

Off-Label Use of Prescription Drugs

Standard opening (lead-in music)

Canned: This is a Medicaid Program Integrity Podcast. The Centers for Medicare & Medicaid Services developed and produced these podcasts to keep you informed about Medicaid program integrity topics.

Narrator: Welcome to the “Fraud, Waste and Abuse Program” podcast on Off-Label Use of Prescription Drugs. This podcast provides information on Federal guidance for such programs in a health care setting. By being more aware of the program safeguards contained in an effective compliance plan, providers can focus on serving the health care needs of their patients. Let’s join Dr. Williams, the managing partner of a large family practice clinic, and Carolyn, his office manager, as they discuss their practice’s education plan to prevent inappropriate off-label use of prescription drugs.

(End music)

Scene – Dr. Williams’ office:

Carolyn: Good morning, Dr. Williams. Do you have time to talk about our monthly staff meeting scheduled for tomorrow? You’re on the agenda to make the opening remarks.

Dr.: I do have time. Come in. I look forward to our monthly meetings and the chance to talk with all of our clinical staff at one time.

Carolyn: I’m glad you enjoy it. I’m on the agenda, too. As part of my compliance monitor duties,[1] I plan to speak about the inappropriate use of off-label drugs. My research shows the use of pharmaceuticals for unapproved symptoms or conditions, in unapproved patient groups, or in unapproved dosages is referred to as “off-label” use. The promotion of off-label use by pharmaceutical manufacturers is among the top four drug promotion problems identified by the FDA.[2] Since I’m not a clinician, I want to talk to you first about my presentation.

Dr.: OK, tell me what’s on your mind.

Carolyn: Well, I received a suggestion from a staff member to provide the training on off-label use of drugs. She saw a news story about a report on off-label use of atypical antipsychotic drugs in children.[3] According to the story, these medications were prescribed for an indication that’s not FDA approved. The story said antidepressant medications have been shown to increase the risk of suicidal thinking and behavior in children. Other common problems identified with off-label use of these medicines were drowsiness, dizziness, blurred vision, rapid heartbeat, sensitivity to the sun, skin rashes, menstrual problems, and weight gain.

Dr.: Some of our staff might not know this is such a big problem. Go on.

Carolyn: I want to talk to our staff about the importance of protecting our patients and the integrity of our clinic practice. I plan to share a CMS fact sheet about off-label promotion and the False Claims Act.[4]

Dr.: What's in the fact sheet?

Carolyn: The fact sheet says that the Department of Justice and the State Attorneys General invest significant effort into fighting unlawful off-label drug promotion 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 not covered by Medicaid. Most, if not all, State Medicaid programs exclude coverage for drugs used in off-label indications that are not medically accepted. Department of Justice and State enforcement efforts have identified a wide range of deceptive practices that promoted off-label uses of many prescription drugs. These practices resulted in large monetary settlements with some pharmaceutical manufacturers.

Dr.: OK. Tell me how that impacts our clinic practice.

Carolyn: Well, first there is the potential for patient harm. There's also the potential waste of taxpayer funds when Medicaid pays for off-label uses that are not medically accepted. It's important for our clinical staff to be alert and report unlawful off-label promotion.

Dr.: What's considered unlawful promotion?

Carolyn: The fact sheet shows that unlawful off-label promotion by pharmaceutical manufacturers can take a number of forms, including:

- Paying incentives to sales representatives based on sales for off-label use;
- Paying kickbacks to physicians to prescribe drugs for off-label use;
- Sharing misleading posters promoting off-label use;
- 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;
- Publicizing studies showing efficacy of off-label uses while suppressing studies show no efficacy;
- Making false representations directly to Medicaid to influence decisions about payment for drugs used off-label; and
- Paying physicians to:
 - Serve as authors of articles about off-label uses written by manufacturers' agents;
 - Serving as members of "advisory boards" promoting off-label use;
 - Traveling to resort locations to listen to promotions about off-label use; or
 - Giving promotional lectures in favor of off-label use to fellow practitioners.

- Dr.:** Wow. That's certainly a lot of good information.
- Carolyn:** Yes, it is, and there's more. CMS also has an Off-Label Promotion Resource Guide that I'll post on the bulletin board.[5]
- Dr.:** What's in the resource guide?
- Carolyn:** It lists cases and settlements involving off-label use of drugs and gives other information. It shows how serious law enforcement is about this matter.
- Dr.:** Do we know how to report a suspected violation?
- Carolyn:** Yes we do, the fact sheet says we should report suspected violations to the FDA, the State Medicaid Fraud Control Unit or the U.S. Department of Health and Human Services, Office of the Inspector General. It gives contact information for these agencies.
- Do you have any questions or concerns about my presentation for the meeting tomorrow?
- Dr.:** No, I don't. I think this is an important topic and good information for our clinicians to know. Thanks. I look forward to your presentation.

(Standard closing with music)

Canned: More questions? For additional information about off-label use of drugs, contact your State Medicaid agency or the Centers for Medicare & Medicaid Services at [www \[dot\] cms \[dot\] gov](http://www.cms.gov). Follow us on Twitter  [#MedicaidIntegrity](https://twitter.com/MedicaidIntegrity)

References

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