and assessment of the organization's survey process.

++ Determine the adequacy of DNV GL's staff and other resources.

++ Confirm DNV GL's ability to provide adequate funding for performing required surveys.

++ Confirm DNV GL's policies with respect to surveys being unannounced.

++ Confirm DNV GL's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain DNV GL's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

++ As authorized under § 488.8(h), CMS reserves the right to conduct onsite observations of accrediting organization's operations at any time as part of the ongoing review and continuing oversight of an AO's performance.

In accordance with section 1865(a)(3)(A) of the Act, the March 2, 2020 proposed notice also solicited public comments regarding whether DNV GL's requirements met or exceeded the Medicare CoPs for psychiatric hospitals. We received 4 comments in response to our proposed notice. We thank the commenters for their support. We agreed with the commenters that a new psychiatric hospital accreditation organization would provide hospitals further options in regards to accreditation. Based on our comprehensive review of their program, we have approved DNV GL as such a program.

IV. Provisions of the Final Notice

A. Differences Between DNV GL's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared DNV GL's psychiatric hospital accreditation program requirements and survey process with the Medicare CoPs at 42 CFR part 482, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of DNV GL's psychiatric hospital application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, DNV GL has revised its standards and certification processes in order to meet the requirements at:

- *Section 482.41(c)(1):* DNV GL revised its standards to not require the hospitals to adopt Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code.
- *Section 482.61(a) through (a)(3):* DNV GL revised its standards to require a diagnosis for all patients.
- *Section 482.61(b):* DNV GL revised its standards to require a record of mental status.
- *State Operations Manual Chapter 3 Section 3012:* DNV GL revised its materials to reflect its timeframe(s) for follow-up activities, including follow-up surveys for facilities that have previously demonstrated non-compliance at the condition level.
- *Section 488.5(a)(12):* DNV GL revised its policies to ensure a clearly defined complaint investigation process is in place that meets the requirements in the State Operations Manual Chapter 5 Section 5010 and Chapter 5 Section 5075.2 that includes the following:

++ Complete and accurate tracking of complaints as well as a process for maintaining a documented record of contacts made (for example, phone, email and United States mail) with the complainant, and others, if applicable.

++ Defining the number of contact attempts required before closing out a complaint if the complainant does not respond.

++ Educating DNV GL complaint intake staff that when complaint allegations could potentially result in condition-level non-compliance affecting the health and safety of patients, a survey is to be considered regardless if the allegation also involves payment related allegations.

++ Investigating complaints onsite within an appropriate timeframe.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that DNV GL's psychiatric hospital accreditation program requirements meet or exceed our requirements, and its survey processes are also comparable. Therefore, we approve DNV GL as a national AO for psychiatric hospitals that request participation in the Medicare program, effective July 30, 2020 through July 30, 2024.

V. 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), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: July 24, 2020.

Lynette Wilson,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–16453 Filed 7–28–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1339]

Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff; 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 entitled ''Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff.'' This final guidance provides FDA's regulatory approach for device products with multiple functions including at least one device function and includes such device products that are part of combination products, in accordance with the 21st Century Cures Act (Cures Act).

DATES: The announcement of the guidance is published in the **Federal Register** on July 29, 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–2018–D–1339 for ''Multiple Function Device Products: Policy and Considerations; 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.

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 ''Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff'' to the Office of Policy, 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; or the Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993–0002, 301–796–5528; 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; or Kristina Lauritsen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6162, Silver Spring, MD 20993–0002, 301–796–8936.

SUPPLEMENTARY INFORMATION:

I. Background

On December 13, 2016, the Cures Act (Pub. L. 114–255) was signed into law. Section 3060(a) of this legislation entitled ''Clarifying Medical Software Regulation'' amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add section 520(o) (21 U.S.C. 360j(o)), which excludes certain software functions from the definition of device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)). In addition, section 520(o)(2) of the FD&C Act describes the regulation and assessment of a product with multiple functions including at least one device function and at least one software function that is not a device. Although section 520(o)(2) of the FD&C Act applies to the regulation of software products containing at least one device function and at least one non-device software function, FDA believes that a similar approach should be used for the assessment of all multiple function device products that contain at least one device function and one ''other function'', which may be a non-device software function; a function that meets the definition of a device, but is not subject to premarket review; or a function that meets the definition of device, but for which FDA has expressed its intention not to enforce compliance with applicable regulatory controls. This approach also applies to multiple function device products that are device constituent parts of combination products. FDA considered comments received on the draft guidance that appeared in the **Federal Register** of April 27, 2018 (83 FR 18570). FDA revised the guidance as appropriate in response to the comments.

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 ''Multiple Function Device Products: Policy and Considerations; Guidance for Industry and Food and Drug Administration Staff.'' 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.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Multiple Function Device Products: Policy and Considerations; 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 17038 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 have been approved by OMB as follows:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
803	Medical device reporting	0910–0437
807, subparts A through D	Registration and listing	0910–0625
807, subpart E	Premarket notification	0910–0120
812	Investigational device exemption	0910–0078
814, subparts A through E	Premarket approval applications	0910–0231
814, subpart H	Humanitarian use devices	0910–0332
820	Current good manufacturing practice and the quality system regulation.	0910–0073
312	Investigational New Drug Regulations	0910–0014
314	Applications for FDA Approval to Market a New Drug	0910–0001
314	Abbreviated New Drug Applications and 505(b)(2) Applications	0910–0786
601; Form FDA 356h	Biologics License; Application to Market a New Drug or Abbreviated New Drug or Biologic for Human Use—Form FDA 356h.	0910–0338
''User Fees for 513(g) Requests for Information'' and ''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act''.	513(g) requests	0910–0705
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo requests	0910–0844

Dated: July 23, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16394 Filed 7–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on September 8, 2020, from 8 a.m. to 6 p.m. Eastern Time and on September 9, 2020, from 8 a.m. to 1 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform held via webcast only. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* The meeting will be webcast both days and will be available at the following link:

Webcast link for Day 1: http://fda.yorkcast.com/webcast/Play/8ef8ac6b36f244beaced2a3031eebc621d.

Webcast link for Day 2: http://fda.yorkcast.com/webcast/Play/0e1b175674de4b1e8a4675cf5096aa601d.

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993–0002, *Patricio.Garcia@fda.hhs.gov,* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On September 8, 2020, during session 1, the committee will discuss and make recommendations regarding the classification of facet screws systems which are currently unclassified pre-amendment devices to Class II (general and special controls). During session II, the committee will discuss and make