

Vermont Pharmaceutical Marketer Price Disclosure Guide  
Questions and Answers  
February 26, 2005

1. The Final Guide states that pharmaceutical manufacturers must make disclosures using the Long Form Disclosure by publishing the information on "a website made available in all circumstances described in Sections III.A and V." Are companies required to place these disclosures on their own individual websites or will the state maintain a central website for this purpose?

**ANSWER:** Pharmaceutical marketers are required to place the disclosures on their own websites, and they are required to list the correct web address on the Short Form Disclosure.

2. Under the Final Guide are price catalogues considered reminder communications that do not trigger the price disclosure requirements?

**ANSWER:** No. Price catalogues are not reminder communications. If price catalogues are sent to physicians or other prescribers under circumstances described in Section III (A) of the Guide, then the price disclosures are required. If the price catalogues are sent as part of marketing efforts to state or private payers of pharmaceutical benefits, or for use in hospitals or a health care facility, then, as described in Section III (B), no disclosure is required.

3. Although the Final Guide and the intent of the law appear to be to provide prescribers with information on human drugs, does the price disclosure requirement apply to marketing to veterinarians? They clearly are "other persons authorized to prescribe drugs" and neither the statute nor the Final Guide limits the drugs at issue to human drugs.

**ANSWER:** The price disclosure requirement does not apply to marketing activities aimed at or directed solely to veterinarians.

4. Under the Final Guide do the disclosure requirements only apply to promotional activities made within (or into, in the case of telephone and e-mail) Vermont, or do they extend to similar interactions with professionals who may be licensed in Vermont but practice elsewhere?

**ANSWER:** Section III (A) makes clear the circumstances under which the disclosure requirement applies. In general, it applies to promotional activities made within or into Vermont.

5. Under the Final Guide are medical affairs people or medical science liaisons (MSLs) covered as marketers? In most cases these are purely scientific questions being addressed.

**ANSWER:** Unsolicited requests for information by prescribers DO NOT trigger the disclosure requirement. See Section III (B) (6).

6. If a pharmaceutical company provides grant funding to a CME conference that is strictly to fund a display fee, is the company's representative required to provide the price disclosure form in their interactions with the prescriber at the display?

**ANSWER:** Yes, this is a face-to-face promotional activity.

7. If there is a drug in the same therapeutic class with one that has a different delivery method, e.g., extended release versus immediate release, must the drug with the different delivery method be included in the price disclosure?

**ANSWER:** If the extended release product, or other product with a different delivery method, is listed as a different product by the three AWP sources, then the drug with the different delivery method must be separately included in the price disclosure forms.

8. What are the sources of redress if the AWP of a manufacturer's product is misrepresented (whether intentionally or inadvertently) by another manufacturer on their price disclosure form when listing the drugs in the same therapeutic class?

ANSWER: The Pharmaceutical Marketers Price Disclosure Law and the Guide do not make any provision for remedies by one manufacturer against another if the latter does not accurately represent the AWP of the former's product. Common law may provide such remedies.

9. What is the definition of an "unrestricted grant" under the Final Guide in sections III.A.2 and III.B.3?

ANSWER: "Unrestricted grant" has the same definition as in 33 V.S.A. Section 2005(c)(6), which provides:

"Unrestricted grant" means any gift, payment, subsidy, or other economic benefit to an educational institution, professional association, health care facility, or governmental entity which does not impose any restrictions on the use of the grant, such as favorable treatment of a certain product or an ability of the marketer to control or influence the planning, content, or execution of the education activity.

10. Please provide clarification of section III.A.6. Does this provision mean that activities are covered only if the manufacturer is responding to an unsolicited request from a physician or prescriber?

ANSWER: Section III (A)(6) has been deleted. Now unsolicited requests for information from a physician or other prescriber DO NOT trigger the disclosure requirement. See Section III (B)(6).

11. If a pharmaceutical company decides to stop promoting in Vermont, is there any need to comply with any part of the price disclosure law?

ANSWER: If a pharmaceutical company or marketer does not engage in any covered activity, for whatever reason, then it need not make the disclosures described in the law and Guide.

12. Will the state be offering access to the 2004 American Hospital Formulary Service Pharmacologic-Therapeutic Classification?

ANSWER: No. The pharmaceutical marketers must obtain the list on their own. From March 1, 2005, through December 31, 2005, pharmaceutical marketers may use either the 2004 or 2005 AHFS Classification System. After January 1, 2006, the then-most recent version of the AHFS Classification System must be used.

13. Does Section III (A) (6) of the guideline apply to unsolicited requests from prescriber's for scientific, medical, or off-label information? We would like clarity on this point.

ANSWER: Section III (A)(6) has been deleted. Now unsolicited requests for information from a physician or other prescriber DO NOT trigger the disclosure requirement. See Section III (B)(6).

14. Confirm that Section III (B) 4 means that we do not have to make such disclosures when marketing drugs to managed care entities such as HMOs, PBMs, GPOs, and to the State of Vermont.

ANSWER: Yes, Section III (B) (4) means that pharmaceutical marketers do not have to make the price disclosures when marketing drugs to managed care entities such as HMOs, PBMs, GPOs and to the State of Vermont. However, when the pharmaceutical manufacturer is marketing

drugs to prescribers within the HMO, PBM, or GPO, for the purpose of convincing the prescriber to prescribe the drug rather than purchase it, then the disclosure must be made.

15. The statute defines Average Wholesale Price ("AWP") as "the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and listed in a nationally recognized drug pricing file." Vt. Stat. tit. 33 § 2005a(d)(1). The Guide appears to clarify that the "nationally recognized drug pricing file" is limited to the following sources: (1) First Databank; (2) Medispan; or (3) Redbook. These provisions appear to mean that if the manufacturer does not assign the AWP that is published in the three listed sources, the manufacturer does not have a disclosure obligation under Vermont's price disclosure law. Could you please confirm this?

ANSWER: No, this analysis is not correct. The pharmaceutical marketer is required to make the disclosure even if the AWP source it chooses to use does not list the AWP exactly as assigned by the manufacturer.

16. The Guide states that "[t]here is no disclosure requirement for a marketed drug if First Databank, Medispan and Redbook *all* do not publish an AWP for the marketed product." It is unclear whether this means that there is no disclosure requirement: (1) if an AWP for the marketed drug is not published in ANY of the three sources, *i.e.*, the AWP is not published by First Databank, Medispan or Redbook; or (2) there is no disclosure requirement if AWP is published in only two of the three sources, *i.e.*, a disclosure requirement exists only if AWP is published in all three of the publications. In both cases the AWP is not published by *all* of the pricing sources. Could you please clarify?

ANSWER: There is no disclosure requirement for the marketed drug only if all three of the sources do not publish the AWP for the marketed product, that is, the AWP for the marketed product is not published by First Databank, Medispan, or Redbook. If only one of the three sources publishes an AWP for the marketed product, then the pharmaceutical marketer must use that source of the disclosures required by the law.

With respect to the related drug, the Guide now allows pharmaceutical manufacturers to omit the AWP of the related drug from the Long Form Disclosure if the data source it chooses to use does list an AWP for that related drug. Similarly, the Guide now allows the pharmaceutical manufacturer to omit the related drug from the Short Form Disclosure if the data source it chooses does not list an AWP for that related drug.

17. Is it permissible for manufacturers to use Wholesale Acquisition Cost ("WAC") instead of AWP for both the marketed drug and drugs in the same therapeutic class on the Short and Long disclosure forms?

ANSWER: No. Pharmaceutical marketers must use AWP, not WAC.

18. We assume, since neither the law nor the guidance prohibit it, that manufacturers may include in their Short and Long Forms other disclaimers in addition to those provided in the Guidance. For example, a manufacturer may want to include a disclaimer that expands on the one already provided regarding the nature of the AWP number provided.

ANSWER: Pharmaceutical marketers may not expand on the disclaimers in the Short Form Disclosure. They may expand upon the disclaimers in the Long Form Disclosure, as long as the meaning of the required disclaimers is not altered.