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:* Indirect Medical Education and Direct Graduate Medical Education; *Use:* Section 1886(d)(5)(B) of the Social Security Act requires additional payments to be made under the Medicare Prospective Payment System (PPS) for the indirect medical educational costs a hospital incurs in connection with interns and residents (IRs) in approved teaching programs. In addition, Title 42, Part 413, sections 75 through 83 implement section 1886(d) of the Act by establishing the methodology for Medicare payment for the costs of direct graduate medical educational activities. These payments, which are adjustments (add-ons) to other payments made to a hospital under PPS, are largely determined by the number of full-time equivalent (FTE) IRs that work at a hospital during its cost reporting period. In Federal fiscal year (FY) 2018, the estimated Medicare program payments for indirect medical education (IME) costs was $6.4 billion. Medicare program payment for direct graduate medical education (GME) is also based upon the number of FTE–IRs that work at a hospital. In FY 2018, the estimated Medicare program payments for GME costs was $3.1 billion. Since it is important to accurately count the number of IRs FTEs working at each hospital, original approval was obtained from the Office of Management and Budget (OMB) in 1985 to collect the IR information required in 42 CFR 412.105(f) and timeframes for filing. All Medicare health plans are required to use these standardized notices. *Form Number:* CMS–R–64 (OMB control number: 0938–0456); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-profit institutions); *Number of Respondents:* 1,245; *Total Annual Responses:* 1,245; *Total Annual Hours:* 2,490. (For policy questions regarding this collection contact Owen Osaghae at 410–786–7550.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Information Collection Requirements Associated with Drug Pricing Transparency and Supporting Regulations in 42 CFR 403.1202; *Use:* The Department of Health and Human Services proposed a rule (78 FR 52789) to revise the Federal Health Insurance Programs for the Aged and Disabled by amending regulations for the Medicare and Medicaid program, to require direct-to-consumer (DTC) television advertisements of prescription drugs and biological products for which payment is available through or under Medicare or Medicaid to include the Wholesale Acquisition Cost (WAC, or list price) of that drug or biological product. This rule is intended to improve the efficient administration of the Medicare and Medicaid programs by ensuring that beneficiaries are provided with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize not only their out-of-pocket costs, but also expenditures borne by Medicare and Medicaid, both of which are significant problems. It is necessary for manufacturers to display the list price in direct-to-consumer television advertisements of prescription drugs and biological products to provide relevant information to beneficiaries to allow them to work with their prescribers to select the best overall treatment. *Form Number:* CMS–10699 (OMB control number: 0938–New); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 25; *Total Annual Responses:* 1,200; *Total Annual Hours:* 300. (For policy questions regarding this collection contact Cheri Rice at 410 786–6499.)

Dated: April 3, 2019.

William N. Parham, III,

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

[FR Doc. 2019–06884 Filed 4–5–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Building Evidence on Employment Strategies for Low-Income Families (BEES) (New Collection)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is proposing a data collection activity as part of the Building Evidence on Employment Strategies for Low-Income Families (BEES). The purpose of BEES is to evaluate the effectiveness of a broad range of innovative programs designed to boost employment and earnings among low-income Americans. Within this general focus area, ACF has a particular interest in programs that serve adults whose employment prospects have been affected by substance use disorder (SUD), opioid use disorder (OUD), mental health conditions, and justice involvement. ACF expects that a subset of programs to be evaluated will serve these specific target populations. To meet these objectives, this study will include impact and implementation evaluations for up to 21 sites, as well as descriptive work focused on other sites that have a focus on clients with opioid use and other substance abuse disorders. When possible, a randomized control trial research design will be used for the impact evaluations. The purpose of the current submission is to request approval for data collection needed for the BEES study.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing *OPREinfo collection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The BEES impact studies call for multiple data collection points with study participants. Data will be collected from study participants through the following methods: (1) Baseline information form completed by study participants at study entry, (2) study participants will also be asked to periodically update their contact information, (3) interview administered to participants in non-behavioral health sites 6 months after study entry to learn

about program participation, (4) interview administered to participants in behavioral health sites approximately 12 months after study entry to learn about employment and related outcomes, (5) individual interviews with up to 6 participants in each site and their case managers. These data will be used to assess the extent to which the programs being evaluated improve participants' employment, earnings, income, behavioral health, and well-being. They will also be used to assess the extent to which individuals in the study receive employment services.

The research team will also collect data from researchers, policy experts, state and local administrators, and program staff to identify potential sites. These data will be collected primarily by telephonic staff interviews using discussion guides.

For the implementation studies, the research team will collect data from program staff to assess program implementation. Information will be collected in consistent ways across sites and, to the extent feasible, will use the same measures and data collection procedures. Data collected from program staff during the study will include the following: (1) Site visit data including staff interviews, (2) interviews with case managers as part of the participant case studies mentioned above, and (3) program staff surveys. These data will be used to measure program implementation and fidelity, factors affecting service delivery, program staff characteristics, and staff time allocation. All impact study sites will include an implementation study. In addition, there will be several descriptive studies of other sites that use some of the implementation instruments to better understand programs serving clients with opioid use and other substance abuse disorders.

Future information collection requests and related **Federal Register** Notices will describe future data collection efforts for this project.

Respondents: The respondents in this study will include 18,600 participants enrolled in the study, 888 program staff, 10 national policy experts and researchers, and 55 state and local administrators.

ANNUAL BURDEN ESTIMATES

[3 year clearance]

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Baseline information form for participants	18,600	6,200	1	0.25	1,550
Contact update request form	5,520	1,840	1	0.1	184
6-month follow-up participant interview	1,680	560	1	0.25	140
12-month follow-up participant interview	3,840	1,280	1	0.5	640
Participant case study interview guide	126	42	1	1.5	63
Discussion guide for national policy experts and researchers	10	3	1	1	3
Discussion guide for state and local administrators	55	18	1	2	36
Discussion guide for program staff at potential sites	72	24	1	2.75	66
Program managers, staff, and partner interview guide	270	90	1.5	1.5	203
Program staff case study interview guide	126	42	1	1	42
Program staff survey	420	140	1	0.5	70

Estimated Total Annual Burden Hours: 2,997.

Authority: Section 413 of the Social Security Act, as amended by the FY 2017 Consolidated Appropriations Act, 2017 (Pub. L. 115–31).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–06898 Filed 4–5–19; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1043]

Pharmaceutical Science and Clinical Pharmacology Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on May 7, 2019, from 9 a.m. to 4 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2019–N–1043. The docket will close on May 6, 2019. Submit either electronic or written comments on this public meeting by May 6, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 6, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 6, 2019. 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.

Comments received on or before April 29, 2019, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way: