ESTIMATED ANNUALIZED BURDEN HOURS

Forms	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Recruit Letters	10,754	1	15/60	2,689
Web Survey	10,754	1	20/60	3,585
Total				6,274

Seleda Perryman,

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

[FR Doc. E8–24297 Filed 10–10–08; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality (AHRQ), Office for Civil Rights (OCR)

Implementing the Patient Safety and Quality Improvement Act of 2005 Including How to Become a Patient Safety Organization: Interim Guidance Availability

October 14, 2008.

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Office for Civil Rights (OCR), HHS.

ACTION: Notice of Availability.

SUMMARY: AHRQ and OCR are announcing the availability of the guidance entitled ''Implementing the Patient Safety and Quality Improvement Act of 2005 Including How to Become a Patient Safety Organization.'' The Interim Guidance document explains how the Department of Health and Human Services (HHS) will begin implementing the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), how an entity can become a Patient Safety Organization (PSO), and how information may be protected as Patient Safety Work Product (PSWP) in the interim period prior to the promulgation of a final regulation. To access the Interim Guidance, visit AHRQ's PSO Web site at *http://www.pso.ahrq.gov.*

DATES: The Interim Guidance is effective immediately with the publication of this notice. The Interim Guidance will remain effective until the effective date of the final regulation, which is expected to be promulgated before the end of 2008.

SUPPLEMENTARY INFORMATION:

I. Background

The Interim Guidance document is intended to inform private, public and nonprofit health care communities, the legal community and others of HHS's policies and procedures for implementing the Patient Safety Act, prior to the promulgation of a final regulation. This Interim Guidance interprets the Patient Safety Act. The Patient Safety Act (Pub. L. 109–41) amended the Public Health Service Act (42 U.S.C. 299 *et seq.*) by renumbering existing sections and inserting new sections 921 through 926 (42 U.S.C. 299b–21 through 299b–26). The Patient Safety Act authorizes the listing by the Secretary of statutorily defined PSOs. PSOs are to carry out statutorily defined patient safety activities on behalf of providers in order to assist them to improve patient safety. To encourage providers to submit information to PSOs and PSOs to conduct analyses regarding patient safety, the statute establishes privilege and confidentiality protections to protect certain information, including information collected by providers for sharing with PSOs for analysis, analyses performed by the providers and/or the PSOs, and information shared between the PSOs and the health care providers they serve. This information is defined in the statute as PSWP.

II. Significance of the Interim Guidance

The Interim Guidance establishes the process by which the Secretary will list PSOs. Once PSOs are listed by the Secretary, providers can: (1) Voluntarily submit information to PSOs, and (2) seek PSOs' analysis of patient safety events. These activities should lead to improvements in patient safety. The protections established by the Patient Safety Act will permit and encourage numerous providers to submit pertinent data to PSOs so that the PSOs will be able to aggregate and analyze the data from multiple providers, thus enabling the identification of patterns that could suggest underlying or systemic causes of patient risks and hazards that then can be addressed to improve patient safety and quality.

III. Paperwork Reduction Act of 1995

The listing of PSOs under the Interim Guidance involves collecting of information that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). These collections of information have been approved under OMB control number 0935–0143.

Dated: October 7, 2008.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. E8–24267 Filed 10–8–08; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0448]

International Drug Scheduling; Convention of Psychotropic Substances; Single Convention on Narcotic Drugs; Gamma-hydroxybutyric acid; Ketamine; Dextromethorphan; N-benzylpiperazine; 1-(3-trifluoromethylphenyl) piperazine; 1-(3-chlorophenyl) piperazine; 1-(4-Methoxyphenyl) piperazine; 1-(3,4-methylenedioxybenzyl) piperazine; Gamma-butyrolactone; 1,4-Butanediol; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until October 20, 2008, the comment period for the notice on ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs,'' published in the **Federal Register** of September 5, 2008 (73 FR 51823), requesting comments on abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of 10 drug substances. FDA is taking this action in response to a request for a reopening of the comment period to allow interested persons additional time to review the notice and submit comments.