Implementing Industry Standards.[3] This toolkit is dedicated to developing and implementing WMPs and can inform conversations with building owners and managers on how to reduce the risk of *Legionella* growth and transmission in their building water systems.

Information Needs

While a consensus standard and guidance exist regarding development and implementation of WMPs, there are gaps regarding the most effective methods to encourage WMP implementation. A variety of stakeholders (*e.g.,* public health partners, industry leaders, accreditation or licensing bodies) routinely work with building owners and managers on WMPs or on related policies. However, successful communication and implementation of WMPs can be challenging, and more information is needed on how implementation of WMPs can be improved. CDC seeks public comments in response to the following questions to guide best practices, especially regarding the dissemination and implementation of WMPs. The information gathered will be used to guide best practices regarding effective strategies to prevent Legionnaires disease in the United States. Information gathered can also inform efforts to prevent disease due to other waterborne pathogens.

Please feel free to respond to any or all of the questions. Possible domains to consider in answering these questions include (but are not limited to):

- Local knowledge about Legionnaires disease, *Legionella* growth, and prevention strategies
- Stakeholder engagement (key supporters and opponents)
- Feasibility of WMP implementation
- Costs and benefits of WMP implementation
- Availability of effective communication strategies
- Possible impact of proposed solutions including unintended consequences such as degradation of plumbing infrastructure or pathogen substitution (*e.g.,* remediation directed at one pathogen, such as *Legionella*, leading to increases in a second pathogen, such as nontuberculous mycobacteria)
- Historical context in which a WMP was or was not adopted
- Influence of local regulations

Questions

(1) What existing standards or guidance does your organization use for the prevention of *Legionella* growth and transmission?

(2) Are there other standards or guidance for the prevention of *Legionella* growth and transmission that you would find useful but do not exist or are not currently available to you? If so, what information should those standards or guidance contain?

(3) What is your organization's role, and your role within the organization, in achieving implementation of WMPs by owners and managers of buildings at increased risk for *Legionella* growth and transmission?

(4) In your organization's experience, what are the principal barriers to implementation of WMPs by building owners and managers?

(5) Where there are barriers, what has your organization done to overcome these barriers?

(6) Where implementation of WMPs has gone smoothly, what factors (*e.g.,* resources, guidance, activities) contributed to this success?

(7) Has your organization had experience with approaches to WMP implementation that are specific to certain settings (*e.g.,* hotels, hospitals) or devices (*e.g.,* cooling towers, potable water)? If so, have you learned anything from these different approaches that could be used to improve WMP implementation? Have you looked for or experienced any unintended consequences related to a WMP?

(8) A limited number of jurisdictions have implemented regulations to reduce the risk of *Legionella* growth and transmission (*e.g.,* New York, New York City). In your state or local jurisdiction, should building codes or other types of public health regulation or legislation be used to help prevent Legionnaires' disease? Why or why not?

(9) Are there other approaches to reducing the risk of Legionnaires' disease that your organization has found to be useful besides implementation of WMPs?

(10) What additional considerations are relevant to developing guidance for preventing Legionnaires disease?

(11) Has your organization implemented specific approaches to reducing the risk of disease due to other opportunistic waterborne pathogens besides *Legionella*? If so, please explain. Do these approaches conflict in any way with your approaches to reducing the risk of Legionnaires disease?

Dated: August 15, 2017.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2017–17491 Filed 8–17–17; 8:45 am]

BILLING CODE 4163–18–P

[3] *https://www.cdc.gov/legionella/downloads/toolkit.pdf.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10437 and CMS–10652]

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

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by September 18, 2017.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, Fax Number: (202) 395–5806 *OR, Email: OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of 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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Generic Social Marketing & Consumer Testing Research; *Use:* The purpose of this submission is to extend the approval of the generic clearance for a program of consumer research aimed at a broad audience of those affected by CMS programs including Medicare, Medicaid, Children's Health Insurance Program (CHIP), and health insurance exchanges. This program extends strategic efforts to reach and tailor communications to beneficiaries, caregivers, providers, stakeholders, and any other audiences that would support the Agency in improving the functioning of the health care system, improve patient care and outcomes, and reduce costs without sacrificing quality of care. The information collected will be used to create a streamlined and proactive process for collection of data and utilizing the feedback on service delivery for continuous improvement of communication activities aimed at diverse CMS audiences.

The generic clearance will allow rapid response to inform CMS initiatives using a mixture of qualitative and quantitative consumer research strategies (including formative research studies and methodological tests) to improve communication with key CMS audiences. As new information resources and persuasive technologies are developed, they can be tested and evaluated for beneficiary response to the materials and delivery channels. Results will inform communication development and information architecture as well as allow for continuous quality improvement. The overall goal is to maximize the extent to which consumers have access to useful sources of CMS program information in a form that can help them make the most of their benefits and options.

The activities under this clearance involve social marketing and consumer research using samples of self-selected customers, as well as convenience samples, and quota samples, with respondents selected either to cover a broad range of customers or to include specific characteristics related to certain products or services. All collection of information under this clearance will utilize a subset of items drawn from a core collection of customizable items referred to as the Social Marketing and Consumer Testing Item Bank. This item bank is designed to establish a set of pre-approved generic question that can be drawn upon to allow for the rapid turn-around consumer testing required for us to communicate more effectively with our audiences. The questions in the item bank are divided into two major categories. One set focuses on characteristics of individuals and is intended primarily for participant screening and for use in structured quantitative on-line or telephone surveys. The other set is less structured and is designed for use in qualitative one-on-one and small group discussions or collecting information related to subjective impressions of test materials. Results will be compiled and disseminated so that future communication can be informed by the testing results. We will use the findings to create the greatest possible public benefit. *Form Number:* CMS–10437 (OMB control number: 0938–1247); *Frequency:* Yearly; *Affected Public:* Individuals; *Number of Respondents:* 41,592; *Number of Responses:* 28,800; *Total Annual Hours:* 21,488. (For policy questions regarding this collection contact Allyssa Allen at 410–786–8436126.)

2. *Type of Information Collection Request:* New collection of information request; *Title of Information Collection:* Virtual Groups for Merit-Based Incentive Payment System (MIPS); *Use:* CMS acknowledges the unique challenges that small practices and practices in rural areas may face with the implementation of the Quality Payment Program. To help support these practices and provide them with additional flexibility, CMS has created a virtual group reporting option starting with the 2018 MIPS performance period. CMS held webinars and small, interactive feedback sessions to gain insight from clinicians as we developed our policies on virtual groups. During these sessions, participants expressed a strong interest in virtual groups, and indicated that the right policies could minimize clinician burden and bolster clinician success.

This information collection request is related to the statutorily required virtual group election process proposed in the CY 2018 Quality Payment Program proposed rule. A virtual group is a combination of Tax Identification Numbers (TINs), which would include at least two separate TINs associated with a solo practitioner TIN and National Provider Identifier (TIN/NPI) or group with 10 or fewer MIPS eligible clinicians and another solo practitioner (TIN/NPI) or group with 10 or fewer MIPS eligible clinicians.

Section 1848(q)(5)(I) of the Act requires that CMS establish and have in place a process to allow an individual MIPS eligible clinician or group consisting of not more than 10 MIPS eligible clinicians to elect, with respect to a performance period for a year to be in a virtual group with at least one other such individual MIPS eligible clinician or group. The Act also provides for the use of voluntary virtual groups for certain assessment purposes, including the election of practices to be a virtual group and the requirements for the election process.

Section 1848(q)(5)(I)(i) of the Act also provides that MIPS eligible clinicians electing to be a virtual group must: (1) Have their performance assessed for the quality and cost performance categories in a manner that applies the combined performance of all the MIPS eligible clinicians in the virtual group to each MIPS eligible clinician in the virtual group for the applicable performance period; and (2) be scored for the quality and cost performance categories based on such assessment.

CMS will use the data collected from virtual group representatives to determine eligibility to participate in a virtual group, approve the formation of that virtual group, based on determination of each TIN size, and assign a virtual group identifier to the virtual group. The data collected will also be used to assign a performance score to each TIN/NPI in the virtual group. *Form Number:* CMS–10652 (OMB control number: 0938–NEW);

Frequency: Annually; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and Individuals; *Number of Respondents:* 16; Total *Annual Responses:* 16; *Total Annual Hours:* 160. (For policy questions regarding this collection contact Michelle Peterman at 410–786–2591.)

Dated: August 15, 2017.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–17495 Filed 8–17–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4069]

Bayer Healthcare Pharmaceuticals; Withdrawal of Approval of a New Drug Application for BAYCOL (cerivastatin sodium) Tablets, 0.05 Milligrams, 0.1 Milligrams, 0.2 Milligrams, 0.3 Milligrams, 0.4 Milligrams, and 0.8 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of new drug application (NDA) 020740 for BAYCOL (cerivastatin sodium) tablets, 0.05 milligrams (mg), 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, and 0.8 mg, held by Bayer Healthcare Pharmaceuticals (Bayer). Bayer requested withdrawal of this application, and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of August 18, 2017.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: NDA 020740 for BAYCOL (cerivastatin sodium) tablets, 0.05 mg, 0.1 mg, 0.2 mg, and 0.3 mg, was received on June 26, 1996, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA approved NDA 020740 on June 26, 1997, as safe and effective as an adjunct to diet for the reduction of elevated total and LDL cholesterol levels in patients with primary hypercholesterolemia and mixed dyslipidemia (Frederickson Types IIa and IIb) when the response to dietary restriction of saturated fat and cholesterol and other non-pharmacological measures alone has been inadequate. Supplemental NDAs were received by FDA on July 17, 1998, for the 0.4 mg strength of the drug (approved on May 24, 1999) and on September 23, 1999, for the 0.8 mg strength of the drug (approved on July 21, 2000). The most recently approved labeling (May 21, 2001) for this drug stated that: ''BAYCOL® (cerivastatin sodium tablets) is indicated as an adjunct to diet to reduce elevated Total–C, LDL–C, apo B, and TG and to increase HDL–C levels in patients with primary hypercholesterolemia and mixed dyslipidemia (Fredrickson Types IIa and IIb) when the response to dietary restriction of saturated fat and cholesterol and other non-pharmacological measures alone has been inadequate.''

Over time, however, reports associating cerivastatin with rhabdomyolysis, a potentially fatal condition involving muscle weakness, increased. Because of these reports, Bayer withdrew BAYCOL from the market on August 8, 2001. On January 24, 2014, Bayer wrote to FDA asking the Agency to withdraw approval of NDA 020740 under 21 CFR 314.150(d) and waived its opportunity for a hearing.

Accordingly, under section 505(e) of the FD&C Act (21 U.S.C. 355(e)) and section 314.150(d), approval of NDA 020740, and all amendments and supplements thereto, is withdrawn. Distribution of BAYCOL (cerivastatin sodium) tablets, 0.05 mg, 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, and 0.8 mg in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: August 15, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17510 Filed 8–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Mental Health Council.

Date: September 14, 2017.

Open: 9:00 a.m. to 12:45 p.m.

Agenda: Presentation of the NIMH Director's Report and discussion.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Closed: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Jean G. Noronha, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9609, 301–443–3367, *jnoronha@mail.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml.,* where an agenda and any additional information for the meeting will be posted when available.