information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of the currently approved collection; *Title of Information Collection:* Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment; *Use:* The data collection and reporting requirements will be used by HHS to run the permanent risk adjustment program, including validation of data submitted by issuers, on behalf of States that requested HHS to run it for them. Risk adjustment is one of three market stability programs established by the Patient Protection and Affordable Care Act and is intended to mitigate the impact of adverse selection in the individual and small group health insurance markets inside and outside of the Health Insurance Exchanges. HHS will also use this data to adjust the payment transfer formula for risk associated with high-cost enrollees. Issuers and providers can use the alternative reporting requirements for mental and behavioral health records described herein to comply with State privacy laws. *Form Number:* CMS–10401 (OMB control number: 0938–1155); *Frequency:* Annually; *Affected Public:* State, local, or Tribal governments; *Number of Respondents:* 650; *Total Annual Responses:* 3,250; *Total Annual Hours:* 4,154,150. (For policy questions regarding this collection contact Jacqueline Wilson at (301–492–4400.)

Dated: May 12, 2023.

William N. Parham, III,

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

[FR Doc. 2023–10594 Filed 5–17–23; 8:45 am]

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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, 2021 and 2022 Updates; Request for Comments

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 with updates made in 2021 and 2022. 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 to 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 18, 2023.

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 (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.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.

FOR FURTHER INFORMATION CONTACT: Deborah (Wang) 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.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 511A of the Federal Food, Drug, and Cosmetic Act (the 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 Interpretive Criteria web page is deemed to be recognized as a standard under section 514(c)(1) of the FD&C Act (21 U.S.C. 360d(c)(1)). The Susceptibility Test Interpretive Criteria web page can be found at *https://www.fda.gov/STIC.*

On March 1, 2018, FDA published a notice in the **Federal Register** (83 FR 8883) requesting comments on FDA's initial susceptibility test interpretive criteria recognition and listing determinations on the Susceptibility Test Interpretive Criteria web page (*https://www.federalregister.gov/documents/2018/03/01/2018-04175/susceptibility-test-interpretive-criteria-recognized-and-listed-on-the-susceptibility-test*). FDA may consider information provided by interested third parties as a basis for evaluating new or updated interpretive criteria standards (section 511A(c)(2)(B) of the FD&C Act); third parties should submit any information they wish to convey to the Agency to Docket No. FDA–2017–N–5925. If comments are received, FDA will review those comments and will make, as appropriate, updates to the recognized standards or susceptibility test interpretive criteria.

At least every 6 months after the establishment of the Susceptibility Test Interpretive Criteria web page, FDA is required, as appropriate to: (1) publish on that web page a notice recognizing new or updated susceptibility test interpretive criteria standards, or recognizing or declining to recognize parts of standards; (2) withdraw recognition of susceptibility test interpretive criteria standards, or parts of standards; and (3) make any other necessary updates to the lists published on the Susceptibility Test Interpretive Criteria web page (section 511A(c)(1)(A) of the FD&C Act). FDA has provided notices of updates on the Susceptibility Test Interpretive Criteria web page, which can be found here: *https://www.fda.gov/drugs/development-resources/notice-updates.* Interested parties may also sign up to receive emails informing them of these updates as they occur by using the link provided either on the main Susceptibility Test Interpretive Criteria web page (*https://www.fda.gov/STIC*) or on the updates page.

Once a year, FDA is required to compile the new notices published on the Susceptibility Test Interpretive Criteria web page, publish them in the **Federal Register**, and provide for public comment (see section 511A(c)(3) of the FD&C Act). This **Federal Register** notice satisfies that requirement. If comments are received, FDA will review them and make updates to the recognized standards or susceptibility test interpretive criteria as needed.

II. Annual Compilation of Notices, 2021: Web Page

TABLE 1—NOTICES OF UPDATES TO RECOGNIZED OR UPDATED SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA BY DRUG [1]

Drug	Route of administration	Action taken	Therapeutic category	Date
Azithromycin	Oral, Injection	For *Neisseria gonorrhoeae,* FDA has reviewed susceptibility test interpretive criteria and concludes no changes are needed at this time. (Rationale available at *https://www.fda.gov/drugs/development-resources/rationale-fdas-position-azithromycin-susceptible-only-breakpoint-neisseria-gonorrhoeae*).	Antibacterial	10/14/21
Cefazolin	Injection	For Enterobacterales, FDA has reviewed susceptibility test interpretive criteria and the updated standard is recognized. (Rationale available at *https://www.fda.gov/drugs/development-resources/.rationale-fdas-position-cefazolin-breakpoints-enterobacterales*)	Antibacterial	10/14/21
Cefiderocol	Injection	FDA recognizes M100 MIC standard for *Enterobacteriaceae*	Antibacterial	10/14/21
Ceftolozane; tazobactam.	Injection	FDA recognizes M100 standard for *Haemophilus influenzae*	Antibacterial	10/14/21
Colistimethate	Injection	FDA does not recognize M100 standard for *Enterobacteriaceae*	Antibacterial	10/14/21
Imipenem/cilastatin/relebactam.	Injection	FDA recognizes M100 standard for *Enterobacteriaceae, Pseudomonas aeruginosa,* and anaerobes.	Antibacterial	10/14/21
Lefamulin	Oral, Injection	FDA recognizes M100 standard for *Staphylococcus aureus, Streptococcus pneumoniae,* and *Haemophilus influenzae*.	Antibacterial	10/14/21
Polymyxin B	Injection	FDA does not recognize M100 standard for *Enterobacteriaceae* and *Pseudomonas aeruginosa*.	Antibacterial	10/14/21

TABLE 1—NOTICES OF UPDATES TO RECOGNIZED OR UPDATED SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA BY DRUG [1]—Continued

Drug	Route of administration	Action taken	Therapeutic category	Date
Telithromycin	Oral	FDA has removed telithromycin susceptibility test interpretive criteria as the drug is no longer approved in any application under section 505 of the FD&C Act (21 U.S.C. 355) (see 84 FR 47309).	Antibacterial	10/14/21

[1] M100 standard in the table refers to Clinical and Laboratory Standards Institute (CLSI) Performance Standards for Antimicrobial Susceptibility Testing, 31st ed. CLSI supplement M100; 2021.

III. Annual Compilation of Notices, 2022: Susceptibility Test Interpretive Criteria Web Page

A. Updates to Standards Recognition

As of May 18, 2022, the following standards are no longer recognized: ''Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility Testing. 31st ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2021.''

As of May 18, 2022, with certain exceptions, FDA recognizes the standards published in: ''Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility Testing. 32nd ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2022.''

B. Updates by Drug

TABLE 2—NOTICES OF UPDATES TO RECOGNIZED OR UPDATED SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA BY DRUG [1]

Drug	Route of administration	Action taken	Therapeutic category	Date
Amoxicillin and clavulanate.	Oral	FDA does not recognize M100 standard and provides susceptibility test interpretive criteria for *Haemophilus influenzae*.	Antibacterial	5/17/22
Cefadroxil	Oral	FDA removed the statement ''*Susceptibility of Enterobacteriaceae to cefadroxil may be deduced from testing cefazolin.*'' (Rationale available at *https://www.fda.gov/drugs/development-resources/rationale-fdas-position-cefadroxil.*)	Antibacterial	4/27/22
Cefazolin	Injection	FDA does not recognize M100 standard for cefazolin as a surrogate to predict susceptibility of oral cephalosporins when used for the treatment of uncomplicated urinary tract infections caused by *Escherichia coli, Klebsiella pneumoniae* and *Proteus mirabilis.* (Rationale available at *https://www.fda.gov/drugs/development-resources/rationale-fdas-position-use-cefazolin-breakpoints-surrogate-determining-breakpoints-oral.*).	Antibacterial	10/20/22
Cefoxitin	Injection	FDA recognizes M100 standard for *Staphylococcus aureus* complex and *Staphylococcus lugdunensis.* FDA recognizes M100 disk diffusion standard for *Staphylococcus epidermidis* and other Staphylococci spp.	Antibacterial	10/4/22
Ceftolozane and tazobactam.	Injection	FDA recognizes M100 disk diffusion standard for Enterobacterales	Antibacterial	5/17/22
Lefamulin	Oral, Injection	FDA does not recognize M100 disk diffusion standard and provides susceptibility test interpretive criteria for *Streptococcus pneumoniae* and *Haemophilus influenzae*.	Antibacterial	5/17/22
Oxacillin	Injection	FDA concurs with the revised CLSI susceptibility test interpretive criteria for *Staphylococcus* by species level. (Rationale available at *https://www.fda.gov/drugs/development-resources/rationale-fdas-position-oxacillin-breakpoints-staphylococcus*). FDA references Cefoxitin susceptibility test interpretive for *Staphylococcus* spp. as a surrogate test.	Antibacterial	10/4/22
Piperacillin and tazobactam.	Injection	FDA does not recognize M100 standard for Enterobacterales	Antibacterial	5/17/22

[1] M100 standard in the table refers to CLSI Performance Standards for Antimicrobial Susceptibility Testing, 32nd ed. CLSI supplement M100; 2022.

Dated: May 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–10603 Filed 5–17–23; 8:45 am]

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