REMS Tools in Dispensing Settings

Food and Drug Administration
Standardizing and Evaluating
Risk Evaluation and Mitigation Strategies

July 25, 2013

Katie Stabi, PharmD, BCPS
REMS Drug Information Pharmacist
Cleveland Clinic Health System
Cleveland Clinic Health System

- 44,000 caregivers
- 145,000 hospital admissions
- 5 million outpatient visits
FDA Questions Addressed

• Site versus health care system certification

• Standardize REMS tools in different dispensing settings

• Difficulties of authorized dispensers to obtain drugs

• Improve effectiveness of existing REMS tools and reduce burden
Health System Certification

Cleveland Clinic Main Campus

Electronic Medical Record

Cleveland Clinic Community Hospitals

Cleveland Clinic Outpatient Clinics and Pharmacies
Integrated Health Care System Certification

• Benefits
  — Care of patient managed within system
  — Access to electronic medical record
    — Increased screening
  — Increase access to medications
    — Prevent increased health care costs
  — Decrease burden of REMS programs

• Potential consequence
  — Removal of drug from all pharmacies in system if one is found noncompliant
Patient Example

• Patient receives monthly maintenance therapy
  — REMS drug only available from specialty pharmacy
  — Lab monitoring completed in health system

• Patient runs out of therapy and refill not yet processed
  — Outpatient pharmacy does not stock drug
  — Inpatient pharmacy is certified and stocks drug

• REMS program solution
  — Admit patient to receive therapy
Recommendations

• Create single health system certification
  — “Master” enrollment with pharmacies indexed by DEA
  — Provide access to medication for all pharmacies in the system certification

• Assess pharmacies individually
Standardize REMS in Different Dispensing Settings

• Create standards based upon dispensing setting
  — Inpatients versus outpatients
  — Consider burden of requirements

• Create standards based upon therapy
  — Initiation versus continuation of therapy
  — Outpatient prescriptions versus inpatient order

• Make requirements transparent
Difficulties of Authorized Dispensers to Obtain Drugs and Dispense to Patients

• Outpatient pharmacies are type of specialty pharmacy
  — Access to some restricted distribution drugs

• Requirements are too burdensome for inpatient pharmacy to dispense

• REMS Program states pharmacy enrollment requirements and process
  — Does not allow pharmacies to enroll
Difficulties of Authorized Dispensers to Obtain Drugs and Dispense to Patients

• Select hospital trial programs
  — Patient safety risk
  — Ethical issues

• Delay of therapy
  — Patient safety risk
  — Potential increased health care costs
Recommendations

• Make requirements transparent

• Increase access to REMS drugs

• Standardize requirements based on dispensing setting

• Allow exceptions to prevent patient harm
Improve Effectiveness and Reduce Burden

• Design REMS programs to interface with existing healthcare system technology
  — Verify prescriber certification
  — Verify patient enrollment
  — Monitoring alerts

• Create Master Repository of REMS information

• Create Shared System REMS with similar programs
Conclusion

• Standardize REMS based on type of dispensing setting

• Maintain patient care within health system

• Increase access to medications

• Utilize technology

• Create centralized website or database

• Increase Shared System REMS
Cleveland Clinic

Every life deserves world class care.