

Estimated Annual Hours Burden: 3,069,314 hours (170,417 hours for manufacturers + 2,898,897 hours for retailers).

- Manufacturers account for approximately 170,417 hours ((742 large manufacturers × 21.5 hours) + (30,287 small manufacturers × 5.1 hours))
- Retailers account for approximately 2,898,897 hours ((8,628 large retailers × 20.8 burden hours) + (566,549 small retailers × 4.8 burden hours))

Estimated Annual Cost Burden: \$70,594,222 (which is derived from \$36,831,768 for sales associates + \$33,762,454 for clerical workers).⁴

- Sales Associates: (1,534,657 hours) (\$24/hour) = \$36,831,768
- Clerical Workers: (1,534,657 hours) (\$22/hour) = \$33,762,454

Total Annual Capital or Other Non-labor Costs: De minimis.

Request for Comment

Your comment—including your name and your state—will be placed on the public record of this proceeding at the <https://www.regulations.gov> website. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone's Social Security number; date of birth; driver's license number or other state identification number; or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

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⁴ The wage rates used in this Notice reflect data from the Bureau of Labor Statistics, Occupational Employment and Wages (May 2018), available at <http://www.bls.gov/news.release/pdf/ocwage.pdf>.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project "AHRQ Managing Unhealthy Alcohol Use in Primary Care Initiative."

DATES: Comments on this notice must be received by 60 days after date of publication of this notice.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT:

Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by emails at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

AHRQ Managing Unhealthy Alcohol Use in Primary Care Initiative

The Affordable Care Act established the Patient-Centered Outcomes Research Trust Fund (PCORTF) and authorized AHRQ to broadly disseminate the research findings published by the Patient-Centered Outcomes Research Institute (PCORI) and other government-funded research relevant to comparative clinical effectiveness research. AHRQ's PCORTF-funded initiative identifies research findings that could significantly improve patient outcomes through broader implementation in clinical practice. Under this initiative, in 2019 AHRQ launched a new initiative, Managing Unhealthy Alcohol Use in Primary Care, in order to promote the uptake of evidence-based practices for unhealthy alcohol use (UAU). As part of this initiative, AHRQ selected six grantees and funded a contractor to support and evaluate the grantees. The grantees will collectively work with more than 700 primary care

practices over three years to implement and evaluate strategies to increase the use of evidence-based interventions such as screening for unhealthy alcohol use, brief interventions for adult patients who drink too much, and medication-assisted therapy (MAT) for patients with an alcohol use disorder. The contractor will develop a resource center, convene a technical expert panel, conduct an ongoing environmental scan, support a learning community of grantees, and complete a multisite, mixed methods evaluation.

Unhealthy alcohol use, defined as behaviors ranging from risky drinking to alcohol use disorders (AUD), is estimated to be the third leading cause of preventable death in the United States. Between 2006 and 2010, nearly one in ten deaths were alcohol-related. In addition to early mortality, UAU is associated with a host of adverse outcomes, including unintentional injuries and the development or exacerbation of a range of physical and behavioral health conditions. The Centers for Disease Control and Prevention estimates suggest that excessive alcohol consumption costs the United States \$249 billion annually.

Under the UAU initiative, six AHRQ grantees will work to improve the management of UAU in primary care by disseminating and implementing evidence-based practices for screening and brief intervention, referral to treatment (SBI/RT), and MAT in primary care practices. The multi-site, mixed-methods evaluation will include primary data collection by the evaluator, NORC at the University of Chicago. The evaluation will also include secondary data collected by the six grantee teams working with 750 primary care practices. Collectively the data will allow the evaluator to assess the implementation and impact of the six grants.

The project goals, as laid out in the AHRQ request for applications include:

- Success of recruitment and retention strategies across all six grantees to engage primary care practices for implementation of SBI/RT and MAT, across the initiative;
- Effectiveness of the grantees' collective dissemination and implementation strategies, and the factors associated with the success and/or failure of the strategies as it relates to populations, settings and the influence of contextual factors;
- Success at the practice level in increasing the number of patients screened, identified, and treated; and
- Overall impact on changes in processes or outcomes that can be attributed to the initiative.

This study is being conducted pursuant to AHRQ's statutory authority to broadly disseminate research findings published by the Patient-Centered Outcomes Research Institute and other government-funded research relevant to comparative clinical effectiveness research to physicians, health care providers, and patients. 42 U.S.C 299b-37.

Method of Collection

To achieve the goals of the multi-site evaluation (MSE), AHRQ is requesting OMB approval for three years for new data collection by the evaluator. The evaluator's primary data collection is requested to achieve the goals of the MSE and includes the following data collection activities:

Semi-Structured Qualitative Interviews will take place in-person and/or by telephone with key staff from each grantee team (*i.e.*, principal investigator, co-investigator, evaluation lead, practice facilitation/implementation lead, and project manager) and with clinicians and staff at one primary care practice working

with each grantee. Interviews will be conducted annually beginning at the end of Year 1, for a total of three time points per grantee. During Years 1 and 3 the interviews will be conducted by phone, while Year 2 interviews will be collected in-person. The interviews for both grantee teams and primary care practice staff will cover domains such as understanding the practice implementation and changes overtime, methods of supporting practices, barriers and facilitators to implementation, strategies to overcome barriers, and the number and type of staff implementing SBI/RT and MAT.

Secondary data collected by grantees and analyzed by the evaluator will include:

Aggregated process measure data that will be used to assess whether the number of patients receiving SBI/RT and/or MAT increased at the practice level. Grantees will survey all participating primary care practices at the beginning of the initiative to collect data on basic practice characteristics (*e.g.*, size, ownership, staff, and patient

population) that can be used to evaluate relationships between practice characteristics and the number of patients receiving SBI/RT and/or MAT. Grantees will also collect quantitative information about the number, duration, and function of contact between practice facilitators and primary care practices to evaluate the relationship between duration, frequency, and type of practice facilitator-practice engagement, and the number of patients screened, receiving brief intervention, and/or treated for UAU. The practice facilitators will collect data to track changes in practices over time and facilitate an overall assessment of what activities the practice is conducting to identify and manage UAU.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to complete the semi-structured Key Informant Interviews. For the three-year clearance period, the estimated annualized burden hours for the interviews are 60.

EXHIBIT 1

| Data collection activity | Number of respondents | Number of responses per respondent | Hours per response | Total burden hours |
|----------------------------------|-----------------------|------------------------------------|--------------------|--------------------|
| Semi-Structured Interviews | 60 | 1 | 1.0 | 60 |
| Total | 60 | | | 60 |

Exhibit 2 shows the estimated annualized cost burden based on the

respondents' time to complete the Key Informant Interviews. The total

annualized cost burden is estimated to be \$6,109.

EXHIBIT 2 ESTIMATED ANNUALIZED COST BURDEN

| Form name | Number of respondents | Total burden hours | Average hourly wage rate* | Total cost burden |
|----------------------------------|-----------------------|--------------------|---------------------------|-------------------|
| Semi-Structured Interviews | 60 | 60 | ^a \$101.82 | \$6,109 |
| Total | 60 | 60 | | 6,109 |

* National Compensation Survey: Occupational wages in the United States May 2018 "U.S. Department of Labor, Bureau of Labor Statistics:" https://www.bls.gov/oes/current/oes_stru.htm.

^a Based on the mean wages for 29-1062 Family and General Practitioners.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of

AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent

request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: March 25, 2020.

Virginia L. Mackay-Smith,
Associate Director.

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