

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10411]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* State Balancing Incentive Payments Program (BIPP); *Use:* The Balancing Incentive Program requires that States undertake three structural changes to their long-term services and supports (LTSS) systems to increase nursing home diversions and access to community-based care: implementation of a No Wrong Door/Single Entry Point System, conflict-free case management, and the use of a core standardized assessment for supporting eligibility determination and service planning. In addition, grantee States must increase their community-based LTSS expenditures relative to their overall expenditures on LTSS to a minimum of 25% or 50%. State Medicaid agencies are responsible for developing the submissions to CMS in order to participate in this opportunity. If the statutory requirements are met, CMS will approve the State's submission, giving the State the authority to implement the changes in the program and to draw down the increased FMAP funds. *Form Number:* CMS-10411 (OMB 0938-1145); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 56; *Total Annual*

Responses: 56; *Total Annual Hours:* 2,240. (For policy questions regarding this collection contact Effie George at 410-786-8639. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by November 15, 2011:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: September 13, 2011.

Martique Jones,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Conference on the International Conference on Harmonisation Q10 Pharmaceutical Quality System: A Practical Approach to Effective Life-Cycle Implementation of Systems and Processes for Pharmaceutical Manufacturing; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA), in cosponsorship with the

Parenteral Drug Association (PDA), is announcing a public conference dedicated to teaching the principles of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) entitled "Pharmaceutical Quality System (ICH Q10) Conference: A Practical Approach to Effective Life-Cycle Implementation of Systems and Processes for Pharmaceutical Manufacturing." The conference will span 2-and-one-half days and will be a unique opportunity to learn the principles from companies that have implemented a Pharmaceutical Quality System across the product life cycle according to the ICH Q10 model. These companies are reaping the benefits that come from establishing and maintaining a state of control, continual improvement, enhancing regulatory compliance, and meeting quality objectives every day.

Date and Time: The public conference, which will include an exhibition, will be held on Tuesday, October 4, 2011, from 8:30 a.m. to 6:30 p.m.; Wednesday, October 5, 2011, from 8 a.m. to 5:30 p.m.; and Thursday, October 6, 2011, from 8 a.m. to 1 p.m.

Location: The event will be held at the Crystal Gateway Marriott, 1700 Jefferson Davis Hwy., Arlington, VA, 703-920-3230, *Fax:* 703-271-5212.

Contact Person: Wanda Neal, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East West Hwy., suite 200, Bethesda, MD 20814; 301-656-5900, ext. 111; *Fax:* 301-986-1093; e-mail: neal@pda.org.

Attendees are responsible for their own accommodations. To make reservations at the reduced conference rate, contact the Marriott Crystal Gateway Hotel (see *Location*) and cite meeting code "PDA." Room rates are single/double: \$229.00, plus 10.5 percent State and local taxes. Reservations can be made on a space and rate available basis.

Registration: You are encouraged to register at your earliest convenience. The PDA registration fees cover the cost of facilities, materials, and breaks. Seats are limited; please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Those accepted into the conference will receive confirmation. Registration will close after the conference is filled. Onsite registration will be available on a space-available basis on the day of the public conference beginning at 7 a.m. on October 4, 2011.

The cost of registration is as follows: