	• VFC guidelines do not require a specific form. • This applies to all screening not only the initial screening. • There is no requirement for Patient signature for VFC screening. • Provider does not need to keep physical copy of the form for audits (just some evidence of eligibility screening actually needed). According to VFC guidelines, initial screening must be documented and as long as the Patient's eligibility status doesn't change, verbal screening at subsequent encounters is sufficient.
12	BR612	**When to record** Record Vaccination Event after the Vaccine has been administered.	• Document the Vaccination Event only after the vaccination has been administered , so that the data reflects what actually happened (e.g., Vaccine could be declined by the Patient/parent). • IIS could have functionality in place to allow Provider Organization to verify that Vaccine (dose) about to be given is correct, augmenting the post-administration validation functionality.

13	BR613	**How often to report Patient's eligibility**
		
		Provider Organization should report Patient's eligibility to IIS for every Vaccination Event (dose administered)
			• On the same date (encounter), Patient can be eligible for one VFC Vaccine and not eligible for another VFC Vaccine. Associating Patient Eligibility with the Vaccination Event (dose administered) provides the most complete and detailed information.
			  o Scenario: Patient is underinsured. Insurance covers one Vaccine, but does not cover another Vaccine.
			  o Scenario: Patient has dual-coverage, e.g., Medicaid and private health insurance. Provider chooses to administer one Vaccine based on the Patient's eligibility to Medicaid and another Vaccine – based on the private coverage.
			  o Scenario: Patient is VFC eligible for one Vaccine and Grantee eligible for another Vaccine (e.g., for non-VFC Vaccine)
			• Situations when Patient is VFC eligible for one Vaccine and has insurance coverage for another Vaccine on the same visit (e.g., insured for one Vaccine and underinsured for another Vaccine) often happen due to delays with outcomes of the insurance claims. This provides for situations when Patient who initially was

	BR ID	Principle/Business Rule Statement	Remarks
			perceived as having private insurance coverage for a Vaccine, actually does not have the coverage. • See BR616 for guidance on how to assign Patient Eligibility for a Vaccination Encounter when the Patient meets various eligibility criteria for Vaccines administered during the encounter, i.e. different eligibility status for Vaccination Events occurring during one Vaccination Encounter (visit).

14	BR614	**What information to report (minimum set)**
		
		<u>Minimum set</u> of Patient's eligibility data that Provider Organization should report to IIS includes a single data item/element from the following list:
		• Medicaid
		• AI/AN
		• Uninsured
		• Underinsured (FQHC/RHC/Provider Organizations with Delegated Authority only)
		• Grantee eligible (various degree of granularity, Grantee-specific)
		• Private coverage (Private insurance or out-of pocket pay) = VFC Ineligible
			• All data items/elements from this list could be implemented as a drop-down list that allows selection of a single item or a set of radio-buttons, where only one radio-button can be selected at a time.
			• VFC Eligibility Status can be derived on the IIS side based on the reported data item/element, e.g., if AI/AN reported, then Patient would be considered VFC eligible, and if Private coverage is reported, then Patient will be considered VFC ineligible.
			  • When a Patient meets more than one eligibility criteria, the hierarchy of eligibility categories is:
			  o Medicaid
			  o AI/AN
			  o Uninsured
			  o Underinsured
			  Example: A Patient is AI/AN, does not have Medicaid, does not have private health insurance. Then the Patient's eligibility should be reported as AI/AN (AI/AN is higher in the hierarchy than Uninsured)
			  • Sole private insurance coverage is reported as Patient being VFC ineligible. It is not necessary to differentiate between private insurance coverage and out-of-pocket payment. It is only necessary to know that Vaccine is not coming from the publicly-purchased Vaccine inventory.
			  • Bottom-line answer (e.g. eligibility status) must be documented, not all the answers that led to the final choice of eligibility.
			  • See Appendix C: HL7 considerations.

	BR ID	Principle/Business Rule Statement	Remarks
15	BR615	**What information to report (expanded set – best practice)** The best practice set of Patient's eligibility data that Provider Organization should report to IIS includes an applicable valid combination of data items/elements from the following list: • Medicaid • AI/AN • Uninsured • Underinsured (FQHC/RHC/Delegated Authority Provider Organizations only) • Grantee eligible (various degree of granularity, Grantee-specific) • Private coverage (Private insurance or out-of pocket pay) = VFC Ineligible	• Data items/elements from the bulleted list are NOT mutually exclusive. For example, both Medicaid and AI/AN can be reported. Implementation could include a set of check boxes to allow simultaneous selection of multiple items. Example: Patient is AI/AN, does not have Medicaid, does not have private health insurance. Then the Patient's eligibility should be reported as AI/AN and Uninsured. • Not all combinations of data items/elements are valid and should be allowed, e.g., Patient can't be reported as Medicaid and Uninsured (see BR606). The following lists of valid and invalid combinations are based on the work group's recommendation that ***Patient's eligibility/coverage status should be deduced from the reported data items/elements***. Note that the interpretation of the recorded/reported combinations of eligibility data items is based on the scenarios' logic presented in the decision table 2. o Valid combinations to report include the following: ✓ Medicaid and AI/AN (should be interpreted as VFC eligible) ✓ AI/AN and Uninsured (should be interpreted as VFC eligible) ✓ AI/AN and Underinsured (should be interpreted as VFC eligible) ✓ Private coverage (or VFC Ineligible) and any VFC-related data items, such as Medicaid, AI/AN, Uninsured, Underinsured. Private Coverage takes precedence and should be interpreted as Private Coverage (or VFC Ineligible); in this case the Private insurance coverage has been selected for a Patient who is also VFC-eligible: see Table 2, scenarios 6 and 14. ✓ Private coverage (or VFC Ineligible) and Grantee eligible – Grantee eligibility takes precedence and reporting should be interpreted as Grantee eligible (in this case it actually means that the Patient is VFC Ineligible and Grantee eligible, see Table 2, scenarios 20, 23, and 25) o Invalid combinations to report include the following: ✓ Medicaid and Uninsured (see BR606) ✓ Medicaid and Underinsured (see BR605) ✓ Uninsured and Underinsured ✓ Grantee eligible and any VFC-related data item, such as Medicaid, AI/AN, Uninsured, Underinsured ✓ Any combination of three data items of different types: 1)VFC-related data

	BR ID	Principle/Business Rule Statement	Remarks
			item, such as Medicaid, AI/AN, Uninsured, Underinsured, and 2) Private coverage (or VFC Ineligible) and 3) Grantee eligible • Reporting of other items, e.g. VFC eligibility reasons and VFC ineligibility reasons should be left for every Grantee to decide. The work group decided not to include VFC eligibility/ineligibility reasons into best practices (benefits of including these data items were not apparent). Eligibility/Ineligibility reasons include (see partitioned decision tables in the appendix B and Fig. 10-B3): ➢ Eligibility Reason (relevant for Underinsured Patients) ✓ Insurance Vaccine cap reached ✓ Insurance does not cover Vaccine (a specific Vaccine or any Vaccine) ➢ Ineligibility Reason ✓ Not at appropriate type of Provider Organization (Underinsured, not at FQHC/RHC or Delegated Authority Provider Organization) ✓ Vaccine covered by private insurance (sole coverage) ✓ Choose to use private insurance (dual coverage) • In dual-coverage situations, when private coverage is selected, it is not necessary to report Patient's Medicaid and AI/AN (VFC Eligibility criteria). It is not required by the VFC Program. However, reporting of this additional information can be useful for statistical purposes of the Grantee Programs.
16	BR616	**How to count VFC eligible Patients for the Vaccination Encounter (visit)** If Patient is VFC eligible for at least one Vaccine during the Vaccination Encounter, he/she should be counted for the purposes of the Provider Profile report as VFC eligible for that Vaccination Encounter.	• This business rule is applicable to establish a Patient's eligibility for a year for purposes of the Provider Profile report – see BR617 and Chapter 5. • Situations when Patient is VFC eligible for one Vaccine and has insurance coverage for another Vaccine on the same visit (e.g., insured for one Vaccine and underinsured for another Vaccine) often happen due to delays with outcomes of the insurance claims (this could also represent a real difference between Vaccine types, i.e., Vaccine eligibilities for different programs). This may result in situations in which a child who initially was perceived as having private insurance coverage for a

	BR ID	Principle/Business Rule Statement	Remarks
			Vaccine, actually does not have the coverage. See BR610. • Requirements for the Provider Organization Profile report could be changed in the future and that would require the appropriate modification of the business rule.
17	BR617	**How to count VFC eligible Patients for a year** If Patient is VFC eligible at the last immunization encounter of the year, he/she should be counted for the purposes of the Provider Profile report as VFC eligible for that year.	• See Chapter 5 for a description of the Provider Organization Profile Report.

Chapter 5: IIS Reports to Support Needs of VFC/Grantee Immunization Programs and Provider Organizations

This chapter contains descriptions of recommended reports that IIS produces in order to support management of Vaccines and Patients by VFC/Grantee Programs, as well as Provider Organizations.

Provider Organization Profile Report

Overview: The Provider Organization Profile Report is a report required by CDC once per year at the time of Provider Organization enrollment or re-enrollment. The report is also referred to as a "Provider Profile." The report is generated by a Provider Organization (or by the IIS on behalf of the Provider Organization) at the time of enrollment or re-enrollment in the VFC Program. The report is based on actual eligibility data from a stated time period. The Provider Organization (or Grantee Vaccine Program, on behalf of the Provider Organization) uses the Provider Organization Profile Report to generate a projection of the number of Vaccines that will be administered by the Provider Organization for the following year. The Grantee Vaccine Program aggregates Provider Organization Profile Reports to be used with other information to estimate the Grantee Vaccine Program's annual need for federally-funded Vaccines and monthly ordering patterns.

- Purpose of Report: To estimate the number of Vaccines that will be administered by the Provider Organization during the following year.
- Entity that generates report: Provider Organization, or the IIS or Grantee Vaccine Program on behalf of the Provider Organization.
- When: Annually (required by the VFC Program) at the time of enrollment or re-enrollment in the VFC Program; can be generated semi-annually, quarterly, or as often as once per month.
- Key Elements of Report: Number of VFC Eligible Patients for the Provider Organization in the categories identified in BR615 (best practice) or BR614 (minimum) in specified age groups (<1, 1–2, 3–6 and 7–12 years are minimum age groups) during the specified time period; VFC Enrollment—Facility Type (e.g., Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC), or Delegated Authority Provider Organization).
- Key Considerations:
    - BR616: Provides that if Patient is VFC eligible for at least one Vaccine during the Vaccination Encounter, (s)he should be counted for the purposes of the Provider Profile report as VFC eligible for that Vaccination Encounter.
    - BR617: Provides rules for how to count the number of VFC Eligible Patients per year for purposes of the Provider Profile Report. {For example, based on the Patient's eligibility on the last (or first) date of service (Vaccination Encounter), or based on the fact that child was eligible at least once during a year}.
    - Adjustments to the actual data in the Provider Organization Profile Report to make estimates of the number of Vaccines that will be administered by the Provider Organization during the following year could include:
        - Change in number of Providers included in the Provider Organization.
        - Change in population served.

Provider Organization Profile Report (Aggregated)
Overview: The Provider Organization Profile Report (Aggregated) is the aggregated total of the Provider Organization Profile Reports used with other information by the Grantee Vaccine Program in the Population Estimate Survey to CDC.

- Purpose of Report: To be used with other information to estimate the Grantee Vaccine Program's annual need for federally-funded Vaccine and monthly ordering patterns.
- Entity that generates report: Grantee Vaccine Program.
- When: Annually.
- Key Elements of Report: Aggregated number of VFC Eligible Patients for all Provider Organizations enrolled in the VFC Program in the Grantee Jurisdiction in the categories identified in BR614 (minimum) in specified age groups (<1, 1–2, 3–6 and 7–12 years) during the specified time period.
- Key Considerations: Provider Organization Profile Report totals are aggregated for purposes of this report.

Doses Administered Report – Provider Organization
Overview: The Doses Administered Report is a breakdown of the doses administered by a particular Provider Organization by a specific criteria.

- Purpose of Report: To be used to assist with Vaccine accountability and determining appropriate ordering patterns. See Vaccine Accountability section below for more detail.
- When: Best Practice-Monthly, Good Practice-At the time an order is placed by the Provider Organization.
- Key Elements of Report: Number of doses of Vaccine administered by the Provider Organizations enrolled in the VFC Program in the Grantee Jurisdiction by eligibility categories by Vaccine Type during a specified time period.
    - Secondary report could be eligibility by specified age groups (<1, 1-2, 3-6 and 7-12 years). Note that these are the minimum age groups; 13-18 years and other age groups would be optional.
- Key Considerations: Aggregated doses administered report can take on several formats dependent on the desired output. Any of these reports could also have additional filters to narrow report down by other criteria such as funding source, Patient or Vaccine eligibilities.

Other Reports
Specific detail is not included for the following reports because it was determined there were too many variances among Grantees to outline and all reports are not strictly used for just the VFC Program. However a broad description of such reports was agreed to be important enough to include. Each IIS will need to decide if/how to implement these reports as necessary.

Patient Detailed List Reports
IIS should be able to identify any specific Patient or series of Patients that may have received a Vaccine incorrectly/inadvertently or are incorporated into an aggregated total.

- List of Patients with a specific insurance source or program eligibility (VFC) indicated per age range. This could identify list of Patients that may have aged out of a specific eligibility.

- List of Patients that may have received a non-eligible Vaccine per their Patient Eligibility (i.e., received VFC Vaccine if fully insured or vice versa).
- List of Patients missing immunizations.
- List of Patients that may be included in a Vaccine recall.
- List of Patients that may have received a dose of Vaccine off label (too early by age or interval) or incorrect Vaccine causing it to be an invalid dose.
- List of Patients that shows the detailed version of an aggregate total to help identify if there were inappropriate Patients marked in that total.

Vaccine Accountability Reports (inventory tracking)
Vaccine accountability reports should help a Provider Organization and/or the Grantee (IIS) to summarize and identify if Vaccine given to a Provider Organization is administered as required under the program guidelines (VFC, Grantee, etc.).

- Compare how many Vaccines were administered, wasted, received, expired, etc. for each Vaccine type. Also shows beginning Vaccine inventory for a time frame, ending inventory for that time period, and how many doses are unaccounted for.
- Compare number of doses administered vs. doses distributed to a Provider in a given timeframe. This report can be used to identify if Vaccine usage and ordering is within appropriate limits to avoid wastage.
- Report to identify Providers with high volume of Vaccine (in excess) so that redistribution can occur to avoid wastage.

Quality Assurance Reports
Specific data quality reports can be created to help identify data entry errors, inappropriate documentation of Vaccines, identify where data are incomplete, inaccurate, or not timely. All these examples can help to improve the accuracy of doses administered and Vaccine accountability promoting more accurate reporting to program (VFC, etc.).

Data Completeness Reports
This report can look at several data elements such as date of birth, Patient/Vaccine VFC eligibility, race, ethnicity, and Vaccine full documentation of dose administered, including manufacturer and lot number. If these fields are not completed by Provider Organization then could prove to be a gap in reporting.

Accuracy Reports
In this context we mean accuracy of Vaccine administration. Checks to see how many doses were administered before/after a specific age range for specific types of Vaccines (e.g., DTaP before 6 weeks old) or by total number of doses in a series before a certain age range. Reports can also be developed to identify if Patients in IIS were marked with doses administered before DOB, after the expiration date of the Vaccine, or a date of administration after the encounter date. Although, steps can be taken to prevent some of these errors from being entered into the system in the first place (user interface edit checks, training of users, etc.), it is still important to check periodically if data were submitted in an inappropriate way.

Timeliness Reports
Can determine if administered doses are documented timely or not to help determine how accurate reports are when generated. Timeliness can be defined as a time period between dose administered and dose reported.

Pockets of Need Report
This report can be used to identify areas of low immunization coverage for any Vaccine or Vaccine series as needed to boost immunization rates. This report could also be used to identify areas of low saturation rates of an IIS if used against census data to identify if Providers are missing (especially if not required to report to IIS).

- Aggregated doses administered per type of Vaccine (or antigen group)
- Age range of desired population
- Provider information (name, pin, address, etc.)

Provider Coverage Report
This report gives statistics in terms of Patients that are properly immunized according to a specific series (e.g., 4-3-1-3-3-1) of Vaccines. A user needs to specify age range of report and time frame. The report will generate an assessment of Patients associated with a Provider Organization. Once the report is generated, it will provide the user with the number and percentage of the clients that meet the selected criteria, the number of clients not meeting the selected criteria, and the total number of clients evaluated.

Chapter 6: General Recommendations

This chapter contains general recommendations (GR) for IIS functionality and various operational aspects of IIS-VFC/Grantee Immunization Program collaboration.

General recommendations are arranged in the Table 5 in the following order:

- GR601: Record eligibility information in IIS
- GR602: Validate data at the time of recording and periodically
- GR603: Validate individual and aggregated data
- GR604: Establish QA process for data from non-IIS systems
- GR605: Use IIS reports to analyze Providers' practices
- GR606: Generate aggregated reports from IIS
- GR607: Inform Underinsured Patient
- GR608: Vaccine Borrowing
- GR609: Access to reports

Table 5. General Recommendations

#	ID	General Recommendation Statement	Notes
1	GR601	**Record eligibility information in IIS** Vaccination Event information (including Patients' eligibility information) should be recorded in the IIS Application.	• Could also be submitted via an EMR/EHR system or billing system to an IIS. • Should be recorded for every Vaccination Event (see BR613).

2	GR602	**Validate data at the time of recording and periodically**
		
		The Provider Organization and the IIS Program should validate eligibility information related to Vaccination Event (dose administered)
		• At the time of recording the Vaccination Event to ensure most complete and accurate data
		• By routinely running reports to proactively ensure they have produced the appropriate information (e.g., monthly)
			• This could occur at the same time that the Provider Organization enters the Vaccination Event information and be facilitated by the IIS Application.
			• For electronic entry, this may be implemented via application logic (e.g. required fields, call out common mistakes, etc.).
			• This helps decrease the problems found in data quality aggregate reports (e.g. report of Vaccines shipped to Provider Organization vs. Vaccines administered by Provider Organization, doses administered out of age range) .
			• This could include ensuring that all Vaccination Events have been recorded.
			• Potential validation:
			  o Ensure Lot # is for VFC (in cases where a clear distinction between lot numbers for public and private stock, as well as between various public funding sources can be made).
			  ➢ See BR110 from MIROW Data Quality Assurance guidelines [1.2, p. 38]
			  o NDC points to a Vaccine Type, so it can be used to validate eligibility of a Vaccine to be administered under a program.
			  o VFC-funded Vaccines should have NDC associated with the VFC contract.
			  o Note that NDC and lot numbers are duplicated in both VFC Vaccines and in privately purchased Vaccines. This duality increases the opportunity for error.
			• This should be done using aggregate and Patient-level information.
			  o E.g., there are no 19 year olds.
			  o E.g., all vaccinations were VFC.
			  o E.g., the Provider Organization's billing system changes the information from

#	ID	General Recommendation Statement	Notes
			what was originally reported. • IIS application should be able to generate data validation report at the Patient level finding common errors specific to VFC Program (e.g., Patient is coded as VFC eligible, but his age is 25). • IIS Application should be able to generate a report of the individuals who received VFC Vaccines within a range of dates.

3	GR603	**Validate individual and aggregated data**
		
		The IIS application should have functionality to validate Patients' eligibility data for individual Vaccination Events, as well as aggregated eligibility information for a Provider Organization and for selected subsets of Provider Organizations.
			• Potential validations may include a review of combinations of checked eligibility reasons vs. supporting conditions.
			• Analysis of submitted data can be used to identify poor reporters and develop appropriate interventions.
			  o If VFC Provider Organizations have no VFC Vaccines administered.
			  o If doses reported from VFC Provider Organizations are missing eligibility information.

4	GR604	**Establish QA process for data from non-IIS systems** QA process should be in place to assure that information that has been provided as compiled by non-IIS systems is accurate (practice-management systems, EMR/EHR system, billing system).	• This should be a collaborative effort between IIS Program, the Provider community, and the vendor community. • Example: practice management systems are operated based on CPT codes. This information should be cross-checked with IIS information. • QA process could be based, in part, on information generated in the data validation recommended in current GR603. However, the QA process would be more extensive by examining the accuracy of data at all points: Point of care, initial recording (paper or digital into third party electronic data source), validation at each point of data transformation/mapping in the third party data source, data extraction to send to the IIS, data messaging to the IIS, data import into the IIS.
5	GR605	**Use IIS reports to analyze Providers' practices** IIS application should have reports available to	• Scenario: Questions about Provider Organization and its practices. IIS can provide information to VFC – breakdown of Vaccines administered by Provider Organization over time, by Vaccine type, Patient ages, etc. • IIS captures information associated with a Vaccine given to a Patient.

#	ID	General Recommendation Statement	Notes
		support detailed analysis by the Vaccine Program of Provider Organization practices for example: • Provider Organization Profile Report. • Doses Administered to support Vaccine accountability. • Vaccine ordering patterns. • Coverage audits, other.	• VFC Program captures aggregated information associated with Provider Organization (Practice).
6	GR606	**Generate aggregated reports from IIS** Aggregated reports that support the Vaccine Program should be generated from the IIS application (as compared to reports that aggregate information directly reported from the Provider Organization to the Vaccine Program).	• Good Practice: Generate the majority of aggregated reports from the IIS (with a limited number of reports directly from the Provider Organization to the Vaccine Program). • Aggregated reports include the Provider Organization Profile Report (Aggregated) and the Doses Administered Report. See the Chapter 5 for the reports section of this document. • Completeness of reporting from all Provider Organizations is crucial to enable IIS support of Vaccine Programs and Provider Organizations with quality data for aggregated reporting purposes. GR601 provides that Patient-specific Vaccination Event information be recorded in the IIS Application; however, not every Provider Organization may report regularly or completely to the IIS. • The VFC and IIS community need to evaluate current practices nationwide that support doses administered and other reports through the IIS (with what is currently unfolding through the interoperability between EMR/EHR systems and IIS's) so that doses administered can be supported through the IIS as well as possible. With the interfacing efforts underway, a disconnect between VFC active inventory and doses reported through the interface may exist and viable solutions should be thought through as IIS managers consider implementing the recommendations set forth in this document ─ to ensure that all data elements necessary to generate reports to support VFC and Grantee Programs are recorded in EMR/EHR systems and transmitted to the IIS.

#	ID	General Recommendation Statement	Notes

7	GR607	**Inform Underinsured Patient**
		
		If an Underinsured Patient is ineligible for VFC Program due to not being at a FQHC, RHC, or Provider Organization with Delegated Authority and also not eligible for a state Grantee Vaccine Program,
		then the IIS application should inform the Provider Organization that Patient could be eligible to receive a VFC Vaccine at an alternative Provider Organization (a FQHC, RHC, or Provider Organization with Delegated Authority).
			• Contradiction between medical considerations (Medical Home) and fiscal considerations (Patient paying out of pocket).
			• The Patient has the option to stay and pay out of pocket.
			• This applies only in states that don't have an underinsured purchase policy
			  o VFC only.
			  o VFC and Underinsured Select.

8	GR608	**Vaccine Borrowing**
		
		IIS should have functionality in place to assist
		• The Vaccine Program with monitoring of Vaccine borrowing between the public and private stocks, and
		• Provider Organizations to meet reporting and accountability requirements for Vaccine borrowing and replacement.
			• Origination of borrowing situations:
			  o Inventory shortages.
			  o Delays with outcomes of private insurance claims. This provides for situations when child who initially was perceived as having private insurance coverage for a Vaccine, actually does not have coverage. As a result, Vaccine "borrowing" occurs: a Vaccine from the private stock is used when, actually, a Vaccine from the public stock should have been used.
			• Such functionality also would be helpful for monitoring and analyzing Provider's borrowing practices.
			• Example to consider: Michigan IIS captures every borrowing of a dose from the public inventory. When the Vaccine is shipped from McKesson, the inventory information is uploaded automatically into the Provider Organization's public inventory (lot numbers are identified as public). This provides the starting point for public stock and initiating accountability of the inventory items. When a dose from the public inventory is administered to a private pay Patient, it creates a borrowed transaction. IIS counts such transactions and reports them to CDC in the Management Survey (currently, monitoring of borrowing activities have moved from

#	ID	General Recommendation Statement	Notes
			the VFC Management Survey to the VFC Site Visit Questionnaire). It was a huge number: around 20,000 doses were borrowed from public and given to private pay Patients. There is a transaction in the IIS to allow for replacement, so the Provider Organization can show that they have replaced the borrowed doses. The inventory report for Providers displays the number of doses borrowed and they must show replacement for all borrowed doses. ***Note: there are cases when public and private Vaccines have the same lot number.*** • This level of accountability could become more difficult as the IIS community continues to mature with interoperability between EMR/EHR systems and IIS's. Many EMR/EHR systems lack a strong inventory module to separate Vaccine inventory by funding source and eligibility screening varies between EMR/EHR system products. • "At the Grantee's discretion borrowing between the two inventories may occur but must be a rare occurrence". VFC Operations Guide, Module 3, page 14 [2.7]
9	GR609	**Access to reports** IIS reports that are limited to data from a single Provider Organization (e.g., Provider Organization Profile report) can be either • "Pulled"—generated in IIS Application by the Provider Organization, IIS, or Grantee Vaccine Program, or • "Pushed"—generated in IIS Application by IIS or Grantee Vaccine Program and sent to a Provider Organization. Reports that include information from multiple Provider Organizations can be generated only by the IIS and/or the Grantee Vaccine Program.	This relates to IIS functionality that facilitates responsibility for and access to the information.

Chapter 7: Implementation Considerations

While this document reflects best practice guidelines developed at the requirements/analysis level, the MIROW panel of experts felt that in order to facilitate utilization of formulated recommendations some implementation considerations should be provided. This brief chapter focuses on a few aspects of capturing Patient's eligibility and recording it in the IIS.

Accuracy. Provider leans towards expediency over accuracy when recording information. The IIS Application (or other applications used to capture Patient's eligibility) should balance expedience and ease of entry with accuracy. To assure accuracy, checkboxes on the front end should be used, helping reduce the number of issues that may need to be addressed, especially for real-time entry. Some implementation approaches may include: creating a drop-down list to record a single eligibility/coverage data item, creating one checkbox (yes/no) per eligibility data item and, if feasible, allow multiple selections. Also, collected screening date should be the same as the vaccination date.

Front-end. Interface should support entry of information that stays the same across the Vaccination Events within an encounter (e.g., Patient's AI/AN designation). Also, a consistent interface across applications helps to support interoperability between IIS and third party systems, such as EMR/EHR systems. Since recording of eligibility happen after the Vaccination Event, a Provider should be given an opportunity to accurately record the actual vaccination. Accordingly, the pre-population of drop-down lists should not be restrictive. Although automatic specification could lead to miscoding, the IIS system could automatically generate choices of the VFC eligibility categories that the Provider can choose from. Also, the VFC eligible checkboxes should be displayed only where the Provider Organization is enrolled in the VFC Program. The system should be able to know who the VFC eligible Provider Organizations are.

Back-end. The IIS application's database should be able to store the eligibility information. This information may be acquired through an HL7 message or some other mechanism (e.g., entered directly by a Provider Organization to the IIS Application). Any electronic message should include a screening date and Patient's eligibility information (see Appendix C). VFC eligibility status should be deduced from the reported eligibility data items by the IIS Application. In other words, the system should be able to automatically choose the General VFC Eligibility status for a Patient based on the selected eligibility categories or other demographic data.

Chapter 8: Barriers to Implementation of Best Practice Recommendations

This chapter briefly describes barriers to implementation of the IIS-VFC/Grantee Immunization Program collaboration functionality as it relates to the eligibility issues, as well as some possible ways (*shown in an italic font*) to address these barriers based on MIROW best practice recommendations for this topic.

1. Data Collection

- Data elements are not captured by some or all IIS's
  - *Business rules BR614 and BR615 can provide standards for requirements to inform updates of IIS Applications.*
- Data elements are not captured by electronic medical record applications. EMR/EHR system developers are reluctant to provide updates without standard requirements.
  - *The recommendations in this document can provide standards for requirements to inform EMR/EHR systems development.*

2. Collaboration between IIS and Vaccine Programs

- Vaccine Programs and IIS have been developed and operated independently with respect to determination, recording and reporting eligibility information.
  - *This document is a result of proactive collaboration among IIS Programs and Vaccine Programs to provide agreed upon processes, rules and recommendations for how IIS can support the Vaccine Programs.*
- Other collaboration-related issues identified by the work group include the following:
  - IIS & VFC don't have the time for proper requirements and planning. A lot of times we are reacting rather than having an opportunity to plan it through.
  - Vaccine Program eligibility changes so often that it is hard to make changes to the IIS Application screens and reports.
  - Not enough guidance coming from CDC on how to build the system or what the limits are. Not a lot of requirements regarding accountability and what registries (IIS) are supposed to do.
  - Not required for a Provider Organization to be a member of the registry (IIS) to participate in the VFC Program.
  - Data quality and timeliness of data. As CDC becomes more prescriptive about what they want to know and when IIS will have to get that information from Provider Organizations. How to keep in synch and up-to-date?
  - Both programs are moving at warp speed trying to stay ahead of the curve. Difficult to get the skill sets up to speed to support everything that is going on.

3. Recording and Reporting

- Variation in definitions of terms used in connection with eligibility (e.g., that leads to a confounding of eligibility and funding sources)
  - *The recommendations in this document provide a set of agreed upon terms and definitions (Appendix A, pp. 66-68, 72, 74)*

- Lack of standardized reporting

- *The recommendations in this document provide standards for recording and reporting eligibilities by Provider Organizations.*

- Other reporting-related issues identified by the work group include:
  - Lack of consistent reporting by providers. Turnover of Provider Organization staff without training. Provider Organizations going to different/new EMR/EHR systems that they don't know how to use. Providers not being trained to properly enter information into EMR/EHR. Just because you certify an EMR/EHR system doesn't mean that Providers will properly submit the information. Inconsistencies between IIS and EMR/EHR data fields and requirements lead to problems in exchanging data. Because of that, Providers have to enter data into two different systems to accommodate for lack of exchange capabilities.

Conclusions

The guidelines provide best practices to use immunization information systems (IISs) as a base for handling eligibility-related activities – such as screening for eligibilities, validating recorded information, and providing aggregated reports to support the needs of Provider Organizations and Grantee Vaccine Programs. The guidelines will assist IIS in aligning practices through adherence to a set of common recommendations and guidelines.

The following is a brief description of the key outcomes and accomplishments of the MIROW workgroup:

- Developed and reconfirmed key definitions for IIS-VFC/ Grantee Vaccine Programs collaboration, such as Patient Eligibility, Vaccine Eligibility, and Vaccination Event Eligibility
- Developed detailed decision tables presenting logic for screening a Patient for VFC and Grantee Vaccine Program eligibilities; developed **26 eligibility screening scenarios**
- Formulated **17 business rules** to guide operational aspects of eligibility screening, e.g., how often to screen, how to resolve dual-coverage, and what information to record.
- Formulated **9 general recommendations** for IIS functionality and various operational aspects of IIS-VFC/Grantee Vaccine Program collaboration.
- Described key eligibility reports, with a focus on the Provider Organization Profile Report, Provider Organization Profile Report (Aggregated), and Doses Administered Report
- Described key implementation concerns
- Described barriers to implementation of developed IIS-VFC/Grantee Vaccine Program collaboration guidelines, and how the guidelines address implementation barriers
- Composed a set of literature references.
- Described key HL7 considerations for VFC-IIS collaboration
- Developed a paper-based tool to facilitate determination of Patient Eligibility

The work group brought together experts from the federal VFC Program, Grantee Vaccine Programs and IIS. The resulting guidelines are a key step in standardizing practice and reports in the area of VFC-IIS/Grantee Vaccine Program eligibility. Developed recommendations are intended to be at the business/operational level. As a result, they are independent from particular IIS implementations and technology solutions. Accordingly, the recommendations can be used to support the wide variety of IIS implementation strategies on different technological platforms.

The approach and results presented are relevant for and can be used beyond immunization information systems—for developing and documenting best practices and operational requirements for application in public health, health care, and other areas.

The National Vaccine Advisory Committee (NVAC) has included a recommendation to "Promote the adoption of a guidebook and best practices for IIS as started by the CDC/NIP and AIRA/MIROW workgroup to adopt consistent operational guidance and quality control procedures that ensure good data quality." This guide is one example of addressing this recommendation in the area of VFC-IIS collaboration.

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Abbreviations

Abbreviation	Definition
ACIP	Advisory Committee on Immunization Practices
AI/AN	American Indian or Alaska Native
AIRA	American Immunization Registry Association
BR	Business Rule
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
CPT code	Current Procedural Terminology code
CVX	Health Level Seven code for Vaccine Administered
EMR/EHR	Electronic Medical Record/Electronic Health Record
EPSDT	Early and Periodic Screening Diagnostic and Treatment
DAR	Doses administered report
DOB	Date of Birth
DT	Decision Table
EMR/EHR	Electronic Medical Record/Electronic Health Record
FQHC	Federally Qualified Health Center
GR	General Recommendation
HL7	Health Level Seven
IIS	Immunization Information System
MIROW	Modeling of Immunization Registry Operations Work Group
MMWR	Morbidity and Mortality Weekly Report
N/A, NA, na	Not Applicable
RHC	Rural Health Center
SME	Subject Matter Expert
UML	Unified Modeling Language
VFC	Vaccines for Children
VTrckS	Vaccine Tracking System
Y/N	Yes/No

Appendix A: Domain Model and Definitions of Terms

Background
In developing the domain model presented in this section, the MIROW defined a set of terms and definitions identifying concepts and data elements relevant for the IIS-VFC/Grantee Immunization Program topic. The resulting set of terms and definitions, captured in the domain model, provides a vocabulary for consensus-based best practice recommendations formulated by the group. The MIROW used existing models constructed for topics [1.1 – 1.4] as a starting point. These models were modified and harmonized to fit the needs of the IIS-VFC/Grantee Immunization Program topic. The resulting domain model was developed during the preliminary phase of this project in a series of Web-based teleconferences among MIROW experts, and was finalized during the face-to-face meeting.

Domain model purpose
A domain is an area of knowledge or activity characterized by a set of concepts and terminology understood by the business practitioners in the area.

A domain model captures a business vocabulary—terms and definitions. It ensures that all terminology and concepts that will appear in the process description, principles, and business rules are known and understood by the domain practitioners (agreed-upon definitions and meaning).
A domain model includes:

- Domain diagram(s) that shows major business entities, their relationships and responsibilities (**Fig. 6-A1** and **Fig. 7-A2**).
- A table of entities and attributes that provides the full descriptive details of the components represented on the diagram (**Table 6-A1)**.
- A description of the domain diagrams (presented below).

Unlike a data model diagram that depicts storage of information, or a workflow/process diagram that depicts the sequence of steps in a process, a domain diagram is a high-level static representation of the main "things" (entities) involved in the immunization process, including a description of how these "things" (entities) are related. It is important to note that the domain diagram is not a technical specification. Instead, the domain diagram provides the foundation for other modeling diagrams and materials.

<u>How to read and interpret the domain diagram</u>
(see Fig. 6-A1):

- Relationships between entities are visualized by connecting lines.
- Names associated with these lines describe the type of the relationship between entities. Example: a relationship between *Population Group* and *Jurisdiction* is shown as a connecting line with the word (label) "belongs to". Such a relationship should be read as "*Population Group belongs to Jurisdiction.*"
- The general convention for interpretation of relationships between entities is to construct such a description by <u>reading clockwise</u>, starting from the first entity name (*Population Group*), then relationship name—*belongs to* (note, that the name is shown left from the line, supporting a clockwise reading), then the second entity name (*Jurisdiction*).

- If we need to read the same description in the opposite direction, from *Jurisdiction* to *Population Group*, we would have to place a second name— "includes" —right from the line. In this case, using the clockwise reading rule, a description would be "*Jurisdiction includes Population Group.*" In most cases just one name for a relationship is employed (such as "*belongs to*" in the example just considered), assuming that it should be sufficient for a proper interpretation of a relationship in both directions.

Description of the domain diagrams
The entities and their characteristics (attributes) presented on domain diagrams **(Fig. 6-A1, 7-A2)** describe a limited fragment of the overall immunization domain that is related to the IIS-VFC/Grantee Immunization Program topic. Entities (and attributes) presented on these diagrams are described in **Table 6-A1**.

Elements (presented as boxes) on the diagram 7-A2 are color-coded: blue – for items related to Patient Eligibility Status, green – for Vaccine Eligibility Status, brown – for Provider Organization, yellow – for Vaccination Event Status.

a) Grantee Organization/Public Health Entity - Jurisdiction – Population Group (Fig. 6-A1)
A ***Grantee Organization/Public Health Entity*** is accountable for a ***Jurisdiction***, and, therefore, for the ***Population Group/Cohort*** that is associated with the Jurisdiction, which contains a collection of ***Individuals***. Through a Jurisdiction level accountability, a Grantee/Public Health Entity is responsible for an Individual.

A ***Grantee Organization*** includes an ***Immunization Program*** that contains a ***Vaccine Program*** and an ***IIS Program***. The Vaccine Program includes two components: ***Grantee Vaccine Program*** and ***VFC Vaccine Program***. The IIS Program operates ***IIS Application***.

b) Patient – Provider Organization – Immunization Home (Fig. 6-A1)
A ***Provider Organization*** is an organization that administers immunization to a **Patient**. ***Patient*** is a "type of" ***Individual***. Every ***Patient*** is an ***Individual***, but not every ***Individual*** is a ***Patient***. ***Individual*** may be recognized as a ***Patient*** of a ***Provider Organization*** not only when given an immunization by a Provider Organization, but also when the Patient is assigned by a health plan, or a Provider Organization identifies the Individual as a Patient, or Patient's birth is reported by a Provider Organization, or other medical information identifies the Individual as a Patient.

A ***Patient*** may have a relationship with more than one ***Provider Organization***, but only one ***Provider Organization*** may be designated their **Immunization Home** [1.4, p. 29]. An act of vaccination "activates" the Patient for a Provider Organization, but it does not automatically designate or change the Immunization Home for a Patient. A Patient's Immunization Home can be determined by parent/guardian election or last immunization from a Provider Organization, or assignment by a health plan.

A ***Provider* Organization** is accountable for its ***Patients***, thus establishing Provider level accountability. More than one ***Provider Organization*** may be accountable for a ***Patient***.

c) Vaccination Encounter – Vaccination Event – Vaccine (Fig. 6-A1, 7-A2)
Patient is getting vaccinated as a result of the ***Vaccination Event***. More than one Vaccination Event can happen during the ***Vaccination Encounter*** (office visit). In other words, the Patient can receive several Vaccines administered during a single office visit. Each Vaccine administered would be represented by a dedicated Vaccination Event. Accordingly, the relationship between Vaccination Event and Vaccination Encounter on a more detailed diagram (Fig. 7-A2) is labeled with "1" for the Vaccination Encounter and "1…n" (meaning one or many) for the Vaccination Event.

Vaccine refers to a product that produces an immune response in a Patient and is administered during the Vaccination Event. It is described by a set of characteristics (attributes), such as **(**see domain model in [1.2]**)** Vaccine type, CVX code, CPT code, trade name, lot number, etc. A single Vaccine can be related to multiple ***Families/Groups.*** Vaccine that belongs to multiple Vaccine Families/Groups is referred to as a "combo" Vaccine. A single Family/Group can be related to multiple ***Antigens***, such as tetanus, diphtheria, pertussis.

d) Patient Eligibility, Vaccine Eligibility, Vaccination Event Eligibility (Fig. 7-A2)
A primary focus for the MIROW IIS-VFC/Grantee Immunization Program topic is on resolving and tracking the VFC Program and Grantee Vaccine Program eligibility status for a Patient. Concepts that are related to and/or support the determination of Patient's eligibility include:

- Vaccine Eligibility – based on ACIP recommendations and Grantee policies (e.g., VFC Select state)
- Vaccination Event Eligibility – based on agreement (match) between Patient Eligibility and Vaccine Eligibility

Patient Eligibility indicates eligibility of a client to receive services and/or products from a public health program. In other words, Patient Eligibility indicates eligibility of a Patient to receive Vaccines from federal (VFC) or Grantee Vaccine Program.

Patient Eligibility is determined by the VFC Program rules—for the VFC Program and Grantee policies—for the Grantee Vaccine Program. There are four VFC-defined Patient Eligibility categories:

- Medicaid eligible: A child who is eligible for the Medicaid program. (For the purposes of the VFC Program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent and refer to children who have health insurance covered by a state Medicaid program)
- Uninsured: A child who has no health insurance coverage
- American Indian or Alaska Native (AI/AN): As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603)
- Underinsured (see BR605):
    - A child who has commercial (private) health insurance but the coverage does not include Vaccines,
    - A child whose insurance covers only selected Vaccines (VFC-eligible for non-covered Vaccines only),
    - A child whose insurance caps Vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.

Underinsured children are eligible to receive VFC Vaccine only through a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC), or a Provider Organization with Delegated Authority.

While first three VFC eligibility categories for a Patient are relatively stable and do not change during the day (visit/Vaccination Encounter), the fourth category – Underinsured – can vary during the day (visit/Vaccination Encounter). During the same visit/Vaccination Encounter, Patient can be Underinsured for one Vaccine and not Underinsured for another Vaccine. Accordingly, these two different kinds of Patient Eligibility can be described as ***Patient Full VFC Eligibility*** (Medicaid. AI/AN, Uninsured), when Patient is eligible for all VFC Program Vaccines, and ***Patient Conditional VFC Eligibility*** (Underinsured), when Patient does have a private insurance coverage and is dependent on whether the specific Vaccine needed is covered by the Patient's private insurance and whether the Patient is at a certain type of Provider Organization (see BR605).

Patient can be eligible for the Vaccine Program (VFC Program, Grantee Vaccine Program) and have a private health insurance coverage at the same time (i.e., Patient can have a "dual-coverage"). In this case, a single eligibility/coverage should be selected for a Patient from a pool of applicable eligibilities/coverages. Reporting Patient Eligibility as "Private Coverage" is equivalent to reporting it as "VFC Ineligible" (see BR607, BR608, BR609, BR614).

Patient Eligibility/coverage should be associated, for the reporting and accounting purposes, with a Vaccination Event (dose administered) – see BR613. This allows to properly account for

- Underinsured situations, when a Patient is VFC-eligible for one Vaccine, and VFC-Ineligible for another Vaccine
- Dual-coverage situations, when a single eligibility/coverage is selected for a Patient from a pool of applicable eligibilities/coverages for every Vaccination Event (dose administered) and this selection differs from one Vaccine (dose administered) to another

Patient Eligibility for a visit/Vaccination Encounter can be deduced from Patient eligibilities for Vaccination Events of this encounter (e.g., if Patient is VFC eligible for at least one Vaccine during the Vaccination Encounter, (s)he should be counted as VFC eligible for that Vaccination Encounter) – see BR616.

Patient Eligibility for a Vaccination Event (dose administered) is the only type of eligibility that is reported by a Provider Organization to IIS. Vaccine Eligibility and Vaccination Event Eligibility, described below, are not reported. See Chapter 2 "Process model" and business rules BR614-615 for details.

Vaccine Eligibility indicates eligibility of a product or service to be provided under a public health program. In other words, Vaccine Eligibility indicates eligibility of Vaccine (based on the Vaccine Type) to be administered under federal (VFC) or Grantee Vaccine Program. Vaccine can be eligible for VFC Program and for the Grantee Vaccine Program at the same time. Vaccine Eligibility is determined by the ACIP VFC Resolutions – for Vaccines covered by the VFC Program and Grantee policies – for Vaccines covered by Grantee Vaccine Program.

Vaccination Event Eligibility indicates a validity of the match between Patient Eligibility and Vaccine Eligibility. A Vaccination Event is valid (eligible) for a given public health program if the Patient is eligible for participating in the program and the Vaccine administered is eligible to be used in the same program. The concept of Vaccination Event Eligibility is different from the described above concept of Patient Eligibility which is reported for a Vaccination Event (dose administered).

- Illustrative example 1: Patient is VFC eligible, administered Vaccine is VFC eligible. Then the Vaccination Event is valid (eligible).
- Illustrative example 2: Patient is VFC eligible, administered Vaccine is not VFC eligible. Then Vaccination Event is not valid (not eligible)

Eligibility versus Coverage

- Eligibility describes an association with the public Vaccine Program, e.g., Patient is ***eligible*** for the VFC Program
- Coverage describes an association with the private insurance, e.g., Patient is ***covered*** by private insurance.
- Dual coverage describes a situation when Patient is eligible for the VFC Program and also has private insurance coverage.

On the domain diagram 7-A2: During the Vaccination Encounter (e.g., office visit) a Provider conducts the Vaccination Event, administering a Vaccine to the Patient. Provider works for Provider Organization. VFC Enrollment indicates if Provider Organization being enrolled in VFC Program; it also contains characteristics (attributes) of such an enrollment – VFC PIN Number, Facility Type, and others. Provider Organization characteristics, such as Facility Type for the VFC Enrollment, support the determination of Patient's eligibility (e.g., underinsured children are eligible to receive VFC Vaccine only through a FQHC, RHC, or Delegated Authority clinic).

Patient Eligibility and Vaccine Eligibility are defined by the Vaccination Program. Patient Eligibility and Vaccine Eligibility inform Vaccination Event Eligibility. Patient Eligibility is associated with and reported for a Vaccination Event. Patient Eligibility for a Vaccination Event is selected from the pool of applicable Patient eligibilities (VFC, Grantee Programs) and coverage (e.g., private coverage – private health insurance). Reporting Patient Eligibility for a Vaccination Event as "Private Coverage" is equivalent to reporting it as "VFC Ineligible" (see BR614).

f) Discussion of a Funding Source concept

A concept of ***Funding Source*** versus a concept of ***Patient Eligibility*** caused prolonged discussions among MIROW subject matter experts. This issue is addressed below within a framework of Provider Organization reporting to IIS and then IIS providing aggregated information to Vaccine Program.

Every Vaccine (dose administered) was purchased with one of the funding sources (e.g., VFC funds, 317 funds, Grantee funds). At the same time, tracking of a funding source for every dose administered and its association with Patient and Vaccine Eligibility concepts are not possible at the Provider Organization level (see explanation in the next paragraph). Therefore, a discussion of funding sources and its relation to Patient and Vaccine Eligibility concepts should be outside of the scope for these MIROW efforts.

Provider Organization is responsible for reporting eligibility for doses administered from a publicly funded stock (Provider Organization maintains two stocks of Vaccines: publicly funded and privately funded). Provider Organization cannot distinguish between various funding sources used to purchase Vaccines for a publicly funded stock of Vaccines. In other words, Provider Organization is "blind" to funding sources. What Provider Organization does know is Patient's eligibility (since it is responsible for screening Patients and reporting their eligibility).

Eligibility reports that Provider Organizations send to IIS can be aggregated at IIS to provide the Grantee Vaccine Program with aggregated eligibility information. Then this is a task of the Grantee Vaccine Program to use that aggregated eligibility information for accounting and balancing of aggregated administered doses between various funding sources (see Fig. 1-3); ***this task is outside of the scope for this MIROW topic***.

Eligibility versus Funding Source

- Provider Organization evaluates and reports eligibilities. Patient Eligibility indicates who should pay for a vaccine.
- Vaccine Program manages funding sources. Funding source indicates who actually pays for a vaccine.
- Vaccine Program utilizes aggregated eligibilities information to balance accounting for funding sources.

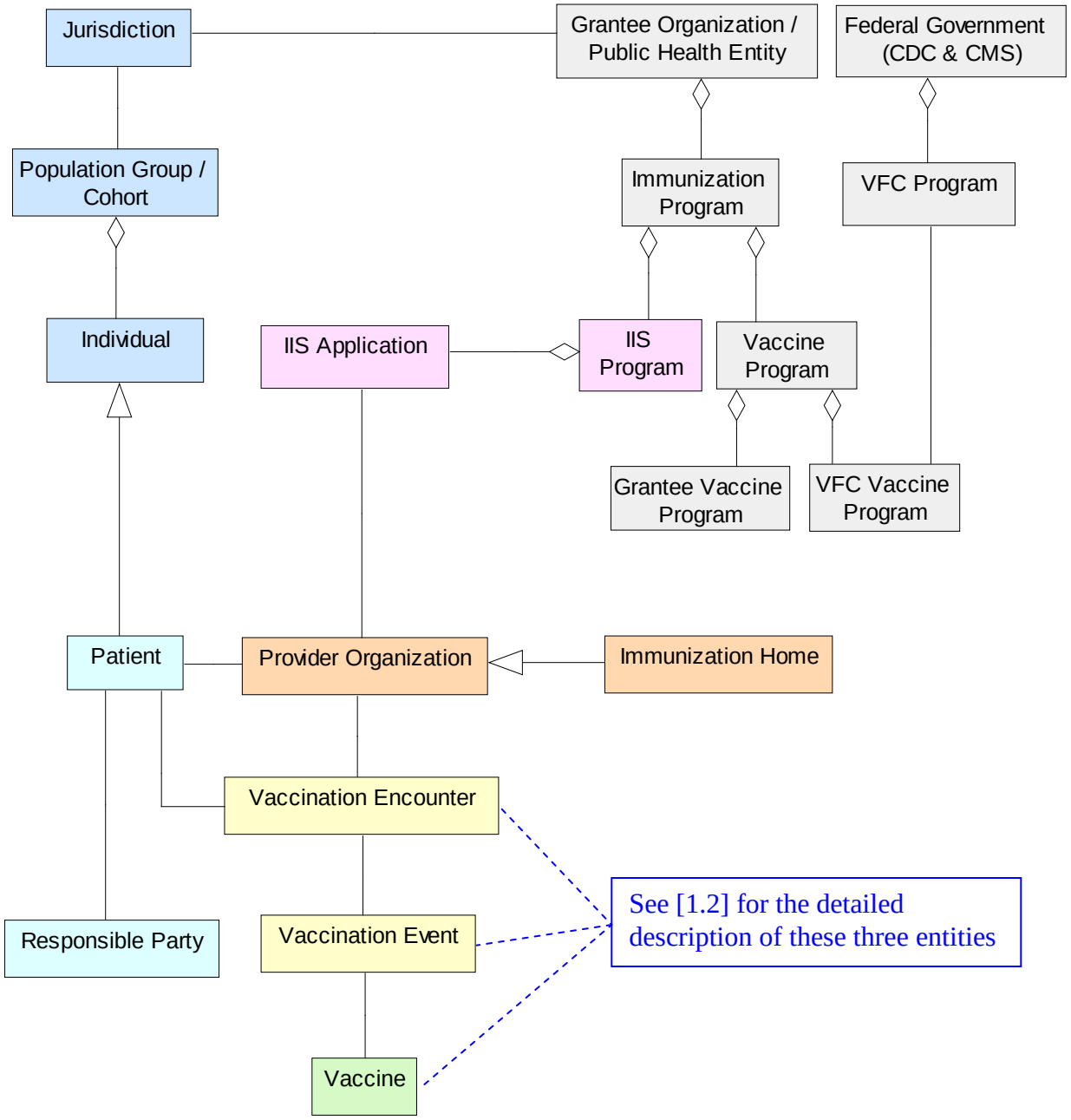
Supporting example: Provider Organization received 100 publicly funded Vaccines. Sixty of these were purchased on VFC funds, 10—on 317 funds, and 30—on Grantee funds (if such a breakdown could be known at the Provider Organization level). Provider Organization maintains a single stock of 100 publicly funded Vaccines. IIS aggregates reports of Provider Organization and aggregated numbers are as follows: all 100 publicly funded Vaccines are administered, 70—to VFC eligible Patients and 30—to Grantee eligible Patients. That aggregated information is reported to the Grantee Program and Grantee Program do balancing and accounting based on information on all Provider Organizations and other factors.

Example from Michigan. Provider Organization has following Patient Eligibility categories to select from: MI-VFC fund (Patient VFC Program Eligibility), 317 Special Funds (Patient Grantee Program Eligibility), Other Public Funds, All Hazard, Private insurance coverage.

In spite of the word "fund" incorporated in the labels/names, these are eligibilities and not funding sources. The Provider has two stocks of Vaccine, one private and one public. He does not know how the public Vaccines were purchased. When taking a dose of Vaccine from the public stock, the Provider has no way of knowing if it was purchased with the VFC funds or any of the Grantee funds. However, the Provider does know and report to IIS (and Vaccine Program) the Patient's eligibility, which can be VFC eligibility or any of the Grantee eligibilities listed above.

The FQHCs and LHDs in Michigan have the options of knowing more of their funding sources for Vaccines and may choose "other public funds" if public monies were used to buy a special Vaccine for that facility. All-Hazard category was used for the H1N1 Vaccine funding. A special module was activated in Michigan registry to operate the H1N1 Vaccines and anti-viral medications distribution, administration and tracking of inventories. Providers were told they could only enter H1N1 Vaccines and meds in this special module, it was separate from VFC in the IIS. All doses entered into that module were coded all hazard and funding was pandemic flu.

Revision date: 04-11-2011



Notes:

- See Table 3 for the description of entities presented on this diagram
- This diagram is coordinated with the sketch on Fig 1, p. 13

Figure 6-A1. Domain diagram: IIS-VFC/Grantee Immunization Program collaboration

Revision date: 03-01-2011

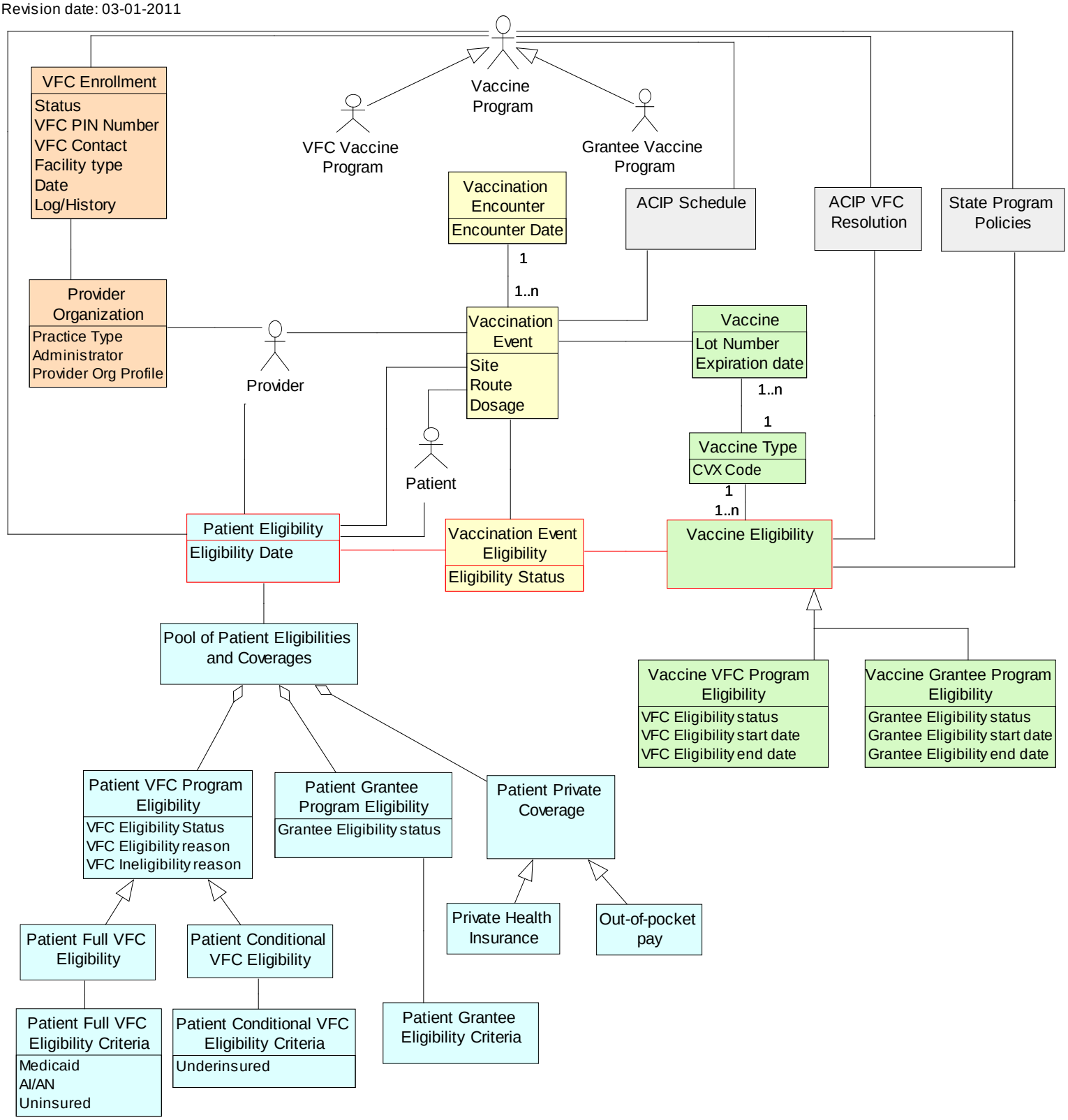


Figure 7-A2. Domain diagram: eligibilities fragment

Table 6-A1. Terms and Definitions
Note: includes terms and definitions for entities presented on Fig. 6-A1 and Fig. 7-A2

Name	Description	Remarks
ACIP Schedule	ACIP Schedule: Recommended immunization schedule, contains recommendations/ requirements concerning when a vaccination is due or past due. ACIP = Advisory Committee on Immunization Practices, provides advice and guidance to the Secretary, the Assistant Secretary for Health, and the Centers for Disease Control and Prevention (CDC) on the control of Vaccine-preventable diseases. http://www.cdc.gov/Vaccines/recs/acip/	See http://www.cdc.gov/Vaccines/recs/schedules/child-schedule.htm The Advisory Committee on Immunization Practices (ACIP) has the ***advisory*** role to determine what Vaccines should be recommended for administration to children, adolescents, and adults in the U.S. and the ***operational*** role to approve which Vaccines should be available through the VFC Program. See, also ACIP VFC Resolution below.
ACIP VFC Resolution	• VFC resolutions passed by the ACIP form the basis for VFC Program policies on Vaccine availability and usage. • VFC Vaccine must be administered according to the guidelines outlined by the ACIP in the VFC resolutions. (VFC Vaccine may also be administered in accordance with State school attendance laws.) • In most cases, a VFC resolution takes effect after a CDC contract for the purchase of that Vaccine in the necessary amounts is established. • see [2.14]	VFC Resolutions follow ACIP schedule, in general, but do differ in details. See PCV Resolution which appears to allow PPSV VFC Vaccine to be given to Native ethnicity without regard to medical status. Both ACIP schedules and VFC Resolutions change all the time and *the bottom line may be that the IIS cannot/should not collect all the detailed underlying information but rely on the screening and clinical judgment of the Provider*. The Patient characteristics that are necessary to determine if a particular child is eligible to receive a specific VFC Vaccine are: Age of child, Sex of Child (e.g. see HPV), medical status of child (e.g. see PCV which requires immunosuppression for some ages), and prior immunization history (e.g. recommendation of some Vaccines are dependent on which Vaccines have already been administered and there are always the intervals to take into account).

Name	Description	Remarks
Federal Government (CDC and CMS)	Implements the VFC Program	• CDC: Centers for Disease Control and Prevention, www.cdc.gov • CMS: Centers for Medicare and Medicaid Services, www.cms.gov
Funding Source	Funds to cover the cost of Vaccines provided via following programs: • Vaccines for Children (VFC) program: provides free vaccinations to Medicaid-eligible children, Alaska Natives, American Indians, children who have no health insurance, and privately insured children with no coverage for vaccinations (called underinsured children) who are served at a Rural Health Center (RHC) or Federally Qualified Health Center (FQHC). • Section 317 program: provides free vaccinations to populations determined by the Grantee. Most Grantees use 317 to provide vaccinations to the underinsured seeking services at health departments and/or their medical homes. • State or locally funded Vaccine Program: provides free vaccinations to populations determined by the Grantee. • Private coverage – private health insurance or out-of-pocket pay	See [2.11], [4.3]. Federal 317 funds and Grantee/local funds constitute non-VFC public funds; they are managed by Grantee Vaccine Programs.
Grantee Organization/Public Health Entity	A Grantee Organization/Public Health Entity is a governmental agency that receives 317 funds under Public Health Service Act. It is a governmental agency with public health oversight or management responsibilities over a particular public health Jurisdiction (e.g., state, city) and associated Population (Individuals).	Grantee Organization/Public Health Entity receives federal funds for the Grantee Immunization Program. Currently there are 64 Grantee Organizations: 50 states, 6 cities, 5 U.S. territories, and 3 freely-associated compact nations in the Pacific.

Name	Description	Remarks
Grantee Vaccine Program Policies (State Program Policies)	Define which Vaccines are eligible for a Grantee Program (Vaccine Eligibility).	There are six types of Grantee Immunization Program Policies: Universal, Universal-select, VFC & Underinsured, VFC& Underinsured-select, VFC only, Other. See Table 7-A2, and [2.11], pp. 6-7 for detailed definitions
IIS Program	Immunization Information Systems or Immunization Registries are confidential, computerized information systems that collect vaccination data within a geographic area.	See http://www.cdc.gov/Vaccines/programs/iis/what-iis.htm IIS Program includes IIS Application (see also the scope illustration on Fig. 1)
Immunization History	A collection of Vaccination Events records for an Individual/ Patient, as well as health conditions of interest and demographic factors.	
Immunization Home	An Immunization Home is the practice (Provider) where the Patient receives immunization services. A Patient can be active with many Providers, but only one Provider will be considered as the Immunization Home.	See [1.4, p.29 and p.42] Also: Medical Home – a Provider Organization that accepts primary responsibility for an Individual's health care. In an ideal situation, Immunization Home and Medical Home are the same for a Patient. In practice, often, they are not.

Immunization Program	Immunization Program at the Grantee level includes (see also the scope illustration, Fig. 1):
	• Vaccine Program, including
	  o VFC Vaccine Program
	  o Grantee Vaccine Program
	• IIS Program, including
	  o IIS Application
		VFC Program is implemented on federal, Grantee, and Provider Organization levels.
		
		Immunization Programs of Grantees = CDC Grantee Immunization Programs = Immunization Programs of CDC Grantees.

Individual	A person. Population is comprised from Individuals. A Patient is "a type of" (sub-group) Individual.	Entity/Party - An individual or organization of interest (e.g., Patient, Clinic). Organization - A type of Entity/Party, such as clinic, foster home, etc.

Name	Description	Remarks
Jurisdiction	The geographic Jurisdiction could be a State, a metropolitan area (New York City, Chicago, etc.), a county within a State, or some other subdivision of a larger Jurisdiction.	A Jurisdiction might encompass the entire country, as is the case with nationwide Jurisdictions such as the Jurisdictions of the Veterans Administration ("non-geographic Jurisdiction").
Patient	An Individual who is associated with a Provider (e.g., immunized by a Provider). For this topic we are going to focus on Patients aged 0-18, as defined by the VFC Program eligibility requirements.	Medical Assistance program can extend this age to 20 years old for certain Vaccines for Patients who already started a vaccination series at age 18. Medical Assistance program funded by a mix of programs administered by Department of Public Welfare (example for PA state) and CMS (federal) Also, some states, e.g. WA, can treat a Patient up to 20 years old if he/she belongs to a high-risk group (not for all Vaccines).
Patient Eligibility	See this Appendix A, pp. 64-66 for a detailed discussion Patient Eligibility indicates eligibility of a client to receive services and/or products from a public health program. In other words, Patient Eligibility indicates eligibility of a Patient to receive Vaccines from federal (VFC) or Grantee Immunization Program. Patient can be eligible for the VFC Program and for the Grantee Immunization Program at the same time. Two different kinds of Patient Eligibility for VFC Program: • ***Patient Full VFC Eligibility*** (Medicaid. AI/AN, Uninsured), when Patient is eligible for all VFC Program Vaccines	• Patient can be eligible for one publicly funded Vaccine and not eligible for another. • Patient can be eligible for one Vaccine from a publicly funded source and not eligible for another Vaccine from the same publicly funded source (but eligible -or not - for that Vaccine from a different publicly funded source). Patient Eligibility is determined by the VFC rules – for the VFC Program and Grantee policies – for Grantee Immunization Programs. Patient VFC Eligibility Criteria includes: • Medicaid eligible: A child who is eligible for the Medicaid program. (For the purposes of the VFC Program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent and refer to children who have health insurance

Name	Description	Remarks
	• ***Patient Conditional VFC Eligibility*** (Underinsured), when Patient does have a private insurance coverage and is dependent on whether the specific Vaccine needed is covered by the Patient's private insurance and whether the Patient is at a certain type of Provider Organization. Patient Eligibility screening consists of evaluating and documenting, whether or not a child is enrolled in Medicaid, Uninsured, Underinsured, or is American Indian or Alaska Native; eligible for the Grantee Vaccine Program; has a private coverage for a needed Vaccine.	covered by a state Medicaid program) • Uninsured: A child who has no health insurance coverage • American Indian or Alaska Native: As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603) • Underinsured: A child who has commercial (private) health insurance, but the coverage does not include Vaccines, a child whose insurance covers only selected Vaccines (VFC-eligible for non-covered Vaccines only), or a child whose insurance caps Vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured. Underinsured children are eligible to receive VFC Vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC). http://www.cdc.gov/Vaccines/programs/vfc/providers/elig-scrn-rec-doc-req.htm
Population Group / Cohort	Part of the population (individuals) within a Jurisdiction.	
Provider	A medical practitioner (e.g., physician, nurse) who administers the immunization (conducts Vaccination Event).	IIS captures Provider information associated with a Vaccine administered to a Patient. VFC Program captures Provider information associated with Provider Organization (Practice). Scenario: VFC audit. Questions about Provider John Doe, his practices. IIS can provide information to VFC – breakdown of Vaccines administered by Provider John Doe over the years, by a month, Patient ages, etc.

Name	Description	Remarks
Provider Organization See also: VFC Enrollment	An Organization that administers immunizations. A Provider Organization is a collection of related Providers (clinicians – physicians, nurses) that are treated as an entity that administer immunizations. It may include a number of different clinical offices/sites and physician groups. Some IIS set up a Provider Organization for every site; ***for the purposes of this project a site has the same definition as a Provider Organization***. • A public Provider Organization is funded by a governmental agency directly. A unit of government is responsible for managing operations. • A private Provider Organization is funded privately and indirectly by a governmental agency (CMS for instance). A non-governmental unit is responsible for managing operations.	Provider's organization "owns" the immunization. Practice Type, e.g., Family Practice, Internal Medicine, etc. VFC-enrolled Provider Organization maintains two inventories of Vaccine: publicly funded and privately funded. (In some cases Provider Organizations maintain one inventory of Vaccines, e.g., Kaiser Permanente of Southern California, Provider Organizations in Oregon. VFC Vaccines are replenished based on doses reported to IIS). See VFC Enrollment: a Provider Organization can be enrolled in the VFC Program or not. Provider Organization Profile: used for the annual re-enrollment in the program and Vaccine ordering. The profile categorizes children among Patient Eligibility categories. Provider Organization characteristics, such as facility type and enrollment in the Vaccine Program (see VFC Enrollment below), support the determination of Patient's eligibility (e.g., underinsured children are eligible to receive VFC Vaccine only through FQHC or RHC or Delegated Authority clinic).
Responsible Party	Entity/Party responsible for an Individual/Patient	Examples are: Parent/Guardian, foster home
Vaccination Encounter	Interaction between a Provider and Patient resulting in one or more Vaccination Events.	Example: An office visit, at school, at work or in the grocery store. Reference [1.2] for a detailed description
Vaccination Event	Administration of one Vaccine to a Patient.	Several Vaccination Events can happen within one Vaccination Encounter.

Name	Description	Remarks
		Reference [1.2] for a detailed description
Vaccination Event Eligibility	See this Appendix A, pp. 64-66 for a detailed discussion Vaccination Event Eligibility indicates the eligibility of a Vaccination Event to be conducted under a public health program. A Vaccination Event is eligible for a given public health program if the recipient of the event is eligible for participating in the program and the Vaccine administered is eligible to be used in the program. Vaccination Event Eligibility indicates the eligibility of providing a certain product or service to a certain client under a public health program. Vaccination Event Eligibility depends on the agreement (match) between eligibility of Patient and eligibility of Vaccine: a Vaccination Event is eligible for a given Immunization Program if the Patient is eligible for participating in the program and the Vaccine administered is eligible to be used in the same program. Simply speaking, Vaccination Event Eligibility indicates a validity of the match between Vaccine Eligibility and Patient Eligibility.	• Illustrative example 1: Patient is VFC eligible, administered Vaccine is VFC eligible. Then the Vaccination Event is valid (eligible). • Illustrative example 2: Patient is VFC eligible, administered Vaccine is not VFC eligible. Then Vaccination Event is not valid (not eligible)
Vaccine	A product that produces an immune response in a Patient. (a.k.a., dose administered) Vaccine Type classifies Vaccines (e.g., using CVX codes). A Patient is eligible for a type of Vaccine not the specific Vaccine.	Reference [1.2] for a detailed description
Vaccine Eligibility	See this Appendix A, pp. 64-66 for a detailed discussion Vaccine Eligibility indicates eligibility of a product or	Vaccine Eligibility is determined by the ACIP VFC Resolutions – for Vaccines covered by the VFC Program and Grantee policies – for Vaccines covered by Grantee

Name	Description	Remarks
	service to be provided under a public health program. There are two types of Vaccine Eligibility: • Vaccine VFC Program Eligibility • Vaccine Grantee Program Eligibility Vaccine Eligibility indicates eligibility of Vaccine to be administered under federal (VFC) or Grantee Immunization Program. Vaccine can be eligible for VFC Program and for the Grantee Immunization Program at the same time. Certain types of Vaccines covered by VFC (according with ACIP VFC Resolution), others – not. Same – for Vaccine Grantee Program Eligibility. • Eligibility status (Vaccine covered by program, Vaccine not covered by program) • Eligibility start date • Eligibility end date	Immunization Programs. For a Vaccine to be covered through the VFC Program two events must occur: 1. VFC Resolution must be established by the ACIP 2. CDC must obtain a federal contract for that Vaccine Once these events occur that Vaccine can be purchased using VFC funds and distributed to VFC-enrolled Provider Organizations to administer to VFC-eligible children. ***The determination if a Vaccine is a VFC Vaccine is NOT dependant on a Grantee's Vaccine purchase policy it is based on having a VFC resolution and a federal contract to purchase the Vaccine.*** The Vaccine that is effected by a Grantee's purchase policy is a Vaccine that is purchased with 317 or state funds. A state may purchase additional Vaccine off the federal contract to administer to STATE VACCINE ELIGIBLE CHILDREN using 317 or state funds but Vaccine purchase with these funds ***should be never be considered "VFC" Vaccine it is state Vaccine purchased off the federal contract***. The state also determines who is eligible to receive the state purchased Vaccine. Along with who is eligible to receive the state purchased Vaccine, what Vaccines are purchased determine the state's purchase policy. There are 6 purchase policies: Universal, Universal-select, VFC & Underinsured, VFC& Underinsured-select, VFC only, Other – refer to the Table 7-A2 below.
Vaccine Program	Vaccine Program includes (see Fig. 6-A1, 7-A2 and the scope illustration, Fig. 1): • VFC Vaccine Program	

Name	Description	Remarks
	• Grantee Vaccine Program	
VFC Enrollment (for Provider Organization)	This reflects a fact of Provider Organization being enrolled in VFC Program (eligible for the VFC Program). There are private Provider Organizations that are not enrolled in VFC Program. Provider Organization characteristics, such as facility type and enrollment in the Vaccine Program, support the determination of Patient's eligibility (e.g., underinsured children are eligible to receive VFC Vaccine only through FQHC or RHC or Delegated Authority clinic).	Status: A Provider Organization can be enrolled in the VFC Program or not. For enrolled Provider Organizations, they can be enrolled or enrolled and active meaning that they ordered VFC Vaccine within current year. VFC PIN number is assigned to a Provider Organization. VFC Contact is a person who has a fiduciary responsibility for conducting VFC Program activities within Provider Organization. Facility Type, e.g., Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC), or Provider Organization with Delegated Authority. Underinsured children are eligible to receive VFC Vaccine only through FQHC or RHC or Delegated Authority clinic. The facility type would not affect what VFC Vaccines the Provider Organization could receive, Delegation of authority is a contractual agreement defined by the FQHC and the Grantee. Delegated Authority is a Clinic/Provider Organization for which a VFC delegated authority agreement exists.
VFC Program	The VFC Program is a federally funded program that provides Vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay.	VFC = Vaccines for Children http://www.cdc.gov/Vaccines/programs/vfc/default.htm

Table 7-A2. VFC Purchasing Schemes
Note: based on [2.16]; see also [2.11], pp. 6-7

#	Name	Description	Notes
1.	VFC Only	Through the use of VFC funds, the immunization project supplies all routinely recommended pediatric Vaccines to private VFC enrolled Provider Organizations to vaccinate VFC eligible children only. (Select this option if only VFC funded Vaccine is supplied to private Provider Organizations. Private Provider Organizations do not receive 317 or state funded Vaccine for underinsured children. However, the underinsured may be served via VFC, 317, and/or state/local funds in public clinics.).	VFC Only means that there is no Grantee Program for private Provider Organizations.
2.	VFC & Underinsured	Through a combination of VFC, 317 and state funds (if applicable), the immunization project supplies ALL routinely recommended pediatric Vaccines to all public and private VFC enrolled Provider Organizations to vaccinate ONLY VFC and under-insured children. (Select this option ONLY if your policy applies to both public and private Provider Organizations.)	
3.	VFC & Underinsured Select	Through a combination of VFC, 317 and state funds (if applicable), the immunization project supplies ALL but a few, routinely recommended pediatric Vaccines to ALL public and private VFC enrolled Provider Organizations to vaccinate ONLY VFC and under-insured children. (Select this option if the project limits the supply of certain Vaccines such as PCV7 or MCV4 to VFC eligible children ONLY in BOTH public and private settings.)	
4.	Universal	Through a combination of VFC, 317 and state funding, the immunization project supplies ALL routinely recommended pediatric Vaccines to all public and private VFC enrolled Provider Organizations to vaccinate all children in the project area. (Select this option ONLY if this policy applies to both public and private Provider Organizations).	In Universal states the Patient will always be eligible for either the VFC Program or Grantee Program. In Universal Select states the Patient will be eligible for the majority of the Vaccines. In a Universal state Medicaid and Private insurance may get billed for a Vaccine administration fee even if no one is being billed for the Vaccine. Medicaid and Private insurance Provider Organizations are each putting money into the pool so they would want to

#	Name	Description	Notes
			know how many Patients they paid for.
5.	Universal Select	Through a combination of VFC, 317 and state funding, the immunization project supplies all, but a few, routinely recommended pediatric Vaccines to ALL public and private VFC enrolled Provider Organizations to vaccinate all children in the project area. (Select this option ONLY if your policy applies to both public and private Provider Organizations).	In Universal states the Patient will always be eligible for the VFC Program or Grantee Program. In Universal Select states the Patient will be eligible for the majority of the Vaccines.

Appendix B: Partitioned Decision Tables and Associated Screening Process

This appendix contains a detailed description of a particular Patients' eligibility screening sequence performed by a Provider Organization. This sequence reflects a recommendation captured in the business rule BR604. Different approaches can be developed with corresponding specialized decision tables and associated screening sequences that reflect characteristics and established practices of Provider Organizations, depending on such factors as established office workflows, proportion of Patients with private coverages, type of practice, and many others. Presented here process model specifies and provides details for the general process overview described in the Chapter 2. In order to support the specific eligibility screening sequence described in this Chapter, the complete decision table 2 has been partitioned on tables 9-B2, 11-B4, 13-B6.

First, a Patient is screened for the Full VFC Program Eligibility (Medicaid, AI/AN, and Uninsured eligibility categories). If the Patient fits one of these three eligibility categories, the Patient is eligible for all VFC Program Vaccines. If the Patient does not have private health insurance, then no further screening is necessary.

However, if the Patient does have private health insurance, then, regardless of the outcome of the screening for the Full VFC Program Eligibility, the Patient has to be screened for the Conditional VFC Eligibility (Underinsured - when the Patient's eligibility is dependent on whether the specific Vaccine needed is covered by the private insurance and whether the Patient is at a certain type of Provider Organization), dual-coverage (Medicaid and AI/AN, plus a private insurance coverage), and sole coverage (private insurance coverage only). The Conditional VFC Eligibility screening has to be conducted for every Vaccine needed. As a result of the Patient's screening for the Conditional VFC Eligibility one of the three outcomes can emerge: 1) Patient is VFC-eligible for a specific Vaccine, 2) Patient is covered by a private insurance for a specific Vaccine, and 3) Patient is VFC-ineligible for the needed Vaccine and private insurance doesn't cover it. First two outcomes signify the end of the Patient's screening process. The third outcome leads to an additional step – Patient's screening for a Grantee Vaccine Program Eligibility.

The described sequence of the Patient's eligibility screening does not create a comprehensive pool of Patient's eligibilities and coverages to select from, but rather presents a logical order of steps to determine which eligibility/coverage to use. For example, if the Patient has Full or Conditional VFC Eligibility, when no screening for the Grantee Vaccine Program Eligibility would be conducted. This reflects the understanding that Grantee Vaccine Program funds should be used only in cases when Patient is not eligible for VFC Program and does not have a private insurance coverage.

Revision date 04-07-2011

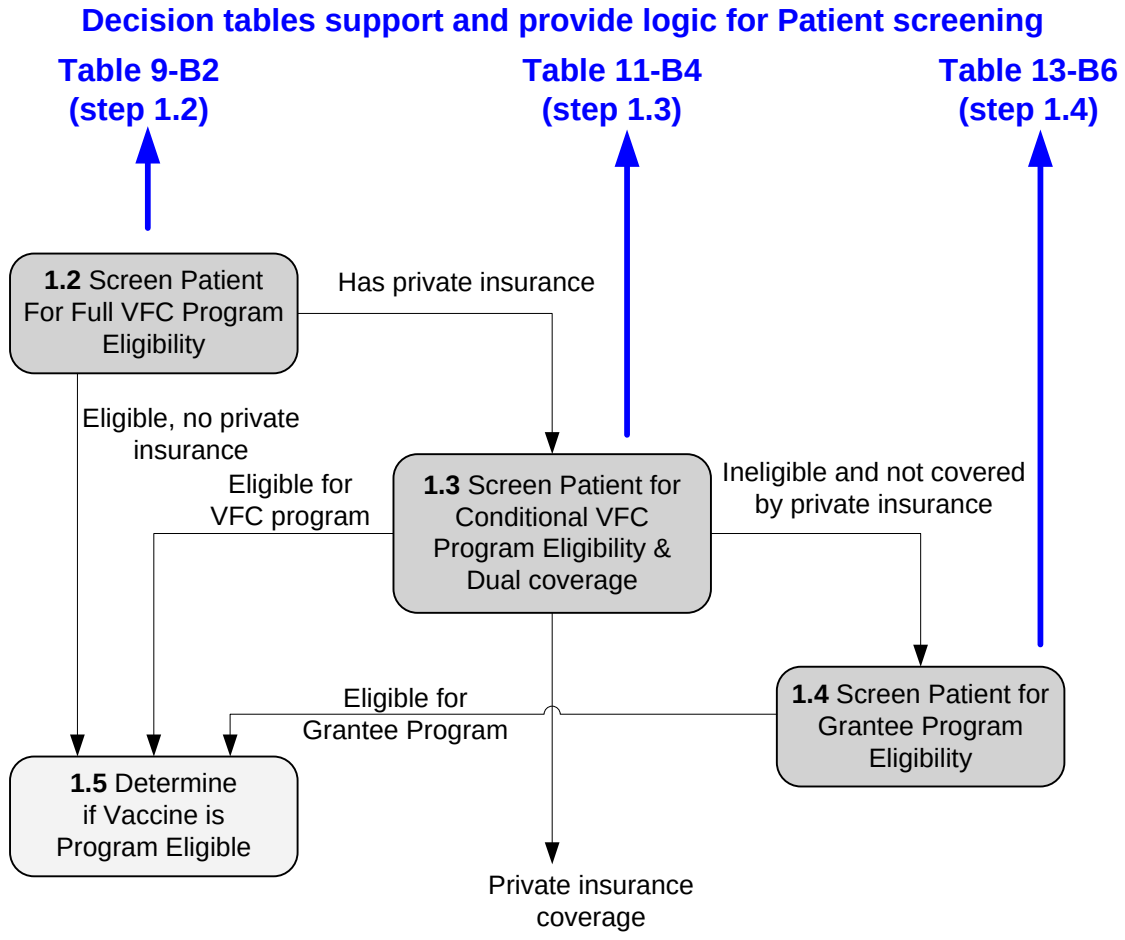


Figure 8-B1. Process diagram (a fragment): Patient screening for Vaccine Program eligibility and private insurance coverage

Notes:

- See Fig. 4 and Fig. 5 for the process overview and Fig. 9-B2 for the detailed screening process
- This diagram is for Patients under 19 years old (see next diagram on Fig. 9-B2)

Revision date 04-14-2011

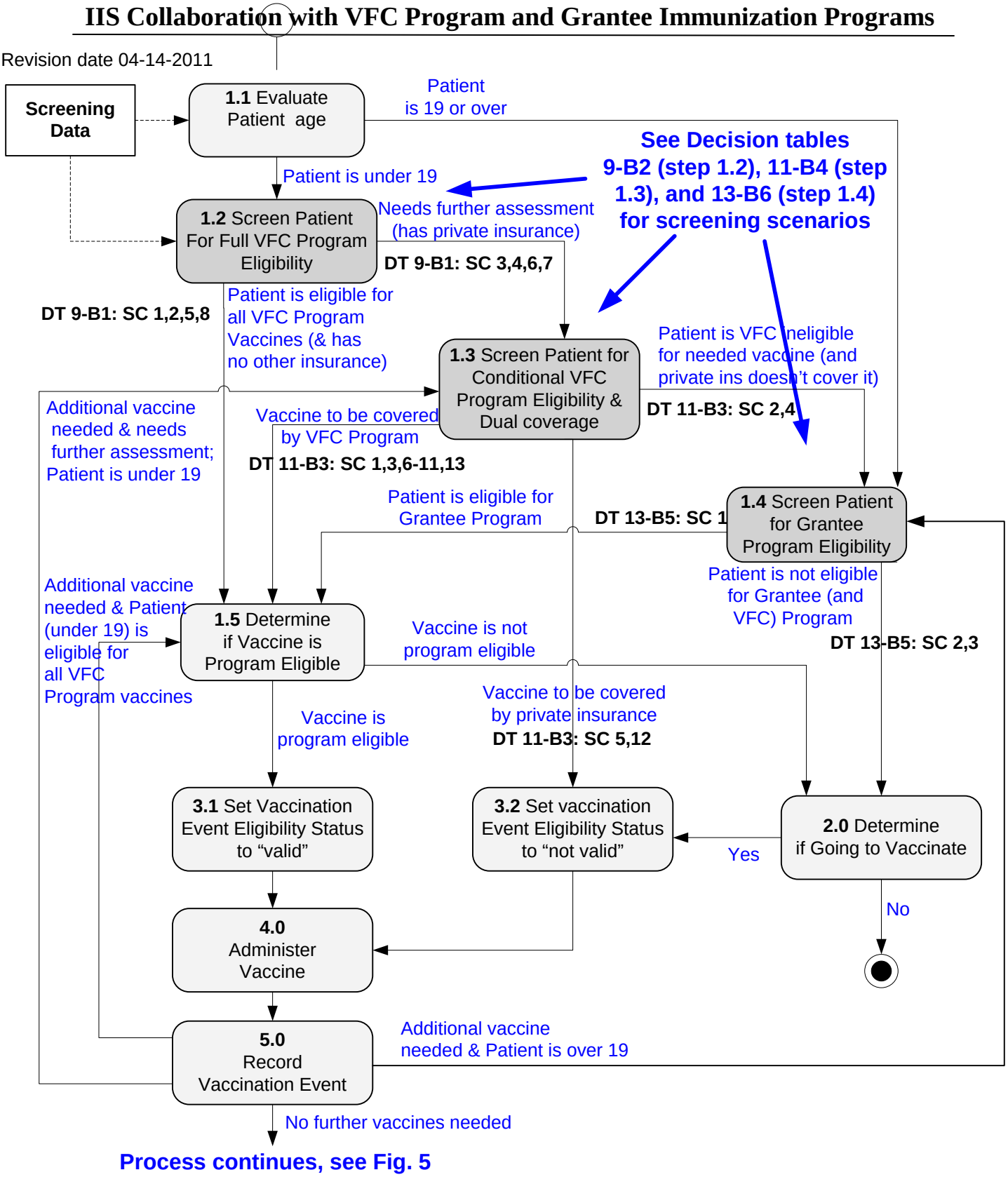


Figure 9-B2. Process diagram (detailed): Patient screening for Vaccine Program eligibility and private insurance coverage
Note: See Fig. 4 and Fig. 5 for the process overview

Table 8-B1. Process Description for Steps 1.1 – 1.5
Note: See Table 1 for the overall description of step 1.

ID	Name	DTs, BRs, GRs	Description/Notes/ Issues/Inputs/Outputs
1.1	Evaluate Patient's age	BR601 BR602	• Input: Patient's birth date in screening data • Possible outcomes: o Patient is under 19 years old and therefore potentially eligible for VFC Program o Patient is 19 years or older and therefore potentially eligible for a Grantee Program.
1.2	Screen Patient for Full VFC Program Eligibility	Decision Table 9-B2 BR603	• Input: Screening data • Possible outcomes: o Patient is found to be fully eligible for all VFC Program Vaccines (Full VFC Program Eligibility) and has no private insurance, or Patient has a private insurance and needs to be assessed further (may also already be fully eligible for VFC.) • This must be done for each Vaccination Encounter, but does not have to be repeated for each Vaccination Event within an encounter for Patients without private insurance. If Patient has a private insurance, then, regardless of Patient's status for the Full VFC Program Eligibility, the screening for Conditional VFC Eligibility and Dual Coverage has to be conducted for every Vaccination Event (see step 1.3). • This screening begins when the Patient arrives at the office and specifies financial responsibility (e.g., insurance) • This assumes that the Provider Organization is eligible (enrolled in VFC Program).
1.3	Screen Patient for Conditional VFC Eligibility and Dual Coverage	Decision Table 11-B4 BR603	• Inputs: Vaccine required, Patient's Full VFC Program Eligibility, Patient's Insurance coverage • Possible outcomes: o Patient is eligible for the VFC Program for the specific Vaccine o Patient has a private insurance coverage for the specific Vaccine o Patient is VFC ineligible for needed Vaccine and private insurance doesn't cover it (proceed to step 1.4 to screen for a Grantee Program Eligibility) • Two types of screenings take place in this process. 1) The first is to determine if the Patient is eligible for VFC due to being "underinsured (i.e., at the FQHC, RHC, or Delegated Authority Provider Organization)." 2) The second is to determine if the Patient has ***dual coverage, i.e. private insurance which covers the Vaccine needed and also VFC eligibility (Medicaid and/or AI/AN).***

ID	Name	DTs, BRs, GRs	Description/Notes/ Issues/Inputs/Outputs
			• This screening must take place for each Vaccine needed by the Patient, because the results could be different each time.
1.4	Screen Patient for Grantee Program Eligibility	Decision Table 13-B6 BR603	• Inputs: Vaccine required, Rules for the Grantee Vaccine Program • Possible outcomes: o Patient is eligible for Grantee Program o Patient is not eligible for Grantee Program • Pre-conditions to enter this step: o Patient is under 19 years old: Patient is not eligible for VFC, and private insurance does not cover needed Vaccine, or o Patient 19 years old or older. In this case screening for private insurance coverage can be included into the screening for Grantee Program eligibility (Decision Table 13-B6.) • This step is Grantee-specific. The screening applies to Grantees/states with the following Vaccine purchasing schemes: VFC & Underinsured, VFC & Underinsured Select State, Universal Select State. See Appendix A, Table 7-A2 for a description of various Vaccine purchasing schemes.
1.5	Determine if Vaccine is Program Eligible		• Input: Vaccine required • Possible outcomes: o Vaccine is program eligible o Vaccine is not program eligible • Review the list of ACIP-recommended and state-allowed Vaccines. • This must be done for each Vaccination Event. • All ACIP-recommended Vaccines are eligible for VFC. Grantee Vaccine Programs may only cover certain Vaccines.
2.0	Determine if Going to Vaccinate	GR607	• If Patient isn't eligible for Vaccine Program, doesn't have private insurance and is not willing to pay out-of-pocket, or if the Vaccine is not eligible, then the Provider Organization may decide not to vaccinate the Patient. • Input: Patient Eligibility, Vaccine Eligibility • Possible outcomes: o To vaccinate the Patient (use Private Coverage) o Not to vaccinate the Patient (***see general recommendation GR607 for considerations regarding Patients referrals to a FQHC, RHC or Delegated Authority Provider Organization)*** There are other considerations, e.g., contraindications for a Vaccine.

Revision date 04-13-2011

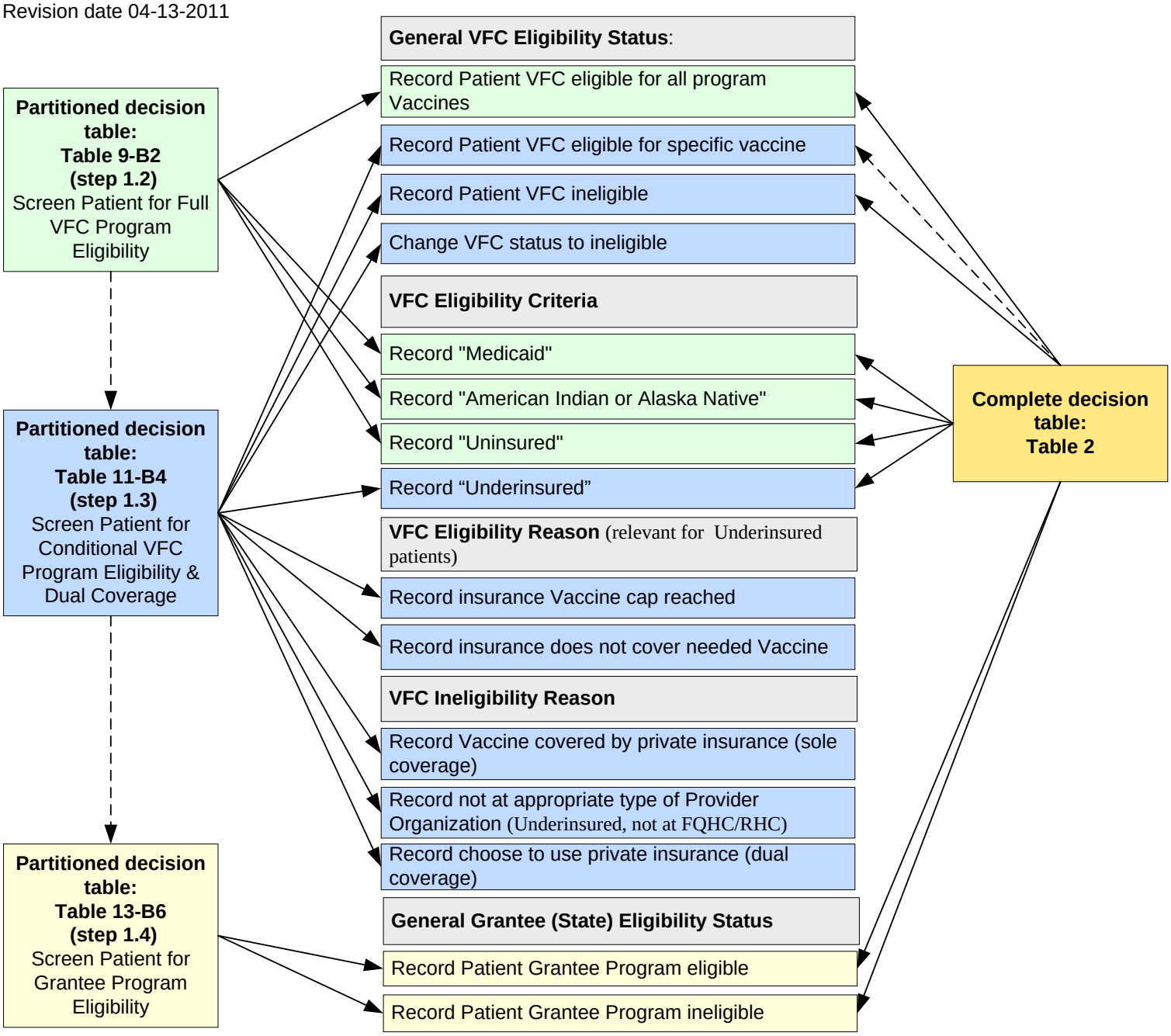


Figure 10-B3. Decision tables: actions—recorded screening information

Notes:

- There is no differentiating among "Full VFC Eligibility" and "VFC Eligibility for a specific Vaccine" in the Complete decision table (Table 2)
- Underinsured – at the FQHC, RHC, or Delegated Authority Provider Organization
- See BR614

Table 9-B2. Partitioned Decision Table for the Process Step 1.2: Screen Patient for Full VFC Program Eligibility

	SCENARIOS							
	1	2	3	4	5	6	7	8
Reference to complete Decision Table 2	1	7	8,9	2-6	10	11-16	18-24	17
Reference to partitioned Decision Table 11-B4 (step 1.3)	na	na	9	6,9, 12,13	na	7,8, 10-13	1 –5	na
CONDITIONS:								
Medicaid: Y/N	Y	Y	Y	Y	N	N	N	N
American Indian or Alaska Native: Y/N	N	Y	Y	N	Y	Y	N	N
Patient has private health insurance: Y/N *	N	N	Y	Y	N	Y	Y	N
ACTIONS:								
General VFC Eligibility Status								
1. Record Patient VFC eligible for all program Vaccines	X	X	X	X	X	X		X
2. Further assess Patient's private insurance coverage - see Decision Table 11-B4 (step 1.3)			X	X		X	X	
VFC Eligibility Criteria								
3. Record "Medicaid"	X	X	X	X				
4. Record "American Indian or Alaska Native"		X	X		X	X		
5. Record "Uninsured"					X			X

Notes:

- Abbreviations: "Y" = Yes, "N" = No, dash "-"means that it does not matter for the outcome of a scenario if it is "Y" or "N", "X" points to actions that should be taken for this scenario, and blank indicates actions that are not applicable for this scenario.
- Pre-condition: Patient's age determined to be less than 19 years old.
- * The "Patient has private health insurance" condition specifies whether or not the Patient has health insurance, not whether the insurance covers the needed Vaccine.
- Any Patient who has private health insurance needs further assessment—See table 11-B4 (step 1.3).
- See BR614 and BR615 for documenting/reporting situations when a Patient meets more than one eligibility criteria

Table 10-B3. Scenario Notes for Partitioned Decision Table 9-B2, Process Step 1.2

	Scenario Notes	Business Rule
1	Patient has Medicaid and does not meet any other VFC eligibility criteria.	
2	Patient is AI/AN and also has Medicaid.	BR614, BR615
3	Patient is AI/AN and also has Medicaid and private insurance and therefore potentially has dual coverage.	BR614, BR615, BR609
4	Patient has both Medicaid and private insurance and therefore potentially	BR614, BR615,

Scenario Notes		Business Rule
	has dual coverage.	BR609
5	Patient is AI/AN and is also Uninsured. The Provider should document both eligibility criteria.	BR614, BR615, BR606
6	Patient is AI/AN and also has private insurance.	BR609
7	Patient has private insurance – does not meet criteria for being eligible for all program Vaccines.	BR610
8	Patient has no insurance and does not meet any other criteria for VFC Program. Is fully eligible as Uninsured.	BR606

Table 11-B4 Partitioned Decision Table for the Process Step 1.3: Screen Patient for Conditional VFC Program Eligibility and Dual Coverage

	18	19	21	22, 23	24	4	15	16	2, 3, 8, 9	11	12	5, 14	6, 13
	7	7	7	7	7	4	6	6	3, 4	3	3	4, 6	4, 6
	na	1-3	na	1-3	na	na	na	na	na	na	na	na	na
Private insurance covers needed Vaccine: Y/N **	N	N	Y	Y	Y	N	N	N	Y	Y	Y	Y	Y
Private insurance Vaccine cap reached: Y/N	-	-	Y	Y	N	-	-	-	Y	Y	Y	N	N
Patient at appropriate Provider Organization type: Y/N • RHC or FQHC or Delegated Authority	Y	N	Y	N	-	-	Y	N	-	Y	N	-	-
Already has VFC eligibility (AI/AN and/or Medicaid): Y/N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y
Patient has Medicaid: Y/N	--	-	-	-	-	Y	N	N	Y	N	N	-	-
Choose to use private insurance: Y/N	-	-	-	-	-	-	-	-	-	-	-	Y	N
1. Record Patient VFC eligible for specific Vaccine	X		X										
2. Record Patient VFC ineligible		X		X	X								
3. Change VFC status to ineligible												X	
4. Record “Underinsured”	X		X				X			X			
5. Record insurance Vaccine cap reached			X							X			
6. Record insurance does not cover needed Vaccine	X						X						
7. Record Vaccine covered by private ins (sole coverage)					X								
8. Record not at appropriate type of Provider Organization		X		X									
9. Record choose to use private ins (dual coverage)												X	
10. No further action						X		X	X		X		X
11. Evaluate Patient for Grantee Program eligibility		X		X									

Notes:

- Abbreviations: "Y" = Yes, "N" = No, dash "-"means that it does not matter for the outcome of a scenario if it is "Y" or "N", "X" points to actions that should be taken for this scenario, and blank indicates actions that are not applicable for this scenario.
- Pre-condition: Patient needs further assessment (i.e. has private insurance).
- The screening represented in this decision table would need to be done for each Vaccine required by the Patient, because Patient's eligibility could differ from Vaccine to Vaccine.
- If a Patient's insurance doesn't cover the specific Vaccine needed by the Patient, the Patient may be "conditionally" eligible for VFC for that specific Vaccine.
- If a Patient has full VFC eligibility (Medicaid and/or AI/AN) and private insurance that will cover the Vaccine, then that Patient has "dual coverage." The Provider can choose whether to record the Patient as VFC eligible based on Medicaid and/or AI/AN or to use the Patient's private insurance.
- Private insurance is any insurance other than Medicaid (some state insurance plans are expansions of Medicaid and some, for example, in Michigan, are considered private.)

Table 12-B5. Scenario Notes for Partitioned Decision Table 11-B4, Process Step 1.3

Scenario Notes		BRs, GRs
1	Patient's private insurance does not cover the Vaccine needed and Patient is at a qualifying Provider Organization. Patient has no other basis for VFC eligibility, therefore Patient is VFC eligible due to being "Underinsured."	BR605, BR610
2	Patient's private insurance does not cover the Vaccine needed but Patient is not at a qualifying Provider Organization. Therefore Patient is not eligible for VFC for the specific Vaccine needed.	GR607
3	Patient's private insurance does cover the Vaccine needed but Patient's Vaccine cap has been reached. Patient meets no other criteria for VFC eligibility, and is at a qualifying Provider Organization. Therefore Patient is VFC eligible due to being "Underinsured."	BR605, BR610
4	Patient's private insurance does cover the Vaccine needed, but the Vaccine cap has been reached. Patient is not at a qualifying Provider Organization and therefore Patient is not eligible for VFC for the specific Vaccine needed.	GR607
5	Patient has private insurance which covers the specific Vaccine being evaluated (although it may not cover other needed Vaccines.)	BR610
6	Patient's private insurance does not cover the Vaccine needed, but the Patient has Medicaid and is therefore already fully VFC eligible. Because Medicaid is considered "public" insurance, a Patient with Medicaid will not be marked "Underinsured." Therefore no further action is needed.	BR605
7	Patient's private insurance does not cover the Vaccine needed and Patient is at a qualifying Provider Organization. Even though Patient is already fully VFC eligible due to being AI/AN, the Patient meets 2 criteria and will also be marked "Underinsured."	BR605, BR614, BR615
8	Patient's private insurance does not cover the Vaccine needed but Patient is not at a qualifying Provider Organization. Patient is already fully VFC eligible due to being	GR607, BR605

Scenario Notes		BRs, GRs
	AI/AN, therefore no further action is needed.	
9	Patient's private insurance does cover the Vaccine needed, but the Patient's Vaccine cap has been reached. The Patient has Medicaid and is therefore already fully VFC eligible. Because Medicaid is considered "public" insurance, a Patient with Medicaid will not be marked "Underinsured" and therefore no further action is needed.	BR605
10	Patient's private insurance does cover the Vaccine needed, but the Vaccine cap has been reached. Patient is at a qualifying Provider Organization and so even though Patient is already fully VFC eligible due to being AI/AN, the Patient meets two criteria and will also be marked "Underinsured."	BR614, BR615, BR605, BR610
11	Patient's private insurance does cover the Vaccine needed, but the Vaccine cap has been reached. Patient is not at a qualifying Provider Organization and therefore cannot be marked "underinsured." However, Patient is already fully VFC eligible due to being AI/AN, and no further action is needed.	
12	Patient's private insurance covers the Vaccine needed, and Patient is also fully eligible for VFC. Provider chooses to use the private insurance, so Patient's VFC status will be changed to "ineligible – choose to use private insurance." Choosing ineligible even though they are "eligible" because do not want to confuse people or have the potential for fraud or double counting people. They are eligible, but the Provider Organization is deciding to use private insurance instead of Medicaid.	BR609, BR607
13	Patient's private insurance covers the Vaccine needed, and Patient is also fully eligible for VFC. Patient (or Provider) chooses to use VFC, so no further action is needed.	BR609, BR607

Table 13-B6. Partitioned Decision Table for the Process Step 1.4: Screen Patient for Grantee Program Eligibility

	SCENARIOS		
	1	**2**	**3**
Reference to complete Decision Table 2	20,23,25	26	19,22,26
Reference to partitioned Decision Table 11-B4 (step 1.3)	2,4	2,4	2,4
CONDITIONS:			
Are you one of these VFC State Vaccine purchasing policies? (VFC & Underinsured , or VFC & Underinsured Select, or Universal, or Universal Select State, or Other – meaning not VFC Only) In other words, does your State have a Vaccine purchase policy in addition to VFC?	Y	Y	N
Meets Grantee Program criteria: Y/N	Y	N	-
ACTIONS:			
General Grantee (State) Eligibility Status			
1. Record Patient Grantee Program eligible	X		
2. Record Patient Grantee Program ineligible		X	X
Grantee Eligibility Criteria			
Record … <to be developed by each Grantee>			

Notes:

- Abbreviations: “Y” = Yes, “N” = No, dash “-“means that it does not matter for the outcome of a scenario if it is “Y” or “N”, “X” points to actions that should be taken for this scenario, and blank indicates actions that are not applicable for this scenario.
- Pre-condition: Patient is not eligible for VFC
- One of the things that Grantee can include in this table is screening for private insurance for Patients over 19 years old and/or Child Health Program (Children's Health Insurance Program (CHIP) under Title XXI of the Social Security Act).
- ***Because Grantees have different policies and conditions, this decision table is intended to be developed by every Grantee***

Table 14-B7. Scenario Notes for Partitioned Decision Table 13-B6, Process Step 1.4

	Scenario Notes	Business Rules
1	A Patient who lives in a State that have a Vaccine purchase policy in addition to VFC (VFC & Underinsured , or VFC & Underinsured Select, or Universal, or Universal Select State, or Other—meaning not VFC Only) and who meets any other Grantee Program criteria will be eligible for their State’s Grantee	

Scenario Notes		Business Rules
	Program.	
2	A Patient who lives in a State that have a Vaccine purchase policy in addition to VFC (VFC & Underinsured , or VFC & Underinsured Select, or Universal, or Universal Select State, or Other – meaning not VFC Only) but does not meet the Grantee Program criteria will be ineligible for their State's Grantee Program.	
3	A Patient who whose state is "VFC Only" State Vaccine purchasing policies has no Grantee Program (for Underinsured) available. Other Grantee Programs, e.g., for HepB at birth, still can be available in the VFC Only states.	

Notes:

- This applies to Grantees/states with the following Vaccine purchasing schemes: VFC & Underinsured , or VFC & Underinsured Select, or Universal, or Universal Select , or Other—meaning not VFC Only. In other words, for states that has a Vaccine purchase policy in addition to VFC. Refer to Appendix A, Table 7-A2 for a description of various Vaccine purchasing schemes.

Appendix C: HL7 Considerations

This appendix will document how the Eligibility categories can be included in an HL7 VXU message (immunization history). This document specifies that Patient Eligibility should be associated with each Vaccination Event (Vaccine administered). In the past eligibility was recorded at the Patient visit level. While IIS may continue to receive Patient Eligibility at the visit level, this is not preferred.

Reporting Patient Eligibility at the vaccination level requires a different approach than the one used in the past. In the previous approach, the Financial Class field in the PV1 segment was coded, based on User Table 0064 (see below).

Since eligibility data items for a Patient are related to the Vaccination Event (dose administered) and not to the specific date/time, the PV1-20 field of the HL7 message cannot be used for the transmission. Instead, these data items should be transmitted using the Observation (OBX) segment of the HL7 message. In order to use the OBX segment, an appropriate LOINC is required (This will be requested and when available will be found in the tables associated with the Implementation Guide).

The following Table 15-C and associated notes is an excerpt from the HL 7 Implementation Guide for Immunization Messaging [2.17, pp. A4-A5]

Table 15-C. HL7 Codes

Code	Label	Definition
V01	Not VFC eligible	Client does not qualify for VFC because they do not have one of the statuses below. This category does not include the underinsured (see V08).
V02	VFC eligible- Medicaid/Medicaid Managed Care	Client is currently on Medicaid or Medicaid managed care.
V03	VFC eligible- Uninsured	Client does not have insurance coverage for vaccinations. *Note: This does not match the VFC definition of Uninsured.*
V04	VFC eligible- American Indian/Alaska Native	Client is a member of a federally recognized tribe.
V05	VFC eligible-Federally Qualified Health Center Patient (under-insured)	Client has insurance that partially covers Vaccines received on visit and so is eligible for VFC coverage at a Federally Qualified Health Center. The client must be receiving the immunizations at the FQHC.
V06	VFC eligible- State specific eligibility (e.g., S-CHIP plan)	Client is eligible for VFC, based on State-specific rules, such as S-CHIP.
V07	VFC eligibility- Local-specific eligibility	Client is eligible for VFC, based on local-specific rules.
V08	Not VFC eligible-Under-insured	Client has insurance that partially covers Vaccines received on visit. The immunizations were not administered at a Federally Qualified Health Center (FQHC).

Notes:

- Financial class references a client's eligibility status at a point in time.
- The values in this table relate to eligibility for the Vaccine for Children (VFC) Program. Local implementations may define and document local codes meeting the definition of Patient Eligibility.

An example of codes that could be used to convey Patient Eligibility, based on the definition in this document may be found in Table 16-C (see business rules BR614, BR615). Tentatively, eligibility codes from the Table 15-C should be used for answers ***(This approach reflects a plan for a future enhancement, i.e., the HL7 Implementation Guide will illustrate it in the Appendix B)***.

Table 16-C. HL7-related Notes for Eligibility Data Items (related to a Vaccination Event) that Provider Organization Should Report to IIS
(see business rules BR614, BR615)

Eligibility Data Items (related to a Vaccination Event) as Defined in this Document (BR614, BR615)	HL7-Related Notes
Medicaid	Should be transmitted in the Observation segment, eligibility code V02 should be used for the answer.
AI/AN	Should be transmitted in the Observation segment, eligibility code V04 should be used for the answer.
Uninsured	Should be transmitted in the Observation segment, eligibility code V03 should be used for the answer.
Underinsured (FQHC/RHC/Delegated Authority Provider Organizations only)	Should be transmitted in the Observation segment, eligibility code V05 should be used for the answer.
Grantee eligible (various degree of granularity, Grantee-specific)	Should be transmitted in the Observation segment, eligibility codes V06, V07, as well as locally-defined codes should be used for the answer.
Private coverage (Private insurance or out-of pocket pay) = VFC Ineligible	Should be transmitted in the Observation segment, eligibility code V01 should be used for the answer.
Any valid combination of the above data items, as described in BR615	Should be transmitted in the Observation segment, as repeating elements. Appropriate eligibility codes should be used for the answers, e.g., V02 and V04 should be used for the combination of Medicaid and AI/AN.

Appendix D: Paper-Based Eligibility Assessment Tool

The goal of this paper-based eligibility assessment tool is to assist Provider Organizations to identify which Vaccine Program a Patient is eligible for. This tool reflects an idea to create a paper-based form that would be much simpler for Providers to complete compared to direct use of the scenarios from the decision tables.

A Patient can fit into one or more eligibility categories (Medicaid, AI/AN, Uninsured, Underinsured) of the VFC Program. In some cases, the Patient may also be eligible for Grantee Vaccine Programs and have a private coverage (private health insurance or out-of-pocket pay). If a Patient fits more than one VFC category and an EMR/EHR system or IIS may only record one category, the primary category should be selected for reporting/recording (BR614). In some cases, a person may be eligible for one program for a given Vaccine, but not eligible for the same program for another Vaccine. This will occur primarily when a Patient has a private insurance and is underinsured. There may also be Vaccine administered that are not VFC Eligible, i.e. travel Vaccines, Vaccines administered that are not covered by the ACIP schedule, or ACIP Vaccines administered during the time period before the VFC Resolution. Eventually, a single eligibility/coverage status should be assigned to a Patient for every dose administered (VFC Program eligible, or Grantee Program eligible, or Private Coverage – see BR607, BR608).

Client Identity:_____

Assessment Date:_____

VFC Eligibility:*_____ **Primary VFC eligibility reason: _____**

* This is determined in the tables that follow. The choices are: VFC, Private Coverage, Grantee Program. This is not determined by which Vaccine Program actually covered the immunization, but rather the one that ought to cover it.

Table 17-D1. Initial VFC Eligibility

Criteria	Check all that apply	Notes
Patient is on MEDICAID		
Native American or Alaska Native		
Patient has no private insurance (uninsured)		
Patient is under 19 years old		

If Patient is at least 19 years old, skip to Table 21-D5.

Table 18-D2. VFC Logic
Patient is under 19 years old and has no private health insurance.
Uninsured means no private health insurance (and no Medicaid)

Check only the one that applies	Conditions	VFC Eligible	Eligibility Reason code	Primary Eligibility Reason code
	Patient is under 19 = yes Private insurance = no Medicaid = yes AI/AN = no	• VFC eligible-Medicaid	• V02	
	Patient is under 19 = yes Private insurance = no Medicaid = no AI/AN = yes	• VFC eligible- AI/AN • VFC eligible - Uninsured	• V04 • V03	V04
	Patient is under 19 = yes Private insurance = no Medicaid = yes AI/AN = yes	• VFC eligible-Medicaid • VFC eligible- AI/AN	• V02 • V04	V02
	Patient is under 19 = yes Private insurance = no Medicaid = no AI/AN = no	• VFC eligible- Uninsured	• V03	

If Patient meets the criteria in Table 18-D2, then stop here. Client is VFC eligible.

Table 19-D3. Insurance Coverage Assessment
Patient has a private health insurance and, therefore, needs further assessment.
This assessment should be done for every Vaccine needed.

Criteria	Check all that apply	Notes
Insurance covers all Vaccines at today's visit.		
Insurance covers only some Vaccines or partially covers Vaccines at today's visit.		
Patient is receiving immunizations from FQHC or RHC or Delegated Authority Provider Organization		

Table 20-D4. VFC Extended Logic

Check only the one that applies	Logic If …	VFC Eligible	Eligibility Reason code
	Patient has coverage for all Vaccines and is not otherwise VFC eligible	Not VFC eligible	V01
	Patient does not have coverage for needed Vaccine(s) and is receiving immunization care at an FQHC (or RHC or Delegated Authority Provider Organization)	VFC eligible-Underinsured	V05
	Patient does not have coverage for needed Vaccine(s) and is not receiving immunization care at an FQHC (or RHC or Delegated Authority Provider Organization)	Not VFC eligible-underinsured	V08
	Patient has MEDICAID and has insurance which covers immunization (Provider organization selects Private coverage to be used)	Not VFC eligible	V01
	Patient has MEDICAID and has insurance which covers immunization (Provider organization selects Private coverage to be used)	VFC eligible-Medicaid	V02
	Patient is AI/AN and has insurance which covers immunization (Provider organization selects VFC eligibility or Private coverage to be used based on the best financial interests of the Patient)	VFC eligible- AI/AN	V04
	Patient is AI/AN and has insurance which covers immunization (Provider organization selects VFC eligibility or Private coverage to be used based on the best financial interests of the Patient)	Not VFC eligible	V01

***If Patient is not eligible for VFC and does not have a private health insurance that covers needed Vaccine(s), then proceed to State specific Vaccine Program eligibility assessments t*able 21-D5**

Table 21-D5. State Vaccine Program Eligibility

Criteria	Applies	Notes
E.g., family income < family income guidelines>		

1. This table is a placeholder for Grantee-specific eligibilities.
2. Patient is not eligible for VFC and is under age 19 years and not insured for Vaccines and family income < family income guidelines then Patient is eligible for Grantee's Program>.
3. Patient is 19 or older.

Appendix E: Scope—Detailed Focus Statement

1) **Breadth**
   a) All activities involved in determining and tracking Vaccine Program (VFC Program or Grantee Vaccine Program) eligibilities
      i) **From:** Provider has decided which vaccinations need to be administered
      ii) **To:** Vaccine Program has received the aggregated Patients' eligibility information from the IIS Application
      iii) Including, for routinely administered vaccinations:
         (1) Screening and reporting Patients for Vaccine Program eligibility (Provider Organization reporting eligibilities to IIS, including non-VFC Provider Organizations)
         (2) IIS providing information to the Vaccine Programs
         (3) IIS providing information to the Provider Organizations
         (4) Determining Vaccine Eligibility
         (5) Determining Vaccination Event Eligibility
         (6) Documenting eligibilities as a part of documenting administration of Vaccines
         (7) Confirming Vaccine Program enrollment and facility type for Provider Organizations
         (8) Maintaining status and history of Patient Eligibility
      iv) Excluding:
         (1) Recording or reporting Vaccine funding source by Provider Organizations
         (2) Reconciling Vaccines administered during Vaccination Events by the Vaccine Program and funding source (this is done at the Grantee level)
         (3) Ordering and delivering publicly-funded Vaccines
         (4) Enrolling in Vaccine Programs
         (5) Making clinical decisions about which immunizations are needed
         (6) Billing
         (7) Provider Organization reimbursements
         (8) AFIX
         (9) Other information that could be captured in the IIS Applications that would benefit the Grantee Programs, such as
            (a) Pre-Vaccine administration (e.g. getting parent's consent)
            (b) Special projects
   b) Individual less than 19 years old
   c) Data quality requirements for all information collected
2) **Problem Set**
   a) **Including:** Publicly-funded Vaccines
   b) **Excluding:** Privately-funded Vaccines
3) **Emphasized Perspectives**
   a) IIS
   b) VFC Program
   c) Grantee Vaccine Programs
   d) Provider Organizations
4) **Scope of Integration** (this topic should be integrated with …)

a) Reference Advisory Committee on Immunization Practices (ACIP) recommendations for immunization schedules and policies regarding provided Vaccines

5) Depth

a) Conceptual level requirements – not emphasizing implementation details (e.g. position in HL7 Record)

6) Universality

At the time of development of these guidelines it is not possible to foresee the exact impact of health care reform on VFC and Grantee Vaccine Program policies related to the eligibility of a Patient for publicly-purchased Vaccines. However, it is possible that the number of Patients in both the Underinsured and Uninsured categories will be reduced. The majority of best practice recommendations presented in this guideline will still be applicable and the document can be modified by users as necessary to reflect the impact of health care reform.