

Current Challenges for Medication Guide Distribution

Paul Johnson R.Ph.

Clinical Manager

Wolters Kluwer Health

Challenges

- Usefulness - Content and Format Issues
- Awareness
- Practitioner and Patient Access
- Poor Document Quality - Technical Issues
- Rapid Growth of the Medication Guide Program
- Cost / Inefficiency

Improve Usefulness

- Clearly define and standardize scope of content
 - Balance risk and benefit information
 - Refer to CMI
 - Limit length
- Clearly define and standardize format
 - Action Plan criteria ??

Improve Awareness and Access

- Specific alert mechanism re: availability of new or revised Medication Guides
- Maintain **UP-TO-DATE** repository for **ALL** current Medication Guides
 - CDER website / DailyMed
- Promote multiple avenues of distribution
 - Physician / Pharmacy
 - Paper / Electronic
 - Patient Access via Internet

Technical Issues

- Final Medication Guide approved by FDA should be a separate document from product labeling and available in electronic form.
- Allowance for format alternatives when necessary to facilitate electronic distribution to pharmacies and pharmacy software vendors

Rapid Growth

- Define specific criteria for Medication Guide eligibility
- Utilize class Medication Guides as appropriate
- Avoid proprietary information (eg, brand names) within the Medication Guide.

Conclusion

