and Hematology Research, National Institutes of Health, HHS)

Dated: January 8, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–00620 Filed 1–14–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurodevelopment and Neuroplasticity.

Date: January 28, 2013.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Toby Behar, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4136, MSC 7850, Bethesda, MD 20892, (301) 435–4433, *behart@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 9, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–00615 Filed 1–14–13; 8:45 am]

BILLING CODE 4140–01–P

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 (SAMHSA) 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 (240) 276–1243.

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) and Opioid Treatment Programs (OTPs)—Revision

42 CFR part 8 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 seeks continued approval of the information collection requirements in the regulation and of the 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); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form SMA–163); and 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. Form SMA–168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions.

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.

There are no changes being made to the forms. The reason for the reduction in burden hours is due to more respondents submitting information through an online function. The forms are available online with a unique feature for both the SMA–162 and SMA–168 that pre-populates certain information within the form. This in turn reduces the program's time spent

filling out the forms as well as the staff time spent on processing it. Also, a final rule effective January 7, 2013, (77 FR 72752, **Federal Register** December 6, 2012) eliminated dispensing restrictions for buprenorphine products used in OTPs. As a result there OTPs will complete and submit fewer SMA–168 forms, therefore reducing burden hours.

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	Total responses	Hours/ response	Total hours
8.3(b)(1–11)	Initial approval (SMA–163)	1	1	1	6.0	6
8.3(c)	Renewal of approval (SMA–163)	2	1	2	1.0	2
8.3(e)	Relinquishment notification	1	1	1	0.5	0.5
8.3(f)(2)	Non-renewal notification to accredited OTPs.	1	90	90	0.1	9
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant OTPs.	2	2	4	1.0	4
8.4(b)(1)(iii)	Notification to OTP for serious noncompliance.	2	10	20	1.0	20
8.4(d)(1)	General documents and information to SAMHSA upon request.	6	5	30	0.5	15
8.4(d)(2)	Accreditation survey to SAMHSA upon request.	6	75	450	0.02	9
8.4(d)(3)	List of surveys, surveyors to SAMHSA upon request.	6	6	36	0.2	7.2
8.4(d)(4)	Report of less than full accreditation to SAMHSA.	6	5	30	0.5	15
8.4(d)(5)	Summaries of Inspections	6	50	300	0.5	150
8.4(e)	Notifications of Complaints	12	6	72	0.5	36
8.6(a)(2) and (b)(3)	Revocation notification to Accredited OTPs.	1	185	185	0.3	55.5
8.6(b)	Submission of 90-day corrective plan to SAMHSA.	1	1	1	10	10.0
8.6(b)(1)	Notification to accredited OTPs of Probationary Status.	1	185	185	0.3	55.0
Sub Total	54		1,407		394.20	

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS

42 CFR citation	Purpose	Number of espondents	Responses/ respondent	Total responses	Hours/ response	Total hours
8.11(b)	Renewal of approval (SMA–162)	386	1	386	0.15	57.9
8.11(b)	Relocation of Program (SMA–162)	35	1	35	1.17	40.95
8.11(e)(1)	Application for provisional certification.	42	1	42	1	42.00
8.11(e)(2)	Application for extension of provisional certification.	30	1	30	0.25	7.50
8.11(f)(5)	Notification of sponsor or medical director change (SMA–162).	60	1	60	0.1	6.00
8.11(g)(2)	Documentation to SAMHSA for interim maintenance.	1	1	1	1	1.00
8.11(h)	Request to SAMHSA for Exemption from 8.11 and 8.12 (including SMA–168).	1,200	20	24,000	0.07	1680
8.11(i)(1)	Notification to SAMHSA Before Establishing Medication Units (SMA–162).	10	1	10	0.25	2.5
8.12(j)(2)	Notification to State Health Officer When Patient Begins Interim Maintenance.	1	20	20	0.33	6.6
8.24	Contents of Appellant Request for Review of Suspension.	2	1	2	0.25	.50
8.25(a)	Informal Review Request	2	1	2	1.00	2.00
8.26(a)	Appellant's Review File and Written Statement.	2	1	2	5.00	10.00
8.28(a)	Appellant's Request for Expedited Review.	2	1	2	1.00	2.00
8.28(c)	Appellant Review File and Written Statement.	2	1	2	5.00	10.00
Sub Total		1,775		24,594		1868.95

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS—Continued

42 CFR citation	Purpose	Number of espondents	Responses/ respondent	Total responses	Hours/ response	Total hours
Total		1,829		26,001		2,263.15

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 2–1057, One Choke Cherry Road, Rockville, MD 20857 or email her a copy at *summer.king@samhsa.hhs.gov.* Written comments should be received by March 18, 2013.

Summer King,

Statistician.

[FR Doc. 2013–00585 Filed 1–14–13; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2012–0034]

Privacy Act of 1974; U.S. Customs and Border Protection; DHS/CBP–004–Intellectual Property Rights e-Recordation and Search Systems, System of Records

AGENCY: Department of Homeland Security, Privacy Office.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security, U.S. Customs and Border Protection proposes to establish a new system of records titled, ''U.S. Customs and Border Protection, DHS/CBP–004–Intellectual Property Rights e-Recordation and Search Systems System of Records.'' This system of records allows the Department and CBP to collect and maintain records on copyrights, trademarks, and trade names that the respective owners have applied to have recorded with CBP. In addition, the Department is issuing a Notice of Proposed Rulemaking elsewhere in the **Federal Register** to exempt this system of records from certain provisions of the Privacy Act. This newly established system will be included in the Department's inventory of record systems.

DATES: Submit comments on or before February 14, 2013. This new system will be effective February 14, 2013.

ADDRESSES: You may submit comments, identified by docket number DHS–2012–034 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Jonathan R. Cantor, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: Laurence E. Castelli, 202–325–0280, CBP Privacy Officer, Office of International Trade/Regulations and Rulings, U.S. Customs and Border Protection, Mint Annex, 799 9th Street NW., Washington, DC 20229–1177. For privacy issues, please contact: Jonathan R. Cantor, 202–343–1717, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS), U.S. Customs and Border Protection (CBP) proposes to establish a new DHS system of records titled, ''DHS/CBP–004–Intellectual Property Rights e-Recordation and Search Systems System of Records.''

The Intellectual Property Rights e-Recordation and Search Systems (IPRRSS) collect, use, and maintain records related to intellectual property rights recordations and their owners. The purpose of IPRRSS is to aid in the enforcement of intellectual property rights by making intellectual property recordations available to the public and to CBP officials.

IPRRSS collectively encompasses three separate systems. The first system is the online Intellectual Property Rights e-Recordation (IPRR) system, which allows intellectual property owners to submit applications for trademark and copyright recordations. The IPRR system shares information with the public Intellectual Property Rights Search (IPRS) system and the CBP Intellectual Property Rights Internal Search (IPRiS) system. Because CBP may collect personally identifiable information (PII) about intellectual property rights holders, their agents, or their licensees in IPRR, IPRS, and IPRiS (collectively IPRRSS), CBP is providing the public notice about how CBP collects, uses, and maintains records related to intellectual property rights recordations.

The authority for this system derives from Section 42 of the Lanham Act (Trademark Act of 1946), as amended, 15 U.S.C. 1124; Sections 101 and 602 through 603 of the Copyright Act of 1976, as amended, 17 U.S.C. 101, 602–603; and Sections 526, 595a, and 624 of the Tariff Act of 1930, as amended, 19 U.S.C. 1526, 1595a, and 1624. The cited sections provide that intellectual property rights owners may submit information to CBP to enable CBP officials to identify infringing articles at the borders and prevent the importation of counterfeit or pirated merchandise. Owners seeking to have merchandise excluded from entry must provide proof to CBP of the validity of the intellectual property rights they seek to protect.

Pursuant to the Independent Offices Appropriations Act of 1952, 31 U.S.C. 9701, and regulations at 19 CFR 133.3, 133.13, and 133.33, intellectual property rights owners or their agents must pay a fee when they apply for the recordation with CBP of their trademark, trade name, or copyright. Through IPRR's web-based interface, the user will be prompted through several steps that capture the user's required application information. Once the applicant has entered all required application information, IPRR will guide the applicant through a series of prompts seeking his/her billing name, billing address, and credit card information. IPRR forwards this payment information to Pay.gov for payment processing, and the applicant name and an IPRR tracking number to the DHS/CBP–003 Credit/Debit Card Data System (CDCDS) System of Records for payment reconciliation. Pay.gov sends a nightly activity file, including the last four digits of the credit card, authorization number, billing name, billing address, IPRR