

contact: nationalconversation@cdc.gov or Julie Fishman at 770-488-0629.

Tanja Popovic,

*Deputy Associate Director for Science,
Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-437]

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:* Extension of currently approved collection; *Title of Information Collection:* Psychiatric Unit Criteria Work Sheet and Supporting Regulations 412.25 and 412.27; *Use:* Certain hospital units are excluded from the Medicare Prospective Payment System (PPS). The exclusion of units is not optional on the part of the provider but is required by section 1886(d)(1)(B) of the Social Security Act. That section excludes psychiatric hospitals, rehabilitation hospitals, hospitals whose inpatients are predominantly individuals under 18 years of age (children's hospitals), and psychiatric and rehabilitation units which are a distinct part of a hospital.

CMS proposes to continue the current process of performing initial verifications and annual reverifications to determine that psychiatric units

continue to comply with the regulatory criteria at 42 CFR 412.25 and 42 CFR 412.27 of the PPS regulations. These regulations state the criteria that distinct part units must meet for exclusion.

If, as a result of the regular survey process a hospital is certified as a psychiatric hospital by the State survey agency (SA), then it automatically satisfies the regulatory criteria for exclusion. Thus, no additional verification is required for psychiatric hospitals. Some verification is needed, however, to ensure that other types of hospitals and units meet the criteria for exclusion.

Consequently, CMS instructed the Fiscal Intermediaries (FIs) and SAs to perform certain verification activities, beginning in October 1983 when PPS was implemented. CMS originally developed the CMS-437 as SA Worksheet for verifying exclusions from PPS for psychiatric units.

Since April 9, 1994, PPS-excluded psychiatric units already excluded from the PPS have met CMS's annual requirement for PPS-exclusion by self-attesting that they remain in compliance with the PPS exclusion criteria. Under the current procedure, all psychiatric units applying for first-time exclusion are surveyed by the SAs. The SAs also perform surveys to investigate complaint allegations and conduct annual sample reverification surveys on 5 percent of all psychiatric units.

The aforementioned exclusions continue to exist and thus CMS proposes to continue to use the Criteria Worksheet, Forms CMS-437 for verifying first-time exclusions from the PPS, for complaint surveys, for its annual 5 percent validation sample, and for facility self-attestation. These forms are related to the survey and certification and Medicare approval of the PPS-excluded units. *Form Number:* CMS-437 (OMB#: 0938-0358); *Frequency:* Annually; *Affected Public:* Private sector businesses or other for-profits; *Number of Respondents:* 1,333; *Total Annual Responses:* 1,333; *Total Annual Hours:* 333. (For policy questions regarding this collection contact Kelley Leonette at 410-786-6664. 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 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 *February 1, 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: November 24, 2010.

Martique Jones,

Director, Regulations Development 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-2010-N-0597]

Agency Information Collection Activities; Proposed Collection; Comment Request; Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

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, 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 the burden hours associated with indexing of legally marketed unapproved new animal drugs for minor species.