ASSEMBLYMEMBER ADRIN NAZARIAN

46TH ASSEMBLY DISTRICT

AB 1278: Medical and Drug Disclosure

BILL SUMMARY:

This bill would empower patients with important information about their recommended treatment so they can make informed choices about their health care. AB 1278 would require doctors who receive payments from a drug or device company to disclose those relationships both orally and in writing to each patient prior to treatment.

The written disclosure would require a link to the Federal Centers for Medicare and Medicaid Services (CMS) Open Payments website and a patient signature acknowledging receipt of the disclosure. Additionally, notice of CMS Open Payments website shall be required at physician's offices and websites.

BACKGROUND:

The relationship between patients and their physicians is based on trust. 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."[1] At present there are no provisions in place to ensure physicians comply with this moral obligation. While accepting payments from drug or device companies does not necessarily translate into a conflict of interest, physicians failing to affirmatively disclose potentially relevant information to a patient puts the relationship at risk. In absence of disclosure, it may be questionable whether the physician is placing his or her self-interests above the patient's well-being.

Furthermore, patients lack complete information to weigh all factors related to their treatment. In 2010, the federal government took an important step to promote a more transparent healthcare system with the Physician Payments Sunshine Act (PPSA). This law made financial exchanges between manufacturers and health care providers available to the public on a website maintained by CMS[2]. Thanks to PPSA, we know that the total dollar amount of payments made to physicians and teaching hospitals in California was $306,944,215 in 2018 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.

Financial relationships between physicians and medical product manufacturers are common and include, but 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 Public found that on average, doctors who received payments prescribed 58% more of that drug than doctors who did not.[3] A separate study concluded that

[1] American Medical Association: Patient Rights, Code of Medical Ethics, Opinion 1.1.3 (https://www.ama-assn.org/delivering-care/ethics/patient-rights) (March 22, 2020).

[2] See https://openpaymentsdata.cms.gov

[3] Fresques, Hannah. "Doctors Prescribe More of a Drug If They Receive Money From a Pharma Company Tied To It." ProPublica, December 20, 2019

the receipt of industry-sponsored meals was associated with an increased rate of prescribing the promoted brand-name medication relative to alternatives within the drug class.[4]

The PPSA is an important framework for transparency. Yet the information now publicly available has no bearing without the corollary requirement that the patient who needs to know about potential physician conflicts of interest receives that information. Without laws requiring physicians to disclose payments to patients prior to a procedure or treatment, amassing this information in a database fails to serve its intended purpose. The PPSA was always considered a starting place- mandating at the federal level that drug and device manufacturers report payments to physicians and hospitals. It is time to go a step further and add accountability to the transparency.

PROBLEM:
Disclosure of financial conflict by doctors is a moral obligation not enforced by law. AB 1278 would remedy this problem by mandating physician disclosure 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.

The need for this legislation is highlighted by a Studio City constituent who underwent breast reconstruction in 2015 following a double mastectomy. She opted for the surgeries after testing revealed she has the BRCA gene. Her physician was highly recommended for the reconstruction and worked at the same hospital as her husband. Now the constituent is living with chronic pain and is pushing the Medical Board of California to investigate her doctor. After experiencing severe complications following her surgery, she learned that her physician had received more than $461,000 over a four year period from the manufacturer of the device used in her surgery. Not only that, she also learned that the device itself was experimental for breast reconstruction and had not been approved by the FDA for that purpose. Had she known any of this information she would never had gone forward with the surgery.

SOLUTION:
By requiring greater transparency between patients and their physicians, AB 1278 would require doctors who receive payments from drug or device companies to disclose their financial ties *before* treatment. By requiring both oral and written disclosure as well as access to the CMS Open Payments website link, patients become empowered to make more informed choices about the type of healthcare they receive.

SUPPORT:
The Center for Public Interest Law (Sponsor)
Dr. Charles Rosen, President for Medical Ethics at UC Irvine

STAFF CONTACT:
Autumn McCreary
916-319-2046 (Office)
Autumn.McCreary@asm.ca.gov

(https://www.propublica.org/article/doctors-prescribe-more-of-a-drug-if-they-receive-money-from-a-pharma-company-tied-to-it).

[4] DeJong, Colette; Aguilar, Thomas; Tseng, Chien-Wen. "Pharmaceutical Industry-Sponsored Meals and Physician Preserving Patterns for Medicare Beneficiaries, JAMA Network, August 2016. (https://jamanetwork.com/article.aspx?articleid=2528290)