

Off-Label Pharmaceutical Marketing: How to Recognize and Report It

The use of pharmaceuticals for unapproved symptoms or conditions, in unapproved patient groups, or in unapproved dosages is referred to as “off-label” use.[1] Promotion of such off-label use by pharmaceutical manufacturers is among the top four types of drug promotion problems identified by the U.S. Food and Drug Administration (FDA).[2]

Off-Label Promotion and the False Claims Act

Unlawful off-label drug promotion has been the subject of significant health care fraud enforcement efforts by the United States Department of Justice (DOJ) and the State attorneys general using the Federal False Claims Act. The theory underlying these efforts is that, by promoting off-label uses that are not medically accepted, the manufacturers caused pharmacies to claim Medicaid payment for drugs used in ways that are not covered by Medicaid. Most, if not all, State Medicaid programs exclude coverage for drugs that are used in off-label indications that are not medically accepted. DOJ and State enforcement efforts have identified a wide range of deceptive practices that promoted off-label uses of many prescription drugs. These practices have resulted in large monetary settlements with a number of pharmaceutical manufacturers.

How to Recognize Unlawful Off-Label Promotion

Unlawful off-label promotion by pharmaceutical manufacturers can take a number of different forms. These forms include the following:

- Paying incentives to sales representatives based on sales for off-label use;[3]
- Paying kickbacks to physicians to prescribe drugs for off-label use;[4, 5]
- Disseminating misleading posters promoting off-label use;[6]
- Paying physicians:
 - To serve as authors of articles about off-label uses written by manufacturers’ agents;
 - To serve as members of “advisory boards” promoting off-label use;
 - To travel to resort locations to listen to promotions about off-label use; or
 - To give promotional lectures in favor of off-label use to fellow practitioners;[7, 8]
- Providing advice to prescribers on how to code their claims and document their medical records to support payment for off-label uses not covered by Medicaid;[9]
- Publicizing studies showing efficacy of off-label uses while suppressing studies showing no efficacy;[10] and
- Making false representations directly to Medicaid to influence decisions about payment for drugs used off-label.[11, 12]

How to Report Unlawful Off-Label Promotion

Because of the potential for patient harm that some off-label drug uses can cause, and because of the potential waste of taxpayer funds when Medicaid pays for off-label uses that are not medically accepted, it is important for health care professionals, manufacturers, and pharmaceutical representatives to report unlawful off-label promotion in Medicaid.

Individuals that recognize off-label drug promotion should report it to:

- The FDA at BadAd@fda.gov or 855-RX-BadAd, 877-RX-DDMAC;

- The State Medicaid agency or Medicaid Fraud Control Unit at the contact numbers found on the list at http://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/fraudabuseforconsumers/report_fraud_and_suspected_fraud.html on the Centers for Medicare & Medicaid website; or
- The U.S. Department of Health and Human Services, Office of Inspector General, at HHSTips@oig.hhs.gov or 1-800-447-8477 (1-800-HHS-TIPS).

References

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