TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of interview	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
In-Person Individual IDIs	1,092	1	1,092	1	1,092
IDI Screener	1,800	1	1,800	.083 (5 minutes)	149
Focus Group Interviews	4,701	1	4,701	1.5	7,052
Focus Group Screener	3,996	1	3,996	.25 (15 minutes)	999
Usability Testing	2,322	1	2,322	.5 (30 minutes)	1,161
Usability Testing Screener	2,028	1	2,028	.083 (5 minutes)	168
Total					10,621

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents to be included in each new pretest may vary, depending on the nature of the material or message being tested and the target audience. Table 1 provides examples of the types of studies that may be administered and estimated burden levels during a 3-year period. Time to read, view, or listen to the message being tested is built into the ''Hours per Response'' figures.

FDA has updated the estimated burden that was published in the 60-day notice. The estimated burden for this collection has increased by 4,437 hours from 6,184 to 10,621. FDA attributes this increase to adding usability testing, and increasing the overall number of studies planned the next 3 years.

Dated: May 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10457 Filed 5–15–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990—New]

Agency Information Collection Request. 30-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 June 15, 2018.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990—New—30D and project title for reference.

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: Trafficking Victim Assistance Program Social Network Analysis—Network Survey.

Type of Collection: New.

OMB No. 0990–NEW—Office of the Assistant Secretary for Planning and Evaluation—Administration for Children and Families' Trafficking Victim Assistance Program.

Abstract

The Office of the Assistant Secretary for Planning and Evaluation (ASPE), in partnership with the Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is requesting Office of Management and Budget (OMB) approval for a new information collection request titled, ''Trafficking Victim Assistance Program (TVAP) Social Network Analysis—Network Survey.'' Under the guidance of ASPE and ACF, a contractor is carrying out this assessment. The data collected and analyzed under this submission will help HHS better understand the type and extent of the relationship between the TVAP grantees, TVAP subrecipients, and other service providers operating in TVAP subrecipient areas. It will also help illuminate each grantee's and subrecipient's types and number of services provided, estimated costs of services, service coordination between grantees or subrecipients and other services providers, and type and strength of relationships between grantees and subrecipients. This information will enable HHS to understand the structure of the grantee/subrecipient network and inform recommendations for more efficient network management and distribution of support.

TVAP, as authorized by the Trafficking Victims Protection Act of 2000, provides comprehensive case management services to foreign-born victims of human trafficking residing in the United States. Since its inception, TVAP funding and infrastructure have remained relatively unchanged: Services are paid on a per capita basis, and funds are managed through three primary grantees that enter into cooperative agreements with service providers (subrecipients). Given the changing landscape and the greater understanding of the nature and extent of trafficking, HHS is undertaking a program assessment to understand whether any efficiencies can be gained in the program administration and structure. To supplement an earlier fiscal year 2018 assessment to solicit qualitative feedback from a range of program stakeholders, the information collected for this program survey aims to help HHS determine if efficiencies can be gained through improved coordination among TVAP grantees, TVAP subrecipients, and other service providers.

Data will be collected through an electronic survey of fiscal year 2016 TVAP grantees and subrecipients. Key staff at grantee sites and subrecipient organizations will complete a self-administered online survey that will include questions about each respondent's services provided, estimated costs of services, service coordination between grantees or subrecipients, and type and strength of

relationships between grantees and subrecipients. With this data, the contractor, to inform ASPE and ACF, will build a social/organizational network to depict how grantee and subrecipient organizations collaborate with one another through TVAP to better understand the existing network and identify potential opportunities for improving the efficiency of the network. ASPE anticipates completion of all data collection activities by October 2018.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
TVAP grantees	3	1	45/60	2.25
TVAP Subrecipients	253	1	45/60	189.75
Total	256	1	45/60	192

Terry Clark,

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

[FR Doc. 2018–10394 Filed 5–15–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

RIN 0991–ZA49

HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

AGENCY: Department of Health and Human Services.

ACTION: Policy Statement; Request for information.

SUMMARY: Through this request for information, HHS seeks comment from interested parties to help shape future policy development and agency action.

DATES: Comments must be submitted on or before July 16, 2018.

ADDRESSES: You may submit comments in one of three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Department of Health and Human Services, 200 Independence Ave. SW, Room 600E, Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Department of Health and Human Services, 200 Independence Ave. SW, Room 600E, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: John O'Brien, (202) 690–7886.

SUPPLEMENTARY INFORMATION: The United States is the world's leader in biopharmaceutical innovation. American innovation has improved health and quality of life for billions of people, and was made possible by our intellectual property system, decades of government and privately-funded research, strong capital markets, and the world's largest scientific research base. By rewarding innovation through patent and data protection, American companies hold the intellectual property rights for most new, and potentially life changing, medicines. Our regulatory system is the most rigorous in the world, ensuring the safety and efficacy of drugs for American patients. Medicare, Medicaid, other Federal health programs, and private payers ensure Americans have access to medicines, from innovative new cures, to generic versions of medications that have markedly lowered costs for consumers.

As part of President Trump's bold plan to put American patients first, the Department of Health and Human Services has developed a comprehensive blueprint that addresses many of the challenges and opportunities impacting American patients and consumers. The blueprint covers multiple areas including, but not limited to:

- Improving competition and ending the gaming of the regulatory process,
- supporting better negotiation of drug discounts in government-funded insurance programs,
- creating incentives for pharmaceutical companies to lower list prices, and,
- reducing out-of-pocket spending for patients at the pharmacy and other sites of care.

HHS also recognizes that achieving the goal of putting American patients first will require interagency collaboration on pharmaceutical trade policies that promote innovation, and are transparent, nondiscriminatory, and increase fair market access for American innovators. Furthermore, HHS seeks to identify when developed nations are paying less for drugs than the prices paid by Federal health programs, and correct these inequities through better negotiation.

HHS has already acted to increase the affordability of medicines for millions of our citizens, but is also going much further in response to President Trump's call to action. Through the work of the Food and Drug Administration and the Centers for Medicare & Medicaid Services, HHS has tremendous ability to change how drugs are developed and paid for in the United States.

The status quo is no longer acceptable. Millions of Americans face soaring drug prices and higher out-of-pocket costs, while manufacturers and middlemen such as pharmacy benefit managers (PBMs) and distributors benefit from rising list prices and their resulting higher rebates and administrative fees. An unprecedented re-examination of the whole system and opportunities for reform is long overdue. We believe a national focus on lowering list prices and out-of-pocket costs has the potential to create new and disruptive alternatives to the current system, while maintaining its many virtues. It is time to realign the system in a way that promotes the development of affordable innovations that improve health outcomes and lower both out-of-pocket cost and the total cost of care.

Through this request for information, HHS seeks comment from interested parties to help shape future policy development and agency action.

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