

Supporting Statement A For:
Surgeon General's Pledge to End the Opioid Crisis

Request for OMB Approval of an Emergency ICR

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LIST OF ATTACHMENTS

Attachment 1: List of questions and selection options for the information collection

Attachment 2: Screenshots of the information collection

The Office of the Surgeon General (OSG), Office of the Secretary, Department of Health and Human Services (HHS) requests that the Office of Management and Budget (OMB) approve an information request for the Surgeon General's Pledge to End the Opioid Crisis. This information request involves collecting information from users for this pledge which recruits doctors, dentists, nurses, and physician assistants to utilize their unique position in the community and in their practice to take notice of the opioid crisis and commit to taking action that could save lives.

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

This information collection is a critical component of a campaign to encourage health care prescribers (the user) to take action in their clinical practice to reduce the number of prescription drug overdoses and reduce the likelihood of prescription opioid drugs ending up in the possession of those who may abuse them. This information collection involves obtaining user contact information, medical profession category, medical specialty, and responses to short questions specifically designed to provide anecdotal information and contextualize the impact of the prescription opioid epidemic.

There are several advantages that the Surgeon General's Pledge to End the Opioid Crisis has in comparison to other government programs aimed at addressing the prescription opioid problem. Foremost, the Surgeon General is recognized as one of the nation's top medical officials and is in a unique position as a government official responsible for communicating key public health messages to the nation. This advantage allows his office to speak with authority to both the public as well as public health professionals who prescribe opioids. The pledge is aimed at prescribers to encourage them to take note of the crisis and commit to addressing it in their practice and in their communities.

Title 42 of the United States Code (sections 300u(a)(8) and 300u-3) authorizes the collection of the information included in this request.

A.2 Purpose and Use of the Information

The current proposal is to collect contact information from clinical prescribers including full name, zip code, e-mail address, profession, medical specialty, and responses to two short answer questions describing how prescription opioid addiction has impacted their patients and/or their practice. Personally identifiable information will not be displayed on the website and taking the pledge is an optional activity. Each collected element is vital to the pledge process. The information collection must collect name to ensure the legitimacy of the pledging aspect of the campaign. Zip code, profession, and specialty will be collected and analyzed to present aggregate pledge data. Each element will also be utilized to send personalized campaign communication. Understanding the demographics of the medical practitioners will improve the efficacy of the campaign by allowing for targeted communication. The inability to collect this information will impede OSG's ability to implement the pledge program, which is vital to the overall campaign to end opioid abuse.

The information collection will occur on two separate areas of the website. One webform will collect pledge information including First Name, Last Name, Profession, Specialty (Optional), Zip Code, and Email Address. A separate web form will collect qualitative data. Two fields ask questions regarding prescription experiences and suggestions for improving prescription practices. This qualitative collection explicitly states that form entries may be publically shared and to not include any confidential or privileged information. Name and E-mail will also be

collected with these questions to follow up on certain stories that are chosen to be portrayed on the website. PII will not be disclosed on any area of the site. Should users give consent to share their stories, no PII will be attached to the stories.

The pledge form clearly indicates that by filling out and submitting the pledge, the pledge taker will be receiving communication from the campaign. The share your story form indicates that no information will be disclosed before receiving consent from the sharer.

A.3 Use of Improved Information Technology and Burden Reduction

100 percent of the collection of information will be held electronically to optimize the process.

A.4 Efforts to Identify Duplication and Use of Similar Information

The information request proposed here will not duplicate any existing information collections because this type of pledge has not been done before by a government agency.

A.5 Impact on Small Businesses or Other Small Entities

No information about small businesses or other small entities will be involved in this information collection.

A.6 Consequences of Collecting the Information Less Frequently

Information will be provided voluntarily by the user on an on-going basis.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

None of the special circumstances relating to the guidelines of 5 CFR 1320.5 apply to this information collection, and the proposed guidelines fully comply with 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60 day Federal Register Notice was posted on February 1, 2016 in Volume 81, Number 20 (FR Doc No: 2016-01750) as part of the standard process. However, the following 30 day notice was not submitted due to administrative delays. There were no comments on the initial 60 day Federal Register Notice.

A.9 Explanation of Any Payment or Gift to Respondents

There will be no payments or gifts to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

Personally identifiable information (PII) will be collected in the form of applicant names, zip code, and email address. The HHS Privacy Act Officer has determined that the Privacy Act does not apply to this collection. Personally Identifiable Information will not be utilized to locate or retrieve individual records. Information will only be analyzed and presented in aggregate form. Information will be accessed and reviewed only by HHS staff and non-governmental partners and technical entities understand that they will not be allowed access the information collected. This information will be kept private to the extent allowed by law. Personally identifiable information in reports will not be shared with anyone outside of HHS, and physical copies of

reports will only be kept in aggregate form and not contain PII. Electronic files will be kept on password protected computers and secure servers. The website will clearly specify why it is collecting the information and any disclosure of aggregate data.

A.11 Justification for Sensitive Questions

There are no sensitive questions being asked in the application. We will collect contact information and responses to open ended question describing prescriber experience with prescription opioid addiction and how it has impacted their patients and/or their practice.

A.12 Estimates of Annualized Burden Hours and Costs

We estimate that it will take each individual approximately four minutes to complete this information request. Users should already be familiar with their basic contact information and the majority of the time would be spent responding to the optional open-ended questions. We anticipate receiving approximately 10,000 pledges in the six months in which the emergency clearance applies. During the six months, the OSG will analyze participation rates and will appropriately prepared and submit a standard ICR for OMB review with updated burden hours based on live data. The estimated annual burden is four minutes for each respondent, which works out to be 667 burden hours over the course of one year. The total cost per year to the respondents is \$33,350 calculated using an average salary of \$106,000 (\$50.00 Hourly Wage Rate), which is an estimated average salary of the anticipated respondents.

Table 12-1. Estimated Annualized Burden Hours

| Form Name | Number of Respondents | Number of Responses per | Average Burden per | Total Burden Hours |
|-----------|-----------------------|-------------------------|--------------------|--------------------|
|-----------|-----------------------|-------------------------|--------------------|--------------------|

| | | | | |
|--------------------|-------|------------|------------------------|--------|
| | | Respondent | Response (in hours) | |
| Opioid Pledge Form | 5,000 | 1 | 5/60 | 416.67 |
| | | | | |
| Total | 5,000 | 1 | 5/60 | 416.67 |

Table 12-2. Annualized Cost to Respondents

| Type of Respondents | Number of Respondents | Total Annual Burden Hours | Hourly Wage Rate | Total Annual Respondent Cost |
|---------------------|-----------------------|---------------------------|------------------|------------------------------|
| Prescribers | 5,000 | 416.67 | \$50.00 | 20,833.50 |

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no direct costs to users other than their time to participate.

A.14 Annualized Cost to the Federal Government

The cost of this information collection to the federal government arises entirely from the labor of federal program staff spent on the development of the pledge and supporting content, the review of the responses, and the pledge evaluation. There are no contractors contributing time, energy or effort to this project. We estimate that all work on the review and storage of evaluations will require the effort of two program directors/officials each spending 100 hours reviewing the aggregate information. The responses will not be reviewed individually. It is estimated that the annualized cost to the federal government is \$10,000, calculated using the average hourly wage rate of a GS-14 official.

Table A.14-1. Annual Cost to the Federal Government

| | Estimated Annual Cost |
|---------------|-----------------------|
| HHS Personnel | \$10,000 |

A.15 Explanation for Program Changes or Adjustments

An emergency approval was granted earlier this year for this program. Since June, 2016, we have adjusted the total number of respondents based on three months of data. It is projected that the total number of respondents will be approximately 5,000.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Personally identifiable information will never be published nor used to retrieve records. There may be graphical presentation of aggregate data. Optional information for publication includes short-answers to questions. Quantitative analyses will not be scientific or statistically representative of the respondent universe and any representation of data will explicitly state this. The campaign will collect information under the emergency clearance for a duration of 6 months and a standard ICR will be prepared and submitted to extend the collection beyond 6 months.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

The proposed project does not require any exceptions to the Certification for Paperwork Reduction Act Submissions (5 CFR 1320.9).