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To: California State Assembly Appropriations Committee

May 10, 2022

I am writing today on behalf of my company, Software Partners LLC, to recommend that AB 1797 be substantially amended to limit its scope and target it to the opt-out provisions of the current law. The financial resources committed to the bill should be commensurate with this revised limited and targeted scope.

We listened to the public hearing on AB 1787 in the Assembly Health Committee, and also reviewed letters in support and opposition of the bill. We understand the bill has been further amended by the Education Committee. We find that much in both the public testimony and in the letters in support and opposition reflects inaccurate or incomplete knowledge about immunization registry technology. I enumerate specific examples below. Finally, we suggest alternate approaches to achieving the goals of AB 1797, primarily, that the law regarding patient privacy and "opt-in" has long been in need of revision.

Here is a summary of comments we have heard which may reflect inaccurate or incomplete information about immunization registries generally and CAIR2 specifically:

Information Presented	**Our Information**
Immunization registries are a wonderful idea.	One might have expected this type of conversation in in the 1990s when immunization registries were introduced, but now, immunization registries have already matured. Immunization registry architecture was designed to combat communicable disease by the toolset of population vaccination. Immunization registry software architecture today remains substantially as it when introduced decades ago. The present bill should be argued, not in terms of the value of immunization registries per se, but based upon the differential between present law and changes proposed in AB 1797.
The CAIR2 system has been in existence since 2000	CDPH actually replaced the original 2000 system, CAIR, with CAIR2. CAIR2 went live in around 2016 after a multi-year, multi-million dollar effort which considered other available immunization registry software

	packages on the market at the time.
AB 1797 would require providers and other agencies to disclose vaccine information to CDPH	The vast majority of providers already submit vaccine records to CAIR2 and other California registries. Provider participation in immunization registries quickly shifted from the minority to the majority when the federal "Meaningful Use" incentives began paying providers to submit vaccine records electronically using specific standards ("HL7"). The Meaningful Use incentive program was part of the multi-year, multi-billion dollar federal American Recovery and Rehabilitation Act (ARRA) of 2009.
AB 1797 would give schools and other organizations access to immunization records	Present law already gives organizations access to the records of those individuals on their roles or under their care. The HL7 standard further allows searches of the immunization registry for any individual based upon demographics such as name, date of birth, and so forth. This actually allows an organization to retrieve records for individuals *not* on their roles or under their care. This is one of the things that we feel needs to be fixed (see below).
Current law does not allow school districts to verify a student's vaccination status against COVID-19.	From a technology standpoint, there is nothing preventing schools from accessing the COVID-19 records housed in CAIR2. Vaccine records in registries are uniformly structured, and coded by vaccine type. If something presently disallows school access to COVID-19 records specifically, it is the result of some other policy, not the law that is the subject of AB 1797, nor of present immunization registry technology per se. This is separate from the issue of access to records for individuals *who have opted out.* These two issues may be getting confused. See below.
The bill would also authorize schools, childcare facilities, family childcare homes, and county human services agencies to use the vaccination information to perform immunization status assessments of pupils,	"Status assessments" is undefined. We assume it refers to the "forecast" or vaccine recommendation. The "forecast" is already available in CAIR2 and all immunization registries; it was standard from the beginning of immunization registries in the 1990s.

adults, and clients to ensure health and safety in the event of a public health emergency	The vaccine forecast has technical flaws that have not been presented; its recommendations can be inaccurate. Its present status as advisory, not mandatory, is appropriate.
AB 1797 would require race and ethnicity data elements to be submitted	The standards for vaccine record submission already require race and ethnicity to be submitted to CAIR2 *if available.* Presently, only unique patient identifier, name and date of birth are strictly "required" under the HL7 standard; “required if available” is the appropriate designation when high quality values are not consistently available in each and every record. Experience shows that changing a data element such as race and ethnicity from "required if available" to "required" is likely to lead to poor quality data being added to the CAIR2 database. This is because providers will sometimes be forced to send some default value or best guess in order to satisfy the requirement.
The CAIR2 system is flawed.	This is true. A very rosy picture of CAIR2 was painted in presentations. The extent of flaws has not been discussed. Some public information suggests that a “CAIR3” has already been discussed. CAIR2 has specific technical flaws that lead to incorrect vaccine records for some individuals. In fact, the reputation of immunization registries generally among electronic health record vendors and others is that the quality of data in them is poor.
Concern has been expressed about access in an emergency, both from support and opposition to the bill.	Present law already accounts for emergency situations. In fact, in practice, it is our experience that the state of California immunization registry data and access remains the same in emergency and non-emergency situations. Because of this, the “opt out” provision of present law is not rigorously implemented or fully enforced. Our recommendation is to refocus the bill to insert such rigor by specifying clearly what California immunization registries should do in an emergency vs. non-emergency situation.

Recommendations

Given the above, it is difficult for us to fully understand what the provisions of AB 1797 would effectively provide that CAIR2 does not already do as well as it possibly can. Instead, we suggest that more might be gained by the following:

1. The provisions mandating submissions to CAIR2 should be removed. The harm done by promoting participation requirements from voluntary to mandatory is likely to outweigh the benefit. The few providers that did not take advantage of the Meaningful Use incentive program likely had reasons that would apply even more so under a mandate that does not include such incentive payments.

2. Treatment of race/ethnicity data elements should remain "required if available" as governed by CDC standards and supported in the current law. Should a "health equity" initiative with regard to vaccines be initiated, cross-referencing CAIR2 records with a more reliable source of race/ethnicity data such as a Vital Statistics database might be considered instead.

3. The language around "performing an immunization status assessment" should be removed. Present law is sufficient to support the present "vaccine forecast" and other assessment practices. The language is also too vague and potentially problematic, due to limitations in the number of individual situations ("states") that can correctly be evaluated given the present technical approach.

4. Instead, any amendment to current law should focus on clarifying and correcting implementation of opt-out policy. This is explained below.

Opt-out, privacy, and present law

Since the beginning of our work on California immunization registries in 1997, the method of implementing state-legislated opt-out policy in software has proven problematic, in the following ways:

- There is no provision in the law to enforce the "informed consent" aspects of opt-out. Essentially, there is no mechanism to verify that providers consistently follows through in informing patients that their records are being submitted, and in providing them with a mechanism to opt out at the point of care.

- "Opt-out" should mean that, in a non-emergency situation, a person's record cannot be stored in the immunization registry at all. This has been advocated by some of the commentary on the bill; we agree. A sending Electronic Health Records (EHR) record should suppress the records of any person opting out. In fact, there is evidence that some providers do suppress the submission of such records.

- Because CAIR2 merges records from different providers for a common person, unless the patient "opts out" at each provider site, it is possible that opting out at one location will not

result in locking the merged record. This is especially true if certain providers (correctly) suppress confidential records. CAIR2 never sees a patient's "opt out" request if it never sees the record at all. Therefore it can't know to suppress ("lock") *all* the records for that person.

- An error in determining which multiply-sourced records belong to the same person may also lead to inadvertent disclosure of some of the records. These are known as "matching" or "de-duplication" errors. Immunization registry "de-duplication" algorithms are based upon demographic data, and are inherently imperfect (in technical terms, "heuristic"). Thus, errors can and do occur.

- To compound "matching" or "de-duplication" errors, CAIR2, and all other U.S. immunization registries (except the recently "transitioned" San Diego registry) use a "merge" deduplication algorithm instead of the more current and correct "link" method. In the "merge" method, two records, each created by a different provider, are combined into a single record. During this process, some data (technically, the "non-surviving" data) are discarded. As a result, no automated "unmerge" process exists. To undo a mistake, the record has to be separated by a manual process. Even then, some original data is usually lost.

- Other technical flaws in CAIR2 can also lead to errors which could inadvertently result in disclosure of confidential records. Our most recent information is that, upon receiving an electronic update to an existing record, CAIR2 uses demographic data to locate the record to update instead of the industry standard method of using the unique record identifier from the sending provider EHR. Sometimes, this leads to applying an update to the wrong person's record in the CAIR2 database. This is because it is common for individuals in a large population to share the same demographics (same name, date of birth, etc.); and, in any event, differences in data entry lead to errors (misspelling a name, using a nickname, transposing a date of birth, etc.). As a result, an update indicating that a patient opted out might never be applied to that patient's record, and/or incorrectly applied to another person's record instead.

- Even if records are "locked" when a person "opts out", public health has access to them, even in non-emergency situations.

- Finally, security violations can and do occur. Any such violation is doubly harmful to a person who believes they "opted out" of the immunization registry in the first place.

Recommended Changes to Opt-out

Enforcement of Informed Consent

Provisions should be made for enforcement of "informed consent", including regular audits of provider practices, and penalties for non-conformance.

Limit query access to "patients under care", etc.

According to the legislative analysis compiled by the Education Committee, present law:

> 9) Permits LHDs and the CDPH to disclose the information set forth in 8) above to each other and, upon a request for information pertaining to a specific person, to health care

providers taking care of the patient and to the Medical Board of California (MBC) and the Osteopathic Medical Board of California (OMBC).

10) Permits LHDs and the CDPH to disclose the information in paragraphs 8) a) through g), and paragraphs 8) i) through k) to schools, childcare facilities, county welfare departments, and family childcare homes to which the person is being admitted or in attendance, foster care agencies in assessing and providing medical care for children in foster care, and WIC service providers providing services to the person, health care plans arranging for immunization services for the patient, and county welfare departments assessing immunization histories of dependents of the California Work Opportunity and Responsibility to Kids Program participants, upon request for information pertaining to a specific person.

(emphasis added)

Presently, users and querying systems do not have to provide evidence of registration or enrollment in querying for a patient. Instead, HL7 queries to immunization registries are allowed to supply only demographics as search criteria (name, date of birth, etc.). This can result in an intentional or unintentional retrieval of records for a person not legitimately covered by the sections of the law cited above.

The remedy is to require the querying system or user to supply the unique identifier or medical record number of the individual whose record is being sought, and for CAIR2 to use that identifier or medical record in locating the correct record to return. This is practically accomplished by HL7 convention, in the case of electronic interfaces, by first sending an Admit, Discharge, Transfer ("ADT") message to the immunization registry, then using the unique identifier sent in the ADT to retrieve the record via query. For data entry users, it would mean creating a new record for a patient, then using the identifier or medical record number to search for the immunization registry records submitted by other providers for that person.

The use of ADTs just described is conventional in enterprise healthcare systems, Health Information Exchanges, and elsewhere. We understand CAIR2 began accepting ADTs in the last year or so as part of a "smart card" vaccine record initiative. Thus, implementing the requirement in the interests of patient privacy should likewise not be excessively onerous or costly.

Declaration of Emergency Status

What constitutes "an emergency" should be clearly defined, and should follow some external, general government declaration of an emergency. At this writing, the AB 1797 bill draft identifies an emergency state for COVID-19 in effect until 2026. This does not make sense, as there is no guarantee that COVID-19 will be a threat until 2026, or that it will cease to be a threat after 2026. The criteria by which this emergency/non-emergency status is established is what should be codified into law instead of the present, hard-coded language.

Non-Emergency

In a non-emergency status, providers and data entry users should suppress the submission of confidential records altogether; and confidential records should be removed from the CAIR2 database. This is the only way to ensure that records the patient wishes to remain "confidential" *cannot* be returned to other providers, viewed by public health staff, or included in reports. No errors in interpreting the patient's confidentiality request due to matching or other errors can occur, and they cannot be subject to security violations.

CAIR2 as an EHR for immunizations vs a population health database

It may be argued that "opted out" ("confidential" or "locked") records cannot be purged from CAIR2 because data entry providers rely on CAIR2 in the absence of an EHR. In this case, a solution exists whereby CAIR2 software could be modified to keep such records separate from the "merged" version of record. Access for "EHR-like" purposes would be limited to the provider who entered them; they would not become part of the "merged" record.

Declaration of Emergency

In the case of an *emergency,* providers can be requested to submit patient confidential records in batches. Since the percentage of patients who opt out is small, this should not be unduly burdensome. Providers are routinely requested to submit or re-submit certain limited batches of records. Any provider being onboarded must submit a batch initializing the records for their entire patient population. By comparison, requesting a limited set of records is not burdensome.

Limitations of Emergency Record Collection

The collection of "opted out" records in an emergency should be strictly limited by the specifics of the emergency. For example, if the emergency is COVID-19, then only COVID-19 "opted out" records should be collected, and only in relation to a specific public health requirement. For instance, opted-out COVID-19 records should only be collected for access by schools if there is a corresponding legal requirement for COVID-19 vaccination for school entry.

End of Emergency

At the end of the emergency, the confidential records should again be purged from the system.

Financial Commitment and the Future of CAIR2

Given the age of the legacy immunization registry software used by CAIR2, and the fact that the software was just replaced in 2016 after an extensive evaluation of other immunization registry packages, we suggest the changes in this bill be very limited, as described above, and the resources committed commensurate with those limited changes. Instead, in applying the lessons of COVID-19, the State should look for significant paradigm upgrade in the approach to technology for managing communicable disease. If COVID-19 vaccines have taught us any lesson, it is that vaccines alone cannot provide the complete solution to stopping disease transmission and infection. A future approach might combine lab test results, disease history, and other types of data to expand the toolset to support more complex techniques for managing population health.

Our Qualifications

Our company, Software Partners LLC, has 25 years' experience working on immunization registry software in California and elsewhere in the United States. We provided the recently transitioned San Diego immunization registry software. I hold a Master's degree in Computer Science from UCSD. I am the author of a chapter on immunization registry standards in Health Information Management Systems Society (HIMSS) textbook[1]; and am the inventor on two U.S. patents on immunization registry software.

Thank you for considering the above comments. Please feel free to contact me with any questions.

Sincerely,

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[1] Kirnak A. Immunizations. In: Bright L, Goderre J, ed. *Underlying Standards that Support Population Health Improvement.* Boca Raton, FL: Taylor & Francis Group LLC CRC Press; 2018: Chapter 4.