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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item VI: Discussion and Consideration of Possible Statutory Proposal to Require E-Prescribing of Prescription Drugs

Background:

Since at least 1994, California was positioned to allow e-prescribing for dangerous drugs and controlled substances; however, for prescribing controlled substances, California had to wait for the DEA to finish its federal requirements in 2010.

The DEA's Final Rule for Electronic Prescriptions for Controlled Substances (EPCS) was published on March 31, 2010 at 75 FR 16236-16319 and became effective on June 1, 2010. These regulations paved the way for controlled substance prescriptions to be issued electronically.

Prescription medications may be prescribed on paper, verbally or electronically. Controlled medications, a subset of prescription medication, have special restrictions that specify conditions for oral or written prescriptions; electronic prescriptions must comply with federal requirements.

Additionally: in California, if written, the prescriptions must generally be written on prescription forms printed by DOJ-licensed printers with 14 specific features. Schedule II controlled medications, with rare exceptions, cannot be orally ordered or refilled.

Over the past decade, the abuse of pharmaceutical drugs, both controlled and noncontrolled, has skyrocketed in the United States and has led to the current opioid epidemic throughout the country. In California specifically, through this system of paper prescriptions, criminal organizations have been able to take advantage of weaknesses and lack of oversight of the printing program resulting in their ability to counterfeit prescriptions. This has led to the diverting of the most dangerous and addictive drugs prescribed. As recently as November 29, 2017, a member of a drug trafficking organization that illegally acquired and distributed at least 50,000 oxycodone tablets valued at $1.5 million using counterfeit security form prescriptions during a three-year span was convicted in federal court in San Diego.

Some patients who have become addicted to drugs or simply want to divert drugs alter prescriptions to increase the quantity prescribed, add additional drugs, or add refills. Some steal entire prescription pads from prescribers, which are sold to criminal organizations or used by addicts to fill the drugs of their choice. Prescribers routinely report losing their pads to the Board of Pharmacy as well as to other agencies (and we post this information online).

Currently, there are seven states that have passed legislation on e-prescribing. Laws already exist in three states (NY, MN, and ME), while the remaining four will become effective in 2018. Of the three states with active laws,

- Minnesota requires prescribers, pharmacies and health systems to have the capabilities to e-prescribe but does not mandate its use.
- However, NY and ME mandate the use of e-prescribing as the primary means of prescribing any medication.

According to Surescripts data, 98 percent of retail pharmacies are able to accept e-prescriptions, and 45.3 million prescriptions for controlled substances were delivered electronically in 2016 - a 256 percent increase from the 12.81 million controlled substance e-prescriptions in 2015.

In New York, which has had a mandate since March 2016 for both controlled and noncontrolled prescriptions to be e-prescribed:

- 98.1 percent of pharmacies were EPCS-enabled
- 72.1 percent of prescribers were EPCS-enabled (one year before, only 47% of New York prescribers could use EPCS)
- 91.9 percent of controlled substance prescriptions were sent electronically

(According to Surescripts)

The use of e-prescribing in California is increasing because e-prescribing helps to:

- Reduce overall mistakes made in interpreting prescribers' handwriting
- Allow for the prescription information to auto populate in the pharmacy without staff input
- Reduce patients' wait times for filling prescriptions
- Enable fast retrieval of records
- Save space by e-storing records
- Substantially reduce the opportunities for persons to steal, alter, "doctor shop," or counterfeit prescriptions, thus decreasing unsupervised access to medication

<u>For Board Discussion and Consideration:</u>

At a December 2017 committee meeting, the Enforcement and Compounding Committee considered the proposal to require e-prescribing as the primary mode for ordering controlled and other prescription drugs in CA.

They considered that the proposal would need to allow for exemptions to the e-prescribing requirements to address some scenarios, e.g., for terminally ill patients, or when the electronic system is not available. There would still be a need for paper prescriptions and existing patient-care exemptions, etc.

MOTION: Enforcement and Compounding Committee: Recommend that the board sponsor legislation to require e-prescribing but allow for exemptions, including terminally ill exemptions, ER provisions, and staff work with the chair to identify other exemptions.

The California Hospital Association spoke in support of the proposal but requested a phased in approach over a period of time.

Angie Manetti, representing the California Retailers Association, spoke in support of the committee's motion.

Lorri Wamsley, representing Walgreens, spoke in support of the committee motion and indicated that three years may be too long a period for delayed implementation.

Ketan Patel, representing Kaiser, spoke in support of the committee motion and need for exemptions.

CVS Health spoke in support of the proposal. Their representative noted that e-prescribing results in a substantial decrease in the number of prescription transcription errors as well as improvement in medication adherence.

Text of the legislative proposal is being refined as this packet is being prepared, and will be distributed at the meeting.

Following this memorandum includes the DEA press release regarding the criminal arrest for falsified prescription forms

Below is the background that will be released as part of the legislative proposal.

Concept Draft for Mandating E-Prescribing

For many years, electronic prescribing (e-prescribing) has been recognized and lauded as having great potential to dramatically improve prescription delivery, and healthcare more generally. That potential has been illuminated by numerous studies and reports, including a July 2006 Institute of Medicine (IOM) report titled *Preventing Medication Errors*, and a June 2008 report by the Center for Improving Medication Management in collaboration with eHealth Initiative, titled *Electronic Prescribing: Becoming Mainstream Practice*. Previously, in California, a November 2001 study titled *E-Prescribing* prepared for the California Healthcare Foundation similarly identified the values of e-prescribing and barriers to its wider adoption. In 2005, the California Legislature adopted Senate Concurrent Resolution 49 (SCR 49 [Speier]), which created an expert panel to study the causes of medication errors and to recommend changes to the health care system. In March 2007, this "Medication Errors Panel" issued its report, titled *Prescription for Improving Patient Safety: Addressing Medication Errors*, which likewise lauded

the benefits of e-prescribing, and which recommended that by 2010 it be a legally mandated requirement that *all* prescriptions be computer-generated or -typed.

California also has a significant history of being legally prepared for e-prescribing. California has been waiting for fuller implementation of e-prescribing for over two decades. For instance, since at least 1994, California has defined a legal "prescription" to include electronic transmission prescriptions (e-prescriptions), e.g., those transmitted directly from a prescriber to a pharmacy. (See Bus. & Prof. Code, § 4040; Health & Saf. Code, § 11027). Also, since at least 2001, California has allowed direct "entry" (including by transmission) of data by a prescriber into a pharmacy's or hospital's computer. (See Bus. & Prof. Code, § 4071.1; Health & Saf. Code, § 11164.5). But for many years, further progress on adoption of e-prescribing was slowed or curtailed by a federal bar on e-prescribing of controlled substances.

That bar was finally lifted in 2010, with the promulgation of the Drug Enforcement Administration (DEA) Interim Final Rule: Electronic Prescriptions for Controlled Substances at 21 CFR Parts 1300, 1304, 1306, and 1311, effective June 1, 2010. Those regulations set forth the conditions and applications required to engage in e-prescribing of controlled substances. The ability to use e-prescribing to transmit controlled substance prescriptions has made adoption of e-prescribing technology more cost-effective.

However, up to now adoption and implementation of e-prescribing has remained voluntary, and while the pace of e-prescribing has picked up, it has not come close to universal adoption. It was believed that removal of the bar on controlled substance e-prescribing would have a greater impact that it has had; in the seven-plus years since that ban was lifted, results have been disappointing. Moreover, fraudulent preparation, counterfeiting, and use of paper prescriptions has continued unabated.

Accordingly, ten years later, it appears to be finally time to fulfill the command of the 2007 Medication Errors Panel report and mandate the use and acceptance of e-prescriptions by prescribers, pharmacies, and pharmacists.

ATTACHMENT

OFFICE OF THE UNITED STATES ATTORNEY

SOUTHERN DISTRICT OF CALIFORNIA

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For Immediate Release

Oxycodone Trafficker Convicted by Federal Jury

NEWS RELEASE SUMMARY – November 29, 2017

SAN DIEGO – Edwin Fuller, a member of a drug trafficking organization that illegally acquired and distributed at least 50,000 oxycodone tablets valued at $1.5 million during a three-year span, was convicted by a federal jury today following a three-day trial.

Fuller was part of what is believed to be the San Diego region's most prolific and well-organized oxycodone ring. The organization acquired oxycodone via fraudulent prescriptions and phony California identification cards and distributed the pills across the country. One significant seizure involved 7,000 pills sent by this organization to Columbus, Ohio.

Fuller is the fourth key member of the organization that has been convicted in the case so far. The investigation is ongoing.

Two coconspirators testified at trial that Fuller was a recruiter and a "filler" who walked into pharmacies to get bogus prescriptions filled. Fuller received the oxycodone and distributed it to others. Evidence at trial proved that over a six-month period Fuller was able to successfully acquire more than 11,000 30-milligram tablets of oxycodone. The traffickers obtained pills for about $2 each from the pharmacies and then sold them for a street value of up to $30 each.

One coconspirator testified that she was "thankful" for being arrested because she would have died as a result of her addition to oxycodone.

U.S. Attorney Adam Braverman said prosecution of this organization and others like it is a priority for this office because their greed is feeding the addiction crisis in California and other regions of the United States.

"Just yesterday I heard from parents who tragically lost their son to opiate addiction. This case demonstrates that we are holding pill peddlers accountable for the havoc they are wreaking on our country," said U.S. Attorney Adam

Braverman. “We will not tolerate drug trafficking rings that seek to profit by exploiting and endangering people who struggle with substance use disorder.”

Earlier today, Attorney General Jeff Sessions announced new resources and stepped up efforts to address the drug and opioid crisis, including over $12 million in grant funding to assist law enforcement in combating illegal manufacturing and distribution of methamphetamine, heroin, and prescription opioid and a directive to all U.S. Attorneys to designate an Opioid Coordinator to work closely with prosecutors, and with other federal, state, tribal, and local law enforcement to coordinate and optimize federal opioid prosecutions in every district.

Fuller is scheduled to be sentenced on February 15, 2018 at 2:15 p.m. before U.S. District Judge Gonzalo Curiel.

This case is the result of the ongoing efforts by the Organized Crime Drug Enforcement Task Force (OCDETF) a partnership that brings together the combined expertise and unique abilities of federal, state and local law enforcement agencies. The principal mission of the OCDETF program is to identify, disrupt, dismantle and prosecute high level members of drug trafficking, weapons trafficking and money laundering organizations and enterprises.

DEFENDANTS **Case Number 16cr0867**

Edwin Fuller Age: 39 Los Angeles

SUMMARY OF CHARGES

Conspiracy to Possess with Intent to Distribute Controlled Substance – Title 21, U.S.C., Section 841(a) (1) and 846

Maximum penalty: 20 years in prison and $1 million fine

AGENCIES

U.S. Drug Enforcement Administration

California Department of Health Care Services

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