

compliance with Federal policies and good quality drug production, and (3) barriers and opportunities related to outsourcing facility interactions with FDA.

FDA used previous research results under this information collection to develop an understanding of the outsourcing facility sector, the sector's challenges, and opportunities for advancement. The information collected was an essential tool to help FDA identify knowledge and information gaps, operational barriers, and views on interactions with FDA. FDA has presented this information in public settings, such as stakeholder meetings. Continuing this collection will enable FDA to deepen our understanding of the outsourcing facility sector and increase our efficacy in developing a Center of Excellence that is responsive to outsourcing facilities' needs. The research results will inform FDA's future activities for the Center of Excellence in the areas of communication, education, training, and other engagement with outsourcing facilities to address challenges and support advancement.

Researchers engage with pharmacists, staff, management from outsourcing facilities, similar compounding businesses, and related stakeholders and may use surveys, interviews, and focus groups to obtain information about

outsourcing facilities' challenges and opportunities. Within this context, we may pose the following questions or similar, related questions:

1. What financial and operational considerations inform outsourcing facility operational and business model decisions?
2. What factors impact developing a sustainable outsourcing facility business?
3. What financial and operational considerations inform outsourcing facility product decisions?
4. Do outsourcing facilities understand the Federal laws and policies that apply to them? What, if any, knowledge gaps do we need to address?
5. What are outsourcing facilities' challenges when implementing Federal CGMP requirements?
6. How do outsourcing facilities implement quality practices at their facilities?
7. How do outsourcing facilities develop CGMP and quality expertise? How do they obtain this knowledge, and what training do they need?
8. What are the economic consequences of CGMP noncompliance and product failures for outsourcing facilities?
9. What are outsourcing facility management and staff views on current interactions with FDA? How do they want the interactions to change?

10. What are outsourcing facilities' understanding of how to engage with FDA during and following an inspection?

In the **Federal Register** of October 1, 2021 (86 FR 54450), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment from an industry association relating to the quality of questions previously posed to industry stakeholders concerning outsourcing facilities. Specifically, the commenter stated that the proposed questions included in the 60-day notice were insufficient to fully acquire information relating to the challenges and opportunities outsourcing facilities face. Accordingly, the commenter provided a number of additional questions for FDA to use, which the commenter believes will better solicit relevant information. FDA has considered the commenter's additional questions and will take them under advisement for possible inclusion in future studies. However, at this time FDA will not include the commenter's questions in this particular study because we believe the proposed questions listed in the 60-day notice will sufficiently solicit the specific information we are currently seeking.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Surveys, focus groups, and interviews	300	2	600	1	600

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

Our original request for the information collection was approved January 21, 2020; however, the subsequent public health emergency inhibited our ability to administer the requested survey. We have therefore made no adjustments to our current burden estimate.

Dated: December 28, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–28465 Filed 1–3–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 86 FR 48737–48743 dated August 31, 2021).

This reorganization updates the functions of the HIV/AIDS Bureau's Division Policy and Data (RVA).

Chapter RVA—Division of Policy and Data

Section RVA.20 Function

Delete the functional statement for the Division of Policy and Data (RVA) in its entirety and replace with the following:

Division of Policy and Data (RVA)

The Division of Policy and Data serves as the Bureau's focal point for program data collection and analysis, development of policy guidance, advancement of implementation science, and analyses of data for reports for dissemination, coordination of program and clinical performance activities, and technical assistance and training internally and externally. The division directs and manages the portfolio of recipients and programs funded under Special Projects of

National Significance of title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, Public Law 111–87 (the Ryan White HIV/AIDS Program), 42 U.S.C. 300ff–101 (§ 2691 of the Public Health Service Act). The Division advises the Bureau's associate administrator and collaborates with division directors to develop policy, evaluation, data, and clinical proposals to support the Bureau's mission. The Division also coordinates and develops efforts with other HHS components and all HRSA Bureaus and Offices, including HRSA's Office of Planning, Analysis and Evaluation and Office of Legislation, in the preparation of HIV-related program policies.

Section RVA.30 Delegation of Authority

All delegations of authority and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, if allowed, provided they are consistent with this reorganization.

This reorganization is effective upon date of signature.

(Authority: 44 U.S.C. 3101)

Diana Espinosa,
Acting Administrator.

[FR Doc. 2021–28463 Filed 1–3–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–New]

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 March 7, 2022.

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 A. Funn, email:

Sherrette.Funn@hhs.gov, or call (202) 795–7714 the Reports Clearance Officer.

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: Understanding Economic Risk for Low Income Families: Economic Security, Program Benefits, and Decisions about Work.

Type of Collection: New.

OMB No.: 0990–XXXX.

Abstract: The primary purpose of this study is to identify the risks that federal program benefit recipients weigh when faced with an opportunity to increase earnings, including benefit reductions, earnings instability and the ease of regaining lost benefits if needed.

The study will use a discrete choice experiment to explore the importance of these considerations when low-income individuals are presented with a hypothetical opportunity to increase earnings. Statistical analysis will

explore interactions between factors and threshold effects. The focus population will be persons currently receiving benefits from at least one of the following programs: Supplemental Nutrition Assistance Program (SNAP), Medicaid/Children's Health Insurance Program (CHIP), housing assistance, Child Care Development Fund (CCDF) subsidies, and/or Temporary Assistance for Needy Families (TANF). The study will explore whether different preferences are exhibited by parents with children and by persons of different races and ethnicities.

The results of this study will provide HHS with a better understanding of the economic risks that people weigh when they make decisions about increasing earnings, which will inform HHS policy and programs at large, and further lines of research around benefit programs and employment decisions.

The length of the request for data collection is one year. The data will be collected once, using primarily a web-based survey, from a sample of low-income persons receiving one or more federal benefit programs. The survey consists of five vignettes presenting different combinations of experimental conditions surrounding a hypothetical earnings increase. In each vignette, respondents will be presented with a scenario where a hypothetical individual is presented with an opportunity to increase their earnings (by accepting a higher hourly wage); consequences of the earnings increase for his or her receipt of benefits; the risk of going back down to the lower, original hourly wage at a later time; and the prospect of re-applying for lost benefits. Respondents will be asked to review the vignette and choose whether they think the hypothetical individual should accept the earnings increase. In addition, the questionnaire includes follow-up questions for each vignette/experimental condition, and a set of demographic questions.

ANNUALIZED BURDEN HOUR TABLE

Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Approximately 2,000	1	20/60	667

Sherrette A. Funn,
Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

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