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Enforcement Policy Regarding Use of National Health Related Item Code and National Drug Code Numbers on Device Labels and Packages

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Guidance for Industry and Food and Drug Administration Staff

Document issued on May 21, 2021.

This document supersedes Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices, August 30, 2016.

For questions about this document, 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, or by email at ocod@fda.hhs.gov.

U.S. FOOD & DRUG ADMINISTRATION

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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Guidance for Industry and Food and Drug Administration Staff

I. Introduction

This guidance describes the Agency's policy regarding 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 object to the use of legacy FDA identification numbers[1] on device labels and packages for finished devices manufactured and labeled prior to September 24, 2023. In addition, this guidance addresses requests for continued use of FDA labeler codes under a system for the issuance of unique device identifiers (UDIs).

FDA issued a previous version of this guidance on August 30, 2016 ("original guidance"), which stated that the Agency did not intend to enforce the regulation prohibiting 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. For reasons described below, FDA

[1] For the purpose of this document, "legacy FDA identification numbers" refers to both NHRIC and NDC numbers created using labeler codes previously assigned to device manufacturers by FDA. The requirements at 21 CFR 801.57 concern only the use of legacy FDA identification numbers for devices – specifically, NHRIC and NDC numbers – and do not prohibit the inclusion on device labels and packages of other numbers used to facilitate ordering, reimbursement, inventory stocking, or other supply chain activities. As explained in the preamble to the final rule establishing FDA's unique device identification system:

> The use of catalog numbers, inventory numbers, ordering numbers, or any other identification number is neither prohibited nor regulated by this rule, except that § 801.57 rescinds certain legacy FDA identification numbers and requires discontinuation of their use on a device label.

(78 FR 58792).

believes it is appropriate and consistent with the public health to extend this policy for an additional two years. Therefore, we do not intend to object to the use of legacy NHRIC or NDC numbers on a device label or package for finished devices manufactured and labeled prior to September 24, 2023.

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).

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (section 701(h)(1)(C)(i) of the FD&C Act and 21 CFR 10.115(g)(2)). FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, 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 (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. The unique device identification system was designed to be phased in over many years according to a series of compliance dates based

primarily on device classification. Among other requirements, the UDI Rule establishes compliance dates[2] upon which device labels and device packages are required to bear a UDI.

Establishing standardized, uniform identification of most devices through distribution to the point of use is intended to serve several important public health objectives, including reducing medical errors that result from misidentification of a device or confusion concerning its appropriate use and more rapid resolution of reported device problems (78 FR 58786). Other anticipated benefits include enhanced supply chain efficiencies through use of automated systems, and enhanced device adverse event reporting and postmarket surveillance (see 78 FR 58787, 58812-13). However, fully realizing the benefits of the unique device identification system depends on UDIs being integrated into data sources throughout our healthcare system, including in the supply chain, electronic health records, and patient registries. During the phased implementation period, FDA has regularly engaged with members of the device industry on implementation of UDI requirements, as well as with other stakeholders, to encourage the adoption of UDI across the U.S. healthcare system.

B. Legacy FDA identification numbers

Prior to the establishment of the FDA's unique device identification system, the absence of a standardized, unique identification system for devices led some companies to obtain a labeler code from FDA and place NHRIC or NDC numbers on the labels and packages of certain medical devices. In recognition of this practice, and 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).[3] 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)).

The proposed rule to establish the unique device identification system explained that continued use of these legacy 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). The continued use of legacy NHRIC and NDC numbers on device labels would also impede the goal of establishing a standardized,

[2] For more information about UDI compliance dates, please see the UDI webpage, available at: https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/compliance-dates-udi-requirements.

[3] Although 21 CFR 801.57 rescinds any NHRIC or NDC "assigned" to a device, such NDC numbers are not assigned in compliance with 21 CFR 207.33. Rather, some device manufacturers had labeler codes previously assigned to them by FDA, which they used to create numbers that were labeled as "NHRIC" or "NDC." Under 21 CFR 207.37(a)(3), products such as medical devices may be deemed misbranded if they use an NDC. However, FDA does not intend to object to the use of legacy NDCs on device labels and device packages as described in this guidance.

uniform device identification system to enhance clarity and efficiency and achieve related benefits, including the benefits described in the UDI Rule.

C. Reimbursable medical devices available at pharmacies

When FDA issued the original guidance in 2016, medical devices available through a pharmacy and potentially eligible for reimbursement from payors were generally labeled with an 11-digit reimbursement number,[4] often using a legacy NHRIC or NDC number associated with the device. Pharmacies and payors have relied on legacy NHRIC and NDC numbers for device reimbursement in the pharmacy setting. As explained in the original guidance, some stakeholders 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, because pharmacies, payors, and other entities were not prepared to transition away from use of legacy NHRIC or NDC numbers in their systems.

Since that time, the impact of the Coronavirus Disease 2019 (COVID-19) public health emergency has necessitated a shift in priorities for many stakeholders for a significant period, which was not anticipated when this guidance was originally published. Stakeholder groups have also recently informed FDA that some pharmacies, payors, and other entities are still not prepared to transition away from use of NHRIC or NDC numbers in their systems. This readiness challenge creates the risk of disrupting various systems, including reimbursement, supply chain, and procurement processes. Such disruptions could potentially interfere with patient access to devices and be detrimental to the public health. We therefore believe that extending the policy for a limited additional time as stakeholders continue to make changes to transition medical device reimbursement, supply chain, and procurement systems and processes away from use of legacy NHRIC and NDC numbers is appropriate and in the interest of the public health.

In addition, for stakeholders that have not already implemented changes necessary to transition away from use of legacy NHRIC and NDC numbers—including pharmacies and payors—making such changes to various processes and systems while addressing the challenges related to the COVID-19 pandemic could be difficult and could divert resources from COVID-19 response efforts. Labelers of devices that still bear an NHRIC or NDC number on their labels could be similarly affected when implementing labeling changes to remove these legacy identifiers. To the extent this policy helps stakeholders remain focused on public health needs related to COVID-19, we believe the policy is further consistent with the public health.

III. Policy regarding removal of NHRIC and NDC numbers from medical device labels and packages

[4] The 11-digit number used as a reimbursement number in these situations is derived from a legacy NHRIC or from a legacy 10-digit NDC number.

In light of the considerations described above, FDA does not intend to object to the use of legacy NHRIC and NDC numbers on device labels and device packages, with respect to finished devices that are manufactured and labeled prior to September 24, 2023. This enforcement policy 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.

By September 24, 2023, more devices will bear UDIs, and we anticipate reimbursement, supply chain, and procurement systems will be better prepared to rely on UDIs. We also intend to work to encourage UDI adoption throughout healthcare data systems, including in those that currently rely on NHRIC and NDC numbers to help facilitate a smooth transition away from use of these legacy identifiers on device labels and fully realize the benefits of UDI.

IV. Requests for continued use of FDA labeler codes

New labeler codes are not assigned by FDA for the purposes of assigning NDCs to non-drug products or for use under a system for the issuance of UDIs. A labeler who was previously assigned an FDA labeler code to facilitate use of NHRIC or NDC numbers on devices may wish to continue to use that labeler code as part of their UDIs if consistent with their FDA-accredited issuing agency's guidelines. FDA's regulations at 21 CFR 801.57(c) and (d) provide that 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 by September 24, 2014.

FDA does not intend to object if a labeler incorporates a previously assigned FDA labeler code into its UDI where it submits a request by September 24, 2021. If a labeler is interested in continued use of an FDA labeler code under a system for the issuance of UDIs, it may contact FDA at GUDIDSupport@fda.hhs.gov. Labelers should also contact their FDA-accredited issuing agency if they wish to incorporate the FDA labeler code into their UDIs.