AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

MIROW Principles and Business Rules

Simple Report, Version 2.0

September 2022

MIROW Principles and Business Rules Reports

Version 2.0

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Description

The Modeling of Immunization Registry Operations Workgroup (MIROW) has developed 12 guidance documents with over 375 principles and business rules. Principles reflect business guidelines, practices, or norms that we choose to follow. Business rules represent specific requirements and decision-making logic for IIS processes and operations. The goal of the reports is to provide an index of the principles and business rules to allow for more efficient identification of relevant information.

- Principles and business rules are not developed to stand alone, and they benefit from the context provided in the guidance documents.
- The principles and business rules in the reports are taken directly from the existing guidance documents and have not been updated in any manner.
- With the exception of guides Business Continuity (2019) and Data Quality Assurance (2022), the principles and business rules do not currently reflect the updated terminology developed in the MIROW common vocabulary.

For more detailed information about the reports, please refer to the MIROW Principles and Business Rules Reports Support Document.

Principles and Business Rules

For context on how to read this table, please see the MIROW Principles and Business Rules Reports Support Document.

Rule ID - Title	Rule Statement
BC2019 - PR-001 - Business Continuity Plan Content	A business continuity plan should address the following with respect to disruptions: • Prevention • Mitigation • Response • Continuity of operations • Resumption of normal operations.
BC2019 - PR-002 - Security and Confidentiality	All business continuity plans should maintain applicable security and confidentiality requirements.
BC2019 - PR-003 - Maintain Data Integrity	A business continuity plan should ensure the integrity of all data maintained by an IIS that is impacted by a disruption.
BC2019 - PR-004 - Process to Follow Steps	Development of a business continuity plan should follow the steps in the order presented in the business continuity plan development process (Chapter 3 of this guide).
BC2019 - PR-005 - Leadership Commitment	Leadership should demonstrate commitment to the business continuity plan.
BC2019 - PR-006 - Sufficient Resources	Sufficient resources should be made available to develop, adopt, exercise, implement, and regularly review and update the business continuity plan.
BC2019 - PR-007 - Additional Leadership Communication	Ensure that internal partners are aware that the IIS is developing a business continuity plan.
BC2019 - PR-008 - Jurisdiction Plans	The business continuity plan should inform, comply with, and not contradict other applicable plans in the jurisdiction.
BC2019 - PR-009 - Legal Framework	The business continuity plan should inform, comply with, and not contradict applicable legislation, policies, and regulatory requirements.
BC2019 - PR-010 - Critical Time Frames	Recovery time objective and recovery point objective should be set for each selected essential business function.
BC2019 - PR-011 - Risk Calculation	Risk should be analyzed in terms of consequences (impact) and likelihood (probability).
BC2019 - PR-012 - Financial Support	Finance and administrative procedures should be developed to support the business continuity plan before, during and after a disruption.
BC2019 - PR-013 - Competency-Based Training	The IIS program should develop and implement a competency-based training and education curriculum that supports all individuals who have a role in the business continuity plan.

Rule ID - Title	Rule Statement
BC2019 - PR-014 - Regular Review and Update	A business continuity plan should be reviewed regularly and updated as necessary.
CR2017 - BR1001. Data validation	Data validation should occur within each demographic record and between each demographic record and all associated vaccination event records.
CR2017 - BR1002 / BR5802 Prevent overwriting validated data	The consolidating records process should not result in overwriting validated data.
CR2017 - BR1003 / BR5803. No conflict with existing data	The value of any data element should be consistent (i.e., in agreement) with other values in the patient record.
CR2017 - BR101 / BR5001 Base record: existing record over incoming record	Consolidation of an existing record with an incoming record should result in an update of the existing record.
CR2017 - BR102. Base record: two existing records	Consolidation of two existing records (i.e., with two IIS patient IDs) should result in one of the following outcomes: • A new consolidated record with a new IIS patient ID. • An updated consolidated record with one of the existing IIS patient IDs.
CR2017 - BR1101 / BR5901. Local laws, regulations, and policy control	Information should not be used in a consolidated record if local laws, regulations, or policies prohibit utilizing that information.
CR2017 - BR1201 / BR6001. Prevent remerging of previously unmerged records	Consolidation of previously unmerged records should be prevented.
CR2017 - BR201. Information needed to make consolidation decisions	The following information should be known for each data element and data group to make consolidation decisions: • Data source type • Specific data source • Most recent submission date • Confidence level.
CR2017 - BR202. Retain all past IIS patient IDs	All past IIS patient IDs associated with a consolidated demographic record should be retained by the IIS.
CR2017 - BR203. Use current (i.e., active) IIS patient ID	The current IIS patient ID should be included in all IIS-originated communications about a patient.
CR2017 - BR204. Retain past values	IIS should make accessible past values for the following data elements and data groups: • Alternate patient ID • Patient address • Patient alias name • Patient telephone • Patient email address.

Rule ID - Title	Rule Statement
CR2017 - BR301. Data elements considered to be a data group	All of the following collections of data elements should be considered as data groups: • Patient multiple birth (patient birth order and patient multiple birth indicator) • Patient telephone (patient telephone number and patient telephone number type) • Alternate patient ID (patient ID; patient ID: assigning authority ID; patient ID: type) • Responsible person name (first, middle, and last and relationship to patient) • Patient status (patient status indicator- provider facility level and provider facility IIS-IO) • Contraindication(s)/precautions(s) (contradiction(s)/precautions(s), contraindication(s)/precautions(s) observation date(s)) • Exemptions(s) (exemption(s)/parent refusal(s) of vaccine, date of exemption/parent refusal of vaccine) • History of vaccine-preventable disease (history of vaccine-preventable disease and date of history of vaccine-preventable disease) • Vaccine adverse reaction(s) (adverse reaction(s) and date of adverse reaction observation) • Original submission data (original submission date and data source ID for original submission) • Most recent submission data (most recent submission date and data source ID for most recent submission date).
CR2017 - BR302 / BR5203. Data group values are from same data source	The value for each data element in a data group must come from the same data source.
CR2017 - BR303 / BR5204. Treat elements of data group as one	All data elements within a data group should be treated as a single data element.
CR2017 - BR304 / BR5205. Values within a data group must be consistent	Values of all data elements within a data group should be consistent with each other.
CR2017 - BR401 / BR5201. Compare data elements of same type	Only data elements of the same type should be compared for consolidation purposes.

Rule ID - Title	Rule Statement
CR2017 - BR5002. Base record: two existing records	Consolidation of two existing records (i.e., with two IIS vaccination event IDs) should result in one of the following outcomes: • A new consolidated record with a new IIS vaccination event ID • An updated consolidated record with one of the existing IIS vaccination event IDs.
CR2017 - BR501 / BR5501. Use valid values	A valid value for a data element or data group should be used over an invalid value.
CR2017 - BR502 / BR5502. Use either of two identical valid values	A data element value from either one of two records under consideration should be selected as the best value for a consolidated record when all of the following are true: • Values are valid • Values are the same.
CR2017 - BR503 / BR5503. Use populated values over empty values	A valid value for a data element or data group should be chosen over an empty value.
CR2017 - BR504 / BR5504. Use either invalid value for required data elements	A data element value from either one of two records under consideration should be selected as the best value for a consolidated record when all of the following are true: • Values are invalid • Values are the same • Data element is required to have a value.
CR2017 - BR505 / BR5505. Use empty value instead of invalid value for non-required data element	The value of a data element or data group in a consolidated demographic record should be empty if all of the following are true: • The data element is not required by the IIS • The values in both matched records are invalid.
CR2017 - BR506 / BR5506. Use local implementation rules for invalid values for required data element	Local policies should be implemented for choosing between two different invalid values for a required data element in a consolidated record.
CR2017 - BR507 / BR5507. Use invalid value in certain cases	An invalid value should be selected over an empty value for a data element that is required to have a value.
CR2017 - BR508 / BR5508. Use empty value over invalid value for non-required data element	An empty value for a data element should be used over an invalid value when the data element is not required.
CR2017 - BR509 / BR5509. Use either value when both values are empty	The value of a data element in a consolidated record should be empty when the values in both matched records are empty.

Rule ID - Title	Rule Statement
CR2017 - BR5101. Information needed to make consolidation decisions	The following information should be known for each data element to make consolidation decisions: • Data source type • Specific data source • Most recent submission data • Confidence level • Administered/historical indicator value.
CR2017 - BR5102. Administered/historical indicator	The IIS should determine the value of the administered/historical indictor for each vaccination event record.
CR2017 - BR5103. Retain all past IIS vaccination event IDs	All past IIS vaccination event IDs associated with a consolidated vaccination event record should be retained by the IIS.
CR2017 - BR5104. Use current (i.e., active) IIS vaccination event ID	The current IIS vaccination event ID should be included in all IIS-originated communications about a vaccination event.
CR2017 - BR5105. Retain past values	IIS should make accessible past values for the following data group: Alternate vaccination event ID.
CR2017 - BR5202. Data elements considered to be data groups	All of the following collections of data elements should be considered as data groups: • Alternate vaccination event ID (vaccination event ID and vaccination event ID: assigning authority ID) • Vaccine dose volume and unit (vaccine dose volume and vaccine unit) • Contraindication(s)/precautions(s) (contradiction(s)/precautions(s), contraindication(s)/precautions(s) observation date(s)) • Exemptions(s) (exemption(s)/parent refusal(s) of vaccine, date of exemption/parent refusal of vaccine) • History of vaccine-preventable disease (history of vaccine-preventable disease and date of history of vaccine-preventable disease) • Vaccine adverse reaction(s) (adverse reaction(s) and date of adverse reaction observation) • Original submission data (original submission date and data source ID for original submission) • Most recent submission data (most recent submission date and data source ID for most recent submission date).

Rule ID - Title	Rule Statement
CR2017 - BR5301. Data elements with a single value.	The following data elements must have a single value: • Vaccination administration date • Vaccine product type administered (CVX-NDC-CPT) • Vaccine manufacturer name • Vaccine lot number • Vaccine expiration date • Vaccine dose volume and unit • Vaccine site of administration • Vaccine route of administration • Vaccine ordering provider name • Vaccine administering provider name • Vaccination event information source (i.e., administered or historical) • VFC/grantee program vaccine eligibility at dose level • Vaccine funding source • IIS vaccination event ID • Original submission date • Most recent submission date.
CR2017 - BR5401. Use administered vaccination event information over historical	The value of the data element from the administered record should be selected over the value of the same data element from a historical record, except for data elements that can have multiple values.
CR2017 - BR5402. Two administered vaccination event records (different data sources).	The IIS should investigate if two administered vaccination event records are submitted by different data sources.
CR2017 - BR5403. Use information that has most recent submission date.	The value from the vaccination event record with the most recent submission date should be used when comparing two administered vaccination event records from the same source.
CR2017 - BR5701. Use information with highest confidence level.	The value of the higher confidence level should be used for a data element in a consolidated record when comparing two historical vaccination event records.
CR2017 - BR5702. Use information that has most recent submission date.	The value with the most recent submission date should be used in a consolidated record when comparing two historical vaccination event records.
CR2017 - BR5801. Data validation.	Data validation should occur within each vaccination event record and between each vaccination event record and associated demographic record.

Rule ID - Title	Rule Statement
CR2017 - BR601. Supremacy of vital statistics	Vital statistics is a definitive source of information for the following data elements: • Patient date of birth • Patient gender • Patient multiple birth indicator • Patient birth order • Birthing facility name • Patient birth state • Mother's name: maiden last • Birth certificate number.
CR2017 - BR701. Data elements with a single value	The following data elements must have a single value: • Patient date of birth • Patient multiple birth indicator • Patient birth order • Birthing facility name • Patient birth state • IIS patient ID • Original submission date • Most recent submission date.
CR2017 - BR702 / BR5302. Retain all unique values from data elements with multiple values	All unique values should be retained for data elements that can have multiple current values.
CR2017 - BR801/ BR5601. Use more complete information	More complete information should be used over less complete information.
CR2017 - BR802 / BR5602. Use more specific information.	More specific information should be used over less specific information.
CR2017 - BR901. Use information with highest confidence level	The value with the higher confidence level should be used in a consolidated record.
CR2017 - BR902. Use information that has most recent submission date	The value with the most recent submission date should be selected for a consolidated record.
CR2017 - BR903 / BR5703. Use local policies if no selection made based on another business rule	An IIS should consistently implement local policies to select a value for the consolidating records process if other BRs do not result in selection of a value.
CR2017 - P01. Create consolidated record	The IIS should create a single consolidated demographic record for each patient and a single consolidated vaccination event record for each vaccination event.
CR2017 - P02. Use consolidated record	A consolidated record should be used for all IIS functions.
CR2017 - P03. Make original information accessible	Original information should be accessible by an IIS.
CR2017 - P04. Consolidation results	Consolidation should result in either a new record or an updated base record.

Rule ID - Title	Rule Statement
CR2017 - P05. Use best value for each data element	The best value for each data element from all available data sources should be selected for a consolidated record.
CR2017 - P06. Order for applying business rules	Business rules for selecting a best value for a data element should be applied in a specific order.
CR2017 - P07. Accuracy over completeness	Accurate information should be used over more complete information in a consolidated record.
CR2017 - P08. Confidence ranking for data sources	A confidence ranking for data sources should be established and used by the IIS.
CR2017 - P09. Recency	More recent information should be used over older information in a consolidated record when all other factors are equal.
CR2017 - P10. Unmerge	An IIS should be able to unmerge a consolidated record.
CR2017 - P11. Specific local laws control.	Local laws, regulations, and policies regarding opt-out, foster care, protective custody, and adoption supersede all other principles and business rules.
CR2017 - P12. Business routines should not be counterproductive	IIS business routines such as data quality/validation and consolidation should not be counterproductive.
CR2017 - P13. Principles and business rules apply regardless of method of transmission	The Ps and BRs in this guide should be applicable to all methods of data transmission.
DINV2016 - BR101 - Organize inventory information in IIS by the lot number, lot number expiration date, and lot-level public/private indicator	Inventory information should be organized in IIS by the lot number, lot number expiration date, and lot-level public/private indicator.
DINV2016 - BR102 - Prepopulate provider organization’s inventory in IIS	Provider organization's inventory in the IIS should be prepopulated based on the shipment data uploaded in the IIS from VTrckS.
DINV2016 - BR103 - Download shipment information daily	IIS should at least daily download shipment information from VTrckS and update provider organization's inventory in IIS by uploading shipment file into IIS.
DINV2016 - BR104 - Increment inventory item balance with shipment information.	Balance for an existing inventory item should be incremented by quantity of doses in the shipment, identified by lot number, lot number expiration date, and lot-level public/private indicator.
DINV2016 - BR105 - Verify physical contents of a vaccine shipment	A provider organization should verify the physical contents of a shipment against the packing slip and the information in the IIS by the close of business on the day of receipt.
DINV2016 - BR106 - Notify awardee VFC program and IIS of discrepancies between physical contents and packing slip and/or IIS	A provider organization should notify the awardee VFC program and the IIS immediately upon discovery of any discrepancy between physical contents of a shipment and the packing slip and/or information in the IIS.

Rule ID - Title	Rule Statement
DINV2016 - BR107 - Create new inventory item for short-dated doses	Awardee staff or provider organization should create a new inventory item for short-dated doses.
DINV2016 - BR108 - Calculate inventory item balance after creating new inventory item for short-dated doses	When the IIS creates a new inventory item for short-dated doses, the original inventory item balance should be calculated as a current quantity of doses minus the number of short-dated doses (compromised, but viable, and reassigned to the new inventory item).
DINV2016 - BR201 - Document the vaccination event after vaccine administration.	The provider organization should document a vaccination event (enter it in the EHR) after the vaccine is administered (not at the point when the vaccination is prescribed by the provider).
DINV2016 - BR202 - Submit information to IIS to support DI-v-EDE	To support the DI-v-EDE process, submission of vaccination event information should include: Lot number, Dose-level eligibility, Dose-level public/private indicator (optional for DI-v-EDE), Vaccination event date, CVX code, NDC (optional for DI-v-EDE), Provider organization IIS ID, Lot number expiration date.
DINV2016 - BR203 - Decrement only "administered" vaccines.	Only "administered" doses should result in automatic decrementing of inventory through the DI-v-EDE process.
DINV2016 - BR204 - Decrement only “active” inventory	Only "active" inventory may be decremented.
DINV2016 - BR205 - Do not automatically decrement if vaccination event date is earlier or equal to the most recent closed reconciliation date	The IIS should prevent automatic decrementing of inventory and log an issue when the vaccination event date is prior to or on the end date of the most recent closed reconciliation period.
DINV2016 - BR206 - Update patient record regardless of inventory-related issues	The IIS should update a patient record with demographic and immunization information reported in a submission regardless of any inventory-related issues with the submission.
DINV2016 - BR301 - Resolve data quality issues before reconciling	The provider organization should resolve data quality issues prior to reconciling inventory.
DINV2016 - BR302 - Freeze reconciliation results	The IIS should freeze the reconciliation results after the reconciliation process is closed. Updates subsequent to the reconciliation date should not affect ordering.
DINV2016 - BR303 - Reopen reconciliation that is closed	Once reconciliation is closed, it may be reopened only by IIS staff with elevated privileges (admin).
DINV2016 - BR401 - Establish and maintain a preapproval process for provider organizations	IIS should establish and maintain a preapproval process for provider organizations that intend to submit vaccination event information electronically to IIS.

Rule ID - Title	Rule Statement
DINV2016 - BR402 - Establish a testing environment for the preapproval process	IIS should establish a testing environment (technical and operational components) to support the preapproval process for provider organizations.
DINV2016 - BR403 - Establish a preapproval testing process	IIS should establish a preapproval testing process, which includes testing individually with EHR vendor test data and provider organization data.
DINV2016 - BR404 - Develop educational/training offerings	IIS should develop educational/training offerings to support DI-v-EDE process for participating provider organizations.
DINV2016 - BR405 - Document requirements and instructions for using the DI-v-EDE IIS functionality	IIS should document requirements and instructions for using the DI-v-EDE IIS functionality for provider organizations and EHR vendors.
DINV2016 - BR406 - Manage deletion of a patient’s record from IIS	If a patient's record is deleted from IIS, associated vaccination events that have been already accounted for via automatic decrementing should be unassociated from a patient's record and retained for inventory accounting purposes.
DINV2016 - BR407 - Examine all data elements for a DI-v-EDE submission during preapproval	During the preapproval process, the IIS should examine all data elements of a DI-v-EDE submission for accuracy and consistency.
DINV2016 - BR408 - Manage deletion of a vaccination event from IIS	If a vaccination event is deleted from IIS, associated inventory item should be incremented.
DINV2016 - BR409 - Manual corrections made in the IIS should also be made in the EHR	A provider organization should correct the data in the EHR to match any manual changes made in the IIS.
DINV2016 - P01 - DI-v-EDE should support the awardee program policies	DI-v-EDE should support the policies of the awardee immunization program.
DINV2016 - P02 - DI-v-EDE should support inventory tracking and immunization tracking	DI-v-EDE should support both inventory tracking and immunization tracking.
DINV2016 - P03 - The IIS must preapprove a provider organization for DI-v-EDE	A provider organization may participate in the DI-v-EDE process only if the IIS has preapproved the provider organization.
DINV2016 - P04 - Inventory information in the IIS should map to the storage model used by the provider organization	Categorization of information about a provider organization's inventory in the IIS should map to the vaccine storage model used by the provider organization.
DINV2016 - P05 - DI-v-EDE should minimize the burden on provider organizations	The DI-v-EDE process should minimize the burden on provider organizations to the extent possible.
DINV2016 - P06 - DI-v-EDE should support dose-level accountability	DI-v-EDE process should support dose-level accountability for vaccines.

Rule ID - Title	Rule Statement
DINV2016 - P07 - IIS should notify provider organizations of problems in DI-v-EDE process	IIS should notify provider organizations of problems in DI-v-EDE process.
DINV2016 - P08 - IIS should assist provider organizations with correcting data quality issues	IIS should assist provider organizations with correcting data quality issues that affect DI-v-EDE.
DINV2016 - P09 - The IIS should decrement an administered dose only once	Every administered dose should be decremented from a provider organization's inventory only once.
DLE2011 - BR601 - Age Criteria	The Patient has to fit the age criteria of the Vaccine Program.

DLE2011 - 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):
	  ○ Immunization history (if child needs vaccination)
	  ○ Patient Date of Birth (DOB)
	  ○ Patient health insurance plan (Medicaid and/or private insurance)
	  ○ AI/AN status
	  ○ Grantee Vaccine Programs available
	  ○ 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):
	  ○ Outcome of the Vaccination encounter screening
	  ○ Vaccine needed
	  ○ Vaccine Eligibility.

DLE2011 - 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 VFC ineligible and does not have private insurance coverage for a Vaccine, or over 19 years old should be done once per Vaccination Event or once per Vaccination Encounter (driven by the Grantee Vaccine Program rules).

Rule ID - Title	Rule Statement
DLE2011 - 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.
DLE2011 - BR605 - Underinsured vs. Medicaid and Provider Organization type	If the Patient: • 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.
DLE2011 - 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.
DLE2011 - 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 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.
DLE2011 - 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).

Rule ID - Title	Rule Statement
DLE2011 - BR609 - How to deal with dual-coverage	For a VFC eligible Patient who has private 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.
DLE2011 - 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.
DLE2011 - BR611 - What format to use	Screening data should be documented/ recorded electronically.
DLE2011 - BR612 - When to record	Record Vaccination Event after the Vaccine has been administered.
DLE2011 - BR613 - How often to report Patient's eligibility	Provider Organization should report Patient's eligibility to IIS for every Vaccination Event (dose administered).
DLE2011 - BR614 - What information to report (minimum set)	Minimum set 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.

Rule ID - Title	Rule Statement
DLE2011 - 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.
DLE2011 - 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.
DLE2011 - 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.
DQA2013 - BR818 - Org B is a part of Org A, is acquired intact by Org C	If an IIS-AO (Org B) which is part of an existing IIS-AO (Org A) is "acquired" intact by a different IIS-AO (Org C), the IIS should follow one of the following approaches: • Option 1: De-authorize acquired IIS-AO (Org B) and create a new IIS-AO (Org D) with a new IIS-AO ID, and associate it with the acquiring IIS-AO (Org C). • Option 2: Update the structural hierarchy of the acquired (Org B) and acquiring (Org C) IIS-AOs and maintain the acquired IIS-AO ID.
DQA2013 - BR819 - Stand-alone Org A is acquired as an intact sub-unit by another Org	If a stand-alone IIS-AO (Org A) is "acquired" as an intact sub-unit by another IIS-AO, the IIS should follow one of the following approaches: • Option 1: De-authorize the acquired IIS-AO (Org A) and create a new IIS-AO (Org C) with a new IIS-AO ID, and associate it with the acquiring IIS-AO (Org B). • Option 2: Establish a structural hierarchy between the acquired (Org A) and acquiring (Org B) IIS-AOs and retain the acquired IIS-AO ID.
DQA2013 - BR820 - Org A and Org B merge to form one new organization	If two or more IIS-AOs (Org A and Org B) merge to form one new organization, the IIS-AOs (Org A and Org B) should be de-authorized and a new IIS-AO (Org C) should be created with a new IIS-AO ID.

Rule ID - Title	Rule Statement
DQA2013 - BR821 - Org B is part of Org A, becomes new stand-alone entity	If an IIS-AO (Org B) which is part of an existing IIS-AO (Org A) becomes a new stand-alone entity, the IIS should follow one of the following approaches: • Option 1: De-authorize the original sub-unit (Org B) and create a new IIS-AO (Org C) with a new IIS-AO ID. • Option 2: Remove the structural linkage between the spun-off IIS-AO (Org B) and its prior parent IIS-AO (Org A) and maintain the IIS-AO ID of the spun-off IIS-AO.
DQA2013 - BR822 - Portion of Org A is acquired by and becomes a sub-unit of another Org	If a portion of an IIS-AO (Org A) is acquired by and becomes a sub-unit (Org C) of another IIS-AO (Org B): Create a new IIS-AO (Org C) with a new IIS-AO ID, and associate it as a child of the acquiring organization (Org B).
DQA2013 - BR823 - Org A and Org B, containing sub-org units, merge to form one new organization	If two or more IIS-AOs (Org A and Org B), containing sub-org units, merge to form one new organization, each of the sub-units should follow the same best practices which apply.
DQA2022 - BR001 - Minimum/mandatory data elements	The data elements that should be present in each type of submission. Appendix A – Submission Table
DQA2022 - BR101 - Authorized provider organization	An IIS program should only accept submissions from authorized provider organizations.
DQA2022 - BR102 - Establish provider organization profile	An IIS program should have a provider organization profile for each IIS-AO that includes, but is not limited to the following: • IIS-AO ID • Cross-reference to prior IIS-AO ID(s) • Organizational and reporting structure • Provider Organization Type • Frequency of submissions • Estimated volume of vaccination event submissions • Estimated volume of demographic submissions • Method of reporting • Health IT Modules (e.g., 'EHR' vendor, school systems) • Decrementing inventory indicator • Site interface configuration • Training needs • IIS last review of provider organization date.
DQA2022 - BR103 - Establish signed agreements	An IIS program should require a signed agreement with each vaccinating organization, recording organization, and submitting organization that details the procedures for the following: • Reviewing submission errors • Addressing data quality issues within the time frames established by the IIS program.

Rule ID - Title	Rule Statement
DQA2022 - BR104 - Signed security and confidentiality agreement	An IIS program should require a provider organization to sign a security and confidentiality agreement prior to being authorized.
DQA2022 - BR105 - IIS-AO approved for EDE	An IIS program may accept a submission via electronic data exchange (EDE) from an IIS-AO only if the IIS-AO has been approved for EDE submissions.
DQA2022 - BR106 - Administered initial submission	An initial submission for a vaccination event that has the administered/historical indicator as 'administered' should be made within 24 hours of the vaccination event.
DQA2022 - BR107 - Vaccination event submission of hepatitis B birth dose	An IIS program should communicate to Vital Records that the vaccination event submission of the hepatitis B birth dose should be before the due date for the second dose of hepatitis B.
DQA2022 - BR108 - Vaccination event submission action code	An IIS should record and implement the action code submitted for every vaccination event submission.
DQA2022 - BR109 - Standard value tables	An IIS program should have standard value tables for validation of the following data elements: • Patient Gender • Patient Race • Patient Ethnicity • Dose-Level Eligibility • Dose-Level Public/Private Indicator.
DQA2022 - BR110 - Valid calendar dates in a submission	A date in a submission should be a valid calendar date.
DQA2022 - BR111 - Vaccination event date not before patient's date of birth	A vaccination event date should not be before (less than) the patient's date of birth.
DQA2022 - BR112 - Submission not before date of birth	A submission should not be submitted before (less than) the patient's date of birth.
DQA2022 - BR113 - Submission not before vaccination event	A submission should not be submitted before (less than) the vaccination event.
DQA2022 - BR114 - Vaccination event date not after patient's date of death	A vaccination event date in a vaccination event record should not be after (greater than) the patient's date of death.
DQA2022 - BR115 - Vaccination event date not after lot number expiration date	A vaccination event record should not have a vaccination event date that is after (greater than) the lot number expiration date.
DQA2022 - BR116 - Vaccination event date for birth vaccine types	A vaccination event date in a vaccination event record should be the same as (equal to) the patient's date of birth only if the vaccine dose is in the recommended list of birth vaccine types.

Rule ID - Title	Rule Statement
DQA2022 - BR117 - Vaccine type CVX	An IIS program should educate the IIS-AO and other data exchange partners that CVX code is the preferred method of reporting the vaccine type.
DQA2022 - BR118 - Specified formulation for administered	The vaccine type in a vaccination event record should be a specified formulation if it is included in an administered vaccination event submission.
DQA2022 - BR120 - Combination vaccine reported as single vaccination event	An IIS program should educate IIS-AO staff to report a combination vaccine dose as a single vaccination event rather than multiple vaccination events.
DQA2022 - BR121 - Vaccine type available in United States	An administered vaccination event submission submitted by a vaccinating organization that is located in the United States should not include a vaccine type that is not now and has never been available for administration in the United States.
DQA2022 - BR122 - Vaccine has vaccine product type	A vaccination event record should include a vaccine that is classified by a vaccine product type (NDC).
DQA2022 - BR124 - Vaccine product type manufacturer	A vaccination event submission should not include a manufacturer that does not produce the vaccine product type.
DQA2022 - BR125 - Patient age within recommended range	A patient record should not be associated with a vaccination event record where the patient's age is less than or equal to the minimum age or greater than or equal to the maximum age recommended for the vaccine product type.
DQA2022 - BR126 - Vaccine information should be consistent	The vaccine product type, vaccine type, and manufacturer of a vaccine should be consistent with one another.
DQA2022 - BR127 - Vaccination event dosage	An administered vaccination event submission should have a vaccination event dosage with all the following: • A value that is a positive number • A unit of volume measurement (e.g., mL).
DQA2022 - BR128 - Approved vaccine administration method	A vaccine route of administration, vaccine site of administration, and vaccination event dosage should be consistent with the vaccine product type and patient age.
DQA2022 - BR129 - Lot number validation	A lot number in a vaccination event record should include only the following types of characters: • Alphabetic • Numeric • Dash (-).
DQA2022 - BR130 - Number contains information for only one lot number	Lot number in a vaccination event record should contain a single lot number and no other additional information.
DQA2022 - BR131 - Lot number recommended	Lot number information should be reported for every vaccine dose administered.
DQA2022 - BR132 - Lot number accuracy	Lot number should not be prefixed, appended, or embedded with extraneous character strings.

Rule ID - Title	Rule Statement
DQA2022 - BR133 - Vaccine product license	A vaccine product type in a vaccination event record should have all the following: • A vaccine product license begin date before or the same as the vaccination event date • A vaccine product license end date after or the same as the vaccination event date.
DQA2022 - BR134 - Dose-level eligibility indicated	A dose-level eligibility should be indicated for each administered vaccination event submission.
DQA2022 - BR135 - Consistent vaccine eligibility	The dose-level public/private indicator and dose-level eligibility in a vaccination event record should be consistent with each other.
DQA2022 - BR136 - Educate IIS-AO on when to use historical	An IIS program should educate IIS-AO staff that they should only submit a vaccination event submission with an administered/historical indicator of "historical" if their IIS-AO did not administer the vaccine dose described in the vaccination event.
DQA2022 - BR137 - Administered/historical indicator should not be defaulted	An IIS program should not default an administered/historical indicator if it is missing or incorrect in a submission.
DQA2022 - BR138 - Include vaccine administrator and vaccine prescriber in the submission	A vaccination event submission should include the full name and license number for the following: • The provider who prescribed the vaccine • The provider who administered the vaccine.
DQA2022 - BR140 - Expected number of vaccination event records	A patient record should have an expected number of associated vaccination event records based on the patient's age and ACIP recommendations.
DQA2022 - BR141 - Recommended number of vaccine doses	A patient record should not be associated with more than the recommended number of vaccine doses per vaccine type for the patient's age based on ACIP recommendations.
DQA2022 - BR142 - Minimum intervals for vaccination event records	Vaccination event records for a patient should be at intervals that are equal to or greater than the minimum intervals provided in the ACIP recommendations.
DQA2022 - BR143 - Number of vaccine doses in a vaccination encounter	A patient record should not be associated with a vaccination encounter that contains more than the recommended number of vaccine doses.
DQA2022 - BR144 - Same antigen on same day	A patient record should not be associated with multiple vaccination event records with all the following: • The same vaccination event date • Vaccine product types that include the same antigen.

Rule ID - Title	Rule Statement
DQA2022 - BR145 - Allowed character for name	All data elements that contain types of names in a demographic record should contain only the following kinds of characters: • Alphabetic • Hyphen '-' • Apostrophe • Accented characters • Space ' '.
DQA2022 - BR146 - Use official names	An IIS program should educate IIS-AO staff on the importance of using official patient names.
DQA2022 - BR147 - Patient first name	A patient first name in a demographic record should not remain a generic name after a time period determined by the IIS program.
DQA2022 - BR148 - Patient first and last name two characters	A patient first name and a patient last name in a demographic record should each be at least two characters long.
DQA2022 - BR149 - Mothers name	An IIS program should work with Vital Records to encourage collection and submission of the following: • Mother's maiden name • Mother's first name • Mother's middle name • Mother's last name.
DQA2022 - BR150 - Leap year age calculation	Date of birth in a demographic record that is February 29 should be assumed as February 28 when calculating age in a non-leap year.
DQA2022 - BR151 - Minimum date of birth	Date of birth in a demographic submission should be after 1/1/1900.
DQA2022 - BR152 - Date of birth default	An IIS program should educate IIS-AO staff to default all the following: • The month of birth to January if the month is not known for the patient • The day of birth to 1 if the day is not known for the patient.
DQA2022 - BR153 - More than one patient race	A demographic record should support storing multiple values for patient race.
DQA2022 - BR154 - Complete address	An IIS program should educate IIS-AO staff that a patient address should be valid in order to contact the patient by mail.
DQA2022 - BR155 - International address supported	An IIS should have the ability to store international addresses.
DQA2022 - BR156 - Verified address	An IIS program should verify addresses using a standard address verification service.

Rule ID - Title	Rule Statement
DQA2022 - BR157 - Patient phone number format	An IIS should have the capacity to include all the following for a patient phone number: • Country code • Area code • Phone number.
DQA2022 - BR158 - Patient phone number numeric only	A patient phone number should not include any non-numeric characters (e.g., dashes).
DQA2022 - BR159 - Educate on use of medical record numbers	An IIS program should educate IIS-AO staff on the following related to medical record numbers: • Maintain unique medical record numbers assigned to a patient and not reassign the medical record number to another patient • Do not assign a mother's medical record number to a newborn.
DQA2022 - BR160 - Medical record number not equal to Social Security Number	An IIS program should instruct the IIS-AO to not use a patient's Social Security Number as a medical record number.
DQA2022 - BR161 - Record submission errors and submission status	An IIS should record all the following for a submission: • All submission errors • The submission status.
DQA2022 - BR162 - Review rejected submissions within five days	A submission should be reviewed by an IIS program within five business days of the submission date if any of the following are true: • The submission has been rejected • The submission has errors.
DQA2022 - BR163 - Review the submission reports	An IIS program should review submission reports for errors and deviations in trends.
DQA2022 - BR164 - Hepatitis B birth dose	An IIS program should monitor hepatitis B birth dose vaccination event submissions from Vital Records to identify significant deviations in the number of submissions over time.
DQA2022 - BR165 - Vital records submissions	An IIS program should monitor the number of submissions from Vital Records to identify significant deviations in the number of submissions over time.
DQA2022 - BR166 - Rejected vaccination event submission	An IIS program should monitor the percentage of rejected submissions from an IIS-AO to identify significant deviations in the percentage of rejections over time from the IIS-AO.
DQA2022 - BR167 - Historical vaccination event submissions	An IIS program should monitor the percentage of historical vaccination event submissions from an IIS-AO to identify significant deviations in the number of historical submissions over time from the IIS-AO.

Rule ID - Title	Rule Statement
DQA2022 - BR168 - Submissions are appropriate for provider organization type	The administered vaccination event submissions from a vaccinating organization should match all the following for their provider organization type: • Vaccine types • Patient ages.
DQA2022 - BR170 - Monitor data element completeness	An IIS program should monitor data element completeness at the IIS and IIS-AO levels for data elements that have a high importance for • Medical or public health purposes • IIS technical processes • Vaccine accountability.
DQA2022 - BR171 - Educate communicate and perform outreach to improve completeness	An IIS program should educate, communicate, and perform outreach to improve completeness for data elements that have a high importance for • Medical or public health purposes • IIS technical processes • Vaccine accountability.
DQA2022 - BR172 - IIS-AO ID issued once authorized	An IIS program should not issue an IIS-AO ID to a provider organization until it is authorized.
DQA2022 - BR173 - IIS-AO IDs should be unique	An IIS program should assign a unique IIS-AO ID to each IIS-AO and never reuse an IIS-AO ID.
DQA2022 - BR174 - IIS-AO IDs should not embed information about the IIS-AO	An IIS program should not embed information about the IIS-AO in the IIS-AO ID.
DQA2022 - BR175 - Educate submitting organization to include all IIS-AO IDs	An IIS program should educate the submitting organization on ensuring there are valid IIS-AO IDs included for all IIS-AOs involved in the submission.
DQA2022 - BR176 - Maintain both legal and common names for an IIS-AO	An IIS program should capture all the following for an IIS-AO: • IIS-AO common name • IIS-AO legal name.
DQA2022 - BR177 - Validate organizational and reporting structure regularly	An IIS program should review the organizational and reporting structures of its IIS-AOs on a regular basis.
DQA2022 - BR178 - Contact IIS-AO prior to deauthorizing	An IIS program should contact an IIS-AO before deauthorizing the IIS-AO.
DQA2022 - BR179 - Deauthorize IIS-AO if it dissolves	An IIS program should deauthorize an IIS-AO if the IIS-AO dissolves.
DQA2022 - BR180 - Deauthorize IIS-AO if it no longer plays any IIS-AO roles	An IIS program should deauthorize an IIS-AO if the IIS-AO is not operating in any of the following roles: • Vaccinating organization • Recording organization • Submitting organization • Data Consumer.

Rule ID - Title	Rule Statement
DQA2022 - BR181 - Assess necessity to deauthorize IIS-AO that is not required to submit and is not submitting	An IIS program should consider de-authorizing a vaccinating organization if the vaccinating organization is all the following: • Not required to submit submissions to the IIS • Not submitting submissions to the IIS.
DQA2022 - P01 - Multiple approaches to achieve data quality	Data quality should be achieved via multiple approaches such as programmatic and technical resources.
DQA2022 - P02 - Validation priority	The priority of validating a data element is related to the data element's significance in clinical decision-making, public health assessments, and research.
DQA2022 - P03 - Timeliness	Data should be reported to the IIS in a timely manner.
DQA2022 - P04 - Availability	An IIS has the responsibility to ensure data is available to users in a timely manner, once received by the IIS.
DQA2022 - P05 - Mandatory data elements	The submissions should contain the minimum/mandatory set of data elements in order to be accepted by the IIS.
DQA2022 - P06 - Cross-field validation	Cross-field validation should occur between multiple vaccination events that comprise a patient's immunization history as well as between components of individual vaccination events.
DQA2022 - P07 - Consistent application of business rules	All submissions submitted to an IIS should be subject to the same business rules regardless of how the submissions are reported to the IIS.
DQA2022 - P08 - Submit all available information	An IIS program should educate an IIS-AO on collecting and submitting as much information as possible for the demographic and vaccination event submissions.
DQA2022 - P09 - ACIP recommendations	Deviations from ACIP recommendations and FDA licensure are indications of potential data quality problems.
DQA2022 - P10 - Accurately Reflect Vaccination Event	A vaccination event submission should accurately reflect the vaccination event that actually occurred.
DQA2022 - P11 - Develop Data Quality Reports	An IIS program should develop data quality and assessment reports and regularly review and update them.
DQA2022 - P12 - Data Quality Reports for IIS-AOs	An IIS program should develop data quality and assessment reports for IIS-AOs to use.
DQA2022 - P13 - Develop Data Quality Plan	An IIS program should develop and implement a data quality plan that includes the following: • Training of staff • Timely assessment of reports.
DQA2022 - P14 - Educate IIS-AO Staff	An IIS program should educate IIS-AO staff on general expectations for data quality of submissions and how to use data quality and assessment reports.
DQA2022 - P15 - Document Expectations	An IIS program should document expectations of the IIS program and IIS-AO.

Rule ID - Title	Rule Statement
DQA2022 - P16 - IIS should be notified about IIS-AO organizational changes	An IIS-AO should notify an IIS program if the IIS-AO has any organizational changes that may impact the IIS-AO's interaction with the IIS program.
DQA2022 - P17 - Consistent provider organization management	IIS should document and be consistent in the approaches followed for Provider Organization Management.
DQA2022 - P18 - Vital Records	Vital Records should be considered the definitive source for a patient's • Date of Birth • Date of Death.
DQA2022 - P19 - Supremacy of medical records	Medical records are a more reliable and accurate source of immunization data than billing records.
DQA2022 - P20 - Vendor update applications	An IIS program should ensure vendors are using the most up to date version of HL7 specification.
DQA2022 - P21 - Complete chain of submitting organizations	A submission should identify all submitting organizations.
DQA2022 - P22 - Submission retained indefinitely	Every unique submission should be retained per jurisdictional policy, along with all errors identified.
DQA2022 - P23 - Reference a directory of known lot numbers	A directory of known lot numbers should be created, maintained, and referenced for lot number validation purposes.
DQA2022 - P24 - Reference a directory of manufacturer-specific coding schemes for lot numbers	A directory of manufacturer-specific coding schemes for lot numbers should be created, maintained, and referenced for lot number validation purposes.
DQA2022 - P25 - Maintain reliability of reference directories	Reference directories should be periodically reviewed and reconfirmed as reliable reference sources for validating lot numbers.
INV2012 - BR701 - Use NDC received in the shipment file	The NDC received from VTrckS (in the shipment file) should be used for receiving, reporting, and tracking inventory.
INV2012 - BR702 - Lot number must be matched/mapped to NDC for every dose	Lot number for every vaccine dose utilized by a Provider Organization must be matched/mapped to NDC for a specific inventory entry and the appropriate transaction should be created to adjust the inventory appropriately.
INV2012 - BR703 - Make NDC known prior to arrival of a direct vaccine shipment	IIS should make NDC known to Provider Organization prior to arrival of a direct vaccine shipment.
INV2012 - BR704 - Capture the lot number for every vaccine dose administered	A lot number for every vaccine dose administered must be documented and reported by the Provider Organization to the IIS.
INV2012 - BR705 - Capture patient eligibility for every dose administered	A patient eligibility for every vaccine dose administered must be documented and reported by the Provider Organization to the IIS.

Rule ID - Title	Rule Statement
INV2012 - BR706 - Capture Provider Organization responsible for inventory for every dose administered	Provider Organization responsible for the inventory must be associated with every immunization (dose administered transaction).
INV2012 - BR707 - Track borrowing and replacements at the dose level	Borrowing and replacement of borrowed vaccine doses between public and private stocks should be tracked at the dose level.
INV2012 - BR708 - Account for wasted, spoiled/expired, and unaccounted for vaccines at the dose level	Inventory adjustment to account for wasted (non-viable and non-returnable), spoiled/expired (non-viable and returnable), and unaccounted for vaccines should be done at the dose level.
INV2012 - BR709 - Minimum set of data items for every shipment	For every shipment the minimum/mandatory set of data items recorded for the purposes of inventory management should include: • Date shipped • Order ID • Order Line Number (associated with data items below) • NDC • Lot Number • Lot Number Expiration Date • Quantity (in doses) • Public/Private Indicator.
INV2012 - BR710 - Verify shipment information	Provider Organization should verify in terms of quantity, type, etc. a match between a) Vaccines received in a shipment. b) The information on a package slip. c) Information in the IIS. d) Information in the EHR.
INV2012 - BR711 - Minimum set of data items for every vaccine dose	For every vaccine dose the minimum/mandatory set of data items recorded and reported to the IIS for the purposes of inventory management should include: • Lot number (to be matched/mapped to NDC) • Lot Number Expiration Date • Patient eligibility status (for administered vaccines) • Provider Organization (responsible for the inventory) • Public/Private Indicator (optional - see the alternative good practice that involves public/private identification at the lot number level - described in the right column).
INV2012 - BR712 - Use (record) short-dated expiration date when present	When present, the new short-dated Lot Number Expiration Date must be used (recorded) for all inventory transactions instead of the original expiration date.

Rule ID - Title	Rule Statement
INV2012 - BR713 - Minimum data set for vaccine transfers	The following information should be present for vaccine transfers between Provider Organizations: • Sending Provider Organization VFC Pin (or ID for the Provider Organization) • Receiving Provider Organization VFC Pin (or ID for the Provider Organization) • Lot number (maps to vaccine type, NDC) • Lot Number Expiration Date (maybe a short date) • Quantity (in doses) • Public/Private Inventory Indicator • Timestamps of requests/receipt • Reason for transfer (optional) • Person who initiated transfer (optional).
INV2012 - BR714 - Verify condition, types, and quantities of transferred vaccine doses	Provider Organizations should verify condition, types, and quantities received in a transfer from another Provider Organization against expected number and type of doses.
INV2012 - BR715 - Account for non-administration adjustments on the same day	All events generating non-administration adjustments to available on hand inventory should be accounted for in the IIS on the same day they occur.
INV2012 - BR716 - Track the event date and recording date	Both the date that an inventory-related event occurred and the date that the transaction was entered into the IIS should be tracked to facilitate reconciliation.
INV2012 - BR717 - Submit data to IIS before reconciling inventory	Provider Organizations must have their immunization data submitted to and processed by the IIS before reconciling their inventory for the corresponding reconciliation period.
INV2012 - BR718 - Indicate IIS-EHR discrepancies	When inventory information in an electronic feed from an EHR to IIS cannot be matched to a specific provider lot entry, IIS must provide a mechanism to indicate/flag the discrepancy to the Provider Organization.
INV2012 - BR719 - Account for opt-out patients before reconciling	At the appointment time Provider Organization should make inventory adjustments for vaccines administered to opt-out patients before reconciling its inventory for the corresponding reconciliation period.
INV2012 - BR720 - EHR submission for an opt-out patient	For an EHR submission for an opt-out patient, IIS should decrement inventory without updating the patient record.
INV2012 - BR721 - Do physical inventory count for reconciliation on a day boundary	Physical inventory count for reconciliation purposes should always be done on a day boundary (i.e., at the end of a business day or prior to the next business day).
INV2012 - BR722 - Reconcile inventory immediately prior to ordering	Provider Organizations must reconcile their entire physical inventories to the IIS inventory immediately prior to ordering.

Rule ID - Title	Rule Statement
INV2012 - BR723 - Reconciliation frequency	Provider Organizations should reconcile their entire physical inventory to the IIS at least once a month, large, complex Provider Organizations may consider reconciling more frequently (e.g., weekly) to minimize the risk of inventory errors.
INV2012 - BR724 - Ensure accurate inventory count for pre-adoption Provider Organizations	For adoptions where original patient identity needs to be inaccessible, IIS must ensure that inventory levels are accurately maintained for the pre-adoption Provider Organization(s).
INV2012 - BR725 - Borrowing should be done at the single-dose level	When a multi-dose vial is involved, borrowing should be done at the single-dose level.
INV2012 - P701 - NDC supremacy	Vaccine inventory management should be based on the National Drug Code (NDC).
INV2012 - P702 - Dose-lot number accountability	Every vaccine dose should be accounted for with the associated lot number information.
INV2012 - P703 - Completeness	The inventory management information submitted to an IIS must contain the minimum/mandatory set of data items in order to be accepted by the IIS.
INV2012 - P704 - Accurate accounting	Provider Organization's physical inventory (available/on hand) should be accurately reflected in the IIS.
INV2012 - P705 - Timely accounting	Provider Organization's inventory should be adjusted in the IIS as soon as an event requiring the adjustment becomes known.
INV2012 - P706 - Reconciliation frequency	Provider Organizations should reconcile their physical inventories to the IIS at a frequency appropriate to the size and complexity of their practice or clinical setup.
INV2012 - P707 - Comply with privacy guidelines	Comply with HIPAA interpretations and other privacy-related constraints, e.g., handling adoption and opt-out of IIS cases.
INV2012 - P708 - Avoid loaning doses between private and public stock	Borrowing doses between private and public stock should be avoided.

MPS2019 - BR401 - Nomenclature of statuses at the provider organization level	Patient status at provider organization level may have only one of the following designations:
	• Active
	• Inactive, with one of the following reason codes:
	  ○ No longer a patient
	  ○ Lost to follow-up
	  ○ Unspecified
	  ○ Deceased.

Rule ID - Title	Rule Statement
MPS2019 - BR402A - Active status at the provider organization level: 1-1	For the 1-1 approach, patient status with a provider organization should be considered active only if the provider organization is of an acceptable type and any of the following is true: • Provider organization directly identifies the individual as a patient. • Provider organization indirectly identifies the individual as a patient. • Provider organization has conducted the most recent vaccination event during the vaccination encounter of an acceptable type for the patient. • Provider organization has created new patient record in IIS (i.e., submitted or entered patient demographic-only information or historical-only immunization information for a patient not already in IIS).

MPS2019 - BR402B - Active status at the provider organization level: 1-M	For the 1-M approach, patient status with a provider organization should be considered active only if the provider organization is of an acceptable type and any of the following is true:
	• Provider organization directly identifies the individual as a patient.
	• Provider organization indirectly identifies the person as a patient in any of the following ways:
	  ○ Provider organization conducted a vaccination event during a vaccination encounter of an acceptable type for the patient.
	  ○ Provider organization has created new or updated an existing patient record in IIS (i.e., submitted or entered patient demographic-only information or historical-only immunization information for a patient).

MPS2019 - BR404A - Patient status at the provider organization level: inactive: no longer a patient:1-1	For the 1-1 approach, patient status at the provider organization level should be considered inactive (reason code no longer a patient) only if any of the following is true:
	• Relationship between a provider organization and a patient has been terminated by either party, for example:
	  ○ Patient has gone/transferred to another provider organization
	  ○ Patient has moved out of the area
	  ○ Patient has received a more recent immunization from another provider organization.

Rule ID - Title	Rule Statement

MPS2019 - BR404B - Patient status at the provider organization level: inactive: no longer a patient:1-M	For the 1-M approach, patient status at the provider organization level should be considered inactive (reason code no longer active) only if any of the following is true:
	• Relationship between a provider organization and a patient has been terminated by either party, for example:
	  ○ Patient has gone/transferred to another provider organization
	  ○ Patient has moved out of the area.

MPS2019 - BR405 - Patient status at the provider organization level: inactive: lost to follow-up	Patient status at the provider organization level should be considered inactive (reason code lost to follow-up) only if any of the following is true: • Attempts to contact the patient have been documented, but no documented response has been received • Provider organization has no means to contact patient, e.g. no address, no cell phone.
MPS2019 - BR406 - Patient status at the provider organization level: inactive: unspecified	Patient status at provider organization level should be considered inactive (reason code unspecified) only if patient's information has been submitted to an IIS via an electronic interface with inactive status without a reason code being specified.

MPS2019 - BR411 - Nomenclature of statuses at the geographic jurisdiction level	Patient status at the geographic jurisdiction level may have only one of the following designations:
	• Active
	• Inactive, with the following reason code
	  ○ Outside jurisdiction
	• Unknown, with the following reason codes:
	  ○ No address, no vaccination
	  ○ No activity for extended period of time
	• Deceased.

MPS2019 - BR412 - Active status at the geographic jurisdiction level	Individual status with a geographic jurisdiction should be considered active only if any of the following is true: • Individual residence within the geographic jurisdiction has been confirmed. • Individual received an immunization from a provider organization within the geographic jurisdiction, and individual's address is not known (this condition applies only to highest level geographic jurisdiction, such as state or city).
MPS2019 - BR413 - Patient status at the geographic jurisdiction level: inactive: outside jurisdiction	Patient status at geographic jurisdiction level should be considered inactive (reason code outside jurisdiction) only if the patient does not reside in the geographic jurisdiction.

Rule ID - Title	Rule Statement
MPS2019 - BR414 - Patient status at the geographic jurisdiction level: unknown: no address, no vaccination	Individual status at the geographic jurisdiction level should be considered unknown: no address, no vaccination only if the IIS has never received an address and has never received vaccination information about the individual.
MPS2019 - BR415 - Patient status at the geographic jurisdiction level: unknown: no activity for extended period of time	Patient status at geographic jurisdiction level should be considered unknown: no activity for extended period of time only if the IIS has not received demographic and/or immunization information for a patient for an extended period of time.
MPS2019 - BR421 - Deceased status at the provider organization and geographic jurisdiction levels	Patient status at the provider organization and geographic jurisdiction levels should be considered inactive with the reason code deceased only if a patient's death is confirmed.
MPS2019 - P301 - Patient status scope: association between one patient and one party	Each patient status should characterize the association between one patient and one party responsible for the patient's vaccinations.
MPS2019 - P302 - Patient status hierarchy	Statuses for a patient should be maintained in a hierarchical manner, specifically: • At the provider organization level (lower level of the hierarchy) • At the geographic jurisdiction level(s) (higher levels of the hierarchy).
MPS2019 - P303 - Avoid having patients fall through the cracks	A more rigid approach should be used in assigning non-active status at the geographic jurisdiction level than at the provider organization level.
MPS2019 - P304 - Who may assign patient status	Patient status at provider organization level may be assigned by any of the following parties: • Provider organization • Immunization program (at state, city, or county levels) Patient status at geographic jurisdiction level may be assigned only by the immunization program (at state, city, or county levels).
MPS2019 - P305 - Make information available about patient status changes	IIS should make available to a provider organization the information about changes it makes to a status maintained for a patient associated with that provider organization.
MPS2019 - P308 - Supremacy of patient status explicit assignment	Any explicit assignment of patient status by a provider organization of an acceptable type should supersede both • Previous patient status with that provider organization • Patient status that can be indirectly implied by IIS based on the information available up to this moment.
MPS2019 - P309 - Same rules for public and private provider organizations	Rules for status assignment should be the same for public and private provider organizations.

Rule ID - Title	Rule Statement
MPS2019 - P310 - Out-of-state patients	Status should be maintained at the provider organization level for a patient who resides outside the geographic jurisdiction served by the IIS but is associated with a provider organization within that geographic jurisdiction. Status may never be active at the geographic jurisdiction level for a patient who resides outside the geographic jurisdiction served by the IIS but is associated with a provider organization within that geographic jurisdiction.
MPS2019 - P311 - Patient status should be maintained for patients of all ages	Patient status should be maintained for patients of all ages.
MPS2019 - P312 - Any submission should include patient status	Patient status should be included in any submission from a provider organization to the IIS.
MPS2019 - P313 - Opt-out from IIS	Opting out of IIS should not impact patient status. Rather, it should be handled as an additional consideration (filter) for selecting a cohort for reminder/recalls and coverage assessments.
MPS2019 - P314 - Opt-out from reminder/recall	Opting out of reminder/recall notifications should not impact patient status. Rather, it should be handled as an additional consideration (filter) for selecting a cohort for reminder/recall.
RR2009 - BR201	If the Immunization Home is known, that Provider is primarily responsible for RR processes for routine immunizations.
RR2009 - BR202	If the Immunization Home is not known, a geographic Jurisdiction (e.g., State or local public health agency) is primarily responsible for RR processes for routine immunizations.
RR2009 - BR203	For disease outbreaks, the State and local health departments are responsible for RR processes.
RR2009 - BR301	A single Reminder Notification should be considered 2 to 4 weeks before the recommended due date/date range for each recommended vaccine/vaccination visit.
RR2009 - BR305	One reminder and up to 3 follow-up Recall Notifications for each recommended vaccine/vaccination visit should be considered for children 0-6 years of age.
RR2009 - BR306	One reminder and up to 3 follow-up Recall Notifications for each recommended vaccine/vaccination visit should be considered for children 7-18 years of age.
RR2009 - BR307	For adults a single reminder for routine vaccinations recommended by ACIP should be considered.

Rule ID - Title	Rule Statement
RR2009 - BR308	A single Recall Notification should be considered when routine doses or subsequent doses in a multi-dose series are overdue for adults.
RR2009 - BR401	Criteria for inclusion /exclusion of Individuals to/from Reminder/Recall should include (but not be limited to): • Individual's age (DOB) • Established associations between a Provider and Patients, such as medical home or Immunization Home for a Patient • Patient active/inactive status at the Provider and geographic Jurisdiction level • One or more specified Vaccines • Dose number within vaccine series (Vaccine Family/Group) • High risk status for a Patient • Various address attributes: State, county, city, zip code or health district/region • Program/association (e.g., WIC, Medicaid, fire department) • Specified health plan (insurance) or payer source • Permanent and temporary exemptions and contraindications for a Vaccine(s) • Language preference • Occupation • Opt-out from RR in whole or in part • Routine versus emergency RR.
RR2009 - BR501	In the event that we can do only one Recall for children 0-24 months of age it should be between 19 and 21 months.
RR2009 - BR502	In the event that we can do two Recalls for children 0-24 months of age it should be at 19-21 months and 7 months.
RR2009 - BR503	In the event that we can do three Recalls for children 0-24 months of age it should be at 19-21 months, 7 months and 3 months.

Rule ID - Title	Rule Statement

RR2009 - BR601	The most effective RR Notification method to improve timeliness and completion of immunizations, ranked from the most effective to the least effective:
	• Home visit
	• Person to person phone
	  ○ Phone call by Provider
	  ○ Phone call by local or State public health authority
	• Letter
	• Postcard
	  ○ Specific card from Provider
	  ○ Generic card from Provider
	  ○ Specific card from IIS
	  ○ Generic card from IIS
	• Auto dialer.

RR2009 - BR602	The most cost-effective RR Notification method to improve timeliness and completion of immunizations, ranked from the most to least cost effective: • Telephone call (person-to-person) • Letter • Postcard • Auto dialer • Home visit.
RR2009 - BR701	The minimum set of data items for the RR Notification when the RR Notification is going to an Individual: • Individual's name • You/your child is due/overdue for one or more vaccinations" • "Please, contact your health care provider".
RR2009 - BR702	The minimum set of data items for the RR Notification when the RR Notification is going to a Provider: • Patient name • Sufficient information for the Provider to identify the Patient (e.g., the Provider's unique identifier, Patient date of birth, Patient medical record number, etc.) • Immunizations that the Patient is due/overdue to receive.
RR2009 - BR703	The RR Notification should include a statement that encourages the RR Recipient to provide documentation of immunizations that are not recorded in the IIS.
RR2009 - BR704	The RR Notification should state if a Patient is due (Reminder) or overdue (Recall) for immunization(s), as well as whom it is from (Provider or IIS).
RR2009 - BR705	The RR Notification (letter or card) should contain sufficient postage to obtain forwarding addresses from the post office.

Rule ID - Title	Rule Statement
RR2009 - BR706	The RR Notification (letter or card) should contain the return address of the party responsible for collecting results (RR Originator or the IIS).
RR2009 - BR801	In the event there is no State guideline, there should be 3 (three) RR Notification attempts before the RR process is ended.
RR2009 - BR802	In the event there is no State guideline, after 90 days and three (3) unsuccessful attempts Patient active/inactive status should be set to "Inactive" at the Provider level and remain "active" at the geographic Jurisdiction level.
RR2009 - BR803	The time between recall attempts should be 14-30 days for letters and postcards.
RR2009 - P201 - Define ownership principle	The "ownership" (the responsibility) for an Individual/Patient has to be clearly defined.
RR2009 - P202 - Responsible party principle	Party responsible for the Individual / Patient should initiate the RR process.
RR2009 - P203 - Delegate responsibility principle	IIS or other State or local public health agency should be available to assume the responsibility (and cost) of conducting Reminder/Recall on behalf of other parties (e.g., Providers).
RR2009 - P204 - Hierarchy of parties principle	A hierarchy of parties responsible for every Individual/Patient in the IIS should be established.
RR2009 - P301 - RR process initiation principle	RR process can be initiated based on/for: • Current ACIP schedules (e.g., DTaP at 2, 4, 6, 15-18months of age; MMR at 12months; Td every 10 years) • Standard well child visit timeframes (2, 4, 6, 12, 15, 18 and 24 months of age; reminders only) • State-mandated requirements (e.g., school and child care entry requirements).
RR2009 - P302 - RR periodicity principle	The RR process should be initiated on a regular basis (e.g., weekly, monthly, annually) and as needed (based on "well accepted requirements" such as ACIP schedule, standard well child visits, State mandated requirements, etc.)
RR2009 - P303 - Single RR Notification principle	If more than one vaccination is due or overdue at the time of RR, all vaccinations should be accommodated in a single RR Notification.
RR2009 - P304 - Recall principle	Recall should be considered after the recommended period for vaccination has expired.
RR2009 - P401 - Identify all Individuals eligible for RR principle	The RR process should begin by identifying all Individuals/Patients who are eligible for the particular RR process before determination of the RR Notification method.

Rule ID - Title	Rule Statement
RR2009 - P501 - Limited resources principle	Reminder/Recall must be in line with available resources. Accordingly, not every recommended vaccination will result in a Reminder/Recall Notification.
RR2009 - P502 - Limit disturbance principle	For a given set of Vaccines, RR Notifications should be issued only once during a given period of time.
RR2009 - P503 - Coordinate to avoid duplication principle	The RR process must be coordinated to eliminate duplication of RR by various RR Originators.
RR2009 - P504 - Supremacy of Recall over Reminder principle	If resources are limited, Recall is more important than a Reminder.
RR2009 - P505 - Priority for children 0–24 months of age principle	Priority should be given to Recall Notifications for children 0-24 months of age.
RR2009 - P506 - Timeliness principle	Timeliness of data recorded in the IIS should be taken in consideration for issuing/delaying RR Notifications.
RR2009 - P507 - Baseline immunization coverage level principle	Baseline immunization coverage level should be taken in consideration for issuing/delaying RR Notifications.
RR2009 - P601 - A variety of RR Notification methods principle	IIS should have more than one RR Notification method.
RR2009 - P602 - Combine RR Notification methods principle	Effectiveness of Reminder/Recall can be increased by combining various RR Notification methods.
RR2009 - P603 - Consider data quality principle	RR Notification method should take into consideration the available contact information (data quality issue).
RR2009 - P604 - Cost-effectiveness principle	Reminder/Recall should employ the most cost-effective RR Notification method based on resources available.
RR2009 - P605 - Supremacy of Provider communication principle	A communication from a Provider is more effective for the Provider's Patients than a communication from IIS or other RR Originator.
RR2009 - P606 - Impact of selecting RR Notification method principle	The RR Notification method impacts the frequency of RR and target population.
RR2009 - P701 - Comply with HIPAA interpretation principle	The RR Notification content must comply with the RR Originator's interpretation of HIPAA requirements.
RR2009 - P702 - Dependency on data quality principle	The specificity of the RR Notification should reflect the quality of data recorded in the IIS.
RR2009 - P703 - Best message for the audience principle	Social marketing techniques and research should be used to determine best messages for the target audience.
RR2009 - P801 - Track RR results principle	RR results (responses and outcomes) must be systematically tracked.
RR2009 - P802 - RR escalation principle	After an unsuccessful RR attempt, if the RR process is not ended, consider a different RR Notification method. For example, escalation from a post card to a telephone call.

Rule ID - Title	Rule Statement
RR2009 - P803 - Elevation of responsibility principle	After a certain period of time and a number of unsuccessful RR attempts the responsibility for a Patient should be transferred from a Provider level to a geographic Jurisdiction level.
RR2009 - P804 - Repeated Notification principle	Providing multiple RR Notifications is more effective than a single RR Notification.
VD2006 - BR01	If vaccination events for the same Vaccine - Family/Group occur within a maximum window of 23 days, they need to be examined. A registry can set a tighter constraint, based on: • Staffing for manual review; • A trend analysis of the registry data (then it can be constrained appropriately in favor of processing time); • Knowledge of registry's data.
VD2006 - BR02	A record for the vaccination event must be compared with all and any of the vaccination event records with the same Vaccine -Family/Group.
VD2006 - BR03	Identical records should not be selected for deduplication. If there are identical records for the vaccination event, all of them but one has to be deleted.
VD2006 - BR09	Records selected for evaluation at the Selection phase should be considered different until proven to be duplicates
VD2006 - BR10	If vaccine lot numbers are different in evaluated records, these records are most likely to be different (not duplicates).
VD2006 - BR11	If vaccination encounter dates are the same in evaluated records, these records are most likely to be duplicates.
VD2006 - BR12	Distinctive combinations of variables (presented in Table 4) should be considered for the evaluation of candidates records.
VD2006 - BR13	High-confidence and/or most discriminating rules (variables and combinations of variables) should be evaluated first. Evaluation sequence: business rules BR10 and BR11 (as well as most distinctive combinations from Table 4) should be applied first; evaluation of variables Vaccine Type, Vaccine Trade Name, and Provider Organization Name could follow.
VD2006 - BR14	Some immunizations are supposed to be given within 2 days of each other.

Rule ID - Title	Rule Statement
VD2006 - BR15	If Record Source Types are "Administered" in evaluated records and are from different providers, these records are most likely to be different (not duplicates). If Record Source Type is "Administered" in one record and "Historical" in another record and vaccination dates are close (P11), these records are most likely to be duplicates.
VD2006 - BR20	The record with the highest level of confidence should be selected.
VD2006 - BR21	The record with more complete data should be selected.
VD2006 - BR22	The record with more specific data should be selected.
VD2006 - BR23	The record that represents a combo vaccine should be selected.
VD2006 - BR24	The existing record should be selected over the incoming record.
VD2006 - BR25	Records with earlier or later date should be selected consistently within a particular IIS.
VD2006 - BR30	If both records have the same information for a variable, then that information should be used in the consolidated record.
VD2006 - BR31	Known information for a variable should be used instead of unknown.
VD2006 - BR32	If duplicate records have different information for a variable, then information from the record with higher level of confidence in data should be incorporated into the consolidated record.
VD2006 - BR33	If duplicate records have different information for a variable, the more specific information should be incorporated into the consolidated record.
VD2006 - P04	We would like to be more inclusive than exclusive.
VD2006 - P09	A match in some variables is more important than others.
VD2006 - P10	The degree of confidence in the data should be taken into consideration.
VD2006 - P11	If vaccination encounter dates are different in records under evaluation, the proximity of these dates has to be taken in consideration.
VD2006 - P12	Considerations of front-end vs. back-end processing should not have impact on the decision match/differ for the evaluated records.
VD2006 - P13	Registries should track the variable "Vaccination Event Submission-Record Source Type" ("administered" vs. "historical") for each record.

Rule ID - Title	Rule Statement
VD2006 - P15	Business rules should be applied completely, in a specified sequence.
VD2006 - P18	A consolidated record at the vaccination level that merges all available information from duplicate records and other sources should be created.

MIROW Guide Reference

The following MIROW guide reference provides a reference for each of the MIROW Guides, the name of each guide, as well as the acronym used as a reference in the term reports.

Acronym	Guide Name
DQA2022	Data Quality Assurance in Immunization Information Systems
BC2019	Business Continuity Planning for Immunization Information System Programs
MPS2019	Management of Patient Status in Immunization Information Systems
CR2017	Consolidating Demographic Records and Vaccination Event Records
DINV2016	Decrementing Inventory via Electronic Data Exchange
DLE2011	Immunization Information System Collaboration with Vaccines for Children Program and Grantee Immunization Programs
INV2012	Immunization Information System Inventory Management Operations
RR2009	Reminder/Recall in Immunization Information Systems
VD2006	Vaccination Level Deduplication in Immunization Information Systems