

# Obalon Co-op Advertising Program Guidelines

The Obalon® logotype, brand name and associated trademarks are valuable assets. They help consumers identify our products and services.

The appropriate use of consistent imagery and themes depicting confidence, appropriate weight loss and success will support the brand-building efforts at your practice.

The following guidelines have been developed to ensure an understanding of this Co-op Advertising Program ("Program"). If you have any questions regarding the contents of these guidelines, including compliance with specific requirements, please immediately contact your Practice Development Manager ("PDM").

## I. Program Eligibility

Obalon may provide you a co-op advertising allowance that meets certain requirements that may be outlined during an Obalon-sponsored promotion. ***The amount of your co-op allowance is determined by your eligibility based on current program. Please discuss these eligibility details with your Executive Account Manager (EAM) and/or Practice Development Manager (PDM).*** In order to receive co-op advertising reimbursement you must adhere to all brand guidelines and obtain prior approvals from Obalon when required. However, no prior approval is necessary when an account uses any final materials produced by Obalon.

Obalon reserves the right to audit your compliance with these guidelines.

## II. Allowable Expenses

In general, nearly any media that strongly identifies the account with the brand may be allowed. The term "media" refers to broadcast, replicate and distribute print materials or purchased advertising space. Media commissions are allowed only for media planning and other activities directly related to the placement of print, TV, radio and online media.

Any materials that violate any of the provisions set forth in these guidelines are not allowed and may constitute violation of federal, state and/or local law or regulation.

### A. Reimbursable Expenses

- Online banner ads, pay per click and other SEM media including agency fees for media buying support
- Email marketing programs
- Social media (agency support costs only)
- Broadcast or cable television advertising including media commissions
- Sponsorship of local TV or radio shows
- Radio advertising
- Print advertising such as local magazine, newspaper or newspaper inserts
- Direct mail, including printing and postage
- Billboards
- Public bus billboards and ads
- Public bench ads

- Stadium or arena signage

**B. Non-Reimbursable Expenses:**

- Costs for creative writing, design or other production costs associated with the creation of advertisements
- Costs of offering rebates, credit and promotions
- Any advertisements or merchandising that displays competitive items
- Any online efforts directed to a landing page or website home page displaying competitive products
- Creative design and associated costs for any advertising whether print, broadcast or online are not allowed.
- Association dues and publication subscription or contribution expenses
- Items not associated with the promotion of the brand

**III. Material Guidelines**

<b>For account-produced materials</b>	
<b>Obalon and Obalon-related content must represent greater than 50% of the advertisement and must comply with all legal/regulatory requirements discussed below</b>	
<b>Website/Microsite</b>	<ul style="list-style-type: none"> <li>• Obalon logo clearly and prominently featured on home page</li> <li>• Messaging and language is on-label and consistent with that of Obalon.com</li> <li>• Safety/risk information is fairly balanced, as a whole, with benefit information</li> <li>• Content must be accurate and non-misleading</li> <li>• Advertisement should be targeted to avoid audiences that are not age appropriate for the product message</li> </ul>
<b>Online</b>	<ul style="list-style-type: none"> <li>• Obalon logo prominently shown on banner ads</li> <li>• Copy-only based ads must include the use of the Obalon® brand name</li> <li>• Safety/risk information is fairly balanced, as a whole, with benefit information</li> <li>• Content must be accurate and non-misleading</li> <li>• Advertisement should be targeted to avoid audiences that are not age appropriate for the product message</li> </ul>
<b>Mobile</b>	<ul style="list-style-type: none"> <li>• Obalon logo clearly and prominently shown on visual ads</li> <li>• Copy-only based ads must include the use of the Obalon® brand name</li> <li>• Safety/risk information is fairly balanced, as a whole, with benefit information</li> <li>• Content must be accurate and non-misleading</li> </ul>

	<ul style="list-style-type: none"> <li>• Advertisement should be targeted to avoid audiences that are not age appropriate for the product message</li> </ul>
<b>Social Media</b>	<ul style="list-style-type: none"> <li>• Twitter and like feeds must mention Obalon name</li> <li>• Facebook page must clearly and prominently feature Obalon logo</li> <li>• Safety/risk information is fairly balanced, as a whole, with benefit information <ul style="list-style-type: none"> <li>◦ Note that if this is not possible given character-limited formats, the advertisement does not comply with the legal requirements outlined below and may not be undertaken</li> </ul> </li> <li>• Content must be accurate and non-misleading</li> <li>• Advertisement should be targeted to avoid audiences that are not age appropriate for the product message</li> </ul>
<b>TV/Video</b>	<ul style="list-style-type: none"> <li>• Obalon® logo clearly and prominently shown</li> <li>• Audible mention of Obalon name</li> <li>• Safety/risk information is fairly balanced, as a whole, with benefit information</li> <li>• Content must be accurate and non-misleading</li> <li>• Advertisement should be targeted to avoid audiences that are not age appropriate for the product message</li> </ul>
<b>Radio</b>	<ul style="list-style-type: none"> <li>• Audible mention of Obalon name no less than 2x in a 30-second spot and 3x in a 60-second spot</li> <li>• Safety/risk information is fairly balanced, as a whole, with benefit information</li> <li>• Content must be accurate and non-misleading</li> </ul>
<b>TV and Radio Program Sponsorships</b>	<ul style="list-style-type: none"> <li>• Audible mention of Obalon name</li> <li>• Any visual materials featuring account must include the Obalon logo clearly and prominently shown</li> <li>• Safety/risk information is fairly balanced, as a whole, with benefit information</li> <li>• Content must be accurate and non-misleading</li> <li>• Advertisement should be targeted to avoid audiences that are not age appropriate for the product message</li> </ul>
<b>Print</b>	<ul style="list-style-type: none"> <li>• Obalon® logo prominently shown</li> <li>• Logo must be no smaller than the size of the account's logo</li> <li>• Logos within the text or body of an ad or logos appearing in photographs including those depicting imagery are not considered sufficient use</li> </ul>

	<ul style="list-style-type: none"> <li>• Safety/risk information is fairly balanced, as a whole, with benefit information</li> <li>• Content must be accurate and non-misleading</li> <li>• Advertisement should be targeted to avoid audiences that are not age appropriate for the product message</li> </ul>
<b>Billboards</b>	<ul style="list-style-type: none"> <li>• Obalon® logo prominently shown</li> <li>• Logo must be no smaller than the size of the account's logo</li> <li>• Safety/risk information is fairly balanced, as a whole, with benefit information</li> <li>• Content must be accurate and non-misleading</li> </ul>
<b>Testimonials</b>	<ul style="list-style-type: none"> <li>• Must be pre-approved by Obalon and meet all the below criteria regarding testimonials</li> <li>• Individuals giving testimonials have provided Obalon-approved consent release forms</li> <li>• Safety/risk information is fairly balanced, as a whole, with benefit information</li> <li>• Content must be accurate and non-misleading</li> <li>• Endorsements should accurately reflect the opinions, findings, beliefs or experience of the endorser</li> <li>• Advertisement should be targeted to avoid audiences that are not age appropriate for the product message</li> </ul>
<b>General</b>	<ul style="list-style-type: none"> <li>• Advertising not specifically covered by these guidelines should have prior approval from Obalon</li> <li>• Advertising paid for, in whole or in part, through co-op advertising <b>cannot include competitive items or claims or other brand names.</b> (Exception: practice websites may include all brands serviced)</li> <li>• Content must be accurate and non-misleading</li> <li>• Advertisement should be targeted to avoid audiences that are not age appropriate for the product message</li> </ul>

**IV. Additional Legal/Regulatory Guidelines**

Along with the above provisions, your ads must also meet legal and regulatory requirements, including as applicable prior Obalon approval of advertisement content. To be eligible for co-op advertising, follow these guidelines, always be truthful and avoid potential misrepresentation and miscommunication about Obalon products and your services.

Obalon will never condone nor support in any way any materials that violate federal, state or local laws or regulations.

## **A. Product Price in Advertising**

When mentioning price in the advertising, accounts must abide by Obalon's Minimum Advertising Pricing (MAP).

## **B. Special Offers**

When you are advertising a special price, be sure to include language similar to the following: "For a limited time only. Call for details. While supplies last." A discount is an additional cost to promote a sale. When advertising discounts and rebates, you should not raise your price to cover an advertised discount or rebate.

## **C. Advertising Ethics**

When creating your Obalon advertising, you must always display good business ethics—the disparagement of competitors will not be tolerated. Your communications must meet regulations set forth by the Federal Trade Commission (FTC), the Food and Drug Administration (FDA), media outlets, as well as other required federal, state and local laws. Accounts should promote their businesses in a straightforward, factual fashion .

All advertisements must contain a brief statement of the product's intended use and relevant warnings, precautions, side effects and contraindications. 21 U.S.C. § 352(r). Moreover, all advertisements containing product claims must be appropriately balanced with product safety and risk information, and must not be false or misleading in any way. 21 U.S.C. § 352(q). Otherwise, advertisements may violate federal law. 21 U.S.C. 352(a).

## **D. Reimbursement/Payment**

Upon approval to move forward with the co-op advertisement(s), the account will submit all receipts and documentation ("submission") to their PDM confirming the advertisement meets all Obalon guidelines. At that point, Obalon will process payment, matching dollar for dollar up to the eligible amount and reimburse the practice accordingly. Payment will be in the form of a check sent via U.S. Postal Service to the account for receipt within 6-8 weeks after the submission.

Accounts choosing to do online advertising through Obalon's chosen vendor will not have to provide a submission. They can directly pay the vendor the appropriate amount and Obalon will match, dollar for dollar up to the eligible amount, and pay the vendor directly.

Any reimbursement and/or payment presupposes that the requisite Obalon approvals have been made for each piece of advertising material submitted.

## **E. Practitioner/Practice Non-Endorsement**

Participation in this program, including receipt of any reimbursement/payment is in no way an endorsement by Obalon of the practitioner and/or practice and **any services provided and** may not be used as such in any advertising materials in any way. Obalon does not endorse any practitioner or practice for any reason, including but not limited to the quality of service or any specific practitioner/practice reputation.

## **F. Approvals**

All advertisements must be approved by Obalon's Medical-Legal Review (MLR) process prior to dissemination and use. Advertisements using one of our Obalon-approved templates may not require approval from Obalon, provided that no other modifications, changes or additions are made. All other advertising must be submitted to your Obalon Practice Development Manager (PDM) for approval prior to launching.

## **G. Testimonials**

Testimonial advertisements are heavily regulated by the FTC. 15 U.S.C. § 45; 16 CFR Part 255. The following criteria should be followed for all testimonial endorsements:

- Must reflect only honest opinions, findings, beliefs or experiences of the endorser, who must be a bona fide user of the product at the time the endorsement was given
- May only continue to utilize endorsement so long as endorser remains a bona fide user of the product
- Need not be phrased in the exact words of the endorser, unless the advertisement affirmatively represents those exact words
- Must not be edited in a manner that would make them false, misleading or unsubstantiated
- Must disclose material connections between Obalon, the endorser and the physician and/or practice, as applicable

## **H. Consistency with FDA-Approved Labeling**

All advertisement content must not contain any claim or statement regarding the product that represents or implies that the product is safe and effective in any way, population or use that is not approved or cleared by the FDA. FDA Draft Guidance for Industry: Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers Guidance for Industry, (Jan. 2017). Such statements, express or implied, in written, oral, broadcast or otherwise, are unlawful and misbrand the product.

## **I. Safety/Risk Language Requirements**

The following safety/risk information is required to be included on all advertisements:

*The Obalon Balloon System is intended for adults with a body mass index (BMI) of 30 to 40 kg/m<sup>2</sup> (30 to 50 pounds overweight) willing to follow a diet and exercise program. All Obalon balloons must be removed in 6 months. Patients with prior weight loss surgeries are not eligible. The most common side effects reported were mild abdominal pain and nausea which typically resolved within two weeks. You must take daily acid-blocking medicine prescribed by your doctor. For full Important Safety Information go to [www.Obalon.com/safety-information](http://www.Obalon.com/safety-information) or call your doctor.*

## **J. Benefit and Safety/Risk Statement Requirements**

Presentation of safety/risk information is very important and heavily regulated by FDA. FDA law requires that advertisements be (1) consistent with the FDA-approved label, (2) contain a brief statement of the product's intended use and relevant warnings, precautions, side effects and contraindications, (3) be appropriately balanced with product safety and risk information, and (4) must not be false or misleading in any way. 21 U.S.C. § 352(a),(q),(r).

Benefit and safety/risk statement requirements must be viewed as a whole, and the net impression of the advertisement must contain appropriately balanced product safety/risk information. FDA Draft Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion, (May 2009). The following factors must be considered:

- Benefit information must not minimize or downplay safety/risk information
- The total amount of benefit information should not exceed that of safety/risk information
- The location of safety/risk information must not be any harder to find than that of benefit information
- The color/contrast between text and background should not highlight the benefit information more than the safety/risk information
- The font size to be used for the safety/risk information should be no smaller than the smallest font size used in the advertisement
- Audio presentation of safety/risk information should be played in a manner (i.e., speed, loudness, pitch) similar to that of the benefit information