RECORDKEEPING REQUIREMENTS

Data required to be submitted	Number of record keepers	Hours per year	Total burden hours
HPSL, LDS, and PCL Program:			
Documentation of Cost of Attendance	432	1.05	454
Promissory Note	432	1.25	540
Documentation of Entrance Interview	432	1.25	540
Documentation of Exit Interview	*475	0.37	176
Program Records	*475	10.00	4,750
Student Records	*475	10.00	4,750
Repayment Records	*475	19.55	9,286
HPSL/LDS/PCL Subtotal	475		20,496
NSL Program:			
Documentation of Cost of Attendance	304	0.25	76
Promissory Note	304	0.50	152
Documentation of Entrance Interview	304	0.50	152
Documentation of Exit Interview	*486	0.14	68
Program Records	*486	5.00	2,430
Student Records	*486	1.00	486
Repayment Records	*486	2.51	1,220
NSL Subtotal	486		4,584

*Includes active and closing schools.

REPORTING REQUIREMENTS

	Number of respondents	Responses per respondent	Total annual responses	Hours per response	Total burden hours
HPSL, LDS, and PCL:					
Student Financial Aid Transcript	4,600	1	4,600	0.25	1,150
Loan Information Disclosure	325	299.5	97,338	0.63	61,323
Entrance Interview	325	139.5	45,338	0.50	22,669
Exit Interview	*334	113.5	37,909	1.00	37,909
Notification of Repayment	*334	862.5	288,075	0.38	109,469
Notification During Deferment	*333	17	5,661	0.63	3,566
Notification of Delinquent Accounts	334	172.5	57,615	1.25	72,019
Credit Bureau Notification	334	6	2,004	0.50	1,002
Write-off of Uncollectable Loans	520	1	520	3.00	1560
Disability Cancellation	3	1	3	1.00	3
Administrative Hearings record retention	0	0	0	0.00	0
Administrative Hearings reporting requirements	0	0	0	0.00	0
HPSL Subtotal					310,670
NSL:					
Student Financial Aid Transcript	4,100	1	4,100	0.25	1,025
Entrance Interview	282	17.5	4,935	0.42	2,073
Exit Interview	348	9	3,132	0.42	1,315
Notification of Repayment	348	9	3,132	0.27	846
Notification During Deferment	348	1.5	522	0.29	151
Notification of Delinquent Accounts	348	42.5	14,790	0.04	592
Credit Bureau Notification	348	709	246,732	0.06	1,480
Write-off of Uncollectable Loans	23	1	23	3.00	69
Disability Cancellation	16	1	16	1.00	16
Administrative Hearings	0	0	0	0.00	0
NSL Subtotal					7,567

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–02807 Filed 2–10–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI): Accelerating Innovation in Diagnostic Testing for Lyme Disease

AGENCY: Office of the Assistant Secretary for Health (OASH), Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The Office of the Assistant Secretary for Health (OASH) in the Department of Health and Human Services seeks to obtain information regarding the current state of the science and technology to accelerate the pace of innovative solutions for the diagnosis of Lyme disease. A set of questions is available in the **SUPPLEMENTARY INFORMATION** section below.

DATES: To be considered, comments must be received electronically at the email address provided below, no later than 5:00 p.m. Eastern Time (ET) March 15, 2021.

ADDRESSES: Individuals are encouraged to submit responses electronically to Dr. Kristen Honey, Senior Advisor to the Assistant Secretary for Health, 200 Independence Avenue SW, Washington, DC 20201, *LymeInnovation@hhs.gov,* (202) 853–7680. Please indicate ''RFI RESPONSE'' in the subject line of your email. Submissions received after the deadline will not be reviewed. Responses to this notice are not offers and cannot be accepted by the government to form a binding contract or issue a grant. Respond concisely and in plain language. You may use any structure or layout that presents the information well. You may respond to some or all of our questions, and you can suggest other factors or relevant questions. You may also include links to online material or interactive presentations. Clearly mark any proprietary information, and place it in its own section or file. Your response will become government property, and we may publish some of its non-proprietary content.

SUPPLEMENTARY INFORMATION: The HHS Lyme Innovation initiative is a patient-centered, data-driven approach to the threat of Lyme disease and tick-borne diseases. Lyme disease affects more than 300,000 people in the U.S. each year and accounts for more than 70% of all vector-borne diseases in our country. Lyme and other tick-borne diseases cost the U.S. economy billions of dollars annually.

The HHS Lyme Innovation initiative uses strategic public-private partnerships to accelerate advancements in Lyme disease and other tick-borne diseases. The Lyme Innovation initiative aims to build commitment to patient-centered innovations, identify ways to collect and share data while raising awareness, accelerate the discovery of next-generation diagnostic tools and technologies, and lower barriers across all phases of development, testing, and implementation. The recommendations of the Tick-Borne Disease Working Group to HHS inform the Lyme Innovation initiative. The Lyme Innovation initiative represents one way that HHS is executing the strategies described in ''A National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans.''

HHS has entered into a public-private partnership with the Steven and Alexandra Cohen Foundation to form the LymeX Innovation Accelerator (LymeX). LymeX will accelerate the Lyme Innovation initiative's progress and strategically advance tick-borne-disease solutions in direct collaboration with Lyme disease patients, patient advocates, and diverse stakeholders. A primary goal of the LymeX partnership and the Framework is the development of new diagnostic technologies for Lyme disease.

The Centers for Disease Control and Prevention (CDC) website (*https://www.cdc.gov/lyme/index.html*) summarizes information about the stages of Lyme disease, current diagnostic testing recommendations, and treatment options. CDC currently recommends the use of FDA cleared serologic tests in a two-step testing process that detects the presence of antibodies to *Borrelia burgdorferi,* the bacterium responsible for Lyme disease.

Serologic tests for diagnosis of Lyme disease have technical limitations. Antibodies may not be produced by the immune system early enough or in high enough quantities to meet the detection limit of these tests (*https://www.hhs.gov/sites/default/files/tbdwg-report-to-congress-2018.pdf*). As an antibody response in infected persons requires time to develop, serologic tests for Lyme disease may produce false negative results during early infection. In areas where Lyme disease is highly endemic, the infection may be diagnosed without laboratory testing if patients develop a diagnostic skin lesion at the site of the tick bite, which is known as erythema migrans (EM) or a ''bullseye rash.'' However, 20% of patients may not develop this specific rash, and sometimes the rash is not seen or recognized. The rash also might not display the stereotypical presentation. Therefore, these newly infected patients may not be diagnosed in the absence of a sensitive diagnostic test and may not receive prompt or proper treatment for a disease with the potential to cause disabling illness.

Serology tests are also not capable of determining if there is an active infection. As antibodies normally persist for months or even years after the infection is gone, serologic testing cannot be used to determine a cure. Additionally, cross-reactions between serologic tests for Lyme disease and those for other infectious diseases can also yield false positive results.

These limitations of serological testing compound the scientific challenges in identifying specific etiologies for Post-Treatment Lyme Disease Syndrome (PTLDS), which is characterized by persistence of symptoms for more than 6 months following treatment with oral antibiotics. Improvements in Lyme disease diagnostics would enable better clinical management of PTLDS patients as well.

HHS has identified an area of known need in developing more advanced diagnostic tests that diagnose infection at all stages of Lyme disease. Therefore, the LymeX partnership is embarking on a series of initiatives, including prize challenges to develop new diagnostic tests for Lyme disease. This RFI is intended to gather information on the current state of the science and development landscape for new diagnostic tests from the entrepreneurs, scientists, and physicians who will develop and use them.

We encourage responders to answer the following questions:

- What challenges/barriers exist for the development and validation of innovative diagnostic tests for Lyme disease?
- What types of diagnostic technologies are being developed (or could be developed or adapted) to detect Lyme disease, including technologies and breakthroughs adapted from COVID–19 diagnostics with potential applications for Lyme disease (*e.g.,* highly sensitive nucleic acid amplification testing [NAAT])?
- What emerging technologies (*e.g.,* epigenetic mapping, inflammatory markers, gene arrays, NAAT, or others) might be developed or adapted to characterize different stages of Lyme disease, including Post-Treatment Lyme Disease Syndrome (PTLDS), etc.?
- What analyte (*e.g.,* DNA, RNA, protein, metabolite) does existing or developing Lyme disease diagnostic tests detect?
- What is the optimal sample type (*e.g.,* whole blood, plasma) for the detection of a test analyte in patients with Lyme disease? The optimal sample type can be generally defined as the one where the analyte can be best detected.
- What challenges exist in the implementation and use of Lyme disease diagnostic testing in clinical practice?
- What role can or should public-private partnerships play in accelerating

development, validation, or appropriate use of innovative Lyme disease diagnostic tests, and what factors are most critical to ensure their success?

This information will inform the development of the HHS Lyme Innovation initiative and the LymeX public-private partnership to create meaningful incentives to develop or validate new diagnostic tests for Lyme disease.

Kristen Honey,

Senior Advisor to the Assistant Secretary for Health (ASH), Office of the Assistant Secretary for Health, U.S. Department of Health and Human Service.

[FR Doc. 2021–02796 Filed 2–10–21; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–xxxx]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before April 12, 2021.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-New-60D, and project title for reference, to Sherrette Funn, Reports Clearance Officer, *Sherrette.funn@hhs.gov,* 202–795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Family Planning Annual Report 2.0.

Type of Collection: New.

Abstract: The Office of Population Affairs (OPA), within the Office of the Assistant Secretary for Health, seeks approval for a new encounter level data collection for the Family Planning Annual Report (FPAR). Currently collected in aggregate under OMB No. 0990–0221, this new data collection, ''FPAR 2.0'', will collect information at the encounter level and build on the existing data collection and reporting system. This annual reporting requirement is for competitively awarded grants authorized and funded by the Title X Family Planning Program.

Need and Proposed Use of the Information: The Office of Population Affairs' (OPA) Title X Family Planning Program is the only federal grant program dedicated solely to providing comprehensive family planning and related preventive health services.

Annual submission of the FPAR is required of all Title X family planning services grantees for purposes of monitoring and reporting program performance (45 CFR part 74 and 45 CFR part 92). The FPAR is the only source of annual, uniform reporting by all grantees funded under Section 1001 of the Title X Public Health Service Act. Similar to the previous FPAR, FPAR 2.0 will provide consistent, national-level data on the Title X Family Planning program and its users. OPA will be able to assemble and analyze comparable and relevant program data to answer questions about the characteristics of the population served, the provision and use of services, and the impact of the program on certain family planning outcomes. FPAR 2.0 will also collect a standard set of data elements pertaining to users and encounters, such as user demographics, service delivery, family planning intentions and methods, and other indicators, which allow for comparisons over time at all levels of the program (*e.g.,* national, regional, state, and grantee). Encounter level data collected through FPAR 2.0 will ultimately improve the quality of data reported to OPA and reduce reporting burden by grantees. Additionally, the more granular data collected with FPAR 2.0 will help contribute to a learning healthcare environment by greatly expanding the options for data analysis and reporting—for example, through interactive data dashboards and visualizations, customized tabulations and reports, and application of analytics and statistical analyses on the encounter-level data files.

Information from FPAR 2.0 is important to OPA for many reasons, and will be used to:

(1) Monitor compliance with statutory requirements, regulations, and operational guidance.

(2) Comply with accountability and federal performance requirements for Title X family planning funds.

(3) Guide strategic and financial planning, to monitor performance, to respond to inquiries from policymakers and Congress about the program, and to estimate program impact.

Type of respondent: Annual reporting; respondents are all grantees that receive Title X funding from OPA.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
FPAR 2.0	Grantees	74	1	36	2,664
Total			1		2,664