


**NCCN Oncology Summit:
Recommendation for REMS
Stakeholders**

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National Press Club
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www.nccn.org 

Presenters

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Discussion Points

- Provider knowledge about the purpose, benefits, and challenges of REMS
- Impact of REMS on prescribing patterns
- Compensation for complying with REMS regulations
- Patient health literacy
- Minimization of provider burden
- Incorporating drugs with REMS into clinical practice

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Provider Knowledge

- REMS are relatively new and the requirements are not mature
- Clinician knowledge regarding REMS regulations and requirements is sub-optimal
- May increase acceptance if benefits of REMS are better understood

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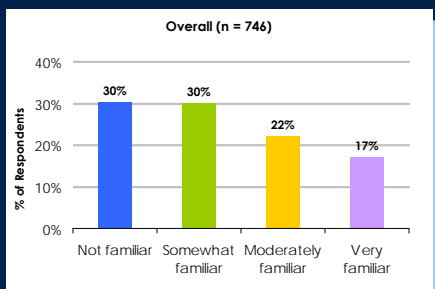
Provider knowledge about the purpose, benefits, and challenges of REMS

Near term	Medium term	Long term
Survey clinician knowledge regarding REMS	Increase provision of REMS as a topic in continuing education programs	Work with medical and pharmacy schools to incorporate REMS into the curriculum

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To what extent are you familiar with the REMS regulation and the different components of REMS?

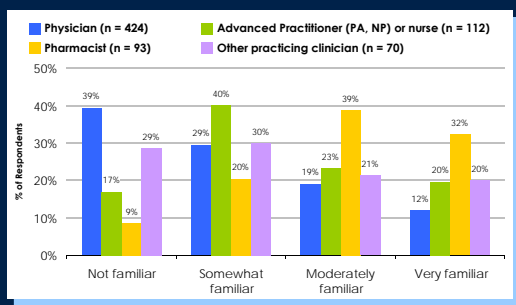


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By Provider Type



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Prescribing Patterns and Access

- Possible that REMS will influence prescribing practices
 - Administrative burden
 - Other available options
- Provider refusal to participate in REMS (therefore decreasing access)
- Possible treatment disparities

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The impact of REMS on prescribing patterns

Near term	Medium term	Long term
Survey clinicians regarding the perceived impact of REMS on prescribing patterns and access to medications	Supply chain considerations must be determined to minimize new costs and indirect impact on prescribing and patient access.	Conduct a long-term assessment of the prescribing patterns of drugs with REMS requirements

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Provider Burden

- An already overburdened system
 - Prior authorization
 - Patient assistance programs
- To meet some REMS requirements, providers must spend additional time on administrative tasks
 - Registration
 - Training and certification
 - Documentation

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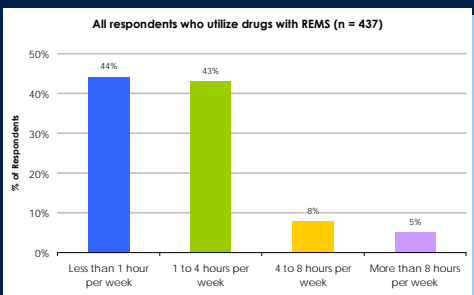
Minimization of provider burden

Near term	Medium term	Long term
FDA must establish a process to allow for provider feedback regarding future and emerging issues with REMS requirements as well as during REMS development.	Conduct a study to benchmark the time spent meeting REMS requirements	An objective assessment of the cost impact of REMS should be performed

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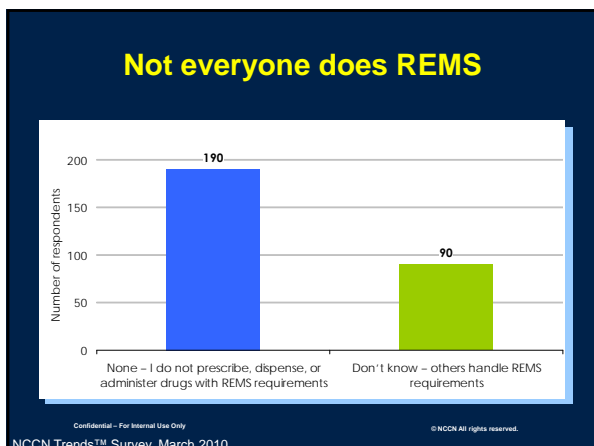
Please estimate the amount of time currently spent by you towards meeting REMS requirements

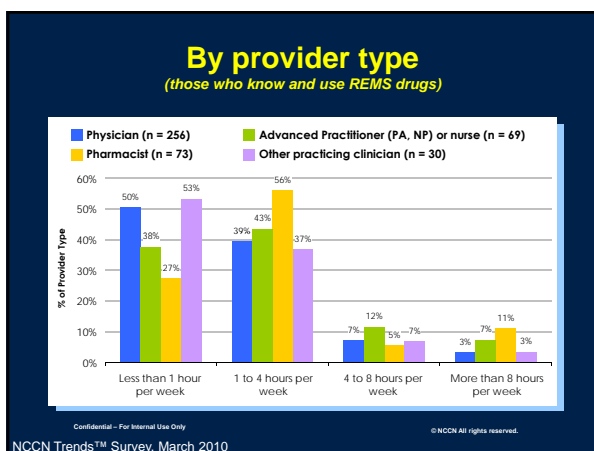


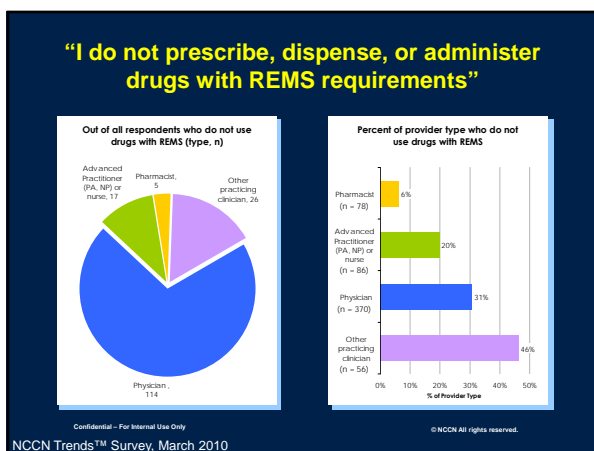
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Compensation for Complying with REMS

- Opportunity cost: less time for patient care
- “Un-funded mandate”
- Who provides compensation?

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Compensation for complying with REMS regulations

Near term	Medium term	Long term
Payers must consider how REMS will affect their formulary process.	Managed care organizations should consider minimizing the burdens placed on providers and patients when administering prior authorizations requirements for drugs with REMS.	Payers and providers should consider an alternative coding system for drugs that require REMS so providers can be compensated for their time.

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Patient Health Literacy

- The documents that must be provided to patients (e.g., medication guides, acknowledgment /consent forms) do not necessarily take into account the issues related to patient health literacy or specific patient populations.

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Development of patient health literacy

Near term	Medium term	Long term
Medication Guides must contain language at a level patients can understand and must be available in a multitude of languages to ensure patient comprehension.	Perform an assessment of public health literacy comprehension	Partnerships should be developed with patient advocacy groups to ensure patients receive accurate and comprehensible information regarding REMS
	Utilize web and social media to communicate REMS requirements to patients	Conduct a longitudinal study as to how REMS will affect patients in underserved populations.

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“I have had patients refuse to take needed medications because of fear due to the unbalanced medication guide that is targeted toward only adverse events, not efficacy.”
- Nurse Practitioner

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Incorporating REMS into Clinical Practice

- **Strategic Planning**
 - Align with other areas of expertise – depends on organization (Patient assistance, investigational drugs, purchasing etc)
 - Incorporate into broader strategy for specialized therapies
- **Specific processes and policies**
- **Institutional formulary system**

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Incorporating drugs with REMS into routine clinical practice

Near term	Medium term	Long term
Specific to institutional practice, the institution's formulary system should be proactive in serving as the body to oversee the implementation of drugs with REMS requirements.	Institutions should build into the medication use system triggers and alarms for compliance with REMS requirements and for quality control purposes.	Share "best practices" surrounding the implementation of REMS into clinical practice

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Summary

- Improve provider knowledge and acceptance
- Influence on prescribing and long term outcomes
- Appropriate compensation for complying with REMS regulations
- Patient health literacy
- Minimization of provider burden
- Incorporating drugs with REMS into clinical practice

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Roundtable Panel

- George Dahlman
- Mohammad Jahanzeb, MD
- Phil Johnson, RPh
- Shirley Johnson, RN
- Scott Reid
- Sharon Weinstein, MD

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