

changes within the Agency for Health Care Policy and Research (AHCPR). Specifically, AHCPR is aligning functions so that the Agency can more efficiently and effectively meet the needs of other organizations for scientific information on which they can base clinical guidelines, performance measures, technology assessments, and other quality improvement tools. The Agency is establishing a new Center for Practice and Technology Assessment, in which will be located the Office of the Forum for Quality and Effectiveness in Health Care as well as the functions of the previous Center for Health Care Technology.

Under *Section E-10, Organization*, following *E. Office of Scientific Affairs*, delete *F. through N.* and insert the following:

F. Center for Cost and Financing Studies.

G. Center for Health Information Dissemination.

H. Center for Information Technology.

I. Center for Organization and Delivery Studies.

J. Center for Outcomes and Effectiveness Research.

K. Center for Primary Care Research.

L. Center for Quality Measurement and Improvement.

M. Center for Practice and Technology Assessment.

Under heading *Section E-20, Functions*, delete the titles and statements for the *Office of the Forum*

for *Quality and Effectiveness in Health Care (EB)* and the *Center for Health Care Technology (EE)*, and following the statement for the *Center for Quality Measurement and Improvement (EL)*, insert the following title and statement:

Center for Practice and Technology Assessment (EM). Conducts and supports systematic assessments of clinical practices and health care technologies as well as methodologic and implementation research. Specifically: (1) Conducts and supports the development of evidence reports and technology assessments on health care treatments, conditions, procedures, and technologies, including alternative and complementary therapies; (2) conducts and supports research focusing on methodologies used in systematic reviews and implementation of evidence-based recommendations, materials, and technologies assessments into the health care system; (3) facilitates the development and operations of a National Guideline Clearinghouse; (4) facilitates the work of the U.S. Preventive Services Task Force; (5) represents the Agency in meetings with experts and organizations in the areas of evidence-based assessments of practice and technologies, and convenes conferences on these topics; and (6) is the focus of the Office of the Forum for Quality and Effectiveness in Health Care.

All delegations and redelegations of authority to officers and employees of the Agency for Health Care Policy and

Research which were in effect immediately prior to the effective date of this reorganization shall continue in effect pending further redelegation, provided they are consistent with this reorganization.

These changes are effective upon date of signature.

Dated: October 31, 1997.

John M. Eisenberg,

Administrator.

[FR Doc. 97-30209 Filed 11-17-97; 8:45 am]

BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission For OMB Review; Comment Request

Title: Order/Notice to Withhold Income for Child Support.

OMB No.: 0970-0154.

Description: The child support enforcement agency needs the information to process court/tribunal administered direct income withholding orders to collect support. The form will provide employers with the required amounts to deduct child support payment from an employee's/obligor's income.

Respondents: State, Local or Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Order/Notice	54	1,620	.1666	14,579

Estimated Total Burden Hours: 14,579.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

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, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Desk Officer for ACF.

Dated: November 12, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97-30219 Filed 11-17-97; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission For OMB Review; Comment Request

Title: Required Data Elements for Paternity Establishment Affidavits.

OMB No.: New Collection.

Description: Public Law 104-193 requires the Secretary of the Department of Health and Human Services to specify the minimum data requirements of an affidavit to be used for the voluntary acknowledgment of paternity. Public Law 104-193 also requires States to enact laws requiring the development and use of an affidavit which met the

minimum requirements specified by the Secretary and to give full faith and credit to such an affidavit signed in any other State according to its procedures. The Department established a task group composed of Federal and State staff to recommend minimum data elements for all State paternity acknowledgment affidavits. The minimum data elements were crafted to balance the need for a tool for collecting

information necessary to the establishment of a child support order and the need for a user-friendly form that addresses only the data necessary to establish legal paternity. *The minimum data elements are:* The current full name, social security number and date of birth of mother, father, and child; address of mother and father, birthplace of child; an explanation of the legal consequences of signing the affidavit; a

statement indicating both parents understand their rights, responsibilities, alternatives and the consequences of signing the affidavit; the place the affidavit was completed; and signature lines for mother, father and witnesses or notaries.

Respondents: Individuals and Households; Not-for-Profit Institutions; and State, Local or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Affidavits	2,000,000	.2243	.166	74,468

Estimated Total Annual Burden Hours: 74,468.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

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, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: November 12, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97-30220 Filed 11-17-97; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0444]

International Conference on Harmonisation; Draft Guidance on the Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft guidance entitled "S4A Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance is intended to provide guidance on the duration of chronic toxicity testing in rodents and nonrodents as part of the safety evaluation of a drug product.

DATES: Written comments by January 20, 1998.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Copies of the draft guidance are available from the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4573.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD-24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6758.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to

promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In July 1997, the ICH Steering Committee agreed that a draft guidance entitled "S4A Duration of Chronic