
Expert Workshop: Designing Pilot Programs to Distribute Patient Medication Information

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Pam Budny, R.Ph.


Answers That Matter.

Outline

- Manufacturer perspective
 - Considerations for pilot PMI
 - Recommendations for consistency of PMI
 - Integration with e-prescribing
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Manufacturers Perspective

- Ensure that patients will receive information at the point of dispensing that
 - Enables understanding of **benefits and risks** as well as **safe and effective use** of medication
 - Can be rapidly **updated** with new information
 - Utilizes a communication **medium** in which they will engage
 - Allows them to locate, interpret, and **act upon** information when they need it
 - Is delivered with content and format from manufacturer **unaltered**
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Considerations for Pilot PMI

- Medication Guide (MG) Products
 - Manufacturers required to provide MG in sufficient numbers or provide means to provide sufficient numbers per CFR 208.24(b)(1)
 - Dispensers required to provide a MG directly to each patient per CFR 209.24(e)
- REMS products that include a Medication Guide
 - Civil and monetary penalties for not complying with REMS
- FDA approval of pilot PMI (or at a minimum review and comment) prior to use in pilot
- PMI should represent both “routine” and “challenging” situations
 - Lengthy safety (black box) warnings
 - Reconstitution, storage, or administration information



Recommendations for Consistency of PMI

- Use of approved templates
- Standardized instructions
 - Reconstitution
 - Storage conditions
 - Administration (e.g. subcutaneous injection)
- Standardized terminology
 - FDA-approved list of lay-friendly terms Mapped to concepts that appear in the US Prescribing Information (USPI)
 - Created by an independent coalition to include FDA representatives; medical, patient education, and communication experts; and pharmaceutical manufacturers and tested with patients



Full Integration in e-Prescribing within EHRs



- Create a single repository of electronic PMI
- Establish that manufacturer's role ends at electronic posting of PMI
- Engage with e-prescribing system developers, data-base developers, standards-setting organizations
- Utilize coding that allows interoperability