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

Appendix B

Interview Recruitment Screener

FDA – IDI Screening Questionnaire for Study to Explore Healthcare Providers' Practices, Perspectives, and Experiences Prescribing/Co-Prescribing Benzodiazepines and Opioids FINAL

Breakdown of the 30 One-on-One Interviews

- 9 interviews among primary care physicians (PCPs) who have **NOT** prescribed MOUD/buprenorphine
- 3 interviews among PCPs who **have** prescribed MOUD [i.e., their main practice is general primary care, but they have prescribed MOUD/buprenorphine to patients for opioid use disorder]
- 2 interviews among PCP specialists in Mental Health who have **NOT** prescribed MOUD/buprenorphine
- 2 interviews among PCP specialists/psychiatrists in Mental Health who **have** prescribed buprenorphine products for OUD in the past 3 months
- 2 interviews among PCP specialists in Neurology who have **NOT** prescribed MOUD/buprenorphine
- 2 interviews among PCP specialist in Emergency Medicine who have **NOT** prescribed MOUD/buprenorphine
- 2 interviews among PCP specialists in Pain Medicine (may have prescribed buprenorphine products for OUD in the past 3 months)
- 2 interviews among PCP specialists in Addiction Medicine who **have** prescribed buprenorphine products or dispensed methadone for OUD in the past 3 months
- 2 interviews among primary care nurse practitioners (NPs) who have **NOT** prescribed MOUD/buprenorphine
- 2 interviews among primary care physician assistants (PAs) who have **NOT** prescribed MOUD/buprenorphine
- 1 interview with a NP specialist in Mental Health who have **NOT** prescribed MOUD/buprenorphine
- 1 interview with a PA specialist in Mental Health who have **NOT** prescribed MOUD/buprenorphine

NOTE TO RECRUITERS:

- **Please make sure respondents are aware the interview they are being recruited for will last about 60 minutes.**
- **Please recruit 36 healthcare providers in total to ensure we have 30 participants (recruiting 2 extra physicians, 2 extra PAs, and 2 extra NPs).**

Introductory Script:

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

We are recruiting health care 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 60-minute one-on-one interviews 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 interviews being conducted.

Q1. To start, which of the following best describes your occupation?

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

<u>Total Number of Recruits per Occupation Type</u>	
Physician (MD, DO) – recruit 26 (including the 2 over-recruits)	
Physician's Assistant – recruit 5 (including the 2 over-recruits)	
Nurse Practitioner – recruit 5 (including the 2 over-recruits)	

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 above3

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/Neurophysiology3
- Emergency Medicine.....4
- Pain Medicine5
- Addiction Medicine6
- Something else **[TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT]**.....7
- Don't know **[TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT]**.....8

Key to Determine Interview-Type Qualifications

- Q5=1 qualifies for the 12 interviews among PCPs who have or have NOT prescribed MOUD and 4 interviews among NPs and PAs
- Q5=2 qualifies for the 4 interviews among PCP specialists in Mental Health, 1 interview with a PA specialist in Mental Health, or 1 interview with a NP specialist in Mental Health
- Q5=3 qualifies for the 2 interviews among PCP specialists in Neurology
- Q5=4 qualifies for the 2 interviews among PCP specialists in Emergency Medicine
- Q5=5 qualifies for the 2 interviews among PCP specialists in Pain Medicine
- Q5=6 qualifies for the 2 interviews among PCP specialists in Addiction Medicine

Total Number of Recruits per Practice Area

Physician (MD, DO) – recruit 26 (including the 2 over-recruits)
 Physician’s Assistant – recruit 5 (including the 2 over-recruits)
 Nurse Practitioner – recruit 5 (including the 2 over-recruits)

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; MOVE TO INELIGIBLE CLOSING SCRIPT}**.....1
- 5 or more patients2
- Does not apply **{TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT}**.....3

- a. Benzodiazepines (e.g., Xanax/alprazolam, Valium/diazepam, Klonopin/clonazepam)
- b. 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% ACROSS INTERVIEWS 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 Interview-Type Qualifications

- Q8=1 qualifies for the 3 interviews among PCPs who have prescribed MOUD, 2 interviews among PCP specialists in Mental Health who have prescribed MOUD, 2 interviews among PCP specialists in Pain Medicine who may have prescribed MOUD, and 2 interviews among PCP specialists in Addiction Medicine who have prescribed MOUD.
- Q8=2 qualifies for the 9 interviews among PCPs who have NOT prescribed MOUD, 2 interviews among PCP specialists in Mental Health who have NOT prescribed MOUD, 2 interviews among PCP specialists in Neurology who have NOT prescribed MOUD, 2 interviews among PCP specialists in Pain Medicine who may have prescribed MOUD, 2 interviews among PCP specialists in Emergency Medicine who have NOT prescribed MOUD, 2 interviews among NPs and 2 interviews among PAs who have NOT prescribed MOUD, 1 interview with a NP specialist in Mental Health and 1 interview with a PA specialist in Mental Health who have NOT prescribed MOUD.

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 years3
- Does not apply4

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 Interview-Type Qualifications

- Q8=1 AND Q10=1 qualifies for the 3 interviews among PCPs who have prescribed MOUD; 2 interviews among PCP specialists/psychiatrists who have prescribed MOUD; 2 interviews among PCP specialists in Addiction Medicine who have prescribed MOUD; and 2 interviews among PCP specialists in Pain Medicine who may have prescribed MOUD;
- Q10=2 qualifies for all interviews except those with PCPs who have prescribed MOUD

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

- Very often.....1
- Often.....2
- Sometimes3
- Rarely.....4

Q12. To your knowledge, have any of your patients misused, abused, and/or become addicted to benzodiazepines? [RECRUIT A MIX ACROSS INTERVIEWS]

Select one

- Yes1
- No2
- Don't know.....3
- Prefer not to answer [TERMINATE; MOVE TO INELIGIBLE CLOSING SCRIPT].....4

Q13. What is your sex?

Select one

- Male [RECRUIT 18].....1
- Female [RECRUIT 18].....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 ACROSS INTERVIEWS] [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

- a. Private health insurance
- b. Medicaid
- c. Medicare
- d. Tricare or other military insurance
- e. Other **[RECORD]**

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

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 ACROSS INTERVIEWS]**

- Yes.....1
- No.....2
- Prefer not to say **[LIMIT TO 5]**.....3

Q22. What is your race? **[RECRUIT AT LEAST 10 PEOPLE OF COLOR ACROSS INTERVIEWS]**

Select all that apply

- White.....1
- Black or African American.....2
- Asian.....3
- American Indian or Alaska Native4
- Native Hawaiian or Other Pacific Islander.....5
- Prefer not to answer **[LIMIT TO 5]**.....7

Closing Scripts

ALL INTERVIEWS: 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 INTERVIEWS: Eligible - Closing Script

[ONLINE] Thank you for answering our questions. Based on your responses, we would like to invite you to participate in a 60-minute virtual one-on-one interview. 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 60-minute virtual one-on-one interview. Your participation is completely voluntary. As a token of appreciation for your participation we will mail you a [Physician: \$225, NP/PA: \$200] Visa gift card sent to your home address 4-6 weeks after you participate in our online interview.

The online interview will be scheduled at your convenience. Of the following dates and times [RECRUITER, PLEASE REFER TO MODERATOR AVAILABILITY SCHEDULE], which 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 interview 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 interview. You MUST return a signed copy of this consent form before the date of the interview 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 INTERVIEW].

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.