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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 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 MOUD
 Physician'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 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 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 patients2
- Does not apply {**TERMINATE**}.....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% 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 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 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
- Sometimes3
- 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

- 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]

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 Native4
- 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 [Physician: \$275, NP/PA: \$250] 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.

