meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kathleen Reedy or Jayne Peterson at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C., app. 2).

Dated: April 11, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–9734 Filed 4–19–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0080]

Draft ''Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires'' dated April 2002. The draft document, when finalized, is intended to provide guidance to blood and plasma collection centers on the recommendations of FDA for implementing self-administered donor questionnaires at the predonation donor screening interview. The draft guidance document also describes the information to be included in a biologics license application supplement or annual report for the implemented changes.

DATES: Submit written or electronic comments on the draft guidance document to ensure their adequate consideration in preparation of the final document by June 21, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires'' dated April 2002. The draft guidance document, when finalized, is intended to provide recommendations to the blood and plasma collection centers on the changes from the current predonation donor screening interview procedure to a self-administered format. The draft guidance document also describes the information to be included in a biologics license application supplement or annual report for the implemented changes. The draft guidance document does not address the informed consent process or specific screening questions, a specific questionnaire, or how to submit changes to the questions on a currently approved questionnaire.

The draft guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance document represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document and on the collection of information. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by June 21, 2002. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: March 12, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–9687 Filed 4–19–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are 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.

Proposed Project: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence—42 CFR part 8 (OMB No. 0930–0206, Revision)—This regulation establishes a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). The regulation requires that Opioid Treatment Programs (OTPs) be certified. ''Certification'' is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission will seek continued approval of the information collection requirements in the regulation and of three forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR 8.11 (Form SMA–162) and the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form SMA–163). SAMHSA plans to also seek approval of a new form that has been developed at the request of the treatment field, the Exception Request and Record of Justification Under 42 CFR 8.12 (Form SMA–168), which may be used on a voluntary basis by physicians when there is a patient care situation in which the physician must make a treatment decision that differs from the treatment regimen required by the regulation. This is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions. The tables that follow summarize the annual reporting burden associated with the regulation, including burden associated with the forms.

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.3(b)(1–11)	Initial approval (SMA–163)	3	1	3.0	9.0
8.3(c)	Renewal of approval (SMA–163)	2	1	1.0	2.0
8.3(e)	Relinquishment notification	1	1	0.5	0.5
8.3(f)(2)	Non-renewal notification to accredited OTP's	1	90	0.1	9.0
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant programs.	2	2	1.0	4.0
8.4(b)(1)(iii)	Notification to OTP for serious noncompliance	2	2	1.0	4.0
8.4(d)(1)	General documents and information to SAMHSA upon request.	7	4	0.5	14.0
8.4(d)(2)	Accreditation survey to SAMHSA upon request	7	50	0.02	7.0
8.4(d)(3)	List of surveys, surveyors to SAMHSA upon request	7	6	0.2	8.4
8.4(d)(4)	Report of less than full accreditation to SAMHSA	7	2.5	0.5	8.75
8.4(d)(5)	Summaries of Inspections	7	50	0.5	175.0
8.4(e)	Notifications of Complaints	7	5	0.5	17.5
8.6(a)(2) and (b)(3)	Revocation notification to Accredited OTP's	1	50	0.3	15.0
8.6(b)	Submission of 90-day Corrective plan to SAMHSA	1	1	10	10.0
8.6(b)(1)	Notification to accredited OTP's of Probationary Status	1	50	0.3	15.0
Total		10			299

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS

42 CFR Citation	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.11(b)	New programs approval (SMA–162)	75	1	1.50	112.50
8.11(b)	Renewal of approval (SMA–162)	350	1	1.00	350.00
8.11(b)	Relocation of Program (SMA–162)	35	1	1.17	40.95
8.11(d)	Application for transitional certification (SMA–162)*	7	1	1.58	11.06
8.11(e)(1)	Application for provisional certification	75	1	1	75.00
8.11(e)(2)	Application for extension of provisional certification	30	1	.25	7.50
8.11(f)(5)	Notification of sponsor or medical director change (SMA–162).	60	1	.2	12.00
8.11(g)(2)	Documentation to SAMHSA for interim maintenance	1	1	1	1.00
8.11(h)	Request to SAMHSA for Exemption from 8.11 and 8.12 (SMA–168).	800	3	.417	1000.80
8.11(i)(1)	Notification to SAMHSA Before Establishing Medication Units (SMA–162).	3	1	.25	.75
8.12(j)(2)	Notification to State Health Officer When Patient Begins Interim Maintenance.	1	20	.33	6.6
8.24	Contents of Appellant Request for Review of Suspension.	2	1	.25	.50
8.25(a)	Informal Review Request	2	1	1.00	2.00
8.26(a)	Appellant's Review File and Written Statement	2	1	5.00	10.00
8.28(a)	Appellant's Request for Expedited Review	2	1	1.00	2.00

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS—Continued

42 CFR Citation	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.28 (c)	Appellant Review File and Written Statement	2	1	5.00	10.00
Total		1,100			1,643

*This is a one-time requirement that will be fully met during the first three years of approval for the final rule.

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 § 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.

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice

Dated: April 16, 2002.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 02–9725 Filed 4–19–02; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

An Assessment of the Status of PASRR and Mental Health Services for Persons in Nursing Facilities—New—SAMHSA's Center for Mental Health Services, in conjunction with the Centers for Medicare and Medicaid Services (CMS), is sponsoring an assessment of the effectiveness of the Pre-Admission Screening and Resident Review (PASRR) program, which is a required component of every State's Medicaid plan. Data will be collected from State Medicaid and Mental Health Authority administrators in 50 states and the District of Columbia as well as administrators and staff in 24 nursing facilities in 4 states (6 facilities per state). In addition, data will be collected from 100 residents in nursing facilities in 2 of the states. Data collection for this study will be conducted over an 8-month period. SAMHSA will use study findings to develop training opportunities for State agencies responsible for overseeing the placement and treatment of people with mental health needs in nursing facilities and by CMS to address specific recommendations of a recent report from the Office of the Inspector General.

Variables of interest for Medicaid Agencies, Mental Health Authorities, and nursing facilities include the following: availability of mental health services; change in condition procedures; alternative placement procedures; and experience with PASRR. Variables of interest for the nursing facility residents include: mental health symptomatology, functioning, and mental health service access. Data will be entered and managed electronically. The total respondent burden is estimated below.

Respondent	Number of respondents	Responses/respondent	Burden/ response (hrs.)	Total burden (hrs.)
Medicaid Administrator	51	1	1	51
Mental Health Authority Administrator	51	1	1	51
Nursing Facility Resident	100	1	.5	50
Nursing Facility Administrator	24	1	1	24
Nursing Facility Staff	48	1	1	48
Total	274			224

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Lauren Wittenberg, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 15, 2002.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 02–9726 Filed 4–19–02; 8:45 am]

BILLING CODE 4162–20–P