1. Each REMS program creates new processes and systems. Pharmacists suggest there must be standardization of REMS program so that any new program in the future will be more alike than different from the Opioid Program

2. The Program must be pilot tested.

-As REMS stakeholders, we need to fully understand the requirements and realities of what is being requested by the FDA before adopting a solution.

-This means conducting sufficient real-life testing before launching so that once implemented, the solution is effective at mitigating the risks that are intended to be reduced.

-Given the scale of the proposed opioid REMS and the number of dispensing events that it will impact, we recommend that the Agency consider pilot testing the REMS so that effectiveness can be measured and glitches can be resolved prior to a nation-wide launch.

3. We must design for the long-term, a process for complying with a REMS can be streamlined. For example, documenting that a pharmacist understands a program and attests to his or her ability and commitment to meet the requirements could be a standard process for any REMS.

1. **Ensure that any solution is not overly burdensome on the healthcare system and does not prevent or delay patient access to appropriate pain therapy.**
2. **Ensure that REMS programs allow any willing pharmacist, physician, or other prescriber the opportunity to participate.**
3. **Ensure that a standardized, system-based approach is developed that can work for any drug, not just select opioids. The design of this system should be useful for future drugs and drug categories as well.**
4. **Ensure that a REMS system integrates seamlessly into practice workflow for physicians, other prescribers, and pharmacists, and integrates with all medical records and pharmacy management systems, including the utilization of electronic prescribing and electronic health records.**
5. **Ensure that the components of an opioid REMS are proven to be effective in mitigating the specific defined risks and are workable for patients, prescribers, pharmacists, manufacturers, wholesalers, and system vendors.**
6. **Clearly define the stakeholder accountable for implementing each REMS component.**
7. **Avoid potential unintended consequences of limiting health care provider participation, creating REMS "fatigue," or shifting risks, such as abuse and misuse, to other medications not included in a REMS.**

- 8. Ensure that educational components are readily available to all physicians, other prescribers, and pharmacists who wish to participate. This education should not be overly burdensome.
- 9. Ensure that educational materials include:
- o A clearly communicated patient care plan;
- o A balance of risk and benefit information;
- o A brief therapeutic overview;
- o An explanation of why a REMS is in place;
- o The risks to be mitigated and tools intended to address those identified risks; and
- o REMS logistics – the procedures required to prescribe, process and dispense the medication to a patient.
- 10. Ensure that a REMS program serves as an adjunct to, not a replacement of
- prescriber/patient and pharmacist/patient dialogue about the benefits and risks of the
- medications and how to properly take, store, discontinue, and dispose of the medication.
- 11. Ensure that a feedback loop is designed to allow continuous improvement by determining why patient failures occur, rather than just documenting the failure.

What works to educate pharmacists?

- Expecting retail/hospital pharmacies to absorb the costs of patient education is unrealistic and unfair to pharmacy stakeholders.
- Develop and utilize a specialty e.g. coumadin clinics, certified diabetes specialists that allows for proper training and utilization that does not unfairly burden the current pharmacy distribution system and can charge for time and effort for patient education-someone has to pay-who?

- Training
- Evaluation
- Information
  - Counseling
  - MedGuide
- Follow-up / Post Assessment

- Discussion
  - Appropriate Use (Pharmacist or Physician)
    - Medication vs. disease (?)
    - Opioid Tolerant (?)
  - Medication overview / explanation:
    - Risks
    - Benefits
    - Storage
    - Handling
    - Disposal
    - Adverse Event Symptons
  - Communication of Safety Message
    - Duplicate Therapies
      - Same Pharmacy
      - Different Pharmacy
    - Refill Too Soon
  - Verify Patient Understanding

- Training Experience
  - Distribution of MedGuide
    - Recognition that MedGuide distribution required
    - Patients are not willing/unable to read
  - Contact Information for further questions (Patient or Pharmacy Initiated)
    - Call Center
    - Web Portal
  - Follow-up with patient after initiation of therapy

- Recommendations
  - Train Pharmacists (Opiates)
    - Tools: Registration Process, Web Portal, Data Base
  - Verify Appropriateness of Therapy?
    - Tools: System, Patient Interview Sheet
  - Verify Physician-Patient Contract Executed
    - Tools: System & Call Center
  - Verify Physician Registered to Prescribe
    - Tools: System & Call Center
  - Distribute Medication Information
    - Tools: Counseling & MedGuide
  - Verify Patient Understanding
    - Tools: ?
  - Complete Post Assessment (?)
    - Tools: Telephone Call, Survey,