

Addressing the Needs of Retail, Reimbursement and UDI Compliance:

Creating New Reimbursement Numbers for Medical Devices

Medical devices available through a pharmacy and potentially eligible for reimbursement from payers are generally labeled with an 11-digit reimbursement number, typically with a National Health Related Item Code (NHRIC), which looks similar to a National Drug Code (NDC) in format and number of digits. The 11-digit reimbursement number is derived from the 10-digit NHRIC or NDC following NCPDP standards, to create a single format code for reimbursement. Pharmacies and payers rely on these reimbursement numbers for device reimbursement in the pharmacy setting.

On September 24, 2013, FDA issued final rules establishing the UDI system, which among other requirements, requires that device labels bear a UDI. In an effort to create a standard for medical device identification, the UDI rule rescinds existing legacy identifiers (e.g., NDC and NHRIC numbers) assigned to medical devices, and states that these identifiers are no longer allowed to appear on the product's label. Furthermore, FDA no longer issues FDA labeler codes to medical device manufacturers; however, NDC and NHRIC numbers previously assigned to medical devices for reimbursement purposes are permitted on the device's label for an interim period. See [Draft Guidance: Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices](#) (Feb. 3, 2016).

Pharmacies and payers are not currently enabled to utilize a device's UDI Device Identifier (DI) for reimbursement activities. As a result, device manufacturers who sell devices through a pharmacy and that are potentially eligible for reimbursement must ensure that an 11-digit reimbursement number for their device will be consistently derived and identified by their customers. Devices that currently utilize a reimbursement number should continue to use the existing number until pharmacies and payers are capable of utilizing the device's UDI for reimbursement activities (this change is not expected to occur until 2021 at the earliest; FDA will establish the sunset date through guidance). Device manufacturers should not alter or change existing reimbursement numbers that pharmacies and payers have used in the past.

Device manufacturers who sell devices through a pharmacy and that are potentially eligible for reimbursement, and for which a reimbursement number does not currently exist, should follow the steps outlined below in order to establish a usable reimbursement number. Device manufacturers should not create a reimbursement number on their own. Please note, the information provided below is relevant only for those manufacturers who use a GS1-issued Global Trade Item Number (GTIN); additional steps and/or criteria may be necessary if the labeler uses a UDI issued by the [Health Industry Business Communications Council or ICCBBA](#). In addition, this document is not intended to provide an exclusive set of instructions to establish a reimbursement number.

1. Contact [GS1 US](#) to obtain a GS1 Company Prefix (GCP). The manufacturer should then build out their GTIN identifier according to the GS1 Standard based on the needs of their product and their distribution channel. The 12-digit GTIN presented in a U.P.C. barcode is used for products sold through retail channels.
 - a. If a U.P.C. is not sufficient to address UDI compliance, the product's label should bear a U.P.C. (DI only) and a larger UDI barcode (DI + PI components). Please contact GS1 US for additional guidance.
2. GS1 US will instruct the manufacturer to contact the [National Council for Prescription Drug Programs](#) (NCPDP) to assist with constructing an 11-digit reimbursement number. NCPDP will work with compendia services to reach consensus on the appropriate conversion of the manufacturer's GTIN to an 11-digit reimbursement number, ensuring that duplicate reimbursement numbers are avoided. Compendia services include Elsevier, First Databank, Wolters Kluwer Medi-Span, and Multum
3. As a result of FDA's UDI rule, the labeler should not identify the 11-digit reimbursement number as an NDC on the product label. Phrases such "Reimbursement Number" (RN) are more appropriate.

The process outlined above is **a temporary solution for manufacturers** who are required to establish a new reimbursement number for a device sold through a pharmacy and that are potentially eligible for reimbursement. At a future date (2021 at the earliest, pending FDA guidance) pharmacies and payers will be capable of utilizing the device's UDI for reimbursement activities.

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