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Feature Article

The California Hurdle

SB 790 and Pharma

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ABSTRACT: Seven states and the District of Columbia currently have regulations that limit or ban industry gifts to physicians, and it seems as though others are following suit. The California state Senate passed SB 790 in May 2017, a bill restricting pharmaceutical companies from giving gifts and incentives to medical professionals. This article reviews the changes SB 790 calls for, and what compliance professionals should keep an eye on.

The California Senate passed a bill ("SB 790") in May 2017 that, if enacted, will change how pharmaceutical companies interact with health care professionals ("HCPs"). While standards and requirements for transfers of value are not new to pharmaceutical companies, SB 790 introduces new concepts for California, including:

- new standards for 'allowable expenditures,' which includes limitations on sponsorship of conferences or seminars that are educational, policy making, medical, or scientific;
- a broader definition and ban on 'gifts'; and
- restrictions on speaker and consulting fees.

California's SB 790 is not a new concept to pharmaceutical companies, as other states currently have their regulations relating to this. However, the question is because California is often a pioneer in state legislation, will other states follow suit?

Background - Is there an association with gifts and prescribing patterns?

Regulation surrounding transfers of value in the life sciences industry has always been controversial – some argue that payments for legitimate services influence prescribing patterns, while others believe that without it, research and development would be impacted. It is a topic that has been debated for years within the academic community. For example, a 2010 study published in the Archives of Internal Medicine found that between one-third and two-thirds of patients surveyed thought it was important to know about financial ties between healthcare professionals, including researchers, and industry.[2]

1 *Thanks to non-author contributors – Hannah Walsh, Vishruti Vaikundan, who contributed in the collection of information and drafting portion of the article and Mark Scallon, Partner – who provided final review of the article. FRA Life Sciences offers a broad set of services to help companies identify global compliance risks and develop practical, yet effective, solutions. www.forensicrisk.com*

2 *See Adam Licurse, et al., The Impact of Disclosing Financial Ties In Research and Clinical Care: A Systematic Review, 170 ARCH. INTERN. MED. 675 (2010); see also Steven Mitchell, Consumers say big pharma influence on docs is concerning, HEALTH BLOG, http://blogs.consumerreports.org/health/2010/08/consumers-say-big-pharma-influence-on-docs-is-concerning-consumer-reports-survey.html (August 24, 2010); see also David Grande, et al., Pharmaceutical Industry Gifts to Physicians: Patient Beliefs and Trust in Physicians and the Health Care System, J. GEN. INTERN. MED. (Jun. 14, 2011), available at http://www.ncbi.nlm.nih.gov/pubmed/21671130 (citing 55% of respondents believe their physician receives gifts, and 34% believe almost all doctors receive gifts, with those believing that almost all doctors accept gifts being more likely to report low physician trust and high health care system distrust); Sarah L. Goff, et al., Patients' Beliefs and Preferences Regarding Doctors' Medication Recommendations, 23 J. GEN. INTERNAL MED. 236, 238 (2008) (some study participants expressed concern over possible financial or social gains for physicians interacting with pharmaceutical companies).*

According to Senator McGuire,[3] sponsor of SB 790, in 2014 California physicians received the highest number of gifts and payments from pharmaceutical companies of any state – $1.44 billion. He argues that "financial incentives change minds" and drive up the cost of branded prescription drugs. The legislative comments of the bill state that the U.S. spends $73 billion annually on brand-name drugs for which generic equivalents are available at a far lower cost.

The impetus for SB 790 is mostly based on a USCF study that showed HCPs who receive industry meals, speaking fees, travel, etc., are more likely to prescribe brand-name drugs. The study published in the Journal of the American Medical Association ("JAMA")[4] reports that approximately half of doctors in the U.S. received payments from pharmaceutical and medical device industries in 2015, amounting to $2.4 billion. These payments included: consulting fees, meals, and royalty, license or research payments. Of these payments to medical professionals, industry-sponsored meals account for approximately 80%. The research concluded that there was an association between industry-sponsored meals and an increased rate of prescribing brand-name medication that was being promoted. It was found that even cheap meals – with a mean value of less than $20 – or doctors who received only one industry-sponsored meal provided by pharmaceutical sales representatives were associated with "significantly higher" prescription rates.

What are the key changes introduced by SB 790?

The intent of the bill is to bring down costs of prescription medicines ultimately. As drafted, SB 790 will only apply to drug manufacturers and prescribed medications, not device manufacturers or any products that have a medical device as part of the combination. Below are highlights of a few of the key changes introduced by SB 790:

1. **Limitations of financial interactions between pharmaceutical companies and HCPs.** As mentioned previously, sponsorships to educational, medical, scientific, or policy-making conferences, which includes meals and food for conference participants, will be allowable under the bill. Consistent with requirements for continuing medical education ("CME") grants, funding must be used solely for bona fide educational purposes, and these conferences must be independent of industry control, cannot promote products, and must be fair and balanced.
2. **The definition of 'gifts' is broader.** Although the provision of 'gifts' that do not serve as educational is prohibited within the Pharmaceutical Research and Manufacturers of America ("PhRMA") Code, SB 790 includes the following under the definition: 'payment, food, entertainment, travel, subscription, advance, service or anything else of value, - unless it is an allowable expenditure -, or the HCP reimburses the cost at fair market value'. Additionally, a cap of $250 per person, per year has been placed on the provision of meals provided to HCPs.
3. **Honoraria and expense reimbursements are only allowable under certain circumstances.** If enacted, honoraria and payment of expenses will only be allowable for HCPs who serve as faculty at a conference or seminar mentioned above, or clinical trials and research, and if expenses are being reimbursed for a bona fide employment opportunity on behalf of the company (e.g., costs related to interviews). This would severely restrict speaking and other consulting fees. In particular, it would restrict the ability of pharmaceutical companies to utilize California HCPs as advisory board members.

Considerations

This is not the first-time lawmakers have moved to curb gifts and payments to HCPs. Prior to 2012, Massachusetts

3 *http://sd02.senate.ca.gov/news/2017-05-18-senate-passes-mcguire%E2%80%99s-bill-severely-restricting-pharmaceutical-industry-gifts. However, in his statement, Senator McGuire mentions there are data to support his position, but he does not cite to a particular study.*

4 *Collette De Jong, et al., "Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries," 176 JAMA INTERNAL MEDICINE 1114 (Aug. 2016).*

did not allow the provision or payment of meals outside of an office or hospital setting to HCPs.[5] This meant speaker programs, food or drinks served at conferences, and refreshments at any other event sponsored by a life science company were off limits.

After severe backlash from the public, who argued that the ban cost millions in foregone revenue, Massachusetts watered down the ban with an amendment in 2012. The amended law now allows for meals or refreshments that are 'modest' per local standards, or similar to what the HCP may purchase at their own expense, in a setting for the purpose of educating HCPs.

Vermont's gift ban is considered to be one of the toughest in the nation, prohibits meals and refreshments similar to Massachusetts' original ban. The result has been that pharmaceutical companies severely risk their involvement with Vermont practitioners, something they cannot afford to do in California. However, like the case in Massachusetts, Vermont practitioners currently are pushing back against the bill, arguing allowance for eating food paid by pharmaceutical companies at conferences, as long as promoting a specific drug is not the focus.[6]

Other California Senators argue that the bill could put a huge chill on the biotech industry in California. Senator Ted Gaines believes that it will affect patients, arguing that "successful products provide funding for the research, for cures." In addition, Senate Minority Leader Patricia Gates argued that gifts from pharmaceutical companies to doctors are already regulated and that doctors may now be deterred from participating in clinical trials and limit Californians' access to experimental drugs.[7] Finally, PhRMA, as to be expected, defends the pharmaceutical industry's financial ties with physicians, stating that drug makers help inform better decision-making by paying expert-caliber speakers to spread their knowledge.

Even the authors of the USCF study published in JAMA that started this legislation rolling recognize the limitations of their analysis, stating that the study's findings represent an 'association,' rather than a cause-and-effect relationship. Furthermore, five months of payment data vs. 12 months of prescription data was used; therefore the payment data may not be representative of a full year. The authors also state that the "questions that [they] examined should be evaluated with alternative study designs and additional years of data." This begs the question of utilizing these types of studies as the basis for the bill.

Considering SB 790 restricts the provision of travel, speaking and consulting fees, meals, and other "gifts" to HCPs, it is difficult to imagine California legislators ignoring public outcry, similar to Massachusetts and Vermont. Whether the bill will be enacted in its entirety, one may assume that at the very least, some of the new limitations will be enacted.

This raises the following questions: because of the compliance challenges to continually adapt to differences in state regulations, just to be safe, will companies begin to evolve their overall practices to address the most stringent laws? Is there a greater need to evolve federal requirements to be more uniform? Will these restrictions ultimately result in the original intent of these laws – to help drive down cost of prescription drugs? Finally, and likely most importantly, has there been an impact on patient outcomes due to these limitations?

Conclusion

As companies continue to adapt to the changing regulatory landscape, it appears that another hurdle may be introduced in California. There is a need to examine further viable correlations between interactions with HCPs and the cost of medicines, as well as the impact on patient outcomes in order to provide a stronger basis for such laws. Until then, SB 790 will head to the California Assembly and if passed, will proceed to the governor's desk for a signature. At this moment, our advice to compliance professionals is that they should monitor this bill very carefully.

5 *105 CMR 97.000: Pharmaceutical and Medical Device Manufacturer Conduct*

6 *http://legislature.vermont.gov/bill/status/2018/S.45*

7 *http://www.policymed.com/2017/05/california-bans-gifts-to-doctors.html*

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