AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

MIROW Principles and Business Rules

Advanced Report, Version 2.0

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MIROW Principles and Business Rules Reports

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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.

BC2019 - PR-001 - Business Continuity Plan Content	
Rule Statement	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	
Rule Statement	All business continuity plans should maintain applicable security and confidentiality requirements.

BC2019 - PR-003 - Maintain Data Integrity	
Rule Statement	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	
Rule Statement	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	
Rule Statement	Leadership should demonstrate commitment to the business continuity plan.

BC2019 - PR-006 - Sufficient Resources	
Rule Statement	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	
Rule Statement	Ensure that internal partners are aware that the IIS is developing a business continuity plan.

BC2019 - PR-008 - Jurisdiction Plans	
Rule Statement	The business continuity plan should inform, comply with, and not contradict other applicable plans in the jurisdiction.

BC2019 - PR-009 - Legal Framework	
Rule Statement	The business continuity plan should inform, comply with, and not contradict applicable legislation, policies, and regulatory requirements.

BC2019 - PR-010 - Critical Time Frames	
Rule Statement	Recovery time objective and recovery point objective should be set for each selected essential business function.

BC2019 - PR-011 - Risk Calculation	
Rule Statement	Risk should be analyzed in terms of consequences (impact) and likelihood (probability).

BC2019 - PR-012 - Financial Support	
Rule Statement	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	
Rule Statement	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	
Rule Statement	A business continuity plan should be reviewed regularly and updated as necessary.

CR2017 - BR1001. Data validation	
Rule Statement	Data validation should occur within each demographic record and between each demographic record and all associated vaccination event records.
Remarks	• Consolidated records should be subject to regular IIS data validation rules. • Best practice: Validate incoming data using the same rules as existing data to prevent a cycle of overwriting validated data. • Good practice: Perform regular data validation on existing data. If the IIS has limited resources, incoming data may be subject to less stringent validation rules.
References	Chapter 7: Implementation Considerations CR2017 - BR1002. Prevent overwriting validated data. CR2017 - BR1003: No conflict with existing data.

CR2017 - BR1002 / BR5802 Prevent overwriting validated data	
Rule Statement	The consolidating records process should not result in overwriting validated data.

Remarks	CR2017 - BR1002 Remarks:
	• CR2017 - BR902 states the general rule that the most recent information should be chosen for a consolidated record. This business rule, BR1002, is an exception to the general rule stated in BR902.
	• If an IIS changes a value through data validation, the value can be locked/flagged for the same value from the same data source.
	  ○ Example: IIS changes an address through data cleansing/validation and the data source submits the same "bad" address.
	• The IIS should make accessible the value that was replaced.
	
	CR2017 - BR5802 Remarks:
	• See CR2017 - BR5403.
	• If an IIS changes a value through data validation, the value can be locked/flagged for the same value from the same data source.
	  ○ Example: IIS strips extraneous characters from a vaccine lot number through data validation and the data source submits the same "bad" information.
	The IIS should make accessible the value that was replaced.

References	CR2017 - BR1002 References: Chapter 7: Implementation Considerations CR2017 - P12: Business routines should not be counterproductive.

	CR2017 - BR902: Use information that has most recent submission date. CR2017 - BR1001. Data validation. CR2017 - BR1003: No conflict with existing data. CR2017 - BR5802 References: Chapter 7: Implementation Considerations CR2017 - P12: Business routines should not be counterproductive. CR2017 - BR5801. Data validation. CR2017 - BR5803: No conflict with existing data. S1105: Data validation by IIS.

CR2017 - BR1003 / BR5803. No conflict with existing data	
Rule Statement	The value of any data element should be consistent (i.e., in agreement) with other values in the patient record.

Remarks	CR2017 - BR1003 Remarks:
	• This BR applies to existing data.
	• Incoming data that are inconsistent with existing data will be used in a consolidated record in accordance with these guidelines and, after consolidation, will be subject to regular data validation.
	• Cross-field validation should be performed across vaccination event record and demographic record.
	  ○ Examples:
	  ▪ Existing record is marked as “deceased patient,” but incoming record has “administered vaccination.” Vaccine type administered is inconsistent with age recommendations.
	  ▪ DOB mismatch between two records.
	  ▪ Gender mismatch between two records.
	• Inconsistent data should be flagged and investigated.
	
	CR2017 - BR5803 Remarks:
	• This BR applies to existing data.
	• Incoming data that are inconsistent with existing data should be used in a consolidated record in accordance with these guidelines and after consolidation subjected to regular data validation.
	• Cross-field validation should be performed across vaccination event record and demographic record.
	  ○ Example: Existing record is marked as “deceased patient,” but incoming record has “administered vaccination.”
	  ○ Example: Vaccine type administered is inconsistent with age recommendations.

	• Inconsistent data should be investigated.
	CR2017 - BR1003 References: Chapter 7: Implementation Considerations CR2017 - P12: Business routines should not be counterproductive. CR2017 - BR1001. Data validation. CR2017 - BR1002. Prevent overwriting validated data. CR2017 - BR5803 References: Chapter 7: Implementation Considerations CR2017 - P12: Business routines should not be counterproductive. CR2017 - BR5801. Data validation. CR2017 - BR5802. Prevent overwriting validated data.

CR2017 - BR101 / BR5001 Base record: existing record over incoming record	
Rule Statement	Consolidation of an existing record with an incoming record should result in an update of the existing record.
Remarks	CR2017 - BR101 Remarks: • An existing record should be used as the base record to consolidate information from an incoming record. • A base record is a record to be updated with information from another record during the consolidating records process. • Consolidation of two demographic records should trigger consolidation of associated vaccination records as well. CR2017 - BR5001 Remarks: • The result is the same regardless of the method of submission. • An existing record should be used as the base record to consolidate information from an incoming record. • Base record is a record to be updated with information from another record during the consolidating records process. • Consolidation of two demographic records should trigger consolidation of associated vaccination records as well.
References	CR2017 - BR101 References: Chapter 3: Fundamentals, Figure 3-3 in Option 1: Incoming record with no IIS ID Chapter 4: Consolidating Records Process CR2017 - P04: Consolidation results. CR2017 - P13: Principles and business rules apply regardless of method of transmission. S101: Base record: incoming and existing demographic records.

	Appendix A: Terms and Definitions Defined via Domain Model CR2017 - BR5001 References: Chapter 3: Fundamentals, Figure 3-3 in Option 1: Incoming record with no IIS ID Chapter 4: Consolidating Records Process CR2017 - P04: Consolidation results. CR2017 - P13: Principles and business rules apply regardless of method of transmission. S1101: Base record: Existing administered and historical vaccination event records. S1102: Base record: Existing versus incoming historical vaccination event records. S1106: Two historical vaccination event records: Valid value versus blank/invalid value. Appendix A: Terms and Definitions Defined via Domain Model

CR2017 - BR102. Base record: two existing records	
Rule Statement	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.

Remarks	• A base record is a record to be updated with information from another record during the consolidating records process.
	• If one of two existing records is updated during consolidation, either of the two existing records may be chosen to be updated with the best information from the other record.
	• Local implementation will determine which one of the two existing patient IDs to use.
	• Factors to consider when determining which of two existing records to use as the base record in consolidation:
	  ○ initial date each record was added to the IIS (may want to use the earliest record added to the IIS)
	  ○ Confidence level in each record (established by each IIS) (BR901).
	  ○ Completeness of the record
	  ○ Association of a demographic record with one or more vaccination event records
	  ○ Consolidation of two demographic records should trigger consolidation of associated vaccination records as well.

References	Chapter 3: Fundamentals, Figure 3-4 in Option 2: Two existing IIS records are determined to match section. Chapter 4: Consolidating Records Process CR2017 - P04: Consolidation results. CR2017 - P13: Principles and business rules apply regardless of method of transmission. S102: Base record: two existing demographic records. Appendix A: Terms and Definitions Defined via Domain Model

CR2017 - BR1101 / BR5901. Local laws, regulations, and policy control	
Rule Statement	Information should not be used in a consolidated record if local laws, regulations, or policies prohibit utilizing that information.
Remarks	CR2017 - BR1101 Remarks: • IIS should consult with local authorities about opt-out, foster care, protective custody, and adoption. For example, local laws, regulations, or policies may prohibit use of an address for a child in protective custody in a demographic record. • Local laws, regulation, or policies may differ in implementation. For example, some IIS may limit access to certain information for some or all entities, but allow the information to be stored in the IIS. Other IIS may prohibit inclusion of information in the IIS (e.g., Social Security number). CR2017 - BR5901 Remarks: • The IIS should consult with local authorities about consent, foster care, protective custody, and adoption. • Local laws, regulations, or policies may differ in implementation—for example, some IIS may limit access to certain information for some or all entities but allow the information to be stored in the IIS. Other IIS may prohibit inclusion of information in the IIS.
References	CR2017 - BR1101/BR5901 References: CR2017 - P11: Specific local laws control.

CR2017 - BR1201 / BR6001. Prevent remerging of previously unmerged records	
Rule Statement	Consolidation of previously unmerged records should be prevented.
Remarks	CR2017 - BR1201 Remarks: • Unmerging and remerging happens often with twins.

	• A special indicator may be used to prevent remerging. CR2017 - BR6001 Remarks: The IIS should have a way (e.g., a special indicator) to flag pairs of records that should not be merged with each other, preventing remerging.
References	CR2017 - BR1201/BR6001 References: Chapter 7: Implementation Considerations CR2017 - P03: Make original information accessible. CR2017 - P10: Unmerge.

CR2017 - BR201. Information needed to make consolidation decisions	
Rule Statement	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.
Remarks	• This business rule may be implemented in multiple ways—for example, storing or inferring (i.e., making accessible) the required information. • The information required by this business rule is sufficient to consolidate records, but not to unmerge records. Additional information may be required to unmerge records. Unmerging may also require manual intervention. BR1201 provides unmerging considerations. • BR301 lists data elements that form data groups. • Appendix A: Terms and Definitions Defined via Domain Model defines data source and discusses use of IIS-AO to identify a specific data source. • BR901 discusses local considerations that influence determination of the confidence level in reported data. • Best practice: The IIS should keep an audit trail of all changes made, especially a subset for each data element that includes original data source, data source for the last modification, and, for data elements from a vaccination event record, administered/historical indicator. The IIS will be able to access the audit trail to know if the record originally came from a record that was changed later by the IIS (for example, data validation or address cleansing [2.8]) or by a provider through a UI.

	• Data retention laws and policies differ. The amount of time data are retained will impact the ability of an IIS to consolidate and unmerge records.
References	CR2017 - P03: Make original information accessible. CR2017 - BR301: Data elements considered to be a data group. CR2017 - BR901: Use information with highest confidence level. CR2017 - BR1201: Prevent remerging of previously unmerged records. Appendix A: Terms and Definitions Defined via Domain Model

CR2017 - BR202. Retain all past IIS patient IDs	
Rule Statement	All past IIS patient IDs associated with a consolidated demographic record should be retained by the IIS.
Remarks	• IIS patient ID has a unique single value per record. When existing records are consolidated, their IIS patient IDs need to be retained. • For example, if a patient had two records with different IIS patient IDs (i.e., the ID assigned by the IIS for each patient) and the records are consolidated, both IIS patient IDs should be retained. • Local laws, regulations, and policies control and may restrict retention of some IIS patient IDs (e.g., adoptions). • Data retention laws and policies differ. The amount of time data are retained will impact the ability of an IIS to consolidate and unmerge records.
References	Chapter 7: Implementation Considerations CR2017 - P11: Specific local laws control. CR2017 - BR203: Use current (i.e., active) IIS patient ID. CR2017 - BR1101: Local laws, regulations, and policy control.

CR2017 - BR203. Use current (i.e., active) IIS patient ID	
Rule Statement	The current IIS patient ID should be included in all IIS-originated communications about a patient.
Remarks	• In response to a query (either electronic or verbal), an IIS should communicate a change in association of an IIS patient ID to an IIS-AO that submitted information for that patient. The IIS does not have an affirmative obligation to communicate a change in association of an IIS patient ID. An IIS should be prepared to respond to queries for IIS patient IDs that no longer exist (e.g., an adoption). • A patient has only one current (active) ID at any point in time. • CR2017 - BR202 states that all IIS patient IDs should be retained by the IIS as historical IIS patient IDs.

References	Chapter 7: Implementation Considerations CR2017 - BR202: Retain all past IIS patient IDs.

CR2017 - BR204. Retain past values	
Rule Statement	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.
Remarks	• Making past values accessible facilitates IIS functions such as matching and unmerging. • In bidirectional data exchanges, challenges caused by changing IIS patient IDs can be mitigated if original medical record patient IDs (i.e., alternate patient IDs) are preserved. • Alternate patient ID and patient telephone are data groups. • All values in a data group should be made accessible as a unit. • Patient address and patient alias name are not data groups because their component data elements can come from multiple data sources. All data elements that comprise patient address and patient alias name should be made accessible. • Date of birth history may be retained by some IIS. • Data retention laws and policies differ among IIS jurisdictions. The amount of time data are retained will impact the ability of an IIS to consolidate and unmerge records.
References	Chapter 7: Implementation Considerations CR2017 - BR202: Retain all past IIS patient IDs. CR2017 - BR203: Use current (i.e., active) IIS patient ID. CR2017 - BR301: Data elements considered to be a data group. CR2017 - BR303: Treat elements of data group as one.

CR2017 - BR301. Data elements considered to be a data group	
Rule Statement	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).
Remarks	• Certain data elements are grouped together and treated as one data group in which the value for each data element must come from the same data source. It is important to select all values for data elements in data groups from the same data source because mixing values from different data sources would incorrectly change the interpretation of the values. For example, the patient telephone data group includes data elements patient telephone number and patient telephone number type. If the two records contain different "patient telephone number type" (e.g., home and cell), then allowing a combination of values from the two data sources would potentially lead to a phone number being assigned to the incorrect telephone number type. • The Grouping of demographic and vaccination event data elements section in Appendix A: Terms and Definitions Defined via Domain Model provides more detail about data groups.
References	CR2017 - BR302: Data group values are from same data source. CR2017 - BR303: Treat elements of data group as one. CR2017 - BR304: Values within a data group must be consistent. S103: Patient first name: two invalid values. Grouping of demographic and vaccination event data elements section of Appendix A: Terms and Definitions Defined via Domain Model

CR2017 - BR302 / BR5203. Data group values are from same data source

Rule Statement	The value for each data element in a data group must come from the same data source.
Remarks	CR2017 - BR302 Remarks: Example: First, middle, and last name and relationship to patient must come from the same source for responsible person. CR2017 - BR 5203 Remarks: Example: Adverse event (vaccine reaction) and adverse event observation/vaccine encounter date must come from the same data source.
References	CR2017 - BR302 References: CR2017 - BR301: Data elements considered to be a data group. CR2017 - BR303: Treat elements of data group as one. CR2017 - BR304: Values within a data group must be consistent. S103: Patient first name: two invalid values. CR2017 - BR5203 References: CR2017 - BR5202: Data elements considered to be data groups. CR2017 - BR5204: Treat elements of data group as one. CR2017 - BR5205: Values within a data group must be consistent.

CR2017 - BR303 / BR5204. Treat elements of data group as one	
Rule Statement	All data elements within a data group should be treated as a single data element.
Remarks	CR2017 - BR303 Remarks: • Data elements within a group are treated together as one. • Example: patient telephone and patient telephone number type. Additional Remarks from CR2017 - BR5204: For example: Alternate vaccination event ID data group with the data elements, vaccination event ID and vaccination event ID: Assigning authority ID (i.e., owning data source).
References	CR2017 - BR303 References: CR2017 - BR301: Data elements considered to be a data group. CR2017 - BR302: Data group values are from same data source. CR2017 - BR304: Values within a data group must be consistent. CR2017 - BR5204 References: CR2017 - BR5202: Data elements considered to be data groups.

	CR2017 - BR5203: Data group values are from same data source. CR2017 - BR5205: Values within a data group must be consistent.

CR2017 - BR304 / BR5205. Values within a data group must be consistent	
Rule Statement	Values of all data elements within a data group should be consistent with each other.
Remarks	CR2017 - BR304 Remarks: • If all elements in a data group are not internally consistent, the IIS should reject all values in the data group. • Example: For the data group "patient multiple birth," birth order and multiple birth indicator must be consistent. If multiple birth indicator is twins, birth order cannot be three. CR2017 - BR5205 Remarks: If all elements in a data group are not internally consistent, the IIS should reject all values in the data group.
References	CR2017 - BR304 References: CR2017 - BR301: Data elements considered to be a data group. CR2017 - BR302: Data group values are from same data source. CR2017 - BR303: Treat elements of data group as one. CR2017 - BR5205 References: CR2017 - BR5202: Data elements considered to be data groups. CR2017 - BR5203: Data group values are from same data source. CR2017 - BR5204: Treat elements of data group as one.

CR2017 - BR401 / BR5201. Compare data elements of same type	
Rule Statement	Only data elements of the same type should be compared for consolidation purposes.
Remarks	CR2017 - BR401 Remarks: • In some cases, a concept of "type" can be applied to some sets of demographic data elements that do not constitute a data group (e.g., patient address contains six data elements: street, city, state, country, zip code, and county of residence). Example: For consolidation purposes, compare a street address to a street address, but do not compare a street address to a PO Box. • Categorization of data elements/groups into types is determined by local implementation. • Examples of types of patient address are:

	○ Physical (for example, street) and mailing (for example, PO Box or street) ○ Primary (home) and secondary CR2017 - BR5201 Remarks: • In some cases, a concept of "type" can be applied to some sets of data elements that do not constitute a data group. • Categorization of data elements/groups into types is determined by local implementation.
References	CR2017 - BR401 References: Chapter 7: Implementation Considerations S105: Address: same type. S107: Phone number: same type. Appendix A: Terms and Definitions Defined via Domain Model CR2017 - BR5201 References: Appendix A: Terms and Definitions Defined via Domain Model

CR2017 - BR5002. Base record: two existing records	
Rule Statement	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.
Remarks	• Base record is a record to be updated with information from another record during the consolidating records process. • If one of two existing records is updated during consolidation, either of the two existing records may be chosen to be updated with the best information from the other record. • Local implementation will determine which one of the two existing vaccination event IDs to use. Factors to consider when determining which of two existing records to use as the base record in consolidation: ○ The initial date each record was added to the IIS (may want to use the earliest record added to the IIS). ○ Confidence level for each record (established by each IIS) • Consolidation of two demographic records should trigger consolidation of associated vaccination records as well.
References	Chapter 3: Fundamentals, Figure 3-4 in Option 2: Two existing IIS records are determined to match section. Chapter 4: Consolidating Records Process

	CR2017 - P04: Consolidation results. CR2017 - P13: Principles and business rules apply regardless of method of transmission. Appendix A: Terms and Definitions Defined via Domain Model

CR2017 - BR501 / BR5501. Use valid values	
Rule Statement	A valid value for a data element or data group should be used over an invalid value.
Remarks	CR2017 - BR501 Remarks: • An IIS should maintain an "invalid value" list for some data elements to be used for data validation purposes. A list of known invalid values should be maintained for fields that do not have valid value code tables (e.g., phone number "999-999-9999" or city "Any town"). • An invalid value in a data element or data group may not be sufficient to reject the entire incoming record; however, the data may be flagged as invalid. • An IIS should perform system validations, including testing for HL7 format conformance and checking for data validation, before the consolidating records process begins (see Data Quality section in Chapter 7: Implementation Considerations). Therefore, the term "invalid value" for a data element in the consolidating records process means an irregular value that did not result in a rejection during the IIS validation process. Usually, invalid values that occur in the consolidating records process result from the requirement that a data element must have a value. Examples of invalid demographic data elements include a "Baby Boy" patient name, a patient date of birth that is "01/01/1900," and an address with a PO Box number in the street field. • In special cases, an empty value should be used instead of other submitted values (CR2017 - BR508). CR2017 - BR5501 Remarks: • An invalid value in a data element or data group may not be sufficient to reject the entire incoming record; however, the data may be flagged as invalid. For example, a vaccine lot number may have extraneous characters (e.g., "ABE123-VFC," indicating that an administered vaccine dose is for a VFC-eligible child). • In special cases, an empty value should be used instead of other submitted values.

References	CR2017 - BR501 References: Step DR1.1 Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 1 CR2017 - P05: Use best value for each data element. CR2017 - BR507: Use invalid value in certain cases. S104: Patient first name: one valid, one invalid value. CR2017 - BR5501 References: Step VER3.1 Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 1 CR2017 - P05: Use best value for each data element. CR2017 - BR5507: Use invalid value in certain cases. CR2017 - BR5508. Use empty value over invalid value for non-required data element. S1106: Two historical vaccination event records: Valid value versus blank/invalid value.

CR2017 - BR502 / BR5502. Use either of two identical valid values	
Rule Statement	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.
References	CR2017 - BR502 References: Step DR1.1A Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 2 CR2017 - BR5502 References: Step VER3.1A Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 2

CR2017 - BR503 / BR5503. Use populated values over empty values	
Rule Statement	A valid value for a data element or data group should be chosen over an empty value.
Remarks	CR2017 - BR503 and BR5503 Remarks: • In special cases, an empty value should be used instead of other submitted values. • A known valid value should be chosen over an unknown (empty, blank) value.

References	CR2017 - BR503 References: Step DR1.1C Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 4 CR2017 - P05: Use best value for each data element. CR2017 - BR507: Use invalid value in certain cases. CR2017 - BR5503 References: Step VER3.1C Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 4 CR2017 - P05: Use best value for each data element. CR2017 - BR5507: Use invalid value in certain cases. S1106: Two historical vaccination event records: valid value versus blank/invalid value. S1107: Record-level completeness.

CR2017 - BR504 / BR5504. Use either invalid value for required data elements	
Rule Statement	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.
Remarks	CR2017 - BR504 and BR5504 Remarks: A data element is required because it is a software minimum field required to save the data element.
References	CR2017 - BR504 References: Step DR1.1D Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 5 CR2017 - BR5504 References: Step VER3.1D Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 5

CR2017 - BR505 / BR5505. Use empty value instead of invalid value for non-required data element	
Rule Statement	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.

Remarks	CR2017 - BR505 and BR5505 Remarks: A data element is required because it is a software minimum field required to save the data element.
References	CR2017 - BR505 References: Step DR1.1E Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 6 CR2017 - BR5505 References: Step VER3.1E Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 6

CR2017 - BR506 / BR5506. Use local implementation rules for invalid values for required data element	
Rule Statement	Local policies should be implemented for choosing between two different invalid values for a required data element in a consolidated record.
Remarks	CR2017 - BR506 and BR5506 Remarks: A data element is required because it is a software minimum field required to save the data element.
References	CR2017 - BR506 References: Step DR1.1F Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 7 S103: Patient first name: two invalid values CR2017 - BR5506 References: Step VER3.1F Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 7

CR2017 - BR507 / BR5507. Use invalid value in certain cases	
Rule Statement	An invalid value should be selected over an empty value for a data element that is required to have a value.
Remarks	CR2017 - BR507 Remarks: • A data element is required because it is a software minimum field required to save the data element. • For example, an IIS may require a patient first name. The only value submitted is “Baby Boy” in one record and an empty value in a second record. “Baby Boy” may be flagged as invalid but must be chosen for a consolidated record because the data element is required. • Application of this business rule requires that the value be flagged as invalid, which is crucial. CR2017 - BR5507 Remarks:

	• A data element value is required because it is a software minimum field required to save the data element. • For example, a vaccine lot number with extraneous characters (e.g., "ABC123-VFC," where "ABC123" is a correct vaccine lot number and "VFC" was added by a provider to indicate the vaccine was from the VFC program). • Best practices for validating vaccine lot numbers are described in MIROW Lot Number Validation Best Practices [1.11].
References	CR2017 - BR507 References: Step DR1.1G Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 8 CR2017 - BR5507 References: Step VER3.1G Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 8

CR2017 - BR508 / BR5508. Use empty value over invalid value for non-required data element	
Rule Statement	An empty value for a data element should be used over an invalid value when the data element is not required.
Remarks	CR2017 - BR508 and BR5508 Remarks: A data element value is required because it is a software minimum field required to save the data element.
References	CR2017 - BR508 References: Step DR1.1H Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 9 CR2017 - BR5508 References: Step VER3.1H Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 9

CR2017 - BR509 / BR5509. Use either value when both values are empty	
Rule Statement	The value of a data element in a consolidated record should be empty when the values in both matched records are empty.
Remarks	CR2017 - BR509 and BR5509 Remarks: IIS may have data quality procedures to assign values.
References	CR2017 - BR509 References: Step DR1.1I Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario

	10 CR2017 - BR5509 References: Step VER3.1I Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 10

CR2017 - BR5101. Information needed to make consolidation decisions	
Rule Statement	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.
Remarks	• This business rule may be implemented in multiple ways—for example, storing or inferring the required information. • The information required by this business rule is sufficient to consolidate records but not to unmerge records. Additional information may be required to unmerge records. Unmerging may also require manual intervention. CR2017 - BR6001 provides unmerging considerations. • Appendix A: Terms and Definitions Defined via Domain Model defines data source and discusses use of IIS-AO to identify a specific data source. • Confidence level: Local considerations influence determination of the confidence level in reported data. • CR2017 - BR5202 lists data elements that form data groups. • Best practice: The IIS should keep an audit trail of all changes made to a data element, especially a subset that includes the original data source and the data source for the last modification. The IIS will be able to access the audit trail to know if the record originally came from a record that was changed later by the IIS (e.g., data validation or address cleansing) or by a provider through a UI. • Data retention laws and policies differ. The amount of time data are retained will impact the ability of an IIS to consolidate and unmerge records.
References	CR2017 - P03: Make original information accessible. CR2017 - BR5202: Data elements considered to be data groups. CR2017 - BR5701: Use information with highest confidence level.

	CR2017 - BR6001: Prevent remerging of previously unmerged records. Appendix A: Terms and Definitions Defined via Domain Model

CR2017 - BR5102. Administered/historical indicator	
Rule Statement	The IIS should determine the value of the administered/historical indictor for each vaccination event record.
Remarks	• IIS implementations differ in the case of an empty administered/ historical indicator. • Best practice: The submitter of a vaccination event record should indicate the value for the administered/historical indicator. • Good practice: The IIS should consistently determine the value for the administered/historical indicator based on local considerations. For legacy records, the IIS may need to assign the value of the administered/historical indicator. • Chapter 7: Implementation Considerations discusses factors to consider in determining the value for the administered/historical indicator.
References	Chapter 7: Implementation Considerations

CR2017 - BR5103. Retain all past IIS vaccination event IDs	
Rule Statement	All past IIS vaccination event IDs associated with a consolidated vaccination event record should be retained by the IIS.
Remarks	• An IIS vaccination event ID has a unique single value per record. When existing records are consolidated, their IIS vaccination IDs need to be retained. • For example, if a vaccination event has two records with different IIS vaccination event IDs (i.e., the ID assigned by the IIS for each vaccination event) and the records are consolidated, both IIS vaccination event IDs should be retained. • Data retention laws and policies differ. The amount of time data are retained will impact the ability of an IIS to consolidate and unmerge records.
References	Chapter 7: Implementation Considerations CR2017 - P11: Specific local laws control. CR2017 - BR5901. Local laws, regulations, and policy control.

CR2017 - BR5104. Use current (i.e., active) IIS vaccination event ID

Rule Statement	The current IIS vaccination event ID should be included in all IIS-originated communications about a vaccination event.
Remarks	• A patient has only one current (active) IIS vaccination event ID at any point in time for a given vaccination event. • CR2017 - BR5103 states that all IIS vaccination event IDs should be retained by the IIS.
References	Chapter 7: Implementation Considerations CR2017 - BR5103: Retain all past IIS vaccination event IDs.

CR2017 - BR5105. Retain past values	
Rule Statement	IIS should make accessible past values for the following data group: Alternate vaccination event ID.
Remarks	• Making past values accessible facilitates IIS functions such as matching and unmerging. • In bidirectional data exchanges, challenges caused by changing vaccination event IDs can be mitigated if vaccination event IDs (i.e., alternate vaccination event IDs) are preserved. • All values in a data group should be made accessible as a unit. • Data retention laws and policies differ among IIS jurisdictions. The amount of time data are retained will impact the ability of an IIS to consolidate and unmerge records.
References	Chapter 7: Implementation Considerations CR2017 - BR5103. Retain all past IIS vaccination event IDs. CR2017 - BR5202: Data elements considered to be a data group. CR2017 - BR5204: Treat elements of data group as one.

CR2017 - BR5202. Data elements considered to be data groups	
Rule Statement	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).
Remarks	Certain data elements are grouped together and treated as one data group in which the value for each data element must come from the same data source. It is important to select all values for data elements in data groups from the same data source because mixing values from different data sources would incorrectly change the interpretation of the values. The Grouping of demographic data elements section of Appendix A: Terms and Definitions Defined via Domain Model provides more detail about data groups.
References	CR2017 - BR5203: Data group values are from same data source. CR2017 - BR5204: Treat elements of data group as one. CR2017 - BR5205: Values within a data group must be consistent. Table A-5 and Grouping of demographic and vaccination event data elements in Appendix A: Terms and Definitions Defined via Domain Model

CR2017 - BR5301. Data elements with a single value.	
Rule Statement	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.
References	Step VER1.1 Table A-4 in Appendix A: Terms and Definitions Defined via Domain Model

CR2017 - BR5401. Use administered vaccination event information over historical	
Rule Statement	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.
Remarks	• For example, vaccine adverse reaction(s) can have multiple values. • Sometimes historical and administered are mislabeled. • See the remarks for vaccination event record data element in the domain model and Table A-5 for information included in a vaccination event record. • If multiple values are allowed, all unique values should be selected.
References	Step VER2.1 CR2017 - P07. Accuracy over completeness. CR2017 - BR5302. Retain all unique values from data elements with multiple values. S1101: Base record: existing administered and historical vaccination event records. S1104: Administered vaccination event records compared to historical vaccination event records. Table A-6 in Appendix A: Terms and Definitions Defined via Domain Model

CR2017 - BR5402. Two administered vaccination event records (different data sources).	
Rule Statement	The IIS should investigate if two administered vaccination event records are submitted by different data sources.

Remarks	• All administered vaccination event records for a single vaccination event should be from the same data source.
	• If two administered vaccination event records are submitted by different data sources (incoming versus existing and existing versus existing) for the same vaccination event:
	  ○ Best practice: The IIS should investigate.
	  ○ Good practice: If an IIS does not have resources to investigate, the IIS should establish local rules (e.g., considering recency, completeness, etc.) for an automated process to choose the best value.

References	Step VER2.1A

CR2017 - BR5403. Use information that has most recent submission date.

Rule Statement	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.
Remarks	See BR5802 for an exception to the general rule stated. If the IIS has validated values in a record, a subsequent submission of the same "bad" value by the same data source should not be used in place of the validated value.
References	Step VER2.1B S1105: Data validation by IIS.

CR2017 - BR5701. Use information with highest confidence level.	
Rule Statement	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.
Remarks	Confidence level is discussed in detail in Appendix D: Confidence Level Indicator.
References	Chapter 7: Implementation Considerations Step VER4.1 CR2017 - P07. Accuracy over completeness. CR2017 - P08: Confidence ranking for data sources. Appendix D: Confidence Level Indicator

CR2017 - BR5702. Use information that has most recent submission date.	
Rule Statement	The value with the most recent submission date should be used in a consolidated record when comparing two historical vaccination event records.
Remarks	• For two administered vaccination event records from the same source, use the value from the vaccination event record with the most recent submission date. See BR5403. • For two historical vaccination event records from the same or different sources, use the values from the vaccination event record with the most recent submission date. • Chapter 7: Implementation Considerations discusses action codes.
References	Step VER4.2.

	CR2017 - P09: Recency. CR2017 - BR5403: Use information that has most recent submission date. CR2017 - BR5802: Prevent overwriting validated data.

CR2017 - BR5801. Data validation.	
Rule Statement	Data validation should occur within each vaccination event record and between each vaccination event record and associated demographic record.
Remarks	• Consolidated records should be subject to the same data validation rules as other records in the IIS. • Best practice: Validate incoming data using the same rules as for existing data to prevent a cycle of overwriting validated data. • Good practice: Perform regular data validation for existing data. If the IIS has limited resources, incoming data may be subject to less stringent validation rules than existing data.
References	Chapter 7: Implementation Considerations CR2017 - BR5802. Prevent overwriting validated data. CR2017 - BR5803: No conflict with existing data. S1105: Data validation by IIS.

CR2017 - BR601. Supremacy of vital statistics	
Rule Statement	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.
Remarks	• Some IIS do not receive data from vital statistics. • Local law, regulations, or policy may provide that vital statistics is a definitive source of information for patient name. In this case, the IIS could store the patient name from vital statistics in a separate field in addition to a consolidated patient name. Even though vital statistics is a definitive source of information, they may be incorrect in some instances. For example, a change of gender may be communicated to

	the IIS by a call from a provider. CR2017 - BR1003 provides guidance on investigating incoming data that are inconsistent with existing data. • Vital statistics is a definitive source for birth certificate number. A birth certificate number is one value for Alternate Patient ID: Type. • The 2013 MIROW guide [1.3] Data Quality Assurance in Immunization Information Systems: Selected Aspects also discusses vital statistics as being the authoritative source for some data elements (see DQA2013 - BR104 in the 2013 guide, items 7.2, 7.3 in the Table 3 Domain model - terms and definitions).
References	Step DR1.2 CR2017 - BR1003: No conflict with existing data. CR2017 - BR1101. Local laws, regulations, and policy control. S103: Patient first name: two invalid values. S108: Patient last name: vital statistics compared with later provider submission. S109: Patient last name: provider submission compared with later vital statistics submission. S110: Address: vital statistics compared with later provider submission. S111: Patient date of birth: vital statistics compared with later provider submission. Appendix A: Terms and Definitions Defined via Domain Model, Table A-4

CR2017 - BR701. Data elements with a single value	
Rule Statement	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.
Remarks	An alias date of birth should be stored separately from the date of birth.
References	Step DR1.2B Appendix A: Terms and Definitions Defined via Domain Model, Table A-4

CR2017 - BR702 / BR5302. Retain all unique values from data elements with multiple values

Rule Statement	All unique values should be retained for data elements that can have multiple current values.

Remarks	CR2017 - BR702 Remarks:
	• A demographic record may have multiple values for the following data elements/groups:
	  ○ Alternate patient ID (but only one per type and data source)
	  ○ Patient address
	  ○ Patient alias name
	  ○ Responsible person name (can have multiple per type)
	  ○ Patient telephone (can have multiple per type)
	  ○ Race
	  ○ Mother's name
	  ○ Patient e-mail address
	  ○ Patient active/inactive status indicator (PAIS) (but only one per provider)
	  ○ Contraindication(s)/precaution(s)
	  ○ History of vaccine-preventable disease
	  ○ Exemption(s)
	  ○ Vaccine adverse reaction(s)
	• For example, there may be multiple patient home addresses if a child lives at multiple homes.
	• IIS may have different implementations for capturing race.
	• See MIROW 2015 Management of Patient Active/Inactive Status Guidelines [1.2] for a discussion of PAIS.
	• Each of four data groups (contraindication(s)/precautions(s), history of vaccine-preventable disease, exemption(s), and vaccine adverse reaction(s)) may be associated by the data source with a vaccination event or with a patient or encounter date. For example, a vaccine adverse reaction may be submitted to the IIS through a UI and associated with a specific vaccination. Future modifications to HL7 may also allow association of an adverse event with a specific vaccination. Alternatively, a data source may not know the date of vaccination or the specific vaccinations given and may submit a vaccine adverse reaction with an observation date or date of vaccination encounter (but not a specific vaccine). The IIS should associate contraindication(s)/precautions(s), history of vaccine-preventable disease, exemption(s), and vaccine adverse reaction(s) with a demographic record, vaccination event record, patient, or encounter as reported by the data source.
	
	CR2017 - BR5302 Remarks:
	• See Table A-5 and Table A-6 for data elements and data groups.

	• The following data groups can have multiple current values:
	  ○ Alternate vaccination event ID (one per data source)
	  ○ Contraindication(s)/precaution(s)
	  ○ History of vaccine-preventable disease
	  ○ Exemption(s)
	  ○ Vaccine adverse reaction(s)
	  ○ Each of four data groups (contraindication(s)/precautions(s), history of vaccine-preventable disease, exemption(s), and vaccine adverse reaction(s)) may be associated by the data source with a vaccination event or with a patient or encounter date. For example, a vaccine adverse reaction may be submitted to the IIS through a UI and associated with a specific vaccination. Future modifications to HL7 may also allow association of an adverse event with a specific vaccination. Alternatively, a data source may not know the date of vaccination or the specific vaccinations given and may submit a vaccine adverse reaction with an observation date or date of vaccination encounter (but not a specific vaccine). The IIS should associate contraindication(s)/precautions(s), history of vaccine-preventable disease, exemption(s), and vaccine adverse reaction(s) with a demographic record, vaccination event record, patient, or encounter as reported by the data source.

References	CR2017 - BR702 References: Chapter 7: Implementation Considerations Step DR1.2A S107: Phone number: same type. Table A-4 and Table A-6 in Appendix A: Terms and Definitions Defined via Domain Model MIROW 2015 Management of Patient Active/Inactive Status Guidelines [1.2] CR2017 - BR5302 References: Chapter 7: Implementation Considerations Step VER1.1 S1103. Multiple values permitted. Table A-4 and Table A-6 in Appendix A: Terms and Definitions Defined via Domain Model

CR2017 - BR801/ BR5601. Use more complete information	
Rule Statement	More complete information should be used over less complete information.

Remarks	CR2017 - BR801 Remarks: Examples: • 123 Main St. vs. 123 Main St. Apt 20—an address with an apartment number is more complete than one without. • "E." vs. "Elizabeth"—a full first name is more complete than an initial. CR2017 - BR5601 Remarks: Examples: Data element vaccine ordering provider name: "J. Smith" versus "John Smith"—a name that includes a full first name is more complete than a name with an initial.
References	CR2017 - BR801 References: Step DR1.3 CR2017 - BR5601 References: Step VER3.3 S1107: Record level completeness.

CR2017 - BR802 / BR5602. Use more specific information.	
Rule Statement	More specific information should be used over less specific information.
Remarks	CR2017 - BR802 Remarks: A person listed with a relationship of "Parent" versus the same person listed as "Mother." CR2017 - BR5602 Remarks: For example, a more specific vaccine product type administered (Hib-PRP-T) should be selected over the more generic vaccine product type administered (Hib-unspecified).
References	CR2017 - BR802 References: Step DR1.3 CR2017 - BR5602 References: Step VER3.3

CR2017 - BR901. Use information with highest confidence level	
Rule Statement	The value with the higher confidence level should be used in a consolidated record.
Remarks	• The confidence level indicator aggregates factors that impact selection of the best value for a demographic data element from multiple data sources; it reflects the level of confidence or trust regarding quality of data. These factors include: ○ How a record containing the data element/data group is submitted to an IIS (submission method).

	○ What type of information the record containing the data element/data group represents (submission type). ○ Who submitted the record containing the data element/data group (data source type). ○ When the record containing the data element/data group is submitted (recency). ○ Any specific knowledge of the data source submitting the record containing the data element/data group. • Confidence level is discussed in detail in Appendix D: Confidence Level Indicator.
References	Chapter 7: Implementation Considerations Step DR2.1 CR2017 - P07. Accuracy over completeness. CR2017 - P08: Confidence ranking for data sources. S101: Base record: incoming and existing demographic records. S106: Patient first name: demographic record recency. Appendix D: Confidence Level Indicator

CR2017 - BR902. Use information that has most recent submission date	
Rule Statement	The value with the most recent submission date should be selected for a consolidated record.
Remarks	Dates associated with data elements and/or records are important for determinations in addition to consolidating records. For example, for timeliness calculations, an IIS should make accessible 1) the date a record was originally created (loaded) in the IIS and 2) the date a record was first created (loaded) in the IIS if two existing records are consolidated. See CR2017 - BR1002 for exceptions to this general rule.
References	Step DR2.2 CR2017 - P09: Recency. S105: Address: same type. S106: Patient first name: demographic record recency. S107: Phone number: same type. S108: Patient last name: Vital statistics compared to later provider submission. S109: Patient last name: Provider submission compared to later vital statistics submission. S110: Address: Vital statistics compared to later provider submission.

CR2017 - BR903 / BR5703. Use local policies if no selection made based on another business rule	
Rule Statement	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.
Remarks	CR2017 - BR903 Remarks: • If no value is selected for consolidation after application of another BR, the IIS should develop a policy to consistently choose one of the two values. • Considerations for local policies could include the date of the most recent vaccination event record submitted with a demographic record, if any. CR2017 - BR5703 Remarks: If no value is selected for the consolidated record after application of other business rules, the IIS should develop a policy to consistently choose one of the two values.
References	CR2017 - BR903 References: Step DR2.2A CR2017 - BR5703 References: Step VER4.2A

CR2017 - P01. Create consolidated record	
Rule Statement	The IIS should create a single consolidated demographic record for each patient and a single consolidated vaccination event record for each vaccination event.
Remarks	This document provides best practices for consolidating demographic records and vaccination event records.
References	Chapter 3: Fundamentals Chapter 4: Consolidating Records Process Chapter 5: Principles and Business Rules CR2017 - P02: Use consolidated record.

CR2017 - P02. Use consolidated record	
Rule Statement	A consolidated record should be used for all IIS functions.
Remarks	The consolidated demographic record for each patient and consolidated vaccination event record for each vaccination event should be used for all IIS functions, including clinical decision support, query responses,

	reminder/recall, VFC activities, and coverage assessment reports, and for viewing via direct UI.
References	Chapter 3: Fundamentals Chapter 7: Implementation Considerations CR2017 - P01: Create consolidated record.

CR2017 - P03. Make original information accessible	
Rule Statement	Original information should be accessible by an IIS.

Remarks	• The words "retain," "store," and "keep" are used to indicate the IIS should save originally submitted data values. The term "accessible" in this principle implies that the originally submitted values can be kept, stored, or retained and that they can be derived from other values. Chapter 7: Implementation Considerations discusses these terms.
	• Original information consists of the data values as originally submitted to an IIS and information about the data elements containing those values.
	  ○ For a demographic record, original information consists of:
	  ▪ data source type
	  ▪ specific data source (vaccinator IIS-AO)
	  ▪ date of submission to the IIS
	  ▪ confidence level
	  ○ For each vaccination event record, original information consists of:
	  ▪ data source type
	  ▪ specific data source (vaccinator IIS-AO)
	  ▪ date of submission to the IIS
	  ▪ confidence level
	  ▪ value of the administered/historical indicator
	  ▪ alternate vaccination event ID
	• Original information is necessary to make future consolidation decisions as new information becomes available for consolidation and for unmerging incorrectly merged records.
	• The subset of original information necessary to make consolidation decisions is listed in CR2017 - BR201 for demographic record and in CR2017 - BR5101 for vaccination event record.
	• The subset of original information required to consolidate records is not sufficient to unmerge records.

References	CR2017 - P10: Unmerge. CR2017 - BR201: Information needed to make consolidation decisions.

	CR2017 - BR1201: Prevent remerging of previously unmerged records. CR2017 - BR5101: Information needed to make consolidation decisions. CR2017 - BR6001: Prevent remerging of previously unmerged records.

CR2017 - P04. Consolidation results	
Rule Statement	Consolidation should result in either a new record or an updated base record.
References	Chapter 3: Fundamentals Chapter 4: Consolidating Records Process CR2017 - BR101: Base record: existing record over incoming record. CR2017 - BR102: Base record: two existing historical records. BR5001: Base record: existing record over incoming record. BR5002: Base record: two existing records.

CR2017 - P05. Use best value for each data element	
Rule Statement	The best value for each data element from all available data sources should be selected for a consolidated record.
Remarks	This principle should not be applied to data elements that can have multiple values. For example, all unique values for adverse reactions should be selected and retained in a consolidated record.
References	Chapter 3: Fundamentals Chapter 4: Consolidating Records Process Chapter 5: Principles and Business Rules CR2017 - BR501. Use valid values. CR2017 - BR503. Use populated values over empty values. CR2017 - BR5501. Use valid values. CR2017 - BR5503. Use populated values over empty values.

CR2017 - P06. Order for applying business rules	
Rule Statement	Business rules for selecting a best value for a data element should be applied in a specific order.
Remarks	• Process diagrams in Chapter 4: Consolidating Records Process present business rules in a specific order. • Table 5-2 in Chapter 5: Principles and Business Rules presents business rules for consolidating demographic records in the order in which the business rules are to be applied.

	• Table 5-3 in Chapter 5: Principles and Business Rules presents business rules for consolidating vaccination event records in the order in which the business rules are to be applied.
References	Chapter 4: Consolidating Records Process Chapter 5: Principles and Business Rules

CR2017 - P07. Accuracy over completeness	
Rule Statement	Accurate information should be used over more complete information in a consolidated record.
Remarks	• This principle indicates that accurate information is preferable over more complete inaccurate information. • With respect to a vaccination event record, the administering provider has the most knowledge of vaccination event information. CR2017 - BR5401 provides that, if multiple values are not allowed, the value from an administered vaccination event record should be chosen over the value from a historical vaccination event record. Note: This is a different recommendation from that in the MIROW 2006 Vaccine Deduplication Guidelines [1.8]. • In consolidating demographic records, an IIS could implement this principle as one aspect of local considerations for confidence level of a data source. Appendix D: Confidence Level Indicator discusses confidence level.
References	CR2017 - BR901: Use information with highest confidence level. CR2017 - BR5401: Use administered vaccination event information over historical. CR2017 - BR5701: Use information with highest confidence level. Appendix D: Confidence Level Indicator

CR2017 - P08. Confidence ranking for data sources	
Rule Statement	A confidence ranking for data sources should be established and used by the IIS.
Remarks	• The consolidating records process may result in selection of a value before consideration of confidence level. • Using local considerations, the confidence ranking is specified at the record level.
References	Chapter 4: Consolidating Records Process Chapter 7: Implementation Considerations Step DR2.1 Step VER4.1

	CR2017 - BR901: Use information with highest confidence level. CR2017 - BR5701: Use information with highest confidence level. Appendix D: Confidence Level Indicator

CR2017 - P09. Recency	
Rule Statement	More recent information should be used over older information in a consolidated record when all other factors are equal.
Remarks	• Exceptions to this principle are stated in CR2017 - BR101, CR2017 - BR102, CR2017 - BR5001, and CR2017 - BR5002 regarding choosing a base record. • Recency is used in determining the confidence level for a data source.
References	Step DR2.2 Step VER2.1B Step VER4.2 CR2017 - BR902: Use information that has most recent submission date. CR2017 - BR5403: Use information that has most recent submission date. CR2017 - BR5702: Use information that has most recent submission date. Appendix D: Confidence Level Indicator

CR2017 - P10. Unmerge	
Rule Statement	An IIS should be able to unmerge a consolidated record.

Remarks	• Implementation will differ among IIS.
	• Unmerging may involve both manual and automated methods.
	• CR2017 - BR1201 and CR2017 - BR6001 describe unmerging considerations.
	• An unmerge can be triggered when:
	  ○ Records that were deemed to be a match are later deemed not to be a match.
	  ○ An incoming vaccination event record contains a delete code and the vaccination event record had been previously consolidated. Chapter 7: Implementation Considerations discusses the delete action code. When considering historical vaccination event records, an unmerge triggered by a delete action code may result in more than one remaining vaccination event record that will then be reconsolidated.
	• For unmerging records:
	  ○ Best practice: To facilitate unmerging, all original records should be retained.

	○ Good practice: To facilitate unmerging, data source information for all data elements and data groups selected for a consolidated record should be accessible by the IIS.
References	Chapter 3: Fundamentals Chapter 7: Implementation Considerations CR2017 - P03: Make original information accessible. CR2017 - BR1201: Prevent remerging of previously unmerged records. CR2017 - BR6001: Prevent remerging of previously unmerged records.

CR2017 - P11. Specific local laws control.	
Rule Statement	Local laws, regulations, and policies regarding opt-out, foster care, protective custody, and adoption supersede all other principles and business rules.
References	Chapter 7: Implementation Considerations CR2017 - BR1101: Local laws, regulations, and policy control. CR2017 - BR5901: Local laws, regulations, and policy control.

CR2017 - P12. Business routines should not be counterproductive	
Rule Statement	IIS business routines such as data quality/validation and consolidation should not be counterproductive.
Remarks	An IIS should ensure that its consolidating records process does not result in overwriting validated data.
References	Chapter 7: Implementation Considerations CR2017 - BR1002: Prevent overwriting validated data. CR2017 - BR1003: No conflict with existing data. CR2017 - BR5802: Prevent overwriting validated data. CR2017 - BR5803. No conflict with existing data.

CR2017 - P13. Principles and business rules apply regardless of method of transmission	
Rule Statement	The Ps and BRs in this guide should be applicable to all methods of data transmission.
Remarks	Data transmission methods include: Direct UI, HL7 messages, and electronic files.
References	Chapter 7: Implementation Considerations

DINV2016 - BR101 - Organize inventory information in IIS by the lot number, lot number expiration date, and lot-level public/private indicator	
Rule Statement	Inventory information should be organized in IIS by the lot number, lot number expiration date, and lot-level public/private indicator.
Remarks	• For example, a provider organization using the two-stock model has lot number ABC123 (with the same lot number expiration date) in both public and private stocks. The IIS should categorize the doses within inventory items to replicate the physical inventory in provider organizations' storage unit: 1) lot number ABC123, lot-level public/private indicator = public, and 2) lot number ABC123, lot-level public/private indicator = private. • For three-stock and four-stock storage models, the assignment of a lot number to the appropriate inventory item in IIS should be based on the fund type designated in the order. The IIS may determine the appropriate inventory item based on the vaccine order or the provider organization can determine the appropriate inventory item based on the shipment packing slip. • Since VTrckS shipments contain only public vaccines, for the two-stock storage model, the IIS assigns lot numbers to the public inventory item.
References	DINV2016-P04. Inventory information in the IIS should map to the storage model used by the provider organization. DINV2016-P06. DI-v-EDE should support dose-level accountability. DINV2016-BR104. Increment inventory item balance with shipment information. DINV2016-BR107. Create new inventory item for short-dated doses. DINV2016-BR108. Calculate inventory item balance after creating new inventory item for short-dated doses. Step 1.3 and Step 2.3. Scenario S102.

DINV2016 - BR102 - Prepopulate provider organization's inventory in IIS	
Rule Statement	Provider organization's inventory in the IIS should be prepopulated based on the shipment data uploaded in the IIS from VTrckS.
Remarks	• DI-v-EDE should minimize manual data entry by provider organizations. • Prepopulation can occur through either new shipment data or a transfer from another provider organization.
References	INV2012 - GR710 Minimize manual inventory data entry in MIROW 2012 Inventory Management Guidelines

	DINV2016 - P05. DI-v-EDE should minimize the burden on provider organizations. DINV2016 -BR103. Download shipment information daily. DINV2016 - BR104. Increment inventory item balance with shipment information. Step 1.2 and Step 1.3. Scenario S102.

DINV2016 - BR103 - Download shipment information daily	
Rule Statement	IIS should at least daily download shipment information from VTrckS and update provider organization's inventory in IIS by uploading shipment file into IIS.
Remarks	The exception to the daily download would be when VTrckS has planned or unplanned downtime.
References	DINV2016 - P05. DI-v-EDE should minimize the burden on provider organizations. DINV2016 - BR102. Prepopulate provider organization’s inventory in IIS. DINV2016 - BR104. Increment inventory item balance with shipment information. Step 1.2 Scenario S102.

DINV2016 - BR104 - Increment inventory item balance with shipment information.	
Rule Statement	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.
Remarks	For example, a provider organization using the two-stock model has lot number ABC123 in both public and private stocks. If the provider organization receives a new shipment containing 5 VFC doses, 3 317 doses, and 4 state doses with the same lot number ABC123, the balance for the lot number ABC123 inventory item for a public stock (i.e., lot number public/private indicator = public) should be incremented by 12 doses. To avoid duplication of lot numbers, inventory items can be incremented for active or inactive lot numbers.
References	DINV2016 - BR101. Organize inventory information 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.

	DINV2016 - BR103. Download shipment information daily. Step 1.3 Scenario S102.

DINV2016 - BR105 - Verify physical contents of a vaccine shipment	
Rule Statement	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.
References	Step 1.5 and Step 1.6. Scenario S101.

DINV2016 - BR106 - Notify awardee VFC program and IIS of discrepancies between physical contents and packing slip and/or IIS	
Rule Statement	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.
References	Step 1.5 and Step 1.6. Scenario S101.

DINV2016 - BR107 - Create new inventory item for short-dated doses	
Rule Statement	Awardee staff or provider organization should create a new inventory item for short-dated doses.
Remarks	• The new inventory item is identified by the same lot number and lot-level public/private indicator as an original inventory item, but with a different lot number expiration date. See domain model, item 8.0 Inventory. • The vaccine manufacturer initially establishes lot number expiration date and all doses in a lot have the same expiration date. In some cases, vaccine is subject to temperature variations in storage that are outside the recommended range. The doses of vaccine that were subject to the temperature variations may be given a new expiration date that is sooner than the original expiration date (short-dated). • According to INV - BR712, MIROW 2012 Inventory Management Guidelines [p.44]: "When present, the short-dated lot number expiration date must be used (recorded) for all inventory transactions instead of the original lot number expiration date". ○ For additional discussion of short-dated lot number expiration date, see MIROW 2012 Inventory Management Guidelines,

	specifically, INV - BR711, p. 43, INV - BR712, p. 44,INV - GR706, p. 55, and INV - BR718, p. 47. • When vaccine doses are compromised (usually, due to a temperature excursion), there are three possible outcomes: a) all affected doses are viable and don't need to be short-dated, or b) all affected doses are viable and get short-dated, or c) all affected doses are non-viable and are considered to be wasted. Our focus, from perspective of the DI-v-EDE process, is on scenario (b) handling short-dated doses. See Table 3 for additional considerations. • In rare circumstances, the lot expiration dates can be given an extension by the Federal Drug Administration, particularly in the case of a pandemic with vaccine that is part of the Strategic National Stockpile.
References	DINV2016 - BR101. Organize inventory information in IIS by the lot number, lot number expiration date, and lot-level public/private indicator. DINV2016 - BR108. Calculate inventory item balance after creating new inventory item for short-dated doses. • Scenario S601. Appendix E. Handling Doses with Short-dated Lot Number Expiration Dates.

DINV2016 - BR108 - Calculate inventory item balance after creating new inventory item for short-dated doses	
Rule Statement	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).

Remarks	• Short-dated doses should be reassigned to the new inventory item with the same lot number and lot number public/private indicator, but with a different expiration date (see DINV2016 - BR107).
	• The IIS should reduce the balance of the original inventory item by the number of compromised, but still viable, doses that are now grouped in the new inventory item with the short-dated expiration date.
	• If the original inventory item (with the original expiration date) still has a positive balance, it should remain active; otherwise, it should be deactivated.
	  ○ To ensure that short-dated vaccines are used before doses with the original expiration date, some IIS temporarily deactivate the original inventory item (with the original expiration date) even when it has a positive balance.
	  ○ If the lot number expiration date is not included in an HL7 message, the inactive and active flag on the lot number can be

	used to distinguish between inventory item with original and short-dated expiration date.
References	DINV2016 - BR101. Organize inventory information in IIS by the lot number, lot number expiration date, and lot-level public/private indicator. DINV2016 - BR107. Create new inventory item for short-dated doses. Scenario S601. Appendix E. Handling Doses with Short-dated Lot Number Expiration Dates.

DINV2016 - BR201 - Document the vaccination event after vaccine administration.	
Rule Statement	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).
Remarks	Sometimes the actual vaccine administered is different from what was ordered by the provider. • This should be part of provider training. • Not all clinical work-flows support this approach.
References	Step 2.5

DINV2016 - BR202 - Submit information to IIS to support DI-v-EDE	
Rule Statement	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.

Remarks	• This list includes only data elements relevant for inventory tracking purposes. Submission may include additional information for vaccination event tracking.
	• For the recommended minimum set of data items for every vaccine dose, see INV2012 - BR711, MIROW 2012 Inventory Management Guidelines [p. 43].
	• Vaccination event date is used to:
	  ○ Determine if the vaccine was administered before or after the reconciliation date.
	  ○ Validate against lot number expiration date.
	  ○ Log when the transaction occurred for auditing purposes.
	• CVX code:
	  ○ If the lot number is incorrect, the IIS can still store the vaccination using CVX code.
	  ○ Used for data quality validation.

	○ EHR already have the ability to store and transmit, so no reengineering required. • NDC: ○ See MIROW 2012 Inventory Management Guidelines. ○ NDC is proposed as a replacement for CVX in MU Stage 3, so NDC would replace CVX as the required vaccine coding system for HL7. If providers have to enter this manually, it would be an opportunity for errors. ○ Currently, lot number ties to only one NDC in IIS; could be used for additional validation. • The following excerpt was taken from the MIROW 2012 Inventory Management Guidelines. ○ Possible additional data item: In situations when Provider Organization gives two doses of a pediatric vaccine for an adult dose or a half-dose of an adult vaccine for a pediatric dose (e.g., when vaccine has been used not according with the adult/pediatric "intention"), IIS can either use a dose trigger function (designate dose size as half, full, or double) or manually decrement the second dose or a half-dose from the inventory.
References	For discussion of short-dated lot number expiration date, see MIROW 2012 Inventory Management Guideline: INV2012 - BR711 Minimum set of data items for every vaccine dose INV2012 - BR712 Use (record) short-dated expiration date when present INV2012 - GR706 IIS should be able to record both the original and short-dated expiration dates INV2012 - BR718 Indicate IIS-EHR discrepancies For discussion of provider organization ID, see MIROW 2013 Data Quality Assurance Guidelines. DINV2016 - P06. DI-v-EDE should support dose-level accountability. DINV2016 - BR407. Examine all data elements of a DI-v-EDE submission during preapproval. Step 2.5 and Step 2.6. Scenarios S201, S701, S702, S703, and S704.

DINV2016 - BR203 - Decrement only "administered" vaccines.	
Rule Statement	Only "administered" doses should result in automatic decrementing of inventory through the DI-v-EDE process.
References	Item 14.2 Administered/ Historical Indicator in Appendix A: Terms and Definitions.

	Step 2.9 Scenarios S201, S901, and S902.

DINV2016 - BR204 - Decrement only “active” inventory	
Rule Statement	Only "active" inventory may be decremented.
Remarks	• Administering a vaccine from a lot that has not yet been accepted in the inventory can cause duplication and complications in the reconciliation. • Some programs have policies that allow decrementing inactive inventory, but this is NOT a best practice. • Clinical errors may result in administration of inactive inventory (for example, administration of vaccine past its expiration date). The IIS should reflect what actually happened in the clinical encounter, even if it was a clinical error. The provider organization should manually decrement inactive inventory to reflect clinical practice. • IIS may consider implementing a validation rule that allows decrementation of inventory if the date of vaccine administration is prior to the date the lot number was made inactive. Note: For IIS that close reconciliations, DINV - BR205 may be a factor in this validation rule.
References	8.3 in Appendix A: Terms and Definitions. Steps 1.4, 1.8, and 2.13. Scenarios S201, S501, S502, and S503.

DINV2016 - BR205 - Do not automatically decrement if vaccination event date is earlier or equal to the most recent closed reconciliation date	
Rule Statement	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.
Remarks	• Submitting vaccination event info after reconciliation date leads to decrementing issues. • Reconciliations can be reopened after they have been closed to make any potential data corrections. • If this occurs, an issue should be logged for manual intervention. • Current practices vary regarding whether reconciliations are closed, and if they are closed, whether they can be reopened to make manual corrections.

	• Each IIS should discuss this issue with the awardee's VFC program to determine how to deal with these issues. • For discussion of reconciliation end dates, see MIROW 2012 Inventory Management Guidelines, specifically, INV2012-BR717 and INV2012-BR721.
References	DINV2016 - BR302. Freeze reconciliation results. DINV2016 - BR303. Reopen reconciliation that is closed. Step 2.11. Scenario S1203 and S1204.

DINV2016 - BR206 - Update patient record regardless of inventory-related issues	
Rule Statement	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.
Remarks	Decrementing inventory is not the only function that uses submitted vaccination event data. See HL7 Immunization Messaging in Chapter 9: Implementation Considerations.
References	DINV2016 - P02. DI-v-EDE should support inventory tracking and immunization tracking. Step 2.9. Scenarios S201, S501, S502, S503, S701, S704, S801, S901, and S1001.

DINV2016 - BR301 - Resolve data quality issues before reconciling	
Rule Statement	The provider organization should resolve data quality issues prior to reconciling inventory.
References	DINV2016 - P08. IIS should assist provider organizations with correcting data quality issues. Step 3.2. Scenario S1301. INV2012 - P07 in MIROW 2012 Inventory Management Guidelines accurate accounting. Any inventory transaction should be reversible and can be corrected as necessary. INV2012 - BR101 (and associated notes), MIROW 2008 Data Quality Assurance Guidelines [1.6].

DINV2016 - BR302 - Freeze reconciliation results

Rule Statement	The IIS should freeze the reconciliation results after the reconciliation process is closed. Updates subsequent to the reconciliation date should not affect ordering.
Remarks	• Freeze (meaning prevent further changes) inventory after close of a reconciliation period. • IIS should store reconciliation "completed" or "closed" date to ensure the integrity of the reconciliation. • The results of a "frozen" reconciliation are a snapshot of a provider organizations' ending inventory at that time. The ending inventory is required by VTrckS to place new vaccine orders. • Current practices vary regarding whether reconciliations are closed, and if they are closed, whether they can be reopened to make manual corrections. Each IIS should discuss this issue with the awardee's VFC program to determine how to deal with these issues.
References	DINV2016 - BR205. Do not automatically decrement if vaccination event date is earlier or equal to the most recent closed reconciliation date. DINV2016 - BR303. Reopen reconciliation that is closed. Step 2.11 and Step 3.3. Scenarios S1203, S1204, and S1301. INV2012 - BR717 Submit data to IIS before reconciling inventory

DINV2016 - BR303 - Reopen reconciliation that is closed	
Rule Statement	Once reconciliation is closed, it may be reopened only by IIS staff with elevated privileges (admin).
Remarks	• Reopening of a closed reconciliation should be done manually (not through the EDE). • If reconciliation is reopened after being closed, an issue should be logged for manual intervention. • This business rule is an exception to DINV - BR302 Freeze reconciliation results.
References	DINV2016 - BR205 Do not automatically decrement if vaccination event date is earlier or equal to the most recent closed reconciliation date. Step 3.3 Scenarios S1203, S1204, and S1301.

DINV2016 - BR401 - Establish and maintain a preapproval process for provider organizations

Rule Statement	IIS should establish and maintain a preapproval process for provider organizations that intend to submit vaccination event information electronically to IIS.
References	DINV2016 - P03 The IIS must preapprove a provider organization for DI-v-EDE. DINV2016 - BR402 Establish a testing environment for the preapproval process. DINV2016 - BR403 Establish a preapproval testing process. DINV2016 - BR407 Examine all data elements of a DI-v-EDE submission during preapproval. Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. Scenario S301

DINV2016 - BR402 - Establish a testing environment for the preapproval process	
Rule Statement	IIS should establish a testing environment (technical and operational components) to support the preapproval process for provider organizations.
Remarks	The testing environment should have a copy of production data, including active lot numbers, so provider organizations can simulate real-case scenarios of administering a vaccine and having that vaccination event submitted to the IIS and, in turn, decremented appropriately.
References	Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance. DINV2016 - P03. The IIS must preapprove a provider organization for DI-v-EDE. DINV2016 - BR401. Establish and maintain a preapproval process for provider organizations. DINV2016 - BR403. Establish a preapproval testing process. • DINV2016 - BR407. Examine all data elements of a DI-v-EDE submission during preapproval. Scenario S301.

DINV2016 - BR403 - Establish a preapproval testing process	
Rule Statement	IIS should establish a preapproval testing process, which includes testing individually with EHR vendor test data and provider organization data.
References	Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance.

	DINV2016 - P03. The IIS must preapprove a provider organization for DI-v-EDE. DINV2016 - BR401. Establish and maintain a preapproval process for provider organizations. DINV2016 - BR402. Establish a testing environment for the pre-approval process. DINV2016 - BR407. Examine all data elements of a DI-v-EDE submission during pre-approval. Scenario S301

DINV2016 - BR404 - Develop educational/training offerings	
Rule Statement	IIS should develop educational/training offerings to support DI-v-EDE process for participating provider organizations.
Remarks	Materials should include troubleshooting information and what to do when DI-v-EDE issues are identified. IIS should consider providing ongoing user training via video format (prerecorded or live webinar style) to accommodate learning styles and to build community partnerships.
References	DINV2016 - P05. DI-v-EDE should minimize the burden on provider organizations. Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance.

DINV2016 - BR405 - Document requirements and instructions for using the DI-v-EDE IIS functionality	
Rule Statement	IIS should document requirements and instructions for using the DI-v-EDE IIS functionality for provider organizations and EHR vendors.
References	DINV2016 - P05. DI-v-EDE should minimize the burden on provider organizations. Preapproval and monitoring process in Chapter 7: Preapproval and Maintenance.

DINV2016 - BR406 - Manage deletion of a patient's record from IIS	
Rule Statement	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.

Remarks	• Deletion both applies to electronic deletions and via direct UI. • IIS needs to retain linkage between dose administered and decremented inventory. • State laws vary with respect to treatment of patient data (i.e., adoptions, opt-out, etc.). Some require deletion of the record, and some allow the retention of that record.
References	DINV2016 - BR408. Manage deletion of a vaccination event from IIS. Scenarios S1201, S1202, and S1203.

DINV2016 - BR407 - Examine all data elements for a DI-v-EDE submission during preapproval	
Rule Statement	During the preapproval process, the IIS should examine all data elements of a DI-v-EDE submission for accuracy and consistency.
References	DINV2016 - P03. The IIS must preapprove a provider organization for DI-v-EDE. DINV2016 - BR202. Submit information to IIS to support DI-v-EDE. DINV2016 - BR401. Establish and maintain a preapproval process for provider organizations. DINV2016 - BR402. Establish a testing environment for the preapproval process. DINV2016 - BR403. Establish a preapproval testing process. Scenarios S201 and S301.

DINV2016 - BR408 - Manage deletion of a vaccination event from IIS	
Rule Statement	If a vaccination event is deleted from IIS, associated inventory item should be incremented.
Remarks	Balance of a lot number inventory should be incremented by one when a vaccination event associated with that lot number inventory is deleted.
References	DINV2016 - BR406. Manage deletion of a patient's record from IIS. Scenarios S1201, S1202, and S1203.

DINV2016 - BR409 - Manual corrections made in the IIS should also be made in the EHR	
Rule Statement	A provider organization should correct the data in the EHR to match any manual changes made in the IIS.
References	Data Quality section in Chapter 9: Implementation Considerations.

DINV2016 - P01 - DI-v-EDE should support the awardee program policies	
Rule Statement	DI-v-EDE should support the policies of the awardee immunization program.
References	VFC program resources [2.6, 2.7]. INV2012 - GR701 IIS inventory management functionality should reflect policies and practices of a Grantee Vaccine Program in the MIROW 2012 Inventory Management Guidelines.

DINV2016 - P02 - DI-v-EDE should support inventory tracking and immunization tracking	
Rule Statement	DI-v-EDE should support both inventory tracking and immunization tracking.
Remarks	• Inventory tracking means following a dose of vaccine from order fulfillment at the provider's office to administration to a patient or other disposition (e.g., expired, wasted). • Immunization tracking means following a dose of vaccine from the vaccination event through entering information about that event in the IIS. • A submission from the provider organization to the IIS contains information for both inventory tracking and immunization tracking areas of IIS operations. Development of best practices for DI-v-EDE should take into account the dual use of vaccination event submissions.
References	DINV2016 - BR206. Update patient record regardless of inventory-related issues. Step 2.9 Scenarios S501, S502, S503, S701, S704, S901, S902, S1001, S1201, S1202, S1203, S1204.

DINV2016 - P03 - The IIS must preapprove a provider organization for DI-v-EDE	
Rule Statement	A provider organization may participate in the DI-v-EDE process only if the IIS has preapproved the provider organization.

Remarks	• A preapproval process should be initiated when:
	  ○ A provider organization enrolls in DI-v-EDE process.
	  ○ The EHR of a previously approved provider organization changes in a manner that affects the DI-v-EDE process (e.g., changes in the data scheme for storage and retrieval of immunization data).

	• The IIS should indicate that a provider organization is preapproved for DI-v-EDE at the end of a successful preapproval process. • If a provider organization is not approved, IIS staff should work with the provider organization to resolve issues that prevented its approval.
References	Chapter 7: Preapproval and Maintenance. DINV2016 - BR401. Establish and maintain a preapproval process for provider organizations. DINV2016 - BR402. Establish a testing environment for the preapproval process. DINV2016 - BR403. Establish a preapproval testing process. DINV2016 - BR407. Examine all data elements of a DI-v-EDE submission during preapproval. Scenario S301.

DINV2016 - P04 - Inventory information in the IIS should map to the storage model used by the provider organization	
Rule Statement	Categorization of information about a provider organization's inventory in the IIS should map to the vaccine storage model used by the provider organization.
Remarks	A single awardee immunization program may have multiple vaccine storage policies, i.e., some provider organizations may have replacement storage, while others have two, three, or multi-stock storage. In theory, an IIS can categorize inventory information in the IIS at a more specific level (fund type) than the storage model used by a provider organization.
References	Vaccine storage models section in this chapter. DINV2016 - BR101. Organize inventory information in the IIS by the lot number, lot number expiration date, and lot-level public/private indicator. Step 1.3, Step 1.7

DINV2016 - P05 - DI-v-EDE should minimize the burden on provider organizations	
Rule Statement	The DI-v-EDE process should minimize the burden on provider organizations to the extent possible.
Remarks	• The DI-v-EDE process should minimize manual interventions by provider organizations at all stages of decrementing inventory from initial population of data elements to correction of errors and reconciliation.

	• There is a trade-off between minimizing manual interventions and the amount of information recorded and submitted by provider organizations to the IIS.
References	INV2012 - GR710 Minimize manual inventory data entry in the MIROW 2012 Inventory Management Guidelines [1.3, p.56]. Chapter 9: Implementation Considerations. DINV2016 - P08. IIS should assist provider organizations with correcting data quality issues. DINV2016 - BR102. Prepopulate provider organization's inventory in the IIS. DINV2016 - BR103. Download shipment information daily. DINV2016 - BR404. Develop educational/training opportunities. DINV2016 - BR405. Document requirements and instructions for using the DI-v-EDE IIS functionality. Steps 1.2, 1.3, 2.5, 3.1, and 3.2

DINV2016 - P06 - DI-v-EDE should support dose-level accountability	
Rule Statement	DI-v-EDE process should support dose-level accountability for vaccines.
References	INV2012 - GR702 IIS inventory management functionality should support accountability at the dose/lot number level. INV2012 - P702 Dose-lot number accountability in the MIROW 2012 Inventory Management Guidelines AIRA White Paper regarding Dose-level Eligibility [3.1]. DINV2016 - BR101. Organize inventory information in the IIS by the lot number, lot number expiration date, and lot-level public/private indicator. DINV2016 - BR202. Submit information to the IIS to support DI-v-EDE. Step 2.2, Step 2.12.

DINV2016 - P07 - IIS should notify provider organizations of problems in DI-v-EDE process	
Rule Statement	IIS should notify provider organizations of problems in DI-v-EDE process.

Remarks	• One or more methods can be used to notify provider organizations of errors and other issues:
	  ○ Reports (Chapter 6: Reports)
	  ○ Direct UI
	  ○ HL7 Acknowledgement (ACK) message sent to EHR
	  ○ Other mechanism(s)

	• Different types of problems/issues may require different communication methods. • In the example of the ACK message sent to an EHR, some EHR vendors do not give provider organizations access to the ACK messages, so there may be an issue with using only ACK messages as a way to relay problems with DI-v-EDE (see HL7 immunization messaging in Chapter 9: Implementation Considerations). • The awardee immunization program should review the IIS reports to identify provider organization issues.
References	Alternative paths for Step 2.8, Step 2.9, Step 2.10, Step 2.11, and Step 2.12. Step 3.1 Scenarios S401, S402, S403, S501, S502, S503, S701, S702, S703, S704, S801, S901, and S1001.

DINV2016 - P08 - IIS should assist provider organizations with correcting data quality issues	
Rule Statement	IIS should assist provider organizations with correcting data quality issues that affect DI-v-EDE.

Remarks	• IIS should provide reports and direct UI to assist provider organizations in reconciling inventory to address data quality issues.
	• IIS should support the following:
	  ○ Preapproval process
	  ○ Educational activities,
	  ○ Inventory reconciliation.

References	DINV2016 - P05. DI-v-EDE should minimize the burden on provider organizations. Alternative paths for Step 2.8, Step 2.9, Step 2.10, Step 2.11, and Step 2.12. DINV2016 - BR301. Resolve data quality issues before reconciling. Step 3.2 Scenarios S401, S402, S403, S501, S502, S503, S702, S703, S901, and S1001.

DINV2016 - P09 - The IIS should decrement an administered dose only once	
Rule Statement	Every administered dose should be decremented from a provider organization's inventory only once.
Remarks	Since a vaccination event record can be sent to an IIS multiple times over the lifespan of the patient, it is important that the IIS ensures the administered dose is only decremented one time from inventory, rather than every time it is sent to the IIS.

References	Step 2.12 Scenario S1101.

DLE2011 - BR601 - Age Criteria	
Rule Statement	The Patient has to fit the age criteria of the Vaccine Program.
Remarks	E.g., for the VFC Program a Patient has to be less than 19 years old

DLE2011 - BR602 - What information is needed for Patient's eligibility screening	

Rule Statement	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.

Remarks	• Screening for the Vaccination Event means screening for a specific Vaccine - this is what changes compare to screening for the Vaccination Encounter ○ Vaccination Encounter (visit) may include many Vaccination Events; see Appendix A for definitions. • Facility Type indicates the level of services covered by the VFC Program. Accordingly, for the purposes of screening for and documenting eligibilities, the type of Provider Organization should be recorded at the specific site/facility. See Appendix A, Table 6-A1, VFC Enrollment and Provider Organization entities: some IIS set up a Provider Organization for every site/facility; for the purposes of this project a site/facility has the same definition as a Provider Organization.
References	See Appendix A, pp. 65, 74-75 for definitions of Patient Full and Conditional VFC Program eligibility.

DLE2011 - BR603 - How often to screen	
Rule Statement	• 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).

Remarks	• See BR613 for a guideline on how often to report Patient's eligibility - once per Vaccination Event (dose administered).
	• According to VFC guidelines, screening must be done once per Vaccination Encounter.
	• Conditional VFC Program eligibility – Patient is eligible for a specific Vaccine (applicable for Underinsured category).
	  ○ See Appendix A, pp. 65, 74-75 for definitions of Patient Full and Conditional VFC Program eligibility.
	• Dual coverage – Patient has private insurance which covers the Vaccine and also has either Medicaid or is AI/AN.
	  ○ In the dual-coverage situation, see BR604 and BR609 for a decision-making logic on whether to use public Vaccine or private Vaccine
	  ○ Example. A Patient could be VFC eligible for the ACIP recommended Vaccine, but VFC ineligible for the travel Vaccine (e.g. typhoid). However, the Patient may be eligible for the travel Vaccine via a Grantee Vaccine Program.
	• Screening data must be documented every time the screening process is conducted.
	• The screening documentation may be outside of the IIS.
	• The VFC requirement is that all children must be screened.
	• According to VFC guidelines, initial screening must be documented and as long as the Patient's eligibility status doesn't change, verbal screening at subsequent encounters is sufficient.
	• Record has to reflect screening for the date of vaccination.
	• Patient's VFC eligibility should always be documented, even if the Grantee Vaccine Program eligibility will apply instead (i.e., VFC-ineligible).

	• In states with a universal purchase policy, screening for VFC eligibility is still required, so that Grantee can determine which Patients were not VFC-eligible. This allows the Grantee Vaccine Program to use aggregated eligibility data to reconcile balance sheets for funding sources.
References	DLE2011 - BR613: How often to report Patient's eligibility

DLE2011 - BR604 - Patient Eligibility screening sequence	
Rule Statement	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.
Remarks	• There is a common practice among many private Providers (who can't administer a Vaccine to underinsured children and who see primarily privately insured Patients) to screen for private insurance coverage, and, if Patient has private insurance, record Patient as VFC Ineligible, and not conduct a further VFC screening for Medicaid and AI/AN. While this is an acceptable practice, the best practice would be to screen Patient for both – private insurance coverage and VFC eligibility – and then, in dual-coverage situations, select (under certain guidelines) what coverage/eligibility to use. See Appendix B for a detailed discussion of a screening sequence described in this business rule BR604. • For a given Vaccination Encounter, if a Patient has been found to be "fully" eligible for all VFC Program Vaccines (by virtue of having Medicaid, being AI/AN or being totally uninsured), then there is no need to rescreen the Patient for each Vaccine needed. • However, Patients with private insurance need an additional screening for each Vaccine to determine if the Patient's private insurance covers the Vaccine. • Some Provider Organizations add VFC eligibility screening to the insurance screening workflow, which is conducted before the Patient is seen. When a Patient's insurance status changes, so does the VFC eligibility status. The Provider still gets to choose what the Patient's VFC eligibility is at the dose administered level, but the value is defaulted to whatever value they chose during the insurance screening stage. • Screening for Grantee Program eligibility is necessary only when Patient is not eligible for the VFC Program and Vaccine is not covered by the Patient's insurance.

	• For private Provider Organizations that are not enrolled in VFC Program the screening sequence includes screening for a private coverage and for Grantee Program eligibility.

DLE2011 - BR605 - Underinsured vs. Medicaid and Provider Organization type	
Rule Statement	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.
Remarks	• FQHC and RHC Provider Organizations can delegate authority to non-FQHC and non-RHC Provider Organizations. • Delegation of authority is a contractual agreement defined by the FQHC/RHC and the Grantee. • Also, the Patient cannot be classified as Uninsured if he/she has Medicaid (see BR606). • Underinsured does not include the Patient being unable to pay the co-pay or deductible.
References	DLE2011 - BR606: Uninsured vs. Medicaid

DLE2011 - BR606 - Uninsured vs. Medicaid	
Rule Statement	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.
Remarks	• Private insurance is any insurance other than Medicaid. ○ Some state insurance plans (e.g., Child Health Plan and Child Health Plan Plus) are expansions of Medicaid and some (e.g., in Michigan) are considered private. • Medicaid is the payer of last resort. Medicaid is always secondary insurance to private insurance.

DLE2011 - BR607 - Hierarchy of choices for Patient's eligibility/coverage

Rule Statement	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.
Remarks	• If a Patient has a private insurance and Medicaid (dual-coverage), the Patient can receive either VFC Vaccine or private insurance Vaccine at the Providers/Patients discretion. If the child receives VFC Vaccine, the Provider Organization bills Medicaid for the regional administration fee, Medicaid pays the fee to the Provider Organization and then bills the private insurance company to recoup the fee to the extent that is financially feasible for the Medicaid agency to do so. • When a Patient is eligible for publicly-purchased Vaccines (VFC or/and Grantee Program) and has private insurance coverage for immunizations (i.e., a dual-coverage situation), the Provider Organization should also take under consideration which option results in the least out of pocket costs for the Patient (i.e., use of public or private Vaccine) o Dual-coverage: VFC eligible (Medicaid and/or AI/AN) and Private insurance >> the selection should be made by a Provider based on the best financial interest of a Patient. • Use of the private insurance coverage leaves more public funds available for Patients without private insurance. • There is no reason to use state funds instead of VFC funds. o State funds are limited and should be used sparingly, with the focus on Patients who are not eligible for other vaccination choices. • There are certain types of state defined incidents (e.g. pandemics) in which this does not apply. In a public health emergency eligibilities might not be assessed.
References	DLE2011 - BR604: Patient Eligibility screening sequence

DLE2011 - BR608 - Single eligibility/coverage status	
Rule Statement	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).
Remarks	There is no need to differentiate between Private insurance coverage and Out-of-pocket pay: it is sufficient for IIS/Vaccine Program to know that Patient was vaccinated from the Provider Organization's privately purchased Vaccine inventory (i.e., VFC ineligible). For VFC Program eligible and Grantee Program eligible Patients Vaccine should be administered from the publicly-purchased inventory. For Patients with Private Coverage Vaccine should be administered from the privately-purchased inventory. See Fig. 4 - Simplified process diagram.
References	DLE2011 - BR613: How often to report Patient's eligibility

DLE2011 - BR609 - How to deal with dual-coverage	
Rule Statement	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.
Remarks	This describes the scenarios 5, 13 and 6, 14 in the decision table 2 and scenarios 12, 13 in the decision table 11-B4. VFC recommendation: Medicaid is the payer of last resort. Medicaid should always be a secondary insurance to private insurance.

DLE2011 - BR610 - Private insurance - dealing with unknown	
Rule Statement	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.
Remarks	• Private insurance coverage/cap in many cases is not known to the Provider Organization until after a submission to the private insurance.

	The Provider Organization does not know if private insurance actually pays for a Vaccine until months after the administration of the Vaccine. • Vaccine borrowing - VFC Operations manual (See [2.8] VFC: Frequently Asked Questions): If the primary insurance is billed first and the insurance denies the claim, the Provider could replace the private stock Vaccine used with VFC Vaccine and then bill the maximum regional charge for the Vaccine administration fee to Medicaid. The Medicaid agency should bypass their cost avoidance edit allowing the claim to be considered for payment. ○ See also general recommendation GR608 for a discussion of borrowing. • The Provider Organization must not change information about which specific Vaccine (lot #) was given. • It is a challenge to get a Provider Organization to go back into Patient's record and IIS to change Patient VFC eligibility status. • When Provider Organization is not FQHC, RHC, or an entity with Delegated Authority, and the Provider Organization learns later that the Patient is underinsured (i.e. claim rejected two months later), the Provider Organization should not change the information in IIS because the VFC Vaccine cannot be used in any case (see SC2 in the partitioned Decision Table 11-B4).

DLE2011 - BR611 - What format to use	
Rule Statement	Screening data should be documented/ recorded electronically.
Remarks	• VFC guidelines do not require a specific form. • This applies to all screening not only the initial screening. • There is no requirement for Patient signature for VFC screening. • Provider does not need to keep physical copy of the form for audits (just some evidence of eligibility screening actually needed). According to VFC guidelines, initial screening must be documented and as long as the Patient's eligibility status doesn't change, verbal screening at subsequent encounters is sufficient.

DLE2011 - BR612 - When to record	
Rule Statement	Record Vaccination Event after the Vaccine has been administered.
Remarks	• Document the Vaccination Event only after the vaccination has been administered, so that the data reflects what actually happened (e.g., Vaccine could be declined by the Patient/parent).

	• IIS could have functionality in place to allow Provider Organization to verify that Vaccine (dose) about to be given is correct, augmenting the post-administration validation functionality.

DLE2011 - BR613 - How often to report Patient's eligibility	
Rule Statement	Provider Organization should report Patient's eligibility to IIS for every Vaccination Event (dose administered).

Remarks	• On the same date (encounter), Patient can be eligible for one VFC Vaccine and not eligible for another VFC Vaccine. Associating Patient Eligibility with the Vaccination Event (dose administered) provides the most complete and detailed information.
	  ○ Scenario: Patient is underinsured. Insurance covers one Vaccine, but does not cover another Vaccine.
	  ○ Scenario: Patient has dual-coverage, e.g., Medicaid and private health insurance. Provider chooses to administer one Vaccine based on the Patient's eligibility to Medicaid and another Vaccine – based on the private coverage.
	  ○ Scenario: Patient is VFC eligible for one Vaccine and Grantee eligible for another Vaccine (e.g., for non-VFC Vaccine)
	• Situations when Patient is VFC eligible for one Vaccine and has insurance coverage for another Vaccine on the same visit (e.g., insured for one Vaccine and underinsured for another Vaccine) often happen due to delays with outcomes of the insurance claims. This provides for situations when Patient who initially was perceived as having private insurance coverage for a Vaccine, actually does not have the coverage.
	• See BR616 for guidance on how to assign Patient Eligibility for a Vaccination Encounter when the Patient meets various eligibility criteria for Vaccines administered during the encounter, i.e. different eligibility status for Vaccination Events occurring during one Vaccination Encounter (visit).

References	DLE2011 - BR616: How to count VFC eligible Patients for the Vaccination Encounter (visit)

DLE2011 - BR614 - What information to report (minimum set)	
Rule Statement	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.

Remarks	• All data items/elements from this list could be implemented as a drop-down list that allows selection of a single item or a set of radio-buttons, where only one radio-button can be selected at a time.
	• VFC Eligibility Status can be derived on the IIS side based on the reported data item/element, e.g., if AI/AN reported, then Patient would be considered VFC eligible, and if Private coverage is reported, then Patient will be considered VFC ineligible.
	• When a Patient meets more than one eligibility criteria, the hierarchy of eligibility categories is:
	  ○ Medicaid
	  ○ AI/AN
	  ○ Uninsured
	  ○ Underinsured
	• Example: A Patient is AI/AN, does not have Medicaid, does not have private health insurance. Then the Patient's eligibility should be reported as AI/AN (AI/AN is higher in the hierarchy than Uninsured)
	• Sole private insurance coverage is reported as Patient being VFC ineligible. It is not necessary to differentiate between private insurance coverage and out-of-pocket payment. It is only necessary to know that Vaccine is not coming from the publicly-purchased Vaccine inventory.
	• Bottom-line answer (e.g. eligibility status) must be documented, not all the answers that led to the final choice of eligibility.

References	Appendix C: HL7 considerations.

DLE2011 - BR615 - What information to report (expanded set – best practice)	
Rule Statement	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.

Remarks	• Data items/elements from the bulleted list are NOT mutually exclusive. For example, both Medicaid and AI/AN can be reported. Implementation could include a set of check boxes to allow simultaneous selection of multiple items. Example: Patient is AI/AN, does not have Medicaid, does not have private health insurance. Then the Patient's eligibility should be reported as AI/AN and Uninsured. • Not all combinations of data items/elements are valid and should be allowed, e.g., Patient can't be reported as Medicaid and Uninsured (see BR606). The following lists of valid and invalid combinations are based on the work group's recommendation that Patient's eligibility/coverage status should be deduced from the reported data items/elements. Note that the interpretation of the recorded/reported combinations of eligibility data items is based on the scenarios' logic presented in the decision table 2. o Valid combinations to report include the following: ▪ Medicaid and AI/AN (should be interpreted as VFC eligible) ▪ AI/AN and Uninsured (should be interpreted as VFC eligible) ▪ AI/AN and Underinsured (should be interpreted as VFC eligible) ▪ Private coverage (or VFC Ineligible) and any VFC-related data items, such as Medicaid, AI/AN, Uninsured, Underinsured. Private Coverage takes precedence and should be interpreted as Private Coverage (or VFC Ineligible); in this case the Private insurance coverage has been selected for a Patient who is also VFC-eligible: see Table 2, scenarios 6 and 14. ▪ Private coverage (or VFC Ineligible) and Grantee eligible – Grantee eligibility takes precedence and reporting should be interpreted as Grantee eligible (in this case it actually means that the Patient is VFC Ineligible and Grantee eligible, see Table 2, scenarios 20, 23, and 25) o Invalid combinations to report include the following: ▪ Medicaid and Uninsured (see BR606) ▪ Medicaid and Underinsured (see BR605) ▪ Uninsured and Underinsured ▪ Grantee eligible and any VFC-related data item, such as Medicaid, AI/AN, Uninsured, Underinsured • Any combination of three data items of different types: 1)VFC-related data item, such as Medicaid, AI/AN, Uninsured, Underinsured, and 2) Private coverage (or VFC Ineligible) and 3) Grantee eligible

	• Reporting of other items, e.g. VFC eligibility reasons and VFC ineligibility reasons should be left for every Grantee to decide. The work group decided not to include VFC eligibility/ineligibility reasons into best practices (benefits of including these data items were not apparent). Eligibility/Ineligibility reasons include (see partitioned decision tables in the appendix B and Fig. 10-B3).
	• Eligibility Reason (relevant for Underinsured Patients)
	  ○ Insurance Vaccine cap reached
	  ○ Insurance does not cover Vaccine (a specific Vaccine or any Vaccine)
	• Ineligibility Reason
	  ○ Not at appropriate type of Provider Organization (Underinsured, not at FQHC/RHC or Delegated Authority Provider Organization)
	  ○ Vaccine covered by private insurance (sole coverage)
	  ○ Choose to use private insurance (dual coverage)
	• In dual-coverage situations, when private coverage is selected, it is not necessary to report Patient's Medicaid and AI/AN (VFC Eligibility criteria). It is not required by the VFC Program. However, reporting of this additional information can be useful for statistical purposes of the Grantee Programs

DLE2011 - BR616 - How to count VFC eligible Patients for the Vaccination Encounter (visit)	
Rule Statement	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.
Remarks	• This business rule is applicable to establish a Patient's eligibility for a year for purposes of the Provider Profile report – see BR617 and Chapter 5. • Situations when Patient is VFC eligible for one Vaccine and has insurance coverage for another Vaccine on the same visit (e.g., insured for one Vaccine and underinsured for another Vaccine) often happen due to delays with outcomes of the insurance claims (this could also represent a real difference between Vaccine types, i.e., Vaccine eligibilities for different programs). This may result in situations in which a child who initially was perceived as having private insurance coverage for a Vaccine, actually does not have the coverage. See BR610.

	• Requirements for the Provider Organization Profile report could be changed in the future and that would require the appropriate modification of the business rule.
References	DLE2011 - BR610: Private insurance - dealing with unknown DLE2011 - BR617: How to count VFC eligible Patients for a year

DLE2011 - BR617 - How to count VFC eligible Patients for a year	
Rule Statement	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.
Remarks	See Chapter 5 for a description of the Provider Organization Profile Report.

DQA2013 - BR818 - Org B is a part of Org A, is acquired intact by Org C	
Rule Statement	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.
Remarks	(See guide for supporting diagram) Consideration needs to be given to impact on master/patient index, as well as to other concerns (e.g., patient's consent to share, primary care physician, reminder/recall, Medical Record Number)
References	DQA2013 - P801 Consistency PM 1.0 - IIS: Set Up IIS-AO PM 11.0 - IIS: Update Organization's Details PM 12.0 - IIS: De-authorize IIS-AO

DQA2013 - BR819 - Stand-alone Org A is acquired as an intact sub-unit by another Org	
Rule Statement	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.
Remarks	(See guide for supporting diagram) Consideration needs to be given to the nature of the structural change and applicable jurisdictional rules, etc., to ensure integrity of patient's association with the appropriate IIS-AO.
References	DQA2013 - P801 Consistency PM 1.0 - IIS: Set Up IIS-AO PM 11.0 - IIS: Update Organization's Details PM 12.0 - IIS: De-authorize IIS-AO

DQA2013 - BR820 - Org A and Org B merge to form one new organization	
Rule Statement	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.
Remarks	(See guide for supporting diagram)
References	PM 1.0 - IIS: Set Up IIS-AO PM 11.0 - IIS: Update Organization's Details PM 12.0 - IIS: De-authorize IIS-AO

DQA2013 - BR821 - Org B is part of Org A, becomes new stand-alone entity	
Rule Statement	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.
Remarks	(See guide for supporting diagram) Note: Option 2 will maintain association of IIS data with original IIS-AO. Option 1 may not.
References	DQA2013 - P801 Consistency PM 1.0 - IIS: Set Up IIS-AO

	PM 11.0 - IIS: Update Organization's Details PM 12.0 - IIS: De-authorize IIS-AO

DQA2013 - BR822 - Portion of Org A is acquired by and becomes a sub-unit of another Org	
Rule Statement	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).
Remarks	(See guide for supporting diagram) • Note: This is not the same as Providers (i.e., persons) from one organization leaving one IIS-AO and joining another IIS-AO (no changes to be made in this case). • In this scenario, Providers will no longer be associated with data related to the original IIS-AO.
References	PM 1.0 - IIS: Set Up IIS-AO PM 11.0 - IIS: Update Organization's Details

DQA2013 - BR823 - Org A and Org B, containing sub-org units, merge to form one new organization	
Rule Statement	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.
Remarks	(See guide for supporting diagram) In the above illustration, Org A.1 through Org A.x and Org B.1 through Org B.y would each need to be evaluated separately to determine how to proceed. For example, if Org A.1 is being dissolved, then BR824 should be followed for Org A.1 only. The remaining Org A.2 through Org A.x still need to be evaluated to determine the appropriate action.
References	DQA2013 - BR818 Org B is a part of Org A, is acquired intact by Org C DQA2013 - BR819 Stand-alone Org A is acquired as an intact sub-unit by another Org DQA2013 - BR820 Org A and Org B merge to form one new organization DQA2013 - BR821 Org B is part of Org A, becomes new stand-alone entity DQA2013 - BR822 Portion of Org A is acquired by and becomes a sub-unit of another Org DQA2013 - BR824 De-authorize IIS-AO if it dissolves

DQA2022 - BR001 - Minimum/mandatory data elements				
Rule Statement	The data elements that should be present in each type of submission.			
	Submission			
	Demographic-Only	Administered Vaccination Event + Demographic	Historical Vaccination Event + Demographic	Demographic from Vital Records
Vaccinating Organization		x		
Recording Organization			x	
Submitting Organization	x	x	x	x
Patient First Name	x	x	x	x
Patient Last Name	x	x	x	x
Date of Birth	x	x	x	x
Birth Certificate Number				x
Birth Facility				x
Patient Gender				x
Vaccination Event Date		x	x	
Vaccine Type		x	x	
Administered/ Historical Indicator		Administered	Historical	

DQA2022 - BR101 – Authorized provider organization	
Rule Statement	An IIS program should only accept submissions from authorized provider organizations.
Remarks	Ensuring that all submissions come from provider organizations that have completed enrollment helps set expectations of IIS-AOs prior to the submittal of data. IIS-AOs also go through the onboarding process which assesses whether:

	• The EHR can capture and submit the appropriate information to the IIS • Each IIS-AO using the system is entering the appropriate content.

DQA2022 - BR102 - Establish provider organization profile	
Rule Statement	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.
Remarks	• Baseline data can be captured when an IIS-AO is initially enrolled with the IIS program and should be periodically updated. Not all information will or needs to be available when the profile is established. • The baseline data should be re-established when an IIS-AO is transitioning from one submission method to another or the IIS-AO has a change in its patient population or EHR vendor. • For VFC provider, data could be captured from the provider profile developed during VFC certification process and updated during the annual VFC re-certification process.

DQA2022 - BR103 - Establish signed agreements	
Rule Statement	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.
Remarks	• Possible submission chains (routes) should be determined when the IIS program is onboarding the IIS-AO.

	• Agreements should be established between all parties in the submission chain. • A specific point of contact (e.g., an IIS-AO staff person) at each organization should be included in the agreement. • Re-examine the signed agreements as needed when submission method changes. • An IIS program should establish a method of organizing the signed agreements so they can track if and when an agreement needs to be signed again.

DQA2022 - BR104 - Signed security and confidentiality agreement	
Rule Statement	An IIS program should require a provider organization to sign a security and confidentiality agreement prior to being authorized.
Remarks	• A security and confidentiality agreement describes the security and confidentiality policies of the IIS and other applicable federal, state, local, and territorial laws. • Exact agreements vary by jurisdiction. • An IIS program should establish a method of organizing the signed agreements so they can track if and when an agreement needs to be signed again.

DQA2022 - BR105 - IIS-AO approved for EDE	
Rule Statement	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	
Rule Statement	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.
Remarks	If the vaccination event is reported after this time frame, it should remain as "administered". Resubmission may fall outside the 24 hour window.

DQA2022 - BR107 - Vaccination event submission of hepatitis B birth dose	
Rule Statement	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.

Remarks	The rule is specific to Vital Records, which has a different process that takes more time (thus more time is allowed). For any other IIS-AO (e.g., a birth hospital), an administered vaccination should be reported within one day. If Vital Records feed is not reported within the agreed upon time frame, follow up with Vital Records.

DQA2022 - BR108 - Vaccination event submission action code	
Rule Statement	An IIS should record and implement the action code submitted for every vaccination event submission.
Remarks	• This rule applies for data submitted via electronic data exchange. • At a minimum, action codes of "A" for add and "D" for delete should be supported by an IIS. • More information is provided in Action Codes (RXA-21) in Chapter 9.

DQA2022 - BR109 - Standard value tables	
Rule Statement	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.
Example	Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS) IIS Health Level 7 (HL7) Implementation

DQA2022 - BR110 - Valid calendar dates in a submission	
Rule Statement	A date in a submission should be a valid calendar date.
Remarks	• For example: patient date of birth, vaccination event date. • Only complete dates are the best practice, but if the day is not available, then the 15th of the month can be submitted. Patient date of birth has a separate default business rule (DQA2022 - BR152).

DQA2022 - BR111 - Vaccination event date not before patient's date of birth	
Rule Statement	A vaccination event date should not be before (less than) the patient's date of birth.

DQA2022 - BR112 - Submission not before date of birth	
Rule Statement	A submission should not be submitted before (less than) the patient's date of birth.

DQA2022 - BR113 - Submission not before vaccination event	
Rule Statement	A submission should not be submitted before (less than) the vaccination event.

DQA2022 - BR114 - Vaccination event date not after patient's date of death	
Rule Statement	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	
Rule Statement	A vaccination event record should not have a vaccination event date that is after (greater than) the lot number expiration date.
Remarks	An IIS should accept submissions that may reflect possible administration errors.

DQA2022 - BR116 - Vaccination event date for birth vaccine types	
Rule Statement	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.
Remarks	It is possible for vaccines that are not recommended at birth to be given to a patient at birth and these should be recorded in the IIS.
Example	Hepatitis B

DQA2022 - BR117 - Vaccine type CVX	
Rule Statement	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.
Remarks	This rule is addressing the desire to have CVX code for vaccine type instead of Current Procedural Terminology (CPT) codes. Billing systems are

	consistent in using CVX, however pharmacies and others tend to send CPT.

DQA2022 - BR118 - Specified formulation for administered	
Rule Statement	The vaccine type in a vaccination event record should be a specified formulation if it is included in an administered vaccination event submission.
Remarks	• The vaccine type in an administered vaccination event submission should not be an unspecified formulation. • "Unspecified formulation" is a CVX code that allows reporting of a vaccination when vaccine formulation is unknown. Further information is found in the CDC code set tables. https://www.cdc.gov/vaccines/programs/iss/code-sets.html
Example	CVX45 = hepatitis B vaccine, unspecified formulation

DQA2022 - BR120 - Combination vaccine reported as single vaccination event	
Rule Statement	An IIS program should educate IIS-AO staff to report a combination vaccine dose as a single vaccination event rather than multiple vaccination events.
Remarks	• CDC's Updated Guidance for Documenting Vaccine National Drug Codes (NDCs) and Lot Numbers in IISs and EHRs provides additional input on this topic. • Example: If a patient is given MMRV, it should be reported as a dose of MMRV vaccine rather than a dose of MMR vaccine and a dose of varicella vaccine. • Further information can be found at https://www.cdc.gov/vaccines/programs/iis/2d-barcodes/downloads/guidance-documenting-ndc.pdf

DQA2022 - BR121 - Vaccine type available in United States	
Rule Statement	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

Rule Statement	A vaccination event record should include a vaccine that is classified by a vaccine product type (NDC).

DQA2022 - BR124 - Vaccine product type manufacturer	
Rule Statement	A vaccination event submission should not include a manufacturer that does not produce the vaccine product type.
Remarks	It is possible for older vaccination events to have a vaccine type or vaccine product type attributed to a manufacturer (MVX) which no longer makes that vaccine type or vaccine product type.

DQA2022 - BR125 - Patient age within recommended range	
Rule Statement	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	
Rule Statement	The vaccine product type, vaccine type, and manufacturer of a vaccine should be consistent with one another.

DQA2022 - BR127 - Vaccination event dosage	
Rule Statement	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).
Remarks	If the value is zero (represented by 999 in HL7), the presumption is that field is not filled.

DQA2022 - BR128 - Approved vaccine administration method	
Rule Statement	A vaccine route of administration, vaccine site of administration, and vaccination event dosage should be consistent with the vaccine product type and patient age.
Remarks	The route, site and dosage should match to the CDC's approved usage list. Examples of incorrect combinations: • Hep B site reported as subcutaneous rather than intramuscular.

	• Vaccine is Rotavirus, Route is PO (oral) and site is Left Deltoid.
Example	Vaccine is Rotavirus Route is PO (oral) and site is Left Deltoid

DQA2022 - BR129 - Lot number validation	
Rule Statement	A lot number in a vaccination event record should include only the following types of characters: • Alphabetic • Numeric • Dash (-).
Remarks	IIS programs should educate IIS-AOs that a "-" is the only type of special character that a lot number can contain. Spaces around the dash are not allowed.

DQA2022 - BR130 - Number contains information for only one lot number	
Rule Statement	Lot number in a vaccination event record should contain a single lot number and no other additional information.
Remarks	A helpful pattern to recognize rule's violation: In some cases, when lot number data element contains information about two or more lot numbers (which is a violation of this business rule), these lot numbers are separated by "/" or ",". Other forms of separation are possible, for example, second lot number may start from "AHBV" or another combination of characters. For more information see Appendix K: Lot Number Data Quality (DQA2022 MIROW guide).

DQA2022 - BR131 - Lot number recommended	
Rule Statement	Lot number information should be reported for every vaccine dose administered.
Remarks	Further guidance regarding lot numbers can be found at Updated Guidance for Documenting Vaccine NDCs and Lot numbers in IIS and EHRs, https://www.cdc.gov/vaccines/programs/iis/2d-barcodes/downloads/guidance-documenting-ndc.pdf

DQA2022 - BR132 - Lot number accuracy

Rule Statement	Lot number should not be prefixed, appended, or embedded with extraneous character strings.
Remarks	See Appendix K: Lot Number Data Quality (DQA2022 MIROW guide) for examples of potential extraneous character strings that may occur.

DQA2022 - BR133 - Vaccine product license	
Rule Statement	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.
Remarks	This can be a challenging collection of data to maintain over time. An exception to this rule may be vaccines administered as part of a clinical trial.
Example	CVX code = 51 (Hep B-Hib) should not be recorded as given in 1957 (it was implemented in USA around 1989)

DQA2022 - BR134 - Dose-level eligibility indicated	
Rule Statement	A dose-level eligibility should be indicated for each administered vaccination event submission.

DQA2022 - BR135 - Consistent vaccine eligibility	
Rule Statement	The dose-level public/private indicator and dose-level eligibility in a vaccination event record should be consistent with each other.
Remarks	• This rule is important for vaccine accountability. For more information see Immunization Information System Inventory Management Operations and Decrementing Inventory via Electronic Data Exchange. • The recipient of the vaccine should be eligible to receive that vaccine from the program offering it. • This rule is might not be applicable for pandemic-specific vaccines.

DQA2022 - BR136 - Educate IIS-AO on when to use historical	
Rule Statement	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	
Rule Statement	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	
Rule Statement	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	
Rule Statement	A patient record should have an expected number of associated vaccination event records based on the patient's age and ACIP recommendations.
Example	Example: No more than: • 35 vaccination events before two years of age • 50 vaccination events before five years of age

DQA2022 - BR141 -Recommended number of vaccine doses	
Rule Statement	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.
Remarks	There are rare occasions when a vaccine dose may not have been valid and needed to be repeated or a patient may be re-starting a vaccine series.
Example	Seven DTaP vaccines by seven years of age.

DQA2022 - BR142 - Minimum intervals for vaccination event records	
Rule Statement	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	
Rule Statement	A patient record should not be associated with a vaccination encounter that contains more than the recommended number of vaccine doses.
Remarks	This business rule is intended to identify outliers. The number of doses recommended per vaccination encounter that would exceed reasonable expectations should be set by the IIS program.

DQA2022 - BR144 - Same antigen on same day	
Rule Statement	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.
Remarks	• Antigen is determined from the vaccine product type reported, and vaccination event records are matched on antigen. • There are instances where the vaccination was compromised, and a repeat dose was given on the same day. • The vaccines may have been administered by the same or different vaccinating organizations. • This rule will often be implemented via the deduplication process. (there is a footnote for this remark: The scope in Chapter 1: Introduction references several resources for deduplication and consolidation.)

DQA2022 - BR145 - Allowed character for name	
Rule Statement	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 ' '.
Remarks	For example: patient first name, mother's maiden name. There may be names that are used that are exceptions to this rule.

DQA2022 - BR146 - Use official names

Rule Statement	An IIS program should educate IIS-AO staff on the importance of using official patient names.
Remarks	Since naming requirement vary by jurisdiction, there may be legitimate exceptions to this rule in some jurisdictions. As well, the documentation used to provide the official patient name may be different based on jurisdiction.

DQA2022 - BR147 - Patient first name	
Rule Statement	A patient first name in a demographic record should not remain a generic name after a time period determined by the IIS program.
Remarks	It can be challenging to determine which names are classified as generic since some terms that are used as placeholder names (e.g., Baby, Male) can also be an official patient first name. IIS programs should establish a specific time period for validating generic names (e.g., three months). The intent is to flag records for the IIS program to look at after a period of time, once that time has passed the record is not reviewed again for the name anomaly.

DQA2022 - BR148 - Patient first and last name two characters	
Rule Statement	A patient first name and a patient last name in a demographic record should each be at least two characters long.
Remarks	There may be names that are used that are exceptions to this rule.

DQA2022 - BR149 - Mothers name	
Rule Statement	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	
Rule Statement	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.

Remarks	This business rule is intended to assist an IIS that is not currently performing leap year age calculations.

DQA2022 - BR151 - Minimum date of birth	
Rule Statement	Date of birth in a demographic submission should be after 1/1/1900.

DQA2022 - BR152 - Date of birth default	
Rule Statement	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.
Remarks	This rule applies for patients that do not know their own date of birth. If a date of birth is known by the patient or guardian, it should be used. This rule is not a substitute for collecting and recording a date of birth.

DQA2022 - BR153 - More than one patient race	
Rule Statement	A demographic record should support storing multiple values for patient race.

DQA2022 - BR154 - Complete address	
Rule Statement	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	
Rule Statement	An IIS should have the ability to store international addresses.

DQA2022 - BR156 - Verified address	
Rule Statement	An IIS program should verify addresses using a standard address verification service.
Remarks	This eliminates the need to check for mismatches across address components (e.g., ZIP code and state mismatch). If an IIS program is unable to use a standard address verification service then it should develop validation rules to verify address in other ways.

DQA2022 - BR157 - Patient phone number format	
Rule Statement	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	
Rule Statement	A patient phone number should not include any non-numeric characters (e.g., dashes).

DQA2022 - BR159 - Educate on use of medical record numbers	
Rule Statement	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	
Rule Statement	An IIS program should instruct the IIS-AO to not use a patient's Social Security Number as a medical record number.
Remarks	The Social Security Administration communicated that "the card was never intended to serve as a personal identification document- that is, it does not establish that the person presenting the card is actually the person whose name and SSN appear on the card."

DQA2022 - BR161 - Record submission errors and submission status	
Rule Statement	An IIS should record all the following for a submission: • All submission errors • The submission status.
Remarks	IIS-AO should be notified of errors in the submission.

DQA2022 - BR162 - Review rejected submissions within five days	
Rule Statement	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.
Remarks	There should be a method to review aggregate numbers and be able to address trends. It is not intended to be a review of each submission error.

DQA2022 - BR163 - Review the submission reports	
Rule Statement	An IIS program should review submission reports for errors and deviations in trends.
Remarks	• Trends for submitting organizations should be monitored for errors and accepted submissions alike. • Review information like the rejection rate, and processing rate. • This could be done automatically depending on available IT resources.

DQA2022 - BR164 - Hepatitis B birth dose	
Rule Statement	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	
Rule Statement	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	
Rule Statement	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	
Rule Statement	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.

DQA2022 - BR168 - Submissions are appropriate for provider organization type

Rule Statement	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	
Rule Statement	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.
Remarks	Best practices for an IIS to determine a list of data elements is found in Table 1 of the IIS Data Quality Practices - To Monitor and Evaluate Data at Rest guide.

DQA2022 - BR171 - Educate communicate and perform outreach to improve completeness	
Rule Statement	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.
Remarks	Best practices for an IIS to determine a list of data elements is found in Table 1 of the IIS Data Quality Practices - To Monitor and Evaluate Data at Rest guide.

DQA2022 - BR172 - IIS-AO ID issued once authorized	
Rule Statement	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	
Rule Statement	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

Rule Statement	An IIS program should not embed information about the IIS-AO in the IIS-AO ID.
Remarks	• The intent of this rule is to minimize the need to change IIS-AO IDs over time. For example information that should not be embedded in the IIS-AOs includes the relationship to other organizations (e.g., submitting organization for, parent of), IIS-AO location, or jurisdiction. • Embedding information that can change over time (e.g., relationships, locations) could lead to revising IIS-AO IDs on a regular basis, which is not consistent with best practices. • An alternative to embedding information in the IIS-AO ID may be to create a new field on the provider organization profile to capture the information.

DQA2022 - BR175 - Educate submitting organization to include all IIS-AO IDs	
Rule Statement	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	
Rule Statement	• An IIS program should capture all the following for an IIS-AO: IIS-AO common name • IIS-AO legal name.
Remarks	For implementation, may need to shorten the common name in systems that have character limits (e.g., VTrckS allows 35 characters). An IIS should display enough of the name for the IIS-AO to be accurately identified.

DQA2022 - BR177 - Validate organizational and reporting structure regularly	
Rule Statement	An IIS program should review the organizational and reporting structures of its IIS-AOs on a regular basis.
Remarks	• The organizational and reporting structures are maintained as part of the provider organization profile that is reviewed on a regular basis. • There should be an awareness on the part of the IIS-AOs that they have a responsibility to report any changes to their IIS program, in addition to the IIS program regular reviews. • The IIS program should update IIS-AO attributes and relationships any time a structural change occurs regarding the provider organization structure.

DQA2022 - BR178 - Contact IIS-AO prior to deauthorizing	
Rule Statement	An IIS program should contact an IIS-AO before deauthorizing the IIS-AO.
Remarks	The purpose of contacting the IIS-AO before de-authorization is to confirm that the IIS-AO is closing, opting not to use the IIS (if not required to submit data), or not capable of meeting the requirements of the IIS.

DQA2022 - BR179 - Deauthorize IIS-AO if it dissolves	
Rule Statement	An IIS program should deauthorize an IIS-AO if the IIS-AO dissolves.
Remarks	For example: The provider at a single provider practice retires and the site closes permanently.

DQA2022 - BR180 - Deauthorize IIS-AO if it no longer plays any IIS-AO roles	
Rule Statement	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.
Remarks	• An IIS-AO may no longer have a business need to submit or view immunization data. • This could be the result of structural changes. The IIS program determines the appropriate length of time for inactivity. • An IIS-AO could be re-authorized in the future if necessary and appropriate.

DQA2022 - BR181 - Assess necessity to deauthorize IIS-AO that is not required to submit and is not submitting	
Rule Statement	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.
Remarks	• This rule only applies to vaccinating organizations (defined as an IIS-AO that vaccinates a patient).

	• This rule is intended to support data security. The IIS program determines the appropriate length of time for inactivity. It is only applicable to jurisdictions without a reporting mandate.

DQA2022 - P01 - Multiple approaches to achieve data quality	
Rule Statement	Data quality should be achieved via multiple approaches such as programmatic and technical resources.

DQA2022 - P02 - Validation priority	
Rule Statement	The priority of validating a data element is related to the data element's significance in clinical decision-making, public health assessments, and research.
Remarks	This principle provides priorities for resources that are needed to perform the validation of a data element.

DQA2022 - P03 - Timeliness	
Rule Statement	Data should be reported to the IIS in a timely manner.
Remarks	Immunization data should be submitted to the IIS on or soon after the vaccination event date to support clinical decision-making and public health assessments.

DQA2022 - P04 - Availability	
Rule Statement	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	
Rule Statement	The submissions should contain the minimum/mandatory set of data elements in order to be accepted by the IIS.
Remarks	• The minimum/mandatory set of data is necessary to support the functionality of an IIS. Additional relevant data, if available, are valuable when they improve the functionality of IIS (i.e.," we do not want minimum data; we want good data"). • Additional data elements could be important, e.g., for epidemiologic surveys and school assessments.

	• The goal is to capture all relevant data on patients and their vaccination events.

DQA2022 - P06 - Cross-field validation	
Rule Statement	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.
Remarks	This principle is a basis for all cross-field validations. Examples: • vaccine type should match administration route (BR128). • vaccine product type should be paired with the licensed vaccine manufacturer (BR124).

DQA2022 - P07 - Consistent application of business rules	
Rule Statement	All submissions submitted to an IIS should be subject to the same business rules regardless of how the submissions are reported to the IIS.
Remarks	For example, if certain data elements are mandatory for records submitted via electronic data exchange, those data elements should also be mandatory for records submitted via other methods. The technical processes may differ for doing this, but the result should be the same.

DQA2022 - P08 - Submit all available information	
Rule Statement	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	
Rule Statement	Deviations from ACIP recommendations and FDA licensure are indications of potential data quality problems.
Remarks	In general, vaccine doses should be valid per the ACIP recommendations. When ACIP recommendations are violated, records should be investigated (flagged and researched).

DQA2022 - P10 - Accurately Reflect Vaccination Event

Rule Statement	A vaccination event submission should accurately reflect the vaccination event that actually occurred.
Remarks	Even if a vaccination event submission does not meet data quality standards (i.e., correct vaccination site per vaccine type, an >=65 flu vaccine mistakenly given to an adolescent), it is considered accurate if it reflects what occurred at the vaccination event.

DQA2022 - P11 - Develop Data Quality Reports	
Rule Statement	An IIS program should develop data quality and assessment reports and regularly review and update them.

DQA2022 - P12 - Data Quality Reports for IIS-AOs	
Rule Statement	An IIS program should develop data quality and assessment reports for IIS-AOs to use.
Remarks	These are reports that will be available to the IIS-AO for its own internal use.

DQA2022 - P13 - Develop Data Quality Plan	
Rule Statement	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	
Rule Statement	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	
Rule Statement	An IIS program should document expectations of the IIS program and IIS-AO.
Remarks	When enrolling a new IIS-AO, current and future expectations should be documented and agreed upon by the IIS program and IIS-AO.

DQA2022 - P16 - IIS should be notified about IIS-AO organizational changes

Rule Statement	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.
Remarks	For example: open, close, move, acquire, sell, merge or otherwise update. IIS programs should specify in their memorandums of understanding the requirement for IIS-AOs to notify the IIS program of changes to their organization.
Example	E.g., open, close, move, acquire, sell, merge

DQA2022 - P17 - Consistent provider organization management	
Rule Statement	IIS should document and be consistent in the approaches followed for Provider Organization Management.

DQA2022 - P18 - Vital Records	
Rule Statement	Vital Records should be considered the definitive source for a patient's • Date of Birth • Date of Death.

DQA2022 - P19 - Supremacy of medical records	
Rule Statement	Medical records are a more reliable and accurate source of immunization data than billing records.

DQA2022 - P20 - Vendor update applications	
Rule Statement	An IIS program should ensure vendors are using the most up to date version of HL7 specification.

DQA2022 - P21 - Complete chain of submitting organizations	
Rule Statement	A submission should identify all submitting organizations.
Remarks	This principle is referring to the complete "chain" of submitting organizations.

DQA2022 - P22 - Submission retained indefinitely	
Rule Statement	Every unique submission should be retained per jurisdictional policy, along with all errors identified.

DQA2022 - P23 - Reference a directory of known lot numbers	
Rule Statement	A directory of known lot numbers should be created, maintained, and referenced for lot number validation purposes.
Remarks	Implementation of this principle is challenging. It is difficult to create and manage a directory of this type at a national level; however, it is also hard to accomplish at a jurisdiction level and may be a poor use of resources for each IIS program to individually develop and manage.

DQA2022 - P24 - Reference a directory of manufacturer-specific coding schemes for lot numbers	
Rule Statement	A directory of manufacturer-specific coding schemes for lot numbers should be created, maintained, and referenced for lot number validation purposes.
Remarks	Further information is available: https://repository.immregistries.org/files/resources/596f7218ad93e/aira_sisc_vaccine_lot_number_guidance_20180614.pdf

DQA2022 - P25 - Maintain reliability of reference directories	
Rule Statement	Reference directories should be periodically reviewed and reconfirmed as reliable reference sources for validating lot numbers.
Remarks	The objective of this principle is to maintain a level of confidence in the reference source.

INV2012 - BR701 - Use NDC received in the shipment file	
Rule Statement	The NDC received from VTrckS (in the shipment file) should be used for receiving, reporting, and tracking inventory.
Remarks	• Note that the NDC to be used for ordering, reporting inventory or submitting returns is the one in the CDC contract. • In cases where the shipment file has not been received and the vaccine is packaged in a larger container, the NDC on the outside packaging (e.g., box) should be used. • Currently McKesson does not provide (and in many cases does not know) the codes for items inside the package.
References	INV2012 - P701: NDC supremacy. INV2012 - BR702 Lot number must be matched/mapped to NDC for every dose,

	INV2012 - BR703 Make NDC known prior to arrival of a direct vaccine shipment. State/event model references: INV2012 - EV01, INV2012 - EV10.

INV2012 - BR702 - Lot number must be matched/mapped to NDC for every dose	
Rule Statement	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.
Remarks	• The mapping of lot number to NDC and expiration date is needed in order to support inventory on hand reporting to VTrckS. A lot number should be matched to one NDC, as discussed in the NDC Considerations section and in the Appendix A, domain model. • For inventory management, it is not sufficient just to map lot number to NDC: also have to know whether to deduct the transaction from public or private inventory. If lot numbers were always distinctly different for public and private inventory, it would not be a problem. But sometimes the same lot number exists for both public and private stocks. ○ On the administration side, patient eligibility reporting with dose administered is sufficient, except the "borrowed" situation. For borrowing situations a public/private inventory designation for every dose should be known.
Example	Kansas IIS has experienced this issue – with providers using the wrong vaccine for VFC and for non-VFC patients in cases where borrowing was not intended. Knowing the VFC eligibility status of the patient helped to resolve these situations.
References	INV2012 - P701: NDC supremacy. INV2012 - P702: Dose-Lot Number accountability. INV2012 - BR709 Minimum set of data items for every shipment. State/event model references: INV2012 - EV05, INV2012 - EV06, INV2012 - EV07, INV2012 - EV09, INV2012 - EV12-14.

INV2012 - BR703 - Make NDC known prior to arrival of a direct vaccine shipment	
Rule Statement	IIS should make NDC known to Provider Organization prior to arrival of a direct vaccine shipment.
Remarks	• IIS knows the NDC based on the Provider Organization's original order. • IIS loads Provider Organization's public inventory with NDC from outer package, Lot Number, Lot Number Expiration Date, and quantity.

References	See INV2012 - P701: NDC supremacy. See INV2012 - BR701 Use NDC received in the shipment file, INV2012 - BR702 Lot number must be matched/mapped to NDC for every dose. State/event model references: INV2012 - EV01.

INV2012 - BR704 - Capture the lot number for every vaccine dose administered	
Rule Statement	A lot number for every vaccine dose administered must be documented and reported by the Provider Organization to the IIS.

Remarks	• Rule applies to reporting done either electronically or on paper.
	  ○ Will require a major change of mindset because lot number is currently not well populated in IIS. But there are many benefits if this is done.
	• For historical vaccine doses, the lot number in many cases is not known and is not required. It is not needed for inventory control (these would not be considered administered, but historical doses).
	  ○ Historical doses - administered at some point in the past and now being entered into a patient's record (e.g., patient moved from one state to another and brings the immunization record).
	• Encourage Provider Organizations to adopt technologies that can facilitate lot number reporting. Examples: barcoding, new inventory modules, publish tables that describe vaccine products and their lot numbers. That can facilitate implementing drop-down reporting in EHR systems.
	• For many IIS, decrementing inventory at the dose level based on lot numbers in data exchanged may be new functionality they need to build.
	• In case of a multi-component vaccine (i.e., a product with diluents or components that must be combined together), each component has its own lot number. However, there is always one lot number and one NDC available that characterize such a multicomponent vaccine. The information about these lot number and NDC should be taken from the label located outside on the package/box, as indicated in a comment for the business rule INV2012 - BR701 Use NDC received in the shipment file.

References	INV2012 - P702: Dose-Lot Number accountability. INV2012 - BR701 Use NDC received in the shipment file. INV2012 - GR716 Data quality assurance measures for vaccine shipments for data quality assurance as it relates to lot numbers. General recommendation applies to reporting done either electronically or on

	paper. See the discussion regarding lot number assumptions in the NDC Considerations chapter. State/event model references: INV2012 - EV05, INV2012 - EV12.
Violation Action	Reject reporting without lot number.

INV2012 - BR705 - Capture patient eligibility for every dose administered	
Rule Statement	A patient eligibility for every vaccine dose administered must be documented and reported by the Provider Organization to the IIS.

Remarks	• Patient eligibility is needed to decrement the appropriate stock (public or private).
	  ○ It is possible to have the same lot number and NDC for both public and private vaccines. Patient eligibility helps to distinguish between public and private vaccines.
	• Patient eligibility is not relevant for historically administered vaccines.
	• Provider Organizations which do not provide dose-level patient eligibility:
	  ○ May not be able to do automated reporting of dose-level accountability at the lot level in IIS.
	  ○ May need to make aggregate corrections at the lot level within the IIS.

References	INV2012 - P702: Dose-Lot Number accountability. INV2012 - BR702 Lot number must be matched/mapped to NDC for every dose. INV2012 - GR702 IIS inventory management functionality should support accountability at the dose/lot number level State/event model references: INV2012 - EV05, INV2012 - EV12.
Violation Action	Reject reporting without patient eligibility for immunization administration purposes.

INV2012 - BR706 - Capture Provider Organization responsible for inventory for every dose administered	
Rule Statement	Provider Organization responsible for the inventory must be associated with every immunization (dose administered transaction).
Remarks	• The Provider Organization responsible for the inventory may be different from the Provider Organization administering the vaccine (see discussion in the Appendix A: Domain model).

	• Whenever possible, and in accordance with VFC policy, vaccine should be shipped to and received by the administering site, situations that include redistribution by a centralized vaccine depot should be minimized.
	• Organizations that do not report responsible Provider Organization:
	  ○ Will not be able to implement automated reporting of dose-level accountability at the lot level in IIS.
	  ○ Will need to make aggregate corrections at the lot level within the IIS.

References	INV2012 - P702: Dose-Lot Number accountability. State/event model references: INV2012 - EV05, INV2012 - EV12.
Violation Action	• Accept reporting without Provider organization responsible for inventory for immunization administration purposes. • Reporting without Provider Organization responsible for inventory may be accepted for inventory tracking if the Provider Organization responsible inventory can be determined based on information submitted (e.g. not an umbrella organization).

INV2012 - BR707 - Track borrowing and replacements at the dose level	
Rule Statement	Borrowing and replacement of borrowed vaccine doses between public and private stocks should be tracked at the dose level.
References	INV2012 - P702: Dose-Lot Number accountability. INV2012 - P708: Avoid loaning doses between private and public stock. INV2012 - BR725: Borrowing should be done at the single-dose level. See VFC Operations Guide for guidance. See the borrowed/replaced report in the IIS Reports section. State/event model references: INV2012 - EV05, INV2012 - EV12, INV2012 - EV17-20.

INV2012 - BR708 - Account for wasted, spoiled/expired, and unaccounted for vaccines at the dose level	
Rule Statement	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.
Remarks	• A status “unaccounted for” should be assigned to a vaccine dose only when all other means of subtraction (e.g., administered, spoiled/expired, wasted, etc.) have been ruled out. • Measurements of wasted, spoiled/expired, and unaccounted for doses (possibly, against a certain threshold) would help to address the

	requirement that "Vaccine loss and waste should be minimized and measured" from [2.13] IPOM: Immunization Program Operations Manual, Chapter 2
References	INV2012 - P702: Dose-Lot Number accountability. INV2012 - P704: Accurate accounting. "Vaccine loss and waste should be minimized and measured" from [2.13] IPOM: Immunization Program Operations Manual, Chapter 2 (http://www.cdc.gov/vaccines/vac-gen/policies/ipom/). See also reports 1.5 Vaccine Loss Report (% Vaccine Loss - based on total doses ordered) and 2.4 Loss/Wasted Report in the Recommendations for IIS Reports section of this document. State/event model references: INV2012 - EV07, INV2012 - EV08, INV2012 - EV13, INV2012 - EV14.

INV2012 - BR709 - Minimum set of data items for every shipment	
Rule Statement	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.
Remarks	• Each morning McKesson sends grantees two files (in MS Excel and text format) with information about non-direct vaccine orders shipped the previous day. Grantees can use this information to pre-populate Provider Organization inventory in the IIS and to let Provider Organizations know to expect a shipment. • Shipment data for both direct and non-direct orders is available for download from VTrckS in a time interval that the user specifies. As with the McKesson shipment file, grantees can use VTrckS shipment data to pre-populate Provider Organization inventory in the IIS and to let Provider Organizations know to expect a shipment. • The timeliness of shipment data available through VTrckS continues to improve. It is planned that by fall 2012 all manufacturers will be communicating with VTrckS in a way that will ensure timely shipment data for both direct and non-direct ship orders. For complete and timely shipment data, CDC recommends that the ExIS shipment data file - not the McKesson shipping file - be imported into the IIS.

	• The discussion is centered around public-funded vaccine available from the CDC via VTrckS, but the same business rule could also apply to private-funded vaccine shipments. All shipments from VTrckS should be categorized as public (in the public/private indicator).

INV2012 - BR710 - Verify shipment information	
Rule Statement	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.

Remarks	• Implementation considerations:
	  ○ Minor issues may be addressed with editable fields (e.g. expiration date, vaccine quantity) in the system.
	  ○ Major issues may require immediate communication and be in non-editable fields (e.g. vaccine type) in the system.
	• Vaccine Programs provide guidelines on which issues are classified as major or minor and what actions must be taken when issues occur (e.g. immediate phone call).

References	INV2012 - P703: Completeness. INV2012 - GR716 Data quality assurance measures for vaccine shipments. State/event model references: INV2012 - EV01, INV2012 - EV10.
Violation Action	If vaccines shipped do not match the packing slip and/or expected receipt quantities, types, etc.: a) Inventory in the IIS should be corrected to reflect the actual vaccine received (e.g., correct the lot number). b) Vaccine Program should be notified.

INV2012 - BR711 - Minimum set of data items for every vaccine dose	
Rule Statement	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).
Remarks	• VTrckS specification requires that quantity by lot number, lot number expiration date, and NDC all be reported in the current inventory file needed to place vaccine orders. • Lot Number Expiration Date: In some cases this data item would contain a short-dated expiration date. A possible additional data item, expanding the minimum recommended data set, would be a short-dated expiration date or a flag indicating a short-dated expiration date. See INV2012 - BR712: When present, short-dated lot number expiration date should be used for all inventory transactions instead of the original expiration date. Note that two inventory items (vaccine doses) can have the same lot number, but different expiration dates: one – with the original date, another – with the short-dated date (Michigan IIS example). • When a Public/Private inventory indicator for a dose administered to a Patient is “private” and Patient eligibility is “public” (or vice versa), a borrowing transaction is created. • Reporting of the Public/Private Inventory Indicator for every inventory transaction at the dose level, while providing a comprehensive solution, requires that an additional data item be reported/recorded. That is a burden on Provider Organizations and EHR vendors. The alternative recommended good practice, as implemented in Michigan IIS, would be to record public/private designation at the lot number level (as opposed to the dose level) - for every lot number. When a vaccine dose is administered to a patient and reported to IIS by a Provider Organization, IIS searches for the lot number in public and private inventories to properly designate the administered dose as public or private. This approach still presents a problem in cases when the same lot number has both public and private doses. In these cases, when a Patient’s eligibility is public, Michigan IIS defaults the dose designation to public. (Note that this is only true in instances where a Provider Organization transfers data via their EHR. If a Provider Organization manually enters their data into the IIS, they select the lot number administered from a drop down box. Lot numbers in the private inventory are indicated with an *). As a result, in this particular scenario, borrowing cannot be identified. • Another option for inferring public/private inventory status in the absence of a dose level public/private inventory indicator is through dose-level patient’s eligibility (i.e., a code of V02 represents patient’s eligibility for Medicaid, this can be inferred as a public vaccine dose).

	However, this does not allow the IIS to audit potential mismatches between public/private patient's eligibility and public/private funding source, so it is not recommended as a best practice. • Best practice for the IIS is to use a separate variable (not the lot number) – Private/Public Indicator - to capture public/private designation of the inventory. • Although available as a field within some IIS databases, Public/Private Indicator is a data item that is not currently received from or stored in the vast majority of EHR systems. It could be challenging to argue for EHRs to store and submit the Public/Private Indicator data item. • EHR use lot numbers for various purposes, including extending the lot number fields to indicate public/private inventory designations. The IIS needs to be able to derive the actual lot number and the actual public/private indicator and document them in two separate fields. • Possible additional data item: In situations when Provider Organization gives two doses of a pediatric vaccine for an adult dose or a half-dose of an adult vaccine for a pediatric dose (e.g., when vaccine has been used not according with the adult/pediatric "intention"), IIS can either use a dose trigger function (designate dose size as half, full, or double) or manually decrement the second dose or a half-dose from the inventory.
References	INV2012 - P703 Completeness INV2012 - BR712 Use (record) short-dated expiration date when present State/event model references: INV2012 - EV02, INV2012 - EV05-08, INV2012 - EV12-14, INV2012 - EV17-20.

INV2012 - BR712 - Use (record) short-dated expiration date when present	
Rule Statement	When present, the new short-dated Lot Number Expiration Date must be used (recorded) for all inventory transactions instead of the original expiration date.
Remarks	When a lot number has been short-dated, two expiration dates can be recorded - the original expiration date and the short-dated expiration date. Reporting two dates is a "good to have" practice, but is not mandatory. The original expiration date is not currently needed for reporting to VTrckS. A possible reason for short-dating might be a temporary temperature drop in the refrigerator.
References	INV2012 - P703: Completeness. INV2012 - GR706 IIS should be able to record both the original and short-dated expiration dates

	State/event model references: INV2012 - EV01, INV2012 - EV05, INV2012 - EV07, INV2012 - EV12,

INV2012 - BR713 - Minimum data set for vaccine transfers	
Rule Statement	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).
Remarks	• Inventory adjustments should be made in IIS for both the sending Provider Organization and the receiving Provider Organization. The sending Provider Organization will need transaction recorded to deduct doses from inventory and the receiving Provider Organization will need transaction recorded that will add doses to their inventory. • The Grantee Vaccine Program (or LHD) should be notified of all transfers and receipts of public vaccines (depending on grantee requirements). • It is a good practice to know the ID of the Person at the Provider Organization who initiated the transfer ("pushed the button"). That information can be available through the user interface or through accessing audit tables.
References	INV2012 - P703: Completeness. INV2012 - GR705 IIS should reflect transfers of vaccines INV2012 - BR711 Minimum set of data items for every vaccine dose (alternative approaches to track the public/private indicator described in the comments). State/event model references: INV2012 - EV02.

INV2012 - BR714 - Verify condition, types, and quantities of transferred vaccine doses

Rule Statement	Provider Organizations should verify condition, types, and quantities received in a transfer from another Provider Organization against expected number and type of doses.
Remarks	• Vaccines received in a transfer between Provider Organizations should match the expected number and type of doses. • Condition refers to viability (e.g., no cracks in box, no ice forming, temperature log with recorded temperatures during transport are within normal limits). • The sending and receiving Provider Organizations should resolve the issues and ensure the resolution is appropriately reflected in the IIS.
References	INV2012 - P703: Completeness. State/event model references: INV2012 - EV02.

INV2012 - BR715 - Account for non-administration adjustments on the same day	
Rule Statement	All events generating non-administration adjustments to available on hand inventory should be accounted for in the IIS on the same day they occur.
Example	Examples include breakage, bonus doses, wasted/spoiled doses.
References	INV2012 - P705: Timely accounting. State/event model references: INV2012 - EV01-04, INV2012 - EV06-11, INV2012 - EV13-20.

INV2012 - BR716 - Track the event date and recording date	
Rule Statement	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.
Remarks	• This is to facilitate reconciliation. Important to know for monthly reporting the actual date the event occurred. ○ Example: At the date of service may think the patient is insured - but get a rejection back three months later and now the Provider Organization needs to replace the dose with VFC and designate the patient as uninsured or underinsured. • Good practice: Track at least the date the event occurred
References	INV2012 - P706: Reconciliation frequency. INV2012 - P703: Completeness. State/event model references: INV2012 - EV01-20.

INV2012 - BR717 - Submit data to IIS before reconciling inventory	
Rule Statement	Provider Organizations must have their immunization data submitted to and processed by the IIS before reconciling their inventory for the corresponding reconciliation period.
References	INV2012 - P706: Reconciliation frequency. State/event model references: INV2012 - EV08.

INV2012 - BR718 - Indicate IIS-EHR discrepancies	
Rule Statement	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.
Remarks	• Short-date is one example of why there might be a discrepancy. "Short-dating" could lead to more than one expiration date for a lot number (INV2012 - BR711, INV2012 - BR712). Another example: an inventory lot is not found in IIS due to a data entry error in the EHR or IIS (wrong lot entered in one system or the other) or because inventory lot was not entered into IIS. • Another common problem is inventory lot from EHR matches more than one lot in IIS. IIS will not deduct inventory if it cannot match a unique lot. • Therefore lot number alone is not sufficient to determine expiration date. • Currently, dose-level reports on administered vaccines could come into the IIS manually (direct user interface) or electronically (messages from EHR), all other transactions – only manually, through the IIS direct user interface. Currently there are no electronic exchange standards that allow for such submissions of inventory transactions (non-administered doses) in addition to doses administered, however this would not preclude encouraging such standards to be developed.
References	INV2012 - P706: Reconciliation frequency. INV2012 - BR711: Minimum set of data items for every vaccine dose INV2012 - BR712: Use (record) short-dated expiration date when present
Violation Action	Best practice: Discrepancies should be addressed immediately. Good practice: Discrepancies must be addressed before the close of the reconciliation period.

INV2012 - BR719 - Account for opt-out patients before reconciling

Rule Statement	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.

Remarks	• Opt-out means a patient has chosen not to be in the registry (IIS).
	• Legal requirements for handling opt-out (and/or non-consented) patients vary among grantees based on local laws and regulations. Accordingly, approaches to inventory adjustments for opt-out patients vary.
	  ○ A typical scenario (KS, OR): IIS retains demographic information for opt-out patients. Vaccine doses administered to an opt-out patient are reported to IIS as usual. Because IIS has demographic information for a patient it recognizes that a patient is opted out. IIS decrements the Provider Organization's inventory by one dose, without updating the patient vaccination record.
	  ○ Another typical scenario (MI): IIS retains the opted-out patients name and DOB and flags these patients as opted-out. When data is transferred from an EHR, IIS will block the transfer of those doses and will not accept the vaccine information for a person who has opted-out (in other words, such a transmission of any information for the opted-out patient is rejected). A provider manually deducts the administered dose from the IIS inventory with a reason "Patient opted-out from IIS".

References	INV2012 - P706: Reconciliation frequency. INV2012 - P707: Comply with privacy guidelines. INV2012 - BR720: EHR submission for an opt-out patient State/event model references: INV2012 - EV05, INV2012 - EV12.

INV2012 - BR720 - EHR submission for an opt-out patient	
Rule Statement	For an EHR submission for an opt-out patient, IIS should decrement inventory without updating the patient record.
Remarks	• Good practice: make a manual adjustment with reason of "administered to patient who opted-out of registry." • Good practice: create an audit trail (time stamp, user ID, etc.) to ensure QA in case of questions around reconciliation time.
References	INV2012 - P706: Reconciliation frequency. INV2012 - P707: Comply with privacy guidelines. State/event model references: INV2012 - EV05, INV2012 - EV12.

INV2012 - BR721 - Do physical inventory count for reconciliation on a day boundary	
Rule Statement	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).
References	INV2012 - P706: Reconciliation frequency. State/event model references: INV2012 - EV08.

INV2012 - BR722 - Reconcile inventory immediately prior to ordering	
Rule Statement	Provider Organizations must reconcile their entire physical inventories to the IIS inventory immediately prior to ordering.
Remarks	• VTrckS requirement: Grantee must submit the Provider Organization's physical inventory ("Provider Ending Inventory Data") to VTrckS no more than 14 days prior to order placement. • Good practice: Provider Organizations not utilizing the IIS for inventory management must submit physical inventory counts at the lot level. Some Provider Organizations will opt not to use the inventory module in the IIS, but these same Provider Organizations will need to submit physical counts to VTrckS to support ordering.
References	INV2012 - P706: Reconciliation frequency. INV2012 - GR702: IIS inventory management functionality should support accountability at the dose/lot number level. State/event model references: INV2012 - EV08.

INV2012 - BR723 - Reconciliation frequency	
Rule Statement	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.

Remarks	• Parameters that describe what is a large or small organization should be established at a grantee level.
	• More frequent reconciliations could be beneficial in a variety of situations, including:
	  ○ Provider Organizations with a large volume of transactions.
	  ○ Provider Organizations with a history of inventory management issues.
	  ○ Provider Organizations that are new and/or transitioning onto inventory management within the IIS.

	○ Provider Organizations with multiple individuals using inventory or multiple refrigerators. • In these cases, more frequent reconciliations are a proven mechanism for helping the Provider Organization identify and resolve any discrepancies.
References	INV2012 - P706: Reconciliation frequency. State/event model references: INV2012 - EV03, INV2012 - EV08, INV2012 - EV09.
Violation Action	Provider Organizations not complying with monthly accountability requirements may be required to conduct more frequent reconciliations (e.g., once a week).

INV2012 - BR724 - Ensure accurate inventory count for pre-adoption Provider Organizations	
Rule Statement	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).
Remarks	• Immunization information (without provider information) from original identity should be carried forward to the new identity. • There are many ways to maintain anonymity. One option is to add doses back to the inventory and then subtract these doses back at the lot level, use subtraction reason of “administered to patient who was adopted.”
References	INV2012 - P707: Comply with privacy guidelines. State/event model references: INV2012 - EV05, INV2012 - EV12.

INV2012 - BR725 - Borrowing should be done at the single-dose level	
Rule Statement	When a multi-dose vial is involved, borrowing should be done at the single-dose level.
Remarks	• A single dose should be borrowed -- not the whole vial. • Current practice in some states (e.g., Pennsylvania) is to borrow the whole multi-dose vial. But this is not a system limitation, it is a policy decision.
References	INV2012 - P708: Avoid loaning doses between private and public stock. INV2012 - BR707: Track borrowing and replacements at the dose level. State/event model references: INV2012 - EV17-20.

INV2012 - P701 - NDC supremacy

Rule Statement	Vaccine inventory management should be based on the National Drug Code (NDC).
Remarks	In accordance with VFC program and VTrckS system requirements, vaccine inventory must be reported based on the NDC.
References	INV2012 - BR701: Use NDC received in the shipment file. INV2012 - BR702: Lot number must be matched/mapped to NDC for every dose. INV2012 - BR703: Make NDC known prior to arrival of a direct vaccine shipment.

INV2012 - P702 - Dose-lot number accountability	
Rule Statement	Every vaccine dose should be accounted for with the associated lot number information.

Remarks	• All additions to and subtractions from inventory levels should be accounted for and measured.
	• According to the state/event model (Figure 4, Tables 3 and 4), the following vaccine dose states (types/categories) should be measured (further sub-categories may be implemented locally): available (on-hand), in-transit (transferring), administered, wasted (nonviable, not returnable), expired/spoiled (nonviable, returnable), unaccounted for, over-estimated, returned shipment, transferred out, repaid (previously borrowed), and borrowed out.
	  ○ Some jurisdictions may choose to apply a threshold to some of these categories. When the threshold is reached (e.g., on wasted vaccine doses) certain actions can be initiated.
	• The lot number must be captured at the dose level for inventory accountability purposes.
	• Lot number needs to be captured to support the mapping to NDC (can be done behind the scenes).
	  ○ IIS can enable the mapping by associating lot number to NDC.
	  ○ Refer to a discussion in the “NDC Considerations” section of this document.

References	INV2012 - BR704: Capture the lot number for every vaccine dose administered. INV2012 - BR705: Capture patient eligibility for every dose administered. INV2012 - BR706: Capture Provider Organization responsible for inventory for every dose administered INV2012 - BR707: Track borrowing and replacements at the dose level INV2012 - BR708: Account for vaccines at the dose level. INV2012 - GR702: IIS inventory management functionality should support

	accountability at the dose/lot number level. State/event model references: INV2012 - EV05-08, INV2012 - EV12-14.

INV2012 - P703 - Completeness	
Rule Statement	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.
Remarks	The set of required data items should be the same regardless of how these data items have been reported to an IIS.
References	INV2012 - BR709: Minimum set of data items for every shipment. INV2012 - BR710: Verify shipment information INV2012 - BR711: Minimum set of data items for every vaccine dose INV2012 - BR712: Use (record) short-dated expiration date when present INV2012 - BR713: Minimum data set for vaccine transfers INV2012 - BR714: Verify transferred vaccine doses. State/event model references: INV2012 - EV05-08, INV2012 - EV12-14.

INV2012 - P704 - Accurate accounting	
Rule Statement	Provider Organization's physical inventory (available/on hand) should be accurately reflected in the IIS.
Remarks	• Any inventory transaction should be reversible and can be corrected as necessary. • Inventory may be located in one or more cold storage units. • Provider Organization has one inventory in IIS per VFC PIN and IIS ID. Provider. Organization’s inventory can include both publicly-funded and privately-purchased vaccines.
References	See INV2012 - BR708: Account for vaccines at the dose level. State/event model references: INV2012 - EV10.

INV2012 - P705 - Timely accounting	
Rule Statement	Provider Organization's inventory should be adjusted in the IIS as soon as an event requiring the adjustment becomes known.
Remarks	Administration can be reported right away in case of direct data entry, or reporting can be delayed if reporting is arranged through another Provider Organization’s level or EHR systems.

Example	Examples include administration, breakage, new inventory, wasted/spoiled doses, bonus doses.
References	INV2012 - BR715: Account for non-administration adjustments on the same day. INV2012 - BR716: Track the event date and recording date. State/event model references: INV2012 - EV01-EV20.

INV2012 - P706 - Reconciliation frequency	
Rule Statement	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.
Remarks	• P705 reflects already known adjustments. This principle describes a process to discover adjustments that are not already known. • Reconciliation involves counting physical inventory. • Size (e.g., large or small) of a Provider Organization is defined by how many doses this Provider Organization administers in a period of time or size of their orders or frequency of the orders (e.g., if ordering monthly, when it is a large Provider Organization).
Example	Examples of complexities include challenges with EHR systems, multiple refrigerators and freezers, complex Provider Organization structures (umbrella, parent-child relationships), re-distributions of vaccines within health systems.
References	INV2012 - PR705: Timely accounting - reflects already known adjustments. INV2012 - BR717: Submit data to IIS before reconciling inventory. INV2012 - BR718: Indicate IIS-EHR discrepancies INV2012 - BR719: Account for opt-out patients before reconciling INV2012 - BR720: EHR submission for an opt-out patient INV2012 - BR721: Do physical inventory count for reconciliation on a day boundary INV2012 - BR722: Reconcile inventory immediately prior to ordering INV2012 - BR723: Reconciliation frequency State/event model references: INV2012 - EV08.

INV2012 - P707 - Comply with privacy guidelines	
Rule Statement	Comply with HIPAA interpretations and other privacy-related constraints, e.g., handling adoption and opt-out of IIS cases.
References	INV2012 - BR719: Account for opt-out patients before reconciling. INV2012 - BR720: EHR submission for an opt-out patient.

	INV2012 - BR724: Ensure accurate inventory count for pre-adoption Provider Organizations. State/event model references: INV2012 - EV05, INV2012 - EV12.

INV2012 - P708 - Avoid loaning doses between private and public stock	
Rule Statement	Borrowing doses between private and public stock should be avoided.
Remarks	• All borrowed doses must be repaid. • See VFC Operations Guide, Module 3 for guidance on borrowing ○ Excerpt: "At the grantee's discretion, borrowing between the two inventories of vaccines may occur but must be a rare occurrence. Please note: for seasonal influenza vaccine, providers may use private stock seasonal influenza vaccine to vaccinate VFC eligible children if VFC seasonal influenza stock is not yet available. Those private stock doses used on VFC eligible children can later be replaced when VFC stock becomes available. This one-directional borrowing exception is unique to seasonal influenza vaccine. For all other vaccines, limited borrowing may occur bi-directionally. All borrowing, regardless of direction, must be documented on the VFC vaccine borrowing report located at the end of this module."
References	INV2012 - BR707: Track borrowing and replacements at the dose level. INV2012 - BR711: Minimum set of data items for every vaccine dose. INV2012 - BR725: Borrowing should be done at the single-dose level. INV2012 - GR701: IIS inventory management functionality should reflect policies and practices of a Grantee Vaccine Program, Figure 5 – state/event diagram for public vaccines, ST10, ST11, INV2012 - EV17-EV20 for a discussion of borrowing issues. State/event model references: INV2012 - EV05, INV2012 - EV12, INV2012 - EV17-20.

MPS2019 - BR401 - Nomenclature of statuses at the provider organization level	

Rule Statement	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.
References	MPS2019 - P301. Patient status scope: association between one patient and one party

MPS2019 - BR402A - Active status at the provider organization level: 1-1	
Rule Statement	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).
Remarks	Exception: Updates to an existing patient record in IIS (i.e., submission or entry of a patient demographic-only information or historical-only immunization information to IIS) does not result in active status in the 1-1 approach.
Example	• Vaccine type should not impact patient status determination. • Patient status with a provider organization should be set to inactive when patient status for this patient is set to active with another provider organization. • Patient status should remain active when a provider organization conducts a vaccination event for a patient who already has active status with that provider organization.
References	MPS2019 - P308. Supremacy of patient status direct identification MPS2019 - S101. Patient moved out of state but uses in-state provider organization MPS2019 - S301. Patient lives with divorced parents: 1-1 MPS2019 - S501. Provider organization of an acceptable type: 1-1 MPS2019 - S504. Birth dose submitted by hospital, acceptable type MPS2019 - S601. Vaccination encounter of an acceptable type: 1-1 MPS2019 - S701. Patient demographics received with no address and no vaccination: 1-1 MPS2019 - S703. Patient demographics and historical immunizations, no existing record MPS2019 - S704. Patient demographics and historical immunizations,

	existing record: 1-1 MPS2019 - S706. Patient demographics and historical immunizations, no existing record; not acceptable provider type: 1-1 MPS2019 - S801. Patient demographics and historical immunizations, existing record: 1-1

MPS2019 - BR402B - Active status at the provider organization level: 1-M	

Rule Statement	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).

Example	• Vaccine type should not impact patient status determination. • Patient status should remain active when a provider organization conducts a vaccination event for a patient who already has active status with that provider organization.
References	MPS2019 - S101. Patient moved out of state but uses in-state provider organization MPS2019 - S302. Patient lives with divorced parents: 1-M MPS2019 - S502. Provider organization of an acceptable type: 1-1 MPS2019 - S504. Birth dose submitted by hospital, acceptable type MPS2019 - S602. Vaccination encounter of an acceptable type: 1-M MPS2019 - S702. Patient demographics received with no address and no vaccination: 1-M MPS2019 - S703. Patient demographics and historical immunizations, no existing record MPS2019 - S705. Patient demographics and historical immunizations, existing record: 1-M MPS2019 - S706. Patient demographics and historical immunizations, no existing record; not acceptable provider type: 1-1

MPS2019 - BR404A - Patient status at the provider organization level: inactive: no longer a patient:1-1

Rule Statement	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.

Remarks	• There may be overlap in the criteria elements (i.e., criteria elements are not mutually exclusive). • The criterion "moved out of area" should be locally defined. • There are cases when a patient has moved but still receives immunizations from the provider organization. In some areas, it is not unusual for a patient to continue receiving services from a provider organization that is a long distance away. Therefore, criteria should be established by each IIS based on local circumstances to define when a patient's move should result in inactive status with a provider organization. The key factor should be that a provider organization does not recognize an individual as a patient. • A provider organization may choose to code patients who have not been seen for an extended period of time as inactive: no longer a patient.
Example	Examples include notations in a patient's chart that the patient is moving or a record release that indicates the patient is seeing a different provider organization.
References	MPS2019 - P308. Supremacy of patient status explicit assignment MPS2019 - S102. Patient moved out of state and ceased to use in-state provider organizations MPS2019 - S201. Transfer of medical records MPS2019 - S301. Patient lives with divorced parents: 1-1 MPS2019 - S501. Provider organization of an acceptable type: 1-1 MPS2019 - S601. Vaccination encounter of an acceptable type: 1-1 MPS2019 - S801. Patient demographics and historical immunizations, existing record: 1-1

MPS2019 - BR404B - Patient status at the provider organization level: inactive: no longer a patient:1-M

Rule Statement	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.

Remarks	• There may be overlap in the criteria elements (i.e., criteria elements are not mutually exclusive). • The condition "moved out of area" should be locally defined. There are cases when a patient has moved but still receives immunizations from the provider organization. In some areas, it is not unusual for a patient to continue receiving services from a provider organization that is a long distance away. Therefore, criteria should be established by each IIS based on local circumstances to define when a patient's move should result in inactive status with a provider organization. The key factor should be that a provider organization does not recognize an individual as a patient. • A provider organization may choose to code patients who have not been seen in an extended period of time as inactive: no longer a patient.
Example	Examples include notations in a patient's chart that the patient is moving or a record release indicating that the patient is seeing another provider organization.
References	MPS2019 - P308. Supremacy of patient status explicit assignment MPS2019 - S102. Patient moved out of state and ceased to use in-state provider organizations MPS2019 - S201. Transfer of medical records

MPS2019 - BR405 - Patient status at the provider organization level: inactive: lost to follow-up	
Rule Statement	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.
Remarks	• In the absence of any state guideline, after 90 days and a minimum of three unsuccessful attempts to contact a patient, patient status at the

	provider organization level should be set to inactive (reason code lost to follow-up) and remain active at the geographic jurisdiction level. • This is an update to RR2009 - BR802 from the 2009 MIROW Reminder/Recall guide (1.4, p. 50). • Consider following the escalation principle RR2009 - P802 from the MIROW Reminder/Recall guide (1.4, p. 49) to increase likelihood of successful contact: ○ "After an unsuccessful RR attempt, if the RR process is not ended, consider a different RR Notification method. For example, escalation from a postcard to a telephone call
References	RR2009 - P802 in the 2009 MIROW Reminder/Recall guide (1.4, p. 49) RR2009 - P803 in the 2009 MIROW Reminder/Recall guide (1.4, p. 49)

MPS2019 - BR406 - Patient status at the provider organization level: inactive: unspecified	
Rule Statement	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.
Remarks	• MPS2019 - BR406 should be used only by provider organizations that are technically not able to specify a reason, (e.g., EHR system is in transition). • Provider organizations should not set the inactive unspecified status arbitrarily but, rather, base it on rules defined in this guide.

M**PS2019 - BR411 - Nomenclature of statuses at the geographic jurisdiction level**	

Rule Statement	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	
Rule Statement	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).
Remarks	Status should not be set to active at the geographic jurisdiction level for an individual who received an immunization from a provider organization within the geographic jurisdiction and has an address outside of that jurisdiction.
References	MPS2019 - BR413. Inactive status at the geographic jurisdiction level (reason code outside jurisdiction) MPS2019 - S103: Patient address not known, patient receives services within state MPS2019 - S401. In-state patient uses out-of-state provider organization MPS2019 - S504. Birth dose submitted by hospital, acceptable type MPS2019 - S505. Birth dose submitted by hospital, not an acceptable type MPS2019 - S703. Patient demographics and historical immunizations, no existing record MPS2019 - S706. Patient demographics and historical immunizations, no existing record, not acceptable provider type: 1-1

MPS2019 - BR413 - Patient status at the geographic jurisdiction level: inactive: outside jurisdiction	
Rule Statement	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.
Example	• Individual once had a valid address in the jurisdiction but now has a known address outside the jurisdiction. • Individual has a known residence outside the highest level geographic jurisdiction (such as state) but receives health care within the state. ○ In this specific example (not all cases of this scenario), the patient will be active with at least one provider organization at the provider organization level. • Change of address received in a submission from a provider organization may include a partial address, such as when only the patient's state of residence is known (in which case the individual status is inactive: outside jurisdiction), and if there is an address-unknown flag (in which case it cannot be concluded that patient has

	moved outside of the geographic jurisdiction and the status remains active at the geographic jurisdiction level).
References	MPS2019 - S101. Patient moved out of state but uses in-state provider organization MPS2019 - S102. Patient moved out of state and ceased to use in-state provider organizations

MPS2019 - BR414 - Patient status at the geographic jurisdiction level: unknown: no address, no vaccination	
Rule Statement	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.
Remarks	• Other types of contact information (e.g., email address) might be available, which can be used to attempt contact. IIS should consider using other sources (e.g., health information exchange) to find contact information. • IIS should use reliable data sources and must be careful about what sources they authorize to provide data (i.e., IIS should avoid situations in which they have no address and no immunization). • This BR applies to incoming data. An IIS might have existing data that was not coded as required by this BR.
Example	• Demographic data received with no address. • Birth record where child is up for adoption and no birth dose. • Patient may be homeless (and has not received immunization).
References	Table 6, Assessment report at the geographic jurisdiction level. MPS2019 - S701: Patient demographics received with no address and no vaccination: 1-1 MPS2019 - S702: Patient demographics received with no address and no vaccination: 1-M

MPS2019 - BR415 - Patient status at the geographic jurisdiction level: unknown: no activity for extended period of time	
Rule Statement	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.

Remarks	• The SME panel had extensive discussions about defining "extended period of time" and was not able to provide a specific (numeric) recommendation. • Extended period of time could be different for different age cohorts. For example, adults might not be eligible for anything other than flu vaccination for an extended period of time. • Each IIS should (1) document its practices and the specific (numeric) period of time used to determine unknown status at the geographic jurisdiction level (reason code no activity for extended period of time) and (2) share the documented practices with AIRA to ensure transparency and to inform a future recommendation for a specific (numeric) period of time. • Some IIS currently require seven years of inactivity to classify someone as unknown. Other IIS never assign inactive status due to lack of activity at the jurisdictional level.
References	Table 6, Assessment report at the geographic jurisdiction level.

MPS2019 - BR421 - Deceased status at the provider organization and geographic jurisdiction levels	
Rule Statement	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.
Remarks	• For a deceased patient, patient status should be changed to deceased at both the provider organization level and the geographic jurisdiction level. • Patient status at both levels—geographic jurisdiction and provider organization—should be coordinated (i.e., if status is set to deceased at the geographic jurisdiction level, it should also be set to deceased at the provider organization level for all provider organizations associated with the patient, and vice versa).
Example	Examples of confirmation include a family member informing the IIS or provider organization, or a notification from Vital Records.

MPS2019 - P301 - Patient status scope: association between one patient and one party	
Rule Statement	Each patient status should characterize the association between one patient and one party responsible for the patient's vaccinations.
References	MPS2019 - P313. Opt-out from IIS MPS2019 - P314. Opt-out from reminder/recall

	MPS2019 - BR401. Nomenclature of statuses at the provider organization level MPS2019 - BR411. Nomenclature of statuses at the geographic jurisdiction level

MPS2019 - P302 - Patient status hierarchy	
Rule Statement	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).
Example	Examples of the geographic jurisdiction level(s) of the hierarchy include state, city, county, and other geographic area covered by a local public health authority.

MPS2019 - P303 - Avoid having patients fall through the cracks	
Rule Statement	A more rigid approach should be used in assigning non-active status at the geographic jurisdiction level than at the provider organization level.
References	MPS2019 - BR413. Inactive patient status at the geographic jurisdiction level (reason code outside jurisdiction) MPS2019 - BR415. Unknown patient status at the geographic jurisdiction level (reason code no activity for extended period of time) MPS2019 - BR421. Deceased patient status at the provider organization and geographic jurisdiction levels

MPS2019 - P304 - Who may assign patient status	
Rule Statement	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).
References	MPS2019 - BR413. Inactive status at the geographic jurisdiction level (reason code outside jurisdiction)

MPS2019 - P305 - Make information available about patient status changes

Rule Statement	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	
Rule Statement	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.
Remarks	Exception: A date of death received by IIS from Vital Records supersedes a status set by a provider organization. IIS should communicate such information to the provider organization.
Example	• For 1-1 and 1-M approaches, if a provider organization directly sets patient status to inactive, the status should be considered as inactive regardless of any vaccination events the provider organization conducted for the patient. However, future vaccination events conducted by the provider organization for the patient may result in the patient status being changed to active. • If a provider organization submits information about a vaccination event that it conducted and the submission has a patient status of inactive, the status should be considered inactive. • If a provider organization has not conducted any vaccination events for the patient but sets patient status to active, the status should be considered active. • For the 1-1 approach, setting patient status to active by one provider may affect the patient status with other provider organizations ○ For example, if provider organization A gave the most recent vaccination but provider organization B claims a patient by setting the patient status to “active,” then the patient status should be considered “active” with provider organization B and “inactive” with provider organization A. In other words, in the 1-1 approach, the provider organization that gave the last shot “wins”; i.e., most recent immunization trumps. It should be a rare occurrence that two providers vaccinate the same patient on the same day. • A provider organization may submit a status for a patient it expects to see on an upcoming date but who has not yet received vaccination services from that provider organization.

References	MPS2019 - S801. Patient demographics and historical immunizations, existing record: 1-1

MPS2019 - P309 - Same rules for public and private provider organizations	
Rule Statement	Rules for status assignment should be the same for public and private provider organizations.

MPS2019 - P310 - Out-of-state patients	
Rule Statement	• 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.
References	MPS2019 - S101. Patient moved out of state but uses in-state provider organization MPS2019 - S102. Patient moved out of state and ceased to use in-state provider organizations MPS2019 - S103. Patient address not known, patient receives services within state MPS2019 - S401. In-state patient uses out-of-state provider organization

MPS2019 - P311 - Patient status should be maintained for patients of all ages	
Rule Statement	Patient status should be maintained for patients of all ages.

MPS2019 - P312 - Any submission should include patient status	
Rule Statement	Patient status should be included in any submission from a provider organization to the IIS.

MPS2019 - P313 - Opt-out from IIS	
Rule Statement	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	
Rule Statement	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	
Rule Statement	If the Immunization Home is known, that Provider is primarily responsible for RR processes for routine immunizations.
References	RR2009 - P201. Define ownership principle RR2009 - P202. Responsible party principle

RR2009 - BR202	
Rule Statement	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.
References	RR2009 - P201. Define ownership principle RR2009 - P202. Responsible party principle RR2009 - P204. Hierarchy of parties principle

RR2009 - BR203	
Rule Statement	For disease outbreaks, the State and local health departments are responsible for RR processes.
References	RR2009 - P201. Define ownership principle RR2009 - P202. Responsible party principle

RR2009 - BR301	
Rule Statement	A single Reminder Notification should be considered 2 to 4 weeks before the recommended due date/date range for each recommended vaccine/vaccination visit.
Remarks	• RR Originator should decide is this 2–4 weeks before the first possible date in a date range or before the last date in a date range. • If the minimum interval between doses requires Vaccine to be administered after the age for which it is normally scheduled (catch-up schedule) then Reminder Notifications for a catch-up vaccine should either specify that the vaccine is due as soon after the <Due Date> as

	possible, or not be sent prior to the first date the Individual is eligible to receive the Vaccine.

RR2009 - BR305	
Rule Statement	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.
Example	• Reminder to start a schedule on time - at 2 months. • Reminder at the beginning of the child's second year. • Recall: after 7 months of age, then after 19 months of age.
References	See the section "Resource limitations and other restrictions" for various restrictions: resources, disturbance to the Patient, timeliness of reporting, baseline immunization coverage level of target population, etc. RR2009 - P301. RR process initiation principle RR2009 - P302. RR periodicity principle

RR2009 - BR306	
Rule Statement	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.
References	RR2009 - P301. RR process initiation principle RR2009 - P302. RR periodicity principle

RR2009 - BR307	
Rule Statement	For adults a single reminder for routine vaccinations recommended by ACIP should be considered.
Example	• Annually for influenza vaccination (50 years of age and older) • Once for a zoster vaccination (at 60 years of age) • Once for a pneumococcal vaccination (at 65 years of age) • Once for a Td vaccination (every 10 years)
References	RR2009 - P301. RR process initiation principle RR2009 - P302. RR periodicity principle

RR2009 - BR308	
Rule Statement	A single Recall Notification should be considered when routine doses or subsequent doses in a multi-dose series are overdue for adults.

References	RR2009 - P301. RR process initiation principle RR2009 - P302. RR periodicity principle

RR2009 - BR401	
Rule Statement	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.
Remarks	• Provider-based Reminder/Recall should be based on the established associations between a Provider and Patients, such as Medical Home or Immunization Home for a Patient [1.1]. • Patient active/inactive status at the Provider and geographic level should be considered for Patients' inclusion in a RR campaign. Patients with any status other than "active" for a particular Provider or geographic area should be excluded from the RR campaign. • Patients with temporary contraindications should be reconsidered for inclusion in subsequent RR campaign(s). • In the case of outbreaks, RR Notifications may be considered for all Individuals with non-medical exemptions.

RR2009 - BR501	
Rule Statement	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.

References	RR2009 - P501 Limited resources principle RR2009 - P504 Supremacy of Recall over Reminder principle RR2009 - P505 Priority for children 0-24 months of age principle

RR2009 - BR502	
Rule Statement	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.
References	RR2009 - P501 Limited resources principle RR2009 - P504 Supremacy of Recall over Reminder principle RR2009 - P505 Priority for children 0-24 months of age principle

RR2009 - BR503	
Rule Statement	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.
References	RR2009 - P501 Limited resources principle RR2009 - P504 Supremacy of Recall over Reminder principle RR2009 - P505 Priority for children 0-24 months of age principle

RR2009 - BR601	

Rule Statement	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.

Remarks	• Based on Cochrane Review [4.2] • Email, text and other electronic messages are new/emerging RR Notification methods and are therefore not ranked. Utilization of these and other new/emerging methods will increase in the future. • See also Fig.18. Illustration of person-to-person telephone-based RR

References	RR2009 - P605 Supremacy of Provider communication principle

RR2009 - BR602	
Rule Statement	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.
Remarks	• This ranking is based on the opinion of subject matter experts (SMEs). • The cost and effectiveness should be evaluated by the IIS to determine what RR method is the most cost-effective given their population, budget, and other circumstances. • There is insufficient experience with email and text messages to be able to rank the cost-effectiveness of those RR Notification methods. • Assumptions for RR Notification method cost-effectiveness: • Reporting functionality is in place that allows the IIS to produce a list of RR candidates • All systems supporting RR are in place (i.e., no development cost, e.g., for auto dialers) • Contact information is available for selected method, e.g., 100% of telephone numbers for autodialing are available and they are current (data quality) • Targeted audience is Individual or responsible party • Content of the RR Notification is appropriate for the targeted audience: i.e., language, level of literacy • See also Fig.18. Illustration of person-to-person telephone-based RR
References	RR2009 - P604 Cost-effectiveness principle

RR2009 - BR701	
Rule Statement	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

Rule Statement	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	
Rule Statement	The RR Notification should include a Rule Statement that encourages the RR Recipient to provide documentation of immunizations that are not recorded in the IIS.
Remarks	See illustrations below for examples.

RR2009 - BR704	
Rule Statement	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	
Rule Statement	The RR Notification (letter or card) should contain sufficient postage to obtain forwarding addresses from the post office.

RR2009 - BR706	
Rule Statement	The RR Notification (letter or card) should contain the return address of the party responsible for collecting results (RR Originator or the IIS).
Remarks	See “Reactions to RR responses”

RR2009 - BR801	
Rule Statement	In the event there is no State guideline, there should be 3 (three) RR Notification attempts before the RR process is ended.
Remarks	• The number of attempts might differ for different RR methods, e.g., for the post card 3, for the phone call 2, and for the home visit 1. Note that the RR Notification method can be changed after the first or second unsuccessful attempt (P802).

	• IIS should allow for a maximum number of RR attempts. Once the maximum number of RR attempts has been reached, these Patients should be excluded from future RR campaigns [1.1]. • Refer to Table 8 (item I) and P802 for handling the unsuccessful RR attempts.
References	RR2009 - P802 RR escalation principle RR2009 - BR802.

RR2009 - BR802	
Rule Statement	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.
Remarks	Note: Responsibility for a Patient is elevated to a geographic Jurisdiction level. See the domain model section for a definition of the unsuccessful attempt.
References	RR2009 - P803 Elevation of responsibility principle RR2009 - BR801.

RR2009 - BR803	
Rule Statement	The time between recall attempts should be 14-30 days for letters and postcards.
Remarks	For telephone calls and auto dialers this time can be much shorter, e.g., one day.

RR2009 - P201 - Define ownership principle	
Rule Statement	The "ownership" (the responsibility) for an Individual/Patient has to be clearly defined.
Remarks	• The ownership concept can be related to the assignment of a medical home or Immunization Home for a Patient. • This association should be used to determine the Patient population served by a particular Provider and/or Jurisdiction and establishes the initial Patient cohort for the particular RR process.

References	RR2009 - BR201. RR2009 - BR202. RR2009 - BR203.

RR2009 - P202 - Responsible party principle	
Rule Statement	Party responsible for the Individual / Patient should initiate the RR process.
References	RR2009 - P203 – Delegate responsibility principle RR2009 - BR201. RR2009 - BR202. RR2009 - BR203.

RR2009 - P203 - Delegate responsibility principle	
Rule Statement	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).
Remarks	• As a matter of policy, in collaboration with Providers, local and State health departments should be able to assume responsibility (and cost) for generating and distributing RRs on behalf of a Provider. • IIS should provide functionality that allows Providers to initiate and implement an RR process for the Provider's Patients, and that also allows local and State public health agencies to initiate and implement an RR process on behalf of individual Providers or on a geographic Jurisdiction basis. • Local and/or State public health agencies should partner with Providers to develop collaborative RR projects and processes that utilize the IIS. • Centralization of RR operations would reduce the overall cost. • Also, refer to the section "Selection of RR Notification method" where cost-effectiveness issues are discussed.

RR2009 - P204 - Hierarchy of parties principle	
Rule Statement	A hierarchy of parties responsible for every Individual/Patient in the IIS should be established.
References	See beginning of this section and [1.1] RR2009 - BR202.

RR2009 - P301 - RR process initiation principle	
Rule Statement	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 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).
Remarks	Recall Notifications must be based on individual vaccine history in association with applicable requirements or schedules.

RR2009 - P302 - RR periodicity principle	
Rule Statement	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.)
Remarks	• There is not sufficient evidence on effectiveness to recommend an optimal frequency for initiation of the RR process. • The frequency of RR process initiation depends on age of cohort, goal(s) for the particular RR process, available resources, and size/nature of the target population. • RR frequency can vary depending on the RR Notification method (see sections “Selection of the RR Notification method” and “Reaction to the RR Response” in this chapter).

RR2009 - P303 - Single RR Notification principle	
Rule Statement	If more than one vaccination is due or overdue at the time of RR, all vaccinations should be accommodated in a single RR Notification.
Remarks	• An RR process should not include a separate RR Notification for each vaccine group for which an Individual/Patient needs doses for (due or overdue). • This approach avoids triggering multiple RR Notifications to the same Individual/Patient on the same day.
References	See the section “Content of the RR Notification” in this chapter. RR2009 - P502 – Limited disturbance principle.

RR2009 - P304 - Recall principle

Rule Statement	Recall should be considered after the recommended period for vaccination has expired.
Remarks	• If immunization is recommended for a Patient 2 months of age, the recall for this immunization could be initiated at 3 months of age. For a dose of vaccine recommended for a Patient 15–18 months of age, the recall could be initiated at 19 months of age. • The RR Originator should consider the timeliness of reporting and recording data in the IIS in determining when to initiate an RR process. For example, if a Provider reports data to the IIS monthly, a RR process for recall of immunizations due at 2 months of age could be initiated at 4 months of age to account for the delay of up to one month in reporting data. • When a catch-up schedule is used (minimum intervals instead of the normally recommended ages), a certain time after the minimum interval should be allowed before a recall notice is sent.

RR2009 - P401 - Identify all Individuals eligible for RR principle	
Rule Statement	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.
Remarks	From a general Public Health perspective, it is more prudent to first find Patients who are due for RR, and only after that decide how to contact them (i.e., select an RR Notification method).

RR2009 - P501 - Limited resources principle	
Rule Statement	Reminder/Recall must be in line with available resources. Accordingly, not every recommended vaccination will result in a Reminder/Recall Notification.
Remarks	Resource-related considerations refer to the fact that IISs have limited human and financial resources to devote to RR
Example	Examples of resource limitation: • Personnel to validate and correct the contact and immunization information, make phone calls, and/or keep up with RR responses; • Personnel to train and re-train Providers • Mailing costs and postal fees, etc.

RR2009 - P502 - Limit disturbance principle

Rule Statement	For a given set of Vaccines, RR Notifications should be issued only once during a given period of time
Remarks	• Coordination of efforts among all the parties with responsibility for immunizations is important to avoid duplication of efforts – see P503. • For example, Individuals/Patients might be excluded from the RR process if they have already been issued a RR Notification within the past 30 days for a postcard or letter method (see P301, BR801, BR803).
References	RR2009 - P301 RR process initiation principle RR2009 - P303 Single RR Notification principle RR2009 - P503 Coordinate to avoid duplication principle RR2009 - BR801 RR2009 - BR803

RR2009 - P503 - Coordinate to avoid duplication principle	
Rule Statement	The RR process must be coordinated to eliminate duplication of RR by various RR Originators.
Remarks	• For example, the RR functionality would include a flag for Patients to whom an RR Notification was issued. • IIS should record number of RR Notification attempts for each Patient, the date, type, and RR Originator. This information should be accessible to IIS users.

RR2009 - P504 - Supremacy of Recall over Reminder principle	
Rule Statement	If resources are limited, Recall is more important than a Reminder.
Remarks	Exception: in public health emergency situations available resources might be focused on emergency-related reminders.
References	RR2009 - BR501 RR2009 - BR502 RR2009 - BR503

RR2009 - P505 - Priority for children 0–24 months of age principle	
Rule Statement	Priority should be given to Recall Notifications for children 0-24 months of age.
Remarks	• Since infants are at most risk for serious disease if they are not vaccinated the IIS may choose to target infants who do not have any record of immunization by a certain age, e.g., by 3 months of age.

	• Vaccine series completion rates for different age groups should be taken into consideration when prioritizing use of limited resources (e.g., series completion by 19 months of age is 90%; but series completion is 60% at 4 months of age).
References	RR2009 - BR501 RR2009 - BR502 RR2009 - BR503

RR2009 - P506 - Timeliness principle	
Rule Statement	Timeliness of data recorded in the IIS should be taken in consideration for issuing/delaying RR Notifications.
Remarks	For example, if a Provider reports data to the IIS monthly, a RR process for recall of immunizations due at 2 months could be initiated at 4 months to account for the delay of up to one month in reporting data.

RR2009 - P507 - Baseline immunization coverage level principle	
Rule Statement	Baseline immunization coverage level should be taken in consideration for issuing/delaying RR Notifications.
Remarks	For example, if the “on-time” baseline immunization coverage level is low, a Reminder plus one or more Recall Notifications may be cost-effective. If the baseline “on-time” immunization coverage level is high, Reminders may not be as cost effective as one or more Recall Notifications.

RR2009 - P601 - A variety of RR Notification methods principle	
Rule Statement	IIS should have more than one RR Notification method.
Remarks	Availability of multiple RR Notification methods allows more flexible and cost-effective approach to RR.

RR2009 - P602 - Combine RR Notification methods principle	
Rule Statement	Effectiveness of Reminder/Recall can be increased by combining various RR Notification methods.
Remarks	Based on [4.7], a letter followed by a telephone message was significantly more effective than either a letter alone or a telephone message alone. A telephone message followed by a letter was more effective than either alone, although the differences were not statistically significant.

References	RR2009 - P802 RR escalation principle

RR2009 - P603 - Consider data quality principle	
Rule Statement	RR Notification method should take into consideration the available contact information (data quality issue).
Example	To use phone as an RR Notification method, the IIS must have current phone numbers recorded.
References	RR2009 - GR601 in chapter 4

RR2009 - P604 - Cost-effectiveness principle	
Rule Statement	Reminder/Recall should employ the most cost-effective RR Notification method based on resources available.
Remarks	• The most cost-effective method of RR Notification is a method that brings the highest return in terms of timeliness and completion of immunizations per dollar spent. • Cost effectiveness of methods will change as technology progresses
References	RR2009 - BR602

RR2009 - P605 - Supremacy of Provider communication principle	
Rule Statement	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	
Rule Statement	The RR Notification method impacts the frequency of RR and target population.
Remarks	• For example, a telephone call may be followed by a second phone call the following day, but two postcards should be separated by several weeks. • IIS might use modern electronic methods to communicate with adolescents.

RR2009 - P701 - Comply with HIPAA interpretation principle	
Rule Statement	The RR Notification content must comply with the RR Originator's interpretation of HIPAA requirements.

Remarks	For example, the RR Originator may require that information concerning specific immunization must be in a letter and not on a postcard

RR2009 - P702 - Dependency on data quality principle	
Rule Statement	The specificity of the RR Notification should reflect the quality of data recorded in the IIS.
Remarks	For example, the RR Notification could read: "Your child is missing the 4th DTaP" vs. "Your child may be overdue for an immunization".

RR2009 - P703 - Best message for the audience principle	
Rule Statement	Social marketing techniques and research should be used to determine best messages for the target audience.
References	RR2009 - GR402 (in chapter 4) RR2009 - GR403 (in chapter 4)

RR2009 - P801 - Track RR results principle	
Rule Statement	RR results (responses and outcomes) must be systematically tracked.
Remarks	Systematic tracking means that the RR Status Indicator (not just text-based RR Log) should be used to monitor the status of RR Notifications (See the Chapter 5 "Evaluation of Reminder/Recall outcomes and responses").
References	RR2009 - GR103.

RR2009 - P802 - RR escalation principle	
Rule Statement	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.
Remarks	• A letter followed by a telephone message was significantly better than either a letter alone or a telephone message alone in one study [4.7]. A telephone message followed by a letter, also was more effective than either alone, although the differences were not statistically significant. [4.7] • See the domain model section for a definition of "unsuccessful attempt". • See Chapter, 3 section "Selection of the RR Notification method".

	• The number of RR attempts is associated with changes in Patient status. The rules regarding changes in Patient's status prescribe that a certain number of RR attempts to be made; in some cases, RR Notification methods can be prescribed as well. See MIROW MOGE document [1.1].

RR2009 - P803 - Elevation of responsibility principle	
Rule Statement	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.
References	RR2009 - BR802.

RR2009 - P804 - Repeated Notification principle	
Rule Statement	Providing multiple RR Notifications is more effective than a single RR Notification.
Remarks	Based on the literature sources, e.g., [4.2]

VD2006 - BR01	
Rule Statement	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.
Remarks	• This business rule is applied first and is the precondition for the use of any other business rules. • An explanation for 23 days window: most shots allowed to be made within 28 days of each other, minus 4 days grace period. Not all states use such a grace period (e.g., Vermont). • Size of the date window should be the same regardless of how data came to the registry (e.g., user interface, electronic upload, etc.), or the source or nature of the data (billing/clinical). Also, see the discussion of the recommended size for the date window – below. • Additional conditions should be evaluated to exclude typos-related errors and generic—e.g. month/year, without a date—entries.
References	Illustrative scenarios S001 – S005 at the end of this chapter.

VD2006 - BR02	
Rule Statement	A record for the vaccination event must be compared with all and any of the vaccination event records with the same Vaccine -Family/Group.
Remarks	Combination vaccines are related to more than one Vaccine – Family/Group. If there is a partial match within the Vaccine Family/Group Name (a combination vaccine), they need to be examined.
References	Illustrative scenarios S004, S005 at the end of this chapter.

VD2006 - BR03	
Rule Statement	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.
Remarks	This business rule addresses the real probability that a provider will continue to send in complete histories for a patient and so the same record will be received many times. Two records can be considered identical if they have identical values for the following minimum set of variables: date, provider, vaccine type. This business rule cannot be applied to incomplete records, where some of these data elements are missing.

VD2006 - BR09	
Rule Statement	Records selected for evaluation at the Selection phase should be considered different until proven to be duplicates.
Remarks	• At the beginning of evaluation it should be assumed that two records are different; the information that contradicts that assumption should be looked for. • Reason: false-negatives (false non-matches) are better than false-positives (false matches) because false positives result in the loss of the immunization data. See also the discussion on pp. 76-78. • When evaluation of two potentially duplicate records results in the decision “Don’t know,” manual review should be conducted to clarify the situation in terms Match/Differ. If the manual review cannot help to determine the outcome or if registry does not have resources to conduct a manual review, then this business rule BR09 should be applied and these records should be designated as different (not duplicates).

	• This business rule should be applied last, only after evaluation with other business rules is inconclusive.
References	Illustrative scenarios S006, S012 for implementation examples.

VD2006 - BR10	
Rule Statement	If vaccine lot numbers are different in evaluated records, these records are most likely to be different (not duplicates).
Remarks	• Additional conditions could be evaluated to exclude typos-related errors and generic—e.g. 9999—entries. • Lot number provides the most discriminating information, but is present only in ~10% of records in Wisconsin, 35% in Michigan, 15% in Minnesota. • The same lot number could be used by a single provider (as well as by different providers) over a period of time; therefore match in lot numbers is not decisive for the records evaluation. • At this point, in the Evaluation phase, family/group name is the same since only records that belong to the same family/group were selected during the previous, Selection phase.
References	Illustrative scenarios S007, S008 for implementation examples.

VD2006 - BR11	
Rule Statement	If vaccination encounter dates are the same in evaluated records, these records are most likely to be duplicates.
Remarks	• Additional conditions could be evaluated to exclude typos-related errors. • At this point – in the Evaluation phase - family/group name is the same since only records that belong to the same family/group were selected during the previous – Selection phase.
References	Illustrative scenario S014 for the implementation example.

VD2006 - BR12	
Rule Statement	Distinctive combinations of variables (presented in Table 4) should be considered for the evaluation of candidates records.
Remarks	This business rule is based upon principle P09 and provides general clues for the evaluation of candidate records.
References	Illustrative scenarios S009, S017 for implementation examples.

VD2006 - BR13	
Rule Statement	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.
Remarks	The following method of combining sequential (deterministic) and weighted (probabilistic) approaches is recommended: evaluate most discriminating variables and combinations of variables first (e.g., lot number, encounter date), then use aggregated score (weights-based) to confirm results of that evaluation.

VD2006 - BR14	
Rule Statement	Some immunizations are supposed to be given within 2 days of each other.
Example	Rabies, oral typhoid vaccines.

VD2006 - BR15	
Rule Statement	• 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.
Remarks	• Record Source Type is “Administered” or “Historical” (see item 30 in Table A-1, Appendix A). • “Administered” is from Primary Submitter, “Historical” is from Secondary Submitter – see Matrix of confidence levels - Table 9. • If both records are “historical”, it does not provide the distinctive information to make a decision match/differ.
References	VD2006 - P10 Illustrative scenarios S0010, S0011, S013, S006A for implementation examples.

VD2006 - BR20	
Rule Statement	The record with the highest level of confidence should be selected.

Remarks	• See Table 9 for the matrix of confidence levels for vaccination data. • Additionally, confidence level can be adjusted based on a personal profile of each provider/submitter (see notes for Table 13 below and the "Providers-related recommendations" discussion on pp. 73-74).
References	Illustrative scenarios S011-RES, S013-RES, S006A-RES for the implementation examples.

VD2006 - BR21	
Rule Statement	The record with more complete data should be selected.
Remarks	• The record with more important variables (Table 10) present should be selected. • This rule specifies preferences of one variable over another variable: e.g., presence of the lot number is more important than trade name or vaccine type as per Table 10.
References	Illustrative scenario S014-RES for the implementation example.

VD2006 - BR22	
Rule Statement	The record with more specific data should be selected.
Remarks	For example, a record with more specific vaccine type—Hib-PRP-T—should be selected over the record with more generic vaccine type—Hib-unspecified.
References	Illustrative scenario S016-RES for the implementation example.

VD2006 - BR23	
Rule Statement	The record that represents a combo vaccine should be selected.

VD2006 - BR24	
Rule Statement	The existing record should be selected over the incoming record.

VD2006 - BR25

Rule Statement	Records with earlier or later date should be selected consistently within a particular IIS.
Remarks	• This business rule should be applied only if implementation of business rules BR20-24 has not resulted in selection of the best record. • If a particular IIS has resources available, records can be sent to a manual review. • If a particular IIS has resources available, selection of the record can be made based on the influence of this selection on the clinical status of the immunization series (see the following notes). • Selection of the record with earlier or later date in some cases can affect the clinical status of the vaccine series and lead to the extra-immunization of a patient (extra-immunization is preferred over the under-immunization). • Example 1: a child has records of DTP1 shots given on 6/6/05 and on 6/16/05; these records found to be duplicates. DTP2 for that child is given on 7/8/05. If 6/6/05 shot is selected, then DTP2 is valid, but if 6/16/05 shot is selected, then DTP2 is not invalid (22 days between DTP 1-2, the minimum interval of 24 days has been violated). So, the DTP2 shot will have to be repeated in a later case. • Example 2: a symmetrical to Example 1 case in which selecting the later date would not lead to a repeated immunization of the patient. One DTP1 dose given on 6/16/05. Then you have DTP2 doses given on 7/8/05 and 7/18/05; and these are found to be duplicates. Choosing the later DTP2 on 7/18/05 means the doses are far enough apart and valid. Choosing the earlier DTP2 would make it invalid and result in it having to be repeated. Here, the earlier choice leads to a repeated immunization, as contrasted with the Example 1. • Note: at this stage records under consideration cannot be absolutely identical, otherwise they would not be selected as potential duplicates at the beginning of the process during the Selection phase (see BR03 “Identical records should not be selected for deduplication”).
References	Illustrative S009-RES for the implementation example.

VD2006 - BR30	
Rule Statement	If both records have the same information for a variable, then that information should be used in the consolidated record.
Remarks	Although seemingly obvious, the rule should be stated explicitly to cover all situations.

VD2006 - BR31	
Rule Statement	Known information for a variable should be used instead of unknown.
Remarks	If the best record does not have information for a certain variable and another duplicate record does have that information, the known information for a variable should be used in the consolidated record.

VD2006 - BR32	
Rule Statement	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.
Remarks	See Table 9 for the matrix of confidence levels for vaccination data. BR32 has to be applied before BR33.

VD2006 - BR33	
Rule Statement	If duplicate records have different information for a variable, the more specific information should be incorporated into the consolidated record.
Remarks	For example, a more specific vaccine type—Hib-PRP-T—should be selected over the more generic vaccine type —Hib-unspecified. Another example could be unspecific date (month and year only) versus a specific (complete) date.
References	See scenario S016-RES for the implementation example.

VD2006 - P04	
Rule Statement	We would like to be more inclusive than exclusive.
Remarks	See discussion of false positives versus false negatives on p.76 See discussion regarding the size of the window for selecting candidate duplicate records below.

VD2006 - P09	
Rule Statement	A match in some variables is more important than others.

Remarks	E.g., lot number vs. vaccine event route: difference in lot numbers is much more important.

VD2006 - P10	
Rule Statement	The degree of confidence in the data should be taken into consideration.
Remarks	Additional conditions should be evaluated if confidence in the data quality is low; see matrix of confidence levels, p. 56.
References	VD2006 - BR15

VD2006 - P11	
Rule Statement	If vaccination encounter dates are different in records under evaluation, the proximity of these dates has to be taken in consideration.
Remarks	• Records that are 2 days apart are more likely to be duplicates than records that are 22 days apart. • A measure of difference should be used for the Vaccine Encounter Date variable since 23-day window is implemented. The bigger the difference between dates, the smaller the weight should be. In other words, for the weights-based approach weights should be adjusted for dates mismatch relative to the degree of difference, e.g. -1 weight if 1 day difference, -10 weight for 23 days difference. • Note: Records selected during the Selection phase belong to the same family/group and have vaccination date within a certain date window.
References	Illustrative scenario S016 for the implementation example.

VD2006 - P12	
Rule Statement	Considerations of front-end vs. back-end processing should not have impact on the decision match/differ for the evaluated records.
Remarks	The fact that one of the records is incoming and another record is existing, or both records are existing, or both records are incoming has no impact on the decision match/differ for the evaluated records.

VD2006 - P13	
Rule Statement	Registries should track the variable "Vaccination Event Submission-Record Source Type" ("administered" vs. "historical") for each record.

Remarks	Presence of this information could make a decisive difference: see, for example, illustrative scenarios S006 and S006A at the end of this chapter.
References	Illustrative scenarios S006 and S006A at the end of this chapter.

VD2006 - P15	
Rule Statement	Business rules should be applied completely, in a specified sequence.
Remarks	The sequence is: BR20-BR21- BR22-BR23-BR24. See Figure 6 below for the illustration of sequential implementation of business rules.

VD2006 - P18	
Rule Statement	A consolidated record at the vaccination level that merges all available information from duplicate records and other sources should be created.
Remarks	Creation of a consolidated record at the vaccination level that merges all available information from duplicate records and other sources is the only way to ensure that the immunization event is documented most comprehensively into a single, accurate immunization record.

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