Ready, Set, Go: Know Your Risks

Leadership Tool for a Learning Organization

Off-Label Use of Medical Products

WHY ARE THE RISKS OF OFF-LABEL USE OF MEDICAL PRODUCTS IMPORTANT?

- ❑ For a variety of reasons, the labeled indications arising during the U.S. Food and Drug Administration (FDA) approval process may not include all conditions for which a medical product might be useful.[1]
- ❑ Despite the prevalence and acknowledged benefits of the practice, by virtue of not undergoing safety and efficacy evaluation by the FDA, off-label use may be associated with potential harm in patients.
- ❑ Off-label use of medical products can increase the likelihood of a malpractice lawsuit.[2]
- ❑ Certain types of off-label use—prescribing significantly higher doses than approved in labeling, prescription for an unapproved indication, and prescription for patients not part of a population included in clinical trials—have been more frequently targeted in litigation following adverse events.[3]

DID YOU ASK?

- ❑ Has our organization established a committee to develop a framework to best guide off-label use of medical products?
- ❑ Is our organization aware of regulatory developments and enforcement actions regarding off-label promotion of medical products?
- ❑ Does our organization involve patients and family in a comprehensive informed consent process regarding the risks and benefits of off-label medication use?
- ❑ Are members of our organization familiar with strategies to decrease risks related to off-label prescribing?

Need More Information?

As a member of ECRI Institute's risk and patient safety program, you and your staff can access guidance outlining strategies for managing off-label use of medical products:

- ▶ Guidance: Off-Label Use of Medical Products
- ▶ Tool: Consent to Off-Label Treatment
- ▶ Guidance: Clinical Trials: Risk, Safety, and Liability
- ▶ Guidance: Informed Consent

ECRI Institute can help you with all of your patient safety, quality, and risk management projects. E-mail us at hrc@ecri.org.

1 U.S. Food and Drug Administration. Understanding investigational drugs and off label use of approved drugs. [cited 2015 Feb 3]. http://www.fda.gov/ForPatients/Other/OffLabel/default.htm

2 Wittich C, Burkle C, Lanier W. Ten common questions (and their answers) about off-label drug use. Mayo Clin Proc 2012 Oct;87(10):982-90. PubMed: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538391

3 Liability and off-label prescriptions. Psychiatry (Edgmont) 2009 Feb 6(2):43-4. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2719453 PubMed: https://www.ncbi.nlm.nih.gov/pubmed/19724748

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