

Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, 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 function; (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:* Independent Renal Dialysis Facility Cost Report and supporting regulations 42 CFR 413.20 and 42 CFR 413.24; *Form No.:* CMS-265-94 (OMB# 0938-0236); *Use:* Providers of services participating in the Medicare program are required under sections 1815(a), 1833(e), 1861(v)(1)(A) and 1881(b)(2)(B) of the Social Security Act to submit annual information to achieve reimbursement for health care services rendered to Medicare beneficiaries. The Form CMS 265-94 cost report is needed to determine the amount of reasonable cost due to the providers for furnishing medical services to Medicare beneficiaries.

The data collected will be used for the following additional purposes: (a) Determination of reimbursement rates for renal dialysis treatments, self-dialysis training, and other reasonable and medically necessary services rendered in connection with these treatments; (b) justification of requests for adjustments or exceptions in the reimbursements rates; and, (c) accumulation of data for overall evaluation. Worksheet B, Worksheet C and Worksheet D have been modified to implement provisions of the Medicare Prescription Drug Improvement and Modernization Act of 2003. On Worksheet B, the allocation of Administrative and General cost to Separately Billable Drugs was eliminated. On Worksheet C, two columns were sub-divided to identify services before, on or after 4/1/2005. A line was added to Worksheet D to report bad debts for dual eligible beneficiaries. None of these changes request new information; rather, the changes require reporting of data in greater detail than was previously reported. *Frequency:*

Reporting—Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 4,885; *Total Annual Responses:* 4,885; *Total Annual Hours:* 957,460.

#### 2. Type of Information Collection

*Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Participating Physician or Supplier Agreement; *Form No.:* CMS-460 (OMB# 0938-0373); *Use:* The CMS-460 is the agreement a physician, supplier or their authorized official signs to participate in Medicare Part B. By signing the agreement to participate in Medicare, the physician, supplier or their authorized official agrees to accept the Medicare-determined payment for Medicare covered services as payment in full and to charge the Medicare Part B beneficiary no more than the applicable deductible or coinsurance for the covered services. For purposes of this explanation, the term a supplier means any person or entity that may bill Medicare for Part B services (e.g. DME supplier, nurse practitioner, supplier of diagnostic tests) except a Medicare provider of services (e.g. hospital), which must participate to be paid by Medicare for covered care.

There are additional benefits associated with payment for services paid under the Medicare fee schedule. Payments made under the Medicare fee schedule for physician services to participating physicians and suppliers are based on 100 percent of the Medicare fee schedule amount, while the Medicare fee schedule payment for physician services by nonparticipating physicians and suppliers is based on 95 percent of the fee schedule amount. Physicians and suppliers who do not participate in Medicare are subject to limits on their actual charges for unassigned claims for physician services. These limits, known as limiting charges, cannot exceed 115 percent of the non-participant fee schedule, which is set at 95 percent of the full fee schedule amount. In addition, if a physician or supplier does not accept assignment on a claim for Medicare payment, the physician or supplier must collect payment from the beneficiary. If the physician or supplier accepts assignment on the claim, Medicare pays its share of the payment directly to the physician or supplier, resulting in faster and more certain payment. *Frequency:* Reporting, Other—when starting a new business; *Affected Public:* Business or other for-profit; *Number of Respondents:* 6000; *Total Annual Responses:* 6000; *Total Annual Hours:* 1500.

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](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 or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: May 10, 2007.

**Michelle Shortt,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

*Title:* Income Withholding for Support (IWO) (Formerly: Order to Withhold Income for Child Support and Notice of an Order to Withhold Income for Child Support).

*OMB No.:* 0970-0154.

*Description:* Pub. L. 104-193, The Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996, Section 324, requires the Federal Office of Child Support Enforcement (OCSE) to develop a standardized form to collect child support payments from an obligor's employer. The form, which promotes standardization and is used for title IV-D and non-IV-D cases that require income withholding, expires 5/31/2007, and the Administration for Children and Families is taking this opportunity to revise the form and its instructions.

Overall, the language and format of the form have been edited, modified, and made easier to read and comprehend. The two-page form provides a detailed legal description of the established order, support amounts, and remittance information an employer

needs to withhold payments from an obligor who owes child support. One of the new fields on the form is for the attachment of lump sum payments by employers. This addition allows the issuing entity to instruct the employer with respect to the attachment and remittance of lump sum payments. Fields for child's name and date of birth

have been moved to the front of the form, allowing the employer community to easily identify who the form is for and to avoid implementation of duplicate orders. Other changes that have enhanced the form include: A simplified title, clear identification of who is sending the form, and

modifications to allow the employer to easily report employee terminations. The electronic IWO (e-IWO) allows States to transmit IWOs electronically and employers to notify States electronically regarding the status of IWOs. *Respondents:* States, Territories, Tribes, and Courts.

ANNUAL BURDEN ESTIMATES

| Instrument                                      | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Income Withholding for Support (IWO) .....      | 58                    | 206,897                            | .0017                             | 20,400             |
| ELECTRONIC Income Withholding for Support ..... | 20                    | 60,000                             | .0008                             | 960                |
| IWO—Submitted Manually .....                    | 1,800                 | 1,321                              | .0840                             | 199,735            |

*Estimated Total Annual Burden Hours:* 221,095.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: May 15, 2007.

**Robert Sargis,**

*Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2007D-0166]

**International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products, VICH GL43, Request for Comments; Availability**

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

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability for comments of a draft guidance document for industry (#185) entitled "Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products," VICH GL43. This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document has been developed as a harmonized standard to aid in development of mutually acceptable target animal safety (TAS) studies for the relevant governmental regulatory bodies.

**DATES:** Submit written or electronic comments on the draft guidance by June 18, 2007, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center

for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Laura Hungerford, Center for Veterinary Medicine, (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6439, e-mail: [laura.hungerford@fda.hhs.gov](mailto:laura.hungerford@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical