EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Total	255	75	53.95	4,046.78

* National Compensation Survey: Occupational wages in the United States May 2019, ''U.S. Department of Labor, Bureau of Labor Statistics'', *https://www.bls.gov/oes/current/oes_nat.htm#b29-0000.htm.*
[a] Based on the mean wages for *all occupations (00–0000).*
[b] Based on the mean wages for *Family Medicine Physicians (29–1215).*

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, 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: October 8, 2020.

Marquita Cullom-Stott,

Associate Director.

[FR Doc. 2020–22837 Filed 10–14–20; 8:45 am]

BILLING CODE 4160–90–P

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 ''Programmatic Information Collection for the AHRQ Initiative to Support Primary Care to Advance Cardiovascular Health in States with High Prevalence of Preventable CVD Events.''

This proposed information collection was previously published in the **Federal Register** on August 5th, 2020 and allowed 60 days for public comment. AHRQ received no substantive comments from members of the public. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received within 30 days of the date of publication.

ADDRESSES: Written 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.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Programmatic Information Collection for the AHRQ Initiative To Support Primary Care To Advance Cardiovascular Health in States With High Prevalence of Preventable CVD Events

Despite improvements in recent years, cardiovascular disease (CVD) is a significant national health burden and the leading cause of death, involved in nearly one of every three deaths. Modifiable risk factors for CVD, such as high blood pressure, high cholesterol, and smoking, remain poorly controlled. Evidence from patient-centered outcomes research (PCOR) shows that increasing the delivery of the ABCS of heart health—Aspirin in high-risk individuals, Blood pressure control, Cholesterol management, and Smoking cessation—can reduce risk and reduce heart attacks and strokes.

In 2010, Congress established the Patient-Centered Outcomes Research (PCOR) Trust Fund and instructed AHRQ to support the dissemination of PCOR findings. In accordance with its mandated role, AHRQ issued a Request for Applications (RFA) entitled Supporting Primary Care to Advance Cardiovascular Health in States with High Prevalence of Preventable CVD Events. AHRQ anticipates investing up to $18 million to support a maximum of 4 awards. Each grantee will establish a state-level entity—known as a Cooperative—to support primary care improvement and run a Heart Health Quality Improvement (QI) project. The expected earliest start date for the grants is December 30, 2020.

This initiative has the following goals:

1. To improve heart health and help reduce CVD disparities by engaging with primary care practices, and disseminating and implementing PCOR findings to improve care delivery.

2. To learn how to develop sustainable state-level primary care QI infrastructure to improve the uptake of PCOR evidence in primary care.

3. To disseminate lessons learned, which take into consideration the context in which each program operated, on how to replicate successes and avoid challenges.

This new grant initiative is being conducted pursuant to AHRQ's statutory authority to support the agency's dissemination of PCOR findings. 42 U.S.C. 299b–37(a)–(c). The information collection described in this request is being collected under AHRQ's authority in 42 U.S.C. 299b–37(c), which authorizes AHRQ to gather feedback about the value of the PCOR information it disseminates. The information described in this request will be collected by AHRQ's contractor, Abt Associates.

Method of Collection

To achieve the goals of this project the following data collections will be implemented:

1. Key informant interviews. AHRQ will conduct phone interviews with a variety of state-level organizations involved in primary care support and

with primary care practices. This information will be used to develop case studies for each Cooperative as well as program-level generalizations and lessons learned that might inform other efforts to improve care delivery.

2. Member check-in sessions. AHRQ will conduct group phone discussions with a subset of participants in the key informant interviews to corroborate case studies and lessons learned, and to provide additional shared insights across participants.

Key Informant Interviews

Individual key informant interviews will be conducted with the following groups:

- Grantee and Cooperative leadership, and Cooperative partners—about decision to participate in the project, prior collaborations, organization and governance of the Cooperative, nature and extent of partnerships, what worked well and barriers, changes to the Cooperative and their impact on provision of quality improvement (QI) support, QI support strategies and their perceived effectiveness, successful strategies for recruiting practices and types of practices recruited, success in establishing state-level capacity to provide QI support, factors associated with successful implementation of QI, longer-term impact of the grant and sustainability of capacity developed, suggestions for improvement, and lessons learned from the project.
- Unaffiliated organizations involved in or knowledgeable about primary care in the states—nature and extent of connection to the Cooperatives, awareness of the project, views about the organization and effectiveness of the Cooperatives and their networks, other local activities that may have affected the work of the Cooperatives, views on changes in practice capacity to deliver better care and on sustainability of improvements, benefits to and any potential adverse consequences for patients, suggestions for improvement and lessons learned from the project.
- Practices within the network not participating in the Heart Health QI project—prior collaboration and experience of recruitment to the network, decision to participate, nature of engagement with the Cooperative and network, benefits and drawbacks of network participation, interest in participating in Heart Health QI project, strategies employed to improve heart health, knowledge of and views on QI strategies at participating practices, concurrent efforts to improve care delivery, plans to continue participating in the network, suggestions for improvement and lessons learned.
- Practices within the network participating in the Heart Health QI project—prior collaboration and experience of recruitment to the network and Heart Health QI project, decision to participate, nature of engagement with the Cooperative and network, benefits and drawbacks of network participation, weaknesses in care delivery that QI strategies are designed to address and how the practices handle these, expectations for improvements stemming from QI projects and any potential challenges, nature of and satisfaction with support for Heart Health QI project, contribution of QI support to practice capacity to improve heart health outcomes, concurrent efforts to improve care delivery, plans to continue implementing the intervention, other benefits of participation in the Heart Health QI project, plans to remain in the project, suggestions for improvement and lessons learned.

A total of 200 interviews is anticipated over the course of three years.

All interviews will be conducted by telephone and are expected to take 45–60 minutes. Grantee and Cooperative leadership and Cooperative partner groups will be interviewed annually for three years, while the grants are active. Unaffiliated organizations and network practices, including those participating in the Heart Health QI project, will be interviewed in years 2 and 3 of the grants . This schedule of interviews reflects the anticipated evolution of the state-level entity, development of new partnerships, recruitment of practices to the network, and implementation of Heart Health QI project.

All interviews will include at least one lead interviewer and a note-taker and will be recorded with respondents' permission as a back-up. Detailed notes will be prepared after each interview. The purpose of the proposed information collection effort is to explore each grantee's primary care quality improvement, including their members and partners; and their experiences and achievements. Additionally, this information collection will serve to help synthesize insights from across grantees, identify key themes, and distill lessons learned, taking into consideration the context in which each program operated.

The following knowledge will be generated to understand the contribution of the program to developing sustainable state-level capacity to implement PCOR findings in primary care and the pros and cons of various Cooperative models, as well as lessons learned about approaches to assisting practices in implementing evidence to improve care.

Estimated Annual Respondent Burden

Table 1 presents estimates of the reporting burden hours for the information collection efforts. Time estimates are based on prior experiences and what can reasonably be requested of participating entities.

Key-informant interviews. In-depth interviews will be conducted with the total of up to 88 individuals. Respondents from Grantee and Cooperative leadership and Cooperative partner groups will be interviewed every year for three years. Respondents from unaffiliated organizations and non-participating practices will be interviewed twice, in years 2 and 3, and respondents from participating practices once or twice in years 2 and 3. The interviews are expected to last for up to 1 hour.

Member-checking sessions. Three member-checking sessions will be conducted with a total of up to 36 participants. Grantee and Cooperative leadership and key Cooperative organizations and partners will participate in two sessions, in year 1 and year 3. Network practices (those participating and not participating in heart health QI project) will participate in a member-checking session only in year 3. The sessions are expected to last for up to 1.5 hours.

TABLE 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection method or project activity	A. Number of respondents	B. Number of responses per respondent	C. Hours per response	D. Total burden hours A * B * C
Key Informant Interviews:				

TABLE 1—ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Data collection method or project activity	A. Number of respondents	B. Number of responses per respondent	C. Hours per response	D. Total burden hours A * B * C
Grantee leadership	12	3	1	36
Cooperative leadership	12	3	1	36
Cooperative partners	24	*2.5	1	60
Unaffiliated organizations	12	2	1	24
Practices in network not participating in Heart Health QI project	8	2	1	16
Practices in network participating in Heart Health QI project	20	**1.4	1	28
Member Checking Sessions:				
Grantee leadership	4	2	1.5	12
Cooperative leadership	4	2	1.5	12
Cooperative partners	2	2	1.5	6
Unaffiliated organizations	2	2	1.5	6
Network practices	12	1	1.5	18
Total	112	.....	.....	254

* **Note:** This number reflects that in Year 1 we will only interview 12 respondents, but 24 in years 2 and 3, hence 2.5 # of responses.
** This number reflects that in Year 2 we will interview 8 respondents and in year 3 we will interview 20 respondents.

Table 2 presents the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated to be $29, 260.96.

TABLE 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection method or project activity	A. Number of respondents	B. Total burden hours	C. Average hourly rate	D. Total cost burden B * C
Key Informant Interviews:				
Grantee leadership	12	36	$110.74	$3,986.64
Cooperative leadership	12	36	110.74	3,986.64
Cooperative partners	24	60	110.74	6,644.40
Unaffiliated organizations	12	24	110.74	2,657.76
Practices in network not participating in Heart Health QI project	8	16	136.49	2,183.84
Practices in network participating in Heart Health QI project	20	28	136.49	3,821.72
Member Checking Sessions:				
Grantee leadership	4	12	110.74	1,328.88
Cooperative leadership	4	12	110.74	1,328.88
Cooperative partners	4	6	110.74	664.44
Unaffiliated organizations	2	6	110.74	664.44
Network practices	12	18	110.74	1,993.32
Total	112	254	.....	29,260.96

Note: the rates were based on the mean hourly wages from the Bureau of Labor & Statistics for the closest categories of respondents and doubled to account for overhead and fringe.

The mean hourly wage rates were obtained from the Bureau of Labor & Statistics and doubled to account for overhead and fringe benefits. The occupational codes used were as follows:

- For grantee and cooperative leadership, partners, and unaffiliated organizations—medical and health service managers (11–9111, $53.37)
- For practices—an average of physicians (29–1228, $97.81), medical and health services managers (11–9111, $53.37), and nurse practitioners (29–1171, $53.77)

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, 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: October 8, 2020.

Marquita Cullom-Stott,

Associate Director.

[FR Doc. 2020–22795 Filed 10–14–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1261]

Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Technical Considerations for Non-Clinical Assessment of Medical Devices containing Nitinol.'' The Agency has developed this guidance to provide FDA's current thinking on technical considerations specific to devices using nitinol due to the unique properties of nitinol. This guidance document is intended to provide clarity and consistency in recommended non-clinical assessments across a variety of medical devices that contain nitinol.

DATES: The announcement of the guidance is published in the **Federal Register** on October 15, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–1261 for ''Technical Considerations for Non-Clinical Assessment of Medical Devices containing Nitinol.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Technical Considerations for Non-Clinical Assessment of Medical Devices containing Nitinol'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Matthew Di Prima, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 2124, Silver Spring, MD 20993–0002, 301–796–2507.

SUPPLEMENTARY INFORMATION:

I. Background

The use of nitinol in medical devices began over three decades ago in product areas such as orthodontic archwires, cardiovascular guidewires, and surgical instruments. Its use has increased over the past two decades into different device areas such as orthopaedic fracture fixation, coronary stents, and transcatheter heart valves. With an increasing trend to treat patients using minimally invasive procedures, nitinol has become a popular choice of material due to its ability to return to its original shape after being mechanically deformed or after heat is applied. Given