promote and operationalize the program.

Program applicants are people with ESRD who: (1) Are adults over the age of 18; have been receiving in-center or home dialysis or have been transplanted for at least six months; actively engage in the care plan; consistently demonstrate leadership qualities at facility Quality Assurance & Performance Improvement (QAPI) meetings, Lobby Days, and other facility activities; and wish to be a peer mentor; or (2) are over 18 years of age; are newly diagnosed patients but have been on in-center dialysis for at least six months; are looking for peer support to help them transition to their new reality; and are known as a peer mentee.

To participate in the ESRD Network Peer Mentoring Program, peer mentors and mentees will complete an online application form stored in Confluence. The application serves to validate the peer mentor or peer mentee interest in the ESRD Network Peer Mentoring Program. Information collection is important to the process of pairing peer mentors and mentees with similarly lived experience and interests with their kidney disease. In addition, the application collects information about the peers' interest in kidney disease, treatment modality, age range, preferred gender recognition, and attitudes toward their kidney disease diagnosis. It also supports aligning hobbies, and genders to support best matched peers with each other. *Form Number:* CMS–10768 (OMB control number: 0938–NEW); *Frequency:* Once; *Affected Public:* Individuals and Households; *Number of Respondents:* 75; *Total Annual Responses:* 75; *Total Annual Hours:* 19. (For policy questions regarding this collection, contact Lisa Rees at 816–426–6353.)

7. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* Conditions of Coverage for Portable X-ray Suppliers and Supporting Regulations; *Use:* The requirements contained in this information collection request are classified as conditions of participation or conditions for coverage. Portable X-rays are basic radiology studies (predominately chest and extremity X-rays) performed on patients in skilled nursing facilities, residents of long-term care facilities and homebound patients. The CoPs are based on criteria described in the law, and are designed to ensure that each portable X-ray supplier has properly trained staff and provides the appropriate type and level of care for patients. The information collection requirements described below are necessary to certify portable X-ray suppliers wishing to participate in the Medicare program. There are currently 506 portable X-ray suppliers participating in the Medicare program.

On September 30, 2019 (84 FR 51732), CMS updated the personnel requirements for portable X-ray technicians at 42 CFR 486.104(a), to focus on the qualifications of the individual performing services removing school accreditation requirements and simplifying the structure of the requirements. Additionally, CMS also revised the requirements for referral of service at 42 CFR 486.106(a) for portable X-ray requirements for orders. This change removed the requirement that physician or non-physician practitioner's orders for portable X-ray services must be written and signed and replacing the specific requirements related to the content of each portable X-ray order with a cross-reference to the requirements at 42 CFR 410.32, which also apply to portable X-ray services. *Form Number:* CMS–R–43 (OMB Control number: 0938–0338); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 506; *Total Annual Responses:* 1,012; *Total Annual Hours:* 324. (For policy questions regarding this collection contact James Cowher at 410–786–1948.)

8. *Title of Information Collection:* Medicare Fee-for-Service Prepayment Review of Medical Records; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* The Medical Review program is designed to prevent improper payments in the Medicare FFS program. Whenever possible, Medicare Administrative Contractors (MACs) are encouraged to automate this process; however, it may require the evaluation of medical records and related documents to determine whether Medicare claims are billed in compliance with coverage, coding, payment, and billing policies. Addressing improper payments in the Medicare fee-for-service (FFS) program and promoting compliance with Medicare coverage and coding rules is a top priority for the CMS. Preventing Medicare improper payments requires the active involvement of every component of CMS and effective coordination with its partners including various Medicare contractors and providers. The information required under this collection is requested by Medicare contractors to determine proper payment, or if there is a suspicion of fraud. Medicare contractors request the information from providers/suppliers submitting claims for payment when data analysis indicates aberrant billing patterns or other information which may present a vulnerability to the Medicare program. *Form Number:* CMS–10417 (OMB control number: 0938–0969); *Frequency:* Occasionally; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 485,632; *Number of Responses:* 485,632; *Total Annual Hours:* 242,816. (For questions regarding this collection, contact Christine Grose at (410–786–1362).

Dated: October 8, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–22444 Filed 10–13–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6841]

Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of the draft guidance entitled ''Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff.'' This draft guidance explains that there are certain class I devices for which FDA does not intend to enforce Global Unique Device Identification Database (GUDID) submission requirements and describes how a labeler of a class I device can determine if its device is one of these devices in the revised section III of this draft guidance. When this draft guidance is finalized, the updates in section III of this draft guidance would supersede the recommendations in section III of the guidance ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking''

(''2020 UDI Compliance Policy Guidance,'' available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices-and*). This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by December 13, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2017–D–6841 for ''Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the 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 ''Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Center for Biologics Evaluation and Research, Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Steven Luxenberg, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–5995; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff.'' On September 24, 2013 (78 FR 58786), FDA published a final rule establishing a unique device identification system designed to adequately identify devices through distribution and use (the UDI Rule). Phased implementation of the regulatory requirements set forth in that final rule is based on a series of established compliance dates based primarily on device classification.

The UDI Rule requires a device to bear a UDI on its label and packages, unless an exception or alternative applies (see 21 CFR 801.20), and special labeling requirements apply to stand-alone software regulated as a device (21 CFR 801.50). The UDI Rule also requires that data pertaining to the key characteristics of each device required to bear a UDI be submitted to FDA's GUDID (§ 830.300 (21 CFR 830.300)). In addition, the UDI Rule added 21 CFR 801.18, which requires certain dates on device labels to be in a standard format.

For devices that: (1) Must bear UDIs on their labels and (2) are intended to be used more than once and reprocessed between uses, 21 CFR 801.45 requires the devices to be directly marked with a UDI. Compliance dates for these labeling, GUDID data submission, standard date format, and direct marking requirements can be found in the preamble to the UDI Rule (78 FR 58786 at 58815 to 58816). For more information about UDI compliance dates, please see the UDI web page, available at: *https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/compliance-dates-udi-requirements.*

For labelers of class I devices, FDA has developed this draft guidance to revise section III. ''Policy On Standard Date Formatting, UDI Labeling, and GUDID Submission Requirements for Class I and Unclassified Devices'' of the guidance entitled ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking'' (''2020 UDI Compliance Policy Guidance'', available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices-and*), which was issued on July 1, 2020. When this draft guidance is finalized, the updates in section III of this draft guidance would supersede the recommendations in section III of the 2020 UDI Compliance Policy Guidance. FDA considered comments received on the guidance that appeared in the **Federal Register** on July 1, 2020 (85 FR 39477) as the Agency revised the guidance.

This draft guidance explains that there are certain class I devices for which FDA does not intend to enforce GUDID submission requirements under § 830.300 and describes how a labeler of a class I device can determine if its device is considered a consumer health product. FDA has determined that the entry of UDI data into GUDID for these devices is burdensome to stakeholders. After undertaking a public health impact analysis, the Center for Devices and Radiological Health has a better understanding of the devices and device characteristics for which GUDID information is particularly useful in evaluating and improving device safety throughout a product life cycle, as well as the ones for which GUDID information may be less important in this regard. The policy proposed in this draft guidance is based on this analysis. We are proposing this change in policy through guidance to allow FDA and stakeholders an opportunity to fully assess its impact on public health. FDA will take the assessment into account in determining whether regulations on this subject should be amended in the future.

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 ''Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff''. 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
801 subpart B and 830	Unique Device Identification	0910–0720
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

III. 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 *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Draft Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17029 and complete title to identify the guidance you are requesting.

Dated: October 7, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–22308 Filed 10–13–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0055]

Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in