OMB Control No.: 0910-0695

Expiration Date: 3/31/2024

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0695. The time required to complete this portion of the information collection is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRAStaff@fda.hhs.gov.

**Appendix A**

**Focus Group Recruitment Screener**

**FDA – Focus Group Screening Questionnaire for Study to Explore Healthcare Providers’** **Practices, Perspectives, and Experiences Prescribing/Co-Prescribing Benzodiazepines and Opioids**

**FINAL**

|  |  |  |
| --- | --- | --- |
| **Group #** | **Date/Time**  | **Demographics** |
| 1 | TBD  | Primary Care Physicians (PCPs) who have NOT prescribed MOUD/buprenorphine  |
| 2 | TBD  | PCPs who have NOT prescribed MOUD/buprenorphine  |
| 3 | TBD  | PCPs who have NOT prescribed MOUD/buprenorphine |
| 4 | TBD  | PCPs who have NOT prescribed MOUD/buprenorphine |
| 5 | TBD  | PCPs who have NOT prescribed MOUD/buprenorphine |
| 6 | TBD  | PCPs who have prescribed buprenorphine products for OUD in the past 3 months  |
| 7 | TBD  | Specialists/All Mental Health Specialists who have NOT prescribed MOUD/buprenorphine |
| 8 | TBD  | Specialists/Neurology who have NOT prescribed MOUD/buprenorphine |
| 9 | TBD  | Specialists/Emergency Medicine who have NOT prescribed MOUD/buprenorphine |
| 10 | TBD  | Specialists/Pain Medicine (some may have prescribed buprenorphine products for OUD in the past 3 months) |
| 11 | TBD  | Specialists/Addiction Medicine who have prescribed buprenorphine products or dispensed methadone for OUD in the past 3 months  |
| 12 | TBD  | Specialists/Only Mental Health Psychiatrists who have prescribed buprenorphine products for OUD in the past 3 months  |
| 13 | TBD  | Primary Care NPs who have NOT prescribed MOUD/buprenorphine |
| 14 | TBD  | Primary Care PAs who have NOT prescribed MOUD/buprenorphine |
| 15 | TBD  | Specialist NPs (Mix of above specialties) who have NOT prescribed MOUD/buprenorphine |
| 16 | TBD  | Specialist PAs (Mix of above specialties) who have NOT prescribed MOUD/buprenorphine |

**NOTE TO RECRUITERS:**

* **Please make sure respondents are aware the focus group they are being recruited for will last about 90 minutes.**
* **Please recruit 12 healthcare providers per focus group to ensure we meet our goal of “seating” 9 participants per group.**

**Introductory Script:**

[Hello [Name of HCP from file], /Hello. May I please speak to [name of HCP from file]?]

We are recruiting healthcare providers for a study sponsored by the U.S. Food and Drug Administration (FDA). The FDA has asked Lake Research Partners (LRP), an independent research company, to conduct 90-minute focus groups with healthcare providers about benzodiazepine and opioid medications. I work with Schlesinger, the recruiting partner working with LRP, and would like to ask you a few questions to see if you qualify for one of the focus groups being conducted.

Q1. To start, which of the following best describes your occupation? [RECRUIT A MIX]

Select one

Physician (MD, DO) 1

Physician’s Assistant 2

Nurse Practitioner 3

Psychologist 4

None of the above [**TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT**] 5

|  |
| --- |
| Key to Determine Focus Group Qualification * Q1=1 qualifies for group numbers 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, or 12
* Q1=2 qualifies for group numbers 14 or 16
* Q1=3 qualifies for group numbers 13 or 15
* Q1=4 qualifies for group numbers 7 or 12

Total Number of Recruits per Occupation Type Physician (MD, DO) – recruit 144, including 12 who have prescribed MOUDPhysician’s Assistant – recruit 24 Nurse Practitioner – recruit 24 Psychologist – recruit 24, including at least 12 who have prescribed MOUD |

Q2. In the last 12 months, have you participated in any focus groups or interviews about prescription opioids, opioid analgesics or benzodiazepines?

Select one

Yes [**TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT**] 1

No 2

Don't know [**TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT**] 3

Q3. Have you ever worked for any of the following entities?

Select one

Any office, division, or agency within the Department of Health and Human Services (HHS) [ **TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT**] 1

A pharmaceutical company [**TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT**] 2

Neither of the above 3

Q4. Do you currently, or have you ever, received consulting payments from a pharmaceutical company?

Select one

Yes, currently 1

Yes, have in the past 2

No 3

Prefer not to answer 4

Q5. Which of the following best describes your area of practice? [RECRUIT A MIX]

Select one

Primary care, (family practice, or general, internal, or geriatric medicine) 1

Mental health, psychiatry, geriatric psychiatry, or psychology 2

Neurology/Neurophysiology 3

Emergency Medicine 4

Pain Medicine 5

Addiction Medicine 6

Something else [**TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT**] 7

Don't know [**TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT**] 8

|  |
| --- |
| Key to Determine Focus Group Qualification * Q5=1 qualifies for group numbers 1, 2, 3, 4, 5, 6, 13, or 14
* Q5=2 qualifies for group numbers 7, 12, 15, or 16
* Q5=3 qualifies for group numbers 8, 15, or 16
* Q5=4 qualifies for group numbers 9, 15, or 16
* Q5=5 qualifies for group numbers 10, 15, or 16
* Q5=6 qualifies for group numbers 11, 15, or 16
 |

Q6. In a typical month, for about how many different patients do you prescribe the following medications for conditions NOT related to procedure pre-medication, acute seizure management, or end-of-life care?

For each option, select one of the following responses:

1 to 4 patients {**TERMINATE**} 1

5 or more patients 2

Does not apply {**TERMINATE**} 3

1. Benzodiazepines (e.g., Xanax/alprazolam, Valium/diazepam, Klonopin/clonazepam)
2. Opioid analgesics (e.g., OxyContin/oxycodone, Vicodin/hydrocodone, MS Contin/morphine)

Q7. In a typical month, do you prescribe benzodiazepines in conjunction with opioid analgesics for conditions NOT related to procedure pre-medication, acute seizure management, or end-of-life care? This could include prescribing benzodiazepines to a patient receiving opioids from another prescriber or opioids to a patient receiving benzodiazepines from another prescriber. [RECRUIT AT LEAST 50% PER GROUP WHO SAY “YES”]

Yes 1

No 2

Prefer not to answer [**TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT**] 3

Q8. Do you have the DATA 2000 or “X” waiver from the DEA to prescribe buprenorphine to treat opioid use disorder?

Select one

Yes 1

No [**SKIP TO Q12**] 2

Prefer not to answer [**TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT**] 3

|  |
| --- |
| Key to Determine Focus Group Qualification * Q8=1 qualifies for group numbers 6, 10, 11, or 12

TERMINATES for group numbers 1-5, 7-9, and 13-16 * Q8=2 qualifies for group numbers 1-5, 7-10, and 13-16
 |

Q9. [IF Q8=1, yes] How long have you had the DEA DATA 2000 or “X” Waiver?

Select one

Less than 1 year 1

1 to 4 years 2

5 or more years 3

Does not apply 4

Q10. [IF Q8=1, yes] In the past 3 months, have you prescribed a buprenorphine-containing medication to treat opioid use disorder?

Select one

Yes 1

No 2

Prefer not to answer [**TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT**] 3

|  |
| --- |
| Key to Determine Focus Group Qualification * Q10=1 qualifies for group numbers 6, 10, 11, or 12

TERMINATES for group numbers 1-5, 7-9, and 13-16 * Q10=2 qualifies for group numbers 1-5, 7-10, and 13-16
 |

Q11: [IF Q8=1 and Q10=1, yes] How often do you prescribe medication for opioid use disorder?

Very often 1

Often 2

Sometimes 3

Rarely 4

Prefer not to answer 5

Q12. To your knowledge, have any of your patients misused, abused, and/or become addicted to benzodiazepines?

Select one

Yes [**RECRUIT 3-4 FOR EACH GROUP**] 1

No [**RECRUIT 3-4 FOR EACH GROUP**] 2

Don't know 3

Prefer not to answer [**TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT**] 4

Q13. What is your sex?

Select one

Male [**RECRUIT 4-6 FOR EACH GROUP**] 1

Female [**RECRUIT 4-6 FOR EACH GROUP**] 2

Q14. How many years have you been in practice post-residency? If you did not do a residency, how many years have you been in practice? [RECRUIT A MIX]

Select one

Less than 10 years 1

10-19 years 2

20-29 years 3

30 years or more 4

Prefer not to say 5

Q15. Would you consider your primary practice location to be…? [RECRUIT A MIX]

Select one

Urban 1

Suburban 2

Rural 3

Q16. In which state do you practice most often? [RECRUIT A MIX ACROSS 9-WAY CENSUS REGIONS: NEW ENGLAND, MIDDLE ATLANTIC, EAST NORTH CENTRAL, WEST NORTH CENTRAL, SOUTH ATLANTIC, EAST SOUTH CENTRAL, WEST SOUTH CENTRAL, MOUNTAIN, AND PACIFIC]

Insert drop-down list of states

Select one

|  |
| --- |
| Key for Recruiters |
| New England | Middle Atlantic | East North Central | West North Central  | South Atlantic | East South Central | West South Central | Mountain  | Pacific |
| CT | NJ | IN | IA | DE | AL | AR | AZ | AK |
| ME | NY | IL | KS | DC | KY | LA | CO | CA |
| MA | PA | MI | MN | FL | MS | OK | ID | HI |
| NH |  | OH | MO | GA | TN | TX | NM | OR |
| RI |  | WI | NE | MD |  |  | MT | WA |
| VT |  |  | ND | NC |  |  | UT |  |
|  |  |  | SD | SC |  |  | NV |  |
|  |  |  |  | VA |  |  | WY |  |
|  |  |  |  | WV |  |  |  |  |

Q17. In which medical setting do you practice most often? [RECRUIT A MIX] [IF SOMEWHERE ELSE PLEASE ASK TO SPECIFY AND RECORD ANSWER]

Select one

Private office/small practice (10 or fewer providers) 1

Private office/large practice (11 or more providers) 2

Outpatient clinic 3

Inpatient hospital 4

Other [**WRITE IN/RECORD**] 5

Q18. About what percentage of your patients are covered by each of the following types of health insurance? [RECRUIT A MIX]

For each option, record volunteered percentage

(Volunteered Percentage: **RECORD**) 1

Does not apply 2

1. Private health insurance
2. Medicaid
3. Medicare
4. Tricare or other military insurance
5. Other [RECORD]

Q19. What is your age? [INCLUDE A CHECK BOX FOR PREFER NOT TO ANSWER] [RECRUIT A MIX]

Enter a number

Q20. [IF AGE IS PREFER NOT TO ANSWER] In which of the follow age ranges do you fall? [RECRUIT A MIX]

Select one

Under 25 [**TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT**] 1

25-34 years 2

35-54 years 3

55 years or older 4

Prefer not to answer 5

Q21. Are you Hispanic, Latino, or of Spanish origin? [RECRUIT A MIX]

Yes 1

No 2

Prefer not to say [**LIMIT TO 2 PER GROUP**] 3

Q22. What is your race? [RECRUIT AT LEAST 4 PEOPLE OF COLOR PER GROUP TO SEAT 3]

Select all that apply

White 1

Black or African American 2

Asian 3

American Indian or Alaska Native 4

Native Hawaiian or Other Pacific Islander 5

Prefer not to answer [**LIMIT TO 2 PER GROUP**] 7

**Closing Scripts**

**ALL GROUPS: Ineligible - Closing Script**

[**ONLINE/PHONE**] I’m sorry, but you are not eligible for this study. There are many possible reasons why people are not eligible. These reasons were decided earlier by the researchers. However, thank you for your interest in this study and for taking the time to answer our questions today.

**ALL GROUPS: Eligible - Closing Script**

[ONLINE] Thank you for answering our questions. Based on your responses, we would like to invite you to participate in a 90-minute virtual focus group. Your participation is completely voluntary. A member of our team will follow up with you shortly to talk through next steps and schedule a time for participating.

[PHONE] Thank you for answering our questions. Based on your responses we would like to invite you to participate in a 90-minute virtual focus group. Your participation is completely voluntary. As a token of appreciation for your participation,we will mail you a $375 Visa gift card sent to your home address 4-6 weeks after you participate in our online focus group.

The online focus group discussion will be held on [**DATE/DATES**] at [**TIME/TIMES**]. [**IF ELIGIBLE FOR MULTIPLE DATES/TIMES**] Which of those dates/times works with your schedule? [**RECORD**]

The discussion will be audio and video recorded, and research team members, including from the FDA, may observe the discussion so they can hear directly from you.

With this additional information in mind, would you like to participate in the group discussion at [**TIME**] on [**DATE**] (to be determined based on the person’s availabilities as noted above)?

Yes [**MOVE TO INFORMED CONSENT SCRIPT**]

No

[**IF NO, DON’T WANT TO PARTICIPATE**] May I ask your reason for not wanting to participate? [**RECORD ANSWER AND CATEGORIZE, DON’T READ OPTIONS TO RECRUIT**]

Honorarium is too low

Dates/times don’t work with my schedule

Changed my mind

Declined to say

Other [**WRITE IN/RECORD**]

**Informed Consent Instructions**

Great. We will send you an informed consent form that includes more information about the study along with a reminder letter and instructions for the focus group. You MUST return a signed copy of this consent form before the date of the focus group to participate in it. I will email the form so you can sign, scan, and email it back.

I will send you an informed consent form by email to [**EMAIL ADDRESS ON FILE**]. Would you please confirm this is the best email address for you? Please read and sign the consent form and send a scanned copy of it to [**EMAIL OF RECRUITER**]. Please remember that to participate, we must receive the signed consent form from you before [**DATE OF THE FOCUS GROUP**].

If you have any questions about the information in the consent form, you can contact the project director, Alysia Snell, at asnell@lakeresearch.com or 202-470-4440.