

United States Food and Drug Administration
Data to Support Drug Product Communications (CDER)
OMB Control Number 0910-0695
Gen IC Request for Approval

Title of Gen IC: Exploring Barriers to Buprenorphine Access for Opioid Use Disorder

1. Statement of Need

Buprenorphine is FDA-approved as a medication to treat opioid use disorder (MOUD) and has been shown to be safe and effective for this purpose. Treatment of opioid use disorder (OUD) is a significant and growing need to help address the U.S. opioid addiction and overdose crisis. Historically, the ability to prescribe buprenorphine-containing products for OUD required prescribers undertake extensive training to obtain a special waiver and complete post-training requirements.

To increase access to buprenorphine for the many people who could benefit, especially given inadequate availability of treatment programs and resources amid growing overdose deaths, the Federal Government began permitting healthcare providers to prescribe buprenorphine for up to 30 patients without the requirements to attend training and provide psychosocial services¹ and subsequently removed the ‘X Waiver’ requirement².

To better understand the remaining barriers to buprenorphine access now that prescribing requirements have been lifted, CDER’s Office of Communications (OCOMM) will conduct a survey to gather data on this critically important topic through the Sermo RealTime survey platform. This collection was originally submitted and received OMB approval in 2022. However, the planned collection could not take place because a necessary contract modification could not be completed in 2022 due to factors outside of CDER/OCOMM’s control. The necessary contract modification was completed in 2023 and will not affect this planned collection.

2. Intended Use of the Information

The information will help inform FDA’s efforts to address barriers and misperceptions, including through communication and education related to prescribing buprenorphine as MOUD. In addition to identifying barriers that can be addressed through outreach, the findings from these surveys will help identify target audience(s) for communications. The findings will also complement other forms of research being conducted in CDER about this topic. The data collected will not be statistically representative of the target population and will not be used for making policy or regulatory decisions.

3. Description of Respondents

¹ SAMHSA, 2022. FAQs About the New Buprenorphine Practice Guidelines. Accessed 7/21/2022 <https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner/new-practice-guidelines-faqs>

² SAMHSA, 2023. Waiver Elimination (MAT Act). Accessed 10/31/2023 <https://www.samhsa.gov/medications-substance-use-disorders/waiver-elimination-mat-act>

Participants for this study will consist of DEA-licensed health care professionals (HCPs): physicians, physician assistants (PAs), and nurse practitioners (NPs) who have self-selected to participate in a healthcare professional networking platform called Sermo and its related survey capability, called Sermo RealTime. To qualify as a member of the Sermo survey panel, individuals must (a) be a licensed health care professional (“HCP”) in the US or in another country and (b) be a registered participant of sermo.com. Prior to the use of this site, members must provide Sermo with valid confirmation of (a) & (b), above, and authorize Sermo to confirm the veracity of such information.

The project materials include a recruitment screener (**Attachment A**) and participant screener (**Attachment B**). Upon OMB approval, a brief participant screener will be used to recruit participants (N=1,519). The participant pool will be comprised of a variety of medical specialties and segmented into respondent pools based on those who have/have not prescribed buprenorphine for OUD. This survey is seeking health care professionals with active DEA licenses to prescribe controlled substances and who spend at least 50% of their time providing direct patient care. The project will seek to obtain a mix of respondents in regard to patient population, specialty certification, demographics and years of practice. Based on previous experience, only approximately 50% of a screened population will be eligible for this survey. While Sermo maintains member profile information regarding specialty certification, the information Sermo collects is limited in regard to other demographic characteristics and therefore we anticipate sending invitations to approximately two times the number of required participants in order to identify and obtain the required number of individuals.

4. How the Information is Collected

The information is being collected through the Sermo RealTime platform. Sermo, for which OCOMM has a contract, is a social media network providing real-time physician discussion and a survey platform that includes more than 1.3 million HCPs across 150 countries. Sermo will recruit respondents from its panel of validated members based on initial screening criteria provided by OCOMM (e.g., related to HCP type).

After identifying participants as initially eligible, SERMO will send potential participants an email invitation to participate in the study. Participants will click a unique link in the email that enables them to take the survey only once. Each participant will first be shown an introduction to the survey and an informed consent form. To advance to the screener questions, they will have to click a button saying they have read the consent form and agree to participate. Those who provide consent will be shown up to 7 screening questions to ensure they meet the recruitment criteria and will then proceed to the questionnaire (**Attachment C**).

5. Confidentiality of Respondents

All respondents will provide informed consent that ensures they understand the project purpose, that their participation is voluntary, and that their responses will be kept secure to the extent permitted by law. Sermo does not collect identifiable personal health information or other health or medical information about individuals and does not possess a data-based key to re-identify patient data. Sermo stores all database member activity and assigns a unique ID number which stays with the member throughout their entire membership. Sermo does not collect or maintain

information that would associate a submission with a specific patient and IP addresses will not be collected by the online survey system. Any data provided to OCOMM will be deidentified and no participant's identifiable information (e.g., name) will be included in the dataset. All information will be stored on a secure network drive, which will only be accessible to individuals granted access to work on the project. No first- or third-party cookies will be stored during questionnaire completion.

FDA's Institutional Review Board (IRB) reviewed this study and determined it is exempt from the requirements of 45 CFR § 46.101b(2) (**Attachment D**).

6. Amount and Justification for Proposed Incentive

Healthcare professionals who register for and Sermo determines are eligible to become members of its RealTime survey panel agree to its conditions for participation. Among these are that Sermo will determine if panel members who respond to surveys or other opportunities may be entitled to honoraria or incentives for completed participation based on multiple factors, such as the length and type of the survey. When Sermo decides to offer an incentive, they are solely responsible for determining the value and form of the incentive, which they notify potential participants of in advance and transfer to each participant's Sermo account upon completion. FDA will not be involved in any aspect of incentives when using the RealTime panel for this study, including determining whether an incentive will be offered for participating in this study, nor does it have any influence on incentive value or knowledge of whether an incentive was provided.

7. Questions of a Sensitive Nature

We do not anticipate asking any sensitive questions in the survey. Nevertheless, respondents will be permitted to stop participating at any time.

8. Description of Statistical Methods

The survey will yield quantitative data that can be used for certain types of statistical analyses and some qualitative data. Statistical software (e.g., SPSS) will be used to clean and organize the quantitative data before analyses. The analyses may include, but are not limited to, comparisons of means, t-tests, calculation of summary statistics and cross-tabulations and any appropriate estimates of uncertainty. Although some statistics will be calculated, the convenience sampling procedures for the survey do not allow for results that are nationally representative, and estimates may not represent the population at-large. Where respondents provide comments, qualitative data will be analyzed with thematic analyses.

9. Burden

Respondent Type/Category	Number of Respondents	Participation Time (minutes)	Total Burden (hours)
Screening	3,000	2**	100
Questionnaire	1,519	10	258
Totals	3,000	12	358

**2 minutes is the average amount of time needed to complete the screener, however, to reduce the burden on respondents to the greatest extent possible, the screening interview is sequentially numbered so questions related to the main eligibility criteria occur first so ineligible participants will be screened out quickly before having to answer additional questions unnecessarily.

10. Date(s) to be Conducted

We plan to begin conducting interviews immediately upon OMB approval.

11. Requested Approval Date

August 2024

12. FDA Contacts

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