



AIRA

AMERICAN IMMUNIZATION
REGISTRY ASSOCIATION

MIROW Principles and Business Rules

Simple Report, Version 1.0

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MIROW Principles and Business Rules Reports

Version 1.0

May 28, 2020

Description

The Modeling of Immunization Registry Operations Workgroup (MIROW) has developed 11 guidance documents with over 300 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.
- 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	Rule Statement
BC2019 - PR-001	Business Continuity Plan Content: A business continuity plan should address the following with respect to disruptions: <ul style="list-style-type: none"> • 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 program 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.

Rule ID	Rule Statement
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.
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: <ul style="list-style-type: none"> • 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.

Rule ID	Rule Statement
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 e-mail address.
CR2017 - BR301	<p>Data elements considered to be a data group: All of the following collections of data elements should be considered as data groups:</p> <ul style="list-style-type: none"> • 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.

Rule ID	Rule Statement
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.
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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • The data element is not required by the IIS. • The values in both matched records are invalid.

Rule ID	Rule Statement
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.
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 indicator 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.

Rule ID	Rule Statement
CR2017 - BR5202	<p>Data elements considered to be data groups: All of the following collections of data elements should be considered as data groups:</p> <ul style="list-style-type: none">• 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	Rule Statement
CR2017 - BR5301	<p>Data elements with a single value: The following data elements must have a single value:</p> <ul style="list-style-type: none"> • 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	<p>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.</p>
CR2017 - BR5402	<p>Two administered vaccination event records (different data sources): The IIS should investigate if two administered vaccination event records are submitted by different data sources.</p>
CR2017 - BR5403	<p>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.</p>
CR2017 - BR5701	<p>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.</p>

Rule ID	Rule Statement
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.
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.

Rule ID	Rule Statement
CR2017 - P04	Consolidation results: Consolidation should result in either a new record or an updated base record.
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.

Rule ID	Rule Statement
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.
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.

Rule ID	Rule Statement
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.
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.

Rule ID	Rule Statement
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.
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.

Rule ID	Rule Statement
DLE2011 - BR602	<p>What information is needed for Patient's eligibility screening: Information needed for determination of Patient's eligibilities include:</p> <ul style="list-style-type: none"> • Vaccination Encounter (screening for full VFC Program eligibility): <ul style="list-style-type: none"> ○ 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): <ul style="list-style-type: none"> ○ Outcome of the Vaccination encounter screening ○ Vaccine needed ○ Vaccine Eligibility
DLE2011 - BR603	<p>How often to screen:</p> <ul style="list-style-type: none"> • 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)
DLE2011 - BR604	<p>Patient Eligibility screening sequence: The sequence of Vaccine Program eligibility screenings for Patient under age of 19 should be:</p> <ul style="list-style-type: none"> • 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

Rule ID	Rule Statement
DLE2011 - BR605	<p>Underinsured vs. Medicaid and Provider Organization type: If the Patient:</p> <ul style="list-style-type: none"> • 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 <p>then the Patient is eligible for VFC (“Underinsured”) Therefore, Patient cannot be Underinsured if he/she has Medicaid.</p>
DLE2011 - BR606	<p>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.</p>
DLE2011 - BR607	<p>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:</p> <ul style="list-style-type: none"> • Private Insurance coverage • VFC Program eligibility (for all program Vaccines or for a specific Vaccine) • Grantee Program eligibility <p>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.</p>
DLE2011 - BR608	<p>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).</p>
DLE2011 - BR609	<p>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:</p> <ul style="list-style-type: none"> • 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 <p>According with BR607, the first option should be selected.</p>

Rule ID	Rule Statement
DLE2011 - BR610	Private insurance - dealing with unknown: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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
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: <ul style="list-style-type: none"> • 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

Rule ID	Rule Statement
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.
DQA2008 - BR128	A patient should not have more than: <ul style="list-style-type: none"> • 50 vaccinations before 5 years of age • 35 vaccinations before 2 years of age • 70 vaccinations regardless of age
DQA2008 - BR129	A patient should not have more than 7 DTaP vaccinations by age 7. (Additional rules should be developed for other types of vaccinations.)
DQA2008 - BR130	Doses should not be recorded as given before the minimum patient age or after the maximum patient age for that particular vaccine.
DQA2008 - BR131	Doses should not be recorded as given before the minimum interval has been met.
DQA2008 - BR132	A patient should not have more than 10 vaccinations per visit.
DQA2008 - P01	Consistency: The conditions (criteria) for validating data items should be the same regardless of how these data items have been reported to an IIS.
DQA2008 - P02	Variable outcomes: When conditions (criteria) of a validation check are not satisfied, the resulting actions (e.g., accept, reject, research) may vary depending on the data item's source and the way data were reported.
DQA2008 - P03	Rejected data: When information is rejected by the IIS, the following actions should be taken: <ul style="list-style-type: none"> • If batch, then log the error and notify Submitter. • If UI, then display an error message and offer the opportunity to correct.
DQA2008 - P04	Internal consistency: Characteristics of the vaccination history should not contradict one another. This includes reported data as well as data already in the IIS.
DQA2008 - P05	Accuracy: The data recorded in the IIS should match exactly what happens in a clinical encounter, whether or not it is clinically appropriate.

Rule ID	Rule Statement
DQA2008 - P06	Appropriate vaccination: The vaccinations reported by a provider should be appropriate for the population served at the clinic.
DQA2008 - P07	Vital Records: Vital Records is the definitive source for Date of Birth and Date of Death.
DQA2008 - P08	Validation priority: The importance of validating a data item is related to the data item's significance in clinical decision making, public health assessments, and research.
DQA2008 - P09	Maintain data integrity: Any modification of the data in the IIS should not violate the integrity of the existing data.
DQA2008 - P10	ACIP recommendations: Deviations from ACIP recommendations and US licensure may indicate data quality problems.
DQA2008 - P11	Timeliness: Data should be timely. Data should be reported and recorded in the IIS, as well as be available to users in a timely manner.
DQA2008 - P12	Completeness: The information submitted to the IIS must contain the minimum/mandatory set of data items in order to be accepted by an IIS.
DQA2008 - P13	Supremacy of medical records: Medical records are a more reliable source of immunization data than billing records.
DQA2013 - BR101	Vaccination Encounter Date must not be before Patient Date of Birth.
DQA2013 - BR102	Vaccination Encounter Date should not be after the Patient Date of Death.
DQA2013 - BR103	Vaccination Encounter Date must be less than or equal to (before or the same as) the Report Submission Date.
DQA2013 - BR104	The minimum/mandatory set of data items for the Demographic-only submission includes: IIS-AO ID (Recorder), Patient Date of Birth, Patient Name (First), Patient Name (Last), Birth Certificate Number, Birth Facility (code, name, address), Gender
DQA2013 - BR105R1	The minimum/mandatory set of data items for the "administered" Vaccination Event submission must include: IIS-AO ID (Vaccinator/Recorder), Patient Name (First), Patient Name (Last), Patient Date of Birth, Vaccination Encounter Date, Vaccine Type, Administered/Historical Indicator = "Administered," Lot Number.

Rule ID	Rule Statement
DQA2013 - BR105R2	The minimum/mandatory set of data items for the “historical” Vaccination Event submission must include: Patient Name (First), Patient Name (Last), Patient Date of Birth, Vaccination Encounter Date, Vaccine Type, Administered/Historical Indicator = “Historical.”
DQA2013 - BR107	Every administered vaccine should be recorded as a single vaccination event.
DQA2013 - BR108	Vaccinations submitted via electronic data exchange to IIS that do not perform a manual review should appear in the IIS within 2 business days of the Submission Date. Vaccinations submitted via electronic data exchange to IIS that perform manual reviews should appear in the IIS within 2 weeks of the Submission Date.
DQA2013 - BR111	Adverse reactions reported on administered vaccines should be identified for tracking and provider follow-up.
DQA2013 - BR112	The percentage of Vaccination Event Submissions from Vital Records with hepatitis B birth doses should be within an expected threshold level (to be determined by each IIS).
DQA2013 - BR113	If the IIS-AO (Vaccinator) is a “specific,” (e.g., pediatric) practice, the currently administered vaccinations should match a pattern in similar practices. Note: This could apply to many practices. A practice includes a unique combination of various groups of the population.
DQA2013 - BR114	Vaccination Encounter Date should not be the same as the Patient Date of Birth unless it is on the list of vaccines recommended for administration on the date of birth, e.g., HepB.
DQA2013 - BR115	For administered Vaccination Event submissions, Submission Date should be within 14 days of Vaccination Encounter Date.
DQA2013 - BR116	Trade Name, Manufacturer, CVX Code, CPT Code and Vaccine Type should not contradict one another.
DQA2013 - BR117	The same patient should not receive the same antigen more than once in single day.
DQA2013 - BR118	Vaccination Encounter Date should not be after the lot number expiration date.
DQA2013 - BR119	Route and Site should not contradict each other for a given Vaccine Type and Patient’s age.
DQA2013 - BR120	Vaccination Encounter Date should be within the Vaccine Product License Date range: after the Vaccine Product License Begin Date and before the Vaccine Product License End Date.

Rule ID	Rule Statement
DQA2013 - BR121	Administered vaccinations should have specific Vaccine Types, e.g., Hib PRP-OMP; unspecified vaccine types, e.g., Hib, UF (unspecified formulation), are not appropriate.
DQA2013 - BR122	A patient's eligibility for a public program (e.g., VFC program, state program) should be consistent with the administered vaccine dose's designation for a stock type (e.g., public, private).
DQA2013 - BR123	The volume of reporting from the Vital Records feed should be within an expected threshold level (to be determined by each IIS).
DQA2013 - BR124	The percentage of vaccination events in which the responsible party name is the same as the patient name should be within an expected threshold level (to be determined by each IIS).
DQA2013 - BR125	The percentage of rejected Vaccination Events submissions in a Combined Submission should be within an expected threshold level.
DQA2013 - BR126	An administered vaccine should not have a medical contraindication for a patient.
DQA2013 - BR127	Hepatitis B birth doses from the Vital Records feed should be reported within an agreed-upon timeframe.
DQA2013 - BR801	Conduct a pre-certification process: IIS should conduct a pre-certification process in order for the IIS-AO system to submit data to the IIS via Electronic Data Exchange.
DQA2013 - BR802	Maintain IIS-AO DQA profile: IIS should identify and maintain baseline (IIS-AO DQA Profile) data for comparison later. Measures for this baseline data may include (not an exhaustive list): frequency of submissions, content of data, volume of vaccination events, volume of demographic events, method of reporting, EHR vendor.
DQA2013 - BR803	Review the submission logs for error trends daily: The IIS should review the submission logs for error trends on a daily basis.
DQA2013 - BR804	Track participants in the submittal chain: Vaccination Event Submission for "administered" Vaccination Events must have the Vaccinator, Recorder, and Submitter(s) IIS-AO ID.
DQA2013 - BR805	All Submitters should be identified: All Submitters in the submission chain should be identified.
DQA2013 - BR806	Track Recorder IIS-AO: For Vaccination Event Submissions, the IIS-AO that enters information into the IIS-AO system or IIS Direct UI should be tracked as the Recorder IIS-AO ID.
DQA2013 - BR807	Track status and status date for all submissions: Status (i.e., accepted, accepted with errors, rejected, etc.) and Status Date should be tracked for all Vaccination Event Submissions.

Rule ID	Rule Statement
DQA2013 - BR808	Include Vaccine Administrator and Vaccine Prescriber in the submission: Vaccine Administrator and Vaccine Prescriber should be included in the Vaccination Event Submission.
DQA2013 - BR809	Record submission error and reason for error: IIS should record error and reason for error of a Vaccination Event Submission and Demographic-only Submission.
DQA2013 - BR810	Maintain unique medical record numbers for IIS-AO patients: During the pre-certification process, the IIS should review with a Submitter the process to be followed to ensure that they maintain unique medical record numbers for patients.
DQA2013 - BR811	IIS-AO IDs must be unique: All IIS-AO IDs must be unique and must never be reused.
DQA2013 - BR812	IIS-AO IDs should not embed information about the IIS-AO: IIS-AO IDs should not embed information about the IIS-AO.
DQA2013 - BR813	User must be associated with IIS-AO: A User who is submitting and/or retrieving data from the IIS must be associated with the IIS-AO that is responsible for those records.
DQA2013 - BR814	Maintain both legal and common names for an IIS-AO: An IIS should maintain both legal and common names for an IIS-AO.
DQA2013 - BR815	Validate organizational and reporting structure periodically: IIS should proactively validate the current organizational and reporting structure for existing IIS-AOs on a quarterly basis.
DQA2013 - BR816	Validate organizational and reporting structure on rejection: IIS should validate the current organizational and reporting structure when a submission gets rejected due to an invalid or unknown IIS-AO ID.
DQA2013 - BR817	Update IIS-AO when a structural change occurs: IIS-AO attributes and relationships should be updated, where necessary, any time a structural change occurs regarding one or more organizations and/or organizational sub-units.

Rule ID	Rule Statement
DQA2013 - BR818	<p>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:</p> <p>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).</p> <p>Option 2: Update the structural hierarchy of the acquired (Org B) and acquiring (Org C) IIS-AOs and maintain the acquired IIS-AO ID.</p>
DQA2013 - BR819	<p>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:</p> <p>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).</p> <p>Option 2: Establish a structural hierarchy between the acquired (Org A) and acquiring (Org B) IIS-AOs and retain the acquired IIS-AO ID.</p>
DQA2013 - BR820	<p>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.</p>
DQA2013 - BR821	<p>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:</p> <p>Option 1: De-authorize the original sub-unit (Org B) and create a new IIS-AO (Org C) with a new IIS-AO ID.</p> <p>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.</p>
DQA2013 - BR822	<p>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).</p>

Rule ID	Rule Statement
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.
DQA2013 - BR824	De-authorize IIS-AO if it dissolves: If an IIS-AO dissolves, it should be de-authorized in the IIS.
DQA2013 - BR825	De-authorize IIS-AO if it no longer plays any of IIS-AO roles: If an existing IIS-AO is no longer a Vaccinator, Submitter, Recorder, or Data Consumer, the IIS-AO must be de-authorized in the IIS.
DQA2013 - BR826	Do not de-authorize IIS-AO that is required to submit but not submitting: If a Vaccinator is required to submit to the IIS and is not submitting to the IIS, the IIS should not de-authorize the IIS-AO.
DQA2013 - BR827	Assess necessity to de-authorize IIS-AO that is not required to submit and is not submitting: If a Vaccinator is not required to submit to the IIS and is not submitting to the IIS, the IIS should assess the necessity to de-authorize the IIS-AO.
DQA2013 - P801	Consistency: IIS should be consistent in the approaches followed for Facility Identification Management.
DQA2013 - P802	Document approaches used: IIS should clearly document the approaches followed for Facility Identification Management.
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	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: <ul style="list-style-type: none"> • 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)

Rule ID	Rule Statement
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.
INV2012 - BR713	<p>Minimum data set for vaccine transfers: The following information should be present for vaccine transfers between Provider Organizations:</p> <ul style="list-style-type: none"> • 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.

Rule ID	Rule Statement
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.
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.

Rule ID	Rule Statement
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.
LNV2014 - BR01	Lot number data item should contain information about one and only one lot number.
LNV2014 - BR02	Lot number should be represented only by combinations of the following characters: Letters, Numbers, Dash.
LNV2014 - BR03	Lot number data item should contain lot number information only.
LNV2014 - BR04	Lot number information should be reported for every vaccine dose administered.
LNV2014 - BR05	Lot number should not start from any of the following strings of characters (currently identified cases): (P), MED, SKB, LOT, PMC, WSD, WAL.
LNV2014 - BR06	Lot number should not end with any of the following strings of characters (currently identified cases): <ul style="list-style-type: none"> • (P), -P, -S, -C, -H, -V, *, #, (S), (P), MSD, HOSP, SELECT, CP, VFC, STATE, CHIP, ADULT, ST-, PRIVATE, PED, UNINSURED, SPECIAL, OVER19, VMC, -COUNT • Vaccine names/abbreviations, such as: REAR, PENT (or PENTACEL), DTAP, IPV, MENA, ACTH, HIB, PFF, FLU, BOOST, HAV, GARDASIL, ROTATEQ, PEDVAX, VARIVAX, PNEU, PNEUMOVAX, MMR, MENVEO, MENACTRA, FLU ZONE
LNV2014 - BR07	Lot number should not contain a dash with spaces (" - ") in the middle of the lot number.
LNV2014 - BR08	Lot number should not be followed by "IC3" and additional text.
LNV2014 - P01	Reference a directory of known lot numbers: A directory of known lot numbers should be created, maintained, and referenced for lot number's validation purposes.
LNV2014 - P02	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's validation purposes.

Rule ID	Rule Statement
LNV2014 - P03	Reference a directory of generic rules (for all manufacturers) for coding lot numbers: A directory of generic manufacturer rules for coding lot numbers should be created, maintained, and referenced for lot number validation purposes.
LNV2014 - P04	Maintain reliability of reference directories: Reference directories (directory of known lot numbers, directory of manufacturer-specific coding schemes, directory of generic manufacturer rules for coding lot numbers) should be periodically reviewed and reconfirmed as reliable reference sources for validating lot numbers.
MPS2019 - BR401	<p>Nomenclature of statuses at the provider organization level: Patient status at provider organization level may have only one of the following designations:</p> <ul style="list-style-type: none"> • Active • Inactive, with one of the following reason codes: <ul style="list-style-type: none"> ○ No longer a patient ○ Lost to follow-up ○ Unspecified • Deceased
MPS2019 - R402A	<p>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:</p> <ul style="list-style-type: none"> • 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).

Rule ID	Rule Statement
MPS2019 - BR402B	<p>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:</p> <ul style="list-style-type: none"> • Provider organization directly identifies the individual as a patient. • Provider organization indirectly identifies the person as a patient in any of the following ways: <ul style="list-style-type: none"> ○ 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	<p>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:</p> <ul style="list-style-type: none"> • Relationship between a provider organization and a patient has been terminated by either party, for example: <ul style="list-style-type: none"> ○ 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
MPS2019 - BR404B	<p>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:</p> <ul style="list-style-type: none"> • Relationship between a provider organization and a patient has been terminated by either party, for example: <ul style="list-style-type: none"> ○ Patient has gone/transferred to another provider organization ○ Patient has moved out of the area

Rule ID	Rule Statement
MPS2019 - BR405	<p>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:</p> <ul style="list-style-type: none"> • 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	<p>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.</p>
MPS2019 - BR411	<p>Nomenclature of statuses at the geographic jurisdiction level: Patient status at the geographic jurisdiction level may have only one of the following designations:</p> <ul style="list-style-type: none"> • Active • Inactive, with the following reason code: Outside jurisdiction • Unknown, with the following reason codes: <ul style="list-style-type: none"> ○ No address, no vaccination ○ No activity for extended period of time • Deceased
MPS2019 - BR412	<p>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:</p> <ul style="list-style-type: none"> • 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	<p>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.</p>

Rule ID	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 the 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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.

Rule ID	Rule Statement
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 <ul style="list-style-type: none"> • 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.
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.

Rule ID	Rule Statement
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.
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	<p>Criteria for inclusion /exclusion of Individuals to/from Reminder/Recall should include (but not be limited to):</p> <ul style="list-style-type: none"> • 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.

Rule ID	Rule Statement
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.
RR2009 - BR601	<p>The most effective RR Notification method to improve timeliness and completion of immunizations, ranked from the most effective to the least effective:</p> <ul style="list-style-type: none"> • Home visit • Person to person phone <ul style="list-style-type: none"> ○ Phone call by Provider ○ Phone call by local or State public health authority • Letter • Postcard <ul style="list-style-type: none"> ○ Specific card from Provider ○ Generic card from Provider ○ Specific card from IIS ○ Generic card from IIS • Autodialer
RR2009 - BR602	<p>The most cost-effective RR Notification method to improve timeliness and completion of immunizations, ranked from the most to least cost effective:</p> <ul style="list-style-type: none"> • Telephone call (person-to-person) • Letter • Postcard • Autodialer • Home visit
RR2009 - BR701	<p>The minimum set of data items for the RR Notification when the RR Notification is going to an Individual:</p> <ol style="list-style-type: none"> 1) Individual's name 2) "You/your child is due/overdue for one or more vaccinations" 3) "Please, contact your health care provider".

Rule ID	Rule Statement
RR2009 - BR702	The minimum set of data items for the RR Notification when the RR Notification is going to a Provider: 1) Patient name 2) 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) 3) 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.
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).

Rule ID	Rule Statement
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: <ul style="list-style-type: none"> • Current ACIP schedules (e.g., DTaP at 2, 4, 6, 15–18 months of age; MMR at 12 months; Td every 10 yrs) • 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.
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.

Rule ID	Rule Statement
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.
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.

Rule ID	Rule Statement
RR2009 - P804	Repeated Notification principle: Providing multiple RR Notifications is more effective than a single RR Notification.
VD2006 - BR01	<p>If vaccination events for the same Vaccine – Family/Group occur within a maximum window of 23 days, they need to be examined.</p> <p>A registry can set a tighter constraint, based on:</p> <ul style="list-style-type: none"> • 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	<p>Identical records should not be selected for deduplication.</p> <p>If there are identical records for the vaccination event, all of them but one has to be deleted.</p>
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	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.
VD2006 - P15	Business rules should be applied completely, in a specified sequence.

Rule ID	Rule Statement
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
BC2019	Business Continuity Planning for Immunization Information System Programs
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
DQA2008	Data Quality Assurance in Immunization Information Systems: Incoming Data
DQA2013	Data Quality Assurance in Immunization Information Systems: Selected Aspects
INV2012	Immunization Information System Inventory Management Operations
LNV2014	Lot Number Validation Best Practices (Micro-Guide)
MPS2019	Management of Patient Status in Immunization Information Systems
RR2009	Reminder/Recall in Immunization Information Systems
VD2006	Vaccination Level Deduplication in Immunization Information Systems