Date of Hearing: April 4, 2017

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Rudy Salas, Chair
AB 602 (Bonta) – As Amended March 28, 2017

SUBJECT: Pharmacy: nonprescription diabetes test devices.

SUMMARY: This bill prohibits the practice of submitting reimbursement claims for diabetes test devices that were obtained other than from the manufacturer or authorized distributor. Directs the California State Board of Pharmacy (Board) to make doing so "unprofessional conduct" for a licensee. Manufacturers of nonprescription diabetes test devices are required to make available on their website and to the Board, the names of authorized distributors, and to update both within 30 days of making changes. Requires pharmacies to retain records of sale for three years.

EXISTING LAW:

1) Clarifies that the provisions of the chapter shall not apply to nonprescription devices, except as provided in Sections 4006, 4240, and 4342. (Business and Professions Code (BPC) Section 4057)

2) Sets standards for the maintenance of records and inventory for dangerous drugs or devices and the criminal penalties for failing to do so. (BPC Section 4081)

3) Sets licensing requirements for wholesalers, third-party logistics providers, and manufacturers involved in medical supplies or pharmaceuticals. (BPC Section 4160)

4) Sets standards for the Board to use when determining if the conduct of a licensee is unprofessional. Includes criminal actions and incompetence, among others. (BPC Section 4301)

THIS BILL:

1) Defines "Nonprescription diabetes device" as a device for use in the treatment of prediabetic or diabetic individuals that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government.

2) Amends section 4081 to require that businesses shall maintain a record of manufacture and sale, acquisition, receipt, shipment, or disposition of dangerous drugs or devices, that records be available to law enforcement, and that they be maintained for at least 3 years. States that the owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible for the maintenance of the records with the pharmacist-in-charge, responsible manager, or designated representative-in-charge.

3) States that the pharmacist-in-charge, responsible manager, or designated representative-in-charge, shall not be criminally liable for acts of the owner, partner, or employee that violate the section.

Adds that unprofessional conduct standards must apply to infractions involving the dispensing of nonprescription diabetes devices.

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

COMMENTS:

Purpose. This bill is sponsored by the California Life Sciences Association (CLSA). According to the author, "More than 23 million Americans have diabetes, and in 2012 diabetes cost the US more than $245 billion. Blood glucose monitors and test strips are an essential tool for patients and their physicians to measure and treat diabetes. Unfortunately, they have also become a tool for nefarious pharmacies who submit millions in fraudulent claims. AB602 will target these abuses, preventing cost increases, and maintaining affordable testing products for the millions who use these test strips daily."

Background. This bill authorizes the Board to prevent the sale and manipulation of the supply chain of glucose blood testing strips used in the evaluation of diabetes patients. To do so it specifies that the Board must apply its "unprofessional conduct standards" to the sale and acquisition of diabetes testing supplies when they are sold by prescription.

In recent years, the acquisition and resale of diabetic test strips has become big business for those participating in the gray and black market. The authorization of the Board to pursue this kind of activity is intended to curtail the resale and counterfeiting of diabetes test strips to turn a profit via manufacturer and Medicare reimbursements. Test strip resellers operate on the fringes of the diabetes community, handing out flyers and advertising of a quick pay off in exchange for excess strips that may have been obtained through Medicare or health insurance.

In 2013, the U.S. Department of Health and Human Services Office of the Inspector General, released a report detailing the significant rise in Medicare fraud involving diabetes test strips. In 2011, Medicare inappropriately allowed $6 million in diabetic test strip claims and identified $425 million in Medicare claims that originated from 10 percent of test strip suppliers and had characteristics of questionable billing.[1]

According to the sponsor, in some cases manufacturers commonly encounter duplicate or triplicate claims for rebate for the same supplies.

In California, the Board is limited in its enforcement efforts because its authority is limited to prescribed drugs and equipment. While diabetes supplies are often prescribed by health care practitioners, their use is not limited to prescription only and may be obtained through mail order and over the counter. The provisions in this bill would extend the authority of the Board to cover diabetes test strips and permit the Board to target bad actors in the industry.

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[1] Inappropriate and Questionable Medicare Billing for Diabetes Test Strips, *Office of the Inspector General, U.S. Department of Health and Human Services*. August 26, 2013. (https://oig.hhs.gov/oei/reports/oei-04-11-00330.asp)

ARGUMENTS IN SUPPORT:

Abbott Laboratories Inc. – "By ensuring that pharmacies can only submit insurance claims for diabetes test devices purchased from authorized distributors, AB 602 will protect patients and save money for Medi-Cal, Medicare, and the overall health care system."

ARGUMENTS IN OPPOSITION:

None on file

REGISTERED SUPPORT:

Abbott Laboratories Inc.

REGISTERED OPPOSITION:

None on file.

Analysis Prepared by: Jimmy Fremgen / B. & P. / 916-319-3301