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Subject: New Hampshire House Passes Sweeping Rules Regarding Physician Relationships With Medical Device Companies



PRACTICE GROUP

email alert

To: Business Law and Governance, Fraud and Abuse, *and* Life Sciences
Practice Group Members

From: Business Law and Governance, Fraud and Abuse, *and* Life Sciences Practice Group Leaderships

Date: April 16, 2012

New Hampshire House Passes Sweeping Rules Regarding Physician Relationships With Medical Device Companies

By Clinton Mikel, Adrienne Dresevic, and Carey Kalmowitz*

New Hampshire's House of Representatives has, quietly, passed broad medical device self-referral legislation. Surprisingly, the legislation has largely flown under the radar, though it is very much of interest to health lawyers and the physicians, medical device companies, and research/university hospitals that they represent.

On March 29, the New Hampshire House of Representatives recommended for passage HB 1725. HB 1725 is broad-reaching, and would prohibit all medical practitioners from prescribing or referring any U.S. Food and Drug Administration class II or class III implantable device in cases where they would gain profit, directly or indirectly, from the sale of the device, or from performing any procedure involving the device. HB 1725 is currently being fast-tracked--the New Hampshire Senate Committee on Health and Human Services has scheduled a hearing on HB 1725 on April 19.

Supporters of the bill assert that it is necessary to protect New Hampshire from the perceived problems associated with physician-owned distributors (PODs). As drafted, however, the bill goes significantly further than merely outlawing PODs; HB 1725 would essentially prohibit physicians from continuing to practice in their specialty in New Hampshire if they create or develop medical devices and receive ongoing payments for their efforts. Thus, even in the absence of any potential abuse or evidence of over-utilization, those physicians would effectively be barred from practice in New Hampshire.

Opponents of the bill argue that it could have significant unintended patient safety implications, as New Hampshire would effectively have outlawed the process by which physicians and legitimate medical device manufacturers continuously develop, promote, test, obtain feedback on, and improve life-saving medical devices. Additionally, HB 1725 could

have significant anti-competitive effects on innovators, small businesses/medical device startup companies, and hospitals that employ physicians who develop intellectual property (such as university hospitals and others who engage in significant research and pay royalties to physicians).

Most of the potentially negative effects of HB 1725 occur because of the breadth of the bill, its lack of exceptions, and the fact that it layers on a statutory definition in New Hampshire's current "self-referral" law, which currently merely requires disclosure of certain ownership interests to patients (similar to the Stark In-Office Ancillary Services exception's disclosure requirement for certain imaging services). That statute defines an "ownership interest" broadly as being:

Any and all ownership interest by a healthcare practitioner or such person's spouse or child, including, but not limited to, any membership, proprietary interest, stock interest, partnership interest, co-ownership in any form, or any profit-sharing arrangement. It shall not include ownership of investment securities purchased by the practitioner on terms available to the general public and which are publicly traded.

HB 1725, as drafted, would prevent a practicing physician (or his/her spouse/children) from receiving royalties for intellectual property that he/she has developed and licensed to a medical device manufacturer. Further, a physician would be subject to liability if he/she, or his/her spouse or children, decided to create or invest in a medical device company for otherwise legal purposes. HB 1725, as drafted, does not distinguish between legitimate physician/medical device company interactions (e.g., bona fide businesses, as opposed to a marketing tool of a device manufacturer, or a sham entity designed to provide remuneration to referring physicians), and creates a near-absolute prohibition on physicians capitalizing on their intellectual property while continuing to practice in their field of specialty.

To date, the legislative passage of New Hampshire's HB 1725 has not been widely publicized. The next significant legislative step occurs on April 19, when the New Hampshire Senate Committee on Health and Human Services has scheduled a hearing on HB 1725.

**We would like to thank Clinton R. Mikel, Esquire, Adrienne L. Dresevic, Esquire, and Carey F. Kalmowitz, Esquire (The Health Law Partners PC, Southfield, MI, and Lake Success, NY), for providing this email alert.*

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