Blue Sky CONSULTING GROUP

MEMORANDUM

To: Interested Parties

From: Tim Gage and Len Finocchio, Blue Sky Consulting Group

Date: March 12, 2014

Re: Proposed statutory initiative (A.G. File No. 13-0016) relating to medical malpractice damage awards, physician substance abuse, and the prescribing and dispensing of drugs by physicians and pharmacists

Introduction

This memo presents our preliminary analysis of the provisions on the proposed statutory initiative (A.G. File No. 13-0016) relating to the prescribing and dispensing of drugs by licensed health care practitioners and pharmacists. Specifically, the proposed initiative would require licensed health care practitioners and pharmacists to consult the state's Prescription Drug Monitoring Program (PDMP) database known as CURES (Controlled Substance Utilization Review and Evaluation System) prior to prescribing or dispensing certain drugs to a patient for the first time.

Our assessment of this provision of the proposed initiative indicates the following:

1. Although the requirement to consult the CURES database would take effect immediately upon passage of the initiative, the technological tools needed to allow health care providers to comply with the initiative's terms are – absent a change in the currently proposed timeframe – very unlikely to be ready at that time, and would require a significant investment of time and resources in order to allow these provisions of the measure to be fully implemented.

2. Without an upgraded database, improved user functionality, and prescriber application process, the initiative would almost certainly result in a situation in which prescribing health care providers would be legally required to use a database that was in practice not available; these providers would, therefore, face the choice of denying treatment to their patients or violating the stated terms of the initiative.

3. Absent legislative or administrative action to accelerate the implementation of the CURES database upgrades, the related provisions of the initiative cannot be implemented immediately upon passage.

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Current State of Affairs

The proposed initiative builds upon a foundation in current law. The existing CURES system allows prescribing health care providers, upon registering with the system, to view the prescription records of patients for whom schedule II – IV drugs have been prescribed and filled. Pharmacists are currently required to report all such prescriptions on a weekly basis.

Although this system has the potential, in theory, to allow prescribing health care providers to check on the relevant prescription drug histories of their patients as required by the proposed initiative, in practice it lacks important functionality needed to allow doctors and other prescribing health care providers to comply with the initiative. According to a 2012 report by the Department of Justice (DOJ) entitled "CURES 2.0," the current system cannot accommodate the approximately 200,000 additional registrants who will need to be added to the system in order to make it universally utilized. In addition, the current system is, according to the DOJ report, "slow and freezes" when certain reports are requested by registered users and involves a registration process that is "time intensive and highly manual." The current system is also constrained in its ability to assist system users: the program's website displays a message indicating that "The California Department of Justice cannot respond to telephone inquiries or emails to the CURES/PDMP Program due to budget-related resourcing issues."

Perhaps most importantly, the current system is utilized by just a fraction of the state's prescribing health care providers. As of August 2013, the system had just 17,820 registrants out of a possible total of more than 200,000, or about 8.4 percent of the total, according to the DOJ.[1] And, these existing registrants are utilizing the system on a voluntary, rather than a mandatory basis, which suggests that the number of requests for "Patient Activity Reports" as requests for the prescription history of patients are known, would increase substantially under the terms of the proposed initiative.

Recognizing the limitations of the current system, in 2013 the legislature passed and the governor signed into law SB 809 (DeSaulnier), which provided funding for improving and maintaining the CURES system. Specifically, SB 809 imposes a $6 fee on prescribing health care providers and allocates the resulting funding for operating and maintaining the CURES system. In addition, the budget act of 2013 appropriated $3.9 million for the purposes of upgrading and modernizing the current system.

SB 809 calls on the DOJ to consult with prescribers and other stakeholders to implement an upgraded CURES system. In addition, SB 809 requires the DOJ to implement a streamlined application and approval process for CURES registrants and requires all health care practitioners prescribing Schedule II – IV drugs to register in the CURES system prior to January 1, 2016. Importantly, SB 809 would not change the requirements with respect to use of the CURES system. That is, in contrast to the mandated use of the system required by the proposed initiative, SB 809 did not impose a requirement that prescribing health care practitioners use the upgraded system. (And, as a consequence, the budget and timeline envisioned by SB 809 do not reflect this mandate requirement.)

[1] See 2013 DOJ CURES report available at: http://www.pdmpassist.org/pdf/PPTs/National2013/26-2-C%20Small.pdf

What Would Implementation Require?

The process set in motion by SB 809 would address important limitations of the current system, as noted above. Nevertheless, important challenges lie ahead, even with respect to implementing a voluntary system. A system that mandates use by prescribing heath care practitioners – as required by the proposed initiative – would impose an even larger challenge.

Upgrading the current CURES system amounts to a large-scale information technology (IT) project. Millions of records of data will be collected and utilized by hundreds of thousands of users each year. These data need to be collected, maintained, and made available to users, all while maintaining privacy and security. And, in order to implement such a system without adding unduly to health care costs, mechanisms for accessing the system must be developed such that the process is not unduly time consuming or cumbersome for health care providers (for example by integrating access of the CURES system into electronic health records systems used by providers).

An upgrade of this complexity will require a significant commitment of resources and involve numerous challenges and important procedural steps along the road to implementation. First of all, upgrading an existing system requires that the current system be maintained and operational while being integrated with the upgraded system. And, as a matter of both law (SB 809 requires as much) and practicality, the new system will need to be developed in consultation with various stakeholders. However, each new or changed system requirement has the potential to add to the cost and/or time required to complete the system upgrades. Other issues common to such a large-scale IT project include development of one or more user interfaces (including interfaces needed to integrate with health care providers' electronic health care records systems), implementation of system redundancy and back-up procedures, development of security measures to protect patient privacy and data integrity, and development of user training and support systems, among others.

These tasks must be accomplished within the context of the state's existing processes for implementation of large-scale IT projects, which necessitate development of business requirements for the system and completion and acceptance of a feasibility study report. If outside contractors are to be utilized for some portion of the implementation, requests for proposals (RFP) must be developed, bids solicited and evaluated, and contractors selected. Next, system improvements must be developed, tested and implemented. Finally, needed equipment must be procured (a process often completed with a separate RFP process). Beyond these technical requirements, new users must be registered with the system, a process that may well require a significant amount of outreach, education, and training.

In any one of these steps, opportunities for cost increases or timeline delays exist. Changes to business requirements (requiring formal change orders if outside contractors are used) can both add to cost and extend completion deadlines. To the extent that the CURES system is integrated with other databases, additional cost and timeline risks would be present, as these other systems are not under the control of the DOJ or its selected vendor(s). Such integration requires comprehensive "end-to-end" testing to identify and correct any defects. Failure to carefully manage such complex projects, identify and address risks, and conduct adequate testing can result in even greater costs and further increases in the timeframe (as the experience of the Affordable Care Act implementation has so famously demonstrated).

SB 809 envisioned an implementation process that extends to January 1, 2016, by which point all users are required to be registered. And, while this implementation timeframe may well have allowed for certain contingencies, it is nevertheless likely that unforeseen obstacles and challenges could extend it further into the future.

What's more, this date is some 14 months after the election at which the initiative would become law were it to be approved by the voters. And, it is reasonable to assume that the requirements for a mandatory, rather than a voluntary system would only serve to increase the timeframe and cost required relative to the voluntary system embodied in current law.

Even if implementation could be expedited in response to the passage of the initiative, the measure does not include any provisions relating to the mechanics of implementation. Under state law, funds generally cannot be spent without an appropriation from the legislature. This includes funds for hiring contractors, purchasing equipment, or hiring staff, all of which would likely be required to implement the requirements of the proposed initiative.

Conclusion

Our preliminary assessment of the requirements of the proposed statutory initiative (A.G. File No. 13-0016) relating to the prescribing and dispensing of drugs by licensed health care practitioners and pharmacists indicates that it would not be possible for the measure to be implemented immediately upon passage. Specifically, the requirement that prescribing health care practitioners consult the CURES database for each new prescription for a schedule II – III drug would take months, if not years to implement. The current system is not adequate to accommodate the requirements imposed by the measure. Furthermore, planned upgrades to the system are not scheduled to be completed until more than a year after the election, and the measure itself would likely require changes to these planned upgrades, further extending the timeframe for and adding to the cost of implementation. Finally, even if the state sought to expedite implementation, such a process would still require some combination of the appropriation of funds, the procuring and negotiating of contracts, and the hiring of staff, all of which are time consuming processes. The result, therefore, would almost certainly be a situation in which prescribing health care providers would be legally required to use a database that was in practice not available; these providers would, therefore, face the choice of denying treatment to their patients or violating the stated terms of the initiative.