

**FDA CDER/OPA
Incorporation of REMS into Prescriber Settings
Prescriber Setting Focus Groups
Interviewer's Guide**

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Event Type: Focus Group Interview

Moderator/Interviewer: _____

Site: _____ Date: _____

Participant Details (Do Not Use Identifying Information):

Research Purpose: To assist FDA CDER/OPA in gaining insight on prescriber settings and processes in your speciality area.

Introduction and Ground Rules

Thank you for being here today. We greatly appreciate your willingness to participate in this <group / interview>. My name is _____, and I work for Deloitte Consulting/Global Prairie, an independent research and consulting firm. The purpose of this session is to support a prescriber setting research study sponsored by the Food and Drug Administration. We invited you here today to help us gain a better understanding of prescriber setting processes in your specialty area.

Your opinions are important to us and to FDA. With your help we will recommend ways FDA can design and implement effective policies around prescriber practices. There are no right or wrong answers here—we're just looking for your thoughts, experiences, and opinions on the issues that we'll be talking about.

Before we begin, I want to briefly go over a few ground rules for our <group / interview> today:

- We're recording this discussion to help facilitate the research. This helps to make sure we capture everything that's said during the conversation.

- <If Focus Group, include the following>
 - Please keep side conversations to a minimum—let us all hear what you’re saying to your neighbor.
 - Please speak one at a time so the recording can clearly pick up what you’re saying.
 - We want to hear from all of you, so as moderator I may ask you specifically to respond to a question.
- We will keep what you say confidential, and will not use your name or share this information beyond our research group.
- Also, I don’t write FDA policies, so don’t worry about offending me if you say something critical of the organization or its policies. You really can’t hurt my feelings here, and getting your honest opinions and feedback is the whole purpose of the <group / interview> today, so don’t feel the need to hold back or pull any punches.

With that being said, let’s begin...

Ice Breaker

To start off, please introduce yourself and respond briefly to the following question(s):

- In what capacity do you currently work?
- In what specialty area do you currently work?

General Practice Questions

1. Please describe your practice setting (see examples below)
 - a. Specialty:
 - b. Practice group/organization (e.g., multispecialty, academic, etc.):
 - c. Size (# of physicians w/in practice, # of support staff):
 - d. Types of insurance accepted:
 - e. Care model:
 - f. Types of prescribers (MDs, DOs, NPs, PAs):
 - g. Typical patient population (e.g., indigent, rural):
 - h. Physical facility (multiple offices, hospital/clinic):
2. What are the biggest challenges you face in your practice?
3. Many practitioners spend significant time on a variety of practice activities outside of direct patient care. Describe the proportion of time you spend on direct patient care vs.

other practice activities (for example, paperwork related to patient care, participation in professional organizations, clinical reading, supervisory work, and administrative/managerial work).

4. What regulations/guidelines does your practice follow (e.g., institutional guidelines, etc.)? How do these guidelines affect your treatment decision-making process and safety practices?
5. To what degree and in what ways are your patients involved in the treatment decision-making process?
6. Describe your experience with EMRs/EHRs
 - a. With a particular emphasis on the prescribing practice.

Prescribing Questions

7. Other than safety & efficacy, what are your top 3 considerations when prescribing a medication/drug? Please explain.
8. What are your biggest burdens in prescribing?
9. Please describe the order of thought process that you go through when determining which scrip to write.
 - a. How do you prioritize this order in making this determination?
 - b. Describe a prescription encounter for me, one that ends in you writing a scrip.
 - c. If you prescribe for multiple disease states, how does your scrip writing decision-making change across disease states?
10. Aside from handing the patient a prescription, what prescribing process do you follow?
 - a. What are the steps?
 - b. What are the handoffs? Internal **and** external?
 - c. How long does each step take? (execution time and lag time)
 - d. How much of the prescribing and/or decision-making process depends on the individual patient (and how much is standard across the board)?
 - e. If you prescribe for multiple disease states, how much of the prescribing and/or decision-making process depends on the disease state?
 - f. Are the same team members always involved in the same activity(ies) of the prescription process?
 - g. To what extent are your prescription processes automated?
 - h. How do you ensure safety?
 - i. To what extent are your prescription processes controlled/monitored/documented?
 - i. What control variables exist within the regular/standard prescription process?
 - ii. What are existing checks for writing a prescription?
 - j. If you have worked in other settings, from your experience, which factors/elements differentiate your settings from other settings?

- k. What happens to the prescription after it leaves your practice?
 - l. If necessary, ask “When you have an ETASU, what is the process that’s followed? To what extent do REMS/ETASUs modify/impact your existing practices (i.e. are there precautionary measures already in place)?
<<Be sure to differentiate from payor hurdles!!>>
11. When you have a choice of which medication to prescribe, how do you choose?
- m. What, if anything, is a real deal-buster for any given med?
 - n. Sure, there are rules in prescribing, but what really happens when you’re making your prescribing decision?
 - o. What is the biggest positive influence on your choosing one med over another?
 - p. What is the biggest negative influence on your choosing one med over another?
 - q. How much are you willing to put up with (in terms of barriers or hoops to jump through) to ensure you can prescribe exactly the medicine you want to for your patients?
12. What critical step(s) or consideration(s) of your prescribing process haven’t we asked about?

Communications Questions

13. How do you learn about the process for prescribing a new medication (the practical process)?
- a. What role (if any) do accrediting organizations (e.g., AMA) play?
 - b. What role do the pharmaceutical companies play?
14. In your experience, what has been the most effective means of learning about prescription safeguards and precautions [REMS/ETASUs]?
15. In your opinion, what are the barriers to patients understanding the full benefits and/or risks of prescription medication?
- <<Potential to discuss time constraints of patient visits, cumbersome patient materials, etc.>>

REMS-specific Questions

16. What is your process for getting a medication to a patient when it is a multistep process?
- a. Do you leave it open or go specific to a REMS?
 - b. If you prescribe for multiple disease states, does this vary across disease states?
17. How do you think REMS affect patient care?
18. In what ways do you think that REMS improve patient safety?
OR: Do you believe that REMS improves patient safety? Why or why not?

19. Do you think that REMS helps **your** patients?

20. What are some of the reasons you think REMs should be in place?

21. If you were tasked by the FDA, how would you make the process of prescribing/working with a REMS with ETASU drug easier?

Conclusion

We'd like to thank you again for being here and for contributing to this discussion. We have learned a lot and really appreciate your ideas and insights. Before we conclude, I'd like to ask just one more question:

- Based on what we've discussed today, what one piece of advice would you give FDA to improve the effectiveness of REMS/ETASUs?

Closing Statement

Well, those are all of the questions I have for you. Thank you very much for your comments. This has been very helpful. Your responses will help us make great recommendations to FDA.