THIRD READING

Bill No: AB 1278
Author: Nazarian (D)
Amended: 8/25/22 in Senate
Vote: 21

SENATE BUS., PROF. & ECON. DEV. COMMITTEE: 8-0, 7/12/21
AYES: Roth, Archuleta, Dodd, Eggman, Hurtado, Leyva, Min, Pan
NO VOTE RECORDED: Melendez, Bates, Becker, Jones, Newman, Ochoa Bogh

SENATE APPROPRIATIONS COMMITTEE: 5-1, 8/11/22
AYES: Portantino, Bradford, Laird, McGuire, Wieckowski
NOES: Jones
NO VOTE RECORDED: Bates

ASSEMBLY FLOOR: 54-9, 5/3/21 - See last page for vote

SUBJECT: Physicians and surgeons: payments: disclosure: notice

SOURCE: Center for Public Interest Law

DIGEST: This bill requires physicians and surgeons licensed by the Medical Board of California (MBC) and Osteopathic Medical Board of California (OMBC) to notify patients in writing every two years about the Open Payments database and requires them to post notice about the Open Payments database in each practice area.

Senate Floor Amendments of 8/25/22 delete the requirement that notification be provided every two years so that the measure specifies notification must be provided at the initial visit; clarify that the notification can be written or electronic; and delay the requirement for notice of the Open Payments database to be posted on physician websites, if they have websites, to take effect until January 1, 2024.
ANALYSIS:

Existing law:

1) Requires every board within the Department of Consumer Affairs to adopt regulations to require its licensees to provide notice to their clients or customers that the practitioner is licensed by this state. (BPC § 138)

2) Requires the MBC to adopt regulations to require its licentiates and registrants to provide notice to their clients or patients that the practitioner is licensed or registered in California by the board, that the practitioner’s license can be checked, and that complaints against the practitioner can be made through the board’s Internet Web site or by contacting the board. (BPC § 2026)

3) Requires the MBC, the OMBC, the Podiatric Medical Board of California, and the Physician Assistant Board to disclose to an inquiring member of the public information regarding any enforcement actions taken against a licensee, including probationary status and limitations on practice. (BPC § 803.1)

4) Enacts the Patient's Right to Know Act of 2018 to require certain healing arts licensees, including physicians and surgeons, who are on probation for certain offenses to provide their patients with information about their probation status prior to the patient's first visit. (BPC § 2228.1)

5) Requires drug manufacturers, under federal law, to obtain approval of new drugs from the federal Food and Drug Administration (FDA).

6) Requires, under the federal Physician Payments Sunshine Act (Sunshine Act), manufacturers of specified drugs, devices, biologicals, or medical supplies to disclose to the federal Centers for Medicare and Medicaid Services (CMS) payments or other transfers of value made to physicians or teaching hospitals.

7) Establishes the Sherman Law, administered by the Department of Public Health (DPH), which, among other things, regulates the packaging, labeling, and advertising of drugs and medical devices in California. (Health and Safety Code (HSC) § 109875 et. seq.)

8) Prohibits, in the Sherman Law, the sale, delivery, or giving away of any new drug or new device unless it is either: (HSC § 111550-111610)

   a) A new drug, and a new drug application has been approved for it by the FDA, pursuant to federal law, or it is a new device for which a premarket
approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under the FDA; or

b) A new drug or new device for which DPH has approved a new drug or device application, and has not withdrawn, terminated, or suspended that approval.

c) Requires DPH to adopt regulations to establish the application form and set the fee for licensure and renewal of a drug or device license.

9) Requires drug companies to adopt a Comprehensive Compliance Program (CCP), as specified, and include limits on gifts or incentives provided to medical or health professionals. Requires drug companies to establish explicitly in its CCP a specific annual dollar limit on gifts, promotional materials, or items. (HSC § 119402)

This bill:

1) Requires a MBC and OMBC licensed physician and surgeon, other than an individual working in a hospital emergency room, to provide each patient at the initial office visit, a written or electronic notice of the federal Open Payments database (created to allow the public to search for data provided pursuant to Section 1320a-7h of Title 42 of the United States Code and that is maintained by the federal Centers for Medicare and Medicaid Services (CMS)). Requires the written to include a signature from the patient or a patient representative and the date of signature. Requires the physician to include a record of the notice in the electronic patient records or written patient records if electronic patient records are not maintained and requires them to give the patient or patient representative a copy of the signed and dated notice. Specifies that the notice contain the following text:

“The Open Payments database is a federal tool used to search payments made by drug and device companies to physicians and teaching hospitals. It can be found at https://openpaymentsdata.cms.gov.”

2) Requires a physician and surgeon, other than an individual working in a hospital emergency room, or health care employer if the physician and surgeon is employed by an employer that provides health care services, to post, in each location where the individual practices, in an area likely to be seen by all persons entering the office, and on the website used for the individual’s practice
For informational purposes only, a link to the federal Centers for Medicare and Medicaid Services (CMS) Open Payments web page is provided here. The federal Physician Payments Sunshine Act requires that detailed information about payment and other payments of value worth over ten dollars ($10) from manufacturers of drugs, medical devices, and biologics to physicians and teaching hospitals be made available to the public.”

3) Makes a violation of these provisions unprofessional conduct.

Background

Open Payments Database. The Sunshine Act is a federal law that was passed in 2010 as part of the Patient Protection and Affordable Care Act and requires manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the federal Health and Human Services Secretary certain payments or other transfers of value to physicians and teaching hospitals. The Act also requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities. Manufacturers and GPOs are subject to civil monetary penalties for failing to comply with the reporting requirements. Annual data on all payments and transfers of value made to physicians must be provided, and physicians have 45 days to review the data and dispute errors before public release. The Secretary is required to publish the reported data on a public website, and information must be downloadable, easily searchable, and aggregated. States are generally preempted from enacting laws that require disclosure of the same type of information by manufacturers, but the Act explicitly permits states to require the reporting of additional data by drug companies. The passage of the Sunshine Act was intended to increase transparency around the financial relationships between physicians, teaching hospitals and manufacturers of drugs, medical devices and biologics.

CMS fulfills the law’s mandate via the Open Payments Program. In June 2016, CMS published the 2015 Open Payments data of financial transactions between drug and medical device makers and health care providers. The data includes information about 11.9 million financial transactions attributed to over 600,000 physicians and more than 1,100 teaching hospitals nationwide, totaling $7.52 billion.
California’s Comprehensive Compliance Program. SB 1765 (Sher, Chapter 927, Statutes of 2004) established the law that requires pharmaceutical companies to adopt and update a CCP for interactions with health care professionals and to establish explicitly in their CCPs an annual dollar limit on gifts, promotional materials or other items or activities, with certain exceptions, in accordance with the PhRMA Code and with specified federal guidance.

**FISCAL EFFECT:** Appropriation: No  Fiscal Com.: Yes  Local: No

According to the Senate Appropriations Committee, this bill will result in indeterminate, but likely absorbable costs to MBC and OMBC to address a potential increase in enforcement workload related to a small increase in complaints, and estimated total costs of $4,000 for the Office of Information Services to create new enforcement codes.

**SUPPORT:** (Verified 8/25/22)

- Center for Public Interest Law (source)
- Association for Medical Ethics
- Breast Implant Safety Alliance
- California Public Interest Research Group
- Consumer Attorneys of California
- Consumer Federation of California
- Consumer Watchdog
- Health Access California
- Heartland Health Research Institute
- Informed Patient Institute
- Medical Board of California
- Mending Kids
- Numerous Individuals

**OPPOSITION:** (Verified 8/25/22)

- Association of Northern California Oncologists
- California Academy of Family Physicians
- California Chapter American College of Cardiology
- California Medical Association
- California Rheumatology Alliance
- California Society of Plastic Surgeons
- Liver Coalition of San Diego
ARGUMENTS IN SUPPORT: Supporters write that “Financial relationships between physicians and medical product manufacturers are common, and include, but are not limited to, free meals, consulting, speaker fees, direct research funding and payments for promoting and using devices and drugs. These relationships can have many positive outcomes and--particularly in the context of consulting and research funding--are often a key component in the development of new drugs and devices. However, they can also create conflicts of interest and in some cases can blur the line between promotional activities and the conduct of medical research, training, and practice. A 2019 analysis by Pro Publica found that on average, doctors who received payments prescribed 58% more of that drug than doctors who did not. The intent of this legislation to create a stronger patient-doctor relationship through greater transparency, and to empower patients to make informed choices about their health care, and improve patient safely.”

ARGUMENTS IN OPPOSITION: Opponents state that this bill diverts crucial patient time to administrative tasks that do not improve patient care…and would require significant resources and be exceedingly time consuming for physician practices, diverting crucial patient time to administrative tasks. Physicians already have limited time with patients. The time should be spent discussing the patient’s health, treatment plans, medications, and any health questions the patient may have. Opponents state “existing federal law includes the Physician Payment Sunshine Act, requiring all drug and device companies to publicly report payments made to physicians and teaching hospitals. This information is available for public review on the Open Payments Database website. This federal law provides full transparency. We believe this process is the best way to allow patients to understand a physician’s relationship with a pharmaceutical or device company. We are concerned that requiring physicians to biannually provide a written disclosure to patients and then maintain a copy in their medical record will result in additional costs and burdens to physician practices to change their medical record systems. We support helping patients understand the existence of this information and the Open Payments Database but believe AB 1278 will result in additional burdens to physician practices that outweigh any benefit in providing the disclosure.”

ASSEMBLY FLOOR: 54-9, 5/3/21
AYES: Aguiar-Curry, Arambula, Bauer-Kahan, Bennett, Berman, Bloom, Boerner Horvath, Burke, Calderon, Carrillo, Cervantes, Chau, Chiu, Cooley, Daly, Friedman, Gabriel, Cristina Garcia, Eduardo Garcia, Gipson, Lorena Gonzalez,

NOES: Cunningham, Flora, Gray, Lackey, Mathis, Patterson, Seyarto, Smith, Voepel

NO VOTE RECORDED: Bigelow, Chen, Choi, Cooper, Megan Dahle, Davies, Fong, Frazier, Gallagher, Kiley, Mayes, Nguyen, Quirk, Valladares, Waldron

Prepared by: Sarah Mason / B., P. & E.D. /
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