

# **FDA Public Hearing Regarding Medication Guide Program Reform**

**June 12, 2007**

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# CVS Caremark Background

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**Integrated pharmacy services provider**

**Largest single provider of prescriptions and related healthcare services in the nation**

**The CVS Caremark organization includes:**

- **CVS/pharmacy stores in 6,200 locations across the nation**
- **Caremark pharmacy services includes pharmacy benefit management, mail order, and specialty pharmacy divisions**
- **Minute Clinic provides retail-based in-store health care clinics**
- **CVS Online delivers internet-based pharmacy services**

**Provide Consumer Medication Information (CMI) to patients with prescriptions**

## Overview

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**Pharmacists want to help patients improve their quality of life**

**Patients need to understand the benefits & risks associated with their medication therapy**

**Medication information needs to be provided to patients in a manner that enables informed decisions regarding the initiation or continuation of therapy**

**Successful execution of large scale programs require standardization and a focus on details**

## Current Status

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**Information for medications that pose a “serious and significant” public health concern is, by design, delivered at a sub-optimum point in the treatment cycle**

**Patients are receiving duplicative information across varying format designs**

- MedGuides
- CMI
- PPI (where required)

**Pharmacists are dependant upon a myriad of distribution methodologies to obtain MedGuides**

**Non standardized program demanding continuous manual intervention to deploy**

**Current Program is Prohibitively Difficult to Consistently Execute**

## General Observations

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**Delivery of Medication Guides at the point of dispensing, with the predominant focus on providing risk information, often results in patient referrals back to the prescriber**

**The volume of consumer information is overwhelming and may not be useful**

**The lack of detailed and consistent program standards to support the distribution of MedGuides will continue to negatively impact program execution**

**Current process requires a high level of continuous manual intervention and maintenance, which does not integrate well into the systems utilized in today's pharmacy**

# Recommendations

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- (I) Assess point of delivery**
  
- (II) Consolidate information delivered to patients**
  
- (III) Develop Program Standards to support execution and success**
  
- (IV) Provide reasonable flexibility to achieve overall desired outcome**

## Recommendations (I)

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### Engage patients with risk information at the point of prescribing

- “Serious and significant” medication risk information warrants informed decisions
- Patients informed while with the physician are able to discuss and assess the risks as well as the benefits
- Patient / MD collaborate on decision to start therapy or consider alternative regimen
- Evaluation of “serious and significant” risks occurs before leaving the MD office

## Recommendations (II)

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### **Consolidate consumer medication information when Medication Guides are required**

- **Cannot evaluate Medication Guides “in a vacuum” independent of other material**
- **Patients are overwhelmed with the sheer volume of information provided**
- **Different writing style / tone of documents required to be provided are confusing**
- **Consolidate all information into one concise FDA approved document that is mandated in lieu of three separate documents today**



## Recommendations (III)

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### Establish detailed program standards

- Large scale program execution requires clarity and consistency for success
- Detailed standards are critical to support all that are delivering information
- A consistent MedGuide distribution approach needs to be applied to all products
- Organizations delivering information to patients cannot bear the financial burden

## Recommendations (IV)

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### Provide reasonable flexibility within the program design

- Today's pharmacy relies on technology to support information dissemination
- Manual processes inherently compromise consistency and ultimate execution
- Approved distribution methods must be able to integrate into pharmacy and include an electronic option
- Greater flexibility is needed to reduce the manual requirement and ensure success

## Conclusion

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**Pharmacists strive daily to improve their patients quality of life**

**Providing balanced, clear and concise medication information is critical to engagement**

**MedGuide information requires greater discussion to support informed decisions. These discussions are most effectively positioned at the point of prescribing**

**Distribution methodologies need to be standardized**

**Program flexibility is necessary to incorporate processes into today's workflow**

**Organizations ultimately executing the delivery cannot bear the financial burden**