# Table of Contents

2. PURPOSE ......................................................................................................................... 5
3. AUDIENCE ....................................................................................................................... 6
4. OVERVIEW ....................................................................................................................... 7
5. PHARMACY eCARE PLAN USE CASES ........................................................................... 9
   5.1 Use Case 1 .................................................................................................................... 9
   5.2 Use Case 2 .................................................................................................................. 10
   5.3 Use Case 3 .................................................................................................................. 11
   5.4 Use Case 4 .................................................................................................................. 12
6. TEMPLATE REQUIREMENTS ............................................................................................ 13
   6.1 US REALM HEADER (V3) - REQUIRED ...................................................................... 13
   6.2 C-CDA CARE PLAN .................................................................................................... 13
      6.2.1 PHARMACIST eCARE PLAN ............................................................................... 14
         6.2.1.1 AUTHOR PARTICIPATION* ......................................................................... 15
         6.2.1.2 ENTRY REFERENCE* ............................................................................... 15
         6.2.1.3 EXTERNAL DOCUMENT REFERENCE* ..................................................... 15
      6.2.2 GOAL SECTION - REQUIRED ............................................................................. 15
         6.2.2.1 GOAL OBSERVATION-REQUIRED ............................................................... 16
         6.2.2.2 AUTHOR PARTICIPATION .......................................................................... 16
         6.2.2.3 ENTRY REFERENCE ................................................................................... 16
         6.2.2.4 PRIORITY PREFERENCE ............................................................................. 16
      6.2.3 HEALTH CONCERNS SECTION - REQUIRED ..................................................... 16
         6.2.3.1 HEALTH CONCERN ACT-REQUIRED .......................................................... 17
         6.2.3.2 HEALTH STATUS OBSERVATION ............................................................... 18
         6.2.3.3 RISK CONCERN ACT (V2)............................................................................. 18
         6.2.3.4 SECTIONS INCLUDED AS PART OF HEALTH CONCERN ACT AND/OR RISK CONCERN ACT ...... 18
            6.2.3.4.1 Allergy- Intolerance Observation - Required ............................................ 18
            6.2.3.4.2 Assessment Scale Observation ................................................................. 19
            6.2.3.4.3 Author Participation .................................................................................. 19
            6.2.3.4.4 Caregiver Characteristics ......................................................................... 19
            6.2.3.4.5 Characteristics of Home Environment ..................................................... 19
            6.2.3.4.6 Cultural and Religious Observation ......................................................... 19
            6.2.3.4.7 Encounter Diagnosis ................................................................................. 19
            6.2.3.4.8 Family History Organizer ........................................................................ 19
            6.2.3.4.9 Functional Status Observation ................................................................. 19
            6.2.3.4.10 Longitudinal Care Wound Observation .................................................. 20
            6.2.3.4.11 Mental Status Observation ...................................................................... 20
            6.2.3.4.12 Nutrition Assessment .............................................................................. 20
            6.2.3.4.13 Nutritional Status Observation ................................................................. 20
            6.2.3.4.14 Pregnancy Observation .......................................................................... 20
            6.2.3.4.15 Priority Preference ................................................................................... 20
            6.2.3.4.16 Problem Concern Act ............................................................................. 20
            6.2.3.4.17 Problem Observation - Required ............................................................... 21
            6.2.3.4.18 Reaction Observation .............................................................................. 21
6.2.3.4.19 Self-Care Activities (ADL and IADL) ................................................................. 21
6.2.3.4.20 Sensory Status ................................................................................................. 21
6.2.3.4.21 Social History Observation ........................................................................... 21
6.2.3.4.22 Substance or Device Allergy - Intolerance Observation ............................... 22
6.2.3.4.23 Tobacco Use ..................................................................................................... 22
6.2.3.4.24 Vital Sign Observation .................................................................................... 22

6.2.4 HEALTH STATUS EVALUATIONS AND OUTCOMES SECTION ........................................... 22
6.2.4.1 ENTRY (ACT) REFERENCE .................................................................................. 23
6.2.4.2 OUTCOME OBSERVATION ................................................................................. 23
6.2.4.2.1 Progress Toward Goal Observation .................................................................. 23

6.2.5 INTERVENTIONS SECTION ....................................................................................... 24
6.2.5.1 HANDOFF COMMUNICATION PARTICIPANTS .................................................... 25
6.2.5.2 INTERVENTION ACT (V2) AND/OR PLANNED INTERVENTION ACT .................. 25
6.2.5.2.1 Immunization Activity and/or Planned Immunization Activity ....................... 25
6.2.5.2.2 Instruction ......................................................................................................... 25
6.2.5.2.3 Medication Activity and/or Planned Medication Activity-Required ............. 25
6.2.5.2.4 Non-Medicinal Supply Activity ...................................................................... 25
6.2.5.2.5 Nutrition Recommendation .......................................................................... 26
6.2.5.2.6 Procedure Activity Act .................................................................................... 26
6.2.5.2.7 Procedure Activity Observation ..................................................................... 26
6.2.5.3 PLANNED INTERVENTION ACT ........................................................................ 26
6.2.5.3.1 Planned Act ..................................................................................................... 26
6.2.5.3.2 Planned Encounter ......................................................................................... 26
6.2.5.3.3 Planned Observation ....................................................................................... 26
6.2.5.3.4 Planned Supply ............................................................................................... 26
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 Pharmacist eCare Plan CDA document. The Pharmacist eCare Plan is used for exchange with the patient and their care team to document medication-related health concerns and goals, as well as, the pharmacist’s assessments, planned activities and interventions, recommendations, referrals and related clinical services. This paper is based on the C-CDA Care Plan Document.

This guidance is intended to be used in conjunction with the specifications as defined in the C-CDA Care Plan. The NCPDP Professional Pharmacy Services Work Group (WG10) Medication Therapy Management (MTM) Communications Task Group has reviewed the C-CDA templates and found the content and functionality of the Care Plan Document Template and other specified templates meet the requirements for structured documentation of the Pharmacist’s eCare Plan and medication-related patient care services.

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 Care Plan in Section 1.1.2 of Volume 2 of the standard. The constraints as defined in the C-CDA are in accordance with Meaningful Use and US realm regulatory health IT certification requirements. This document is available from 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.
2. AUDIENCE

The audience for this recommendation for use of the C-CDA Care Plan is the architects and developers of healthcare information technology (health IT) systems in the US Realm to meet health IT certification requirements for exchange of patient clinical data particularly among pharmacists as well as other healthcare providers, payers and patients. All participants in the healthcare team including patients will benefit from the implementation of these recommendations.
3. OVERVIEW

Pharmacists have unique training and expertise in the appropriate use of medications and provide a wide array of patient care services in many different practice settings. These services reduce adverse drug events, improve patient safety, and optimize medication use and health outcomes. Pharmacists contribute to improving patients’ health by providing patient care services as authorized under their scope of practice and facilitated by collaborative practice agreements.

The Pharmacist Patient Care Process was developed by the Joint Commission of Pharmacy Practitioners (JCPP) to support consistent delivery of patient care services consisting of recurring process steps:

- **Collect** - The pharmacist assures the collection of the necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient.

- **Assess** - The pharmacist assesses the information collected and analyzes the clinical effects of the patient’s therapy in the context of the patient’s overall health goals in order to identify and prioritize problems and achieve optimal care.

- **Plan** - The pharmacist develops an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregiver that is evidence-based and cost-effective.

- **Implement** - The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver.

- **Follow-up: Monitor and Evaluate** - The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed.

This process includes developing and documenting medication-related patient-specific goals.

Pharmacists are increasingly participating on patient-centered care teams as essential members providing clinically oriented patient care services such as medication therapy management, clinical reconciliation (medication, allergies and problems), patient immunization management, disease state monitoring, and therapy adherence programs. The Pharmacist eCare Plan will support the documented integration of these activities into the patient’s comprehensive care plan.

In *Connecting Health and Care for the Nation A Shared Nationwide Interoperability Roadmap* the Office of the National Coordinator for Health Information Technology (ONC) noted the following:

> “Providers should have the tools they need to support care transformation, i.e. using technology that supports the critical role of information sharing. This shift will open up new possibilities for providers in how they engage with patients and interact with other care, support and service team members. For example person-centered planning, which includes individual goals and preferences, is increasingly recognized as an integral tool for supporting person-centered health, individual-provider partnerships, and coordinating care, particularly for individuals with chronic conditions and multiple co-morbidities. In a learning health system, person-centered plans will be

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1 Joint Commission of Pharmacy Practitioners. “Pharmacists’ Patient Care Process.” May 29, 2014
Pharmacist eCare Plan

seamlessly shared amongst a group of individuals in a way that allows all care, support and service
team members to contribute to and maintain the person-centered plan. These interoperable
plans will be used to support informed, shared decision-making between providers, patients and
the full care support team. Further, the learning health system will require nationwide
interoperability to support transparent, integrated cost and quality data, accurate outcome
measures, and a continuous cycle of improvement. Information gathered and decisions made
during the normal course of care will be transformed, in real-time, into computable data and
knowledge that is shared across the learning health system.”

They further note:

“The Pharmacist eCare Plan will enable integration of the pharmacist and their individualized
medication-related care plans into the patient’s comprehensive care plan.”

The recommendations provided for use of the C-CDA Care Plan to construct the Pharmacist eCare Plan
are designed to:

• support the pharmacist in all care settings (facilities, outpatient clinics, community pharmacies,
etc.)
• facilitate patient transitions between settings
• support chronic care management and
• support care coordination

The Pharmacist eCare Plan is a longitudinal person centric dynamic plan that represents a patient’s and
pharmacist’s prioritized concerns, goals, and planned interventions and incorporates medication-related
information captured by all members of the care team. It serves as a blueprint to be shared with all Care
Team Members (including the patient, their caregivers, pharmacists and other healthcare providers), to
guide the patient’s care. The Pharmacist eCare Plan allows integration of multiple medication-related
interventions proposed by multiple healthcare providers and disciplines for multiple conditions. It also
serves to enable longitudinal coordination of care.

The C-CDA Care Plan allows for inclusion of other section and entry level templates beyond those
explicitly stated, as needed, to fully meet the documentation needs of the specific care plan.
Recommendations are included herein for use of some of these additional templates in the Pharmacist
eCare Plan.
4. PHARMACY CARE PLAN USE CASES

4.1 Use Case 1

The community pharmacist meets with the patient and their caregiver after a recent discharge from a hospital for a pulmonary embolism. The patient is diagnosed with hypertension and diabetes. The patient is enrolled in diabetes and anticoagulation OP clinics. The community pharmacist coordinates MTM services (including reconciliation of medications, allergies and indications for medication use) with the PCP and the diabetes and anticoagulation clinics on patient’s medication-related goals. The community pharmacist uses their health IT system to document patient care. The health IT system is then used to generate the Pharmacist eCare Plan to share the patient/caregiver agreed medication related goals and electronically exchanges the Care Plan with the patient’s personal EHR, PCP EHR, and the OP clinics for chronic care management and care coordination.
4.2 USE CASE 2

Patient is scheduled for a hip replacement. The pharmacist under a collaborative practice agreement with the orthopedic surgeon counsels the patient prior to the procedure to assure there are no medication-related problems. After the surgery, the pharmacist coordinates medication-related goals with the patient pertaining to deep vein thrombosis risk and pain management. The community pharmacist uses their health IT system to document patient care. The health IT system is then used to generate the Pharmacist eCare Plan to share the patient/caregiver agreed medication related goals and electronically exchanges the Care Plan with the patient’s personal EHR, orthopedic surgeon’s EHR, PCP EHR, the home health care agency, and rehabilitation center EHR for care coordination.
4.3 Use Case 3

A patient with behavior health issues and multiple chronic diseases meets with their consultant pharmacist for their yearly comprehensive medication review to meet their Medicare Part D MTM requirement. The pharmacist documents conflicting treatment strategies and medications. The pharmacist recommends strategies/alterations to existing treatment, development of a manageable medication schedule, patient education and outcome follow-up. The community pharmacist uses their health IT system to document patient care. The health IT system is then used to generate the Pharmacist eCare Plan to share the patient/caregiver agreed medication related goals and electronically exchanges the Care Plan with the patient’s personal EHR, psychiatrist’s EHR, OP psychiatric clinic EHR, PCP EHR, for chronic care management and care coordination.
4.4 **USE CASE 4**

A patient comes to the community pharmacy to pick up hydrocodone which has been e-prescribed and complains of constipation. After the pharmacist reviewed the State Prescription Drug Monitoring Program (PDMP) database, the pharmacist discovers that multiple physicians have treated the patient for pain. The pharmacist suspects the patient may have an opioid abuse condition. Through patient counseling, the pharmacist discovers the patient is mal-nourished, has 3 chronic care conditions, complains of constipation and also has no primary care provider (PCP). The pharmacist performs a comprehensive medication review and helps the patient identify a PCP. The pharmacist documents conflicting treatment strategies and medications including the need for naloxone. The pharmacist recommends strategies/alterations to existing treatment, pain management, development of a manageable medication schedule, nutritional counseling, patient education and outcome follow-up. The community pharmacist uses their health IT system to document patient care. The health IT system is then used to generate the Pharmacist eCare Plan to share the patient/caregiver agreed medication related goals and electronically refers the patient for nutritional counseling and exchanges the Care Plan with the patient’s personal EHR, new PCP EHR, nutritionist EHR, other physician’s EHR treating the patient, outpatient drug rehabilitation center EHR, for chronic care management and care coordination.
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.

C-CDA R2.1 Table 2: US Realm Header (V3) Contexts

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<thead>
<tr>
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<td>US Realm Date and Time (DTM.US.FIELDED)</td>
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<td>US Realm Person Name (PN.US.FIELDED)</td>
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</table>

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, and any assigned identifiers (health plan IDs, Provider assigned ID’s, etc.) and any other information needed to uniquely identify the patient or responsible party for carrying out the plan of care.

In addition to providing patient information, the US Realm Header provides for identification of the care team members, including care givers, and their roles and where applicable their specialties.

The identification of the service event is also contained in the header including date, time, location (coded or text), type of encounter, indication/reason (if not included in the type code set) and the provider of the service.

5.2 C-CDA CARE PLAN

While the Care Plan is a point in time document and as such may represent the shared concerns and goals of a specific provider and the patient, it may also represent the prioritized concerns, goals, and planned interventions of the care team. The integrated care plan is used to reconcile and resolve conflicts between the plans created in collaboration with the patient by the various care team members. It is the foundation for longitudinal coordination of care. The use case diagrams in Section 4 provide a pictorial demonstration of the interrelationships of the sections contained within the Care Plan document. The Care Plan is an open document template, therefore any C-CDA section or entry templates, even if not explicitly stated in the Care Plan, may be used to fulfill the business need.

The following table illustrates the C-CDA section-level templates that are explicitly contained in the C-CDA Care Plan.

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2 HL7 CDA R2.1 IG: Consolidated CDA Templates for Clinical Note (US Realm), DSTU R2—Vol. 2: Templates
5.2.1 PHARMACIST eCARE PLAN

The Pharmacist eCare Plan standardizes documentation of information gathered and developed through the Pharmacist Care Process in community, hospital and long term post-acute care (LTPAC) settings. It allows for exchange of information between providers of care to optimize medication-related decision support and patient adherence to medication regimens both within a healthcare setting and when a patient moves between healthcare settings.

Standardization of information used in this form will promote interoperability; support a comprehensive, multi-discipline longitudinal care plan; create information suitable for reuse in quality measurement, public health, research, and for reimbursement.

In assessment of and consultation with the patient the focus is on

- maximizing the effectiveness of medications ordered and currently used
- identifying barriers to the successful implementation of the therapy regimen
- assuring patient understanding of the reasons for and use of the medication and the goals of therapy
- resolution of conflicting orders and plans

in order to help the patient achieve the best possible outcomes of treatment and an enhanced sense of wellbeing.

The Pharmacist eCare Plan supports the collection of necessary subjective and objective information about the patient to enable analysis of the clinical effects of the patient’s therapy in the context of the patient’s overall health goals in order to identify and prioritize problems and achieve optimal care. Collected information includes:

- A current and historical medication use history (prescription and nonprescription, herbal products, dietary supplements)
- Relevant health data, concerns and risks (medical history, health and wellness information, biometric test results, physical assessment findings)
- Functional assessments to evaluate the patient’s ability to use the ordered medications
- Patient lifestyle habits, preferences and beliefs, health and functional goals, and socioeconomic factors

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3 HL7 CDA R2.1 IG: Consolidated CDA Templates for Clinical Note (US Realm), DSTU R2—Vol. 2: Templates
Pharmacist eCare Plan

- Planned interventions (diagnostic tests, referrals, follow-up visits)
- Outcome assessment and progress to goals

Each medication is assessed for appropriateness, effectiveness, safety, and patient adherence. Patient risk factors, functional status and access to medications are included in the considerations, as are needs for preventive care, including immunizations, and other healthcare services.

Using the collected information as a basis, the pharmacist works with the patient or care giver to identify health concerns and goals and develop an individualized medication-related care plan. The pharmacist care plan engages the patient through education, empowerment, and self-management in the context of the patient’s overall health care goals and access to care. Collaboration with other members of the healthcare team is used to harmonize the various goals and treatment plans.

The following elements are used as needed in the sections named in the table above. The Entry Reference and External Document Reference templates are used to simplify the creation of the Care Plan by eliminating the need to duplicate information.

### 5.2.1.1 Author Participation

The Author Participation Section identifies the observer, provider or source of the information contained in the section. The author is required in the Header Section and does not need to be repeated unless different than the author reported in the Header Section.

### 5.2.1.2 Entry Reference

Entry Reference identifies other entries (such as encounters, observations, procedures, etc.) contained within this instance of the care plan document eliminating the need for repeated entry. All of the Sections contained in the Care Plan have templates that utilize this template.

### 5.2.1.3 External Document Reference

The External Document Reference allows incorporation by reference external clinical documents such as laboratory or other test results, other provider evaluations, observations and interventions, etc. The External Document Reference template cannot be used independent of the clinical observation being reported.

### 5.2.2 Goal Section - Required

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<td>Priority Preference</td>
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In the Pharmacist eCare Plan the goals are based on optimizing the patient’s medications. These goals may include simplifying with dosing schedules; identifying possible impacts on medication efficacy from drug-drug, drug-food and drug-environment interaction; identifying barriers to patient adherence and drug therapy problems; assuring the patient understands what the medication is for and how to properly handle and use it; and ultimately to achieve the desired therapeutic outcome and enhance the patient’s sense of wellbeing. Examples of Medication - Related Goals include: synchronization of medications, compliance with medication regimen, reduction of opioid use, stabilization of blood pressure, stabilization of blood sugar levels, reduction in break through seizures, control of Parkinson symptoms, etc.
5.2.2.1 Goal Observation-Required

Goal Observation is an entry level template defining the focus of the care plan. The goal observation may define patient goals or the goals of the provider. It may include other goals that are related to the overall goal for the patient or incremental steps toward a particular goal. For example a medication related goal for a patient after a stroke may be prevention of deep vein thrombosis which will have related goals of maintaining a consistent and appropriate international normalized ratio (INR), dietary changes, therapy to improve swallowing, etc. It may also include goals from other providers as in Use Case 2.

5.2.2.2 Author Participation

The Author Participation template identifies the individual who defined the goal, that is, if this is the patient’s goal for himself (if the author is set to the recordTarget) or the provider’s goal (author is set to a provider) for him/her. For the mutually agreed to goals the author is set to both the record target (patient) and the provider.

5.2.2.3 Entry Reference

The Entry Reference identifies other entries (such as encounters, observations, procedures, etc.) contained within this instance of the care plan document eliminating the need for repeated entry. The Goals Observation may reference templates such as the Medications Activity (V2), Problem Concern Act (V3), Health Concern Act (V2) and Risk Concern Act (V2), Interventions Act (V2) Planned Intervention Act (V2) and Outcomes Observation.

5.2.2.4 Priority Preference

The Patient Priority Preference and the Provider Priority Preference allow for ranking the importance of component goals, interventions or acts and provide for staged, incremental movement toward the ultimate goal. The patient’s preferences include their choices for treatment options and information sharing as well as identification of the goals they are most interested in pursuing. They may be defined independently or jointly with their caregivers and/or providers.

5.2.3 Health Concerns Section - Required

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<td>Allergy Intolerance Observation</td>
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<td>Assessment Scale Observation</td>
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<td>Family History Organizer</td>
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<td>Functional Status Observation</td>
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©National Council for Prescription Drug Programs, Inc.
The Health Concerns Section documents the worries and issues expressed by the patient and/or caregiver with regard to the sense of wellbeing, past/present/future treatment, impediments to obtaining and using ordered medications/supplies/equipment, planned encounters/interventions, treatment risks, etc. It also includes provider concerns regarding the course of treatment, drug therapy problems and the patient’s potential for a successful outcome. Important health concerns that require attention are elevated to the problem list. Medication related concerns often involve issues of how the patient reacts to medication, how it makes them feel, problems with the dosing schedule, the need for laboratory testing or charting, etc. Allergy-Intolerance Observation is always included in the pharmacist’s documentation of health concerns. The other sections and entries listed under “Included as part of Health Concern Act and/or Risk Concern Act” are documented as necessary and appropriate to the individual patient’s situation.

5.2.3.1 **HEALTH CONCERN ACT-REQUIRED**

The Health Concern Act describes a single health related issue identified by/with the patient that requires intervention in order to achieve the care plan goals. The health concern may arise from observations by care team members or from information within the EHR such as the Problem List, Family History, Medication Alerts, Hospital Discharge Summary, etc. This section allows for the individual concern to be tracked to its resolution. Medication-related health concerns may include issues such as:

- keeping track of when medication refills are due resulting in a planned intervention for medication synchronization to reduce risk of non-compliance including polypharmacy resulting from multiple physicians and duplicative therapy
- identifying dietary changes resulting from the metabolism of a particular drug
- identifying medication-related adverse events and finding ways to offset side effects like drowsiness, nausea, etc. which may lead to a change in therapy
• monitoring blood pressure, blood glucose levels, INR (reduce risk of bleeds or clots, deep vein thrombosis), etc. and making drug therapy changes or ordering dietary interventions
• identifying risk of cognitive impairment effecting medication use
• conflicting or confusing medication instructions resulting in an intervention for patient instruction or to align dose timing for medications that can be taken together or must not be taken together, etc.
• identifying pharmacokinetic information as part of the pharmacotherapy (determining the correct dose related to patient's physical ability to absorb and eliminate the medication)
• monitoring the side effects of uncontrolled pain (depression, dietary and cognitive disturbances)

5.2.3.2 Health Status Observation
Health Status Observation describes the patient’s general health using an HL7 defined SNOMED code subset. Examples include alive and well, chronically ill, in remission, general health poor, etc.

5.2.3.3 Risk Concern Act (V2)
The Risk Concern Act describes a single risk that is related to a health concern. The risk concern may arise from observations by care team members or from information within the EHR or directly from identified health concerns. The risk represents a potential for a condition or circumstance resulting in a need for intervention and/or monitoring. Risk concerns are identified and tracked with or in addition to related health concerns. The risk may be clinical or socio-economic. Medication-related risk concerns may include issues such as:
• caregiver health concerns potentially leading to their inability to care for the patient
• post stroke physical limitations potentially inhibiting the ability to handle or swallow medications
• lack of transportation availability to enable the patient to obtain medicines or have tests done, or keep follow-up or referred encounters

5.2.3.4 Sections included as part of Health Concern Act and/or Risk Concern Act
The following entries may be used in the identification and description of a health or risk concern.

5.2.3.4.1 Allergy-Intolerance Observation - Required
Allergy Intolerance Observation is required in the Pharmacist eCare Plan and 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 are critical to the Pharmacist eCare Plan including non-medications 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 the management of their medication 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 treatment plan or may represent a concern that the provider is monitoring to assure that it does not impact the therapeutic regimen or treatment outcomes.
5.2.3.4.2 **ASSESSMENT SCALE OBSERVATION**
The Assessment Scale Observation summarizes a series of observations regarding a particular condition made using a specified tool, standard assessment profiles or organization defined templates (for example Mini-Mental Status Exam (assesses cognitive function), Pain Scale, EPS (extrapyramidal symptoms), Activities of Daily Living (ADL), Growth Chart (height/length, weight head circumference), Tanner Stage maturity assessment, etc.). In the Pharmacist eCare Plan a primary focus of the Assessment Scale Observations is whether the patient has the cognitive and functional ability to understand, use and consume medication. Other assessments focus on the effectiveness of medications, for example the pain scale are used to determine the effectiveness of the pain medications or using EPS to measure the adverse effects of antipsychotics, etc. The Assessment Scale Observation is a component of Mental Status Section, Functional Status Section and Sensory Status.

5.2.3.4.3 **AUTHOR PARTICIPATION**
Author Participation identifies the observer or reporter of the identified health concern or risk concern if different from the author reported in the Header Section, i.e., the creator of the care plan.

5.2.3.4.4 **CAREGIVER CHARACTERISTICS**
The Caregiver Characteristics defines the ability and willingness of the caregiver to assist and support the patient in following the plan of care and medication regimen.

5.2.3.4.5 **CHARACTERISTICS OF HOME ENVIRONMENT**
Characteristics of the Home Environment captures information about the type of residence (home, trailer, apartment, assisted living or long term care facility, etc.), homelessness, home ownership, living arrangement (with partner, family, caregiver, or alone), housing conditions (presence or absence of running water, sanitation or electricity, safe or unsafe, etc.) and barriers to mobility (narrow hallways, obstructions, unsafe or many stairs), etc. These can impact the patient’s ability to maintain and store medications, properly administer medications, maintain adequate healthful nutrition, and can exacerbate risk factors and health concerns. These factors need to be factored into the care plan and treatment goals.

5.2.3.4.6 **CULTURAL AND RELIGIOUS OBSERVATION**
Cultural and Religious Observation captures information about a patient’s religious or spiritual beliefs and practices which may need to be factored into the care plan for instance dietary restrictions or fasting rituals, refusal of any blood-based products, etc.

5.2.3.4.7 **ENCOUNTER DIAGNOSIS**
The Encounter Diagnosis depicts the diagnoses and conditions identified during the course of an encounter. For an inpatient encounter the Discharge Diagnosis is used. At least one Problem Observation must be recorded if this is used.

5.2.3.4.8 **FAMILY HISTORY ORGANIZER**
The Family History Organizers allows association of observations about a patient’s family members. This information can be used in the identification of risks or health concerns. A patient with a diagnosis of hypertension whose father also had hypertension and died at age 45 from a massive coronary infarction would trigger a higher priority for treating and monitoring the hypertension and possible associated cholesterol balance.

5.2.3.4.9 **FUNCTIONAL STATUS OBSERVATION**
The Functional Status Observation depicts the patient’s physical development, capabilities and mobility, problems limiting physical functions (dyspnea, dysphagia), the availability of caregiver support, the presence of supplies and equipment to facilitate function (walkers, special feeding utensils, special packaging and dosing mechanisms for medication administration, etc.). It includes an Assessment Scale Observation. For the Pharmacist eCare Plan, these functions include the ability to prepare, administer
and swallow the medication. The Functional Status Organizer may be used to group the functional observation, for example, mobility, self-care, etc.

5.2.3.4.10 Longitudinal Care Wound Observation
Longitudinal Care Wound Observation provides information about the characteristics of a wound such as a pressure ulcer, surgical incisions or deep tissue injuries. In the Pharmacist eCare Plan, the information is used to support and instruct the patient/care giver on the proper cleansing, application of ordered topical medications, monitoring for infection and bandaging. The pharmacist may also assist with assuring that sufficient cleansing and bandaging supplies are on hand.

5.2.3.4.11 Mental Status Observation
The Mental Status Observation combines subjective observation of the patient’s mental health and cognitive abilities with objective information from Assessment Scale Observations. In the Pharmacist eCare Plan, cognitive factors such as the patient’s ability to understand the indication for the medication, the directions for use and storage, potential side effects to watch for and report, and the need to adhere to the medication and other barriers to successful adherence to drug therapy regimen. Identification of available care giver support is important in the decisions regarding the drug form and packaging of the medication. For instance, if there is no caregiver available, dose forms that do not require special handling (e.g., refrigeration) are selected and all the drugs to be taken at a given time are packaged together (adherence packaging) to simplify the regimen and instructions for the patient.

5.2.3.4.12 Nutrition Assessment
The Nutrition Assessment provides information regarding the dietary status quo, i.e., the diet requirements, dietary intake, nutrition abilities and habits. It is included in the Nutritional Status Observation. In the Pharmacist eCare Plan the relationship of preferred foods to the ordered medication is considered. Drug - food incompatibilities are noted.

5.2.3.4.13 Nutritional Status Observation
The Nutritional Status Observation documents the nutritional findings such as, the patient is emaciated, well-nourished or obese; the patient is nutritionally compromised. In defining the nutritional status consideration is given to issues that relate to medication consumption, such as the patient has swallowing difficulty or altered digestive functioning (e.g., malabsorption or short gut syndrome, ulcer, ileostomy, etc.) and drug food interaction issues both drug induced and food induced. The Nutritional Status Observation includes the Nutrition Assessment.

5.2.3.4.14 Pregnancy Observation
Pregnancy Observation provides information on current or prior pregnancy dates. Identification of a pregnancy alerts the pharmacist to review the current and new medication orders for contraindications or special considerations in dosing or drug therapy regimen potentially requiring recommendations for changes to the medications or medication-related therapy.

5.2.3.4.15 Priority Preference
The Patient Priority Preference and the Provider Priority Preference allow for ranking the importance of the healthcare concern or risk. The patient’s preferences reflect the issues that worry them most and they are most interested in pursuing. Preferences may be defined independently or jointly with their caregivers and/or providers. For instance, a patient has a prescribed statin medication that interacts with grapefruit. The patient prefers to eat grapefruit and has decided to change to a cholesterol regulating diet instead of taking the prescribed statin.

5.2.3.4.16 Problem Concern Act
The Problem Concern Act reflects a provider’s ongoing concern regarding a specific condition. The problem may remain in an active status as long as it is a concern even though the particular instance that generated its addition to the Problem List has been resolved. For example a patient experiences a
problem that could possibly be a side effect of medication. The problem resolves, but the pharmacist will continue to monitor for possible recurrence prior to recommending a change in the medication. Multiple Problem Concern Observations may be included in the Problem Concern Act.

**5.2.3.4.17 PROBLEM OBSERVATION - REQUIRED**
The Problem Observation is required in the Pharmacist eCare Plan and 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 that as the effective low date, but no effective high date and will remain 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.

**5.2.3.4.18 REACTION OBSERVATION**
The Reaction Observation depicts the response to administration of, or exposure to a substance or therapy. The reaction may be an undesired symptom or finding, but could also reflect a positive response. The observation includes the severity of the response.

**5.2.3.4.19 SELF-CARE ACTIVITIES (ADL AND IADL)**
Self-Care Activities (Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL)) provide insight into the patient’s ability to function independently and any barriers that must be addressed. Medication-related activities include the ability to drive, shop independently (ability to acquire medication), manage medication (follow dosing instructions, safely handle and store medicines, read the medication label and associated instructions, open the container, etc.), bathe and feed themselves (safe preparation and self-administration), accurately measure liquid doses, and to self-administer the medication. When barriers exist, identification of alternative dose forms (e.g., tablets instead of liquid), packaging (e.g., compliance packaging, use of a regular cap not a safety cap, etc.), dispensing schedules (medication synchronization, delivery or mail to alleviate access or transportation issues, etc.), and referral for personal care service or work with family/caregiver to address the issues.

**5.2.3.4.20 SENSORY STATUS**
Sensory Status provides information about the patient’s ability to see, hear, smell or feel. Limitations of sensory function may necessitate changes in the way the medication is dispensed and used as well as the instructions provided. If the patient has limited vision and is to take two medications where the pills are approximately the same size and shape, there is a risk of a medication misadventure. If there is limited sensation in the fingers it may be difficult to hold the medication. If there is hearing impairment instructions need to be visual (written or pictorial based on the patients reading ability). The observed sensory status may result in altered dose form and/or packaging as well as identification of the need for caregiver assistance.

**5.2.3.4.21 SOCIAL HISTORY OBSERVATION**
Social History Observation contains information about the individual’s employment, school, environment, exposure to toxins, education level, health-related habits (e.g., exercise and diet), drug misuse, illicit and recreational drug use, tobacco use, alcohol use, etc. This information is important in the Pharmacist eCare Plan as it may

- necessitate changes in the ordered medication or time of administration (e.g., an occupation requiring maximum alertness paired with a medication that may cause drowsiness)
- alter monitoring requirements both type or frequency
• alter the instructions provided (e.g., grade level of written material, additional warning about drug alcohol interaction, etc.)
• trigger intervention or referral for dietary evaluation and counseling, substance or opioid abuse counseling, etc.

Identification of the patient’s social barriers and support mechanisms can be used to help the patient in achieving the medication-related therapy goals.

5.2.3.4.22 Substance or Device Allergy - Intolerance Observation
Substance or Device Allergy-intolerance provides current or historical information on the patient’s reaction to foods, environmental factors and non-drug substances. This includes inactive substances in drugs such as bases, coloring or flavoring, and emulsifiers.

5.2.3.4.23 Tobacco Use
Tobacco Use provides information on past and current use of, or exposure to (maternal, in the home, passive, etc.) tobacco products using SNOMED-CT tobacco use and exposure finding codes to define the type of tobacco or exposure. Upper and lower time boundaries are included as are the number of cigarettes consumed per day.

5.2.3.4.24 Vital Sign Observation
Vital Sign Observation provides the basic clinical measurements such as height, weight, blood pressure, body mass index (BMI), etc. In the Pharmacist eCare Plan this information is used in dose calculation, identification of issues related to possible side effects of the ordered medication, assessment of general wellbeing and as tools to evaluate progress to goals.

5.2.4 Health Status Evaluations and Outcomes Section

<table>
<thead>
<tr>
<th>Section</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Status Evaluations and Outcomes Section</td>
<td>Outcome Observation - Required</td>
</tr>
<tr>
<td></td>
<td>Author Participation</td>
</tr>
<tr>
<td></td>
<td>Entry (Act) Reference</td>
</tr>
<tr>
<td></td>
<td>External Document Reference</td>
</tr>
<tr>
<td></td>
<td>Progress Toward Goal Observation</td>
</tr>
</tbody>
</table>

The Health Status Evaluations and Outcomes Section provides insight into the effectiveness of the interventions and treatments defined in the Pharmacist eCare Plan and the progress toward the identified goal(s). It supports identification of the patient’s adherence to and adherence barriers. The status of planned interventions is determined. For those completed, the results are reviewed to assess effectiveness of the course of therapy being pursued. Those not completed are reviewed to determine if there are barriers to their completion. Modifications to the care plan are made as indicated.

Health Status Evaluation includes assessment of whether the patient has the cognitive and functional ability to understand, use and consume medication. For example:
• Cognitive - does the patient understand the indication for the medication, the directions for use and storage, potential side effects to watch for and report, and the need to adhere to the medication
• Functional - ability to swallow - is liquid medication needed, can they physically take/administer the medication, do they have someone to assist, do times of administration conflict with other activities, is adherence packaging needed (also has a cognitive component), are they physically able to access pharmacy to acquire medications
• Patient's Condition - lab requirements (INR, blood glucose, etc.), 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).

These observations and assessments utilize the same section and entry elements described in the Health Concerns Section above.

5.2.4.1 ENTRY (ACT) REFERENCE

Entry Reference makes available information from prior assessments and interventions for use in evaluating the health status and outcomes of interventions that have been completed. This information is used in consultation with the patient to identify patient concerns, problems and need for changes to the plan of care, goals or priorities.

5.2.4.2 OUTCOME OBSERVATION

Outcome Observation provides for point in time assessment of the effectiveness of treatment. The observations may be, for example:

• based on physical findings such as blood pressure or laboratory results
  o reduced BP for a patient with hypertension,
  o changes to the A1C level for a patient with diabetes,
  o therapeutic level of the drug present in the blood sample,
  o changes on pain scale assessment,

• based on the pharmacist's examination
  o presence or absence of petechiae for a patient on a blood thinner,
  o rash or other signs of allergic reaction,
  o changes in appearance
    ▪ color - not pale or flushed,
    ▪ malnourished or well nourished,
    ▪ increased or reduced stress symptoms from pain or anxiety,
    ▪ more or less alert and engaged, and

• based on information reported by the patient and/or caregiver
  o a bleeding event by a patient on a blood thinner,
  o stable blood glucose readings charted by a patient with diabetes,
  o presence or absence of break through seizures,
  o dizziness or nausea after taking the medication,
  o possible allergic reactions,
  o feelings of disorientation since the medication was initiated,
  o feelings of increased wellbeing,
  o uncertainty about the medication schedule.

In evaluating these observations modifications may be made to the treatment plan, medication therapy regimen (drug, dose, strength, and timing), new interventions may be planned, or additional counseling and patient education may occur. Interventions are reviewed to determine if they occurred as planned and if so, was the expected result fully or partially achieved. If not, what was the reason? There may be a delay in scheduling of an appointment or the patient was ill on the originally scheduled date. The ordered medication caused a reaction and was discontinued so the therapeutic outcome was not achieved.

5.2.4.2.1 PROGRESS TOWARD GOAL OBSERVATION

Progress Toward Goal Observation records the clinical judgment regarding the effectiveness of the drug therapy regimen and the interventions outlined in the treatment plan to address the particular goal. This judgment reflects the observations and findings identified through the Health Status Evaluation and
Outcomes Observation. SNOMED CT is the standard vocabulary used to codify the progress for example whether “Goal achieved” or one of the alternatives such as “Goal not achieved” or “Goal not achieved-progressing toward goal”. This observation may trigger modification of the goal or therapy regimen, additional interventions, or re-enforcement of patient education.

5.2.5 INTERVENTIONS SECTION

<table>
<thead>
<tr>
<th>Section</th>
<th>Contains</th>
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</thead>
<tbody>
<tr>
<td>Interventions Section</td>
<td>Handoff Communication Participants</td>
</tr>
<tr>
<td></td>
<td>Intervention Act (V2)</td>
</tr>
<tr>
<td></td>
<td>Planned Intervention Act (V2)</td>
</tr>
<tr>
<td></td>
<td>Author Participation</td>
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<td>Entry (Act) Reference</td>
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<tr>
<td></td>
<td>External Document Reference</td>
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<td></td>
<td>Included as part of Intervention Act and/or Planned Intervention Act</td>
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<tr>
<td></td>
<td>Advanced Directive</td>
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<td></td>
<td>Immunization Activity</td>
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<td></td>
<td>Instruction</td>
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<td></td>
<td>Medication Activity</td>
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<tr>
<td></td>
<td>Non-Medicinal Supply Activity</td>
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<td></td>
<td>Nutrition Recommendation</td>
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<tr>
<td></td>
<td>Procedure Activity Act</td>
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<tr>
<td></td>
<td>Procedure Activity Observation</td>
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<tr>
<td></td>
<td>Procedure Activity Procedure</td>
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<td>Included as part of the Intervention Act</td>
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<tr>
<td></td>
<td>Planned Intervention Act</td>
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<td>Planned Act</td>
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<td>Planned Encounter</td>
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<td>Planned Immunization Activity</td>
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<td>Planned Medication Activity</td>
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<td>Planned Observation</td>
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The Interventions Section provides information about actions taken or planned to further the health related goals of the Pharmacist eCare Plan and the improved health, function and sense of well-being of the patient. Typical medication-related interventions include such activities as managing drug therapy problems (e.g., pain management), medication reconciliation, comprehensive or targeted medication review, blood pressure and blood glucose monitoring, INR & A1C monitoring, medication synchronization and rationalization of medication regimen, patient education and counseling, care coordination, etc. Instructions, whether for the patient/care giver or other providers, are included within interventions to facilitate the fulfillment of the action.
5.2.5.1 Handoff Communication Participants

Handoff Communication Participants is used when patient care is moved from one provider to another and represents the sender who is releasing the care of the patient and the receiver who is accepting the care of the patient.

5.2.5.2 Intervention Act (V2) and/or Planned Intervention Act

Either the Intervention Act or Planned Intervention Act is required in the Pharmacist eCare Plan. The Intervention Act and Planned Intervention Act package together information about activities and observations and planned activities considered to be part of the same intervention. The Intervention Act may include activities taking place during an encounter being reported and Planned Interventions Act outlining planned activities. For example in Use Case 1 the Intervention Act includes Medication Activity (Medication Reconciliation) and Instruction (patient monitoring of blood pressure and glucose levels and the importance of having testing done) along with a Planned Intervention Act with a Planned Encounter, Planned Observations (patient recorded blood pressure and glucose levels) and a Planned Medication Activity. A report of the Planned Intervention Act would include the findings and activities included in the Interventions Act. The activities associated with the Planned Intervention will always have moodCodes indicating they have not occurred.

5.2.5.2.1 Immunization Activity and/or Planned Immunization Activity

Immunization Activity records the details of immunization administration or planned administration. The discrete data required for documentation by the National Childhood Vaccine Injury Act including the dates the Vaccine Information Statement (VIS) was printed and given to the patient/guardian. If the vaccine is refused, the reason for refusal must be captured. CVX codes are used to identify the substance. The Planned Immunization Activity may reflect the timing of the recommended pediatric immunization schedule or fall flu shot for an elderly patient or one with a compromised immune system for example.

5.2.5.2.2 Instruction

The Instruction template is used as part of various activities and planned activities to convey intended instructions. Instructions already provided are recorded using the Procedure Activity template. For example, in Use Case 2 at the patient’s post-operative visit, the pharmacist plans to provide instruction on the use and side effects of the pain medicine and pain control. Education recorded as a Procedure Activity includes information regarding counseling about the side effects of uncontrolled pain and symptoms of deep vein thrombosis. The template uses SNOMED-CT education codes.

5.2.5.2.3 Medication Activity and/or Planned Medication Activity—Required

Medication Activity and/or Planned Medication Activity record self or care giver administration or planned administration of a medicinal substance. The Information includes medication information (name, strength, dose quantity, frequency, duration, drug vehicle, etc.), indication(s), instruction(s), pre-conditions for the administration, reaction observation and monitoring, etc. Planned Medication Activity also includes the patient and/or prescriber’s priority for the activity. For instance, in Use Case 2 the pharmacist reviews the current medications, provides counseling regarding the planned post-operative medications for pain, prevention of DVTs and plans for follow-up monitoring.

5.2.5.2.4 Non-Medicinal Supply Activity

Non-Medicinal Supply Activity documents supplied equipment or devices and includes specific information about the device and, where appropriate, the Unique Device Identifier (UDI) or device identifier (DI portion of the UDI). In the Pharmacist eCare Plan, this normally includes medication-related items such as syringes, alcohol swabs, dosing devices, medication compliance aids, blood pressure monitoring devices, glucose monitoring devices, weight monitoring device, movement tracker, applicators, devices to increase the effectiveness of inhalers, dressing supplies, enteral/parenteral
feeding supplies, etc. Devices such as wheelchairs, crutches, ostomy supplies, etc. may be part of the pharmacist’s activity or referenced in the care plan depending on the particular practice setting.

5.2.5.2.5 Nutrition Recommendation
Nutrition Recommendation documents dietary requirements and limitations, recommended regimens, interventions, procedures and education. It may include Planned Act, Planned Encounter, Planned Observation, Planned Procedure, and Planned Supply. Many medications may affect the patient’s nutritional status and conversely, many foods may interfere with the effectiveness of the prescribed medication or interact with it negatively. Monitoring the patient’s weight should be a component of the nutritional assessment. In Use Case 4, partially as a result of poorly managed pain and chronic opioid use, the patient is observed to be malnourished and reports concern regarding chronic constipation. In addition to evaluating and recommending adjustments to the current medications and providing dietary counseling, the pharmacist refers the patient for a nutritional assessment and treatment plan.

5.2.5.2.6 Procedure Activity Act
Procedure Activity Act records actions not normally classified as procedures, for instance, medication synchronization to help with medication adherence, teaching a patient with asthma to properly use an inhaler, a patient with diabetes to use a glucometer or, if insulin dependent, to self-administer the injection and smoking cessation education.

5.2.5.2.7 Procedure Activity Observation
Procedure Activity Observation records the pharmacist’s observation of new information about the patient obtained from monitoring devices such as blood glucose, blood pressure, weight, movement tracker, etc.

5.2.5.3 Planned Intervention Act
The following sections are part of the Planned Intervention Act. See Intervention Act (V2) and/or Planned Intervention Act.

5.2.5.3.1 Planned Act
Planned Act records intended actions at the next encounter that do not meet the classification of procedures, for instance, reassessment of pain control, review of patient maintained logs (blood pressure, blood glucose, seizure activity, use of a rescue inhaler, etc.).

5.2.5.3.2 Planned Encounter
The Planned Encounter documents scheduled or ordered encounters including information regarding the indication, priority and service location. In Use Case 1, the patient has a planned follow-up visit with the pharmacist to assess the success of the medication regimen, review patient blood pressure and blood sugar logs, and reinforce dietary instructions. The patient also has a referral and priority order for an encounter with the anticoagulation clinic resulting from the hospitalization for a pulmonary embolism.

5.2.5.3.3 Planned Observation
Planned Observation documents the intent to review laboratory and other diagnostic findings. It includes the indication for the observation, instructions and priority. It may also reflect insurance coverage for the planned diagnostic procedures.

5.2.5.3.4 Planned Supply
Planned Supply includes orders for medicines, medicine-related and non-medicine-related supplies and equipment.