



pan-Canadian Patient Summary

Companion Guide: Use Cases and Definitions

Version: 1.1.0

Type: Draft

Release Date: December 15, 2023



Table of Contents

1	Introduction	3
2	Intended Audience.....	4
3	Purpose.....	5
4	Patient Summary Overview.....	6
4.1	What is IPS and Patient Summary?	6
4.1.1	What problems do they solve?	6
4.2	Prioritizing Patient Summary	6
4.2.1	Infoway's Role:	7
4.3	What tangible benefits we can expect?.....	7
4.3.1	Projected Annual Benefits:	9
5	Use Cases.....	10
5.1	Use Case Index	10
5.2	UC-01: HCP Creates a PS-CA	11
5.3	UC-02: HCP Views/Consumes a PS-CA	15
5.4	UC-03: Patient Views/Consumes a PS-CA	18
6	Requirements Definition.....	22
6.1	Requirements Structure	22
6.2	Requirements Identification.....	23
6.3	Requirements for Interoperability Testing	23
6.4	Requirements for Guidance and Support.....	26
6.5	Requirements: Full Set.....	30
6.5.1	Business and Legal Requirements	30
6.5.2	Information and Semantic Requirements	38
6.5.3	Technical Requirements.....	39

1 Introduction

The pan-Canadian Patient Summary - Companion Guide to Use Cases & Definitions is a companion document to the pan-Canadian Patient Summary Interoperability Specification that presents the broader context for clinical, business, interoperability and solution development considerations that were discovered during the development of the PS-CA. It defines the healthcare problem that the PS-CA addresses and includes healthcare use cases and interoperability requirements in terms that will be traceable to the content in the pan-Canadian Patient Summary - Companion Guide to Reference Architecture, which defines the actors and their interactions with other actors and the pan-Canadian Patient Summary – FHIR Implementation Guide, which defines the contents and semantic interoperability of the PS-CA.

This document will also support upcoming releases and roadmap elements of the PS-CA specifications.

2 Intended Audience

The intended audience of the Use Cases & Definitions includes, but is not limited to, the following:

- Non-technical decision makers
- IT departments of healthcare institutions (technical product managers, IT managers, operations staff)
- Technical staff of vendors participating in the IHE initiative
- Experts involved in standards development
- Health Care Providers participating in the creation and use of patient summaries
- Individuals and teams responsible for implementing software solutions such as project managers, CTOs, CISOs, software engineers, technical product managers, IT managers, operations staff, and other similar roles.

3 Purpose

The purpose of this document is to present the use cases and definitions for the Patient Summary-CA project, including:

- the Patient Summary-CA definition
- clinical benefits and value of the Patient Summary-CA, as described by Canadian health care providers
- use cases and scenarios and
- interoperability and solution requirements, categorized as:
 - Business and Legal,
 - Information and Semantic; and
 - Technical.

4 Patient Summary Overview

4.1 What is IPS and Patient Summary?

The IPS (International Patient Summary) is an electronic health record extract containing essential healthcare information about a subject of care. It represents a minimal and non-exhaustive set of clinically relevant standardized patient data, specialty-agnostic, condition-independent, but readily usable by all clinicians for unscheduled (cross-border) patient care. While focused on unscheduled cross border care, it also provides generic and potentially reusable solutions for global application beyond a particular region or country.

The Patient Summary - Canada (PS-CA) standardized profiles (or specification) leverage the principles of the IPS and (currently) its datasets to provide a core patient summary that supports the provision of effective, high quality patient care within the Canadian context. Developed in collaboration with jurisdictions and their clinicians, PS-CA outlines the critical high priority data clinicians want, the data standards (data language) all systems need to speak to exchange the data and standardized methods to exchange the data, such as [CA:FeX](#) (Canadian FHIR exchange).

4.1.1 What problems do they solve?

Even in the age of digital health, system incompatibilities across the spectrum and a lack of data integration and portability at points of care mean that data is often “locked” in an individual system. This causes several issues:

1. Unless visiting their own family physician (where the bulk of primary data resides), most other healthcare episodes typically lack access to data, raising the risk of unintended side effects or adverse reactions and reducing quality of care unintentionally
2. Patient satisfaction suffers as expectations are not met due to extended waiting times for diagnosis, when information is either missing or inaccessible and at times inaccurate
3. Inefficiencies in care provision due to time required to locate information for clinicians already feeling burn-out
4. Inability for funders to receive reliable business intelligence to support the most effective funding decisions

When data language, common data elements and exchange methods are aligned and technical components are available, information can be shared quickly, efficiently, and easily whether within a region, a province, a country or international setting.

4.2 Prioritizing Patient Summary

Patient summary is a container that includes the most relevant health data domains that capture and consolidate patient information across various health care settings. Over 200M transactions occur using these domains, across Primary and Acute care settings alone, through EMR point of service systems; representing the highest contributions to patients’ medical summaries. Solving for the exchange of patient summaries is key to resolving some of the challenges above.

Infoway has a history of collaboration with jurisdictions in supporting foundational and pivotal transformation. Whether the move from paper to electronic records, in-person visits to virtual visits and, standardization of data using internationally recognized standards (common data language for systems), we see the next critical transition to be the unlocking of patient data. The pandemic has further outlined the need to consider patient health data not just from a local or even national perspective, but also from a global perspective.

Many jurisdictions have also recognized this and made patient summary a priority and as we have always done, we will continue to support and align with jurisdictions in meeting their goals and advancing the Canadian healthcare landscape.

4.2.1 Infoway's Role:

Recognizing that healthcare delivery in Canada has several specializations that are the same content but use a different data language, Infoway is:

- Collaborating with jurisdictions and key stakeholders to consolidate the requirements
- Assessing the existing content to define and standardize the common elements across all jurisdictions to outline the base foundational profile for all
- Reviewing jurisdictional profiles to ensure alignment to the common profile
- Aligning the core profiles against internationally recognized standards, including the IPS
- Providing technical and data standards (data language) leadership and expertise
- Representing Canada in the international community focused on data standards and interoperability such as GDHP and its members, IHE International and its affiliates, we bring the Canadian context to advance international specifications and advocate for changes based on stakeholder feedback
- Educating vendors about the new profiles and how to implement them and lastly,
- Testing and scoring vendor implementations on their alignment to the published pan-Canadian specifications

4.3 What tangible benefits we can expect?

PS-CA is a stepping-stone towards the future. It allows access to the most critical patient data now, while allowing the room to build out modern, "just in time", secure and access-controlled ecosystems that respect patient privacy while allowing citizens to participate in the delivery of their own care. Common standards for Patient Summary including the way in which it's exchanged, can realize multiple benefits to different stakeholders, including the ability for a single longitudinal patient record.

Stakeholder	Benefits
Patient	<p>Improved patient experience due to more efficient and comprehensive data sharing between providers leading to improved health outcomes.</p> <p>Having the ability to access and share their own personal health information.</p>
Health Care Funders	<p>Reduction in costs and time to implement patient summary and interoperability solutions due to availability of reusable data content and technical profiles that reflect 80+% of the common requirements.</p> <p>Availability of more reliable automated reporting to better target health care spending according to need.</p>

Jurisdictions	<p>Reduction in implementation burden due to centralized expertise in niche interoperability areas and reusable profile components, which also reduces resource demands.</p> <p>Ability to reuse data content and technical profiles that reflect 80+% of the common requirements which will decrease implementation timelines.</p> <p>Promotes better scalability and enhancements for patient summary solutions with minimal effort into the future where vendors can incorporate new elements without jurisdictional oversight.</p>
Vendors	<p>Ability to reuse significant number of standardized components to implement across all jurisdictions with minimal variability.</p> <p>Reduction in implementation time.</p> <p>Coordinated approach for all jurisdictions reduces complexity and resource requirements.</p> <p>Alignment to global standards also supports international vendors who will no longer need to specialize their solutions specifically for Canada.</p>

Clinicians/ Health Care Providers	<p>Enhanced communication between health providers: Bridged silos within the health system (e.g. between acute, primary and specialist care, long term care) to enable more effective coordination and transitions of care, in addition to improved support for clinical decision-making. The ability to communicate between different solutions, and/or different jurisdiction also facilitates cross-jurisdictional patient flows.</p> <p>Improved provider experience and increased satisfaction: More accessible and better-organized patient information leads to significant time savings, freeing time to spend with patients. Reduced administrative burden, improved workflow efficiencies and more targeted, effective use of practice hours helps prevent clinician burnout and facilitate clinician work-life balance.</p> <p>Improved data quality and currency: Clear, consistent records of past tests and results enable more focused investigations and testing, with reduced redundant/duplicative tests. Patient safety is improved through the availability of more timely, accurate information about the patient's medical history, potentially preventing harm, delayed care or inappropriate treatments.</p> <p>Supports the provision of virtual care: Providers delivering care through different modalities/solutions can access the same health information about a patient. Consistent access to information and better communication also facilitates encounters with unfamiliar providers at the point of care (i.e. a provider delivering care on a telehealth platform to a patient without a regular primary care provider).</p> <p>Better health outcomes: Consistent access to health information aids decision-making for clinicians and patients and supports proactive health management. Better coordination and transitions of care help to increase patient safety by improving timeliness of care, reducing duplicative testing and preventing instances of contraindicated medications and/or treatments. More effective care is received more quickly, across health care settings.</p>
-----------------------------------	--

4.3.1 Projected Annual Benefits:

The projected annual benefits at **50%** adoption are:

- **Safe & improved** transitions of care.
- **Health System = \$490M** in improved ambulatory interactions, effective use of ED, in-patient services and a reduction in duplicate lab/DI tests.
- **Canadians = \$448M** in saved patient time.
- **Clinicians = \$328M** in saved clinician time.

5 Use Cases

The purpose is to describe the use cases and workflow scenarios for sharing a patient summary profile across solutions. Each jurisdiction may have implementation variances within the use cases. Therefore, these use cases provide examples and are not meant to be inclusive of all possible implementation choices and do not represent required implementation choices. The use cases provide high-level interactions between the Health Care Providers, their Health Records System and other Health Records Systems. Use cases provide the business description or "conversation" between the system(s) and its user(s), known as Participants. Participants can be people (e.g., health care providers, patients, etc.) or systems (e.g., EMR, EHR Repository, etc.). Please note that detailed interactions are defined in the pan-Canadian Patient Summary - Companion Guide to Reference Architecture.

Each use case will include:

- use case scenario,
- examples of use case triggers, pre and post conditions,
- who the participants are (i.e., people and systems),
- a use case diagram to provide a visual representation of the interactions between participants,
- use case steps corresponding to the diagram and potential alternate flows; and
- reference to the corresponding business requirements.

5.1 Use Case Index

This section includes a proposed list of use cases which were identified as being priority use cases in the pan-Canadian environmental scan. Subsequently, through collaboration with the participating Canadian jurisdictions, the use case scope was further refined into priorities for the initial releases and those which will be included in future releases.

The scope for this release of the pan-Canadian Patient Summary – Interoperability Specifications has been defined to include use cases UC-01, UC-02 and UC-03.

The list below includes the use cases' ID, name and description. Following each use case is a list of the Canadian jurisdictions that have identified the use case as being applicable to their Patient Summary implementation for Release 1 or beyond.

Use Case ID	Use Case Name	Use Case Description	Identified by:
UC-01	HCP Creates a PS-CA	A Health Care Provider in any care setting creates a Patient Summary for use at point of care, which is made available to Patient Summary consumers.	AB, BC, NL, ON, SK
UC-02	HCP Views/ Consumes a PS-CA	A Health Care Provider in any care setting , views and uses a PS-CA at the point of care.	AB, BC, NL, ON, SK
UC-03	Patient Views/ Consumes a PS-CA	A Patient or Subject of Care accesses/views and can obtain a copy of their own PS-CA.	AB, BC, NL, ON

FUTURE SCOPE

In addition to the use cases identified as in scope for this release of the pan-Canadian Patient Summary – Interoperability Specifications, a set of use cases were identified for future consideration. Uses cases UC-04, UC-05 and UC-06 will be candidates for subsequent releases within the PS-CA Specifications roadmap.

Use Case ID	Use Case Name	Use Case Description	Identified by:
UC-04	HCP Sends PS-CA to another HCP as part of a Clinical Workflow (e.g. eReferral).	A Health Care Provider creates/produces a PS-CA and sends the PS-CA with other clinical documentation as part of a clinical care workflow (e.g. referral, consult etc.).	AB, BC, NL, ON, SK
UC-05	Patient Presents PS-CA to HCP	A Patient or Subject of Care presents their PS-CA to a HCP, who may view/consume the PS-CA, to support care.	AB, BC, NL, ON, SK
UC-06	HCP requests PS on Demand	A Health Care Provider in any care setting requests access to a real-time, on-demand PS-CA to be used at the point of care or as part of a clinical workflow (e.g. referral).	ON

5.2 UC-01: HCP Creates a PS-CA

Description

A Health Care Provider in any care setting creates a Patient Summary for use at point of care, which is made available to Patient Summary consumers.

Scenario

A patient schedules a visit with their regular health care provider, within their Medical Home, with symptoms including dizziness and an earache. The patient mentions that since they last visited, another clinic noted that they have high blood pressure (hypertension) which is being monitored at home for now. The patient also mentions a suspected penicillin allergy. The health care provider determines that the patient has an external ear infection (otitis externa) and prescribes antibiotics. The health care provider creates a clinical note in their EMR, which may trigger automatic updates, such as updates to the prescription information. The health care provider decides to create a new Patient Summary for this patient, or replace an existing Patient Summary if one had previously been created, and submit it to the jurisdictional EHR so that it is available for other health care providers who may be providing care for this patient.

Note that the implementation regarding what triggers the creation of a new Patient Summary or the replacement of an existing Patient Summary may be automated and/or vary between solutions. For example, updates to specific clinical information may trigger an update to an existing Patient Summary.

Triggers, Pre-conditions, Post-conditions

This section describes example triggers, pre-conditions & post-conditions related to the creation of the Patient Summary. It is not inclusive of all potential workflow scenarios which may be implemented within Canadian jurisdictions.

Triggers

- Health Care Provider provides care to a patient and updates the Patient's record.
- Health Care Provider receives additional information for a patient. For example, HCP receives test results for a Patient, updates the Patient's problem list, adds a clinical note, which triggers a new Patient Summary.

Pre-conditions

- Patient Summary shall uniquely identify the Patient so that it can be shared across jurisdictional systems (e.g., uniquely identified by a Client Registry ID)
- In jurisdictions where explicit consent is required to share the Patient Summary:
 - Patient provides, or has previously provided, consent to share their data to the EHR.

Post-conditions

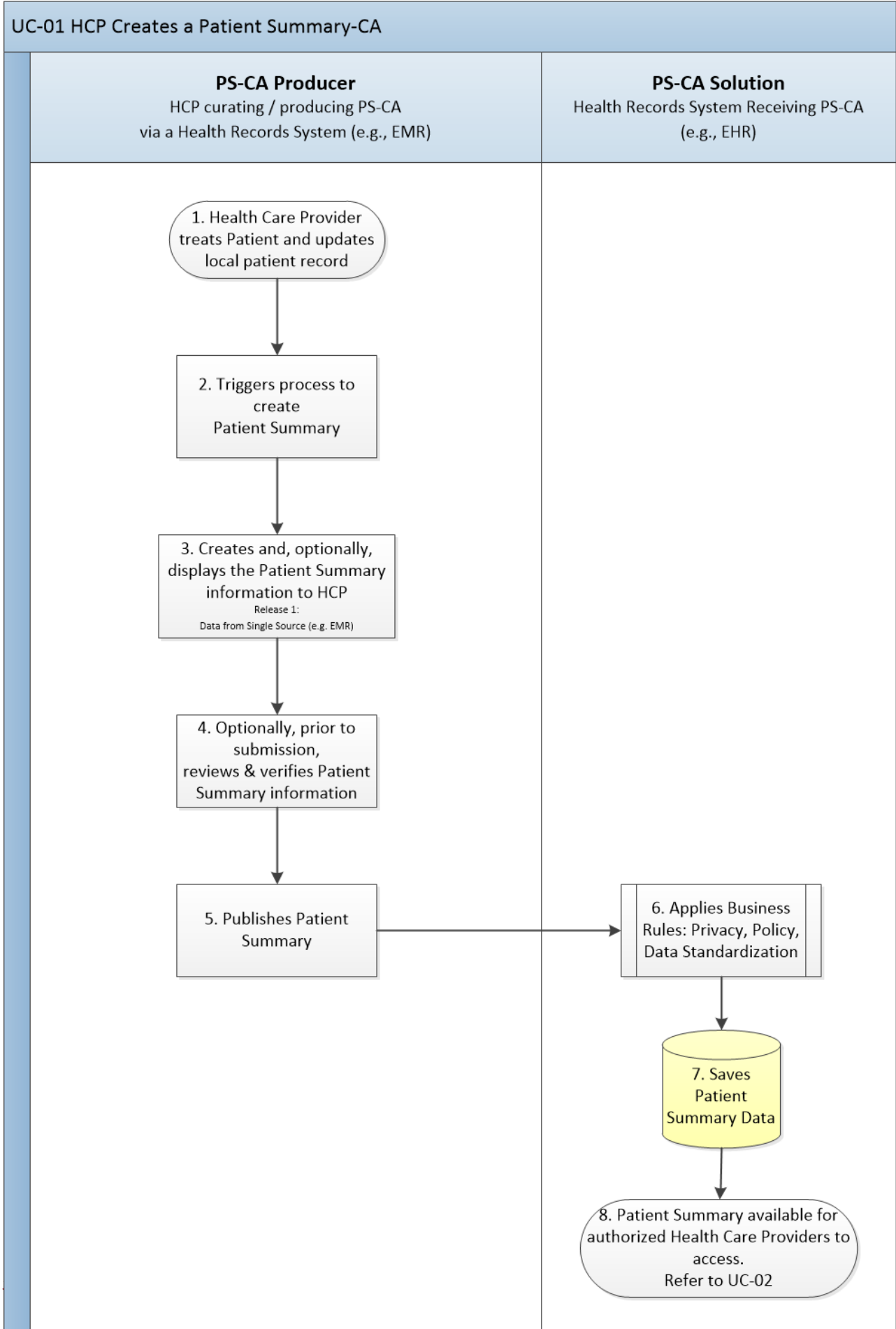
- New Patient Summary recorded/registered in the PS-CA Solution that receives the PS-CA. Where applicable, the Patient Summary may replace an existing Patient Summary (e.g. according to jurisdictional rules such as same Patient, same Provider, same Location)
- Authorized health care providers have access to view the new patient summary or, may receive a notification that a new patient summary is available for their patient.

Use Case Participants & Diagram

The participants involved in this use case are:

- PS-CA Producer (Health Care Provider curating / producing a PS-CA via a Health Records System)
- PS-CA Solution (Health Records System receiving the PS-CA)

This use case diagram represents the participants and their role in the use case with a high-level view of the flow of information.



Use Case - Primary Flow

The following provides a textual description corresponding to the use case diagram.

1. Health Care Provider treats Patient and updates the Patient's health record in their Health Records System (e.g., EMR, HIS).
2. Health Care Provider determines that a new Patient Summary should be created and requests the Health Records System (e.g., EMR) to create the patient summary information.
3. Health Records System (e.g., EMR, HIS) pulls the available Patient Summary information from within the local system (e.g. EMR creates Patient Summary with data solely from the EMR Patient Chart).
4. Health Care Provider, optionally, reviews and validates the Patient Summary prior to sharing/publishing the Patient Summary.
5. Health Care Provider sends / publishes the Patient Summary to the receiving Health Records System (e.g., EHR).
6. Receiving Health Records System (or data processing layer i.e. jurisdictional hub) applies business rules (e.g. data standardization, privacy, policy, etc.).
For example:
 - a. Validation of Patient Summary data (e.g. Provider identified and eligible to submit a Patient Summary, Patient identified, etc.)
 - b. Checks for existing Patient Summary for same patient/same provider - apply replacement / archiving rules
7. Receiving Health Records System records/saves the Patient Summary.
8. Patient Summary available for access by authorized Health Care Providers. (Refer to UC-02 HCP Views/Consumes a PS-CA)

Use Case - Alternate Flow

The following list provides possible alternate flows that may occur within this use case.

- Step 4: Health Care Provider has the option to bypass an additional review of the Patient Summary, allowing the Health Records System to automatically share/publish the Patient Summary to the receiving Health Records System.
- Step 4: Health Care Provider, upon review of the Patient Summary, chooses to make changes to the Patient's medical information within the Patient's health record prior to publishing the Patient Summary. If the changes affect the content of the Patient Summary, a new Patient Summary will be created.
- Step 4: Health Care Provider, upon review of the Patient Summary, chooses to withhold some or all of the information within the Patient Summary from being shared/published to another Health Records System.
- Step 5: Health Care Provider, after submitting the Patient Summary, identifies that there is incorrect or missing information on the patient summary. The HCP will have the option to create and publish a new Patient Summary to replace the previously submitted Patient Summary.
- Step 5: Health Care Provider, after submitting the Patient Summary, identifies that there is incorrect information or the Patient Summary is for the wrong patient. The HCP will have the option to retract / delete the most recent Patient Summary that they submitted with the same Patient, Provider and Location identified.
 - **Note:** Business rules for how a document management system manages documents it has received (e.g., when is it appropriate to delete a document, how long should it be archived, when should the system alert users of new information, etc.) is outside of the scope of the current PS-CA specifications. Additional use cases and business rules will be tackled in forthcoming releases of the

PS-CA specifications. This release is intended to be a technical building block that new use cases can build off of.

5.3 UC-02: HCP Views/Consumes a PS-CA

Description

A Health Care Provider in any care setting , views and uses a PS-CA at the point of care.

Scenario

A patient schedules a visit with a health care provider, outside of their Medical Home, with symptoms including dizziness and an earache. The patient mentions that they have a regular health care provider, within their Medical Home, and experience high blood pressure (hypertension) which is being monitored at home for now. The health care provider collects information from the patient and searches their Patient Summary-CA Solution for an existing Patient Summary (e.g., searches the network to determine if a Patient Summary was created and shared by another Health Care Provider). Upon finding a Patient Summary for their patient, the health care provider views and uses the information in the Patient Summary in support of providing care for this patient.

Triggers, Pre-conditions & Post-conditions

This section describes example triggers, pre-conditions & post-conditions related to the creation of the Patient Summary. It is not inclusive of all potential workflow scenarios which may be implemented within Canadian jurisdictions.

Triggers

- Health Care Provider gathers all available information about their patient to provide care.
- Where applicable, HCP received a notification that new Patient Summary information is available for a Patient to which they have subscribed to receive notifications.

Pre-conditions

- In jurisdictions where a patient may have applied consent directives to their Patient Summary, HCP complies with local/jurisdictional privacy policies.

Post-conditions

- Health Care Provider views and uses the Patient Summary in support of Patient care.

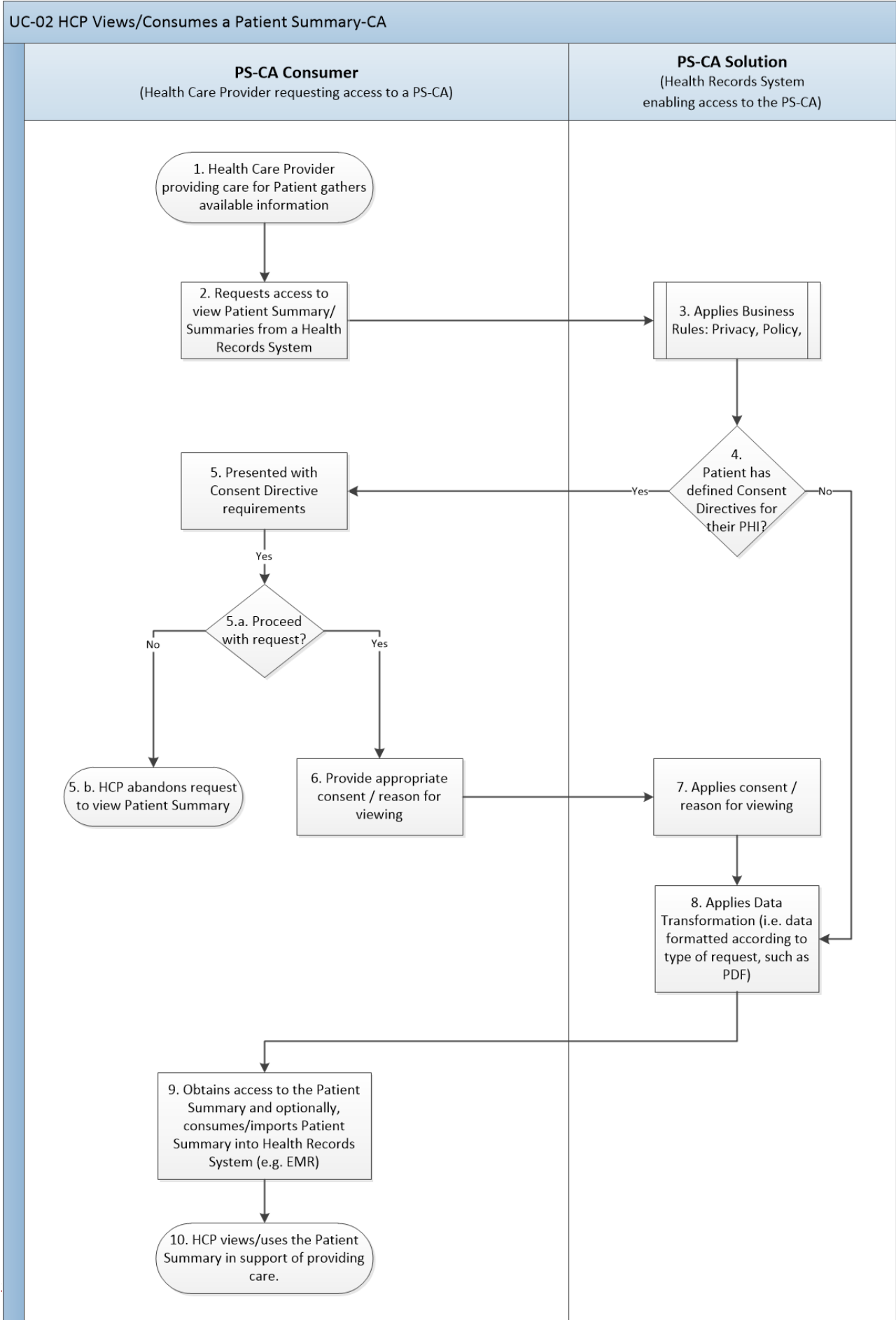
Use Case Participants & Diagram

The participants involved in this use case are:

- PS-CA Consumer (Health Care Provider requesting access to a PS-CA)

- PS-CA Solution (Health Records System enabling access to the PS-CA)

This use case diagram represents the participants and their role in the use case with a high-level view of the flow of information.



Use Case - Primary Flow

The following provides a textual description corresponding to the use case diagram.

1. Health Care Provider, providing care for their Patient gathers information from the Patient and other information that may be available in the PS-CA Solution (e.g. Health Records System such as an EHR).
2. Health Care Provider requests access to view an existing Patient Summary for their Patient from the PS-CA Solution.
3. PS-CA Solution applies applicable business/privacy/policy rules (e.g., privacy rules related to consent).
4. PS-CA Solution determines if there are patient consent directives applied to the Patient Summary. If yes, proceed to step 5. If there are no consent directives applied, proceed to step 8.
5. Health Care Provider is presented with the patient's consent directives in their Health Records System (e.g., EMR).
 - a. HCP chooses to proceed with the request to view the Patient Summary? If yes, proceed to step 6. If no, proceed to step 5 b.
 - b. HCP chooses to abandon the request to view the Patient Summary. Process complete. (Refer to Alternate Flow for step 5 b.)
6. Health Care Provider abides by the applicable local/jurisdictional privacy policies (e.g., provides reason code for viewing the Patient Summary).
7. PS-CA Solution applies the applicable local/jurisdictional privacy policy information provided by the HCP (e.g., records the reason code for viewing the Patient Summary).
8. PS-CA Solution applies data transformation and access to view/consume the Patient Summary (e.g., Provide request to view the PS information in PDF format).
9. Health Care Provider obtains access to the Patient Summary and, optionally, consumes the information into their Health Records System.
10. Health Care Provider views/uses the most current Patient Summary information available in support of caring for the Patient.

Use Case - Alternate Flow

The following list provides possible alternate flows that may occur within this use case.

- Step 5.b. Provider is not authorized to view the Patient Summary. Process abandoned and HCP does not obtain access to Patient Summary. HCP, alternatively, collects additional input from the Patient.

5.4 UC-03: Patient Views/Consumes a PS-CA

Description

A Patient or Subject of Care accesses/views and can obtain a copy of their own PS-CA.

Scenario

A patient, or their designated caregiver, would like to access their patient summary information to stay up to date with their medical health information, contained within the Patient Summary, empowering them to play an active role in their own care.

Note that a jurisdictional implementation may choose to present a different version of the Patient Summary to patients than providers. For example, the patient version of the Patient Summary may use more patient friendly language, certain information that might lead to patient harm may be redacted (for example, in the case of patients undergoing behavioral health treatment).

Triggers, Pre-conditions, Post-Conditions

This section describes example triggers, pre-conditions & post-conditions related to the creation of the Patient Summary. It is not inclusive of all potential workflow scenarios which may be implemented within Canadian jurisdictions.

Triggers

- Patient, or their designated caregiver, chooses to view the patient summary to stay informed of their medical information.
- Patient wants to obtain a copy of their patient summary to have on their person while travelling.
- Patient wants to obtain a copy of their patient summary to share with another care provider.

Pre-conditions

- A jurisdictional clinical system with patient access is available.
- A patient summary has been created for the patient. (Refer to UC-01 and UC-06) Note that the patient summary assembled for a patient may contain a different / modified set of data than is assembled in the patient summary for a health care provider.
- Patient has setup up a personal account, with username/password, in the jurisdictional clinical system (e.g., patient portal)
- If applicable, patient has designated and authorized a designated caregiver to access their personal health record on their behalf.
- Patient, or designated caregiver, has logged into the jurisdictional clinical system (e.g., patient portal).

Post-conditions

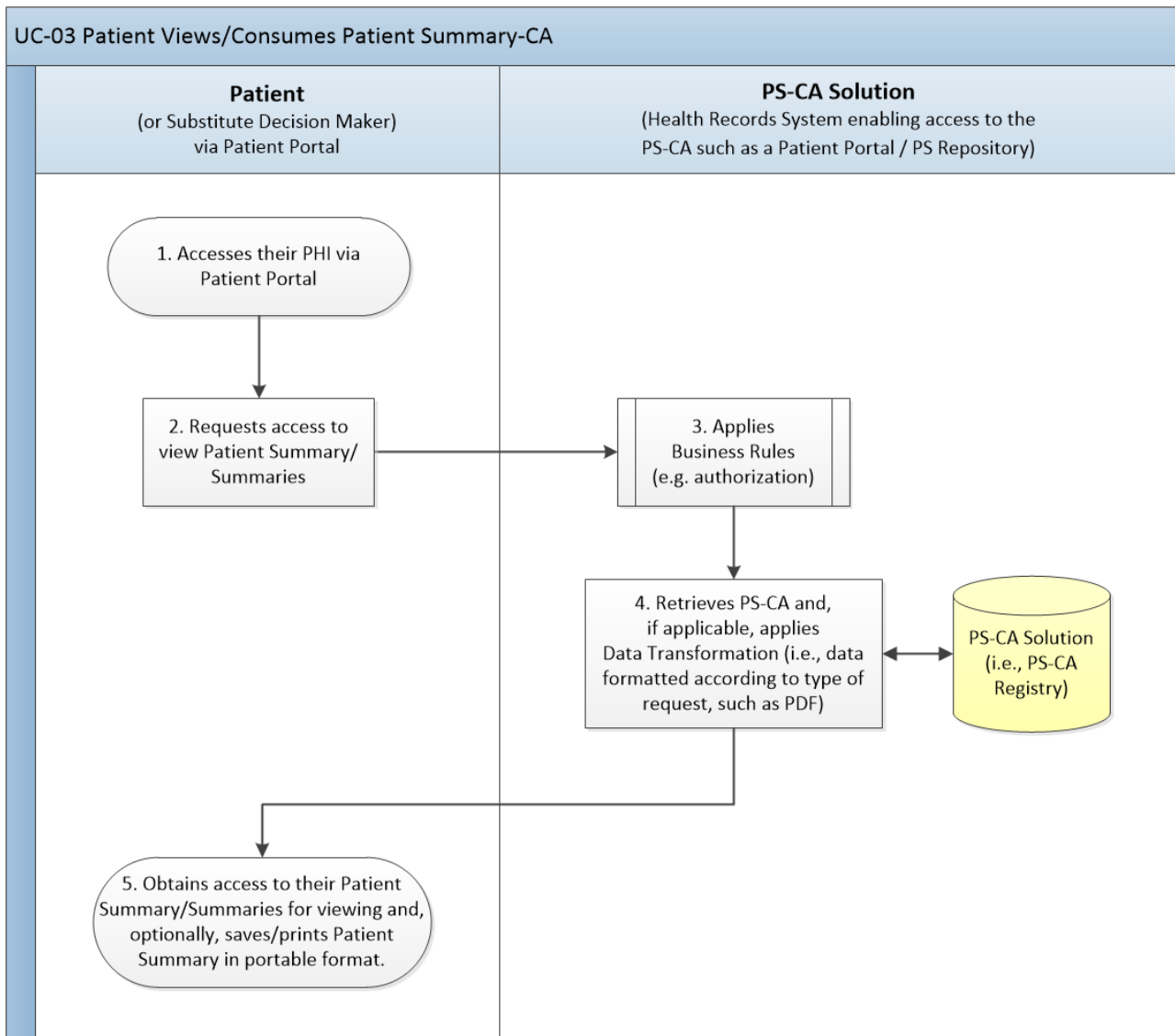
- Patient, or their designated caregiver, accessed and viewed their own patient summary.
- Optionally, the patient, or their designated caregiver, has obtained a copy (e.g. download or printed report) of their patient summary.
- Patient, or their designated caregiver, presents the patient summary to another health care provider to support continuity of care. (Refer to UC-05 where the Patient presents their Patient Summary to a Health Care Provider in another jurisdiction.)

Use Case Participants & Diagram

The participants involved in this use case are:

- Patient / Subject of Care via Patient Portal
- PS-CA Solution (e.g., PHR)

This use case diagram represents the actors and their role in the use case with a high-level view of the flow of information.



Use Case - Primary Flow

The following provides a textual description corresponding to the use case diagram.

1. Patient / Subject of Care navigates to their personal health information via a Patient Portal.
2. Patient / Subject of Care or Substitute Decision Maker requests access to view their Patient Summary / Summaries.
3. PS-CA Solution (e.g., PHR) applies applicable business/policy rules (e.g. validates the patient's credentials).
4. PS-CA Solution (e.g., PHR) retrieves the PS-CA (from local storage or from an external PS-CA Registry). If applicable, the PS-CA Solution may apply data transformation, such as formatting the information into a PDF.

5. Patient / Subject of Care obtains access to their Patient Summary/Summaries and optionally, prints/saves the document in a portable format.

Use Case - Alternate Flow

The following list provides possible alternate flows that may occur within this use case.

- A substitute decision maker, with the designated permissions, accesses/obtains the Patient Summary.

6 Requirements Definition

The requirements definition contains a consolidation of interoperability and solution requirements to support the pan-Canadian Patient Summary Interoperability Specifications. The requirements include:

- interoperability requirements which can be tested/validated through prototyping; and
- a broad set of requirements for consideration and to support and provide guidance to stakeholders in their PS-CA implementations. For example, supporting requirements may refer to local/jurisdictional policies and/or standards indicating that an implementer should validate specific requirement needs, if any, within a jurisdiction.

The requirements refer to a standardized expression of actors, entities, and user-system interactions, which will be further defined within the pan-Canadian Patient Summary - Companion Guide to Reference Architecture.

Definitions of the terms used throughout the requirements may be found in the PS-CA Specification: [Glossary of Terms & Acronyms](#).

Additional requirements may emerge and will be included in subsequent releases of the PS-CA specifications.

6.1 Requirements Structure

The Requirements have been defined within three categories (Business/Legal, Information Semantic, and Technical) and two subcategories (Interoperability and Solution), with three priority types (Shall, Should, and May), as described below:

Requirements Categories	
Business/Legal Requirements	<ul style="list-style-type: none"> • Requirements that enable independent organizations to execute a collaborative process or service.
Information Semantic Requirements	<ul style="list-style-type: none"> • Requirements for syntax and semantics such that data exchanged between health record systems can be interpreted and the meaning of the data ascertained.
Technical Requirements	<ul style="list-style-type: none"> • Requirements for one health record system to send data to another health record system and for the receiving system to acknowledge receipt of the data payload.
Requirements Subcategories	
Interoperability Requirements	<ul style="list-style-type: none"> • Requirements for one IT system to send data to another IT system and for the receiving system to acknowledge receipt of the data payload; • Requirements for syntax and semantics such that data exchanged between IT systems can be interpreted and the meaning of the data ascertained; • Requirements that enable independent organizations to execute a collaborative process or service.

Solution Requirements	<ul style="list-style-type: none"> • This is a broad list of requirements that can be used by jurisdictions to conceptualize how existing systems and COTS (commercial off-the-shelf) solutions may be used to create/produce, communicate, share and access/ consumer patient summaries based on the PS-CA standard. • Requirements may support the development of solutions and go beyond the Interoperability Requirements. • Further definitions of these requirements may be defined by jurisdictional policies.
Requirements Priorities	
Shall	<ul style="list-style-type: none"> • used to indicate a required requirement.
Should	<ul style="list-style-type: none"> • used to indicate that a requirement is recommended and should be considered as best practice for implementation, but not required (i.e., it is optional) for implementation.
May	<ul style="list-style-type: none"> • used to indicate that a requirement is permissible / optional, but not required for implementation.
Shall not	<ul style="list-style-type: none"> • used to indicate that an element or action is prohibited.

6.2 Requirements Identification

Each requirement is identified with a:

- Requirement ID: The first 3 characters of the requirement ID (e.g., BR#) represents the category assignment, followed by "-###" representing the requirement number within the category. For example:
 - **BR1-001** = First requirement within the Business/Legal Requirements category
 - **BR2-001** = First requirement within the Information/Semantic Requirements category
 - **BR3-001** = First requirement within the Technical Requirement category
- Definition
- Requirement Subcategory: Interoperability or Solution
- Type (i.e., Priority): Mandatory, Recommended or Optional

6.3 Requirements for Interoperability Testing

The following tables include a set of interoperability requirements that will be tested as part of the pan-Canadian Patient Summary Interoperability Specifications testing.

Note: Some of the requirements included in the Requirements for Guidance and Support section may be further developed in future PS-CA Specifications releases and re-categorized as Requirements for Interoperability Testing.

Business Legal: Requirements for Interoperability Testing

The following table contains a subset of the business / legal, information / semantic and technical interoperability requirements that will be tested as part of this release.

BR ID	Description	Type	Subcategory
BR1-05	A Patient Summary-CA Solution shall provide the ability for an authorized PS consumer (e.g. authorized health care provider) to ascertain the provenance (PS-CA author, producer, date and subject of care) of a current and historical PS.	Mandatory	Interoperability
BR1-11	A Patient Summary-CA Solution shall limit the sharing of health information to what is clinically necessary and sufficient, in accordance with governing legislation and the Patient Summary-CA specification. Note: For example, the clinician will have the ability to create the PS-CA with a subset of the data domains defined within the PS-CA Interoperability Specifications.	Mandatory	Interoperability
BR1-13	A Patient Summary-CA Solution shall provide the Patient/Subject of Care a right of access to their Patient Summary based on jurisdictional policies and legislative provisions.	Mandatory	Interoperability
BR1-14	A Patient Summary-CA Solution shall limit access to only authorized PS-CA Producers and PS-CA Consumers.	Mandatory	Interoperability

Information and Semantic: Requirements for Interoperability Testing

The following table contains a subset of the information / semantic interoperability requirements that will be tested as part of this release.

BR ID	Description	Type	Subcategory
BR2-01	A Patient Summary- CA Solution shall enable an authorized health care provider to create/ produce a Patient Summary based on the pan-Canadian Patient Summary - FHIR Implementation Guide.	Mandatory	Interoperability

BR ID	Description	Type	Subcategory
BR2-02	A Patient Summary-CA Solution shall adhere to the syntactic, semantic/terminology and content standards for interoperability established in the pan-Canadian Patient Summary - FHIR Implementation Guide.	Mandatory	Interoperability

Technical: Requirements for Interoperability Testing

The following table contains a subset of the technical interoperability requirements that will be tested as part of this release.

BR ID	Description	Type	Subcategory
BR3-01	A Patient Summary-CA Solution shall provide the ability to capture and communicate the identity of the PS subject of care.	Mandatory	Interoperability
BR3-02	A Patient Summary-CA Solution shall provide the ability to capture and communicate the identity of the authorized PS-CA Author.	Mandatory	Interoperability
BR3-04	A Patient Summary-CA Solution shall provide the ability to view the versions of Patient Summaries and render a previous version based on a request in accordance to jurisdictional policies.	Mandatory	Interoperability
BR3-05	A Patient Summary-CA Solution may be able to produce a PS-CA in a portable format (e.g., PDF) that is broadly accessible to patients/subjects of care.	Optional	Interoperability
BR3-08	A Patient Summary-CA Solution shall protect health information in transit, adhering to jurisdictional standards for encryption. Note: For example, jurisdictional standards for encryption should cover concepts of cryptographic algorithms and protocols, management of encryption keys during the transmission of PHI to maintain the confidentiality and integrity of the Patient Summary.	Mandatory	Interoperability

BR ID	Description	Type	Subcategory
BR3-13	A Patient Summary-CA Solution shall provide the ability to uniquely identify a Patient Summary-CA with a unique identifier.	Mandatory	Interoperability
BR3-16	A Patient Summary-CA Solution shall create the PS-CA in a structured format using FHIR R4 (v4.0.1) + JSON and XML.	Mandatory	Interoperability

6.4 Requirements for Guidance and Support

The following tables include a broad set of interoperability and solution requirements for **consideration and to support and provide guidance** to implementers of the pan-Canadian Patient Summary Interoperability Specifications. These requirements will not be included in the set of testable requirements for this release.

Note: Some of the supporting requirements may be further developed in future PS-CA Specifications releases and re-categorized as a Testable Requirement.

Business Legal: Requirements for Guidance and Support

BR ID	Description	Type	Subcategory
BR1-01	A Patient Summary-CA Solution should provide the ability to manage the versioning, storage, preservation, destruction, and archiving of Patient Summaries produced and consumed by authorized users of the system in accordance to jurisdictional policies.	Recommended	Solution
BR1-02	A Patient Summary-CA Solution should provide a health care provider with the option to review and sign-off the Patient Summary content before it is made available to PS-CA Consumers. Note: If the health care provider determines that changes are required to the Patient Summary prior to sign-off, the HCP will make the updates in the patient's chart. If the changes affect the Patient Summary content, a new Patient Summary will be created for review/sign-off by the HCP.	Recommended	Solution
BR1-03	A Patient Summary-CA Solution shall provide a healthcare provider with the ability to invalidate a Patient Summary if they determine it was entered	Mandatory	Interoperability

BR ID	Description	Type	Subcategory
	in error or is invalid as required by jurisdictional policy.		
BR1-04	A Patient Summary-CA Solution should adhere to data retention policies set by local/jurisdictional policies and system requirements.	Recommended	Solution
BR1-06	A Patient Summary-CA Solution may provide the ability to extract and save discrete data from a Patient Summary based on a request by an authorized system user.	Optional	Solution
BR1-07	A PS-CA Author should reasonably ensure that the health information contained in a Patient Summary-CA is accurate, sufficiently complete and up to date to meet the specified clinical purpose.	Recommended	Solution
BR1-08	A Patient Summary-CA Solution should be able to comply with a legal hold from an authorized entity based on jurisdictional policies. *Note: Legal hold policies prevent deletion of any electronically stored information on the PS-CA that may be imminent for a legal case.	Recommended	Solution
BR1-09	A Patient Summary-CA Solution should be able to omit or mask data in a PS-CA in compliance with local/jurisdictional privacy policies.	Recommended	Solution
BR1-10	A Patient Summary-CA Solution shall have the ability to produce a Patient Summary in compliance with a subject of care's consent directives in accordance to local/jurisdictional standards and/or policies. Note: For example, local/jurisdictional standards may include associating consent directives with PHI in the Patient Summary which cover concepts of maintaining association, processing consent directives, blocking transmission of PHI in Patient summary where consent directives are violated or no exception of a disclosure is outlined by law or by jurisdictional policy, and notifications to requesters when data is blocked due to consent directives.	Mandatory	Interoperability

BR ID	Description	Type	Subcategory
BR1-12	A Patient Summary-CA Solution shall have the ability to indicate or make the PS-CA Consumer (e.g. a healthcare provider) aware that information about the subject of care has been omitted or masked based on a consent directives and jurisdictional policies.	Mandatory	Interoperability

Technical: Requirements for Guidance and Support

BR ID	Description	Type	Subcategory
BR3-09	<p>A Patient Summary-CA Solution should adhere to the minimum industry standards for role-based access control and security mechanisms for the Patient Summary, including defining the security level and authorization profile of all authorized actors and mapping each user to one or more roles and each role to one or more system functions, dictated by jurisdictional standards and system requirements.</p> <p>Note: For example, jurisdictional standards for role-based access control should consider the following standards such as ISO 22600-1:2014, which describes the scenarios and the critical parameters in information exchange across policy domains. Another example of a standard is ISO 22600-2:2014, which describes and explains, in a more detailed manner, the architectures and underlying models for privilege management and access control which are necessary for secure information sharing including the formal representation of policies.</p>	Recommended	Solution
BR3-06	A Patient Summary-CA Solution should adhere to minimum local/jurisdictional industry standards for authentication (e.g., multi-factor authentication) of authorized users.	Recommended	Solution
BR3-07	<p>A Patient Summary-CA solution should, where feasible, segregate duties and areas of responsibility to reduce opportunities for unauthorized modification or misuse of PHI based on jurisdictional standards.</p> <p>Note: For example, appropriate access-controls should be put in place to segregate duties for authorized actors who have access and/or can view hosted components of the Patient Summary in order</p>	Recommended	Solution

BR ID	Description	Type	Subcategory
	to reduce opportunities for unauthorized modification or misuse of PHI and security-critical system data according to jurisdictional standards.		
BR3-10	<p>A Patient Summary-CA Solution should adhere to jurisdictional standards for creation of secure audit logs that capture access to, modification or disclosure of Patient Summary-CA information. This includes the activities of PS-CA Producers, Consumers and Requesters.</p> <p>Note: For example, jurisdictional standards for appropriate secure-audit records should log PHI-related events, such as Patient Summary access (including access to confidential data), Patient Summary creation, Patient Summary amendments and changes, traceability of consent, consent directive overrides and more for the Patient Summary.</p>	Recommended	Solution
BR3-11	<p>The Patient Summary-CA Solution should have the ability to capture secure audit log content as dictated by jurisdictional standards and/or system requirements.</p> <p>Note: For example, jurisdictional standards and/or system requirements for secure audit logs should consider Patient Summary schema and log content such as the user ID of authorized actors, the role the user is exercising, the organization of the accessing user (at least in those cases where an individual accesses information on behalf of more than one organization), the patient ID of the data subject (patient/person), the function performed by the accessing user, a timestamp, in the case of access override to blocked or masked records or portions of records, a reason for the override, and in the case of changes to consent directives made by a substitute decision-maker, the identity of the decision-maker.</p>	Recommended	Solution
BR3-12	A Patient Summary-CA Solution may provide the capability for a PS-CA to be de-identified, according to local/jurisdictional requirements.	Optional	Solution
BR3-14	A Patient Summary-CA Solution should retrieve data elements for the PS-CA from the PS-CA Author's local data source.	Recommended	Solution

BR ID	Description	Type	Subcategory
BR3-15	A Patient Summary-CA Solution may provide the ability to convert structured documents (e.g. FHIR-based) to unstructured documents (e.g PDF), and make transformations between structured document formats (e.g. CDA).	Optional	Solution
BR3-17	A Patient Summary-CA Solution should protect health information at rest, adhering to jurisdictional standards for encryption Note: For example, jurisdictional standards for encryption should cover concepts of cryptographic algorithms and protocols, and management of encryption keys to maintain the confidentiality and integrity of the Patient Summary.	Recommended	Solution

6.5 Requirements: Full Set

This section is inclusive of all interoperability and solution requirements that are:

- listed in the Requirements for Interoperability Testing for the pan-Canadian Patient Summary Interoperability Specifications for this release,
- listed in the Requirements for Guidance and Support of the pan-Canadian Patient Summary Interoperability Specifications for this release; and
- targeted as potential for inclusion in a future release.

6.5.1 Business and Legal Requirements

Business/Legal Requirements are requirements that enable independent organizations to execute a collaborative process or service.

The following table provides a summary view of the business / legal interoperability and solution requirements. Additional details of each requirement can be found by clicking on the Business Rule ID.

BR ID	Description	Type	Subcategory
BR1-01	A Patient Summary-CA Solution should provide the ability to manage the versioning, storage, preservation, destruction, and archiving of Patient Summaries produced and consumed by authorized users of the system in accordance to jurisdictional policies.	Recommended	Solution
BR1-02	A Patient Summary-CA Solution should provide a health care provider with the option to review and	Recommended	Solution

BR ID	Description	Type	Subcategory
	<p>sign-off the Patient Summary content before it is made available to PS-CA Consumers.</p> <p>Note: If the health care provider determines that changes are required to the Patient Summary prior to sign-off, the HCP will make the updates in the patient's chart. If the changes affect the Patient Summary content, a new Patient Summary will be created for review/sign-off by the HCP.</p>		
BR1-03	A Patient Summary-CA Solution shall provide a healthcare provider with the ability to invalidate a Patient Summary if they determine it was entered in error or is invalid as required by jurisdictional policy.	Mandatory	Interoperability
BR1-04	A Patient Summary-CA Solution should adhere to data retention policies set by local/jurisdictional policies and system requirements.	Recommended	Solution
BR1-05	A Patient Summary-CA Solution shall provide the ability for an authorized PS consumer (e.g. authorized health care provider) to ascertain the provenance (PS-CA author, producer, date and subject of care) of a current and historical PS.	Mandatory	Interoperability
BR1-06	A Patient Summary-CA Solution may provide the ability to extract and save discrete data from a Patient Summary based on a request by an authorized system user.	Optional	Solution
BR1-07	A PS-CA Author should reasonably ensure that the health information contained in a Patient Summary-CA is accurate, sufficiently complete and up to date to meet the specified clinical purpose.	Recommended	Solution
BR1-08	<p>A Patient Summary-CA Solution should be able to comply with a legal hold from an authorized entity based on jurisdictional policies.</p> <p>*Note: Legal hold policies prevent deletion of any electronically stored information on the PS-CA that may be imminent for a legal case.</p>	Recommended	Solution

BR ID	Description	Type	Subcategory
BR1-09	A Patient Summary-CA Solution should be able to omit or mask data in a PS-CA in compliance with local/jurisdictional privacy policies.	Recommended	Solution
BR1-10	<p>A Patient Summary-CA Solution shall have the ability to produce a Patient Summary in compliance with a subject of care's consent directives in accordance to local/jurisdictional standards and/or policies.</p> <p>Note: For example, local/jurisdictional standards may include associating consent directives with PHI in the Patient Summary which cover concepts of maintaining association, processing consent directives, blocking transmission of PHI in Patient summary where consent directives are violated or no exception of a disclosure is outlined by law or by jurisdictional policy, and notifications to requesters when data is blocked due to consent directives.</p>	Mandatory	Interoperability
BR1-11	<p>A Patient Summary-CA Solution shall limit the sharing of health information to what is clinically necessary and sufficient, in accordance with governing legislation and the Patient Summary-CA specification.</p> <p>Note: For example, the clinician will have the ability to create the PS-CA with a subset of the data domains defined within the PS-CA Interoperability Specifications.</p>	Mandatory	Interoperability
BR1-12	A Patient Summary-CA Solution shall have the ability to indicate or make the PS-CA Consumer (e.g. a healthcare provider) aware that information about the subject of care has been omitted or masked based on a consent directives and jurisdictional policies.	Mandatory	Interoperability
BR1-13	A Patient Summary-CA Solution shall provide the Patient/Subject of Care a right of access to their Patient Summary based on jurisdictional policies and legislative provisions.	Mandatory	Interoperability
BR1-14	A Patient Summary-CA Solution shall limit access to only authorized PS-CA Producers and PS-CA Consumers.	Mandatory	Interoperability

BR1-01

ID	BR1-01
Description	A Patient Summary-CA Solution should provide the ability to manage the versioning, storage, preservation, destruction, and archiving of Patient Summaries produced and consumed by authorized users of the system in accordance to jurisdictional policies.
Type	Recommended
Status	APPROVED
Subcategory	Solution

BR1-02

ID	BR1-02
Description	<p>A Patient Summary-CA Solution should provide a health care provider with the option to review and sign-off the Patient Summary content before it is made available to PS-CA Consumers.</p> <p>Note: If the health care provider determines that changes are required to the Patient Summary prior to sign-off, the HCP will make the updates in the patient's chart. If the changes affect the Patient Summary content, a new Patient Summary will be created for review/sign-off by the HCP.</p>
Type	Recommended
Status	APPROVED
Subcategory	Solution

BR1-03

ID	BR1-03
Description	A Patient Summary-CA Solution shall provide a healthcare provider with the ability to invalidate a Patient Summary if they determine it was entered in error or is invalid as required by jurisdictional policy.
Type	Mandatory

Status	APPROVED
Subcategory	Interoperability

BR1-04

ID	BR1-04
Description	A Patient Summary-CA Solution should adhere to data retention policies set by local/jurisdictional policies and system requirements.
Type	Recommended
Status	APPROVED
Subcategory	Solution

BR1-05

ID	BR1-05
Description	A Patient Summary-CA Solution shall provide the ability for an authorized PS consumer (e.g. authorized health care provider) to ascertain the provenance (PS-CA author, producer, date and subject of care) of a current and historical PS.
Type	Mandatory
Status	APPROVED
Subcategory	Interoperability

BR1-06

ID	BR1-06
Description	A Patient Summary-CA Solution may provide the ability to extract and save discrete data from a Patient Summary based on a request by an authorized system user.

Type	Optional
Status	APPROVED
Subcategory	Solution

BR1-07

ID	BR1-07
Description	A PS-CA Author should reasonably ensure that the health information contained in a Patient Summary-CA is accurate, sufficiently complete and up to date to meet the specified clinical purpose.
Type	Recommended
Status	APPROVED
Subcategory	Solution

BR1-08

ID	BR1-08
Description	A Patient Summary-CA Solution should be able to comply with a legal hold from an authorized entity based on jurisdictional policies. *Note: Legal hold policies prevent deletion of any electronically stored information on the PS-CA that may be imminent for a legal case.
Type	Recommended
Status	APPROVED
Subcategory	Solution

BR1-09

ID	BR1-09
-----------	--------

Description	A Patient Summary-CA Solution should be able to omit or mask data in a PS-CA in compliance with local/jurisdictional privacy policies.
Type	Recommended
Status	APPROVED
Subcategory	Solution

BR1-10

ID	BR1-10
Description	<p>A Patient Summary-CA Solution shall have the ability to produce a Patient Summary in compliance with a subject of care's consent directives in accordance to local/jurisdictional standards and/or policies.</p> <p>Note: For example, local/jurisdictional standards may include associating consent directives with PHI in the Patient Summary which cover concepts of maintaining association, processing consent directives, blocking transmission of PHI in Patient summary where consent directives are violated or no exception of a disclosure is outlined by law or by jurisdictional policy, and notifications to requesters when data is blocked due to consent directives.</p>
Type	Mandatory
Status	APPROVED
Subcategory	Interoperability

BR1-11

ID	BR1-11
Description	<p>A Patient Summary-CA Solution shall limit the sharing of health information to what is clinically necessary and sufficient, in accordance with governing legislation and the Patient Summary-CA specification.</p> <p>Note: For example, the clinician will have the ability to create the PS-CA with a subset of the data domains defined within the PS-CA Interoperability Specifications.</p>
Type	Mandatory

Status	APPROVED
Subcategory	Interoperability

BR1-12

ID	BR1-12
Description	A Patient Summary-CA Solution shall have the ability to indicate or make the PS-CA Consumer (e.g. a healthcare provider) aware that information about the subject of care has been omitted or masked based on a consent directives and jurisdictional policies.
Type	Mandatory
Status	APPROVED
Subcategory	Interoperability

BR1-13

ID	BR1-13
Description	A Patient Summary-CA Solution shall provide the Patient/Subject of Care a right of access to their Patient Summary based on jurisdictional policies and legislative provisions.
Type	Mandatory
Status	APPROVED
Subcategory	Interoperability

BR1-14

ID	BR1-14
Description	A Patient Summary-CA Solution shall limit access to only authorized PS-CA Producers and PS-CA Consumers.

Type	Mandatory
Status	APPROVED
Subcategory	Interoperability

6.5.2 Information and Semantic Requirements

Information/Semantic Interoperability Requirements: requirements for syntax and semantics such that data exchanged between health record systems can be interpreted and the meaning of the data ascertained.

The following table provides a summary view of the information/semantic interoperability requirements. Additional details of each requirement can be found by clicking on the Business Rule ID.

BR ID	Description	Type	Subcategory
BR2-01	A Patient Summary- CA Solution shall enable an authorized health care provider to create/produce a Patient Summary based on the pan-Canadian Patient Summary - FHIR Implementation Guide.	Mandatory	Interoperability
BR2-02	A Patient Summary-CA Solution shall adhere to the syntactic, semantic/terminology and content standards for interoperability established in the pan-Canadian Patient Summary - FHIR Implementation Guide.	Mandatory	Interoperability

BR2-01

ID	BR2-01
Description	A Patient Summary- CA Solution shall enable an authorized health care provider to create/produce a Patient Summary based on the pan-Canadian Patient Summary - FHIR Implementation Guide.
Type	Mandatory
Status	APPROVED
Subcategory	Interoperability

BR2-02

ID	BR2-02
Description	A Patient Summary-CA Solution shall adhere to the syntactic, semantic/terminology and content standards for interoperability established in the pan-Canadian Patient Summary - FHIR Implementation Guide.
Type	Mandatory
Status	APPROVED
Subcategory	Interoperability

6.5.3 Technical Requirements

Technical Requirements: requirements for one health record system to send data to another health record system and for the receiving system to acknowledge receipt of the data payload.

The following table provides a summary view of the technical interoperability and solution requirements. Additional details of each requirement can be found by clicking on the Business Rule ID.

BR ID	Description	Type	Subcategory
BR3-09	<p>A Patient Summary-CA Solution should adhere to the minimum industry standards for role-based access control and security mechanisms for the Patient Summary, including defining the security level and authorization profile of all authorized actors and mapping each user to one or more roles and each role to one or more system functions, dictated by jurisdictional standards and system requirements.</p> <p>Note: For example, jurisdictional standards for role-based access control should consider the following standards such as ISO 22600-1:2014, which describes the scenarios and the critical parameters in information exchange across policy domains. Another example of a standard is ISO 22600-2:2014, which describes and explains, in a more detailed manner, the architectures and underlying models for privilege management and access control which are necessary for secure information sharing including the formal representation of policies.</p>	Recommended	Solution

BR ID	Description	Type	Subcategory
BR3-01	A Patient Summary-CA Solution shall provide the ability to capture and communicate the identity of the PS subject of care.	Mandatory	Interoperability
BR3-02	A Patient Summary-CA Solution shall provide the ability to capture and communicate the identity of the authorized PS-CA Author.	Mandatory	Interoperability
BR3-04	A Patient Summary-CA Solution shall provide the ability to view the versions of Patient Summaries and render a previous version based on a request in accordance to jurisdictional policies.	Mandatory	Interoperability
BR3-05	A Patient Summary-CA Solution may be able to produce a PS-CA in a portable format (e.g., PDF) that is broadly accessible to patients/subjects of care.	Optional	Interoperability
BR3-06	A Patient Summary-CA Solution should adhere to minimum local/jurisdictional industry standards for authentication (e.g., multi-factor authentication) of authorized users.	Recommended	Solution
BR3-07	<p>A Patient Summary-CA solution should, where feasible, segregate duties and areas of responsibility to reduce opportunities for unauthorized modification or misuse of PHI based on jurisdictional standards.</p> <p>Note: For example, appropriate access-controls should be put in place to segregate duties for authorized actors who have access and/or can view hosted components of the Patient Summary in order to reduce opportunities for unauthorized modification or misuse of PHI and security-critical system data according to jurisdictional standards.</p>	Recommended	Solution
BR3-08	<p>A Patient Summary-CA Solution shall protect health information in transit, adhering to jurisdictional standards for encryption.</p> <p>Note: For example, jurisdictional standards for encryption should cover concepts of cryptographic algorithms and protocols, management of encryption keys during the transmission of PHI to maintain the confidentiality and integrity of the Patient Summary.</p>	Mandatory	Interoperability

BR ID	Description	Type	Subcategory
BR3-10	<p>A Patient Summary-CA Solution should adhere to jurisdictional standards for creation of secure audit logs that capture access to, modification or disclosure of Patient Summary-CA information. This includes the activities of PS-CA Producers, Consumers and Requesters.</p> <p>Note: For example, jurisdictional standards for appropriate secure-audit records should log PHI-related events, such as Patient Summary access (including access to confidential data), Patient Summary creation, Patient Summary amendments and changes, traceability of consent, consent directive overrides and more for the Patient Summary.</p>	Recommended	Solution
BR3-11	<p>The Patient Summary-CA Solution should have the ability to capture secure audit log content as dictated by jurisdictional standards and/or system requirements.</p> <p>Note: For example, jurisdictional standards and/or system requirements for secure audit logs should consider Patient Summary schema and log content such as the user ID of authorized actors, the role the user is exercising, the organization of the accessing user (at least in those cases where an individual accesses information on behalf of more than one organization), the patient ID of the data subject (patient/person), the function performed by the accessing user, a timestamp, in the case of access override to blocked or masked records or portions of records, a reason for the override, and in the case of changes to consent directives made by a substitute decision-maker, the identity of the decision-maker.</p>	Recommended	Solution
BR3-12	<p>A Patient Summary-CA Solution may provide the capability for a PS-CA to be de-identified, according to local/jurisdictional requirements.</p>	Optional	Solution
BR3-13	<p>A Patient Summary-CA Solution shall provide the ability to uniquely identify a Patient Summary-CA with a unique identifier.</p>	Mandatory	Interoperability
BR3-14	<p>A Patient Summary-CA Solution should retrieve data elements for the PS-CA from the PS-CA Author's local data source.</p>	Recommended	Solution

BR ID	Description	Type	Subcategory
BR3-15	A Patient Summary-CA Solution may provide the ability to convert structured documents (e.g. FHIR-based) to unstructured documents (e.g PDF), and make transformations between structured document formats (e.g. CDA).	Optional	Solution
BR3-16	A Patient Summary-CA Solution shall create the PS-CA in a structured format using FHIR R4 (v4.0.1) + JSON and XML.	Mandatory	Interoperability
BR3-17	<p>A Patient Summary-CA Solution should protect health information at rest, adhering to jurisdictional standards for encryption</p> <p>Note: For example, jurisdictional standards for encryption should cover concepts of cryptographic algorithms and protocols, and management of encryption keys to maintain the confidentiality and integrity of the Patient Summary.</p>	Recommended	Solution

BR3-01

ID	BR3-01
Description	A Patient Summary-CA Solution shall provide the ability to capture and communicate the identity of the PS subject of care.
Type	Mandatory
Status	APPROVED
Subcategory	Interoperability

BR3-02

ID	BR3-02
Description	A Patient Summary-CA Solution shall provide the ability to capture and communicate the identity of the authorized PS-CA Author.
Type	Mandatory

Status	APPROVED
Subcategory	Interoperability

BR3-03

ID	BR3-03
Description	A Patient Summary-CA Solution shall provide the ability to send a Patient Summary by identifying a recipient health care provider and the appropriate corresponding location/address.
Type	Mandatory
Status	DRAFT FUTURE
Subcategory	Interoperability

BR3-04

ID	BR3-04
Description	A Patient Summary-CA Solution shall provide the ability to view the versions of Patient Summaries and render a previous version based on a request in accordance to jurisdictional policies.
Type	Mandatory
Status	APPROVED
Subcategory	Interoperability

BR3-05

ID	BR3-05
Description	A Patient Summary-CA Solution may be able to produce a PS-CA in a portable format (e.g., PDF) that is broadly accessible to patients/subjects of care.

Type	Optional
Status	APPROVED
Subcategory	Interoperability

BR3-06

ID	BR3-06
Description	A Patient Summary-CA Solution should adhere to minimum local/ jurisdictional industry standards for authentication (e.g., multi-factor authentication) of authorized users.
Type	Recommended
Status	APPROVED
Subcategory	Solution

BR3-07

ID	BR3-07
Description	<p>A Patient Summary-CA solution should, where feasible, segregate duties and areas of responsibility to reduce opportunities for unauthorized modification or misuse of PHI based on jurisdictional standards.</p> <p>Note: For example, appropriate access-controls should be put in place to segregate duties for authorized actors who have access and/or can view hosted components of the Patient Summary in order to reduce opportunities for unauthorized modification or misuse of PHI and security-critical system data according to jurisdictional standards.</p>
Type	Recommended
Status	APPROVED
Subcategory	Solution

BR3-08

ID	BR3-08
Description	<p>A Patient Summary-CA Solution shall protect health information in transit, adhering to jurisdictional standards for encryption.</p> <p>Note: For example, jurisdictional standards for encryption should cover concepts of cryptographic algorithms and protocols, management of encryption keys during the transmission of PHI to maintain the confidentiality and integrity of the Patient Summary.</p>
Type	Mandatory
Status	APPROVED
Subcategory	Interoperability

BR3-09

ID	BR3-09
Description	<p>A Patient Summary-CA Solution should adhere to the minimum industry standards for role-based access control and security mechanisms for the Patient Summary, including defining the security level and authorization profile of all authorized actors and mapping each user to one or more roles and each role to one or more system functions, dictated by jurisdictional standards and system requirements.</p> <p>Note: For example, jurisdictional standards for role-based access control should consider the following standards such as ISO 22600-1:2014, which describes the scenarios and the critical parameters in information exchange across policy domains. Another example of a standard is ISO 22600-2:2014, which describes and explains, in a more detailed manner, the architectures and underlying models for privilege management and access control which are necessary for secure information sharing including the formal representation of policies.</p>
Type	Recommended
Status	APPROVED
Subcategory	Solution

BR3-10

ID	BR3-10
Description	<p>A Patient Summary-CA Solution should adhere to jurisdictional standards for creation of secure audit logs that capture access to, modification or disclosure of Patient Summary-CA information. This includes the activities of PS-CA Producers, Consumers and Requesters.</p> <p>Note: For example, jurisdictional standards for appropriate secure-audit records should log PHI-related events, such as Patient Summary access (including access to confidential data), Patient Summary creation, Patient Summary amendments and changes, traceability of consent, consent directive overrides and more for the Patient Summary.</p>
Type	Recommended
Status	APPROVED
Subcategory	Solution

BR3-11

ID	BR3-11
Description	<p>The Patient Summary-CA Solution should have the ability to capture secure audit log content as dictated by jurisdictional standards and/or system requirements.</p> <p>Note: For example, jurisdictional standards and/or system requirements for secure audit logs should consider Patient Summary schema and log content such as the user ID of authorized actors, the role the user is exercising, the organization of the accessing user (at least in those cases where an individual accesses information on behalf of more than one organization), the patient ID of the data subject (patient/person), the function performed by the accessing user, a timestamp, in the case of access override to blocked or masked records or portions of records, a reason for the override, and in the case of changes to consent directives made by a substitute decision-maker, the identity of the decision-maker.</p>
Type	Recommended
Status	APPROVED
Subcategory	Solution

BR3-12

ID	BR3-12
Description	A Patient Summary-CA Solution may provide the capability for a PS-CA to be de-identified, according to local/jurisdictional requirements.
Type	Optional
Status	APPROVED
Subcategory	Solution

BR3-13

ID	BR3-13
Description	A Patient Summary-CA Solution shall provide the ability to uniquely identify a Patient Summary-CA with a unique identifier.
Type	Mandatory
Status	DRAFT
Subcategory	Interoperability

BR3-14

ID	BR3-14
Description	A Patient Summary-CA Solution should retrieve data elements for the PS-CA from the PS-CA Author's local data source.
Type	Recommended
Status	APPROVED
Subcategory	Solution

BR3-15

ID	BR3-15
Description	A Patient Summary-CA Solution may provide the ability to convert structured documents (e.g. FHIR-based) to unstructured documents (e.g. PDF), and make transformations between structured document formats (e.g. CDA).
Type	Optional
Status	APPROVED
Subcategory	Solution

BR3-16

ID	BR3-16
Description	A Patient Summary-CA Solution shall create the PS-CA in a structured format using FHIR R4 (v4.0.1) + JSON and XML.
Type	Mandatory
Status	APPROVED
Subcategory	Interoperability

BR3-17

ID	BR3-17
Description	A Patient Summary-CA Solution should protect health information at rest, adhering to jurisdictional standards for encryption Note: For example, jurisdictional standards for encryption should cover concepts of cryptographic algorithms and protocols, and management of encryption keys to maintain the confidentiality and integrity of the Patient Summary.
Type	Recommended
Status	APPROVED

Subcategory	Solution
--------------------	----------