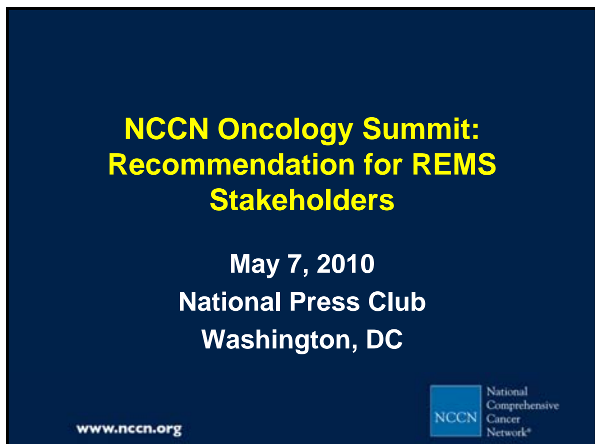


Presenters

Sharon Weinstein, MD, FAAHPM
Director, Pain Medicine and Palliative Care
Huntsman Cancer Institute at the University of Utah

Shirley Johnson, RN, MS, MBA
Chief Nursing and Patient Services Officer
City of Hope Comprehensive Cancer Center

Confidential – For Internal Use Only

© NCCN All rights reserved.

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

Confidential – For Internal Use Only

© NCCN All rights reserved.

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

Confidential – For Internal Use Only

© NCCN All rights reserved.

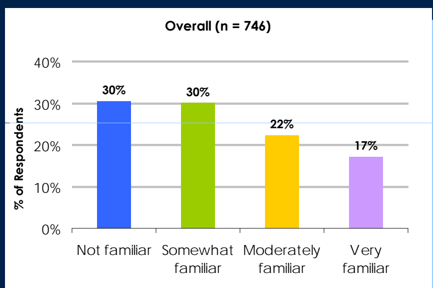
Provider knowledge about the purpose, benefits, and challenges of REMS

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

Confidential – For Internal Use Only

© NCCN All rights reserved.

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

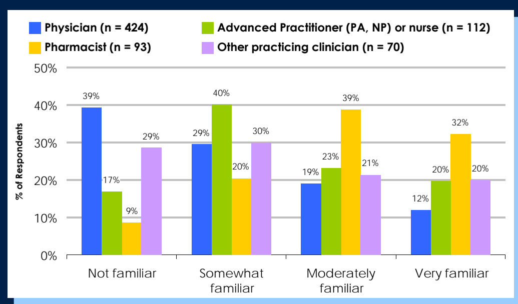


Confidential – For Internal Use Only

© NCCN All rights reserved.

NCCN Trends™ Survey, March 2010

By Provider Type



Confidential – For Internal Use Only

© NCCN All rights reserved.

NCCN Trends™ Survey, March 2010

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**

Confidential – For Internal Use Only

© NCCN All rights reserved.

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

Confidential – For Internal Use Only

© NCCN All rights reserved.

Rate the extent to which you agree or disagree with the following statements

Statement	n	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
REMS will interfere with the provision of patient care.	(n = 700)	5%	16%	31%	33%	15%
REMS will drive utilization towards drugs without REMS.	(n = 701)	3%	15%	28%	39%	14%
REMS will create or increase disparities in care.	(n = 694)	4%	16%	33%	34%	14%

Confidential – For Internal Use Only
© NCCN All rights reserved.

By familiarity of REMS programs

Statement	Familiarity	Strongly Agree	Agree	Disagree	Strongly Disagree	Neutral
REMS will interfere with the provision of patient care.	Not Familiar (n = 186)	8%	24%	18%	4%	46%
	Very Familiar (n = 122)	22%	39%	14%	4%	21%
REMS will drive utilization towards drugs without REMS.	Not Familiar (n = 184)	9%	31%	16%	4%	40%
	Very Familiar (n = 124)	20%	37%	17%	3%	23%
REMS will create or increase disparities in care.	Not Familiar (n = 180)	7%	28%	19%	5%	41%
	Very Familiar (n = 120)	20%	33%	14%	6%	27%

Confidential – For Internal Use Only
© NCCN All rights reserved.

"In an age where reimbursement of medication and office visit/consultation fees are decreasing, increasing paperwork (i.e., REMS) makes practicing medicine less economically feasible."

- Physician

Confidential – For Internal Use Only
© NCCN All rights reserved.

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

Confidential – For Internal Use Only

© NCCN All rights reserved.

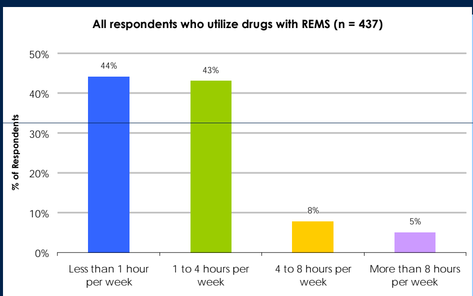
Minimization of provider burden

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

Confidential – For Internal Use Only

© NCCN All rights reserved.

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



Confidential – For Internal Use Only

© NCCN All rights reserved.

NCCN Trends™ Survey, March 2010

Not everyone does REMS

Number of respondents

200
150
100
50
0

190
90

None – I do not prescribe, dispense, or administer drugs with REMS requirements
Don't know – others handle REMS requirements

Confidential – For Internal Use Only
© NCCN All rights reserved.

NCCN Trends™ Survey, March 2010

By provider type

(those who know and use REMS drugs)

Physician (n = 256)
Advanced Practitioner (PA, NP) or nurse (n = 69)
Pharmacist (n = 73)
Other practicing clinician (n = 30)

% of Provider Type

	Physician	Advanced Practitioner or nurse	Pharmacist	Other practicing clinician
Less than 1 hour per week	50%	38%	27%	53%
1 to 4 hours per week	39%	43%	56%	37%
4 to 8 hours per week	7%	12%	5%	7%
More than 8 hours per week	3%	7%	11%	3%

Confidential – For Internal Use Only
© NCCN All rights reserved.

NCCN Trends™ Survey, March 2010

"I do not prescribe, dispense, or administer drugs with REMS requirements"

Out of all respondents who do not use drugs with REMS (type, n)

Advanced Practitioner (PA, NP) or nurse, 17
Pharmacist, 5
Other practicing clinician, 26
Physician, 114

Percent of provider type who do not use drugs with REMS

Provider type	%
Pharmacist (n = 78)	6%
Advanced Practitioner (PA, NP) or nurse (n = 86)	20%
Physician (n = 370)	31%
Other practicing clinician (n = 56)	46%

0% 10% 20% 30% 40% 50%
% of Provider Type

Confidential – For Internal Use Only
© NCCN All rights reserved.

NCCN Trends™ Survey, March 2010

Compensation for Complying with REMS

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

Confidential – For Internal Use Only
© NCCN All rights reserved.

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.

Confidential – For Internal Use Only
© NCCN All rights reserved.

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.

Confidential – For Internal Use Only
© NCCN All rights reserved.

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.

Confidential – For Internal Use Only
© NCCN All rights reserved.

"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

Confidential – For Internal Use Only
© NCCN All rights reserved.

NCCN Trends™ Survey, March 2010

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**

Confidential – For Internal Use Only
© NCCN All rights reserved.

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

Confidential – For Internal Use Only

© NCCN All rights reserved.

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

Confidential – For Internal Use Only

© NCCN All rights reserved.

Roundtable Panel

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

Confidential – For Internal Use Only

© NCCN All rights reserved.