Recommendations for Use of the HL7 Consolidated CDA Templates for Pharmacy

Version 1.Ø

This paper provides the healthcare industry, in particular the pharmacy sector, with guidance on the use of the HL7 C-CDA Templates as the vehicle for capture and exchange of the pharmacist clinical information between pharmacies; a pharmacy and a health care practitioner, payer, patient, etc.; and a pharmacy and a hospital or other inpatient facility and a community pharmacy during a transition of care.

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1. INTRODUCTION

This guide is intended to be used in conjunction with the specification defined in the Health Level Seven International (HL7) Consolidated Clinical Document Architecture C-CDA R1. The NCPDP Professional Pharmacy Services Work Group (WG10) Medication Therapy Management (MTM) Communications Task Group has reviewed the C-CDA and found that the content and functionality of specified templates meet the requirements for structured documentation of patient care services by pharmacists. This enables information exchange related to the following pharmacist provided patient care services documentation:

- Transition of Care Between Inpatient and Community Pharmacy
- Pharmacy/Pharmacist Care Note (PCN)

The C-CDA Continuity of Care Document (CCD) Template meets the requirements for the transition of pharmacy care between an inpatient facility and a community pharmacy. Certain sections of the CCD Template, while not required for conformance with the C-CDA, are considered to be essential for meaningful documentation of this transition between facility and community pharmacies. These sections and the situations in which they are required are discussed in this guidance document.

The C-CDA Progress Note Template meets the requirements for the Pharmacy/Pharmacist Care Note (PCN). Certain sections of the Progress Note Template, while not required for conformance with the C-CDA, are considered to be essential for meaningful PCN documentation. These sections and the situations in which they are required are discussed in this guidance document.

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: IHE Health Story Consolidation, Release 1.1 - US Realm* Section 1.7 and Section 1.8. The full specification of the C-CDA CCD and Progress Note Templates is found in Section 3.8 and Section 3.1 respectively. The specifications for the US Realm Header are found in Section 2. The constraints as defined in the C-CDA are in accordance with Stage 1 Meaningful Use. 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_section.cfm?section=3&ref=nav.

2. AUDIENCE

The audience for this supplement to the C-CDA includes pharmacies (both inpatient and outpatient), pharmacists and other providers of medication management services; pharmacotherapy evaluation/management (PEM) service providers, healthcare practitioners providing services to the patient who is the subject of these documents; pharmacy, EHR and PHR system developers and vendors; care/case managers, payers and quality reporting entities.

3. PURPOSE

The scope of this document is to provide guidance to the pharmacy sector of the healthcare industry on the use of the HL7 C-CDA in documenting patient care services provided by pharmacists and other providers of MTM services.

4. OVERVIEW

The C-CDA is a collection of structured document level templates (e.g., Continuity of Care Document (CCD), Consultation Note, Discharge Summary, Progress Note, etc.) Each of these structured document level templates contains section level templates which in turn contain entry level templates. Conformance criteria are defined in the C-CDA for all levels of the templates.

Pharmacists' patient care services are frequently provided in the day-to-day practice of pharmacy. Such activities include but are not limited to:

- medication therapy management (MTM)
- pharmacotherapy evaluation/management (PEM)
- counseling regarding use of medication, possible side effects, dietary considerations associated with the use of a specific medication,
- health and wellness services
- disease management
- education
- monitoring of clinical indicators such as anticoagulation therapy, insulin therapy, etc.

Documentation and communication of these within the patient records including electronic health records (EHR), personal health records (PHR) and among the patient's care team service locations is critical to optimal patient care. The C-CDA templates provide a vehicle for these functions.

The C-CDA is comprised of the following document level templates:

- Continuity of Care Document (CCD) (Summarization of Episode Note)
- Consultation Note
- Diagnostic Imaging Report
- Discharge Summary
- History and Physical Note
- Operative Note
- Procedure Note
- Progress Note
- Unstructured Document

Each of these templates employs a defined set of optional or required segment level templates, which in turn utilize defined optional and required entry-level templates. The CCD, Progress Note, the Procedure Note and the Unstructured Document all provide potential functionality for documenting pharmacist services.

5. PHARMACY TRANSITION OF CARE

Patients being admitted to an inpatient facility, transferred from one facility to another, (e.g., acute care hospital to long term care facility (LTC)) or discharged to the community require exchange of information related to the patient's medications and management of medication related issues. When such services are provided to a patient in a facility it is necessary to record them in the patient's pharmacy profile, electronic medication administration record (eMAR), (EHR) and/or (PHR) so they may be shared with the patient's other care providers, care management or utilization entities and payers. This section describes the use of the C-CDA/CCD to capture and exchange the necessary content to meet the requirements for documentation of these services.

The Pharmacy Transition of Care guidance utilizing the C-CDA Continuity of Care Document (CCD) template sets out the situations which define requirements for the optional sections of the CCD Template as they relate to pharmacotherapy evaluation/management (PEM) services during transitions of care. While the guidance addresses primarily the use for communication of transition information between the inpatient and community pharmacy settings, it does not restrict use in other setting transfers.

The CCD template requires completion of the following sections;

- Allergies
- Medications
- Problem List
- Procedures (List of Surgeries and/or History of Procedures – required only for inpatient settings)
- Results

In addition, it is recommended that the following optional sections in the CCD be included in the Transitions of Care for Pharmacy:

- Encounters
- Functional Status
- Immunizations
- Plan of Care

All other optional sections may be sent as appropriate to the specific patient and care circumstances and in accordance with jurisdictional law, scope of practice and contractual requirements. These sections include Advance Directives, Family History, Functional Status, Medical Equipment, Payers, Social History and Vital Signs.

A Transitions of Care for Pharmacy summary documents the care provided by a pharmacist before a patient transitions between care settings. The summary includes but is not limited to the following information:

- medications administered/given/taken/dispensed
- medications ordered at discharge/transfer
- a reconciled list of all medications to be used by the patient, (prescribed, non-prescribed and supplement medications)
- results of laboratory tests and orders for follow-up laboratory monitoring
- documentation of patient instructions and counseling provided by the pharmacist
- reported and observed clinical status

- problems and conditions of the patient
- pharmacist identified issues impacting the implementation and potential success of the treatment recommendation
- the proposed plan of care, e.g. medication action plan

The Transitions of Care for Pharmacy uses the CCD Template and must conform to the US Realm Clinical Document Header. It must carry the document-level templateId 2.16.840.1.113883.10.20.22.1.2 "Summarization of Episode Note" asserting conformance with specific constraints of a CCD and the fixed CCD document type LOINC code, 34133-9.

As used in Transitions of Care for Pharmacy the CCD provides a snapshot in time of the pertinent clinical, demographic, and administrative data related to PEM services provided by pharmacists to a specific patient at the point of the transition of care.

The optional sections should be provided where information is available and the pharmacist identifies an impact to the medication management. Medication related problems and concerns should be documented and codified with ICD-10 and/or SNOMED CT as appropriate using the Problem List Section. Lab results obtained from outside sources or assessed by the pharmacist to support the medication orders and instructions should be included as appropriate. Additional content is to be included to meet the specific patient use case and as permitted by pharmacy practice acts, collaborative practice agreements and jurisdictional law.

5.1 ALLERGIES SECTION

The Allergy Section should list currently active and any relevant historical allergies and adverse reactions including 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) that would impact the safety of health care delivery and affect the selection and utilization of specific medication therapies.

5.2 ENCOUNTER SECTION

The Encounter Section as used in Transitions of Care for Pharmacy lists and describes any encounters or interaction, between a patient and a practitioner/pharmacist who is providing PEM services pertinent to the patient's current health status or historical health history, regardless of the setting. The encounter may be face-to-face, by telephone or e-mail for example.

5.3 FUNCTIONAL STATUS SECTION

The Functional Status Section describes the patient's level of awareness, capabilities, strengths/weaknesses and resources including caregiver support. It is recommended for use in Transitions of Care for Pharmacy to address concerns involving the patient's ability to understand, retain and follow the ordered medication instructions (i.e., the capacity for adherence to the medication regimen), ability to use the medication as

prescribed (e.g. a need for compliance packaging, special labeling, liquid rather than solid, etc). The information may include:

- Mental status or competency
- Activities of Daily Living (ADLs), including bathing, dressing, feeding, grooming
- Home or living situation having an effect on the health status of the patient
- Ability to care for self
- Social activity, including issues with social cognition, participation with friends and acquaintances other than family members
- Occupation activity, including activities partly or directly related to working, housework or volunteering, family and home responsibilities or activities related to home and family
- Communication ability, including issues with speech, writing or cognition required for communication
- Perception, including sight, hearing, taste, skin sensation, kinesthetic sense, proprioception, or balance

The reported functional or cognitive status may be based on observations resulting from an assessment scale, evaluation or question and answer assessment.

Any deviation from normal function that would interfere with self care or the medical therapeutic process in any way should be included. A note of normal function or a change in functioning status is also valid for inclusion.

5.4 IMMUNIZATIONS SECTION

The Immunizations Section defines a patient's current immunization status and pertinent immunization history. The primary use case for the Immunization section is to enable communication of a patient's immunization status. The section should include current immunization status (completed, overdue, planned and/or recommended immunizations), and may contain the entire immunization history that is relevant to the period of time being summarized.

It is recommended that any known information, including that derived from registry checks, should be reported. Recommendations and/or scheduling for future immunizations may also be included.

5.5 MEDICATIONS SECTION

The Medications Section defines a patient's current medications and pertinent medication history. At a minimum, the currently active medications are to be listed, with an entire medication history as an option. The section may also include a patient's prescription and dispense history. If the patient is not known to be on medications an entry asserting that is required in the Medications Section.

5.6 MEDICAL EQUIPMENT SECTION

Use of the Medical Equipment Section is recommended for Transitions of Care for Pharmacy to document use of medication related medical equipment, both implantable

and durable equiment. For example: use of insulin, pain management or infusion pumps; glucose monitoring equipment, nebulizers, oxygen, CPAP, mobile health devices, etc.

5.7 PLAN OF CARE SECTION

The Plan of Care Section contains the medication action plan and other pharmacist related care activities for the patient. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current care of the patient should be listed unless constrained due to privacy issues. The plan may also contain information about ongoing care of the patient and information regarding goals and clinical reminders. Information regarding patient education either given or planned may be included.

5.8 PROBLEM LIST SECTION

The Problem List Section lists and describes at a minimum, all pertinent current and historical clinical problems relevant to the patient at the time of the transition of care. For the purpose of the Transition of Care the focus is the relationship between the medication being used or needed and the problem being addressed. Some problems are self identified by the patient and some are identified though the assessment of the patient during the pharmacist process-of-care encounter.

5.9 RESULTS SECTION

The Results Section contains the results of testing performed relevant to the current episode of care including observations such as hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. It can contain all results for the period of time being documented including notable results such as abnormal values or relevant trends. Where allowed by pharmacy practice acts, pharmacists may obtain samples and perform the analysis.

6. PHARMACY/PHARMACIST CARE NOTE

Clinical services are frequently provided by pharmacies and pharmacists in the day-to-day practice of providing medication. Such activities include but are not limited to: counseling regarding use of medication, possible side effects, dietary considerations associated with the use of a specific medication, and monitoring of clinical indicators such as blood sugar levels, etc. When such services are provided it is necessary to record them for the patient's pharmacy profile, electronic health record (EHR) and /or personal health record (PHR) so that they may be shared with the patient's other care providers, care management or utilization entities and payers. This section describes the use of the C-CDA Progress Note Template to capture and exchange the necessary content to meet the requirements for documentation of these services.

The Pharmacy/Pharmacist Care Note (PCN) guidance utilizing the C-CDA Progress Note template sets out the situations which define requirements for the optional sections of the CCD Template as they relate to pharmacotherapy evaluation/management (PEM) services.

The C-CDA Progress Note template requires completion of the Assessment and Plan which may be accomplished as either a single document or as separate Assessment and Plan Documents. In addition to the required section, it is recommended that the following optional sections in the in the Progress Note template be included in the PCN:

- Allergies
- Medications
- Objective
- Problem List
- Results
- Subjective

All other optional sections may be sent as appropriate to the specific patient and care circumstances and in accordance with jurisdictional law, scope of practice and contractual requirements. These sections include Physical Exam, Review of Systems and Vital Signs.

A PCN is a progress note that documents the care provided by a pharmacist as a result of an encounter in any patient care setting. The PCN includes the reported and observed clinical status, problems and conditions of the patient, and the proposed plan of care. Prescribed medications, over the counter (OTC) medications and supplements are recorded.

For the purpose of the PCN it is important that the Objective and Subjective Sections be included along with the Assessment and Plan of Care Sections to meet the industry recommendations for best practice. Medication related problems and concerns should be documented and codified as appropriate using the Problem List Section. Lab results obtained from outside sources or assessed by the pharmacist to support the medication orders and instructions should be included as appropriate. Additional content is to be included to meet the specific patient use case and as permitted by pharmacy practice acts, collaborative practice agreements and jurisdictional law.

The PCN uses the Progress Note and must conform to the US Realm Clinical Document Header. It must carry the document-level templateId 2.16.840.1.113883.10.20.22.1.9 "Progress Note" asserting conformance with specific constraints of a Progress Note as well as the templateId for the US Realm Clinical Document Header template.

The Progress Note recommends use of a single document type LOINC code, 11506-3 "Subsequent evaluation note", with further specification provided by author or performer, setting, or specialty rather than the pre-coordinated LOINC codes (e.g. 34132-1 for outpatient pharmacy services), to avoid conflicting data related to coded values describing the author or performer of the service act or the practice setting at the header level.

6.1 ASSESSMENT AND PLAN SECTION

The Assessment and Plan Section(s) includes the subjective and objective observations resulting from the pharmacist's/clinician's encounter and assessment of with the patient as well as the conclusions and working assumptions used to plan and guide treatment of the patient and identification of pending orders, interventions, encounters, referrals, services, and procedures for the patient.

The C-CDA Progress Note allows the Assessment and Plan Sections to be combined or separated to meet local policy requirements. In order to align with the pharmacist's process of care structure, this guidance document recommends the Assessment and Plan Sections be separate.

6.1.1 ASSESSMENT SECTION

The Assessment Section includes the clincian's "impression" or "diagnoses" used as the basis for fomulation of the treatment plan and recommendations for other services e.g. testing, referrals or procedures. It may include a list of identified diseases and/or problems.

6.1.2 PLAN OF CARE SECTION

The Plan of Care Section contains pending orders, referrals, interventions, encounters, appointments, services, and procedures recommended and/or scheduled or any other pending event of clinical significance to the current care for the patient. It includes information pertinent to the ongoing care of the patient such as MTM treatment goals and clinical reminders such as prompts for disease prevention and management, patient safety, and health-care quality improvements and indication that patient education was given or will be provided.

6.2 ALLERGIES SECTION

The Allergy Section should list currently active and any relevant historical allergies and adverse reactions including 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) that would impact the safety of health care delivery and affect the selection and utilization of specific medication therapies.

6.3 MEDICATIONS SECTION

The Medications Section defines a patient's current medications and pertinent medication history. At a minimum, the currently active medications are to be listed, with an entire medication history as an option. The section may also include a patient's prescription and dispense history. If the patient is not known to be on medications an entry asserting that is required in the Medications Section.

6.4 OBJECTIVE SECTION

The Objective Section contains the information the pharmacist/clinician has accumulated about the patient gathered through tests, measures, or observations that produce a quantified or categorized result. It includes important and relevant positive and negative test results, physical findings, review of systems, and other measurements and observations.

6.5 PHYSICAL EXAM SECTION

The Physical Exam Section includes direct observations of the patient made by the examining pharmacist/clinician as permitted by state regulation and/or business practice. The examination may include the use of simple instruments and may also describe simple maneuvers performed directly on the patient's body. It does not include laboratory or imaging findings. The exam may be comprehensive or limited to areas related to the chief complaint.

6.6 PROBLEM LIST SECTION

This Problem List Section lists and describes all relevant clinical problems at the time of the report. For the purpose of the PCN special attention given to medication related problems. At a minimum, all pertinent current and historical problems should be listed.

6.7 RESULTS SECTION

The Results Section contains the results of testing performed relevant to the current episode of care including observations such as hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. It can contain all results for the period of time being documented including notable results such as abnormal values or relevant trends. Where allowed by pharmacy practice acts, pharmacists may obtain samples and perform the analysis.

6.8 REVIEW OF SYSTEMS SECTION

The Review of Systems Section contains a relevant collection of symptoms and functions systematically gathered by a pharmacist/clinician. It includes symptoms the patient is currently experiencing, some of which were not elicited during the history of present illness, as well as a potentially large number of pertinent negatives, for example, symptoms that the patient denied experiencing.

6.9 SUBJECTIVE SECTION

The Subjective Section records information regarding the current condition, response to or progress of treatment, and/or interval changes as reported to the pharmacist/clinician by the patient or by the patient's guardian or another informant. For the PCN this information might include difficulties in taking the medication, (e.g. problems with the administration timing of administration or dose form), perceived changes in wellbeing associated with taking the medication (e.g. euphoria or depression, dizziness, increase or decrease in appetite) or questions about the effects of the medication in relation to particular activities the patient is planning.

6.10 VITAL SIGNS SECTION

The Vital Signs Section includes vital signs assessed or monitored pursuant to development of the treatment plan and monitoring the patient's response to the treatment regimen., Vital signs particularly relevant to MTM and the PCN include blood pressure, heart and respiratory rate, height, weight, body mass index, and pulse oximetry. The section should include notable vital signs such as the most recent, maximum and/or minimum, baseline, or relevant trends.

Vital signs are represented in the same way as other results, but are aggregated into their own section to follow clinical conventions.