OCM will also provide an opportunity for participating practices to receive retrospective episode-based performance payments. After calculating the benchmark for each OCM participant, CMS will set a target price for chemotherapy episodes, which includes a discount. Participants whose Medicare expenditures are below the target price may receive semi-annual lump-sum performance-based payments, subject to the achievement of quality measures. In addition to the performance-based payments, participants will receive a Per-Beneficiary-Per-Month payment (PBPM) for Medicare beneficiaries with nearly all cancer types for each of the 6 months of the episode. The monthly PBPM payment is intended to pay for the enhanced services driven by the practice requirements, aimed at transforming practices towards comprehensive, person-centered, and coordinated care. The OCM PBPM is $160 per OCM beneficiary per month for the duration of each 6-month episode, and will remain constant for the 5-year model.

OCM also aims to incorporate other payers in addition to Medicare, such as commercial insurers and state Medicaid agencies. Payers must also be able to meet the following requirements for participation in the model:

1. Commit to participation in OCM for its 5-year duration, and start performance period no later than 90 days after OCM–FFS' performance period.

2. Sign a Memorandum of Understanding with the Innovation Center.

3. Enter into agreements with physician practices participating in OCM that include requirements to provide high quality care.

4. Share model methodologies with the Innovation Center.

5. Provide payments to practices for enhanced services and performance as required in the RFA.

6. Align practice quality and performance measures with OCM, when possible.

7. Provide participating practices with aggregate and patient-level data about payment and utilization for their patients receiving care in OCM, at regular intervals.

The OCM start date is expected to be in spring 2016.

For more specific details regarding OCM (including the RFA), we refer applicants to the informational materials on the Innovation Center Web site at: *http://innovation.cms.gov/initiatives/Oncology-Care/*. Applicants are responsible for monitoring the Web site to obtain the most current information available.

III. Collection of Information Requirements

Section 1115A(d)(3) of the Act, as added by section 3021 of the Affordable Care Act (Pub. L. 111–148), states that chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), shall not apply to the testing and evaluation of models or expansion of such models under this section. Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: December 22, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–03060 Filed 2–12–15; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Uniform Project Description (UPD) Program Narrative Format for Discretionary Grant Application Forms.

OMB No.: 0970–0139.

Description: The proposed information collection would renew the Administration for Children and Families (ACF) Uniform Project Description (UPD). The UPD provides a uniform grant application format for applicants to submit project information in response to ACF discretionary funding opportunity announcements. ACF uses this information, along with other OMB-approved information collections (Standard Forms), to evaluate and rank applications. Use of the UPD helps to protect the integrity of ACF's award selection process. All ACF discretionary grant programs are required to use this application format. An ACF application consists of general information and instructions; the Standard Form 424 series, which requests basic information, budget information, and assurances; the Project Description that requests the applicant to describe how program objectives will be achieved; a rationale for the project's budgeted costs; and other assurances and certifications. Guidance for the content of information requested in the Project Description is based in OMB Circular 45 CFR 75.203.

Respondents: Applicants to ACF Discretionary Funding Opportunity Announcements.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF Uniform Project Description	4,850	1	60	291,000

Estimated Total Annual Burden Hours: 291,000.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

ACF specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use

of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–03144 Filed 2–13–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0148]

Complicated Urinary Tract Infections: Developing Drugs for Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Complicated Urinary Tract Infections: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of complicated urinary tract infections (cUTIs). This guidance finalizes the revised draft guidance of the same name issued on February 24, 2012.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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.

FOR FURTHER INFORMATION CONTACT: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Complicated Urinary Tract Infections: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the development of drugs for the treatment of cUTIs.

This guidance includes recommendations for an efficacy endpoint and noninferiority trial design. The efficacy endpoint, based on resolution of clinical symptoms and eradication of bacteria from the urinary tract, was derived from previously conducted clinical trials for the treatment of cUTI. The guidance provides a scientific justification for a noninferiority margin based on historical observational data compared to the results of previously conducted clinical trials. After careful consideration of comments received in response to the revised draft guidance issued on February 24, 2012, important clarifications about trial populations and endpoints for cUTI were included in this guidance. In addition, this guidance reflects recent developments in scientific information that pertain to drugs being developed for the treatment of cUTI.

Issuance of this guidance fulfills a portion of the requirements of title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), which requires FDA to review and, as appropriate, revise not fewer than three guidance documents per year for the conduct of clinical trials with respect to antibacterial and antifungal drugs.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. 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 statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: February 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03100 Filed 2–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Society of Clinical Research Associates—Food and Drug Administration; ''Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance and Good Clinical Practice''

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Public Workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following conference: Educational Conference co-sponsored with the Society of Clinical Research Associates (SOCRA). The public workshop FDA's clinical trial requirements is designed to aid the Clinical Research Professional's understanding of the mission, responsibilities and authority of the FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among the FDA and clinical trial staff, investigators and institutional review boards (IRB). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices and biologics, as well as inspections of