

Medication Guides

Nancy M. Ostrove, Ph.D.
Division of Drug Marketing,
Advertising, and Communications

Patient R_x Drug Information: Independently Produced

- Supplied to pharmacies by information providers not affiliated with drug sponsors
 - private sector program
- Computer-generated at point of purchase
- Fairly wide distribution
- Quality of information variable
 - recent assessment showed improvement needed, especially in risk disclosure

Patient R_x Drug Labeling: Mandated by Specific Regulations

- Sponsor drafts and FDA approves
- Different regulations -- different format and content requirements
- Required to be distributed to patients
 - questions remain about whether distribution requirement is being achieved
- Oral Contraceptives
- Estrogens

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Patient R_x Drug Labeling: Voluntary

- Sponsor drafts and FDA approves
- No uniformity in format or content
- No clear agreement whether distribution is required
- Anecdotal evidence indicates that actual distribution is spotty, especially when not packaged in unit-dose containers

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Medication Guides: A New Type of Patient R_x Labeling

- Sponsor drafts and FDA approves
- Non product specific regulation
 - designed for outpatient products that pose a “serious and significant public health concern”
 - necessary for safe and effective use by patients
- On average, expect 5-10 products annually
- *Requires* distribution

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Medication Guides: Triggering Circumstances

- Could help prevent serious adverse effects
- When patient needs to know of serious risks, relative to benefits, that might affect decision to use drug or continue use
- When drug is important to health, and patient adherence to directions is critical to its effectiveness

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Medication Guide: Requirements

- Written in nontechnical, understandable language
- Not promotional in tone or content
- Scientifically accurate
- Based on and consistent with professional labeling
 - language need not be identical to professional labeling

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Medication Guide: Requirements

- Specific and comprehensive
- At least 10 point minimum type size
- Legible and clearly presented
 - appropriate use of highlighting techniques (**bolding**, underlining, etc.) to emphasize specific portions of text

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Medication Guide: Required Information

- The public health concern that created the need for the Medication Guide
- The disease and benefits of treating
- Contraindications and what to do if any apply
- Instructions for proper use
- Specific, important instructions to ensure safe use
 - activities, substances to avoid, risks to mothers/fetuses
- Side effects

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Distribution is Required

- Manufacturer responsible for ensuring distribution by either:
 - providing enough to dispensers to give one to each patient, or
 - providing “means to produce” enough
- Distributors responsible for passing on
- Notation on container label that Medication Guide needs to be given out
- Authorized dispenser *required* to give out

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Exemptions/Deferrals

- FDA can exempt applicant from any requirement except consistency with labeling and title (Medication Guide)
- Prescriber can direct dispenser to withhold
 - patient can override withhold request

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Conclusions

- Medication Guides:
 - are for products posing a serious and significant public health concern
 - provide a uniform format and content to facilitate finding information
 - are required to be distributed to patients

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