
SUMMARY: Requires a physician and surgeon who receives remuneration from a drug or device company to disclose it both orally and in writing to their patient prior to the intended use or prescription of that drug or device, and requires all physicians and surgeons to post a notice informing patients of a federal database containing information regarding such remunerations.

EXISTING LAW:

1) Establishes the Medical Board of California (MBC), a regulatory board within the Department of Consumer Affairs (DCA) comprised of 15 appointed members, including 7 public members. (Business and Professions Code (BPC) § 2001)

2) Requires the MBC to post on its Internet Web site the current status of its licensees; any revocations, suspensions, probations, or limitations on practice, including those made part of a probationary order or stipulated agreement; historical information regarding probation orders by the board, or the board of another state or jurisdiction, completed or terminated, including the operative accusation resulting in the discipline by the board; and other information about a licensee’s status and history. (BPC § 2027)

3) Establishes the Osteopathic Medical Board of California (OMBC), which regulates osteopathic physicians and surgeons that possess effectively the same practice privileges as those regulated by the MBC but with a training emphasis on diagnosis and treatment of patients through an integrated, whole-person approach. (BPC § 2450)

4) Requires every board under 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)

5) 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)

6) Requires healing arts boards to each create and maintain a central file of the names of all persons who hold a license or similar authority from the board confidentially containing an individual historical record for each licensee containing, among other things, disciplinary information. (BPC § 800)

7) 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)
8) 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)

9) Requires drug companies to adopt a Comprehensive Compliance Program and include limits on gifts or incentives provided to medical or health professionals. (Health and Safety Code § 119402)

**THIS BILL:**

1) Defines “drug or device company” as a manufacturer, developer, or distributor of pharmaceutical drugs or any device used in the context of the physician and surgeon’s or osteopathic physician and surgeon’s practice.

2) Defines “health care employer” as an employer that provides health care services and that employs a physician and surgeon or an osteopathic physician and surgeon.

3) Defines “open payments database” as the database created to allow the public to search for data provided pursuant to federal law and that is maintained by the federal Centers for Medicare and Medicaid Services (CMS).

4) Defines “physician and surgeon” as a physician and surgeon licensed under either the MBC or the OMBC.

5) Requires a physician and surgeon to post in each location where the physician and surgeon practices, in an area that is likely to be seen by all persons who enter the office, an open payments database notice containing the following text:

   “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.”

6) Requires a physician and surgeon who receives remuneration from a drug or device company to disclose the source of the remuneration orally and in writing to each patient or patient representative prior to the intended use or prescription of a device or drug manufactured or distributed by the company.

7) Requires the disclosure to cover any remuneration received on or after January 1, 2014.

8) Requires that the written disclosure shall include a signature from the patient or patient representative and the date of signature.

9) Requires the written disclosure to include the following text: “If you would like further details on the information provided above you may discuss with Dr. ____ and/or visit openpaymentsdata.cms.gov, a federal tool used to search payments made by drug and device companies to physicians and teaching hospitals.”
10) Requires a physician and surgeon to include in the written or electronic records for the patient a record of the disclosure and to give to the patient or patient representative a copy of the signed and dated disclosure.

11) If a physician and surgeon is employed by a health care employer, provides that the health care employer shall be responsible for meeting the posting requirements.

12) Requires a physician and surgeon to conspicuously post the open payments database notice on the internet website used for the physician and surgeon’s practice.

13) Provides that violations of the bill constitute unprofessional conduct.

14) Exempts a physician and surgeon working in a hospital emergency room from the bill.

FISCAL EFFECT: Unknown; this bill is keyed fiscal by the Legislative Counsel.

COMMENTS:

Purpose. This bill is sponsored by the Center for Public Interest Law. According to the author:

“AB 1278 would empower patients with important information about their recommended medical treatment so that they can make informed choices about any treatment prescribed. When it comes down to it, patients deserve transparency and accountability when it comes to treatment. By requiring physicians and surgeons to engage patients as trusted partners in decision making, we are creating local accountability what will both serve the doctor and patients alike.”

Background.

The Physician Payments Sunshine Act (Act) is a federal law that was passed in 2010 as part of the Patient Protection and Affordable Care Act. The Act requires medical product manufacturers to disclose to the Centers for Medicare and Medicaid Services (CMS) any payments or other transfers of value made to physicians or teaching hospitals. The intention of the Act is to increase transparency regarding financial relationships between health care providers and pharmaceutical manufacturers.

Manufacturers are required to submit annual data on all payments and transfers of value made to physicians, who have 45 days to review the data and dispute errors before public release. CMS then publishes the data through its Open Payment Program website, which allows members of the public to search for physicians, teaching hospitals, or companies making payments by name, city, state, and specialty. The Open Payments database enables patients to see if their providers have received some form of payment from the manufacturer of a drug or device that has been recommended as part of their treatment plan, which may ultimately inform their health care decisions.

In addition to allowing the public to search for specific payments and transfers of value, CMS makes its Open Payments data generally available to researchers. In 2016, four key research studies explored the association between industry payments and physician-prescribing patterns by cross-linking federal Open Payments data with national Medicare Part D prescribing information.
When examining general brand-name prescribing rates, one study found that physicians who received any industry payments had, on average, a brand-name prescribing rate two percentage points higher than physicians who did not receive any payments. A dose-response relationship was examined, meaning that as the payment amount increased, the difference in the brand-name prescribing rates of non-payment recipients and payment recipients increased. Another study analyzing 2013 Open Payments data found that even after adjusting for potential influencing factors, industry payments were associated with greater prescription costs per beneficiary. This was again a dose-response relationship, with greater payments associated with greater prescribing costs per patient. One study published in *JAMA Internal Medicine* in August 2016 found that receipt of meals costing as little as $20 were associated with higher relative prescribing rates.

This bill is intended to ensure that patients are informed of when their physician and surgeon has received some form of payment from the manufacturer of a drug or device intended to be prescribed or used in their treatment by requiring all physicians to disclose directly to their patients when they have received remunerations that would be reportable under the Act. Further, the bill would increase consumer awareness of the Open Payments database by requiring all physician and surgeon offices to post a notice advertising the website. The author believes that doing so will greatly increase the impact of the federal law in California and result in a better informed patient population.

**Prior Related Legislation.** SB 790 (McGuire, Chapter 558, Statutes of 2018) would have prohibited or limited the offering or giving of gifts to a health care provider by a drug manufacturer. The contents of this bill were subsequently struck and replaced with provisions relating to dreissenid mussel infestation prevention plans.

SB 1448 (Hill, Chapter 570, Statutes of 2018) requires physicians and surgeons, osteopathic physicians and surgeons, podiatrists, acupuncturists, chiropractors and naturopathic doctors to notify patients of their probationary status beginning July 1, 2019.

SB 798 (Hill, Chapter 775, Statutes of 2017) originally contained language that would have required physicians and surgeons to notify patients of their probationary status. This bill was chaptered with the provisions regarding probation status disclosure removed.

SB 1033 (Hill) of 2016 would have required physicians and surgeons, podiatrists, acupuncturists, chiropractors, and naturopathic doctors to notify patients of their probationary status before visits take place. This bill failed passage on the Senate Floor.

SB 763 (Hill) of 2015 would have required the MBC, the OMBC, and the BPM to disclose to an inquiring member of the public and to post on their websites specified information concerning each licensee including revocations, suspensions, probations, or limitations on practice. This bill died in Assembly Rules following substantial amendments.

**ARGUMENTS IN SUPPORT:**

The *Center for Public Interest Law* (CPIL) is sponsoring this bill. According to CPIL, “Disclosure of financial conflicts of interest by doctors is a moral obligation not enforced by law. AB 1278 would remedy this problem by mandating physician disclosure of any financial conflicts of interest to their patients, and empowering patients to make better and more informed choices about their treatment. Preceding any treatment, physicians would be required to explain their healthcare recommendation, the clinical evidence supporting it, as well as disclosing any financial ties they have to the drug or device manufacturer. The result would be strengthened
trust between patients and doctors, as well as patients being fully apprised of information relevant to their care to aid them as they evaluate health care decisions.”

**Health Access California** also supports this bill. According to Health Access, “in a world where prescription drug prices are consistently rising, despite major innovations and more choices among medications, consumers should be aware if their doctor is receiving financial compensation from these companies. If there is a cheaper or different drug that a consumer can be taking, but the doctor is incentivized to prescribe a costlier pharmaceutical – that not only does the patient a disservice at the pharmacy counter, but it increases prescription drug costs for the system as a whole. There is also a risk of patients being harmed by getting a prescription or medical device that may not be right for them.”

**ARGUMENTS IN OPPOSITION:**

The **California Rheumatology Alliance (CRA)** opposes this measure. The CRA argues that existing law is sufficient to provide full transparency to patients regarding physicians and surgeons who have received payments from drug and device companies. The CRA states that “we believe this process is the best way to allow patients to understand a physician’s relationship with a pharmaceutical or device company.”

The **California Academy of Family Physicians (CAFP)** opposes this bill unless amended to remove the written, spoken, and signatory requirements from the bill, “and instead allow the requested information to be put on the same publicly posted notice regarding Medical Board of California reporting and the Sunshine Act.” CAFP states that “while we appreciate the author’s intent, and share support for transparency, this bill would result in the diversion of crucial patient time when easily accessible information on this issue is readily available.”

**POLICY ISSUE(S) FOR CONSIDERATION:**

Terminology. As drafted, the bill references physicians and surgeons who receive “remuneration” from a drug or device company. While the term “remunerate” does generally mean to provide compensation, it more typically refers to payment for labor or services provided as part of an employment relationship. The CMS Open Payments website refers instead to “the payment or transfer of value,” which may be more appropriately tailored to the intent of the bill.

Duplicative Disclosure. The bill currently requires a physician and surgeon to disclose remunerations from a drug or device company both orally and in writing to patients. However, the bill only requires the patient to sign an acknowledgment that they received the written disclosure. It may be more practical to simply require the written disclosure, which is likely both more effective and more enforceable.

Consolidating Posting Requirements. Existing law already required the MBC to promulgate regulations mandating that every physician and surgeon provide notice to each patient stating that medical doctors are licensed and regulated by the Board and providing the Board’s contact information. This notice can be provided by “Prominently posting the notice in an area visible to patients on the premises where the licensee provides the licensed services, in which case the notice shall be in at least 48-point type in Arial font.” It may be reasonable to allow for a physician and surgeon to post the notice required by this bill within a notice they have already posted to comply with existing disclosure requirements.
AMENDMENTS:

1) To update terminology used in the bill to refer more specifically to the types of payments intended to be covered, the word “remuneration” should be struck and replaced with “payment or transfer of value” throughout.

2) To clarify and simplify the bill’s disclosure requirements, strike “orally and” from the proposed subdivision (a) of Section 661 to only require that the disclosure be provided in writing.

3) To allow for the consolidation of required public postings, subdivision (d) should be added to the bill’s proposed Section 662 to read:

   (d) The posting required by this section may be placed within the same notice posted by the physician and surgeon pursuant to Sections 138 or 2026.

REGISTERED SUPPORT:

Center for Public Interest Law (Sponsor)  
Association for Medical Ethics  
Breast Implant Safety Alliance  
Consumer Attorneys of California  
Consumer Watchdog  
Health Access California  
Heartland Health Research Institute  
Informed Patient Institute  
Mending Kids

REGISTERED OPPOSITION:

California Academy of Family Physicians  
California Chapter, American College of Cardiology  
California Rheumatology Alliance  
California Society of Plastic Surgeons

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