



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-0199]

Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry and FDA staff entitled "Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices." When finalized, this draft document will describe the Agency's intent not to enforce, before September 24, 2021, the prohibition against providing National Health Related Item Code (NHRIC) or National Drug Code (NDC) numbers on device labels and device packages, with respect to certain finished devices manufactured and labeled prior to September 24, 2018. In addition, when finalized, this draft guidance will describe the Agency's intent to continue considering requests for continued use of FDA labeler codes under a system for the issuance of unique device identifiers (UDIs) until September 24, 2018. This draft guidance is not the final version of the guidance nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft

guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-0199 for "Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For

more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

An electronic copy of the draft guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Alternatively, you may submit written requests for a single copy of the draft guidance to the Office of Communications, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to the office that you are ordering from to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave.,

Bldg. 66, rm. 3303, Silver Spring, MD 20993-0002, 301-796-5995, email:
GUDIDSupport@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 226 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85) and Section 614 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) 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 unique device identification system is being phased in over seven years according to a series of compliance dates, based primarily on device classification. These compliance dates establish the dates after which devices placed into commercial distribution must bear a UDI on their labels and device packages as follows: September 24, 2014, for Class III devices and devices licensed under the Public Health Service Act (PHS Act); September 24, 2015, for implantable, life-supporting, or life-sustaining devices; September 24, 2016, for Class II devices; and September 24, 2018, for Class I and unclassified devices (78 FR 58786 at 58815).

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 § 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. For a device 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 (§ 801.57(b)).

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 number assigned to the device. The draft guidance, when finalized, would describe the Agency's intent not to enforce before September 24, 2021, the prohibition against providing NHRIC and NDC numbers on device labels and device packages of finished class III devices; devices licensed under the PHS Act; class II devices; and implantable, life-supporting or life-sustaining devices that are manufactured and labeled prior to September 24, 2018. This timeline would coincide with the schedule by which remaining class I and unclassified devices that do not qualify for an exception or alternative must bear a UDI on their labels and device packages. This enforcement policy, when finalized, would apply to the requirements under § 801.57(a) for class III devices; devices licensed under the PHS Act; class II devices; and implantable, life-supporting or life-sustaining devices only; it would not extend to any of the other requirements of the UDI Rule for these devices.

FDA believes that continued implementation of UDI requirements under 21 CFR 801 subpart B and 21 CFR 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.

Additionally, under § 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. 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 (§ 801.57(c)). Under § 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, 2018. 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 § 801.57(c)(2), if that labeler submits a request that otherwise complies with § 801.57(c) and (d) by September 24, 2018. Labelers who have been granted continued use of an FDA labeler code by FDA should contact their FDA-accredited issuing Agency to incorporate the FDA labeler code into their UDIs.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices". 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.

III. Request for Comments

FDA is seeking additional information on this issue. FDA is particularly interested in receiving information relating to the following question:

- Is a time period through September 24, 2018, an appropriate amount of additional time for stakeholders to adopt medical device reimbursement, supply chain, and procurement systems that do not depend on having NHRIC and NDC numbers on the device label? If not, why is this not an appropriate amount of time and how much more time would be reasonable?

IV. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm> or at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of the draft guidance document entitled "Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices" may send an email request to CDRH-Guidance@fda.hhs.gov or to ocod@fda.hhs.gov, or by calling 1-800-835-4709 or 240-402-7800, to receive an electronic copy of the document. Please use the document number GUD1500044 to identify the guidance you are requesting.

V. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information described in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485, and the collections of information in 21 CFR part 830 have been approved under OMB control number 0910-0720.

Dated: January 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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