SUMMARY: Requires physicians and surgeons licensed by the Medical Board of California (MBC) and Osteopathic Medical Board of California (OMBC) to notify patients in writing annually about the Open Payments database, requires them to post notice about the Open Payments database in each practice area, and requires physicians and surgeons to annually disclose the names of all drug and device manufacturers they received payments from for the most recent three years.

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

6) Under the federal Physician Payments Sunshine Act (Sunshine Act), requires 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, and at an office or telehealth visit annually, a written 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 written or electronic patient records 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 to disclose, at the initial visit and annually, the names of all drug and device companies they received payment or transfers of value from reported on the Open Payments database for the three most recent years available, subject to the same record keeping and patient copy requirements as the notice in 1) above.

3) 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, a notice that includes a link to the Open Payments database website and the following:

“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.”

4) Makes a violation of these provisions unprofessional conduct.

FISCAL EFFECT: This bill is keyed fiscal by Legislative Counsel. According to the Assembly Committee on Appropriations, the measure will result in a potential slight increase in enforcement activity which may result in minor and absorbable costs to MBC and OMBC.

COMMENTS:

1. Purpose. The Center for Public Interest Law is the Sponsor of this bill. According to the Author, “There is currently no state law requiring physicians/surgeons to communicate their financial relationships to patients. This bill empowers patients with relevant information from the Open Payments Database (that already exist) to ask questions about their care or treatment.”

2. 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.

3. **Related Legislation.** SB 790 (McGuire, 2017) would have prohibits a drug manufacturer from offering or giving a gift to a health care provider. The bill would have also prohibited a manufacturer or an entity on behalf of a manufacturer from providing a fee, payment, subsidy, or other economic benefit to a health care provider in connection with the provider’s participation in research, except for the annual direct salary support for principal investigators and other health care professionals for the purposes of a bona fide clinical trial. *(Status: The measure was amended to deal with a different topic.)*

AB 2821 (Feuer, 2008) would have established a gift limit of $250 per physician per year for each pharmaceutical company and required both the public disclosure of gifts of $50 or more and the payment of a disclosure fee to the Department of Health Care Services. *(Status: The measure failed passage in the Assembly Health Committee.)*

AB 103 (Reyes, 2003) would have required pharmaceutical manufacturers to disclose to the Department of Health Services information about gifts made to any person authorized to prescribe, dispense, or purchase prescription drugs. *(Status: The measure failed passage on the Assembly Floor.)*

4. **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.”

Consumer Watchdog echoes these comments, adding that “a Studio City woman is living with chronic pain after the device used in her breast reconstruction procedure
failed, leading to multiple corrective surgeries and ongoing difficulties. She later learned that her doctor had received over $461,000 from the manufacturer of the device, that it was experimental, and had not been approved by the FDA for the purpose it was used. Neither the experimental status of the device nor her doctor’s financial relationship with the manufacturer were ever disclosed. She says she would not have gone ahead with the surgery if she had been informed.”

The Center for Public Interest Law writes that “The patient-doctor relationship is based on trust, and requires transparency between doctor and patient to ensure that trust. This bill makes a critical element of information sharing—potential conflicts of interest—mandatory. The American Medical Association Code of Ethics sets forth the responsibilities of patients and physicians to maintain this relationship, specifically calling out the right of patients ‘to be advised of any conflicts of interest their physician may have in respect to their care.’ At present, there are no statutory mechanisms in place to ensure that physicians comply with this moral obligation. While accepting payments from drug or device manufacturers does not automatically translate into a conflict of interest, physicians failing to affirmatively disclose potentially relevant information to a patient puts the relationship at risk. In the absence of disclosure, patients may question whether their physician is placing their health and wellbeing above their own self-interest. Furthermore, patients lack complete information to weigh all factors related to their treatment… Thanks to [the Sunshine Act], we now know, for example, that the total dollar amount of payments made to physicians and teaching hospitals in California was $300,204,351 in 2019 alone. However, while drug and device manufacturers are now required to disclose payments, and that information is accessible to the public, the onus remains on the patient to know this information is available and seek out the information…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…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.”

The Association for Medical Ethics states that the data made available to the public to be informed of any potential conflicts of interest in both patient care as well as research “is of little use…if patients do not know about how to access the information on physicians or do not even know about the existence of this financial database.”

The Medical Board of California supports this bill, noting that it “furthers the Board’s mission of consumer protection by providing patients with information about potential financial conflicts that a physician may have due to compensation received by a drug or device manufacturer. This information will support consumers as they make informed choices, in partnership with their physician, regarding their medical care and treatment.”

According to the Consumer Federation of California, “It is important for consumers to know if their doctors are being compensated, either directly or indirectly,
by Big Pharma. Pharmaceutical companies have paid doctors billions of dollars for consulting, promotional talks, swag, "samples, etc. However, doctors are not being transparent with their patients about these payments. The financial incentive behind prescriptions can lead to consumers paying more for brand name drugs or paying for unnecessary medication altogether. This kind of financial pressure by pharmaceutical companies can have devastating impacts to individuals and communities, as evidenced by the opioid crisis.”

5. **Arguments in Opposition.** The California Chapter of the American College of Cardiology, California Rheumatology Alliance, and California Society of Plastic Surgeons oppose this bill, noting that “Existing state law requires pharmaceutical and device manufacturers to develop 'comprehensive compliance program' which includes limits on gifts. Existing federal law also 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 also available to public review. 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."

Advanced Medical Technology Association, Biocom California, Biotechnical Innovation Organization, and California Life Sciences argue that the requirements of this bill are burdensome to doctors and unnecessary. The organizations state that the information that the bill requires to be disclosed is already publicly available and easily accessed on the Open Payments database and that unnecessary disclosure that is duplicative of the federal database could discourage physicians and surgeons from attending educational events much needed for training. The organizations state that "These events offer necessary training on the safe and effective use of the life sciences industry’s (complex) technologies that often advance patient access and patient care pathways. Fee for service arrangements between physician thought leaders and life sciences companies could be compromised which will hinder the innovation, safety, and advancement of medical technologies. Physicians play a key role as consultants and advisers in the innovation process. Clinical investigation is crucial in the trial of innovative and breakthrough medical technologies. Physicians provide essential peer-to-peer training on the safe and effective use of medical devices."

The Association of Northern California Oncologists has “concerns with the real-world application of the process this legislation would mandate for oncologists discussing treatment plans with their patients. This new policy would require them to include the creation of this disclosure in the time allotted for what should be solely dedicated to the health and wellbeing of the patient. Once created, the physician must request the patient sign this disclosure before they are able to provide the prescription. Now that a patient has been given a list of payments they must evaluate – without context or valid reason – they will likely have many questions. At this critical point of a patient visit, when a course of treatment has been decided upon and the patient is expected to rely on their physician to have their best interest at heart, the intrusion of this information may create an unintentional erosion of that physician-patient relationship unnecessarily.”
The California Medical Association and Osteopathic Physicians and Surgeons of California write that “Though seemingly innocuous to the author of the bill, there are glaring risks that come with providing unsolicited, out of context information to patients. Threat to the critical physician-patient relationship, damage to the quality of the patient visit, and increased treatment adherence hesitancy, all which seem to have been overlooked or dismissed upon drafting, are among our top concerns.

As consumers, and patients in particular, we are taught that we are provided information for a purpose—most often safety. Forcing the financial information of a physician on a patient prior to a visit implies there is meaning behind that information and puts the onus on the patient to decipher what that meaning is. Presumably, many patients will perceive a conflict. When it comes to healthcare, it is paramount that the patient trust that their physician has their best interest at heart. Walking into an appointment that is intended to improve your health with potential apprehension about your physician is not beneficial for either party.

Physicians serve patients. It is their job to answer questions, assess situations, and assuage fears. Physicians will not shy away from the inquiries that may arise from the financial disclosure their patients receive before entering the exam room. However, they do have a finite amount of time to spend with each patient. Questions about the financial disclosure will be answered, but in shifting the focus from patient health to physician financials, the quality of the visit and value to the patient will degrade significantly. If patients are forgoing, or perhaps even forgetting, their health concerns in lieu of an explanation as to why their physician received money from a particular manufacturer, patient outcomes will undoubtedly suffer.

Hesitancy around treatment adherence may not be mainstream media news, but it is an unfortunate reality in the medical field. In rural and underserved communities in particular, there is an innate degree of suspicion of physicians. This distrust often leads to failure to adhere to medical treatments and increasingly ailing patients. The only way to combat the problem is by relationship building. The unsolicited provision of this information will undoubtedly damage relationships already difficult to cultivate and breed unnecessary skepticism that may result in an even greater hesitation to adhere to medical advice.

CMA prides itself in supporting patient safety, which includes supporting transparency to allow for patients to be their own advocates. Unfortunately, we cannot support a situation that puts the physician-patient relationship, care visit, and ultimate health outcome at risk.”

The Liver Coalition of San Diego states that “Although we are supportive of AB 1278’s intent to promote transparency, we feel this approach may be duplicative with current policy. This bill could also shift the focus of the patient’s visit to the financials of the physician, eroding the quality of the visit. We are not supportive of efforts that would interfere with the highly important “patient-doctor” relationship during the visit. Currently U.S. physicians spend between 13 and 28 minutes with patients during a visit. With 6 in 10 Adults in the US having a chronic disease, and 4 in 10 having two or more, this time should be for patients to ask questions about their treatment plan, medications, or general health.
Additionally, due to COVID-19 many patients have not been able to have in-person visits with their physicians. As stated above, our commitment to safeguarding this time for patients to ensure their healthcare needs are being met remains our top priority."

6. **Proposed Author’s Amendments.** In response to concerns about provisions of the bill requiring physicians and surgeons to disclose the names of manufacturers who reported payments and amounts of those payments, the Author is proposing to strike this language so that the bill will only require notice of the Open Payments database to be provided annually and posting about the Open Payments database in a practice area.

On page 4, strike lines 30-40 inclusive

662. (a) A physician and surgeon shall provide to each patient at the initial office visit, and at an office or telehealth visit annually thereafter, a written disclosure of the names of all drug and device companies the physician and surgeon received payment or transfers of value from as reported on the Open Payments database for the three most recent years available. If a patient does not seek treatment within a 12-month period, the disclosure shall be made at the next office or telehealth visit.
(b) A physician and surgeon shall include in the written or electronic records for the patient a record of the disclosure pursuant to this section.
(c) A physician and surgeon shall give to the patient or patient representative a copy of the signed and dated disclosure.

**SUPPORT AND OPPOSITION:**

**Support:**

Association for Medical Ethics  
Breast Implant Safety Alliance  
Calpirg, California Public Interest Research Group  
Center for Public Interest Law  
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:**

Advanced Medical Technology Association  
Association of Northern California Oncologists  
Biocom California
Biotechnical Innovation Organization
California Academy of Family Physicians
California Chapter American College of Cardiology
California Life Sciences
California Medical Association
California Rheumatology Alliance
California Society of Plastic Surgeons
Liver Coalition of San Diego
Medical Oncology Association of Southern California
Osteopathic Physicians and Surgeons of California

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