

# **Consultant Pharmacist Consult Note**

**Version 1.0**

## **Guidance on the Use of the HL7 CDA Consolidated Templates for Clinical Notes R2.1 Consult Note**

October 2017

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**Published by:**

**National Council for Prescription Drug Programs**

**Publication History:**

**Version 1.0 October 2017**

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## 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* (C-CDA) in creating a Consultant Pharmacist Consult Note. The Consultant Pharmacist Consult Note is used for exchange of the pharmacist's recommendations with the appropriate long term post acute care (LTPAC) facility staff and the physician(s) of record for the patient. This paper is based on the C-CDA Consult Note Document Template.

This guidance is intended to be used in conjunction with the specifications as defined in the C-CDA Clinical Notes Consult Document Template. The NCPDP Long Term and Post Acute Care (LTPAC) Work Group (WG14) Consultant Pharmacist Interoperability Task Group has reviewed the C-CDA templates and found the content and functionality of the Consult Note Document Template and other specified templates meet the requirements for structured documentation of the Consultant Pharmacist's Consult Note.

Information regarding levels of constraint, conformance statements, conformance verbs, cardinality, vocabulary conformance, and null flavor is found in the *HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Standard for Trial Use Release 2.1 Volumes 1 and 2*.

The specifications for the US Realm Header are found in Section 1.1 and the Consult Note in Section 1.1.3 of Volume 2 of the standard. The constraints as defined in the C-CDA are in accordance with Meaningful Use and US realm regulatory healthcare information technology (HIT) certification requirements. This document is available from Health Level Seven International (HL7) at <http://www.hl7.org>. The current specific link for download of the implementation guide is [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=408](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=408).

Note: The Consultant Pharmacist C-CDA Consult Note described herein does not support facility consultations on 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.

## **2. AUDIENCE**

The audience for this recommendation for use of the C-CDA Consult Note is the architects and developers 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

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. For the purpose of this document, the term patient will be used when referring to residents of LTPAC facilities. 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 Revision 157, June 10, 2016. The cms.gov website should be consulted for any updates to regulatory requirements.

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:

- Are receiving respite care;
- Are at the end of life or have elected the hospice benefit and are receiving respite care;
- Have an anticipated stay of less than 30 days; or
- 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.

The recommendations provided for use of the C-CDA Consult Note to construct the Consultant Pharmacist Consult Note are 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 Consult Note 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 Consult Note potentially provide medication-related input into the patient's care plan goals, health concerns and interventions. The Consultant Pharmacist Consult Note is integral to the development and maintenance of the LTPAC resident's longitudinal care plan.

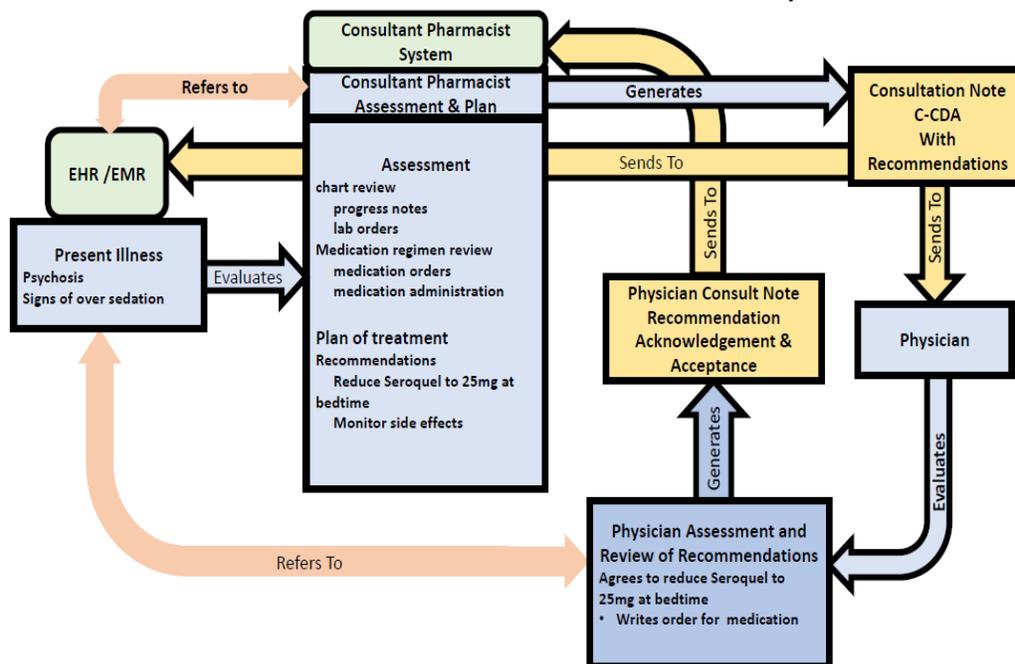
#### 4. CONSULTANT PHARMACIST CONSULTATION USE CASES

The consultant pharmacist role is critical to the management of patients in long term care settings by providing clinical review and medication reconciliation upon admission/readmission/discharge. The consultant pharmacist provides a monthly regimen review of the efficacy and appropriateness of the medications and the overall treatment plan. They serve as a bridge between the facility medical staff (nursing and physician) and the pharmacy. The following use cases demonstrate examples of consultant pharmacist’s activities and clinical documentation.

##### 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.)

#### Use Case 1 - Consultant Pharmacist Monthly Visit



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 C-CDA Consult 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 C-CDA Consult Note. The responses to the recommendations are tracked in the consultant pharmacist software. As a result of the consult note exchange, the information is available for outcomes reporting.

## 4.2 USE CASE 2

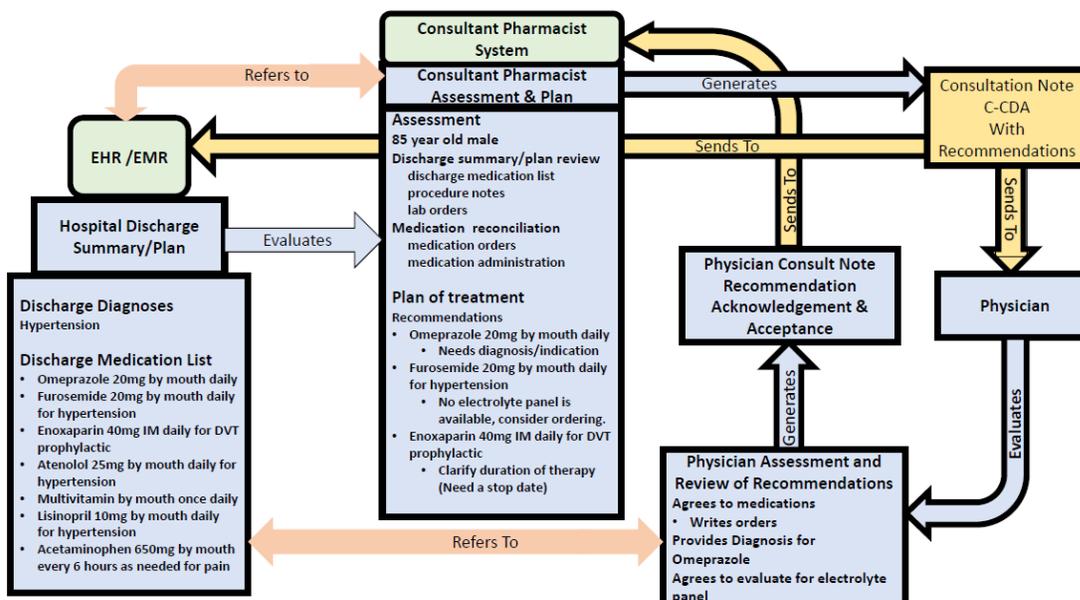
The consultant pharmacist receives information from the SNF that an 85 year old male has been admitted from the hospital. The consultant pharmacist performs a medication reconciliation of all prescribed, and non-prescription medications. During the medication reconciliation process the consultant pharmacist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

### Use Case 2- Consultant Pharmacist New Admission



The consultant pharmacist generates a physician or nursing recommendation in the C-CDA Consult 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 Consultant Consult Note. The responses of the MRR recommendations are tracked in the consultant pharmacist software. As a result of the consult note exchange, the information is available for outcomes reporting.

## 5. TEMPLATE REQUIREMENTS

### 5.1 US REALM HEADER (V3) - REQUIRED

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.

Required Data	Optional Data
Target/Patient ID 1..* Address1..* Telecommunication 1..* Name 1..* Gender 1..1 Birth Date 1..1 Race Code 1..1 Ethnicity Group 1..1 Language Code 1..*	Target/Patient Marital Status 0..1 Religious Affiliation 0..1 Guardian 0..* Birthplace 0..1 Provider Organization 0..1
Author Date and Time 1..1 Assigned Author Person 1..1	Author Assigned Author Device 0..1
Custodian Assigned Custodian 1..1 Represented Custodian Organization 1..1	
	Data Enterer 0..1
	Informant 0..*
	Informant Non-Provider 0..*
	Information Recipient 0..*
	Legal Authenticator 0..1
	Authenticator 0..*
	Participant 0..*
	Documentation Of 0..*
	Performer 0..*
	Authorization Consent 0..*
	Component Of 0..*

#### 5.1.1 CONSULTANT PHARMACIST CONSULT NOTE HEADER

The Header provides a source of demographic and administrative data related to the consultation being documented. The sections of particular importance for the Consultant Pharmacist Consult Note are: Record Target (i.e., the patient), Author (i.e. the consultant 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 long term care 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:

(recordTarget/patientRole/addr):

```
<addr use="PHYS">
  <unitType>Wing</unitType><unitID>12a</unitID>
  <unitType>Room</unitType><unitID>5</unitID>
  <unitType>Bed</unitType><unitID>D</unitID>
  <streetAddressLine>Good Health Long Term Care Facility</streetAddressLine>
  <streetAddressLine>124 Any Street</streetAddressLine>
  <city>Anyville</city>
  <state>CA</state>
  <postalCode>97812</postalCode>
  <country>US</country>
</addr>
```

The telephone number for the patient is required. Where applicable, 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 Consult 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 C-CDA CONSULTANT PHARMACIST CONSULT NOTE

### Consultation Note (V2) Sections

Required Sections	Optional Sections
<b>Allergies and Intolerances Section (entries required) (V2)</b> <b>Assessment and Plan Section (V2) or</b> Assessment Section Plan of Treatment Section (V2) <b>History of Present Illness Section</b> <b>Problem Section (entries required) (V2)</b> <b>Reason for Visit Section</b>	Advance Directives Section (entries optional) (V2) Chief Complaint and Reason for Visit Section Chief Complaint Section Family History Section (V2) Functional Status Section (V2) General Status Section History of Past Illness Section (V2) <b>Immunizations Section (entries optional) (V2) SHOULD</b> Medical Equipment Section (V2) <b>Medications Section (entries required) (V2) SHOULD</b> Mental Status Section Nutrition Section Physical Exam Section (V2) Procedures Section (entries optional) (V2) Results Section (entries required) (V2) Review of Systems Section Social History Section (V2) US Realm Date and Time (DT.US.FIELDDED) Vital Signs Section (entries required) (V2)

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 Consult 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 (ENTRIES REQUIRED) (V3)

This section lists and describes any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives). At a minimum, it should list any currently active and relevant historical allergies and adverse reactions. It contains the Allergy Concern Act, which in turn contains the Allergy-Intolerance Observation.

### **5.2.1.1 ALLERGY CONCERN ACT (V3)**

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**

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

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 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 SECTION (V2)**

This section represents the consultant pharmacist's impressions, conclusions and working assumptions that will guide the recommendations for treatment of the patient. The Assessment and Plan Section may be combined or separated to meet local policy requirements.

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 consultant 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.

### **5.2.3 HISTORY OF PRESENT ILLNESS SECTION**

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.

### **5.2.4 PROBLEM SECTION (ENTRIES REQUIRED)**

All clinical problems connected to a medication may be identified within consultant pharmacist systems as indications or diagnosis. Problems, both past and present, relevant at the time of the consultation are described in this section. Overall health status may also be included.

#### **5.2.4.1 PROBLEM OBSERVATION - REQUIRED**

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 SECTION**

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.

### **5.2.6 IMMUNIZATION SECTION**

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.

### **5.2.7 MEDICATIONS SECTION**

It is expected the Medications Section will be included in most instances in the Consultant Pharmacist Consult Note for reference purposes of the patient's active medication list. In addition to the patient's current medications and pertinent medication history, the Medications Activity Section is a required component of the Medications Section. Medications Activity focuses on drugs administered or planned for administration. It includes the time and duration of the planned or completed medication administration.

### **5.3 PHYSICIAN C-CDA CONSULT NOTE (RESPONSE TO CONSULTANT PHARMACIST)**

The attending physician and/or facility reviews the consultant pharmacist's assessment of the patient, recommendations for treatment or changes to treatment and requests for follow-up actions. By regulation, the physician is required 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 C-CDA 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 Consultant Pharmacist C-CDA Consult Note. The primary differences relate to the changed author, actors and roles.

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