

MEMO

To: Manufacturers of Prescribed Products

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

Date: December 20, 2012

Re: Common Errors in Compliance with Vermont's Prescribed Product Gift Ban and Disclosure Law **That may Result in Enforcement Action**

In the spirit of openness and to facilitate a higher level of compliance with Vermont's Prescribed Product Gift Ban and Disclosure Law, the Office has put together the following list of common errors made by manufacturers that have reported in the FY10, FY11 and 2011 reporting periods. Manufacturers that anticipate reporting 2012 activities and/or collecting data regarding 2013 activities are advised to consult this list to ensure their systems and practices will enable them to comply fully with the law.

To date, the Office has chosen to either work with manufacturers to correct or complete their submissions, correct or complete the submissions in house, or report small amounts of incorrect or incomplete data. Needless to say, incorrect and incomplete data submissions tax the Office's resources, cause delay, and result in imperfect transparency. Despite the Office's best efforts at creating and clarifying guidance for compliance with the law, some very obvious reporting errors remain. Therefore, going forward, the Office expects to take enforcement action against manufacturers with unjustified, obviously and egregiously incomplete or incorrect submissions.

In no particular order, common errors include the following. The 2013 Guide has been supplemented where there was any doubt as to the clarity of previous guidance.

- 1. Leaving fields blank.** The Office codes as mandatory certain fields in the Access databases and forms. Nevertheless, many manufacturer reports contain blanks and "dummy" information. In 2011, for example, there were over 47,000 required fields left blank in the nearly 106,000 samples reported. Particularly numerous and troublesome in both expenditure and samples reporting are omissions of recipient names, recipient license/ID numbers, product types and product names. Manufacturers must disclose required information; questions about how to do so should be researched in this Office's guidance in the first instance. *See*, e.g. p. 21 of 2013 Guide (addressing how to report product names for disease-state-specific or non-product specific spend). Questions that remain after reviewing the guidance

should be directed to prescribedproducts@atg.state.vt.us well in advance of the relevant reporting deadline.

2. **Reporting practices as recipients.** Reporting a multi-prescriber practice as a recipient is generally not allowed. Rather, the gift, expenditure, or sample must be allocated among the prescribers in the practice to which it is relevant. *See* pp. 14, and 16-17 of 2013 Guide (describing how to make this allocation).
3. **Relying on the Office’s “Table of Health Care Professionals with Active Vermont Licenses” and/or “Table of Entity-Recipients” as the sole means of defining the universe of covered recipients and/or finding license numbers.** These tables are meant to facilitate the standardization of the naming of institutional and organizational recipients and to be a helpful resource for looking up an HCP’s license number, not as exclusive lists of individuals and institutions that constitute covered recipients under the law or as the exclusive source of information about license numbers. Manufacturers are responsible for reporting activity relating to recipients covered under the law regardless of whether the recipient name appears on either of these tables. Moreover, manufacturers are responsible for reporting the license number of HCP recipients regardless of whether the number appears on the “Table of Health Care Professionals with Active Vermont Licenses.” *See* pp. 14-16, and 23-24 of 2013 Guide.
4. **Reporting only those educational materials relating to the products for which the majority of spend occurred.** Manufacturers are required to report all covered activity; Vermont law does not exclude expenditures below a certain amount, nor does it exclude activity related to products which are not “top” products.
5. **Reporting dates outside of the reporting period range.** Only data corresponding to the relevant reporting year should be reported with that year’s data. Late or corrected data should be submitted separately to prescribedproducts@atg.state.vt.us. *See* p. 29 of 2013 Guide.
6. **Reporting negative values.** All expenditures should be reported with a positive value, rounded to the nearest dollar. The receipt of money back from a covered recipient (e.g., unused grant money) need not be reported. Negative numbers that are reported will be deleted for purposes of analysis and reporting. *See* p. 16 of 2013 Guide.
7. **Incorrect payment nature characterization.** Generally speaking, these errors take the form of choosing “Other” where another category applies. For example, when

payment is remitted directly to a third party (e.g., an airline) for the permitted payment of an HCP's expenses (e.g., for travel connected to medical device training), manufacturers should choose "Cash, Check or Credit Card." The "Other" category should be used rarely. *See* p. 17 of 2013 Guide.

- 8. Incorrect payment purpose characterization.** Generally speaking, these errors take the form of choosing "Other" or "Other FMV Payment" where another category applies. For example, manufacturers should not choose these categories for faculty fees and expenses, or consulting expenses; instead, choose "Faculty Honoraria/Speaker Fee," "Faculty Expense," or "Consulting," as appropriate. If the expenditure does not fit the description of an allowable expenditure or permitted gift as set out in the law and guidance, it may be a banned gift subject to different reporting rules. These "Other" categories should be used rarely. *See* pp. 17-21, 30 of 2013 Guide.
- 9. Reporting the number of vouchers or coupons redeemed instead of the number of vouchers or coupons distributed.** Manufacturers must report the quantity of vouchers and coupons provided to the covered recipient, not the quantity redeemed by patients. *See* p. 26 of 2013 Guide.
- 10. Failure to report out-of-state activity with covered recipients.** Activity with covered recipients falls under the law whether or not the expense is incurred (or the sample distributed) in Vermont. Therefore, the expense of a hotel room for a Vermont HCP who is on the faculty of a conference outside Vermont must be reported as an allowable expenditure.* *See* pp. 5-6 of 2013 Guide.

* Note that manufacturers failing to report such activity are also at a high risk of committing gift ban violations by giving banned gifts to covered recipients while outside of Vermont. For example, taking a physician who regularly practices in Vermont out to dinner in New Hampshire is a banned gift. *See* p. 6 of 2013 Guide.