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] Promoting off-label use that is not medically accepted may have a negative impact on quality of care. If such promotion causes Medicaid to be billed for pharmaceuticals used in this way, the people responsible for the promotion may be liable for false claims.

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 States' attorneys general using the Federal False Claims Act (FCA). 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 for off-label indications that are not medically accepted. Such use can waste Medicaid funds on ineffective treatments.

DOJ and State enforcement efforts have identified a wide range of deceptive practices by pharmaceutical manufacturers that promoted off-label uses of many prescription drugs. These practices have resulted in large monetary settlements under the FCA. Penalties include up to three times the amount of the damages plus an additional penalty of $5,500 to $11,000,[2] as adjusted for inflation, per false claim.[3, 4]

Potential Patient Harm from Off-Label Uses not Medically Accepted

In addition to causing inappropriate spending of Medicaid funds, off-label uses that are not medically accepted may expose patients to harm. Scholarly literature,[5] as well as government warnings[6] and testimony,[7] have pointed out that possible patient harm may arise from off-label uses that are not medically accepted. Despite these dangers, and despite U.S. Food and Drug Administration (FDA) restrictions on off-label marketing, some pharmaceutical manufacturers have engaged in extensive efforts to market drugs for off-label uses, including uses that are not medically accepted.

How to Recognize Unlawful Off-Label Promotion

Knowing some of the forms that off-label promotion can take will make it easier to recognize this unlawful practice. These forms include the following:

- Paying incentives to sales representatives based on sales for off-label use;[8]
- Paying kickbacks to physicians to prescribe drugs for off-label use;[9]
- Disseminating misleading posters promoting off-label use;[10]
- Paying physicians:
  - To pretend to be the authors of articles about off-label uses when the articles were actually 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;[11]

- 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;[12]
- Publicizing studies showing efficacy of off-label uses while suppressing studies showing no efficacy; [13] and
- Making false representations directly to Medicaid to influence decisions about payment for drugs used off-label.[14]

How to Report Unlawful Off-Label Promotion

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

- The FDA at BadAd@fda.gov or 855-RX-BadAd (855-792-2323);
- The State Medicaid agency or Medicaid Fraud Control Unit at the contact numbers found on the list at https://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/fraudabuseforconsumers/report_fraud_and_suspected_fraud.html on the Centers for Medicare & Medicaid (CMS) website; or
- The U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG), at HHSTips@oig.hhs.gov or 1-800-447-8477 (1-800-HHS-TIPS).

Qui Tam Actions for Unlawful Off-Label Promotion

Health care professionals and pharmaceutical representatives and employees who have inside or special knowledge of unlawful off-label promotion may bring suit on behalf of the government by filing what is called a "qui tam," or whistleblower, lawsuit under the civil FCA.[15] Qui tam lawsuits are brought to the attention of the government, which may intervene and take over the lawsuit. Depending on whether the government intervenes and what the court determines is reasonable, if the lawsuit is successful the person who initiated it may recover up to 30 percent of the funds awarded to the government.[16] Persons bringing qui tam complaints are protected by Federal law from retaliation. Such protection includes reinstatement, twice the amount of back pay with interest, and attorneys' fees.[17] Similar protection against retaliation is also provided under the laws of many States.[18]

More Information on Off-Label Promotion and Use of Pharmaceuticals

People who want to learn more about the parameters of promoting pharmaceuticals can take advantage of materials from the FDA and the American Cancer Society (ACS). The FDA sponsors the "Bad Ad Program," designed to make providers aware of the role they play in promoting truthful advertising for prescription drugs. The program is part of the Office of Prescription Drug Promotion in the Center for Drug Evaluation and Research.[19, 20] The FDA sponsors continuing education about the provider's role in promoting truth in advertising for prescription drugs.[21]

The ACS has an excellent resource to educate consumers about off-label drug use, especially for cancer treatment options. The article discusses the general procedure the FDA uses to approve indications for drugs, then deals with questions specifically related to the constantly changing field of cancer research and treatment.[22]

To see the electronic version of this fact sheet and the other products included in the "Off-Label Pharmaceutical Marketing" Toolkit, visit the Medicaid Program Integrity Education page at https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/edmic-landing.html on the CMS website.

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