ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OTPS

Form name	Number of facilities (OTPs)	Responses per facility	Burden/ response (hours) to OTP	Annual burden (hours) to OTPs
SAMHSA OTP Mortality Form	1,200	2 per year	0.5	1200.00

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR MEDICAL EXAMINER (ME)

Form name	Number of ME follow-ups	Responses per ME	Burden/ response (hours) for ME	Annual burden (hours) for ME
SAMHSA OTP mortality form	230	1 per year	0.1	2.3

SAMHSA believes that the recordkeeping requirements in the regulation are customary and usual practices within the medical and rehabilitative communities and has not calculated a response burden for them. The recordkeeping requirements set forth in 42 CFR 8.4, 8.11 and 8.12 include maintenance of the following: 5-year retention by accreditation bodies of certain records pertaining to accreditation; documentation by an OTP of the following: a patient's medical examination when admitted to treatment, A patient's history, a treatment plan, any prenatal support provided the patient, justification of unusually large initial doses, changes in a patient's dosage schedule, justification of unusually large daily doses, the rationale for decreasing a patient's clinic attendance, and documentation of physiologic dependence.

The rule also includes requirements that OTPs and accreditation organizations disclose information. For example, 42 CFR 8.12(e)(1) requires that a physician explain the facts concerning the use of opioid drug treatment to each patient. This type of disclosure is considered to be consistent with the common medical practice and is not considered an additional burden. Further, the rule requires, under Sec. 8.4(i)(1) that accreditation organizations shall make public their fee structure; this type of disclosure is standard business practice and is not considered a burden.

The information requested from OTPs on mortality report form should be readily available to any OTP that has met accreditation standards. The OTP should not find any need to otherwise analyze or synthesize new data in order to complete this form.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail her a copy at *summer.king@samhsa.hhs.gov.* Written comments should be received within 60 days of this notice.

Dated: June 15, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–14554 Filed 6–19–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–09–0278]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

National Hospital Ambulatory Medical Care Survey [OMB No. 0920–0278]—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on ''utilization of health care'' in the United States. The National Hospital Ambulatory Medical Care Survey (NHAMCS) has been conducted annually since 1992. This revision seeks approval to collect data for an additional three years and to expand the survey to include free-standing ambulatory surgical centers. The purpose of NHAMCS is to meet the needs and demands for statistical information about the provision of ambulatory medical care services in the United States. Ambulatory services are rendered in a wide variety of settings, including physicians' offices and hospital outpatient and emergency departments.

The target universe of NHAMCS is in-person visits made to emergency departments (EDs) and outpatient departments (OPDs) of non-Federal, short-stay hospitals (hospitals with an average length of stay of fewer than 30 days) or those whose specialty is general (medical or surgical) or children's general. In 2009, NHAMCS was expanded to include visits to hospital-based ambulatory surgery centers (ASCs). NCHS seeks OMB approval to expand NHAMCS to include free-standing ASCs in 2010. The objective of this new collection will be to collect data about free-standing ambulatory surgery centers, the patients they serve, and the services they deliver. The intent is for NHAMCS to become the principal source of data on ASC services in the United States. The data to be collected include patient characteristics, diagnoses, surgical and nonsurgical procedures, provider and type of anesthesia, time in and out of surgery and postoperative care, and discharge disposition.

Users of NHAMCS data include, but are not limited to, congressional offices, Federal agencies, State and local governments, schools of public health, colleges and universities, private industry, nonprofit foundations, professional associations, clinicians, researchers, administrators, and health planners. There are no costs to the respondents other than their time. The

total estimated annualized burden hours are 10,832.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)
Hospital Chief Executive Officer	Hospital Induction (NHAMCS–101)	482	1	1
Ancillary Service Executive	Freestanding ASC Induction (NHAMCS–101FS).	200	1	1.5
Ancillary Service Executive	Ambulatory Unit Induction (NHAMCS–101U)	1,779	1	1
Physician/Registered Nurse/Medical Record Clerk.	ED Patient Record form NHAMCS–100 (ED)	225	100	7/60
Physician/Registered Nurse/Medical Record Clerk.	OPD Patient Record form NHAMCS–100 (OPD).	128	200	6/60
Physician/Registered Nurse/Medical Record Clerk.	ASC Patient Record Form NHAMCS–100 (ASC).	208	100	6/60
Medical Record Clerk	Pulling and re-filing Patient Records (ED, OPD, and ASC).	425	133	1/60
Physician/Physician Assistant/Nurse Practitioner/Nurse Midwife.	Cervical Cancer Screening Supplement (CCSS) (NHAMCS–906).	255	1	15/60

Dated: June 15, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–14553 Filed 6–19–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0263]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer Television and Print Advertisements for Prescription Drugs

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Experimental Study of Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs. This study is designed to communicate quantitative information about product benefits in DTC print and television ads.

DATES: Submit written or electronic comments on the collection of information by [*August 21, 2009*

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Liz Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experimental Study of Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs—New

The Federal Food, Drug, and Cosmetic Act (the act) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks.[1] By its nature, the presentation of

[1] For prescription drugs and biologics, section 502 of the act requires advertisements to contain ''information in brief summary relating to side effects, contraindications, and effectiveness'' (21 U.S.C. 352(n)).

[2] See Swartz, L., S. Woloshin, W. Black, et al., The Role of Numeracy in Understanding the Benefit of