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# HL7/NCPDP Informative Document: Pharmacist Consultation Note, Release 1- US Realm

September 2022

## HL7 Informative Ballot

**Sponsored by:**
**Pharmacy Work Group**



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|---|---|
| Current Procedures Terminology (CPT) code set | American Medical Association https://www.ama-assn.org/practice-management/cpt-licensing |
| SNOMED CT | SNOMED International http://www.snomed.org/snomed-ct/get-snomed-ct or info@ihtsdo.org |
| Logical Observation Identifiers Names & Codes (LOINC) | Regenstrief Institute |
| International Classification of Diseases (ICD) codes | World Health Organization (WHO) |
| NUCC Health Care Provider Taxonomy code set | American Medical Association. Please see www.nucc.org. AMA licensing contact: 312-464-5022 (AMA IP services) |

# Pharmacist Consultation Note

## Version 1.1

## Guidance on the Use of HL7 CDA Consolidated Templates for Clinical Notes R2.1 Consultation Note and HL7 C-CDA on FHIR US Core Consultation Note

XXXX 2022

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# Pharmacist Consultation Note

**Version 1.1**



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# Table of Contents

# 1. PURPOSE

The scope of this paper is to provide guidance to the pharmacy sector of the healthcare industry on the use of the *HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Standard for Trial Use Release 2.1*[1] (C-CDA Template) and *C-CDA on FHIR 1.1.0 - (FHIR R4) STU Release 1.1 Consultation Note Profile*[2](FHIR Profile) in creating a Pharmacist Consultation Note. The Pharmacist Consultation Note is used for exchange of a pharmacist's recommendations with the appropriate care providers, including long term and post acute care (LTPAC) facility staff, and the physician(s) of record for the patient. This paper is based on the C-CDA Template and FHIR Profile.

This guidance is intended to be used in conjunction with the specifications as defined in the C-CDA Template and FHIR Profile. The NCPDP Long Term and Post Acute Care (LTPAC) Work Group (WG14) Consultant Pharmacist Interoperability Task Group has reviewed the C-CDA templates and FHIR Profile; and found the content and functionality of the C-CDA Template and FHIR Profile meet the requirements of the structured documentation of the Pharmacist Consultation Note. Information regarding levels of constraint, conformance statements, conformance verbs, cardinality, vocabulary conformance, and null flavor that are pertinent to this guidance can be found in the C-CDA Template and FHIR Profile.

Matters such as the maintenance and storage of medication and storage equipment (e.g., refrigeration, humidity and temperature control, etc.), medication security and access protocols, etc., are not within the scope of this guidance document.

[1] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=408
[2] http://www.hl7.org/fhir/us/ccda/StructureDefinition-Consultation-Note.html

## 2. AUDIENCE

The audience for this guidance document includes architects, developers and implementers of HIT systems in the US Realm to meet health IT certification requirements for exchange of patient clinical data particularly among pharmacists, LTPAC facilities as well as other healthcare providers, and caregivers. All participants in the healthcare team will benefit from the implementation of these recommendations.

# 3. OVERVIEW

Pharmacists act as formal and informal consultants in a variety of settings. A prominent example is the CMS requirement for a pharmacist's monthly review each of each patient's medication regimen in long term and post acute care (LTPAC) facilities[3]. Pharmacists also provide consultive services in inpatient settings (e.g., medication reconciliation, medication dosing and monitoring in renal impairment), clinical outpatient settings (e.g., medication management and education, poly-pharmacy assessment), and retail outpatient (e.g., medication management, therapeutic monitoring, patient education). Previously, many of these "services" were provided but sparsely documented. Increasingly, the role of the consulting pharmacy is being seen as a referred service, and the Pharmacy Consultation Note is presented as formal documentation of the services provided and the recommendations subsequent to the consultation. The Pharmacist Consultation Note, as an electronic document, is compatible with current health information technology for both documenting the consultation and electronically sharing the information with requestor, members of the care team, other specialists, pertinent authorities, and the patient.

This document describes the us C-CDA templates and FHIR Profile components to create the Pharmacist Consultation Note. The C-CDA and FHIR processes allow for inclusion of other section and entry level templates and extensions, to fully meet the documentation needs of the consultant pharmacist's recommendations.

## *3.1 LONG TERM AND POST ACUTE CARE CONSIDERATIONS*

Consultant pharmacists play a pivotal role in the long term and post acute care arena in helping patients/residents attain and maintain the highest practicable level of functional status and preventing or minimizing medication-related adverse consequences. The consultant pharmacist's primary focus is the nursing home population, which may be quite diverse, including geriatric patients as well as individuals of any age with special needs, such as those who are immunocompromised, have end stage renal disease, spinal cord or closed head injuries, neurological syndromes, etc. These patients tend to have multiple risk factors including medication-related adverse consequences.

Medications are used for their therapeutic benefits in diagnosing, managing, and treating acute and/or chronic conditions, as well as for maintaining and/or improving a patient's functional status. Information about indications for use, potential medication irregularities or adverse consequences (such as symptoms of tardive dyskinesia, dizziness, anorexia, or falls) may be attainable only by talking to the staff, reviewing the medical record, and observing and speaking with the patient. However, electronic health and medication records and other available technology may permit the pharmacist to conduct some components of the review from outside the facility.

The following information in this overview references the Centers for Medicare and Medicaid Services (CMS) State Operations Manual Appendix PP - Guidance to Surveyors for Long Term Care Facilities Transmittals for Appendix PP, Revision 173, November 22, 2017. The cms.gov website[3] should be consulted for any updates to regulatory requirements.

[3] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/SOM107ap_pp_Guidelines_ltcf.pdf

The pharmacist must review each patient's medication regimen at least monthly in order to identify irregularities as well as clinically significant risks and/or adverse consequences resulting from or associated with medications. The requirement for the medication regimen review (MRR) applies to each patient, including patients who:

1. Are receiving respite care;
2. Are at the end of life or have elected the hospice benefit and are receiving respite care;
3. Have an anticipated stay of less than 30 days; or
4. Have experienced a change in condition.

Notification of Irregularities Identified in the MRR

The timeliness of notification of irregularities depends on factors including the potential for or presence of serious adverse consequences; for example, immediate notification is indicated in cases of bleeding in a patient who is receiving anticoagulants or of possible allergic reactions to antibiotic therapy. If no irregularities were identified during the review, the pharmacist includes a signed and dated statement to that effect. The facility and the pharmacist may collaborate to identify the most effective means for assuring appropriate notification. This notification may be done electronically.

The pharmacist does not need to document a continuing irregularity in the report each month if the pharmacist has deemed the irregularity to be clinically insignificant or evidence of a valid clinical reason for rejecting the pharmacist's recommendation was provided. In this situation, the pharmacist need only reconsider annually whether to report the irregularity again or make a new recommendation.

The intent of this requirement is that each patient's entire medication regimen be managed and monitored. Monitoring is the ongoing collection and analysis of information (such as observations and diagnostic test results) and comparison to baseline data.

The regulations associated with medication management include consideration of:

- Indications for use of medication (including initiation or continued use of antipsychotic medication);
- Monitoring for efficacy and adverse consequences;
- Dose (including duplicate therapy);
- Duration;
- Tapering of a medication dose/gradual dose reduction for antipsychotic medications; and,
- Prevention, identification, and response to adverse consequences.

Response to Irregularities Identified in the MRR

Throughout this guidance, a response from a physician regarding a medication problem implies appropriate communication, review, and patient management, but does not imply the physician must necessarily order tests or treatments recommended or requested by the staff, unless the physician determines those are medically valid and indicated. For those issues that require physician intervention, the physician either accepts and acts upon the report and potential recommendations or rejects all or some of the report and provides a brief explanation of why the recommendation is rejected, such as in a dated progress note. It is not acceptable for a physician to document only that he/she disagrees with the report, without providing some basis for disagreement.

If there is potential for serious harm and the attending physician does not concur with or take action on the report, the facility and the pharmacist should contact the facility's medical director for guidance and possible intervention to resolve the issue. In cases where the attending physician is also the medical director, the facility should have alternate procedures in place to resolve the

situation. For those recommendations that do not require physician intervention, such as monitoring vital signs or weights, the director of nursing or designated licensed nurse addresses and documents action(s) taken.

As presented in this document, the Pharmacist Consultation Note is designed to:

- support the consultant patient specific recommendations for LTPAC facilities
- to meet the regulatory requirements for nursing facilities
- support LTPAC needs
- support care coordination

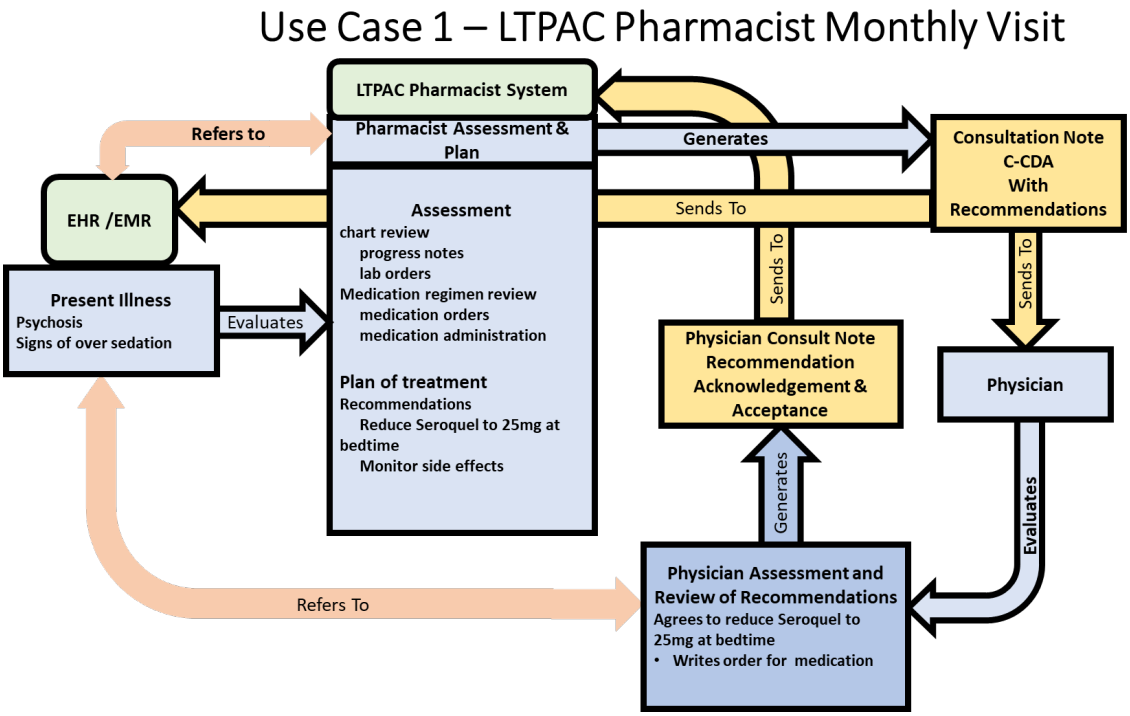
In addition to the stated C-CDA templates and FHIR Profile components, the HL7 process allows for inclusion of other section level and entry level templates, as needed, to fully meet the documentation needs of the consultant pharmacist's recommendations.

The consultant pharmacist recommendations as reported in the Consultation Note (using either or both C-CDA or FHIR) potentially provide medication-related input into the patient's care plan goals, health concerns and interventions. The Pharmacist Consultation Note is integral to the development and maintenance of the LTPAC resident's longitudinal care plan.

# 4. PHARMACIST CONSULTATION NOTE USE CASES

## *4.1.USE CASE 1*

The consultant pharmacist during the monthly visit to the Skilled Nursing Facility (SNF) reviews the patient's chart of an 85 year old female with diagnosis of psychosis and performs an MRR noting the resident is on Seroquel 50mg at bedtime. The consultant pharmacist reviews the notes for targeted behavior and observes the patient is showing signs of oversedation. The consultant pharmacist writes a recommendation to the prescriber to reduce the Seroquel dose to 25mg at bedtime and continue to monitor for side effects. (Recommendation is "dose reduction", reported using Systematized Nomenclature of Medicine [SNOMED CT] Code.)




The consultant pharmacist captures information from the patient's chart, or if electronic, the facility's Electronic Health Record (EHR)/Electronic Medical Record (EMR) (e.g., medication orders, lab orders, progress notes, medication administration record, or targeted facility report). This information is entered or transported into the consultant pharmacist's software. The consultant pharmacist generates the Pharmacist Consultation Note, which is sent to the physician and/or nursing facility's system. The physician responds by accepting or rejecting with comments using a response Consultation Note. The responses to the recommendations are tracked in the consultant pharmacist software. As a result of the consultation note exchange, the information is available for outcomes reporting.

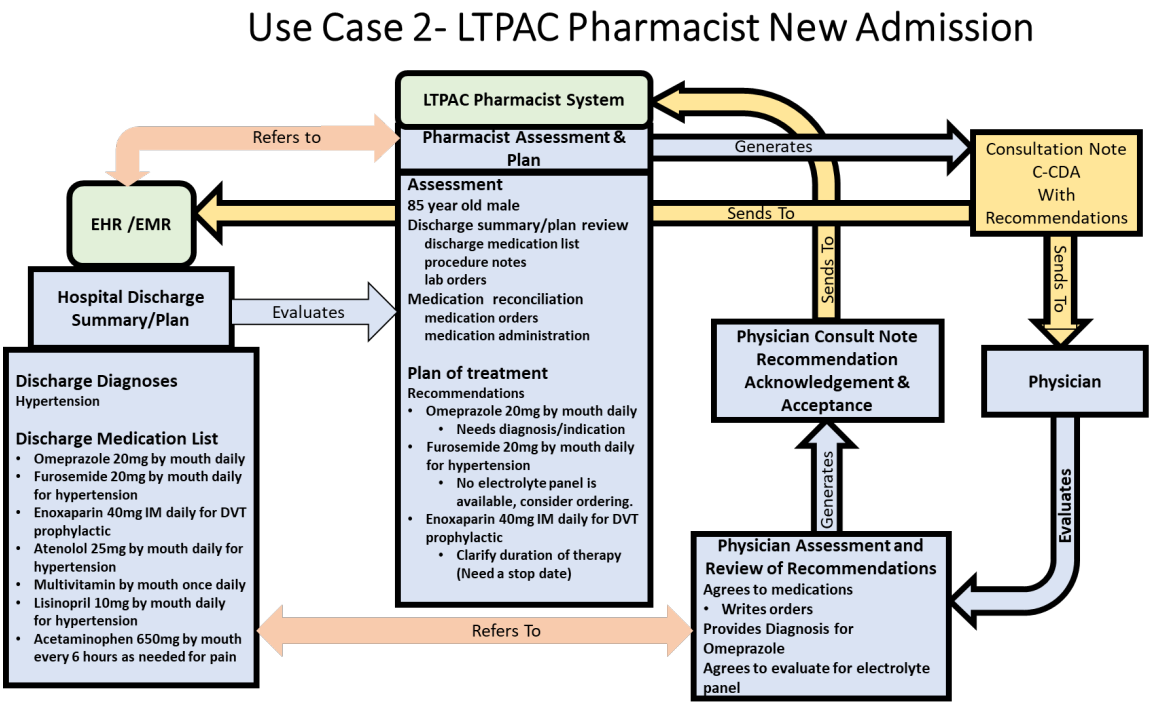
## *4.2.USE CASE 2*

The consultant pharmacist receives information from the SNF that an 85 year old male has been admitted from the hospital. The consultant pharmacist performs a medication reconciliation of all prescribed, and non-prescription medications. During the medication reconciliation process the consultant pharmacist notes the following medication regimen for the resident:

Omeprazole 20mg by mouth daily
Furosemide 20mg by mouth daily for hypertension
Enoxaparin 40mg IM daily for deep vein thrombosis (DVT) prophylactic
Atenolol 25mg by mouth daily for hypertension
Multivitamin by mouth once daily
Lisinopril 10mg by mouth daily for hypertension
Acetaminophen 650mg by mouth every 6 hours as needed for pain

The following recommendations are noted:

Omeprazole 20mg by mouth daily
Needs a corresponding diagnosis
Furosemide 20mg by mouth daily for hypertension
No electrolyte panel is available, consider ordering.
Enoxaparin 40mg IM daily for DVT prophylactic
Clarify duration of therapy (Need a stop date)



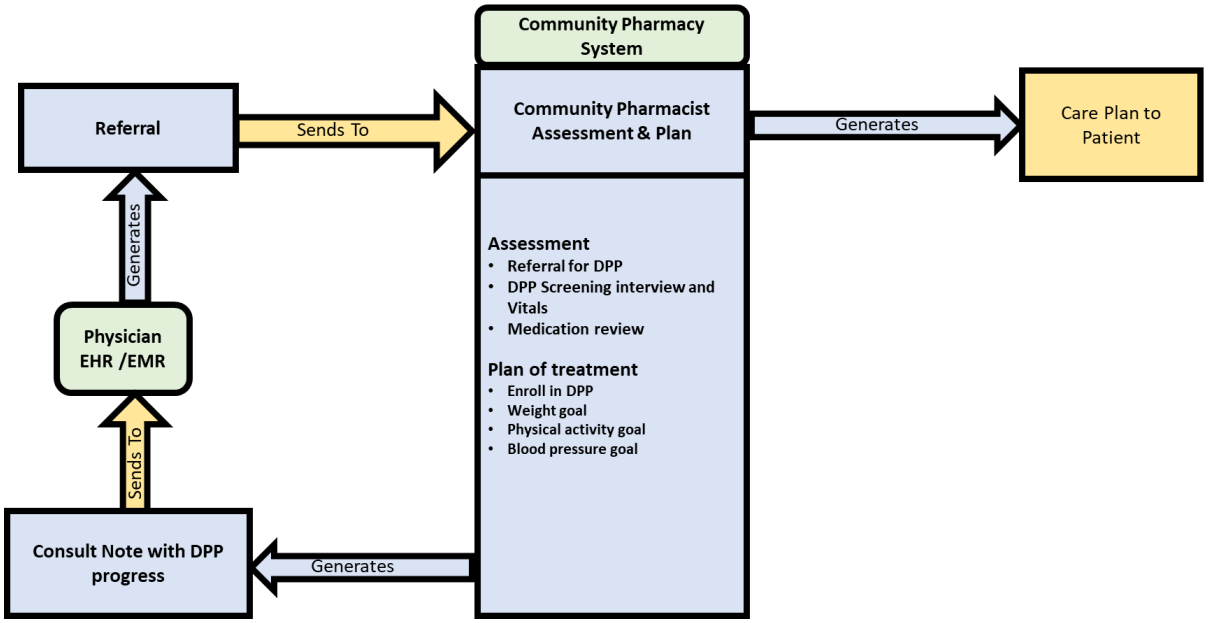

The consultant pharmacist generates a physician or nursing recommendation in a Pharmacist Consultation Note, which is sent to the physician's office and/or nursing facility's system. The physician's office or nursing facility responds by accepting or rejecting with comments using a response C-CDA Consultation

Note. The responses of the MRR recommendations are tracked in the consultant pharmacist software. As a result of the consultation note exchange, the information is available for outcomes reporting.

### *4.3.USE CASE 3*

Community pharmacy operates a CDC-recognized National Diabetes Prevention Program. The prescriber has referred the patient to the program based on her risk for developing type II diabetes and outcomes observed in patients previously referred to the program. Patient's age, family history, blood pressure, and BMI qualify for diagnosis of prediabetes. The pharmacy's care management application will incorporate any data included in the referral from the prescriber, store information related to care provided by the pharmacists and generate structured documents such as a Consultation Note or Pharmacist eCare Plan. The pharmacists will use a Consultation Note to report whether the patient was successfully contacted, whether she enrolled in the program, and her progress in the program. The prescriber is able to have data on the patient's progress to achieve weight loss goals, physical activity goals, labs, and blood pressure goals. As a result of consultation note exchange, the Prescriber's primary care practice has information needed for quality reporting purposes.

Use Case 3 - Community Pharmacist Consultation Note



# 5. TEMPLATE REQUIREMENTS

## *5.1 US REALM HEADER (metadata)*

The US Realm Header template is required for C-CDA documents exchanged within the United States. It provides the common administrative and demographic information associated with the document, such as, identification of and information about the document type, author, patient, informant, service event performer and date of creation/revision. It allows for the identification of the correct patient record and associated treatment course and provides support for the determination of the provenance and authenticity of the document. It supports identification of care team members, their roles and where applicable their specialties, as well as, service event information including date, time, location, etc.

*Table 1 US Realm Header with Consultation Note and Pharmacist Consultation Note specializations,* below, provides a mapping between the C-CDA Consultation Note and FHIR C-CDA on FHIR Consultation Note. Fixed values are provided when that value is always present in an instance of a Pharmacist Consultation Note. The table columns provide the following information:

| | |
|---|---|
| **Description** | Narrative description of the content represented in that row |
| **C-CDA element ClinicalDocument** | The XML element within the ClinicalDocument where the described information is located.<br><br>"---" indicates that the concept does not pertain to the C-CDA structure. Either the concept doesn't apply or the concept is incorporated differently than how it is incorporated in C-CDA<br><br>"ClinicalDocument" is the XML root element of a Pharmacist Consultation Note. |
| **Card** (for C-CDA) | This is the cardinality, the minimum and maximum number of times that the XML element can be present in a Pharmacist Consultation note. The format is<br><br>(minimum)…(maximum)<br><br>A minimum value of 0 indicates the element is optional. A maximum value of * indicates the element can me repeated as many times as necessary. |
| **FHIR Composition** | The FHIR element within the Composition resource where the described information is located. In FHIR, this may be an element that exists in a referenced resource, for example the Composition resource would refer to a Patient resource (i.e., subject(reference(USCore Patient Profile))) where Patient.name contains the patient's name.<br><br>"---" indicates that the concept does not pertain to the FHIR structure. Either the concept doesn't apply or the concept is incorporated differently than how it is incorporated in C-CDA |

| | |
|---|---|
| | "Composition" is the focal FHIR Resource for a Pharmacist Consultation Note. |
| **Card**<br>(for FHIR) | This is the cardinality, the minimum and maximum number of times that the Composition element can be present in a Pharmacist Consultation note. The format is<br><br>(minimum)…(maximum)<br><br>A minimum value of 0 indicates the element is optional. A maximum value of * indicates the element can me repeated as many times as necessary.<br><br>NOTE: A red boxed "S" (S) identifies "must support" FHIR elements. This denotes that the sender of the information must send that information if it exists, and that the receiver of the document must be able to support (e.g., store, display, forward) that information. Even if the receiver does not utilize the information, that information must be retained, stored, displayed, and/or forwarded. |

*Table 1 US Realm Header with Consultation Note and Pharmacist Consultation Note specializations*

| **Description** | **C-CDA ClinicalDocument** | **Card** | **FHIR Composition** | **Card** |
|---|---|---|---|---|
| Document regional use | realmCode<br>fixed code "US" | 1..1 | --- | |
| Base structure definition | typeId<br>fixed OID "2.16.840.1.113883.1.3"<br>"POCD_HD000040" | 1..1 | resourceType<br>fixed value "Composition" | 1..1 |
| Specific structure definition | templateId<br>2 fixed entries<br>@root="2.16.840.1.113883.10.20.22.1.1"<br>@extension="2015-08-01<br>(for US Realm Header)<br><br>"@root="2.16.840.1.113883.10.20.22.1.4"<br>@extension="2015-08-01"<br>(for Consultation Note profile) | 1..* | meta.profile<br>fixed value<br>"http://hl7.org/fhir/us/ccda/StructureDefinition/Consultation-Note" | 0..* |
| A unique identifier for the document (e.g., an OID or GUID) | id | 1..1 | id | 0..1 |
| Identify the document as a "Pharmacist Consult Note" | code<br>fixed value LOINC 93024-8 \| Pharmacist Consult | 1..1 | type<br>fixed value | 1..1 S |

| Description | C-CDA ClinicalDocument | Card | FHIR Composition | Card |
|---|---|---|---|---|
| | note | | coding.system = "http://loing.org",<br>coding.code: "93024-8",<br>coding.display: "Pharmacist Consult note" | |
| A title for the document | title | 1..1 | title | 1..1 |
| Publication date/time of this document | effectiveTime | 1..1 | date | 1..1 |
| Confidentiality | confidentialityCode | 1..1 | meta.security | 0..1 |
| The patient (1 or more) | recordTarget/patientRole | 1..* | subject (reference<br>US Core Patient Profile<br>or<br>Group | 0..1 |
| identifier (1 or more) | ID | 1..* | Patient.identifier | 1..* S |
| address | Address | 1..* | Patient.address | 0..* S |
| communication | Telecommunication | 1..* | Patient.telecom | 0..* S |
| name | Name | 1..* | Patient.name | 1..* S |
| gender | Gender | 1..1 | Patient.gender<br>and<br>Patient.us-core-birthsex | 1..1 S<br><br>0..1 S |
| date of birth | Birth Date | 1..1 | Patient.birthDate | 0..1 S |
| race | Race Code | 1..1 | Patient.us-core-race | 0..1 S |
| ethnicity | Ethnicity Group | 1..1 | Patient.us-core-ethnicity | 0..1 S |
| language(s) | Language Code | 1..* | Patient.communication.language | 1..1 S |
| marital status | Marital Status | 0..1 | Patient.maritalStatus | 0..1 |
| religious preference | Religious Affiliation | 0..1 | --- | --- |
| guardian | Guardian | 0..* | Patient.contact (relationship=”GARD”) | 0..* |
| birthplace | Birthplace | 0..1 | --- (extension: birthplace \|<br>Patient.extension.birthplace ?) | --- |
| Organization that maintains the patient information | Provider Organization | 0..1 | Patient.managingOrganization | 0..1 |
| Author | Author | 1..* | author | 1..* S |
| When the author “signed” the consultation note | Date and Time | 1..1 | attester:professional_attester.time | 0..* S |
| A provider as the author (who is responsible, not who | Assigned Author Person | 1..1 | author reference (<br>US Core Practitioner Profile \| | 1..* S |

| Description | C-CDA ClinicalDocument | Card | FHIR Composition | Card |
|---|---|---|---|---|
| entered the information) | | | US Core PractitionerRole Profile \| PractitionerRole \| US Core Patient Profile \| RelatedPerson ) | |
| A device as the author | Assigned Author Device | 0..1 | author reference ( Device ) | 0..* S |
| Custodian - the organization that oversees maintaining and is entrusted with the care of the document | Custodian | 1..1 | custodian reference ( US Core Organization Profile ) | 1..1 S |
| | Assigned Custodian | 1..1 | --- | --- |
| | Represented Custodian Organization | 1..1 | --- | --- |
| The person who entered the consultation note into the system (if not the author) | Data Enterer | 0..1 | DataEntererExtension | 0..1 S |
| Other practitioners who provided information contained in this consultation note | Informant | 0..* | InformantExtension reference ( US Core Practitioner Profile \| US Core PractitionerRole Profile ) | 0..* S |
| The patient or others (non-practitioners) who provided information contained in this consultation note | Informant Non-Provider | 0..* | InformantExtension reference ( US Core Patient Profile \| RelatedPerson ) | 0..* S |
| The intended recipients for this consultation note | Information Recipient | 0..* | InformationRecipientExtension reference ( US Core Practitioner Profile \| US Core PractitionerRole Profile\| US Core Patient Profile \| RelatedPerson ) | 0..* S |
| A participant who has attested to the accuracy of the composition/document | Legal Authenticator | 0..1 | Attester:legal_attester | 0..1 S |
| | Authenticator | 0..* | Attester:professional_attester | 0..* S |
| The patient, other practitioner(s), or other persons who participated in creating this consultation note. | Participant | 0..* | ParticipantExtension reference ( US Core Practitioner Profile \| US Core PractitionerRole Profile \| US Core Patient Profile \| | 0..* S |

| Description | C-CDA ClinicalDocument | Card | FHIR Composition | Card |
|---|---|---|---|---|
| | | | RelatedPerson ) | |
| The clinical encounter or type of care this documentation is associated with. | Component of encompassingEncounter | 0..* | Encounter reference ( US Core Encounter Profile ) | 1..1 S |
| Performer | | 0..* | PerformerExtension reference ( US Core Practitioner Profile \| US Core PractitionerRole Profile ) | 0..* S |
| Patient consents related to the consultation note | Authorization Consent | 0..* | AuthorizationExtension reference ( Consent ) | 0..* S |
| | | | | |
| The content sections | Component | 1..* | section | |
| Advance Directives Section | Advance Directives Section (entries optional) (V3) | 0..1 | advance_directives_section | 0..1 S |
| Allergies and Intolerances Section | Allergies and Intolerances Section (entries required) (V3) | 1..1 | allergies_and_intolerances_section | 1..1 S |
| Assessment and Plan Section | Assessment and Plan Section (V2) Or Assessment Section | 1..1 | assessment_and_plan_section or assessment_section | 1..1 |
| Chief Complaint and Reason for Visit Section. | Chief Complaint and Reason for Visit Section | 0..1 | chief_complaint_and_reason_for_visit_section | 0..1 |
| Chief Complaint Section | Chief Complaint Section | 0..1 | chief_complaint_section | 0..1 |
| Family History Section | Family History Section (V3) | 0..1 | family_history_section | 0..1 |
| Functional Status Section | Functional Status Section (V2) | 0..1 | functional_status_section | 0..1 |
| General Status Section | General Status Section | 0..1 | general_status_section | 0..1 |
| History of Present Illness Section | History of Present Illness Section | 1..1 | history_of_present_illness_section | 1..1 |
| Immunizations Section | Immunizations Section (entries optional) (V3) | 0..1 | immunizations_section | 0..1 S |
| Medical Equipment Section | Medical Equipment Section (V2) | 0..1 | medical_equipment_section | 0..1 |
| Medications Section | Medications Section (entries required) (V2) | 0..1 | medications_section | 0..1 S |
| Mental Status Section | Mental Status Section (V2) | 0..1 | mental_status_section | 0..1 |
| Nutrition Section | Nutrition Section | 0..1 | nutrition_section | 0..1 |
| Past Medical History Section | Past Medical History (V3) | 0..1 | past_medical_history_section | 0..1 |
| Physical Exam Section | Physical Exam Section (V3) | 0..1 | physical_exam_section | 0..1 S |
| Plan of Treatment Section | Plan of Treatment Section (V2) | 1..1 | plan_of_treatment_section | 1..1 |

| Description | C-CDA ClinicalDocument | Card | FHIR Composition | Card |
|---|---|---|---|---|
| Problem Section | Problem Section (entries required) (V3) | 1..1 | problem_section | 1..1 |
| Procedures Section | Procedures Section (entries optional) (V2) | 0..1 | procedures_section | 0..1 |
| Reason for Visit Section | Reason for Visit Section | 0..1 | reason_for_visit_section | 0..1 S |
| Results Section | Results Section (entries required) (V3) | 0..1 | results_section | 0..1 |
| Review of Systems Section | Review of Systems Section | 0..1 | review_of_systems_section | 0..1 |
| Social History Section | Social History Section (V3) | 0..1 | social_history_section | 0..1 |
| Vital Signs Section | Vital Signs Section (entries required) (V3) | 0..1 | vital_signs_section | 0..1 |

### 5.1.1 PHARMACIST CONSULTATION NOTE HEADER EXAMPLE

The Header provides a source of demographic and administrative data related to the consultation being documented. The sections of particular importance for the Pharmacist Consultation Note are: Record Target (i.e., the patient), Author (i.e., the pharmacist), Custodian (organization maintaining the document), and the information recipient(s) (facility director of nursing, attending physician, prescriber, pharmacy, etc.).

The patient information contained within the Header includes full name, date of birth, gender, physical address (for LTC name, address, room and if applicable bed number), communication information (phone, cell phone, e-mail, etc.), language preference, assigned identifiers (health plan IDs, provider assigned ID's, etc.) and any other information needed to uniquely identify the patient.

In the LTPAC facility setting, it is frequently necessary to provide detailed information on the patient's physical location. The header allows reporting of the precise physical location using multiple iterations of the unit type value. Following is an example of the XML conveying the location as room 5, bed D in wing 12a:

| C-CDA | FHIR |
|---|---|
| recordTarget/patientRole/ | Composition.subject reference to US Core Patient Profile |
| <ClinicalDocument><br>… *[omitted for clarity]*<br><recordTarget><br><patientRole><br>… *[omitted for clarity]*<br><addr use="PHYS"><br><unitType>Wing</unitType><br><unitID>12a</unitID><br><unitType>Room</unitType><br><unitID>5</unitID><br><unitType>Bed</unitType><br><unitID>D</unitID><br><streetAddressLine>Good Health Long Term Care Facility</streetAddressLine><br><streetAddressLine>124 Any Street</streetAddressLine><br><city>Anyville</city><br><state>CA</state><br><postalCode>97812</postalCode><br><country>US</country><br></addr><br>… *[omitted for clarity]*<br></patientRole><br>… *[omitted for clarity]*<br></recordTarget><br>… *[omitted for clarity]*<br></ClinicalDocument> | {<br>"resourceType": "Patient"<br>… *[omitted for clarity]*<br>"address" : [<br>{<br>"type": "physical"<br>"line" : [<br>"Wing 12a",<br>"Room 5",<br>"Bed D",<br>"Good Health Long Term Care Facility",<br>"124 Any Street"<br>],<br>"city" : "Anyville",<br>"state" : "CA",<br>"postalCode" : "97812",<br>"country" : "US"<br>}<br>]<br>… *[omitted for clarity]*<br>} |

| | |
|---|---|

The telephone number for the patient is required. Where applicable within a LTPAC facility setting, the bedside phone for the patient is reported. Otherwise, the phone at the nurse's station or other appropriate facility phone is used.

Within the elements of the header, the Provider Organization provides information on the physician with the primary responsibility for the patient's care or coordination of the care, (e.g., a primary care physician, medical director or appropriate facility staff).

The Custodian is the keeper and maintainer of the original source document. It may be the author, a health information exchange (HIE) or other responsible entity. For patients in an LTPAC facility, the facility is the custodian.

Informants may be facility staff, other professionals involved in the patient's care, or non-providers such as relatives, patient advocates or the patient.

The Information Recipient elements allow the identification of multiple entities to whom the Pharmacist Consultation Note is to be sent. Each iteration provides the name and address of the recipient and, where applicable, identification numbers. In addition to the patient's EHR, the recipients may include facility, attending physician, prescriber, Director of Nursing, responsible party or any other members of the patient's care team.

The Participant elements provide the mechanism for identifying the individuals and organizations in a supporting relationship to the patient and the role they play. Examples include responsible party, next of kin, emergency contact, insurance policy holders, etc.

The Performer elements are used in transfer of care scenarios to identify the care team members actively participating in the patient's care in the discharge and admitting environments. This includes when the discharge is to a community setting. These elements also apply when the patient is seen in outpatient settings such as a dentist or physician office, dialysis center, etc.

## *5.2 PHARMACIST CONSULTATION NOTE*

The content of both the C-CDA Consultation Note and the FHIR Consultation Note are very similar. This section describes the overall content and provides details for the required and recommended content.

The Pharmacist Consult Note requires and recommends some content that is optional in the C-CDA and FHIR Consultation Notes. These changes are noted in the following table with base value marked out and the updated value added (e.g., **Required**).

"Must Support" denotes that the sender of the information must send that information if it exists, and that the receiver of the document must be able to support (e.g., store, display, forward) that information.

| **Sections** | **C-CDA Consultation Note (V2)** | | **FHIR Pharmacist Consultation Note** | |
|---|---|---|---|---|
| Advance Directives | Optional | Advance Directives Section (entries optional) (V2) | Optional<br>Must Support | advance_directives_section |
| Allergies and Intolerances | **Required** | Allergies and Intolerances Section (entries required) (V2) | **Required**<br>Must support | allergies_and_intolerances_section |
| Assessment and Plan | **Required** | Assessment and Plan Section (V2)<br>Or<br>Assessment Section | **Required** | assessment_and_plan_section<br>or<br>assessment_section |
| Chief Complaint | Optional | Chief Complaint Section | Optional | chief_complaint_section |
| Chief Complaint and Reason for Visit | Optional | Chief Complaint and Reason for Visit Section | Optional | chief_complaint_and_reason_for_visit_section |
| Family History | Optional | Family History Section (V2) | Optional | family_history_section |
| Functional Status | Optional | Functional Status Section (V2) | Optional | functional_status_section |
| General Status | Optional | General Status Section | Optional | general_status_section |
| History of Past Illness | Optional | History of Past Illness Section (V2) | Optional | past_medical_history_section |
| History of Present Illness | **Required** | History of Present Illness Section | **Required**<br>Must Support | history_of_present_illness_section |
| Immunizations Section | **Should** | Immunizations Section (entries optional) (V2) | Optional<br>**Must Support** | immunizations_section |
| Medical Equipment | Optional | Medical Equipment Section (V2) | Optional | medical_equipment_section |
| Medications | **Should** | Medications Section (entries SHALL) (V2) | Optional<br>**Must Support** | medications_section |

| Sections | C-CDA Consultation Note (V2) | | FHIR Pharmacist Consultation Note | |
|---|---|---|---|---|
| Mental Status | Optional | Mental Status Section | Optional | mental_status_section |
| Nutrition | Optional | Nutrition Section | Optional | nutrition_section |
| Physical Exam | **Should** | Physical Exam Section (V2) | Optional **Must Support** | physical_exam_section |
| Plan of Treatment | **Required** | Plan of Treatment Section (V2) | **Required** | plan_of_treatment_section |
| Problems | **Required** | Problem Section (entries SHALL) (V2) | **Required** | problem_section |
| Procedures | Optional | Procedures Section (entries optional) (V2) | Optional | procedures_section |
| Reason for Visit | **Should** | Reason for Visit Section | Optional **Must Support** | reason_for_visit_section |
| Results | Optional | Results Section (entries SHALL) (V2) | Optional | results_section |
| Review of Systems | Optional | Review of Systems Section | Optional | review_of_systems_section |
| Social History | Optional | Social History Section (V2) | Optional | social_history_section |
| Vital Signs | Optional | Vital Signs Section (entries SHALL) (V2) | Optional | vital_signs_section |

The consultant pharmacist review of patient status and medications is primarily based in LTPAC regulation but may also occur on referral by the facility physician or other staff to address a specific problem. A consultation is required for all transitions of care, for monthly medication review and the annual comprehensive Medication Therapy Management (MTM). The Pharmacist Consultation Note includes the reason for the consultation, history of present illness, identified problems, medication review, and decision-making components (Assessment and Plan). The consultation may involve face-to-face time with the patient, although frequently in the LTPAC setting the interaction is with staff providing direct care to the patient.

### 5.2.1. ALLERGIES AND INTOLERANCES SECTION

Allergies and Intolerances lists and describes any allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions and metabolic variations to medications, food or other substances (such as latex, iodine, tape adhesives). At a minimum, it should list any currently active and relevant historical allergies and adverse reactions. Each allergy or intolerance is reported in an Allergy and Intolerance observation.

Information on medication-related allergies and adverse reactions is critical, including non-medication substances associated with the administration of the medication. Because of the metabolic interactions between foods and medications and the chemical make-up of foods, it is also important that food allergies and sensitivities be documented and evaluated. Observing patient sensitivities to environmental substances which impact their medication management is important (e.g., the need to increase use of inhalers when the pollen index is high, sensitivity to iodine as a skin preparation for injections, etc.).

The following section/entry table describes key elements in both C-CDA and FHIR presentation.

Sections an Entries for Allergies and Intolerances

| Section | C-CDA Consultation Note (V2) | FHIR US Core Consultation Note |
|---|---|---|

| | | | | |
|---|---|---|---|---|
| **Allergies and Intolerances** | **Required** | Allergies and Intolerances Section (entries required) (V2)<br>Containing one<br>Allergy Concern Act (V3) | **Required**<br>Must support | allergies_and_intolerances_section |
| **Entry** | **C-CDA Consultation Note (V2)** | | **FHIR US Core Consultation Note** | |
| **Allergy and Intolerance Observation** | **One to many** | Allergy - Intolerance Observation (V2)<br>(within Allergy Concern Act(v3)) | **One to many** | US Core AllergyIntolerance |

#### 5.2.1.1 ALLERGY CONCERN ACT (V3) – C-CDA only

The Allergy Concern Act identifies the ongoing concern of the provider who placed the allergy on a patient's allergy list. As long as the underlying condition is of concern to the provider, whether the allergy is active or resolved, the statusCode is "active". Only when the underlying allergy is no longer of concern is the statusCode set to "completed". The effectiveTime, also referred to as the "biologically relevant time", reflects the period when the observation is valid for the patient and is the definitive indication of whether or not the underlying allergy is resolved. The effectiveTime/low of the Allergy Concern Act asserts when the concern became active, i.e., was added as a concern in the patient's chart. The effectiveTime/high asserts when the concern was completed (i.e., there is no longer any need to track the underlying condition). The effectiveTime/high is used when the allergy/intolerance is resolved. A null Flavor is used if the date of resolution is unknown.

#### 5.2.1.2 ALLERGY- INTOLERANCE OBSERVATION - REQUIRED – C-CDA only

Allergy Intolerance Observation includes reactions to foods, chemicals, and other substances, environmental factors in addition to medications (prescription, over the counter (OTC) and herbal).

The Allergy-Intolerance Observation records discrete information regarding past and current reactions, cause of the reaction, the time first noted, the severity, criticality, whether resolved, etc. The observed reaction may be incorporated as a risk in the current Plan of Treatment or may represent a concern the provider is monitoring to assure it does not impact the therapeutic regimen or treatment outcomes.

### 5.2.2. ASSESSMENT AND PLAN

Assessment and Plan represents the pharmacist's impressions, conclusions and working assumptions that will guide the recommendations for treatment of the patient.

In the LTPAC setting the consultant pharmacist's assessment usually is based on review of the facility clinical staff's documented assessments of the cognitive, functional, nutritional, wound and other statuses. Particular attention is given to any assessments related to a need for changes in the medication regimen, for example but not limited to:

- dose too low
- dose too high
- drug intolerance or sensitivity
- effectiveness of the medication in ameliorating the indication
- inability to consume dose form
- changes in mood, behavior, cognitive status after initiation of the medication
- changes in mobility status
- changes in pain level

Attention is also given to laboratory results (e.g., international normalized ratio [INR], blood glucose, etc.) to ascertain pharmacokinetic information as part of the pharmacotherapy including pharmacogenetics (determining the correct dose related to patient's physical and genetic ability to absorb and eliminate the medication).

The Plan of Treatment Section details the pharmacist's recommendations related to modifications to the medication orders, monitoring for specific desired or unwanted results including laboratory or other testing, recommendations for specific evaluations, such as a nutrition consult, detailed charting of blood glucose (including the timing of the test, food intake and medications), seizure activity, pain fluctuations, psychotropic medication gradual dose reductions, management of potentially inappropriate medication use in older adults, etc.

The Assessment and Plan may be Present as a single section (e.g., Assessment and Plan Section) or as two distinct sections (e.g., Assessment Section and Plan section), depending on local policy requirements. The following section/entry tables describe the primary points for both presentation methods, in both C-CDA and FHIR.

Sections an Entries for consolidated Assessment and Plan

| **Section** | **C-CDA Consultation Note (V2)** | | **FHIR US Core Consultation Note** | |
|---|---|---|---|---|
| **Assessment and Plan** | **Required** | Assessment and Plan Section (V2) | **Required**<br>Must support | assessment_and_plan_section |
| **Entry** | **C-CDA Consultation Note (V2)** | | **FHIR US Core Consultation Note** | |
| **Assessment Observation** | **One only Required** | Assessment and Plan Section.text<br>(free-text only) | **One only Required** | assessment_and_plan_section.text<br>(free-text only) |
| **Plan Elements** | **Zero to 1** | Planned Act (V2) | **One to many** | US Core Condition Profile<br>or |

| Section | C-CDA Consultation Note (V2) | | FHIR US Core Consultation Note | |
|---|---|---|---|---|
| | **Zero to many** (within Planned Act (V2)) | Indication (V2)<br>Or<br>Priority Preference<br>Or<br>Instruction (V2)<br>Or<br>Author Participation | | Observation<br>or<br>Communication |

Sections and Entries for Assessment

| Section | C-CDA Consultation Note (V2) | | FHIR US Core Consultation Note | |
|---|---|---|---|---|
| **Assessment** | **Required** | Assessment Section | **Required**<br>Must support | assessment_section |
| **Entry** | **C-CDA Consultation Note (V2)** | | **FHIR US Core Consultation Note** | |
| **Assessment Observation** | **One** | Section.text<br>(free-text only) | **One** | assessment_section.text<br>(free-text only) |
| | | | **Zero to many** | Assessment_section.entry<br>(a means to include supporting information) |

Sections and Entries for Plan

| Section | C-CDA Consultation Note (V2) | | FHIR US Core Consultation Note | |
|---|---|---|---|---|
| **Plan** | **Required** | Plan of Treatment Section (V2) | **Required**<br>Must support | plan_of_treatment_section |
| **Entry** | **C-CDA Consultation Note (V2)** | | **FHIR US Core Consultation Note** | |
| **Plan elements** | **Required** | Plan of Treatment Section.text<br>(free text) | **Required** | Plan_of_treatment_section.text<br>(free text) |
| | **Zero to many** | Goal Observation<br>Or<br>Nutrition Recommendation<br>Or<br>Planned Act (V2)<br>Or<br>Planned Encounter (V2)<br>Or<br>Planned Procedure (V2)<br>Or<br>Planned Observation (V2)<br>Or<br>Planned Supply (V2)<br>Or<br>Planned Medication Activity (V2)<br>Or<br>Handoff Communication Participants<br>Or<br>Instruction (V2)<br>Or<br>Planned Immunization Activity | **Zero to many** | US Core Goal Profile<br>Or<br>US Core MedicationRequest Profile<br>Or<br>US Core1 Encounter Profile<br>Or<br>Communication<br>Or<br>Appointment<br>Or<br>CommunicationRequest<br>Or<br>DeviceRequest<br>Or<br>NutritionOrder<br>Or<br>Task<br>Or<br>ServiceRequest<br>Or<br>VisionPrescription<br>Or<br>RequestGroup |

### 5.2.3. HISTORY OF PRESENT ILLNESS

The History of Present Illness section describes the indications and related medical history under review in this consultation. This establishes the reason for the consultation and recommendations as related to the patient's condition, diagnosis and current status. It contains the historical details leading up to and pertaining to the current consultation.

The following section/entry table describes key elements in both C-CDA and FHIR presentation.

Sections and Entries for History of Present Illness

| Section | C-CDA Consultation Note (V2) | | FHIR US Core Consultation Note | |
|---|---|---|---|---|
| **History of Present Illness** | **Required** | History of Present Illness | **Required**<br>Must support | history_of_present_illness_section |
| **Entry** | **C-CDA Consultation Note (V2)** | | **FHIR US Core Consultation Note** | |
| **History of present illness entries** | **One** | Section.text<br>(free text) | **Required**<br>Must support | history_of_present_illness_section.text<br>(free text) |
| | | | **Zero to many** | History_of_present_illness.entry<br>(optional supporting information) |

### 5.2.4. PROBLEM

Problems, both past and present**,** relevant at the time of the consultation are described in this section. Overall health status may also be included.

The following section/entry table describes key elements in both C-CDA and FHIR presentation.

Sections and Entries for Problem

| Section | C-CDA Consultation Note (V2) | | FHIR US Core Consultation Note | |
|---|---|---|---|---|
| **Problem** | **Required** | Problem Section (entries required) (V3) | **Required** | problem_section |
| **Entry** | **C-CDA Consultation Note (V2)** | | **FHIR US Core Consultation Note** | |
| **Problem entries** | **Required** | Problem Section.text<br>(free text) | **Required** | problem_section.text<br>(free text) |
| | **Required** | Problem Concern Act (V3) which requires Problem Observation (V3) | | |
| | **Zero to One Optional** | Heath Status Observation (V2) | **Zero to many** | US Core Condition Profile |

#### 5.2.1.3 PROBLEM OBSERVATION (V3)

The Problem Observation records a discrete identification of a problem whether past or current. The associated effective low (beginning) date reflects when the problem was first identified. The effective high (end) date reflects when it was resolved, if applicable. For example, a problem observation of an allergic reaction to a medication that occurred five years ago will have the five-year old date as the effective low date, but no effective high date; indicating an ongoing problem of concern. If a pharmacist identifies a problem has been resolved, the pharmacist should document the resolution of the problem with a high date.

The indication for a medication should be matched to a problem noted on the Problem List. If the patient is on a medication that does not reflect an observed problem on the Problem List, it would indicate a need for reconciliation of the Problem list with the Medication list.

### 5.2.5. REASON FOR VISIT

This section provides and documents the classification of the service performed. Most often in the LTPAC setting the reason is administrative (new facility admission, transitions, monthly medication reviews, medication room inspection), but may also include the identification of new problems or activation of new concerns by the facility staff or reported by the patient. Patient expressed problems are documented using the Chief Complaint Section template.

The following section/entry table describes key elements in both C-CDA and FHIR presentation.

Sections and Entries for Reason for Visit

| **Section** | **C-CDA Consultation Note (V2)** | | **FHIR US Core Consultation Note** | |
|---|---|---|---|---|
| **Reason for Visit** | **Optional** | Reason for Visit Section | **Optional** | reason_for_visit_section |
| **Entry** | **C-CDA Consultation Note (V2)** | | **FHIR US Core Consultation Note** | |
| **Plan elements** | **Required** | Reason for Visit Section.text (free text) | **Required** | Reason_for_visit_section.text (free text) |
| | | | **Zero to many Optional** | Reason_for_visit_section.entry (optional supporting information) |

### 5.2.6. IMMUNIZATION

The Immunizations Section defines a patient's current immunization status and pertinent immunization history. In the facility setting, periodic review of the immunization status is important both for the patient's wellbeing and public health.

The following section/entry table describes key elements in both C-CDA and FHIR presentation.

Sections and Entries for Immunization

| **Section** | **C-CDA Consultation Note (V2)** | | **FHIR US Core Consultation Note** | |
|---|---|---|---|---|
| **Immunization** | **Optional** | Immunizations Section (entries optional) (V3) | **Optional** | Immunizations_section |
| **Entry** | **C-CDA Consultation Note (V2)** | | **FHIR US Core Consultation Note** | |
| **Immunization entries** | **Required** | Immunization Section.text (free text) | **Required** | Reason_for_visit_section.text (free text) |
| | **Zero to many** | Immunization Activity (V3) | **Zero to many** | US Core Immunization Profile |

### 5.2.7. MEDICATIONS

It is expected the Medications Section will be included in most instances in the Pharmacist Consultation Note (C-CDA or FHIR) for reference purposes of the patient's active medication list pertinent medication history. Drugs administered or planned for administration may be included.

The following section/entry table describes key elements in both C-CDA and FHIR presentation.

Sections and Entries for Medications

| **Section** | **C-CDA Consultation Note (V2)** | | **FHIR US Core Consultation Note** | |
|---|---|---|---|---|
| **Medications** | ~~**Optional**~~ **Should** | Medication Section (entries required) (V2) | ~~**Optional**~~ **Should** | Medications_section |
| **Entry** | **C-CDA Consultation Note (V2)** | | **FHIR US Core Consultation Note** | |
| **Medication record(s)** | **Required** | Medication Section.text (free text) | **Required** | Medications_section.text (free text) |
| | **One to many** | Medication Activity (V2) | **Zero to many** | MedicationStatement<br>Or<br>US Core Medication Profile<br>Or<br>US Core MedicationRequest Profile |

## *5.3 PHYSICIAN CONSULTATION NOTE (RESPONSE TO PHARMACIST)*

The attending physician and/or facility reviews the pharmacist's assessment of the patient, recommendations for treatment or changes to treatment and requests for follow-up actions. In a LTPAC facility setting, the physician is required by regulation to respond with acceptance/rejection to the specific recommendations made by the consultant pharmacist, including actions taken or planned and the rationale for any rejections. SNOMED CT coding is used to describe the actions and reasons for non-action. The physician response also serves to acknowledge receipt of the consultant pharmacist's recommendations.

For the most part the header echoes the information from the header of the Pharmacist Consultation Note (C-CDA or FHIR). The primary differences relate to the document type (LOINC 11488-4 | Consultation note), author, actors and roles.

The focus of the Physician response is on the Assessment and Plan Section(s). Other sections may provide updates (e.g., History of Present Illness or Allergies and Intolerance) or echo the pharmacist's documentation.

# 6. Appendix A – History of Document Changes

## *VERSION 1.1*

For Version 1.1 there were many updates and additions to the document such as:

1. Throughout document
   a) Standardized to “Pharmacist Consultation Note”
   b) Standardized to “C-CDA”
   c) Editorial changes to refer to both C-CDA and FHIR when applicable
2. Purpose section
   a) Major rewrite of the section
   b) Added footnotes
3. Audience Section
   a) Minor update to the first sentence
4. Overview Section
   a) Added new overview content to broaden scope beyond LTPAC
   b) Moved LTPAC content to new section 3.1
   c) Added footnote to CMS reference and updated the full name (Appendix PP - Guidance to Surveyors for Long Term Care Facilities Transmittals for Appendix PP, Revision 173, November 22, 2017) for the document
5. Section 4 Use cases
   a) Section 4.1 Use Case 1 and throughout the document
   b) Updated C-CDA Consult Note to remove “C-CDA”
   c) Section 4.3 Use Case 3 added
6. Section 5.1
   a) Modified title to add “(metadata)” and remove “(V3) Required”
   b) New table mapping document concepts to both C-CDA and FHIR
7. Section 5.1.1 Consultant Pharmacy Consult Note Header Example
   a) Added table illustrating complex address
8. Section 5.2 Consultant Pharmacist Consultation Note
   a) Major re-write throughout the entire section, tables added throughout
9. Section 5.3 – Clarifications throughout this section