Contains Nonbinding Recommendations

Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document regarding CDRH-regulated devices, contact UDI Regulatory Policy Support, 301-796-5995, email: GUDIDSupport@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Public Comment

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This guidance describes the Agency's intent regarding enforcement of the prohibition against providing National Health Related Item Code (NHRIC) or National Drug Code (NDC) numbers on device labels and device packages set forth at 21 CFR 801.57(a)-(b). As described below, FDA does not intend to enforce this prohibition with respect to finished devices that are manufactured and labeled prior to September 24, 2021. In addition, this guidance describes the Agency's intent to consider requests for continued use of FDA labeler codes under a system for the issuance of unique device identifiers (UDIs) that are submitted before September 24, 2021. For the purpose of this document, "legacy FDA identification numbers" refers to both NHRIC and NDC numbers assigned to devices.

Throughout this guidance document, the terms "we," "us" and "our" refer to FDA staff from Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory

requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

A. Unique device identification system

Section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), 121 Stat. 854, and Section 614 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), 126 Stat. 1061, amended the Federal Food, Drug, and Cosmetic Act to add section 519(f) (21 U.S.C. 360i(f)), which directs FDA to issue regulations establishing a unique device identification system for medical devices along with implementation timeframes for certain medical devices. The final rule (UDI Rule) establishing the unique device identification system was published on September 24, 2013 (78 FR 58786). Among other requirements, the UDI Rule requires that the label and every device package of a medical device distributed in the United States bear a UDI, unless an exception or alternative applies (21 CFR 801.20).

The UDI Rule is intended to create a standardized identification system for medical devices used in the United States that makes it possible to rapidly and definitively identify a device and some key attributes that affect its safe and effective use. Establishing standardized, uniform identification of most devices through distribution to the point of use is intended to reduce medical errors that result from misidentification of a device or confusion concerning its appropriate use (78 FR 58786, Sept. 24, 2013).

The unique device identification system is being phased in over seven years according to a series of compliance dates based primarily on device classification. Among other requirements, the compliance dates establish the dates upon which device labels and device packages are required to bear a UDI. See the UDI webpage (www.fda.gov/udi) or Appendix A for a table of compliance dates for UDI requirements.

B. Legacy FDA identification numbers

In the absence of a standardized, unique identification system for devices, some companies have historically placed NHRIC or NDC numbers on the labels and packages of certain medical devices. To further the objectives of creating a national device identification system, the UDI Rule includes a provision that rescinds any NHRIC or NDC number assigned to a medical device (21 CFR 801.57). Under 21 CFR 801.57(a), on the date a device is required to bear a UDI on its label, any NHRIC or NDC number assigned to that device is rescinded and may no longer be on the device label or on any device package. If a device is not required to bear a UDI on its label, any NHRIC or NDC number assigned to that device is rescinded as of September 24, 2018, and may no

longer be on the device label or on any device package (21 CFR 801.57(b)). As explained in the proposed rule to establish a unique identification system, continued use of NHRIC and NDC numbers on device labels and device packages could cause confusion regarding appropriate identification of the device or obscure the distinction between drug and device identification systems. (77 FR 40753, July 10, 2012.)

C. Reimbursable medical devices available at pharmacies

Currently, medical devices available through a pharmacy and potentially eligible for reimbursement from payers are generally labeled with an 11-digit reimbursement number, typically using an NHRIC or NDC[1] number assigned to the device. Pharmacies and payers rely on NHRIC and NDC numbers for device reimbursement in the pharmacy setting, and some affected stakeholders have expressed concern that pharmacies, payers, and other entities are not prepared to transition away from use of NHRIC or NDC numbers in their systems. Some stakeholders have also expressed concern that removal of these legacy FDA identification numbers from medical device labels according to the timeline required by 21 CFR 801.57 could cause disruption to existing reimbursement, supply chain, and procurement processes.

FDA believes that continued implementation of UDI requirements under 21 CFR part 801, subpart B and 21 CFR part 830, subpart E according to the scheduled compliance dates is important to achieving the objectives of the UDI Rule in a timely manner. However, it is not FDA's intent to cause disruption to existing reimbursement, supply chain, and procurement processes, or to interfere potentially with patient access to treatment. We therefore recognize that additional time is appropriate for stakeholders to make changes to ensure that medical device reimbursement, supply chain, and procurement systems and processes will not depend on NHRIC and NDC numbers.

III. Dates for removal of NHRIC and NDC numbers from medical device labels and packages

FDA does not intend to enforce the prohibition against providing NHRIC and NDC numbers on device labels and device packages, with respect to finished devices that are manufactured and labeled prior to September 24, 2021. The enforcement policy outlined in this guidance applies to the requirement that labelers no longer provide an NHRIC or NDC number on a device label or device package as of the dates specified under 21 CFR 801.57(a)-(b); it does not extend to any of the other requirements under the UDI Rule.

The enforcement policy set forth in this guidance recognizes that additional time is appropriate for stakeholders to adopt medical device reimbursement, supply chain, and

[1] The 11-digit NDC used as a reimbursement number in these situations is a derived version of the FDA's official 10-digit NDC, as defined by 21 CFR 207.35.

procurement systems that do not depend on having an NHRIC or NDC number on the device label. FDA recognizes that the effect of this policy may be to extend the time that there will be multiple identifiers on device labels, which could potentially be confusing. However, we believe the risk of confusion is outweighed by the threat of disrupting reimbursement, supply chain, and procurement processes and potentially interfering with patient access to devices.

During the phased implementation of the UDI requirements, some device labels will bear UDIs and others will bear different types of identifiers. Our intent is that this enforcement policy will both facilitate a consistent date by which all classes of devices have legacy NHRIC and NDC numbers removed, and make the transition away from using these legacy FDA identification numbers less disruptive and more predictable.

IV. Requests for continued use of FDA labeler codes

Under 21 CFR 801.57(c) and (d), a labeler may submit a request to FDA for continued use of a previously assigned FDA labeler code under a system for the issuance of UDIs. FDA-issued labeler codes have been used as part of the 11-digit reimbursement numbers provided on medical device labels. A labeler who has been assigned an FDA labeler code to facilitate use of NHRIC or NDC numbers may continue to use that labeler code under a system for the issuance of UDIs provided that such use is consistent with the framework of the issuing agency that operates that system and that the labeler submits, and obtains FDA approval of, a request for continued use of the assigned labeler code (21 CFR 801.57(c)). Under 21 CFR 801.57(c)(2), the deadline to submit such a request is September 24, 2014.

FDA intends to consider requests submitted to the Agency for continued use of an FDA labeler code under a system for the issuance of UDIs until September 24, 2021. In addition, FDA does not intend to take action against a labeler for incorporating a previously assigned FDA labeler code into its UDI without requesting approval to do so by the deadline set forth in 21 CFR 801.57(c)(2), if that labeler submits a request that otherwise complies with 21 CFR 801.57(c) and (d) by September 24, 2021. Labelers who have been granted continued use of an FDA labeler code by FDA should contact their FDA-accredited issuing agency if they wish to incorporate the FDA labeler code into their UDIs.

Appendix A

Summary of Compliance Dates for UDI Implementation

Device	Label/GUDID/Date Format	Direct Mark (When Required)[2]
Class III (including Humanitarian Use Devices and class III I/LS/LS)[1] Devices licensed under the PHS Act	September 24, 2014	LS/LS Class III devices must be directly marked by September 24, 2015 All other class III devices must be directly marked by September 24, 2016
Implantable (class II, class I & unclassified)	September 24, 2015	N/A
LS/LS (class II, class I & unclassified)	September 24, 2015	September 24, 2015
Class II	September 24, 2016	September 24, 2018
Class I or unclassified	September 24, 2018	September 24, 2020

[1] I/LS/LS = implantable, life-supporting, or life-sustaining

[2] A device that must bear a UDI on its label must also be directly marked if the device is intended to be used more than once and intended to be reprocessed before each use, unless an exception applies (21 CFR 801.45). Direct mark requirements are in addition to label/GUDID/date format requirements.

For details on UDI compliance dates, see the UDI final rule (Sept. 24, 2013).