

from the American Medical Association may be obtained and studied, as well as frames that are not currently in use by NAMCS, such as state and organizational listings of other licensed providers. (2) Within the National Study of Long-Term Care Providers, additional new frames may be sought and evaluated and data items from home care agencies, long-term care hospitals, and facilities exclusively serving individuals with intellectual/developmental disability may be tested. Similarly, data may be obtained from lists compiled by states and other organizations. Data about the facilities as well as residents and their visits will be investigated. (3) In the inpatient and outpatient care settings, the National Hospital Care Survey (NHCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS) may investigate the addition of facility and patient information especially as it relates to

insurance and electronic medical records.

Projects under development or in the planning stages include two projects related to opioid use: One that will investigate adding questions to NAMCS on physician understanding of guidelines for opioid use and one that will test the validation of an algorithm for identifying opioid-involved hospital visits. Another study will develop a Hospital-Based Victim Services Frame.

The National Health Care Surveys collect critical, accurate data that are used to produce reliable national estimates—and in recent years (when budget allows), state-level estimates—of clinical services and of the providers who delivered those services in inpatient, outpatient, ambulatory, and long-term care settings. The data from these surveys are used by providers, policy makers and researchers to address important topics of interest,

including the quality and disparities of care among populations, epidemiology of medical conditions, diffusion of technologies, effects of policies and practice guidelines, and changes in health care over time. Research studies need to be conducted to improve existing and proposed survey design and procedures of the National Health Care Surveys, as well as to evaluate alternative data collection approaches particularly due to the expansion of electronic health record use, and to develop new sample frames of currently out-of-scope providers and settings of care. There is no cost to respondents other than their time to participate. Average burdens are designed to cover 15–40 min interviews as well as 90-minute focus groups, longer on-site visits, and situations where organizations may be preparing electronic data files. The total estimated annualized burden hours are 7,085.

TABLE 1—ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents  | Form name  | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|--|--|-----------------------|------------------------------------|--|
| Health Care Providers and Business entities                                    | Interviews, surveys, focus groups, experiments (in person, phone, internet, postal/electronic mail). | 6,667                 | 1                                  | 1                                      |
| Health Care Providers, State/local government agencies, and business entities. | Interviews, surveys, focus groups, experiments (in person, phone, internet, postal/electronic mail). | 167                   | 1                                  | 2.5                                    |

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-20-0572; Docket No. CDC-2020-0034]

#### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the

general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Possession, Use, and Transfer of Select Agents and Toxins (42 CFR part 73). This information collection intends to support the Public Health Safety and Bioterrorism Preparedness and Response Act of 2002 and ensure select agents or toxins are managed appropriately to prevent any threats to human health or safety. Data will be used to fulfill the requirements promulgated by HHS under this part and also subject to corresponding regulations promulgated by USDA.

**DATES:** CDC must receive written comments on or before June 2, 2020.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-20-0034 by any of the following methods:

- **Federal eRulemaking Portal:** *Regulations.gov*. Follow the instructions for submitting comments.

- **Mail:** Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

**Please note:** Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

### Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920-0576)—Revision—Center for Preparedness and Response (CPR), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

Subtitle A of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, (42 U.S.C. 262a), requires the United States Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of biological agents or toxins that have the

potential to pose a severe threat to public health and safety (select agents and toxins). Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which may be cited as the *Agricultural Bioterrorism Protection Act of 2002*), (7 U.S.C. 8401), requires the United States Department of Agriculture (USDA) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to animal or plant health, or animal or plant products (select agents and toxins). Accordingly, HHS and USDA have promulgated regulations requiring individuals or entities that possess, use, or transfer select agents and toxins to register with the CDC or the Animal and Plant Health Inspection Service (APHIS). See 42 CFR part 73, 7 CFR part 331, and 9 CFR part 121 (the select agent regulations). The Federal Select Agent Program (FSAP) is the collaboration of the CDC, Division of Select Agents and Toxins (DSAT) and the APHIS Agriculture Select Agent Services (AgSAS) to administer the select agent regulations in a manner to minimize the administrative burden on persons subject to the select agent regulations. The FSAP administers the select agents regulations in close coordination with the Federal Bureau of Investigation's Criminal Justice Information Services (CJIS). Accordingly, CDC and APHIS have adopted an identical system to collect information for the possession, use, and transfer of select agents and toxins.

CDC is requesting OMB approval to continue to collect information under the select agent regulations through the use of five forms: (1) Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1); (2) Request to Transfer Select Agents or Toxins (APHIS/CDC Form 2); (3) Incident Notification and Reporting (Theft, Loss, or Release) (APHIS/CDC Form 3); (4) Reporting the Identification of a Select Agent or Toxin (APHIS/CDC Form 4); and (5) Request for Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5).

An entity may amend its registration (42 CFR 73.7(h)(1)) if any changes occur

to the information previously submitted to CDC. When applying for an amendment to a certificate of registration, an entity would complete the relevant portion of the application package (APHIS/CDC Form 1).

Besides the forms listed above, there is no standard form for the following information:

1. An individual or entity may request an exclusion from the requirements of the select agent regulations of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. (42 CFR 73.3(e) and 73.4(e)).

2. Annual inspections that are conducted by the entity must be documented. (42 CFR 73.9(a)(6)).

3. An individual's security risk assessment may be expedited upon written request by a Responsible Official and a showing of good cause. (42 CFR 73.10(f)).

4. An individual or entity may request approval to perform a "restricted experiment" (42 CFR 73.13).

5. An individual or entity must develop and implement a written security plan, biosafety plan, and incident response plan (42 CFR 73.11(a), 42 CFR 73.12(a), and 42 CFR 73.14(a)).

6. The Responsible Official at the must ensure a record of the training for each individual with access to select agents and toxins and each escorted individual is maintained (42 CFR 73.15(d)).

7. An individual or entity may appeal a denial, revocation, or suspension of registration. (42 CFR 73.20(a)).

8. An individual may appeal a denial, limitation, or revocation of access approval. (42 CFR 73.20(b)).

The total estimated annualized burden for all data collection was calculated using the 2018 Annual Report of the Federal Select Agent Program available at <https://www.selectagents.gov/annualreport2018.html> or FSAP IT system and is estimated as 4465 hours. Information will be collected through FSAP IT system, fax, email and hard copy mail from respondents. Upon OMB approval, CDC will begin use of the revised forms in October 2020 through October 2023. There is no cost to the respondents.

### ESTIMATED ANNUALIZED BURDEN HOURS

| Section              | Form name  | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|----------------------|--|-----------------------|------------------------------------|--|--------------------|
| Sections 3 & 4 ..... | Request for Exclusions .....                             | 1                     | 1                                  | 1                                      | 1                  |
| Sections 5 & 6 ..... | Report of Identification of a Select Agent or Toxin .... | 1,181                 | 1                                  | 1                                      | 1,181              |
| Sections 5 & 6 ..... | Request of Exemption .....                               | 1                     | 1                                  | 1                                      | 1                  |

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

| Section          | Form name  | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|------------------|--|-----------------------|------------------------------------|--|--------------------|
| Section 7 .....  | Application for Registration .....                 | 3                     | 1                                  | 5                                      | 15                 |
| Section 7 .....  | Amendment to a Certificate of Registration .....   | 253                   | 5                                  | 1                                      | 1,265              |
| Section 9 .....  | Documentation of self-inspection .....             | 253                   | 1                                  | 1                                      | 253                |
| Section 10 ..... | Request for Expedited Review .....                 | 1                     | 1                                  | 0.5                                    | 1                  |
| Section 11 ..... | Security Plan .....                                | 253                   | 1                                  | 1                                      | 253                |
| Section 12 ..... | Biosafety Plan .....                               | 253                   | 1                                  | 1                                      | 253                |
| Section 13 ..... | Request Regarding a Restricted Experiment .....    | 1                     | 1                                  | 2                                      | 2                  |
| Section 14 ..... | Incident Response Plan .....                       | 253                   | 1                                  | 1                                      | 253                |
| Section 15 ..... | Training .....                                     | 253                   | 1                                  | 1                                      | 252                |
| Section 16 ..... | Request to Transfer Select Agents and Toxins ..... | 253                   | 1                                  | 1.5                                    | 380                |
| Section 17 ..... | Records .....                                      | 253                   | 1                                  | 0.5                                    | 127                |
| Section 19 ..... | Notification of Theft, Loss, or Release .....      | 201                   | 1                                  | 1                                      | 201                |
| Section 20 ..... | Administrative Review .....                        | 28                    | 1                                  | 1                                      | 28                 |
| Total .....      | .....  | .....                 | .....                              | .....                                  | 4465               |

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-20-0995]

#### Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “National Network of Sexually Transmitted Diseases Clinical Prevention Training Centers” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on November 4, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including

whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

#### Proposed Project

National Network of Sexually Transmitted Diseases Clinical Prevention Training Centers (OMB No.

0920-0995, Expiration 05/31/2020)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

The Centers for Disease Control and Prevention (CDC), Division of STD Prevention requests an extension and three-year approval of the currently approved information collection request that comprises the NNPTC Abbreviated Health Professional Application for Training (NNPTC Abbreviated HPAT). This extension will allow the NNPTC Abbreviated HPAT to continue to serve as the official training application form used for training activities conducted by the Sexually Transmitted Disease (STD) Prevention Training Centers’ (PTCs) grantees funded by the (CDC). The PTCs are funded by CDC/Division of STD Prevention (DSTDP) to provide training and capacity-building that includes information, training, technical assistance and technology transfer.

The PTCs offer classroom and experiential training, web-based training, clinical consultation, and capacity building assistance to maintain and enhance the capacity of health care professionals to control and prevent STDs and HIV. The NNPTC Abbreviated HPAT is used to monitor and evaluate performance and reach of grantees that offer STD and HIV prevention training, training assistance, and capacity building assistance to physicians, nurses, disease intervention specialists, health educators, etc. During the previously approved three-year period, data was collected to monitor and evaluate the performance of the NNPTC grantees and the NNPTC program. This data provided the NNPTC with