those patients receiving specific outpatient surgical or procedural services as well as evidence that the policy is based on.

++ Section 482.41(b)(2), to address the requirements regarding Life Safety Code (LSC) waivers.

++ Section 482.41(b)(7), to address the requirements regarding alcohol-based hand rub (ABHR) dispensers.

In addition to the standards review, CMS also reviewed ACHC's comparable survey processes, which were conducted as described in section III., of this notice, and yielded the following areas where, as of the date of this final notice, ACHC has completed revising its survey processes to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

- Revising the complaint response policies and processes to align with the State Operations Manual, Chapter 5 guidance. ACHC revised its Administrative Review Offsite Investigation process to align with CMS' triage process to track and trend for potential focus areas during the next onsite survey or complete an onsite complaint investigation.
- Revising ACHC's hospital accreditation process policies to include the applicable sections of the Health Care Facilities Code National Fire Protection Agency (NFPA 99) in accordance with section 482.41(c).
- Ensuring that all hospital LSC surveyors have received comparable and adequate training or have sufficient experience to make them qualified to survey health care facilities for compliance with both the 2012 LSC and 2012 NFPA 99 requirements.
- Providing guidance and instruction to surveyors on determining the appropriate level of citation for LSC deficiencies.

B. Term of Approval

Based on our review and observations described in section III. and section V. of this final notice, we approve ACHC as a national accreditation organization for hospitals that request participation in the Medicare program. The decision announced in this final notice is effective September 25, 2023, through September 25, 2027 (4 years). In accordance with § 488.5(e)(2)(i) the term of the approval will not exceed 6 years.

While ACHC has taken actions based on the findings annotated in section V.A., of this final notice, (Differences Between ACHC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements) as authorized under § 488.8, we will continue ongoing review of ACHC's hospital processes to ensure full implementation and sustained compliance. In keeping with CMS's initiative to increase AO oversight broadly and ensure that our requested revisions by ACHC are fully implemented, CMS expects more frequent review of ACHC's activities in the future.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: August 31, 2023.

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–19195 Filed 9–5–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1981]

Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.'' This guidance identifies the standards necessary to facilitate adoption of secure, interoperable, electronic data exchange among the pharmaceutical distribution supply chain, and clarifies the trading partners, products, and transactions subject to such standards. This guidance finalizes the revised draft guidance of the same title, ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs,'' issued in July 2022, as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on September 6, 2023.

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–2014–D–1981 for ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain

Human, Finished, Prescription Drugs.'' 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)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lysette Deshields, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov;* or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.'' The FD&C Act, as amended by the Drug Supply Chain Security Act (DSCSA), outlines requirements for enhanced drug distribution security, which include the steps to achieve interoperable, electronic tracing of products at the package level. Section 582(g)(1) of the FD&C Act (21 U.S.C. 360eee–1(g)(1)) sets forth enhanced drug distribution security requirements for trading partners, including adherence to standards established by FDA for the exchange of transaction information and transaction statements in a secure, interoperable, electronic manner and the verification of product at the package level. Section 582(g)(1) of the FD&C Act states that these enhanced drug distribution security requirements go into effect on November 27, 2023. Additionally, section 582(h)(4)(A) of the FD&C Act specifies that FDA issue a guidance to identify and make recommendations with respect to the standards necessary for adoption in order to support the secure, interoperable, electronic data exchange among the pharmaceutical distribution supply chain that comply with a form and format developed by a widely recognized international standards development organization.

In this guidance, FDA considered the standards established pursuant to sections 505D of the FD&C Act (21 U.S.C. 355e). FDA also considered the standards established pursuant to section 582(a)(2) of the FD&C Act and described in the July 2022 revised draft guidance entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.'' The pilot projects conducted per section 582(j) of the FD&C Act also informed this guidance.

In November 2014, FDA issued a draft guidance for industry, entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information.'' In July 2022, FDA issued a revised draft guidance, entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs'' (87 FR 40258), that updated the policies articulated in the 2014 draft guidance. This guidance finalizes the July 2022 revised draft guidance. FDA considered comments received on the revised draft guidance as the guidance was finalized. Changes were made to the guidance to improve clarity. This guidance finalizes the policy articulated in the July 2022 revised draft guidance to reflect the enhanced drug distribution security requirements in section 582(g)(1) of the FD&C Act that will go into effect on November 27, 2023, including that only electronic methods of product tracing will be permitted and verification of product at the package level will be required, unless a waiver, exception, or exemption applies. This guidance is intended to also facilitate the creation of a uniform methodology for product tracing while ensuring the protection of confidential commercial information and trade secrets. FDA also published other guidances describing recommendations for enhanced drug distribution security, including the attributes necessary for enhanced product tracing and verification, which should be read in conjunction with this guidance (see FDA's Drug Supply Chain Security Law and Policies web page at *https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies*).

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 ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.'' 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 includes information collection provisions that 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). FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent substantive or material modifications to those previously approved collections of information found in FDA regulations or guidance.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19182 Filed 9–5–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Financial Resources; Statement of Organization, Functions, and Delegations of Authority

AGENCY: Office of the Assistant Secretary for Financial Resources (ASFR), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is making several updates within the Office of the Assistant Secretary for Financial Resources (AM), the Immediate Office (AMM), the Office of Budget (AML), the Office of Finance (AMS), the Office of Grants (AMU), and the Office of Acquisitions (AMX), to better align office titles with office activities and to clearly delineate ASFR's portfolio across its five components.

FOR FURTHER INFORMATION CONTACT: Christine Jones, Deputy Assistant Secretary for Operations and Management, Office of the Assistant Secretary for Financial Resources, Hubert H. Humphrey Building, 200 Independence Ave. SW, Room 514–G, Washington, DC 20201, (202) 690–7542.

SUPPLEMENTARY INFORMATION: Part A (Office of the Secretary), Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS) is being amended at Chapter AML, Office of Budget, as last amended at 74 FR 150 (39327) dated July 30, 2009; at Chapter AM, ASFR, as last amended at 74 FR 215 dated November 9, 2009; at Chapter AMS, Office of Finance, as last amended at 81 FR 88249, dated December 7, 2016; at Chapter AMX, Office of Acquisitions, as last amended at 84 FR 20154, dated May 8, 2019; at Chapter AMU, Office of Grants, as last amended 85 FR 81935, dated December 17, 2020; and at Chapter AMM, Immediate Office, as last amended at 86 FR 6354, dated January 21, 2021.

This notice realigns the Grants Quality Service Management Office (Grants QSMO) from the Immediate Office (AMM) to the Office of Grants (AMU); and compiles the responsibilities of ASFR into one **Federal Register** notice. All notices above are superseded by the following changes:

(1) Chapter AM, Office of the Assistant Secretary for Financial Resources

Section AM.00 Mission: The mission of the Office of the Assistant Secretary for Financial Resources is to advise the Secretary on all aspects of budget, grants, financial management, acquisitions, and Enterprise Risk Management and to provide direction for these activities throughout HHS.

Section AM.10 Organization: The Office of the Assistant Secretary for Financial Resources is headed by the Assistant Secretary for Financial Resources, who reports to the Secretary, and accomplishes its work through its component offices:

- Immediate Office (AMM)
- Office of Budget (AML)
- Office of Finance (AMS)
- Office of Grants (AMU)
- Office of Acquisitions (AMX)

Section AM.20 Functions: The Assistant Secretary for Financial Resources has several formal and informal roles, including Chief Financial Officer (CFO), Chief Performance Improvement Officer (PIO), Chief Acquisition Officer (CAO), HHS audit follow-up official, and lead official for budget and Department-wide grants policy. The Assistant Secretary is also a close advisor to the Secretary on policy issues.

(2) Chapter AMM, Immediate Office

Section AMM.00 Mission: The Immediate Office is responsible for support, operations, and coordination required to execute the mission of the Office of the Assistant Secretary for Financial Resources (ASFR) and the implementation of HHS's Enterprise Risk Management (ERM) capabilities. The Immediate Office also leads strategic and workforce development initiatives across ASFR.

Section AMM.10 Organization: The Immediate Office is headed by the Deputy Assistant Secretary for Operations and Management, who reports to the Assistant Secretary for Financial Resources, and includes the following:

- Division of Administrative Operations (AMM1)
- Division of Enterprise Risk Management (AMM2)

Section AMM.20 Functions:

1. Division of Administrative Operations (AMM1): The Division:

(a) Provides operational support for the ASFR.

(b) Coordinates administrative and operational issues across ASFR.

(c) Serves as the liaison with internal and external stakeholders regarding operational matters.

(d) Leads activities that enhance ASFR's management and operations.

2. Division of Enterprise Risk Management (ERM) (AMM2): The Division:

(a) Coordinates across HHS to establish, and communicate, and sustain HHS's ERM vision, culture, strategy, and framework.

(b) Designs, implements, and matures an ERM capability across HHS, including governance and community management.

(c) Develops and shares tools, guidance, and best practices regarding ERM.

(d) Provides technical assistance and direction to HHS Operating Divisions (OPDIVs) and Staff Divisions (STAFFDIVs) on implementing ERM.

(e) Facilitates strategic initiatives across HHS's risk portfolio of existing and emerging risks and opportunities, including guiding updates of the agency's risk profile, and management's prioritization of risks and opportunities.

(f) Leads the Department's efforts to meet the ERM requirements in OMB Circular A–123, ''Management's Responsibility for Enterprise Risk Management and Internal Control.''

(g) Prepares reports, briefings, and makes recommendations to senior HHS leadership, OPDIVs, STAFFDIVs and other stakeholders on ERM related activities.