# HOUSE RESEARCH

## Bill Summary =

FILE NUMBER: H.F. 1641 DATE: January 20, 2010

**Version:** As introduced

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**Subject:** Gifts to Practitioners

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#### Overview

This bill modifies the prohibition on gifts from drug manufacturers and other entities to practitioners. The bill adds a definition of gift (that which applies to public and local officials and legislative employees), specifies additional criteria for existing exceptions to the prohibition on gifts, adds practitioner reporting requirements, and makes related changes. The bill also prohibits members of the DHS formulary committee from accepting gifts or professional samples or from being employed by a drug manufacturer or distributor.

#### Section

- 1 Disclosure of payments to practitioners. Adds § 62J.241.
  - **Subd. 1. Disclosure required.** Requires each pharmaceutical manufacturer, wholesale drug distributor, or medical device manufacturer or their agent to file with the commissioner of health an annual report that identifies all payments, honoraria, reimbursement, or other compensation paid to practitioners or to sponsors of a medical conference, professional meeting, or other educational program during the preceding calendar year.
  - **Subd. 2. Report format.** Specifies report format and classifies reports as public data. Requires reports to be made available on the department web site in an easily accessible and searchable format.
- **2 Gifts to practioners prohibited.** Amends § 151.461.
  - **Subd. 1. Prohibition.** Prohibits a pharmaceutical manufacturer, wholesale drug distributor, or medical device manufacturer or distributor, or an agent, from giving any gift (rather than a "gift of value" as under current law), and also prohibits these entities from requesting another person to give a gift. Also removes an exemption from the requirement for medical device manufacturers that distribute drugs as an

incidental part of their business. Prohibits a practitioner from accepting a gift.

**Subd. 2. Definition of gift.** States that "gift" has the meaning provided in § 10A.071. (This is the definition of gift used for public and local officials and employees of the legislature; the Board of Pharmacy currently uses this definition when enforcing the prohibition on gifts).

### **Subd. 3. Exceptions.** Modifies the exemptions from the ban on gifts as follows:

- Exempts professional samples only if they are provided for free distribution to uninsured or low-income patients, if there is evidence-based medicine to support the clear superiority of the drug over less costly alternatives
- Eliminates the exemption for items with a total combined retail value in a calendar year of not more than \$50
- Requires payments to sponsors of conferences, meetings, or other educational programs to be in the form of unrestricted grants; requires the grantor to have no influence on content, presenters, or attendees; requires the grant to be made to underwrite the event and not to subsidize any particular attendees or be tied to the attendance of any particular practitioner
- Allows payment of reasonable honoraria and expenses of a practitioner who serves on faculty only if the honoraria does not exceed the standard hourly billing rate of the practitioner
- Allows compensation for professional or consulting services for research projects only if the project has the potential for advancing medical care or establishing improved understanding of the safety, performance, or improvement in clinical outcomes of the drug or device; limits compensation to the standard hourly billing rate of the practitioner
- Allows provision of informational publications and educational materials only if the materials were produced and published by the drug or device manufacturer
- Requires practitioners practicing in the state who are also employees or agents of a drug manufacturer, wholesale drug distributor, or medical device manufacturer or distributor to report the source, amount, and nature of the compensation received to the Board of Medical Practice, and to notify patients of the employment relationship before prescribing or recommending a medication or device from that manufacturer or distributor to the patient
- Exempts bona fide training or educational programs for the sole purpose of training the practitioner in use of a medical device, and reasonable expenses
- Exempts reasonable payment to a practitioner for intellectual property or patent royalties on a medical device, provided the practitioner is named on the patent

- **Subd. 4. Report.** (a) Require practitioners, when they receive compensation related to serving as faculty, the provision of professional or consulting services, or intellectual property or patent royalties, to report the source, amount, and nature of the compensation to the Board of Medical Practice and notify a patient of the financial relationship before prescribing any medication or device from that manufacturer or distributor to the patient.
- (b) For purposes of this section, provides that "practitioner" includes the employees of the clinic or facility where the practitioner is practicing and family members of the practitioner.
- **Requirements.** Amends § 151.47, subd. 1. Strikes an existing annual reporting requirement for wholesale drug distributors.
- **Formulary committee.** Amends § 256B.0625, subd. 13c. Prohibits a member of the formulary committee from accepting a gift or any professional samples from a drug manufacturer or wholesale drug distributor. Provides that a member of the formulary committee may not be an employee or agent of a drug manufacturer or wholesale drug distributor.