**New Content**

**Each Implantable Device must support:**

1. The Device Identifier (UDI-DI)
2. the manufacture date
3. the expiration date
4. the lot number
5. the serial number
6. the distinct identifier (i.e., the distinct identification code)

**Profile specific implementation guidance:**

This profile supports the requirement to retrieve an 170.315(a)(14) Implantable device list and follows the HL7 Cross Paradigm Implementation Guide: UDI Pattern guidelines for exchanging information about the use of and/or implantation of medical devices in patients.

* A unique device identifier (UDI) is a unique numeric or alphanumeric code. There is a machine-readable version (AIDC - Automatic Identification and Data Capture) as well as a human-readable version of the UDI (HRF - Human Readable Form). This profile specifies that only the HRF must be supported. We note that one may only receive, and thus be able to further share the AIDC. Considering the complexity of parsing AIDCs there is no expectation at this time that one converts an AIDC to HRF upon receipt from a source that may not be conformant to this profile (e.g., by way of C-CDA, v2, or other means).  
  The UDI generally consists of a mandatory Device identifier (DI) and a conditional Production identifier (PI) that identifies one or more of the five UDI-PI elements. The UDI and its components are mapped to the US Core Implantable Device Profile elements in the table below:

**[Table and GUDID references not copied as there is no suggestion to adjust]**

**Conformance Statements:**

Implantable medical devices that have UDI information **SHALL** represent the UDI code in Device.udiCarrier.carrierHRF.

* All of the five UDI-PI elements that are present in the Device.udiCarrier.carrierHRF SHALL be represented in the corresponding US Core Implantable Device Profile element.

UDI may not be present in all scenarios such as historical implantable devices, patient reported implant information, payer reported devices, or improperly documented implants. If UDI is not present and the manufacturer and/or model number information is available, they SHOULD be included to support historical reports of implantable medical devices as follows: