DATES: The meeting will be held on October 27th, 2014 from 9 a.m. to 5 p.m. EDT.

ADDRESSES: The meeting will be held in Room 800 in the Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

Comments: Time is allocated mid-morning on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record to Rohini Khillan, OASPE, 200 Independence Avenue SW., Room 424E, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov.* Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION: Rohini Khillan (202) 690–5932, *rohini.khillan@hhs.gov*. Note: Seating may be limited. Those wishing to attend the meeting must send an email to *napa@hhs.gov* and put ''October 27 Meeting Attendance'' in the Subject line by Friday, October 17, so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: The Advisory Council will hear presentations on the basics of long-term care, including presentations on programs, settings, and payers. The Council will use a portion of the meeting to review the work it has accomplished thus far towards the 2025 goals, and then discuss the process for developing recommendations for the 2015 update to the National Plan. The Council will also hear presentations from the three subcommittees (Research, Clinical Care, Long-Term Services and Supports, and Ethics).

Procedure and Agenda: This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. The meeting will also be webcast at *www.hhs.gov/live* .

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: September 22, 2014.

Richard G. Frank,

Assistant Secretary for Planning and Evaluation.

[FR Doc. 2014–23411 Filed 10–1–14; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0616]

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.'' This guidance identifies cybersecurity issues that manufacturers should consider in preparing premarket submissions for medical devices in order to maintain information confidentiality, integrity, and availability.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: 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 single copies of the guidance document entitled ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices'' 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 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 request.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Abiy Desta, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1682, Silver Spring, MD 20993–0002, 301–796–0293, *Abiy.Desta@fda.hhs.gov;* 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

This guidance provides recommendations to consider and document in FDA medical device premarket submissions to provide effective cybersecurity management and to reduce the risk that device functionality is intentionally or unintentionally compromised. The need for effective cybersecurity to assure medical device functionality has become more important with the increasing use of wireless, Internet- and network-connected devices and the frequent electronic exchange of medical device-related health information.

In the **Federal Register** of June 14, 2013 (78 FR 35940), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by September 12, 2013. Multiple comments were received and in response to these comments, FDA revised the guidance document and policies as appropriate to clarify the types of cybersecurity issues that manufacturers should consider in preparing premarket submissions for medical devices in order to maintain information confidentiality, integrity, and availability.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the Agency's current thinking on management of cybersecurity in medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative

approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* Persons unable to download an electronic copy of ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1825 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: September 26, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23457 Filed 10–1–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Common Data Platform (CDP)—NEW

The Common Data Platform (CDP) includes new instruments for the Substance Abuse and Mental Health Services Administration (SAMHSA). The CDP will replace separate data collection instruments used for reporting Government Performance and Results Act of 1993 (GPRA) measures: The TRansformation ACcountability (TRAC) Reporting System (OMB No. 0930–0285) used by the Center for Mental Health Services (CMHS); the Prevention Management Reporting and Training System (PMRTS—OMB No. 0930–0279) used by the Center for Substance Abuse Prevention (CSAP); and the Services Accountability and Improvement System (SAIS—OMB No. 0930–0208) used by the Center for Substance Abuse Treatment (CSAT).

The CDP will also include two grantee-level data collection forms approved by consensus of offices and Centers within SAMHSA as well as the Department of Health and Human Services (HHS): the Infrastructure, Prevention, and Mental Health Promotion (IPP) Form used by a subset of CMHS grantees and the Aggregate Tool used by CSAT's Addiction Technology Transfer Center (ATCC) grantees.

Approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Modernization Act of 2010 (GPRAMA) reporting requirements and analyses of the data will help SAMHSA determine whether progress is being made in achieving its mission. The primary purpose of this data collection system is to promote the use of common data elements among SAMHSA grantees and contractors. The common elements were recommended by consensus among SAMHSA Centers and Offices. Analyses of these data will allow SAMHSA to quantify effects and accomplishments of its discretionary grant programs which are consistent with the OMB-approved GPRA measures and address goals and objectives outlined in the Office of National Drug Control Policy's Performance Measures of Effectiveness and the SAMHSA Strategic Initiatives.

The CDP will be a real-time, performance management system that captures information on substance abuse treatment and prevention and mental health services delivered in the United States. A wide range of client and program information will be captured through CDP for approximately 3,000 grants (2,224 for CMHS; 642 for CSAT; 122 for CSAP; and 33 for HIV Continuum of Care). Substance abuse treatment facilities, mental health service providers, and substance abuse prevention programs will submit their data in real-time or on a monthly or a weekly basis to ensure that the CDP is an accurate, up-to-date reflection on the scope of services delivered and characteristics of the clients.

In order to carry out section 1105(a)(29) of GPRA, SAMHSA is required to prepare a performance plan for its major programs of activity. This plan must:

- Establish performance goals to define the level of performance to be achieved by a program activity;
- Express such goals in an objective, quantifiable, and measurable form;
- Briefly describe the operational processes, skills and technology, and the human, capital, information, or other resources required to meet the performance goals;
- Establish performance indicators to be used in measuring or assessing the relevant outputs, service levels, and outcomes of each program activity;
- Provide a basis for comparing actual program results with the established performance goals; and
- Describe the means to be used to verify and validate measured values.

This CDP data collection supports the GPRAMA, which requires overall organization management to improve agency performance and achieve the mission and goals of the agency through the use of strategic and performance planning, measurement, analysis, regular assessment of progress, and use of performance information to improve the results achieved. Specifically, this