

divested, or that the manner of the divestitures is not acceptable, the parties must unwind the sale and divest the assets within six months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six months, the Commission may appoint a trustee to divest the Products.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Teva and Barr to provide transitional services to enable the Commission-approved acquirers to obtain all of the necessary approvals from the FDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Teva or Barr. Most of the oral contraceptive products had been divested to Teva pursuant to a Commission Order in the matter of *Watson Pharmaceuticals, Inc./ Andrx Corporation*, Docket No. C-4172 (October 31, 2006). This proposed D&O does not relieve Watson of any of its obligations pursuant to the Commission Order issued in the above referenced Watson/Andrx matter.

The Commission has appointed William Rahe of Quantic Regulatory Services, LLC ("Quantic") to oversee the asset transfer and to ensure Teva's and Barr's compliance with all of the provisions of the proposed Consent Agreement. Mr. Rahe is a senior consultant at Quantic and has several years of experience in the pharmaceutical industry. He is a highly-qualified expert on FDA regulatory matters and currently advises Quantic clients on achieving satisfactory regulatory compliance and interfacing with the FDA. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires Teva and Barr to file reports with the Commission periodically until

the divestitures and transfers are accomplished.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS-0990-New]

**Agency Information Collection Request; 60-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request 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.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number,

OMB number, and OS document identifier, to

*Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690-6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60 days.

*Proposed Project:* Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law—OMB No. 0990-NEW—Office of the Secretary.

*Abstract:* The proposed information collection is contained in the Final Rule entitled, "Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law." The purpose of this collection is to ensure, by requiring written certification of compliance similar to other, existing certifications currently made by funding recipients and applicants, that recipients of Department funds are aware of and comply with the legal obligations imposed on them by the Church Amendments (42 U.S.C. 300a-7), Public Health Service Act section 245 (42 U.S.C. 238n) and the Weldon Amendment (Consolidated Appropriations Act, 2008, Pub. L. 110-161 Div. G section 508(d), 121 Stat. 1844, 2209). We estimate the universe and number of entities that would be required to certify to be 571,947. The act of certification consists of reviewing the certification language, reviewing relevant entity policies and procedures, and reviewing files before signing. Although some entities may need to sign a certification statement more than once, we assume that the entity will only carefully review the language, procedures and their files before signing the initial statement each year.

**ESTIMATED ANNUALIZED BURDEN TABLE**

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Hospitals (less than 100 beds) .....	2403	1	30/60	1202
Hospitals (less than 100 beds) .....	1129	1	30/60	565
Hospitals (200-500 beds) .....	1160	1	30/60	580
Hospitals (more than 500 beds) .....	244	1	30/60	122
Nursing Homes (less than 50 beds) .....	2388	1	30/60	1194
Nursing Homes (50-99 beds) .....	5819	1	30/60	2910
Nursing Homes (99-199 beds) .....	6877	1	30/60	3439
Nursing Homes (more than 200 beds) .....	1037	1	30/60	519
Physicians Offices .....	234200	1	30/60	117100
Offices of Other Health Care Practitioners .....	115378	1	30/60	57689
Outpatient Care Centers .....	26901	1	30/60	13451

ESTIMATED ANNUALIZED BURDEN TABLE—Continued

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Medical and Diagnostics Laboratories .....	11856	1	30/60	5928
Home Health Care Services .....	20184	1	30/60	10092
Pharmacies (chain and independent) .....	58109	1	30/60	29055
Dental Schools .....	56	1	30/60	28
Medical Schools (Allopathic) .....	125	1	30/60	63
Medical Schools (Osteopathic) .....	20	1	30/60	10
Nursing Schools (Licensed practical) .....	1138	1	30/60	569
Nursing Schools (Baccalaureate) .....	550	1	30/60	275
Nursing Schools (Associate Degree) .....	885	1	30/60	443
Nursing Schools (Diploma) .....	78	1	30/60	39
Occupational Therapy Schools .....	142	1	30/60	71
Optometry Schools .....	17	1	30/60	9
Pharmacy Schools .....	92	1	30/60	46
Podiatry Schools .....	7	1	30/60	4
Public Health Schools .....	37	1	30/60	19
Residency Programs (accredited) .....	8494	1	30/60	4247
Health Insurance Carriers and 3rd party Administrators .....	4578	1	30/60	2289
Grant awards .....	63741	1	30/60	31871
Contractors .....	4245	1	30/60	2123
State and territorial governments .....	57	1	30/60	29
Totals .....	571947	.....	.....	285981

**Seleda M. Perryman,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60-Day-09-09AI]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 or send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS D-74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

Evaluation of the Action Plan for the National Public Health Initiative on Diabetes and Women's Health—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Approximately 24 million Americans have diabetes, and more than 9 million of these individuals are women. It is projected that from 2000 to 2025, women will represent more than half of all cases of diabetes in the United States.

Diabetes can have unique and profound effects on women's lives and health. For instance, diabetes is a more common cause of coronary heart disease among women than men. In addition, among people with diabetes, the prognosis of heart disease is worse for women than men, with women having poorer quality of life and lower survival rates. The burden of diabetes for women is also unique because the disease can affect mothers and their unborn children. After pregnancy, as many as

10-50% of women with gestational diabetes mellitus (GDM) are diagnosed with type 2 diabetes within five years of delivery. The offspring of women with a history of gestational diabetes are also at risk for becoming obese during childhood or adolescence, which may increase their risk of developing type 2 diabetes later in life.

To address the burden of diabetes on women's health, the National Public Health Initiative on Diabetes and Women's Health ("The Initiative") was established to provide support and resources for the creation and implementation of a national public health Action Plan. The Initiative is co-sponsored by the American Diabetes Association (ADA), the American Association of Diabetes Educators (AADE), the American Public Health Association (APHA), the Association of State and Territorial Health Officials (ASTHO), and the Centers for Disease Control and Prevention (CDC). CDC's Division of Diabetes Translation is dedicated to the prevention and control of diabetes, and to reducing or eliminating health disparities through targeted research, programs, and partnerships.

The Initiative's Action Plan identifies gaps in diabetes-related research and programmatic activities, and strategic objectives, within the areas of: (1) Community health; (2) diabetes state programs; (3) education and community outreach; (4) quality of care; (5) research; and (6) surveillance. Co-sponsors of the Initiative and other partner organizations have been encouraged to act on the deficiencies