

and Not-for-profit institutions; *Number of Respondents*: 2600; *Total Annual Responses*: 2600; *Total Annual Hours*: 100.

CMS is requesting OMB review and approval of these collections by *September 16, 2005*, with a 180-day approval period. Written comments and recommendation will be considered from the public if received by the individuals designated below by *September 12, 2005*.

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/regulations/prs> or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed to the designees referenced below by *September 12, 2005*:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: William N. Parham, III, and, OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 5, 2005.

**Michelle Shortt,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-29/30, CMS-10150, CMS-381, CMS-10161, CMS-10134, CMS-R-137]

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services.

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 a currently approved collection; *Title of Information Collection:* Request for Certification as Rural Health Clinic and Rural Health Clinic Survey Report Form and Supporting Regulations in 42 CFR 491.1-491.11; *Form No.:* CMS-29 and CMS-30 (OMB #0938-0074); *Use:* The form CMS-29 is utilized as an application to be completed by suppliers of Rural Health Clinic (RHC) services requesting participation in the Medicare/Medicaid programs. This form initiates the process of obtaining a decision as to whether the conditions for certification are met as a supplier of RHC services. It also promotes data reduction or introduction to and retrieval from the Online Survey and Certification and Reporting System (OSCAR) by CMS Regional Offices (RO). The Form CMS-30 is an instrument used by the State survey agency to record data collected in order to determine RHC compliance with individual conditions of participation and to report it to the Federal government. The form is primarily a coding worksheet designed to facilitate data reduction (keypunching) and retrieval into OSCAR at the CMS ROs. The form includes basic information on compliance (*i.e.*, met, not met and explanatory statements) and does not require any descriptive information regarding the survey activity itself; *Frequency:* Reporting—Annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 698; *Total Annual Responses:* 698; *Total Annual Hours:* 1,222.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Collection of Drug Pricing and Network Pharmacy Data from Medicare Prescription Drug Plans (PDPs and MA-PDs) and

Supporting Regulations in 42 CFR 423.48; *Form No.:* CMS-10150 (OMB #0938-0951); *Use:* Both stand alone prescription drug plans (PDPs) and Medicare Advantage Prescription Drug (MA-PDs) plans will be required to submit drug pricing and pharmacy network data to CMS. These data will be made publicly available to Medicare beneficiaries through the new Medicare prescription drug plan finder tool that will be launched in the fall of 2005 on <http://www.medicare.gov>. The purpose of the data is to enable beneficiaries to compare, learn, select and enroll in a plan that best meets their needs; *Frequency:* Reporting—Weekly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 350; *Total Annual Responses:* 18,200; *Total Annual Hours:* 36,400.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Identification of Extension Units of Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP) Providers and Supporting Regulations in 42 CFR Sections 485.701-485.729; *Form No.:* CMS-381 (OMB #0938-0273); *Use:* Medicare provides OPT/OSP providers to be surveyed to determine compliance with Federal regulations. All locations where OPT/OSP providers furnish services must meet these requirements. The CMS-381 is the form used to identify all the OPT/OSP locations. *Frequency:* Reporting—Annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 2960; *Total Annual Responses:* 2960; *Total Annual Hours:* 740.

4. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* New Freedom Initiative—Web-based Reporting System for Grantees; *Form No.:* CMS-10161 (OMB #0938-NEW); *Use:* CMS currently awards competitive grants to States and other eligible entities for the purpose of designing and implementing effective and enduring improvements in community-based long-term services and supporting systems. We currently require grantees to report quarterly, semi-annual, and or annually, depending on the grant type. CMS requires the information obtained through Web-based grantee reporting for two reasons: (1) in order to effectively monitor the grants, and; (2) to report to Congress and other interested stakeholders the progress and obstacles experienced by the grantees. The grantees are the respondents to the Web-based reporting system; *Frequency:* Reporting—Quarterly, Semi-annually,

and Annually; *Affected Public*: State, Local or Tribal Government and Not-for-profit institutions; *Number of Respondents*: 298; *Total Annual Responses*: 836; *Total Annual Hours*: 6,440.

5. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Physician Group Practice (PGP) Standardized Ambulatory Care Quality Measure Collection Initiative; *Use*: The Benefits Improvement & Protection Act of 2000 mandated the Physician Group Practice (PGP) Demonstration and gave the Secretary discretion to use quality measures to assess physician performance in order to reward them for improvements in the quality and efficiency of health care. This demonstration is intended to strengthen the Medicare program by offering innovative models to beneficiaries that improve quality and access and lower costs. As a result, Medicare beneficiaries will directly benefit from these innovative models. The demonstration represents the first pay for performance project for physician group practices and will enable comparisons across groups and geography; *Form Number*: CMS-10134 (OMB #0938-0942); *Frequency*: Annually; *Affected Public*: Business or other for-profit and Not-for-profit institutions; *Number of Respondents*: 10; *Total Annual Responses*: 10; *Total Annual Hours*: 790.

6. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Internal Revenue Service/Social Security Administration/Centers for Medicare and Medicaid Services Data Match and Supporting Regulations in 42 CFR 411.20-491.206; *Form No.*: CMS-R-137 (OMB #0938-0565); *Use*: The Data Match project and information collection activity provides a "check and balance" against the Medicare program relying solely on a single information collection system. It gives CMS the opportunity to pursue collection of identified mistaken payments (within legal constraints) and to update incorrect status indicators to prevent further incorrect suspensions or mistaken payment or denial. Employers identified through a match of IRS, SSA, and Medicare records will be contacted concerning group health plan coverage of identified individuals to ensure compliance with Medicare Secondary Payer provisions found at 42 U.S.C. 1395y(b); *Frequency*: Reporting—Annually; *Affected Public*: Business or

other for-profit, Not-for-profit institutions, Farms, Federal, State, Local or Tribal Government; *Number of Respondents*: 341,065; *Total Annual Responses*: 341,065; *Total Annual Hours*: 1,986,810.

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/regulations/pa/>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice to the address below: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Melissa Musotto, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 5, 2005.

**Michelle Shortt,**

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

[FR Doc. 05-15977 Filed 8-11-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2000D-0835]

#### **Draft Guidance for Industry on Conjugated Estrogens, USP-LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence; Withdrawal of Guidance**

**AGENCY**: Food and Drug Administration, HHS.

**ACTION**: Notice; withdrawal.

**SUMMARY**: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance for industry entitled "Conjugated Estrogens, USP-LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence." FDA is withdrawing the draft guidance because the published methodology limits the submission of scientifically valid information to the agency that may be based on different methodologies. FDA does not want to dictate the scientific approach for developing adequate methods.

**FOR FURTHER INFORMATION CONTACT**: David J. Cummings, Center for Drug Evaluation and Research (HFD-357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5187.

**SUPPLEMENTARY INFORMATION**: FDA is announcing the withdrawal of a draft guidance for industry entitled "Conjugated Estrogens, USP-LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence." The agency announced the availability of the guidance in the **Federal Register** of March 9, 2000 (65 FR 12556). The draft guidance was originally intended to provide recommendations to applicants on how to use the liquid chromatography mass spectrometry (LC-MS) method to address both qualitative chemical characterization and qualitative pharmaceutical equivalence for natural source conjugated estrogens. FDA is withdrawing the guidance because advances in technology allow for the possibility of using different methodologies. FDA does not want to inhibit companies from using a methodology that might provide additional scientific data to support characterization and pharmaceutical equivalence for conjugated estrogens in the future. If submitted, these data would be evaluated to determine applicability of the method before an application could be approved.

Dated: August 5, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2005-22049]

#### **Collection of Information Under Review by Office of Management and Budget (OMB): OMB Control Numbers: 1625-0035 and 1625-0051**

**AGENCY**: Coast Guard, DHS.

**ACTION**: Request for comments.

**SUMMARY**: In compliance with the Paperwork Reduction Act of 1995, the Coast Guard intends to seek the approval of OMB for the renewal of two Information Collection Requests (ICRs). The ICRs are for 1625-0035, Title 46 CFR Subchapter Q: Lifesaving, Electrical, and Engineering Equipment, Construction and Materials & Marine