AMA
AMERICAN MEDICAL ASSOCIATION

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April 28, 2014

The Honorable Mark DeSaulnier
California State Senate
State Capitol, Room 5035
Sacramento, CA 95814-4900

Re: American Medical Association concerns with Senate Bill No. 1258 mandate for electronic prescribing of controlled substances

Dear Senator DeSaulnier:

On behalf of the American Medical Association (AMA) and physician and medical student members, I am writing to express the AMA's concerns with Senate Bill (S.B.) 1258 and its mandate for electronic prescriptions for controlled substances (EPCS). While the AMA believes that automating paper-based prescription processes can help create a safer prescribing environment, mandating EPCS for all physicians does not take into account real technological complexities, the significant disruption to prescriber practice workflows, patients' access to care and the financial implications to physicians, dispensers, health care facilities, rural clinics and hospital systems.

There is no question that California – like much of the United States – has undertaken significant efforts to curb the nation's prescription drug abuse, diversion, overdose and death epidemic. The AMA has worked extensively with many states and national stakeholder organizations in support of policies and legislation that would have real impact while not impeding patients' access to care by overly restricting physicians' ability to provide care.

We understand that the intent behind S.B. 1258 is to help provide a more secure, safer environment to prescribe, dispense and track controlled substances. The mandate, however, does not take into account the real disruption that will occur in physician practices because of the separate, distinct processes required for prescribing non-controlled substances compared to controlled substances. Specifically, the U.S. Drug Enforcement Administration (DEA) requires

a two-factor authentication process to verify a prescriber's identity.[1] The complexity and administrative burden of the two-factor authentication process, however, is a likely factor why unpublished estimates suggest that EPCS comprises a very small fraction of the nation's total prescriptions for controlled substances.

Mandating an electronic prescription for every controlled substance would create a massive disruption to patient care

Consider that, according to IMS Health[2], there are tens of millions of prescriptions for controlled substances written by California practitioners across Schedules II, III, IV and V. Because the national uptake for EPCS is so low, if California suddenly subjected its physicians to tens of millions of new, distinct administrative requirements for every prescription for a controlled substance, workflows and patients access to care would be massive disrupted. Simply put, if physicians spend additional hours (as would be the effect of S.B. 1258) on data entry, verification, authentication and transmittal requirements – those are hours that patients cannot be seen or treated.

In addition, S.B. 1258 does not take into consideration that currently available electronic prescribing systems do not all support EPCS. Thus, the mandate for EPCS is entirely premature given the lack of attention to the real implications of purchasing, implementing and upgrading costs of compliant e-prescribing applications and their availability in the marketplace. We expect the financial burden to be especially harmful for small groups, rural clinics and primary care practices.[3] That is, the physicians who provide care to those in greatest need will be financially impacted the most – a scenario that could force many to simply stop prescribing controlled substances altogether.

Moreover, hospitals and other settings outside the physicians' practice must also be configured to accept hard tokens and biometrics and most of these settings prohibit the connection of foreign devices to their systems due to security concerns. S.B. 1258 simply does not take these realities into account.

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[1] Authentication is information (e.g., PINs, passwords, biometrics) that is used to verify a person's identity for security purposes. For example, ATMs use two-factor authentication—something you know (a personal identification number (PIN)) and something you have (bank card). According to the DEA, e-prescribers for controlled substances would have to prove their identities by using two out of three factors: something you know (e.g., passwords), something you have (e.g., hard token stored separately from the computer being accessed), or something you are (e.g., biometrics such as a fingerprint or iris scan). The DEA is allowing the use of a biometric as a substitute for a hard token or a password. If a biometric is used it may be stored on a computer, a hard token, or a biometric reader. If a hard token is used, it must be a cryptographic device or a one-time-password device that meets Federal Information Processing Standard 140-2 Security Level 1, and it must be stored on a device that is separate from the computer in use (e.g., smart card).

[2] IMS Health is a leading global information and technology services company. More information about IMS Health can be found at www.imshealth.com.

[3] We recognize that S.B. 1258 includes limited phase-in provisions for practices with only one or two physicians and for some rural areas of California, which already is clear indication of the unique challenges posed by EPCS. Yet, despite these exceptions, it is highly unlikely that the challenges faced today will be solved in such a short time period, and they certainly will not be limited to small practices given that every prescriber must comply.

In summary, the AMA supports your efforts to combat prescription drug abuse, misuse, unintentional overdoses and death, but we urge you to reconsider and remove the mandate for EPCS due to the significant and adverse effects it would have on physicians and their patients. If you have any questions, please feel free to contact Daniel Blaney-Koen, JD, Senior Legislative Attorney, Advocacy Resource Center, at daniel.blaney-koen@ama-assn.org or (312) 464-4954.

Sincerely,

James L. Madara, MD

cc: California Medical Association
Ryan Ribeira