

From: AHLA Member Services [<mailto:msc@healthlawyers.org>]

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Subject: Revised and Reissued Email Alert: New Hampshire House Passes New Legislation Regarding Physician Relationships With Medical Device Companies



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 24, 2012

**Revised and Reissued Email Alert: New Hampshire House
Passes
New Legislation Regarding Physician Relationships
With Medical Device Companies**

By Clinton Mikel, Adrienne Dresevic, Carey Kalmowitz, and Tom Bulleit*

New Hampshire's House of Representatives has 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 would prohibit all healthcare practitioners from prescribing or referring any U.S. Food and Drug Administration class II or class III implantable device in cases where they would profit, directly or indirectly, from the sale of the device by any supplier in which the healthcare practitioner has a direct or indirect ownership interest. The next significant legislative step is likely to occur on April 26, when the New Hampshire Senate Committee on Health and Human Services may schedule a vote on HB 1725.

Proponents and opponents of the measure disagree about the meaning of terms contained and referenced in the bill, and the intended and unintended impact of such terms on the bill's reach, including terms

used in the specific definitions that are included in the bill.

For instance, the term "supplier" is defined as:

any entity that sells, or arranges for or negotiates contracts for purchase or sale of, medical devices, including a manufacturer, distributor, group purchasing organization, sales agent, or other medical device supplier.

HB 1725 also uses the following definition of "ownership interest":

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.

Supporters of the bill assert that the legislation will protect New Hampshire from the perceived conflicts of interest associated with referrals by healthcare practitioners to physician-owned distributors (PODs) and other physician-owned companies. They believe that the bill represents a narrow and targeted approach to the potential for patient and program abuse created by self-referral to PODs and physician-owned companies. They argue that the legislation applies to a limited class of product that typically involves highly invasive and risky surgery, which they believe often affects a vulnerable patient population. Supporters reason that the State of New Hampshire has a compelling interest in addressing the perceived conflict of interest that arises when doctors take a financial interest in the suppliers of the implantable medical devices they order for their own patients. They further point out that the bill would apply only to ownership interests in the manufacturer, distributor, or other supplier of the device, and not in the medical device itself.

Opponents argue that the bill goes significantly further than the stated intent of its supporters to outlaw PODs (noting, for instance, that no PODs currently operate in New Hampshire). They believe that HB 1725 would essentially prohibit healthcare practitioners from continuing to practice in their specialty in New Hampshire if they create or develop medical devices and receive ongoing payments for their efforts. Opponents further argue that the legislation could have significant unintended patient safety implications, as New Hampshire would, in their view, effectively have outlawed the process by which healthcare practitioners and legitimate medical device manufacturers continuously develop, promote, test, obtain feedback on, and improve life-saving medical devices.

Additionally, opponents believe that HB 1725 could have significant anti-competitive effects on innovators, small businesses/medical device

startup companies, and hospitals that employ healthcare practitioners who develop intellectual property (such as university hospitals and others who engage in significant research and pay royalties to physicians). They claim that 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, opponents assert that a healthcare practitioner 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.

In this regard, supporters and opponents have disagreed sharply on whether the definition of "ownership interest" will allow or permit "royalty arrangements" between healthcare practitioners and device suppliers. Supporters believe that the text of the legislation should alleviate concerns regarding royalty payments, since royalty arrangements are contractual and the bill's terms apply only where the healthcare practitioners have a "direct or indirect" ownership interest in the "supplier" of the device. Opponents believe that the actual definition of "ownership interest" calls royalty arrangements into question because the definition includes "proprietary interests" and "profit-sharing arrangements" with a "supplier," and royalty contracts are often based on net profits with respect to a specific medical device.

Supporters also resist the implication that the bill would adversely affect a healthcare practitioner's or a healthcare practitioner's family's right to invest in any medical device company, manufacturer, or distributor while the practitioner continues to practice in the practitioner's specialty. Supporters reason that a practitioner would simply be prohibited from ordering the products himself or herself if there were an ownership interest (other than in a public company, where the ability of any individual owner to affect the company's performance is negligible). As such, supporters assert that product development collaboration and innovation can continue uninterrupted where there is a legitimate market for the product beyond the physician owners of the supplier. Opponents believe, however, that a practitioner is forced to choose between being either a physician or an inventor, but cannot do both under HB 1725. Thus, though a cardiologist (or his or her spouse, son, or daughter) may invent the next-generation device and may create his or her own medical device company to bring the same to the market, under HB 1725 the physician would not be able to use the improved device on his or her patients (until, of course, his or her company becomes publicly traded).

Both supporters and opponents of HB 1725 feel strongly about the merits of their respective arguments. This email alert does not endeavor to explore all of the debates that exist over this bill. It is being reissued simply to offer AHLA members the opportunity to appreciate some of the positions on each side of the debate.

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