

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10434 #15]

#### Medicaid and Children’s Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Reopening of Comment Period

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

**ACTION:** Notice; reopening of comment period.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is reopening the comment period for a limited time for a collection of information notice that published in the **Federal Register** on April 22, 2026. The notice is entitled “Medicaid and Children’s Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request”. CMS is taking this action to address an inadvertent issue with posting one of the collection’s revised templates (S89—Citizenship and Noncitizen Eligibility) under Medicaid State Plan Eligibility. While the April 22 notice provided the public with 14-days to comment, we are reopening the comment period for 12 days—the duration of the inaccurate posting.

**DATES:** The comment period for the notice that published on April 22, 2026 (91 FR 21505) is reopened. Comments must be received by May 26, 2026.

**ADDRESSES:** When commenting, please reference the applicable form number (CMS–10434 #15) and the OMB control number (0938–1188). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–10434 #15/OMB control number: 0938–1188, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

To obtain copies of a supporting statement and any related forms for the

proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pralisting>.

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at 410–786–4669.

**SUPPLEMENTARY INFORMATION:** On April 22, 2026 (91 FR 21505), CMS published a notice in the **Federal Register** that requested comment from interested parties on the revision of an active collection of information that had been approved by the Office of Management and Budget (OMB) under control number 0938–1188 (CMS–10434 #15) entitled “Medicaid State Plan Eligibility”. The notice provided a 14-day comment period, which closed on May 6, 2026.

CMS is reopening the comment period to address an inadvertent issue with posting one of the collection’s revised State Plan templates (RU S89—Citizenship and Noncitizen Eligibility (version 04\_2026)). This iteration proposes substantive changes to the template that are related to section 71109 of the Working Families Tax Cut (WFTC) legislation which limits federal financial participation (FFP) for full Medicaid coverage, with limited exceptions, to individuals who are U.S. citizens or nationals or in only three groups of noncitizens, including lawful permanent residents (LPRs), Cuban/Haitian entrants, or COFA (Compact of Free Association) migrants, who CMS refers to as “FFP-eligible noncitizens.”

While the April 22 notice provided the public with 14-days to comment, we are reopening the comment period for 12 days—the duration of the inaccurate posting. This action will allow interested parties additional time to review all of the collection of information materials and prepare/submit comments. CMS is reopening the comment period as indicated in the **DATES** section of this notice. (For policy questions regarding this collection contact: Abby Kahn at 410–786–4321.)

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2026–09329 Filed 5–11–26; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2026–D–5083]

#### Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization; Guidance for Industry; 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 a final guidance for industry entitled “Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization.” This guidance document describes certain enforcement policies with regard to the marketing of certain electronic nicotine delivery systems and oral nicotine pouch products that do not have premarket authorization.

**DATES:** The announcement of the guidance is published in the **Federal Register** on May 12, 2026.

**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-2026-D-5083 for “Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization.” 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](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 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)).

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Samantha Rivera, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 877-287-1373, [CTPRegulations@fda.hhs.gov](mailto:CTPRegulations@fda.hhs.gov).

### SUPPLEMENTARY INFORMATION:

#### I. Background

FDA is announcing the availability of a final guidance for industry entitled “Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization; Guidance for Industry.” We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because this guidance is necessary to promote transparency, and to assist FDA in efficiently allocating enforcement resources by focusing regulatory oversight on products that are more likely to meet the applicable public health standard. FDA’s approach is intended to facilitate an orderly shift toward a regulated market in which compliant products, supported by appropriate evidence and subject to meaningful oversight, can replace unauthorized offerings. FDA expects this approach to encourage the development of applications for potentially less harmful tobacco products and support more timely evaluation and marketing authorization decisions for products that may benefit public health. Although this guidance document is immediately in effect, it

remains subject to comment in accordance with FDA’s GGP regulation.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) provides that new tobacco products<sup>1</sup> may not legally be marketed without premarket authorization. Accordingly, all new tobacco products, including those that are ENDS and nicotine pouch products, on the market without authorization are illegally marketed products. This guidance document describes certain enforcement policies with regard to the marketing of certain electronic nicotine delivery systems and nicotine pouch products that do not have premarket authorization.

The guidance represents the current thinking of FDA on “Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization; Guidance for Industry.” 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

This guidance refers to previously approved FDA 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 21 CFR 1107.1(b) and (c) have been approved under OMB control number 0910-0684; the collections of information under section 910 of the FD&C Act have been approved under OMB control number 0910-0879. The collections of information in section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) have been approved under OMB control number 0910-0673.

#### III. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance-related-tobacco-products/guidance-related-tobacco-products>, <https://www.fda.gov/regulatory>

<sup>1</sup> Section 910 of the Federal Food, Drug, and Cosmetic Act defines the term “new tobacco product” to mean “(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.” 21 U.S.C. 387j(a)(1).

information/search-fda-guidance-documents, or <https://www.regulations.gov>.

**Lowell M. Zeta,**

*Deputy Commissioner for Strategic Initiatives.*

[FR Doc. 2026–09368 Filed 5–8–26; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2017–N–5925]

#### 21st Century Cures Act: Annual Compilation of Notices of Updates From the Susceptibility Test Interpretive Criteria web page

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of the Agency’s annual compilation of notices of updates to the Agency’s Susceptibility Test Interpretive Criteria web page. The Agency established the Susceptibility Test Interpretive Criteria web page on December 13, 2017, and since establishment has provided updates to both the format of the web pages and the susceptibility test interpretive criteria identified and recognized by FDA on the web pages. FDA is publishing this notice in accordance with procedures established by the 21st Century Cures Act (Cures Act).

**DATES:** This notice is published in the **Federal Register** on May 12, 2026.

**ADDRESSES:** You may submit either electronic or written comments and information 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 below (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–N–5925 for “Susceptibility Test Interpretive Criteria Recognized and Listed on the Susceptibility Test Interpretive web page; Request for Comments.” 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.gpo.gov/fdsys/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.

#### **FOR FURTHER INFORMATION CONTACT:**

Deborah Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6349, Silver Spring, MD 20993–0002, 301–796–9053, [Deborah.Wang@fda.hhs.gov](mailto:Deborah.Wang@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Section 511A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360a-2), as added by section 3044 of the Cures Act (Pub. L. 114–255), was signed into law on December 13, 2016. This provision clarified FDA’s authority to identify and efficiently update susceptibility test interpretive criteria, including through the recognition by FDA of standards established by standards development organizations (SDOs). It also clarified that sponsors of antimicrobial susceptibility testing devices may rely upon listed susceptibility test interpretive criteria to support premarket authorization of their devices, provided they meet certain conditions, which allows for a more streamlined process for incorporating up-to-date information into such devices.

In the **Federal Register** notice of December 13, 2017 (82 FR 58617), FDA announced the establishment of the Susceptibility Test Interpretive Criteria web page. This web page recognizes susceptibility test interpretive criteria established by an SDO that fulfills the requirements under section 511A(b)(2)(A) of the FD&C Act; identifies when FDA does not recognize, in whole or in part, susceptibility test interpretive criteria established by an SDO; and lists susceptibility test interpretive criteria identified by FDA outside the SDO process. The susceptibility test interpretive criteria listed by FDA on the Susceptibility Test