|  |  |
| --- | --- |
| V 2.9 HL7 Proposal | |
| *Change Request ID:* | *To be Defined* |
| *File Name:* | *Device Segment Proposal* |
| *Description:* | *Add new two new participations* |
| *Status:* | *New Proposal* |
| *Sponsoring Person* | *Hans Buitendijk / Dan Rutz* |
| *Sponsoring Organization* | *Cerner / Epic* |
| *Date Originated:* | *1/30/2018* |
| *Date HL7 approved:* |  |
| *Backward Compatible:* | *Yes* |
| *Forward Compatible:* | *Yes* |
| *HL7 Status & Date* |  |

# Justification Detail:

To support communication of data beyond the six UDI components (included in the PRT segment), there is a need to add a number of device specific attributes that could be obtained from the GUDID data base and/or the UDI Carrier.

Adding this attributes to PRT segment is inappropriate as they are beyond the core identifying information of the participation. The six UDI components are only included in PRT as they are part of the UDI Carrier and critical to the identification of the related device. Any other data should be communicated in another segment.

While there is an option to send such other data in a set of OBX-es as commonly done as part of ORU messages between devices, for the limited data set involved and the complexities introduced by including an OBX after every PRT to avoid confusion what it applies to and what it represents, the proposal is to add a DEV segment. We note the this does not require existing, non-HL7 implementation guides to alter their approaches, particularly when based on older HL7 V2 versions.

The proposed DEV segment also contains the individual UDI components as this segment may be used without a PRT being present, while a PRT may be sufficient to convey the UDI components. We therefore are not proposing to deprecate the PRT fields for the individual UDI components at this time.

# Open Issues:

* Can we re-use PRT item numbers since only the name changes, not the definition?

# Change Request Impact:

No known impact.

# Documentation Changes:

Include a new Device Segment in Chapter 17

DEV -

| SEQ | LEN | C.LEN | DT | OPT | RP/# | TBL# | ITEM# | ELEMENT NAME |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 |  |  | ID | R |  | 0287 | 00816 | Action Code |
| 2 |  |  | EI | C |  |  | Nnnnn | Unique Device Identifier |
| 3 |  |  | CNE | C |  |  | Nnnnn | Device Type |
| 4 |  |  | CWE | O |  |  | Nnnnn | Status |
| 5 |  |  | XON | O |  |  | 01247 | Manufacturer/Distributor |
| 6 |  |  | ST |  |  |  | 01249 | Brand Name |
| 7 |  |  | ST |  |  |  | 01252 | Model Identifier |
| 8 |  |  | ST | O |  |  | 01253 | Catalog Identifier |
| 9 |  |  | EI | O |  |  | 03476 | UDI Device Identifier |
| 10 |  |  | ST | O |  |  | 03479 | Lot Number |
| 11 |  |  | ST | O |  |  | 03480 | Serial Number |
| 12 |  |  | DTM | O |  |  | 03477 | Manufacture Date |
| 13 |  |  | DTM | O |  |  | 03478 | Expiry Date |
| 14 |  |  | CWE | O | Y |  |  | Safety Characteristic |
| 15 |  |  | EI | O |  |  | 03481 | Donation Identification |

#### DEV-1 Action code (ID) 00816

Definition: This field reveals the intent of the message. Refer to [HL7 Table 0287 – Problem/goal action code](file:///C:\Users\Riki\Documents\Riki%20Laptop\HL7_Ballots\v282%20Ballot\V281_CH02C_CodeTables.doc#HL70287) for valid values.

#### DEV-2 Unique Device Identifier (EI) nnnnn

Components: <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^ <Universal ID Type (ID)>

Definition: This field contains a unique identifier for the Device.

When intended to have the additional device information for the device referenced in a PRT segment in the message, DEV-1 must be equal to PRT-10 Participation Device. When PRT-22 Participation Device Type is used, DEV-?? must be equal

Condition: Either DEV-2 Unique Device Identifier or DEV-3 Device Type must be valued, or both are valued.

#### DEV-3 Device Type (CNE) nnnnn

Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^ <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second Alternate Value Set Version ID (DTM)>

Definition: This field contains the type of device used in the participation.

When intended to have the additional device information for the device referenced in a PRT segment in the message, DEV-1 must be equal to PRT-10 Participation Device. When PRT-22 Participation Device Type is used, DEV-?? must be equal

When communicating a UDI, the UDI may either be uniquely identifying an instance of a device, or a type of device. This can be asserted based on the inclusion or absence of a serial number in the Product Identifier section of the UDI. When the serial number is present, PRT-10 must be used, while if it is absent, PRT-22 must be used.

When communicating a UDI in this field, the coding system used is limited to FDA (FDAUDI), HIBCC (HIBUDI), ICCBBA (ICCUDI), and GS1 (GS1UDI) coding systems defined in [HL7 Table 0396](file:///C:\Users\Riki\Documents\Riki%20Laptop\HL7_Ballots\v282%20Ballot\V281_CH02C_CodeTables.doc#HL70396).

Condition: Either DEV-2 Unique Device Identifier or DEV-3 Device Type must be valued, or both are valued.

#### DEV-4 Implantation Status (CNE) nnnnn

Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^ <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second Alternate Value Set Version ID (DTM)>

Definition: This field contains the implantation status of the device, e.g., pre-implanted, implanted, explanted.

#### DEV-5 Manufacturer/Distributor (XON) 01247

Components: <Organization Name (ST)> ^ <Organization Name Type Code (CWE)> ^ <WITHDRAWN Constituent> ^ <WITHDRAWN Constituent> ^ <WITHDRAWN Constituent> ^ <Assigning Authority (HD)> ^ <Identifier Type Code (ID)> ^ <Assigning Facility (HD)> ^ <Name Representation Code (ID)> ^ <Organization Identifier (ST)>

Subcomponents for Organization Name Type Code (CWE): <Identifier (ST)> & <Text (ST)> & <Name of Coding System (ID)> & <Alternate Identifier (ST)> & <Alternate Text (ST)> & <Name of Alternate Coding System (ID)> & <Coding System Version ID (ST)> & <Alternate Coding System Version ID (ST)> & <Original Text (ST)> & <Second Alternate Identifier (ST)> & <Second Alternate Text (ST)> & <Name of Second Alternate Coding System (ID)> & <Second Alternate Coding System Version ID (ST)> & <Coding System OID (ST)> & <Value Set OID (ST)> & <Value Set Version ID (DTM)> & <Alternate Coding System OID (ST)> & <Alternate Value Set OID (ST)> & <Alternate Value Set Version ID (DTM)> & <Second Alternate Coding System OID (ST)> & <Second Alternate Value Set OID (ST)> & <Second Alternate Value Set Version ID (DTM)>

Subcomponents for Assigning Authority (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Subcomponents for Assigning Facility (HD): <Namespace ID (IS)> & <Universal ID (ST)> & <Universal ID Type (ID)>

Definition: This field contains the identity of the manufacturer/distributor.

#### DEV-6 Brand Name (ST) 01249

Definition: This field contains the name under which the product is marketed by this manufacturer.

#### DEV-7 Model Identifier (ST) 01252

Definition: This field contains the manufacturer's model identifier for the product.

#### DEV-8 Catalogue Identifier (ST) 01253

Definition: This field contains the manufacturer's catalogue identifier for the product.

#### DEV-9 UDI Device Identifier (EI) 03476

Components: <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^ <Universal ID Type (ID)>

Definition: Provides the U.S. FDA UDI *device identifier* (DI) element.

This is the first component in the UDI and acts as the look up key for the Global Unique Device Identification Database (GUDID[[1]](#footnote-1)), and may be used for retrieving additional attributes.

When exchanging Device Identifiers (DI) the root shall be the OID, or standards’ appropriate corollary to the OID, assigned to DI and the extension shall be the Human Readable Form of the content. For example, for DIs the root shall be:

GS1 DIs: 2.51.1.1

HIBCC DIs: 1.0.15961.10.816

ICCBBA DIs: 2.16.840.1.113883.6.18.1.17 for Blood containers and 2.16.840.1.113883.6.18.1.34 otherwise.

Example: |00643169001763^^2.51.1.1^ISO|

#### DEV-10 Lot Number (ST) 03479

Definition: Alphanumeric string that identifies the device’s production lot number.

Example: |123ABC|

#### DEV-11 Serial Number (ST) 03480

Definition: Manufacturer’s serial number for this device.

#### DEV-12 Manufacture Date (DTM) 03477

Definition: Date and time when the device was manufacturered.

Note: The user system may need to convert the date and optional hour from the UDI Human Readable Form to a timestamp style data type, augmenting the date as required to provide for a complete date and optionally the hour.

Example: |20140401|

#### DEV-13 Expiry Date (DTM) 03478

Definition: Date and time when the device is no longer approved for use.

Note: The user system may need to convert the date and optional hour from the UDI Human Readable Form to a timestamp style data type, augmenting the date as required to provide for a complete date and optionally the hour.

Example: |20160712|

CAUTION: See the related privacy considerations discussion in PRT-10.

Example: |21A11F4855|

#### DEV-14 Safety Characteristic (CWE) nnnnn

Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^ <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding System Version ID (ST)> ^ <Original Text (ST)> ^ <Second Alternate Identifier (ST)> ^ <Second Alternate Text (ST)> ^ <Name of Second Alternate Coding System (ID)> ^ <Second Alternate Coding System Version ID (ST)> ^ <Coding System OID (ST)> ^ <Value Set OID (ST)> ^ <Value Set Version ID (DTM)> ^ <Alternate Coding System OID (ST)> ^ <Alternate Value Set OID (ST)> ^ <Alternate Value Set Version ID (DTM)> ^ <Second Alternate Coding System OID (ST)> ^ <Second Alternate Value Set OID (ST)> ^ <Second Alternate Value Set Version ID (DTM)>

Definition: This field a safety characteristic of a device, e.g., latex safety, MRI safety.

#### PRT-15 Donation Identification (EI) 03481

Components: <Entity Identifier (ST)> ^ <Namespace ID (IS)> ^ <Universal ID (ST)> ^ <Universal ID Type (ID)>

Definition: Identifies a device related to a donation (e.g., whole blood).

When exchanging Donation Identification Numbers (DIN) the root shall be the OID assigned to DIN and the extension shall be the Human Readable Form of the content. For example, for DINs the root shall be:

ICCBBA DINs: 2.16.840.1.113883.6.18.2.1

An ICCBBA DIN OID is available for reference where required, but is not required when the specific data element is scoped to ICCBBA DINs.

Example: | RA12345678BA123^^2.16.840.1.113883.6.18.1.34^ISO|

Then insert in the following messages the [{DEV}] at the end of the messages:

* OMG
* OML
* OML
* ORU
* OUL (all events, except R21)
* Etc.

1. See www.fda.gov/udi [↑](#footnote-ref-1)