DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. FDA–2017–D–6841]

Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff; Availability

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

ACTION: Availability of guidance.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance entitled ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff.'' This guidance revises the guidance by the same title issued November 5, 2018, and describes FDA's intention with respect to the enforcement of unique device identification (UDI) requirements for class I and unclassified devices, other than implantable, life-sustaining, or life-supporting (I/LS/LS) devices. In this revised guidance, FDA clarifies that, at this time, in light of the considerations described in the guidance, it does not intend to enforce standard date formatting, labeling, and Global Unique Device Identification Database (GUDID) data submission requirements for these devices before September 24, 2022. The guidance is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on July 1, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect 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 guidance document entitled ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff'' to the Office of the Center Director, 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, Room 3128, Silver Spring, MD 20903. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT:

For Center for Devices and Radiological Health-regulated devices: Christina Savisaar, UDI Regulatory Policy Support, 10903 New Hampshire

Ave., Bldg. 32, Rm. 3255, 301–796–5995, email: *GUDIDSupport@fda.hhs.gov.*

For Center for Biologics Evaluation and Research-regulated devices: Stephen Ripley, Office of Communication, Outreach, and Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, or call 1–800–835–4709 or 240–402–8010.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff.'' On September 24, 2013, 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, which range from September 24, 2014, to September 24, 2020.

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 (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.

This guidance describes FDA's intention with regard to enforcement of these requirements for class I and unclassified devices, other than I/LS/LS devices. This revised guidance supersedes the November 2018 guidance of the same title, ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect Guidance for Industry and Food and Drug Administration Staff.'' In this revised guidance, FDA states that, at this time, in light of the considerations described in the guidance, it does not intend to enforce the requirements under 21 CFR 801.18, 801.20, 801.50, and 830.300 for class I and unclassified devices, other than I/LS/LS devices, prior to September 24, 2022, regardless of the date they are manufactured and labeled. The guidance explains that FDA believes it is important to continue focusing its resources on addressing UDI implementation issues and data quality for higher risk devices and, at this time, concludes that continuing its existing policy with regard to enforcement of these requirements for class I and unclassified devices, other than I/LS/LS devices, is consistent with the public health. In addition, while some editorial changes were made to improve clarity, other policies described in the November 2018 guidance remain the same in the revised guidance.

FDA considered comments received on the guidance that appeared in the **Federal Register** on November 5, 2018 (83 FR 55372) as the Agency revised the guidance.

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). FDA has determined that this guidance presents a less burdensome policy that is consistent with public health. Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking.'' 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. Electronic Access

Persons interested in obtaining a copy of the 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* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking; Immediately in Effect 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.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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. 3501–3521). 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
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: June 25, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14082 Filed 6–30–20; 8:45 am]

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DEPARTMENT OF EDUCATION

34 CFR Part 76

[Docket ID ED–2020–OESE–0091]

RIN 1810–AB59

CARES Act Programs; Equitable Services to Students and Teachers in Non-Public Schools

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Interim final rule with request for comments.

SUMMARY: The U.S. Department of Education (Department) issues this interim final rule to clarify the requirement in the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that local educational agencies (LEAs) provide equitable services to students and teachers in non-public schools under the Governor's Emergency Education Relief Fund (GEER Fund) and the Elementary and Secondary School Emergency Relief Fund (ESSER Fund) (collectively, the CARES Act programs).

DATES:

Effective Date: This interim final rule is effective July 1, 2020.

Comment Due Date: We must receive your comments on or before July 31, 2020.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov,* including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''How to use *Regulations.gov*.''
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about this interim final rule, address them to Amy Huber, U.S. Department of Education, 400 Maryland Avenue SW, Room 3W219, Washington, DC 20202.

Privacy Note: The Department's policy for comments received from members of the public is to make these submissions available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Amy Huber, U.S. Department of Education, 400 Maryland Avenue SW, Room 3W219, Washington, DC 20202. Telephone: (202) 453–6132. Email: *EquitableServices.CaresAct@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments on this interim final rule. We will consider these comments in determining whether to take any future action. See **ADDRESSES** for instructions on how to submit comments.

During and after the comment period, you may inspect all public comments about this interim final rule by accessing *Regulations.gov.* Once the LBJ building reopens to the public, you may also inspect the comments in person in Room 3W219, 400 Maryland Avenue SW, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Eastern time, Monday through Friday of each week except Federal holidays. If you want to schedule time to inspect comments, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Assistance to Individuals with Disabilities in Reviewing the Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public record for this interim final rule. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Background: This rulemaking resolves a critical ambiguity in section 18005(a) of Division B of the CARES Act, Public Law 116–136, 134 Stat. 281 (Mar. 27, 2020) with respect to the equitable services obligation owed by LEAs that receive CARES Act funds to students and teachers in non-public schools. Section 18005(a) of the CARES Act, titled ''Assistance to Non-public Schools,'' requires an LEA to ''provide equitable services in the same manner as provided under section 1117 of the ESEA of 1965 [Elementary and Secondary Education Act of 1965 (ESEA)] to students and teachers in non-public schools, as determined in consultation with representatives of non-public schools.'' Section 18005(b) lodges control of funds for the services and assistance mandated in section 18005(a) in a ''public agency.''

The Department must construe the CARES Act based on plain meaning, context, and coherence within the overall statutory structure. We are obliged to interpret the CARES Act coherently, and fit, if possible, all its parts into a harmonious whole. Finally, we must give meaning to each element of the statute so that no language is surplus.

The CARES Act is a special appropriation to combat the effects of the novel Coronavirus Disease 2019 (COVID–19). The pandemic has harmed *all* our Nation's students by disrupting their education. Nothing in the CARES Act suggests Congress intended to differentiate between students based upon the public or non-public nature of their school with respect to eligibility for relief.

Construing the phrase ''provide equitable services in the same manner as provided under section 1117 of the ESEA of 1965'' as if Congress simply incorporated the entirety of section 1117 by reference requires a wholly inappropriate disregard for statutory text and for controlling legal authorities requiring us to harmonize all relevant statutory provisions. It would create significant and unnecessary interpretative conflicts and ambiguity. Finally, a mechanistic application of section 1117 detached from the relevant CARES Act text would disadvantage some students based simply on where they live. Therefore, exercising our interpretative authority under *Chevron U.S.A., Inc.* v. *Natural Res. Def. Council, Inc.,* 467 U.S. 837, 844 (1984), and relying on statutory language and context to develop a harmonious construction faithful to all relevant CARES Act text and to the entire statutory structure, *see Food and Drug Admin.* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 132–33 (2000), we have concluded the phrase ''in the same manner as provided under section 1117'' does not simply mean ''as provided under section 1117'' and that we must implement section 1117 in a fashion fully consistent with *all* relevant CARES Act text, purposes, and requirements.