

## Memo

To: Manufacturers of Prescribed Products

From: Wendy Morgan, Chief of the Public Protection Division  
Kate Whelley McCabe, Assistant Attorney General  
Vermont Office of the Attorney General

Date: April 25, 2012

Subject: Updates to 2012 Guide to Vermont's Prescribed Product Gift Ban and Disclosure Law

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The Vermont Attorney General's Office has made some updates to its guidance since the publication of the 2012 Guide to Vermont's Prescribed Product Gift Ban and Disclosure Law.

All updates are explained below. The Office expects to incorporate these updates – as well as any changes based on currently-pending legislation – into an amended 2012 Guide by June 1, 2012.

Thank You.

### **Disclosures Related to Members of the Green Mountain Care Board**

It has come to the Office's attention that Dr. Allan Ramsay, one of the members of the Board, is also a practicing physician with an active Vermont license number: 042-0006573. Thus, in contrast to prior guidance, please use Dr. Ramsay's license number to report disclosures related to him. A complete list of the members of the Green Mountain Care Board and the identification/license numbers that should be used in any disclosures related to them are as follows:

Anya Rader Wallack	999-0000001
Al Gobellie	999-0000002
Dr. Karen Hein	999-0000003
Con Hogan	999-0000004
Dr. Allan Ramsay	042-0006573

## **Medical Devices: Capital Equipment and Related Consumables**

The following is a clarification of already-existing guidance:

It is permissible to place capital with a recipient for usage without payment based on an agreement that the recipient will purchase a related consumable. The placement of such capital is neither a gift nor a loan, and need not be reported.

It is also permissible to provide a recipient with consumables for usage without payment as part of a contracted-for use or purchase of a related medical device. The provision of such consumables is not a gift and need not be reported.

## **Reporting Reasonable Distribution of Over the Counter Products**

An amendment to the law that became effective on January 1, 2012 decreases the amount of information manufacturers are required to report about the distribution of over-the-counter drugs, nonprescription medical devices, and items of nonprescription durable medical equipment. As a result, only the product, dosage, number of units, and recipient information of these products need be reported. These are the same categories of information required to be reported of samples of prescription product; thus, manufacturers should disclose the distribution of such over-the-counter product using the samples form and the samples database. **Previous guidance to the contrary – including Example H on page 40 of the 2012 Guide – should be disregarded.** The Office will amend Example H so that it shows the disclosure of the correct information on the correct form in the revised 2012 Guide.

## **Permissibility of Distributing Over the Counter Products**

In response to a question asked during the November 2011 conference call, the Office represented that the distribution of products such as lotions and eye drops was permissible under the exception to the gift ban allowing for the distribution of reasonable amounts of over-the-counter drugs, nonprescription medical devices or nonprescription durable medical equipment to an HCP for free distribution to patients. After seeking guidance from legislators involved in drafting the law, the Office retracts this expansion of the exception. While the Office will not enforce the gift ban with regard to the distribution of lotions, eye drops and like product in 2012, the Office will treat any distribution of these and like items that occurs on or after January 1, 2013 as unlawful. Going forward, the exception will only apply to over-the-counter drugs, nonprescription medical devices and nonprescription durable medical equipment.