

Draft USCDIV4 Data Class Section(s)	Data Element Section(s)	Comment(s)
Allergies and Intolerances / Substance (Non-Medication)	Applicable Standard(s)	Agree with the IMO remarks about the FHIR value set being too extensive. The SNOMED hierarchy referenced is less than a few hundred terms, but I don't know what is missing. FDA Food labeling guidelines could be used to create a starter set. Is it more appropriate to use the "allergy or intolerance to ____" SNOMED hierarchy or just reference the allergen, which is what UMLS could do.
Allergies and Intolerances / Substance (Non-Medication)		The concern about the specific FHIR IG not being "widely implemented" and therefore does not qualify as level 2 seems to be an obstruction to getting a good starter value set together.
Procedures	Time of Procedure	This new data element is probably readily available.
Encounter Information	Encounter Identifier	This new data element is probably readily available, but remember it needs identifier type and assigning entity.
Medications	Medication Instructions	Medication Instructions are available in Medication Request. Dosage Instruction profile should not be a problem if it is being populated in FHIR.
Medications	Medication Adherence	Medication Adherence submission says, "At least 21 pharmacy system vendors are FHIR enabled and are created millions of Pharmacists eCare Plans throughout the US." It appears it would not be burdensome to implement.
Goals	Treatment Intervention Preference	This is a great addition to make "advance directives" more usable. It is well described and in use in HL7 CDA® R2 Implementation Guide: C-CDA R2.1; Advance Directives Templates, Release 1 - US Realm. I was concerned about what happens to the Advance Directives section, but I see "this submission has been added to Draft USCDI v4 as Goals/Treatment Intervention Preference." Much more useful!

Goals	Care Experience Preference	I agree that this is a useful data element promotion. As the Submission grid says, "There are over 5,000 hospitals and 231,000 small practices, long-term post-acute care centers, skilled nursing facilities and other healthcare providers who have clinical record technologies which are suitable for the capture, access, use or exchange of this data element. In addition, over 190 million Americans over the age of 18 who should be creating, digitally storing, and exchanging advance directives data with their healthcare providers."
Vital Signs	Average Blood Pressure Applicable Standard(s)	The submission grid states, "Cerner, Epic, and Higi use Average Blood Pressures (systolic and diastolic)." The only concern is that "average" and "mean" may be conflated, at least as far as the SNOMED CT and LOINC codes listed.
Provenance	Author Organization Author Time Stamp	Many SDOH providers may not be affiliated with an organization. Would the Author organization for single providers default to the provider's name?
Medical Devices	Unique Devices Identifier	Consistent with the work being done by the HL7 Unique Mobile Health Application Identifier Workgroup, we suggest possibly broadening the data class title again to include mobile health applications and devices that may not be designated by the FDA as a medical device. In addition, since some implantables have embedded (native) software, the identifier should include components that allow tracking of the implantable AND the software. Alternatively, there could be data element identifiers that identify the implantable device and a separate one for the embedded health application software.