Conditions for Coverage and Requirements for Outpatient Diabetes Self-Management Training Services

The regulations specifying the Medicare conditions for coverage for outpatient diabetes self-management training services are located in 42 CFR parts 410, subpart H. These conditions implement section 1861(qq) of the Act, which provides for Medicare Part B coverage of outpatient DSMT services specified by the Secretary.

Under section 1865(a)(2) of the Act and our regulations at § 410.142 (CMS process for approving national accreditation organizations) and § 410.143 (Requirements for approved accreditation organizations), we review and evaluate a national accreditation organization based on (but not necessarily limited to) the criteria set forth in § 410.142(b).

We may conduct on-site inspections of a national accreditation organization's operations and office to verify information in the organization's application and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing documentation of meetings concerning the accreditation process, evaluating accreditation results or the accreditation status decision making process, and interviewing the organization's staff.

Notice Upon Completion of Evaluation

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a notice in the **Federal Register** announcing the result of our evaluation.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare-Hospital Insurance Program; and No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: February 10, 2012.

Marilyn Tavenner,

Acting CMS Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–4277 Filed 2–23–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0145]

Agency Information Collection Activities; Proposed Collection; Comment Request; Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey entitled ''Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities.'' The data collection will obtain knowledge of State and local capacities including food safety defense staffing and expertise, laboratory capacities, and information systems to support food and feed safety and defense.

DATES: Submit either electronic or written comments on the collection of information by April 24, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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 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.

Improving Food Safety and Defense Capacity at the State and Local Level: Review of State and Local Capacities—(OMB Control Number 0910—New)

The Food Safety Modernization Act (FSMA) (Pub. L. 111–353) states that a review must be conducted to assess the State and local capacities to show needs for enhancement in the areas or staffing levels, laboratory capacities, and information technology systems. This mandate is referenced again in FSMA section 110 stating that a review of current food safety and food defense capabilities must be presented to Congress no later than 2 years after the date of enactment (enactment date January 4, 2011). In order to facilitate this review, this team must distribute a

survey to State and local health and agriculture agencies. In doing so, this team will be able to analyze the gaps and trends to occur at these respective levels which will allow FSMA counterparts to develop ways to enhance food safety and food defense. In developing these strategies, FDA will be able to work with other Federal Agencies to improve and expand food safety and defense to ultimately reach a state of an integrated food safety system.

FDA will conduct the survey electronically which allows FDA to conduct streamlines analysis while creating a low-burden, user-friendly environment for respondents to complete the survey. Once the results have been tabulated, a report will be generated and given to FSMA section 110 to present to Congress as well as FSMA section 205(c)1 to develop the strategies to leverage and enhance current State and local capacities.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Current State and local government employees	1,400	1	1,400	1	1,400

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

This survey is slated to be a one-time survey. Through testing on six FDA employees who were formerly State employees, the survey development team has come to the conclusion that it should take no longer than 1 hour for the 1,400 current State and local government employees to complete the survey. FDA is requesting this data collection burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: February 17, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4289 Filed 2–23–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0148]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft 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). Specifically, this guidance addresses FDA's current thinking regarding the overall drug development program for the treatment of cUTIs, including clinical trial designs to support approval of drugs.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 24, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft 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 draft guidance for industry entitled ''Complicated Urinary Tract Infections: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors and investigators in the development of drugs for the treatment of cUTIs. This draft guidance revises and replaces the draft guidance for industry entitled ''Complicated Urinary Tract Infections and Pyelonephritis—Developing Antimicrobial Drugs for Treatment'' published in 1998.

Infections of the urinary tract occurring in patients with underlying functional or anatomic abnormalities of the urinary tract are defined as cUTIs. Infections of the kidney, called pyelonephritis, can occur in persons without underlying abnormalities of the urinary tract, but are also considered to be a subset of cUTI. Different types of bacteria can cause cUTI, but Gram-negative bacteria are most often associated with cUTI.

This draft 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 trials for the treatment of cUTI. The draft guidance provides a scientific justification for a noninferiority margin based on historical observational data compared to the results of previously conducted clinical trials. The draft guidance also provides a discussion about patients with unmet need who have an infection caused by bacterial pathogens that show resistance to most antibacterial drugs on in vitro susceptibility testing.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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.