# FDA Regulatory and Compliance Monthly Recap

## SEPTEMBER 2014

### KEY FINDINGS



**Loeb & Loeb LLP's FDA Regulatory and Compliance Practice**

Loeb & Loeb's FDA Regulatory and Compliance Practice comprises an interdisciplinary team of regulatory, corporate, patent and litigation attorneys who advise clients on the full spectrum of legal and business issues related to the distribution and commercialization, including marketing and promotion, of FDA-regulated products. Focusing on the health and life sciences industries, including pharmaceuticals, biologics, medical devices, wellness products, dietary supplements and organics, the practice counsels clients on regulatory issues, compliance-related matters and risk management strategies; advises on laws and regulations related to product advertising and labeling; counsels on FDA exclusivity policies and related Hatch-Waxman issues; and provides representation in licensing transactions and regulatory enforcement actions.

## FDA sends warning letters to companies that made claims on social media that their products treat, cure Ebola, marking the first time the agency singles out Pinterest

*The FDA sent warning letters to three companies making claims on social media platforms that their products are possible treatments and cures for the Ebola virus. This marks the first time that the FDA has taken notice of claims made on Pinterest.*

Social media platforms, and the Internet as a whole, are unlocking new engagement opportunities for drug and device manufacturers with consumers and healthcare professionals, and as a result the FDA has stepped in and released draft guidance for the industry, "Internet/Social Media Platforms With Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices." The guidance, which saw its comment period extended to Oct. 29, 2014, addresses how manufacturers, packers and distributors of drugs and medical devices should present benefit and risk information within the advertising and promotion of their FDA-regulated products on these digital platforms, since companies are limited when it comes to the number of character spaces they can use within these information venues.

On Sept. 24, 2014, the FDA sent letters to three companies, relating to their marketing of products touted as possible treatments or cures for Ebola; this was prompted by the reality that there are currently no approved treatments, cures or vaccines for the disease. The letters document multiple claims from the companies, Natural Solutions Foundation, Young Living and dōTERRA International, or their paid representatives, that their products, such as "CBD Organic Dark Chocolate Bars," "Clary Sage" essential oils and the "Family Protection Pack," can treat, cure or prevent the virus — claims which can only be made by FDA-approved drugs. The promotions appeared on Pinterest, Facebook and blog posts.


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This marks the first time the FDA has targeted a company for its use of Pinterest. The FDA has long included references in its warning letters to social media platforms such as Facebook and Twitter, going as far as to consider that Facebook "likes" could be construed as promotional claims. Despite the agency's release of its guidance on social media, it had yet to make any mention of the Pinterest platform.

## OIG issues special advisory bulletin and report emphasizing prohibition on copay coupons for federally reimbursable medications (including Part D covered drugs), notes potential antikickback violations

*According to the OIG, "Pharmaceutical manufacturers that offer copayment coupons may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal health care program items or services."*

The OIG issued a special advisory bulletin and report in September regarding the prohibition on using copay coupons for medications that are paid for by Medicare Part D. For the report, the OIG surveyed the 30 drugmakers that manufacture the top 100 Part D brand-name drugs for which coupons are offered and generate the highest Medicare expenditures.

The report included the following findings:

- **All surveyed manufacturers provide notices to beneficiaries and pharmacists that copayment coupons may not be used in federal healthcare programs.** These notices state that copayment coupons may not be used to purchase drugs paid for by federal healthcare programs, including Medicare Part D. Notices to beneficiaries and pharmacists are more prevalent for print coupons, which is the most commonly offered coupon format according to the manufacturers surveyed. The coupons, normally delivered via print, websites or advertisements, ask eligibility questions, and if patients indicate that they are enrolled in federal healthcare programs, these manufacturers notify them that they are not eligible to access the coupon. While most forms of advertising used these questions to qualify for eligibility, only 3 percent of websites had a tracking mechanism to prevent a patient from changing his or her answer to the eligibility question to obtain the coupon. Two-thirds of the surveyed manufacturers responded that they provide notices to pharmacists for at least one of the coupon formats they offer.
- **Most surveyed manufacturers use pharmacy claims edits to prevent copayment coupons from being processed for drugs paid for by Part D.** Twenty-eight of the 30 manufacturers surveyed use claims processing edits for at least one of the coupon formats they offer.
- **Surveyed manufacturers' pharmacy claims edits may not prevent copayment coupons from being processed for drugs paid for by Part D.** Pharmaceutical manufacturers' claims processing edits currently in use may not stop all coupons from being processed for drugs paid for by Part D, because manufacturers cannot accurately identify a beneficiary's Part D enrollment status. Manufacturers' claims processing edits use proxies that are substitutes for, but do not replicate, actual enrollment information.
- **Part D plans and other entities cannot identify copayment coupons within pharmacy claims.** It is difficult for entities other than manufacturers to identify coupons as they are processed through the pharmacy claims transaction system or after they are adjudicated. Coupons are not transparent in the pharmacy claims transaction system to entities other than manufacturers. This vulnerability impedes other entities, including Part D plans, other primary insurers and pharmacies, from preventing the use of coupons for drugs paid for by Part D and oversight entities, such as CMS and OIG, from monitoring the use of coupons.

As the bulletin relates, "where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal healthcare program, the anti-kickback statute is violated." Measures that would undermine the antikickback statute diminish the benefits of cost-sharing requirements for federal healthcare program drugs, including "prudent prescribing and purchasing choices by physicians and patients based on the true costs of drugs" and price competition in the pharmaceutical market.

The bulletin concludes by emphasizing coupon offerors are ultimately liable for compliance: "Regardless of future actions by CMS, the offerors of coupons ultimately bear the responsibility to operate these programs in compliance with Federal law. Pharmaceutical manufacturers that offer copayment coupons may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal healthcare program items or services, including, but not limited to, drugs paid for by Medicare Part D."

To help mitigate further issues, the OIG recommended CMS find a way to work with drugmakers to improve the reliability of pharmacy claims and verify enrollment. CMS should also explore ways to make coupons universally identifiable.

## CMS rolls out Open Payments in effort to increase transparency and accountability

*CMS published its first round of data as laid out in the Sunshine Act, and stakeholders, including the American Medical Association, are concerned.*

In an effort to promote transparency and accountability in healthcare stemming from conditions laid out in the Affordable Care Act's Sunshine Act, CMS recently released the first round of Open Payments data to help consumers understand the financial relationships between the healthcare industry and physicians and teaching hospitals. Consulting fees, research grants, travel reimbursements and other gifts the healthcare industry, including medical device manufacturers and pharmaceutical companies, provided to physicians and teaching hospitals during the last five months of 2013 are detailed in the data, which contains 4.4 million payments valued at nearly $3.5 billion attributable to 546,000 individual physicians and almost 1,360 teaching hospitals.

The official numbers bring greater definition to previous research. In one such instance, *ProPublica* tracked relationships between doctors and the pharmaceutical industry for the past four years, finding there were 3.4 million payments since 2009, totaling more than $4 billion, of which $2.5 billion was for research. For 2013 alone, there were 1.2 million payments valued at nearly $1.4 billion.

Dr. Shantanu Agrawal, deputy administrator and director of the Center for Program Integrity at CMS, said the data released does not identify which financial relationships are beneficial, but notes the "data could discourage payments and other transfers of value that might have an inappropriate influence on research, education, and clinical decision-making." Agrawal adds the data could also "help identify relationships that lead to the development of beneficial new technologies."

For its part, the American Medical Association, which had called on CMS in August to delay the publication of the data to "allow physicians adequate time to review and seek correction of inaccurate claims made by pharmaceutical companies, device manufacturers, and group purchasing organizations," remains "very concerned about the accuracy of the data," as only 26,000 out of the nearly 550,000 physicians affected by the Act had time to register and review their data, according to the association.

Over time, CMS plans to make enhancements to the system, including the addition of tools to allow for easier data searches. In the future, reports will be published annually and will include a full year of payment data, beginning in July 2015.

For more information on any of these FDA regulatory and compliance updates, please contact Scott S. Liebman at sliebman@loeb.com.

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