



PATIENT MEDICATION INFORMATION (PMI)



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Pharmacy Quality Alliance
November 3, 2011

For Today:

- Discuss current patient information systems
- Define PMI and describe our current thinking on the PMI framework
- Review ongoing and future PMI activities

Current Systems

- Multiple forms of information
- Developed by different sources
- Can be duplicative, incomplete, or difficult to read and understand
- Includes:
 - Patient Package Inserts
 - Medication Guides
 - Consumer Medication Information

Patient Package Inserts (PPI)

- Originated in 1968 based on a regulation created to increase patient safety
- Developed by manufacturers
- Approved by FDA
- Distribution mandated for specific products (oral contraceptives and estrogen)
- Voluntary submission of other PPI; however, distribution not mandated

Medication Guides (MedGuides)

- Origin based on a 1998 regulation requiring medication guides for a limited number of medications that “pose a serious and significant public health concern”
- Developed by manufacturers
- Approved by FDA
- Distribution mandated each time medication is dispensed
- Reportedly not being dispensed in pharmacies

Consumer Medication Information (CMI)

- Developed by organizations or individuals other than a drug manufacturer
- Not approved by FDA
- Voluntary distribution in pharmacies
- Widespread distribution based on public law 104-180
- CMI not meeting patient needs (PL 104-180 2000 & 2006 goals not met)

Patient Medication Information (PMI)

- Intended to replace Patient Package Inserts, Medication Guides, and Consumer Medication Information
- Single document
- Clear, accessible, and actionable information
- Allows safe and effective use
- Balanced risk and benefit
- Consistent and easily understood format
- Provided with prescription medication
- Used at home
- Not intended to replace patient counseling

PMI will not impact

- Professional Labeling
- Section 17 of Professional Labeling – Patient Counseling Section
- Instructions For Use

Support for PMI

- FDA sees merit in adopting single document standardized with respect to content and format, distribution, and enforcement.
- Support:
 - Stakeholder input
 - Jun 2008: Citizen petition for “one-document solution” to replace PPI, CMI, and MedGuides
 - Feb 2009: Risk Communication Advisory Committee recommends the FDA adopt a single standard document to replace PPI, CMI, and MedGuides

PMI Framework

- Development
- Central Repository
- Distribution

Development

- Created by product manufacturer
- Content, format, and testing standards will dictate PMI design and the information contained therein
- Considerations:
 - PMI information based on approved labeling
 - Balanced risk and benefit information
 - Minimum font size
 - Consumer friendly vocabulary
 - Testing standards and evaluation metrics
 - Link to additional product information (DailyMed)

Central Repository

- Single, accurate PMI data source
- Open access
- Data standards
- Key stakeholder of interest – National Library of Medicine

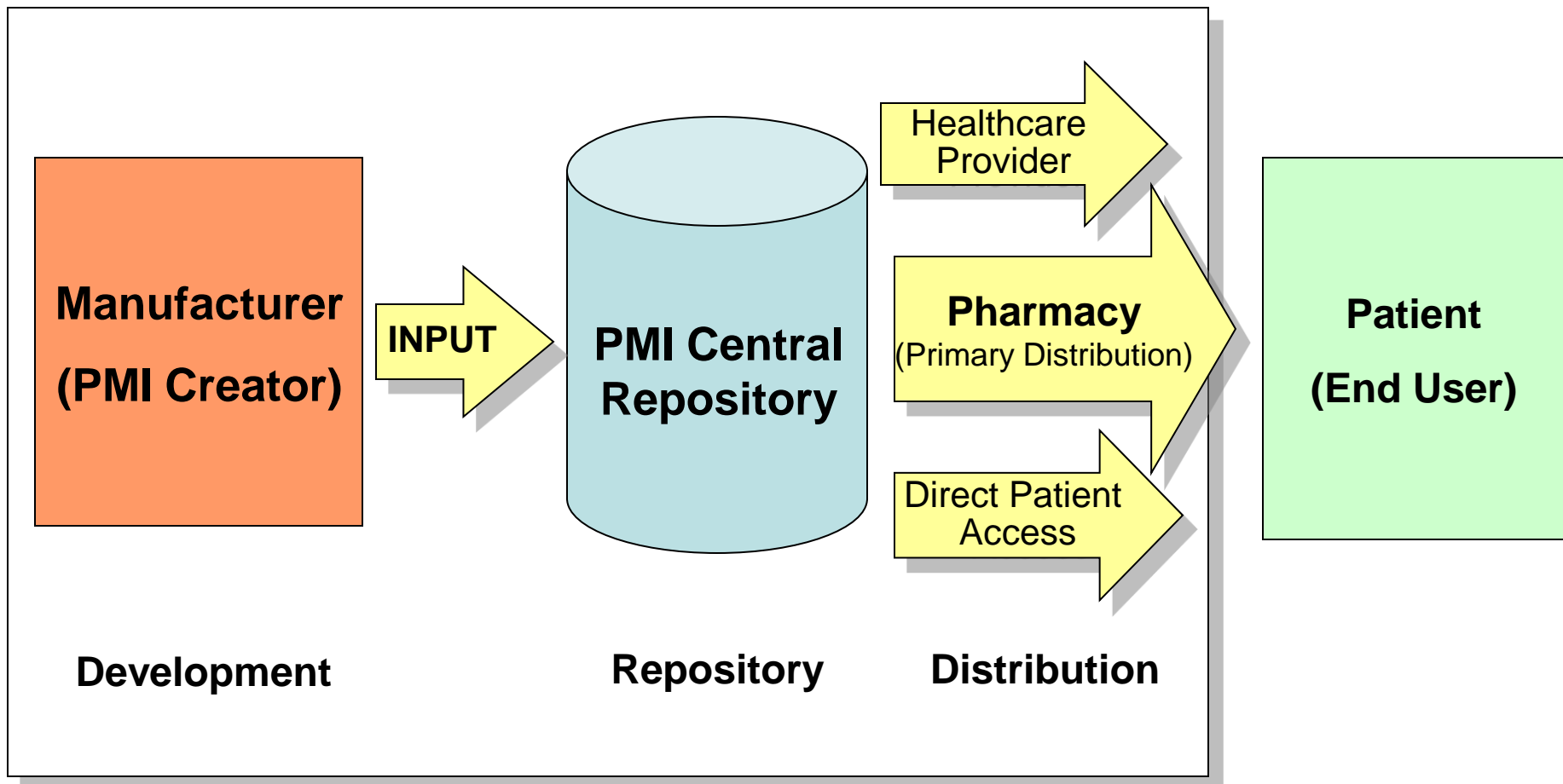
Distribution

- Major pathway: pharmacy distribution
 - Central Repository to Pharmacy
 - Pharmacy to Patient
- Variety of distribution methods available
- Overall distribution issues
 - Ensure pharmacy distribution
 - Impact on pharmacy workflow
 - Manufacturer's role in distribution
 - Situations where distribution may not be appropriate
 - Future link to personal electronic medical records

Quality & Compliance

- FDA will not approve PMI; however, PMI will be based on the approved labeling for that product
- Currently looking at a combination of:
 - Quality surveillance approach with enforcement
 - Metrics for evaluation
 - Content and format standards
 - Promotional review, and
 - Voluntary compliance and quality assurance with consumer testing component

PMI Framework



Current Activities

- Stakeholder outreach and input
- Pilots and studies
- Central Repository development
- PMI website

Stakeholder Outreach

- September 2010: Part 15 Public Hearing on new framework for development and distribution of PMI. Topics included:
 - PMI content and format
 - Creating and distributing PMI
 - Strategies for evaluating PMI effectiveness
- FDA convened a series of expert meetings and public workshops through a cooperative agreement with the Engelberg Center for Health Care Reform at Brookings:
 - Jul 21, 2010: Expert workshop on content and format PMI
 - Oct 12, 2010: Public forum to discuss patient access to effective PMI
 - Feb 23, 2011: Expert workshop that summarized previous activities and considered pilot studies for PMI distribution

Pilots & Studies

- Brookings distribution pilots
 - Performed by Catalina Health Resource and Medco
 - Distribution to include retail and mail order pharmacies as well as an online repository
 - Will look at distribution, pharmacy workflow impact, and patient attitudes on delivery, uptake, access, and content
 - Use of manufacturer developed PMI for real prescription products
- FDA
 - Investigate usefulness of PMI content and format
 - OMB approval received in August 2011
 - _ Phase 1: Qualitative Interviews have begun
 - _ Study is expected to be completed in Spring 2012

FDA Study: Research Questions

- How does format affect comprehension, risk perception, and processing of information?
- How does the context of information affect risk perceptions and preference?

Research Design

- Phase I: Qualitative Interviews
 - One-on-one
 - Face-to-face
 - Conducted with members of the following groups:
 - Low literacy and chronic illnesses
 - RA or another indication of Rheutopia
 - Any chronic illness

Expected N = 90

Research Design

- Phase II: Quantitative Experiment
 - Random assignment to conditions
 - Each person will see only one version
 - Administered via Internet

Expected N = 1,300

Research Design

Phase II: Quantitative Experiment

2 x 2 x 2+ 1 + 1 design

Administration (online, paper) x Context (yes, no) x format
(bubbles, OTC) + online control+ paper control

Research Design

Phase II: Quantitative Experiment

Online Administration

2 X 2 + 1

		Format		
		Bubbles	OTC	+ Control (Med Guide)
Context	Yes	130	130	130
	No	130	130	

Research Design

Phase II: Quantitative Experiment

Paper Administration

2 X 2 + 1

		Format		
		Bubbles	OTC	+ Control (Med Guide)
Context	Yes	130	130	130
	No	130	130	

Study Sample

- Diagnosed with rheumatoid arthritis, ankylosing spondylitis, or plaque psoriasis
- At least 30% of sample will read at or below 8th grade level
- Most will receive prototype embedded within web program

Next Steps

- Continued meetings with stakeholders
- Single-document PMI prototype testing
- Results from distribution pilots
- Standardization of content and format
- Identify and assess mechanisms to ensure PMI distribution

Future of PMI

- Regulation and Guidance Documents
 - Identify regulatory basis and build regulatory approach for PMI
 - Develop regulation and guidance documents based on final PMI framework and regulatory approach
 - Identify impact on related regulations and guidance
- Implementation plan
- Post-Implementation review process

Contact Information

- If you have any questions for the Office of Medical Policy regarding PMI please email PMI@fda.hhs.gov.
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