Hi Khoua,

Due to how important this is, we managed to get it done before I left on vacation. Below are CDPH's comments on the Data Sharing Agreement and Policies.

# DATA SHARING AGREEMENT

## Paragraph 3.

*Definition of Authorization* - Maintenance of the language specifying requirements under applicable Law is necessary as most of CDPH's programs are not covered by HIPAA and the IPA's notice authorization provisions apply. *Definition of Personally Identifiable Information or PII* – Civil Code 1798.140(o) is not applicable to governmental participants therefore CDPH recommends either changing this citation to 1798.29(g) or adding 1798.29(g) in addition to 1798.140.

## Paragraph 4.

It is important for CDPH to include specification in this section or in the policies and procedures that applicable law governing the Governmental Participant would dictate required/permitted purposes and prohibitions on use. CDPH has over 200 programs with myriad laws. Application of one standard is not possible.

## Paragraph 5.

Subsection (a) – It will be difficult to get the department to agree to comply with the terms specified in the policies and procedures if they are not yet developed. Paragraph 6.

CDPH would like to reiterate its statement during the meeting that a universal authorization would not be possible due to the variation in laws and requirements applicable to its programs.

## Paragraph 8.

Subsection (b)(ii) – It is important to maintain this section and language for CDPH due to the fact it has a large number of programs governed by various laws and regulations to the vast majority of which HIPAA does not apply. Subsection (c) – CDPH requests addition of "or applicable law" after the statements requiring training set forth in or defined by the HIPAA Regulations. As previously stated, HIPAA does not apply to the majority of CDPH's programs and requiring a department wide change/update to training would be a challenge both in time and money.

## Paragraph 9.

Subsection (a)(iii) – For the reasons stated above, it is very important that subsection (a)(iii) is maintained as part of this agreement. CDPH acknowledges the other stakeholders' statements as to having HIPAA be the "floor" for privacy and security. However, this would require a complete re-working of CDPH's internal policies, procedures, trainings, and more. The cost of implementation of which, both in manpower and tax dollars would be extraordinarily high to the point of being prohibitive.

#### Paragraph 11.

Subsection (d) – CDPH requires a carveout or exception for governmental programs that have budgets dependent upon collecting fees for distribution of

personal information. For example, the vital records branch of CDPH would be financially devastated if it was not permitted to charge for providing records.

#### Paragraph 13.

CDPH agrees with the other stakeholders' comments and suggestions that the reference to 42 U.S. Code section 300jj-52 be removed from this paragraph. Paragraph 14.

As with paragraph 5 above, it is difficult to agree to requirements set forth in policies and procedures that do not yet exist. Signing the agreement would not be possible until those policies and procedures are finalized.

## Paragraph 15.

Subsection (b) – Due to all the points above, and the complicated nature of CDPH as a Hybrid Entity with over 200 programs governed by myriad laws, the majority of which are not covered components, it is extremely important for CDPH to maintain the following language as part of the agreement:

If a Governmental Participant determines, after reasonable diligence, that any action or inaction relative to an obligation, including conformance to changes in the Specifications or Policies and Procedures will cause it to violate Applicable Law, the Governmental Participant may terminate this Agreement immediately upon sending written notice to the Governance Entity.

## Paragraph 17.

CDPH echoes the other stakeholders' comments regarding this section and the suggestion that it should be re-written. It places a large cost/risk on parties that are either self-insured or unable to obtain cybercrime insurance. A more straight forward anti-indemnity clause would be preferable.

## POLICY: REQUIREMENT TO EXCHANGE HEALTH AND SOCIAL SERVICES

**INFORMATION** – During the meeting it was suggested that a directory of how parties can be contacted and provided data would be helpful. CDPH would like to reiterate its statement from the meeting that due to the size and complexity of its organization and the number of independent programs for which it is responsible, this would be a monumental and potentially impossible task.

**POLICY: PERMITTED, REQUIRED, AND PROHIBITED PURPOSES** – It is important for CDPH that the language specifying public health authorities includes "other applicable law for public health activities and purposes" as many of CDPH's programs are governed not by HIPAA but by the Civil Code and Health and Safety Code. CDPH would prefer stronger language specifying permitted and restricted uses of the data is governed by applicable law.

**POLICY: BREACH NOTIFICATION**: CDPH cannot agree to longer than the 24 hours specified in section III(b) for it to be notified of a breach. It does not require a full report with all elements outlined in subsection (a) within 24 hours, however, notification of at least the fact the breach occurred must be within 24 hours.

**POLICY: DATA ELEMENTS TO BE EXCHANGED**: It is important to CDPH to keep the "applicable law" language in Subsection II(1)(a)(iv) so programs with more restriction than others (e.g., the Office of AIDS) would not be required to share data contrary to state law. CDPH also notes that incorporation of "the most recent published (in non-draft form) United States Core Data for Interoperability" could be a problem if these policies and procedures are determined to be regulatory actions. Proscriptive incorporation is not permitted under the Administrative Procedure Act.

# POLICY: PROCESS FOR AMENDING THE DSA & MODIFICATION TO POLICIES

**AND PROCEDURES**: CDPH agrees with and echoes other stakeholders' comments regarding the timeframe to implement changes to either the DSA or the policies and procedures. A minimum timeframe of 180 days with an option to extend it further would be preferred. Not only, as noted in the meeting, would it be difficult for some small participants to make changes quickly, it would similarly be difficult for a large, complex entity to change policies and procedures.

Sincerely,

Diana R. Kaempfer-Tong *Pronouns: she, her, hers* Regulations, Privacy & Special Projects Office of Legal Services California Department of Public Health