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 a currently approved collection; *Title of Information Collection:* Annual Report on Home and Community Based Services Waivers and Supporting Regulations; *Use:* We use this report to compare actual data to the approved waiver estimates. In conjunction with the waiver compliance review reports, the information provided will be compared to that in the Medicaid Statistical Information System (MSIS) (CMS–R–284; OMB control number 0938–0345) report and FFP claimed on a state's Quarterly Expenditure Report (CMS–64; OMB control number 0938–1265), to determine whether to continue the state's home and community-based services waiver. States' estimates of cost and utilization for renewal purposes are based upon the data compiled in the CMS–372(S) reports. *Form Number:* CMS–372(S) (OMB control number: 0938–0272); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 47; *Total Annual Responses:* 282; *Total Annual Hours:* 12,126. (For policy questions regarding this collection contact Ralph Lollar at 410–786–0777).

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Survey of Retail Prices; *Use:* This information collection request provides for a survey of the average acquisition costs of all covered outpatient drugs purchased by retail community pharmacies. CMS may contract with a vendor to conduct monthly surveys of retail prices for covered outpatient drugs. Such prices represent a nationwide average of consumer purchase prices, net of discounts and rebates. The contractor shall provide notification when a drug product becomes generally available and that the contract include such terms and conditions as the Secretary shall specify, including a requirement that the vendor monitor the marketplace. CMS has developed a National Average Drug Acquisition Cost (NADAC) for states to consider when developing reimbursement methodology. The NADAC is a pricing benchmark that is based on the national average costs that pharmacies pay to acquire Medicaid covered outpatient drugs. This pricing benchmark is based on drug acquisition costs collected directly from pharmacies through a nationwide survey process. This survey is conducted on a monthly basis to ensure that the NADAC reference file remains current and up-to-date. *Form Number:* CMS–10241 (OMB control number 0938–1041); *Frequency:* Monthly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 30,000; *Total Annual Responses:* 30,000; *Total Annual Hours:* 15,000. (For policy questions regarding this collection contact: Lisa Shochet at 410–786–5445.)

Dated: March 12, 2018.

William N. Parham, III,

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

[FR Doc. 2018–05296 Filed 3–14–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0215]

Agency Information Collection Activities; Proposed Collection; Comment Request; Health Care Professional Survey of Professional Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on ''Health Care Professional Survey of Professional Prescription Drug Promotion.'' This study will examine how health care professionals experience and perceive prescription drug promotion directed to them.

DATES: Submit either electronic or written comments on the collection of information by May 14, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 14, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of May 14, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–N–0215 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Health Care Professional Survey of Professional Prescription Drug Promotion.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

• 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under the 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. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Health Care Professional Survey of Professional Prescription Drug Promotion

OMB Control Number 0910—NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

As part of its federal mandate, FDA regulates whether direct-to-consumer (DTC) advertising of prescription drug products is truthful, balanced, and accurately communicated (see 21 U.S.C. 352(n)). Similarly, the FD&C Act prohibits the dissemination of false or misleading information about medications in consumer-directed and professional prescription drug promotion. FDA regulates within the framework of free speech and due process principles of the United States Constitution. To inform current and future policies, and to seek to enhance audience comprehension, the Office of Prescription Drug Promotion conducts research focusing on (1) advertising features including content and format, (2) target populations, and (3) research quality. This proposed research focuses on the physician target population. FDA surveyed physicians about their attitudes toward DTC advertising and its role in their relationships with their patients in 2002 (Ref. 1) and again in 2013 (Refs. 2 and 3). The 2013 survey included multiple types of prescribers: Primary care physicians, specialists, nurse practitioners, and physician assistants. Whereas the focus of both previous FDA surveys was on DTC advertising and promotion, the current study is designed to address issues related to professional prescription drug promotion. The goal is to query a representative sample of health care professionals (HCPs) about their opinions of promotional materials and procedures targeted at HCPs, clinical trial design and knowledge, and FDA approval status. We will also take this opportunity to ask HCPs briefly about their knowledge of abuse-deterrent formulations for opioid products.

To educate themselves about prescription drugs, HCPs sometimes rely on professionally directed promotional information (Refs. 4–8). In 2012, pharmaceutical companies spent more than $24 billion on marketing to physicians (Ref. 9). The industry exposes health care professionals to promotional materials through a variety of mechanisms, including communication with pharmaceutical representatives, journal ads, prescribing software, presentations at sponsored meetings, and direct mail ads (Ref. 10). Several studies indicate that data presented in promotional materials may not be fully comprehended and may even potentially be misleading due to a variety of causes, such as insufficient information, unsupported claims, or a failure to disclose limitations of the information presented (Refs. 11–15).

Although HCPs are learned intermediaries, like most people, they may rely on heuristics in making decisions and may have cognitive biases in the type of information they attend to at any given time. They may be persuaded by strong statements and may not have the time to ascertain accuracy of such information (Ref. 16). The proposed survey will provide further insights about how professionally targeted prescription drug promotion might influence health care professionals' decision-making processes and practices and how

information may be communicated more effectively. It is important to note that FDA does not regulate the practice of medicine. However, as previously mentioned, FDA does regulate prescription drug promotion. This survey is designed to inform FDA of various responses to and impacts of prescription drug promotion of prescription drugs.

The general research questions in the survey are as follows:

1. What methods and/or channels are used to disseminate prescription drug promotional information to health care professionals/prescribers?

2. How knowledgeable and interested are HCPs in clinical trial data and its presence in prescription drug promotion?

3. How familiar are HCPs with the FDA approval of prescription drugs and how does this translate into practice?

In addition, given the critical nature of the opioid situation in the United States at this time, we plan to ask several questions about prescription drug promotion of opioid products.

HCPs who fall into one of four categories will be recruited online through WebMD's Medscape subscriber network. We propose to complete 700 primary care physician, 600 specialist, 350 nurse practitioner, and 350 physician assistant surveys. HCPs will be included if they see patients at least 50 percent of the time. Both Doctors of Medicine and Doctors of Osteopathy will be included. Primary care physicians will include those who indicate they work in general, family, or internal medicine. Specialties were chosen based on prevalence in the United States and prescription drug promotional activity. Specialists will include cardiologists, dermatologists, endocrinologists, neurologists, obstetrician/gynecologists, oncologists, ophthalmologists, psychiatrists, rheumatologists, and urologists. The data will be weighted to adjust for differential coverage of select characteristics such as region and respondent age and gender. Pretesting with 25 respondents will take place before the main study to evaluate the procedures and measures used in the main study.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest Study					
HCP screener	63	1	63	0.08 (5 minutes)	5
Informed Consent	25	1	25	0.08 (5 minutes)	2
HCP Survey	25	1	25	0.33 (20 minutes)	8
Main Study					
HCP screener	5,037	1	5,037	0.08 (5 minutes)	403
Informed Consent	2,000	1	2,000	0.08 (5 minutes)	160
HCP Survey	2,000	1	2,000	0.33 (20 minutes)	660
Total					1,238

[1] There are no capital costs and maintenance costs associated with this collection of information.

II. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Available at: *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm.* Last accessed January 26, 2018.
2. Betts, K.R., A.C. O'Donoghue, K.J. Aikin, et al. (2016). ''Healthcare Professional Social Media Membership and Participation: Findings From a Nationally Representative Sample,'' *Journal of the American Association of Nurse Practitioners.* Doi: 10.1002/2327–6924.12383.
3. O'Donoghue, A.C., V. Boudewyns, K.J. Aikin, et al. (2015). ''Awareness of FDA's Bad Ad Program and Education Regarding Pharmaceutical Advertising: A National Survey of Prescribers in Ambulatory Care Settings,'' *Journal of Health Communication,* vol. 20(11), pp. 1330–1336.
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5. Fischer, M.A., M.E. Keough, J.L. Baril, et al. (2009). ''Prescribers and Pharmaceutical Representatives: Why Are We Still Meeting?'' *Journal of General Internal Medicine,* vol. 24(7), pp. 795–801.
6. C. Robertson, S. Rose, and A.S. Kesselheim. (2012). ''Effect of Financial Relationships on the Behaviors of Health Care Professionals: A Review of the Evidence,'' *The Journal of Law, Medicine & Ethics,* vol. 40(3), pp. 452–466.
7. Srivastava, V., M. Handa, and A. Vohra. (2014). ''Promotional Tools: Do Physicians Really Bite the Hook?'' *Drishtikon: A Management Journal,* vol. 5(2).
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9. Cegedim Strategic Data. (2013). ''2012 U.S. Pharmaceutical Company Promotion Spending.'' Available at: *http://www.skainfo.com/health_care_market_reports/2012_promotional_spending.pdf.*
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11. Villanueva, P., S. Peiró, J. Librero, et al. (2003). ''Accuracy of Pharmaceutical Advertisements in Medical Journals,'' *Lancet,* vol. 361(9351), pp. 27–32.
12. Cooper, R.J. and D.L. Schriger. (2005). ''The Availability of References and the Sponsorship of Original Research Cited in Pharmaceutical Advertisements,'' *Canadian Medical Association Journal,* vol. 172(4), pp. 487–491.
13. Jureidini, J.N., L.B. McHenry, and P.R. Mansfield. (2008). ''Clinical Trials and Drug Promotion: Selective Reporting of

Study 329,'' *International Journal of Risk & Safety in Medicine,* vol. 20(1–2), pp. 73–81.
14. Garcia-Retamero, R. and M. Galesic. (2010). ''Who Profits From Visual Aids: Overcoming Challenges in People's Understanding of Risks,'' *Social Science & Medicine,* vol. 70(7), pp. 1019–1025.
15. Cooper, R.J., D.L. Schriger, R.C. Wallace, et al. (2003). ''The Quantity and Quality of Scientific Graphs in Pharmaceutical Advertisements,'' *Journal of General Internal Medicine,* vol. 18(4), pp. 294–297.
16. Sah, S. and A. Fugh-Berman. (2013). ''Physicians Under the Influence: Social Psychology and Industry Marketing Strategies,'' *The Journal of Law, Medicine & Ethics,* vol. 41(3), pp. 665–672. doi: 10.1111/jlme.12076.

Dated: March 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05235 Filed 3–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Announcing Budget Period Extensions with Funding for the Health Center Program.

SUMMARY: HRSA provided additional grant funds during extended budget periods to prevent interruptions in the provision of critical health care services for funded service areas until new awards could be made to eligible Service Area Competition (SAC) applicants or HRSA could conduct an orderly phase-out of Health Center Program activities by the current award recipients.

SUPPLEMENTARY INFORMATION:

Recipients of the Award: Health Center Program award recipients for service areas that were threatened with a lapse in services due to service area re-announcement or transitioning award recipients, as listed in Table 1.

Amount of Non-Competitive Awards: 33 awards for $17,248,966.

Period of Supplemental Funding: Fiscal years 2016 and 2017.

CFDA Number: 93.224

Authority: Section 330 of the Public Health Service Act, as amended (42 U.S.C. 254b, as amended).

Justification: Targeting the nation's high need populations and geographic areas, the Health Center Program currently funds nearly 1,400 health centers that operate more than 11,000 service delivery sites in every state, the District of Columbia, Puerto Rico, the Virgin Islands, and the Pacific Basin. Nearly 26 million people received accessible, affordable, quality primary health care services through the Health Center Program award recipients in 2016.

Approximately one-third of Health Center Program award recipients' service areas are competed each year, and each competition has the potential to result in a change in award recipient. SACs are also held prior to the current grant's project period end date when (1) a grant is voluntarily relinquished, or (2) a program noncompliance enforcement action taken by HRSA terminates the grant. If the SAC draws no fundable applications, HRSA may extend the current award recipient's budget period to ensure primary health care services remain available while a new competition is conducted for the service area.

The amount of additional grant funds is calculated by pro-rating HRSA's annual funding commitment to the service area. Approximately 6 months is required to announce and conduct a SAC and select a new award recipient. In all cases, current fiscal year funds are used to extend the award recipient's existing budget period award. Through these actions, award recipients receive consistent levels of funding to support uninterrupted primary health care services to the nation's underserved populations and communities during service area award recipient transition.

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant number	Award recipient name	Extension award date	Award amount ($)
H80CS06641	Ko'olauloa Community Health and Wellness Center, Inc	12/01/15	235,116
H80CS26606	Horizon Health and Wellness, Inc	12/23/15	182,771
H80CS26604	Neighborhood Outreach Access to Health	12/23/15	192,815
H80CS00851	Duval County Health Department	01/11/16	480,066
H80CS26560	East Central Missouri Behavioral Health Services, Inc.	01/15/16	281,845
H80CS00048	Santa Cruz County	01/15/16	672,655
H80CS00001	City of Springfield, Massachusetts	01/15/16	606,761
H80CS00384	Monroe County Health Center	01/15/16	640,737
H80CS26631	La Casa de Salud, Inc	01/15/16	563,753
H80CS00400	Circle Family Healthcare Network, Inc	01/22/16	501,296
H80CS00013	Covenant House (Under 21)	02/03/16	279,116
H80CS26632	Whitman-Walker Clinic, Inc	02/06/16	423,273
H80CS00054	Metropolitan Development Council	02/06/16	457,843
H80CS00055	White Bird Clinic	02/10/16	412,985
H80CS26587	Saint Hope Foundation	02/10/16	229,491
H80CS26620	Korean Health, Education, Information and Research Center	02/12/16	504,386
H80CS26513	FirstMed Health and Wellness Center	02/12/16	596,025
H80CS08770	Health Center of Southeast Texas	02/12/16	737,066
H80CS00872	Madison County Community Health Center	03/01/16	467,855
H80CS00622	The Hunter Health Clinic, Inc	03/08/16	450,569
H80CS10606	St. Vincent de Paul Village, Inc	04/06/16	334,418
H80CS06078	Yakima Neighborhood Health Services	04/06/16	1,025,892
H80CS17251	Upper Room Aids Ministry, Inc. Health Care Center	04/06/16	738,043
H80CS00722	Community Clinic of Maui, Inc	04/06/16	570,042
H80CS01443	Lane County	05/15/16	649,218
H80CS00054	Metropolitan Development Council	06/14/16	228,922
H80CS00299	Brazos Valley Community Action Agency, Inc	01/17/17	1,520,645
H80CS00814	Kalihi-Palama Health Center	01/17/17	1,105,506