

Standardized Medication Profile

Version 1

June 2021



The HL7/NCPDP Standardization Medication Profile white paper identifies and defines the components of an interoperable medication profile for clinicians, patients and caregivers to use for the exchange of essential medication information during transitions of care to and from post-acute care settings. This paper also proposes recommendations to the Centers for Medicare & Medicaid Services (CMS) based on what NCPDP and HL7 have identified.

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1 PURPOSE

This white paper identifies and defines the components of an interoperable medication profile for clinicians, patients and caregivers to use for the exchange of essential medication information during transitions of care to and from post-acute care settings. This paper also proposes recommendations to the Centers for Medicare & Medicaid Services (CMS) based on what NCPDP and HL7 have identified.

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2 BACKGROUND AND SIGNIFICANCE

The communication of health information, including medications, is critical to ensuring safe and effective transitions from one health care setting to another. Medication errors, poor communication and poor coordination between providers, along with the rising incidence of preventable adverse events and hospital readmissions, have drawn national attention to the importance of the timely transfer of medication information between post-acute care (PAC) providers, including Long-term Care Hospitals (LTCH), Inpatient Rehabilitation Facilities (IRF), Skilled Nursing Facilities (SNF), Home Health Agencies (HHA) and other settings.

About 40% of patients discharged from acute care receive PAC services (McCarthy, 2021) and in 2018 Medicare fee-for-service spending on PAC expenditures was \$58.6 billion (MedPAC, 2020). However, little is known about the transfer of health information, such as medications, during transitions of care, including the types of medication information transferred or the mode(s) of transfer used.

CMS contracted with RTI International and Abt Associates to develop cross-setting post-acute care transfer of health information and care preferences quality measures in alignment with the mandate of the [Improving Medicare Post-Acute Care Transformation Act of 2014](#) (the IMPACT Act). The measures were required to be cross-setting, meaning the measures were developed to be used by SNF, IRF, LTCH and HHA. Two measures with a focus on the transfer of medication information at PAC discharge were developed with input from a technical expert panel and other stakeholders. One quality measure assesses the transfer of medication information to a subsequent provider (Medication Profile Transferred) and one measure assesses the transfer of medication information to the patient, family and/or caregiver (Medication Profile Transferred to Patient).

2.1 Medication Discrepancies, Medication Errors and Adverse Drug Events

Patient Medication Safety

The exchange of patient medication information during transitions of care, such as admission to and discharge from the hospital, is critical to maintaining patient safety. The 2021 Joint Commission patient safety goal for hospitals to “improve the safety of using medications” underscores the importance of this care process. To meet this goal, the Joint Commission emphasizes the risk points of medication reconciliation and meeting the standard to “maintain and communicate accurate patient medication information” (Joint Commission, 2021). The standard further specifies “coordinating information during transitions of care both within and outside of the organization, patient education on safe medication use and communication with other providers” (Joint Commission, 2021).

Medication Discrepancies

There is compelling evidence to support the significance of adhering to this medication safety standard and medication discrepancies occur during transfers between acute care hospitals and post-acute care settings (Boockvar, Fishman, Kyriacou, Monias, Gavi & Cortes, 2004).

Boockvar and colleagues (2009) examined the link between medication discrepancies at the time of patient transfer and adverse drug events (ADEs) as a health effect in patients transferred between three nursing homes and seven hospitals in New York and Connecticut. While they found that less than 5% of medication discrepancies resulted in an ADE, certain classes of drugs, including opioid analgesics, metronidazole and non-opioid analgesics, had a substantially higher positive predictive value (10%) for an ADE (Boockvar, 2009).

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In a cohort study of 555 nursing home residents who were transferred from the hospital back to the nursing home, adverse events developed in four out of ten discharges. Of the 762 discharges, 379 adverse events were reported. ADEs, among the list of the most common types of events in this study, accounted for 16.9% of adverse events (Kapoor, Field, Handler, Fisher, Saphirak, Crawford, Fouayzi, Johnson, Spenard, Zang & Gurwitz, 2019).

A systematic review (Alqenae, Steinke, Keers, 2020) about the prevalence and nature of medication errors and medication-related harm following discharge from hospital to community settings showed the median rate of medication error or unintentional medication discrepancy* was about 50% in elderly patients, post-hospital discharge. Additionally, 20% of these patients were reported to experience an ADE after hospital discharge. Antibiotics, antidiabetics, analgesics and cardiovascular drugs were the most common medications reported with an ADE. (Alqenae et al., 2020).

Costs of ADEs

Previous studies have estimated the exorbitant costs of ADEs occurring during hospitalization. Sentinel work by Bates and colleagues (1995) estimated the cost of treating ADEs in the hospital is between \$1.56 million and \$5.6 billion annually. Slight et al., (2018) studied the national cost of preventable ADEs resulting from inappropriate medication-related alert overrides in computerized provider order entry (CPOE) in the United States inpatient setting, estimating 29.7 million adult inpatient discharges in 2014 resulting in approximately a billion medication orders and 7.5 million medication alerts in 2014. The authors estimated approximately 5.5 million medication-related alerts were inappropriately overridden, resulting in approximately 196,600 ADEs nationally. They further estimated these ADEs cost between \$871 million and \$1.7 billion. Their findings suggest hospitals optimize their CPOE and decision support tools to mitigate these ADEs.

Medication Error Causes

Medication errors and discrepancies that occur during transitions of care usually stem from a lack of effective communication between healthcare providers (Johnson, Guirguis, Grace, 2015), conflicting information documented in the medical record (Wong, 2008), lapses in documentation, transcription and provider-provider or patient-provider communication (Boockvar et al., 2009). Benefits of using electronic discharge communications (Sevick, Esmail, Tang, Lorenzetti, Ronksley, James, Santana, Ghali, & Clement, 2017) and electronic check lists (Kramer & Drews, 2016) have been suggested to ensure completeness of documentation in the medical record and improved clinical outcomes. Medication Reconciliation, including electronic medication reconciliation, is an important patient safety process and has been identified as an important intervention to address medication accuracy during transitions in care and in identifying preventable ADEs, and to minimize or avoid unintentional medication discrepancies (McKonnen, Abebe, McLachlan & Brien, 2016; Kwan, Lo, Sampson, & Shojania, 2013; Leotsakos, Zheng, Croteau, Loeb, Sherman, Hoffman, Morganstein, O'Leary, Bruneau, Lee, Duguid, Thomeczek, van der Schrieck-De Loos, & Munier, 2014).

Medication Reconciliation

* An **unintentional discrepancy** occurs when the prescriber (usually the physician) **unintentionally** changes, adds or omits a **medication** the patient was taking prior to admission. Accessed on February 23, 2021 from: <https://pubmed.ncbi.nlm.nih.gov/32125666/>

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Medication reconciliation is a formal process of reviewing and comparing the medications a patient is taking, or should be taking, including a review of the medication name, dose, frequency and route (IHI, 2014), with newly ordered medications to identify and correct any potential clinically significant medication issues across transitions of care, such as admission, transfer and/or discharge orders (Joint Commission, 2021; IHI, 2014; Kwan et al., 2013). The goal of medication reconciliation is to provide correct medications to the patient at all transition points (IHI, 2014).

MeKonnen et al., (2016) conducted a systematic review and meta-analysis to investigate the available evidence of the impact of pharmacy-led medication reconciliation that minimized medication discrepancies during transitions of care. Their results showed evidence that pharmacy-led medication reconciliation at hospital transitions (admission or discharge) decrease medication discrepancies compared with usual care (MeKonnen et al., 2016). In another systematic review of medication reconciliation during transitions of care, Kwan et al., (2013) investigated the effect of medication reconciliation on unintentional discrepancies with the potential for harm and hospital utilization after discharge. Hospital utilization after discharge was defined as an unplanned emergency department visit and readmission to the hospital within 30 days. They reported that medication reconciliation alone has the potential to reduce post-discharge hospitalization within 30 days when paired with other discharge coordination interventions (Kwan et al., 2013). Their findings suggest only a few unintended medication discrepancies have clinical significance and pharmacists play a major role in the medication reconciliation intervention (Kwan et al., 2013).

3 JOINT NCPDP/HL7 PROJECT EFFORT

NCPDP WG14/WG10 Standardized Medication Profile Task Group completed an analysis of data fields and transactions available in the current NCPDP SCRIPT and Specialized standards (as defined by the IMPACT Act) and documented existing data fields that meet patient and medication profile attributes and specific gaps.

In September 2019, an HL7 [Standardized Medication Profile Project Scope Statement](#) was initiated.

Scope: Create a white paper that will identify and define the components of an interoperable medication profile. Harmonizing NCPDP and HL7 standards and projects related to the medication related information pertinent to Post-Acute Care settings.

Since NCPDP and HL7 are both Standards Development Organizations that focus on pharmacy information, this project will evaluate commonalities and identify gaps between the NCPDP SCRIPT Standard, the HL7 FHIR Pharmacy Resources and the HL7 Pharmacy CDA Template where it concerns conveying a Medication Profile.

3.1 PACIO Project

In February 2019, the [Post-Acute Care Interoperability \(PACIO\) Project](#) was launched. The goal of this collaborative partnership is to establish a framework for the development of a Fast Healthcare Interoperability Resource (FHIR) technical implementation guide(s) and Reference Implementations that will facilitate health information exchange through standards-based application programming interfaces (APIs). The objective of the PACIO Project is to use a consensus-based approach to advance interoperable health data exchange between post-acute care providers, patients and other key stakeholders across the health care continuum with policy makers, standards organizations and industry.

- Working on two use cases in parallel
 - Functional Status
 - Cognitive Status
- Developed two HL7 FHIR Implementation Guides
 - Functional Status <https://paciowg.github.io/functional-status-ig/>
 - Cognitive Status <https://paciowg.github.io/cognitive-status-ig/>

During the previously identified HL7 gap analysis, FHIR cognitive and functional status resources were missing. To prevent duplication of effort, this project will refer to the PACIO Project for FHIR for functional and cognitive statuses.

3.2 Data Element Library

The Data Element Library (DEL) is relevant to this paper as the US Government points to the DEL for standardized data elements that will be used for responses to information captured in the Standardized Medication Profile. These standardized responses in the DEL are related to FHIR cognitive and functional status previously identified in the HL7 gap analysis (e.g., unable to swallow or inability to read).

The CMS Data Element Library is the centralized resource for CMS assessment instrument data elements (e.g., questions and responses) and their associated health information technology (IT) standards. The goals of the DEL are to:

- Serve as a centralized resource for CMS assessment data elements (questions and response options),

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- Promote the sharing of electronic CMS assessment data sets and health information technology standards and
- Influence and support industry efforts to promote Electronic Health Record (EHR) and other health IT interoperability.

For more information on the DEL, please see: <https://del.cms.gov/DELWeb/pubHome>

3.3 FHIR Version Selection

This document references HL7 FHIR Release 4 (FHIR R4), specifically version 4.0.1, released on October 30, 2019.

FHIR includes Normative, Standard for Trial Use (STU) and work in progress content. FHIR has multiple versions available including released versions (stable for development), intermediate versions (key development points between releases) and the continuous build (all new content, updates can occur hourly, may include unstable content). To address potential issues with implementations using mismatched FHIR versions, a FHIR *release* establishes a version to be employed for product development.

3.4 NCPDP/HL7 Gap analysis – FHIR Release 4 ([HL7 FHIR Overview](#))

Upon forming this task group, members performed a mapping analysis by using the NCPDP SCRIPT Standard Version 2017071 based on the data elements identified by RTI International. In October 2019, the HL7 Pharmacy Work Group members completed a FHIR Release 4 (R4) and CCD 2.1 mapping analysis. The result identified gaps in patient capabilities and medication information.

4 ANALYSIS OF INFORMATION

The mapping analysis and comparison of the identified data elements to the NCPDP SCRIPT Standard Version 2017071, HL7 FHIR R4 and CCDA 2.1 standards are detailed in [Appendix A](#). A synopsis of suggested additions and gaps to the Standardized Medication Profile Elements is outlined in this section.

Standardized Medication Profile Elements

- Data Element Clarifications (list of existing elements the standards accommodate)
- Suggested Additions
 - Recommendation to include time(s) the medication(s) are given to ensure avoidance of competitive inhibition that can lead to adverse drug events.
 - Medication reconciliation takes place after receiving standardized medication profile. Having the time(s) of medication(s) can assist with the medication reconciliation process.
- Gaps in existing standards (including suggested data elements for these gaps)

HL7 Gap Analysis Mapping

- Similar data elements between NCPDP SCRIPT Standard and HL7 FHIR as well as similar gaps
- Patient Information
 - FHIR Gaps
 - *Patient Adherence, Patient Preferences*: gap -There is some work being done in HL7 to work on these but no current mechanism for relaying this.
 - *Patient ability to understand/accept conditions and importance of taking medications as prescribed* – gap
 - Missing Components (in addition to ones already identified by NCPDP)
 - *Birth Sex* – different component from gender
 - *Race/Ethnicity* – It is important that this information is relayed especially when a patient is being discharged to a home health agency. It also supports CMS' focus on social determinants of health.
- Medication Information
 - FHIR Gaps
 - *When final dose should be administered*: Dosing is not normally captured as part of a statement of usage or a request. A possible solution is to use MedAdmin and tie it to a request but cannot tie it to a statement. HL7 would need to ballot to create a link to statement.
 - *Patient education provided about potential risks/side effects/contraindications and when to notify prescriber (for profile provided to patient /family/caregiver)*: knowledgebases would have this information that is normally provided by pharmacies. Did patient receive information about the medication and how to administer it? (e.g., use of inhaler, injections) A possible solution is it could be text-based or flags.
 - *Patient adherence with medication therapy*: Currently being evaluated within HL7 but currently a gap.
 - Missing components (in addition to ones already identified by NCPDP)
 - *When first dose of the medication was administered *if applicable*
 - *When the next dose should be administered*

5 RECOMMENDATIONS AND CONCLUSION

In order to meet the intent of the IMPACT Act to specify quality measures on which PAC providers are required to submit standardized patient assessment data when an individual transitions from a hospital to a post-acute care setting, we must develop standards to assure the data exchange is interoperable.

The identification of gaps and mapping of the NCPDP and HL7 standards are critical components to the advancement in developing an HL7 Standardized Medication Profile FHIR resource. It is our hope this paper will encourage industry partners to work within the HL7 Pharmacy work group to develop and ballot a new HL7 Standardized Medication Profile FHIR resource leading to implementation and adoption of the standard.

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Appendix A – Standardized Medication Profile Mapping

IMPACT ACT ELEMENTS		SCRIPT XML (2017071) MAPPING		FHIR R4 MAPPING	CCDA 2.1 MAPPING (TRANSFER SUMMARY DOCUMENT)
PATIENT DEMOGRAPHICS	CLARIFICATIONS NEEDED	SEGMENT	TRANSACTION		ClinicalDocument/recordTarget/patientRole/patient
Patient Name	Need to clarify which name parts are needed	Patient	Census	Patient.name	./name
Patient Date of Birth		Patient	Census	Patient.birthDate	./birthTime
Primary Physician Name and Contact Information	Need to clarify which name parts are needed and which contact information. What about Credentials and Provider Type?	Patient	Census	Patient.generalPractitioner	./providerOrganization
Gender		Patient		Patient.gender	./administrativeGenderCode
Preferred Language		Patient		Patient.communication	./languageCommunication
Race				Patient.extension[us-core-race]	./raceCode and ./sdct:raceCode
Ethnicity				Patient.extension[us-core-ethnicity]	./ethnicGroupCode and ./sdct:ethnicGroupCode
Birth Sex				Patient.extension[us-core-birthsex]	
PATIENT OBSERVATIONS	CLARIFICATIONS NEEDED	SEGMENT	TRANSACTION		VITAL SIGNS SECTION
Height and Date Taken	Need to distinguish how height is measured?	Observation	NewRx	Observation[code = '8302-2 Body Height']	code = 8302-2 Body Height
Weight and Date Taken	Need to distinguish how weight is measured?	Observation	NewRx	Observation[code = '29463-7 Body Weight']	code = 29463-7 Body Weight

IMPACT ACT ELEMENTS		SCRIPT XML (2017071) MAPPING		FHIR R4 MAPPING	CCDA 2.1 MAPPING (TRANSFER SUMMARY DOCUMENT)
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PATIENT MEDICAL HISTORY	CLARIFICATIONS NEEDED	SEGMENT	TRANSACTION		
Active Diagnoses and other diagnoses that have medication implications	What information is needed here?	DiagnosisGeneral	Census	Condition	PROBLEM SECTION
Known Medication and Other Allergies	What information is needed here?	AllergyOrAdverseEvent		AllergyIntolerance[type = 'Allergy']	ALLERGIES AND INTOLERANCES SECTION (value = 419199007 Allergy to substance)
Known Drug Sensitivities/Reactions	What information is needed here?	AllergyOrAdverseEvent		AllergyIntolerance[type = 'Intolerance AND category = 'medication']	ALLERGIES AND INTOLERANCES SECTION (value = 59037007 Drug intolerance)
PATIENT CAPABILITIES	CLARIFICATIONS NEEDED	SEGMENT	TRANSACTION		
Patient Preferences	Would this be overall or attached to each medication?	GAP		GAP	GAP
Patient Adherence Strategies		GAP		GAP	GAP
Patient Ability to Understand/Accept Condition(s) / Importance of taking medications as prescribed	Boolean type fields? Is it overall or for each medication?	GAP		GAP	GAP
MEDICATION INFORMATION (REPEAT FOR EACH ORDER)					MEDICATIONS SECTION
Medication Name (Generic/Proprietary) and Strength		DrugDescription		MedicationStatement.medication	./consumable/manufacturedProduct
Dose		SIG/SIGText or codified SIG		MedicationStatement.dosage.doseAndRate	./doseQuantity
Route of Administration		SIG/SIGText or codified SIG, sometimes in DrugDescription		MedicationStatement.dosage.route	./routeCode
IMPACT ACT ELEMENTS		SCRIPT XML (2017071) MAPPING		FHIR R4 MAPPING	CCDA 2.1 MAPPING (TRANSFER SUMMARY DOCUMENT)
Frequency		SIG/SIGText or codified SIG		MedicationStatement.dosage.timing	./effectiveTime

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Directions		SIG/SIGText or codified SIG		MedicationStatement.dosage.text	Medication Free Text Sig entry
Special Instruction (e.g., crush medications)		SIG/SIGText or codified SIG, Note		MedicationStatement.patientInstruction	Instruction entry
Reason for holding medication and when medication should resume	What about date hold started?	DrugAdminReason Code/Text	DrugAdministration		GAP
Purpose/Indications/Contraindications		Structured and Codified Sig (Indications for Use)		MedicationStatement.reason[x]	Indication entry
Prescriber		Prescriber		MedicationStatement.basedOn => MedicationRequest.requester	./author
Date of last dose administered		GAP		MedicationAdministration.effective	Substance Administered Act entry
Date of final dose to be administered		GAP		MedicationAdministration.effective	Substance Administered Act entry
Patient education provided about potential risks / side effects / contraindications and when to notify prescriber		GAP		GAP	GAP
Patient adherence with the medication therapy		GAP		GAP	GAP
Relevant lab test results to guide medication management (e.g., serum creatinine)		ObservationDate; Observation		MedicationRequest.supportingInformation	GAP
IMPACT ACT ELEMENTS		SCRIPT XML (2017071) MAPPING		FHIR R4 MAPPING	CCDA 2.1 MAPPING (TRANSFER SUMMARY DOCUMENT)
Drug identifiers				MedicationStatement.medication	./consumable/manufacturedProduct
Diagnosis relevant to the medication				MedicationStatement.reason[x]	Indication entry

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Standardized Medication Profile

Medication Status				MedicationStatement.status	./statusCode
Date of first dose administered				MedicationAdministration.effective	Substance Administered Act entry
Date of next dose to be administered				MedicationAdministration.effective	Substance Administered Act entry

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Appendix B – History of Changes

Version 1.0

Initial release of the paper.

National Council for Prescription Drug Programs

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