March 2, 2022

Dear John, Elaine, and Jennifer:

We are writing to provide feedback on the Data Sharing Agreement draft language you have shared to date. We are also requesting a meeting to discuss our concerns.

MAJOR CONCERNS

We are concerned that the agreement language you have shared is missing key components needed to effectively implement the data sharing mandates enacted in AB 133.

1. **Clearly define data sharing requirements for all entities covered by AB 133**
   The agreement and the related binding policies should include clear language defining the data sharing requirements for all entities covered by AB 133. The language should include sufficient detail so that each entity knows exactly what it needs to do to comply, including obligations to proactively send data, obligations to respond to queries, deadlines for compliance, consequences for non-compliance and details on what data types/formats are required. Murkiness on these requirements will slow implementation, reduce the impact of the law, and make enforcement impossible. In specific the agreement and policies should:

   - Specify what data must be shared and in what standards-based formats. In the absence of this clarity millions of hours will be spent negotiating formats and struggling to make sense of unstandardized data that could be spent sharing and using data.

     For instance, an ambulatory provider might be required to share patient CCDAs in response to queries from signatories or their designated qualified intermediary in both longitudinal and encounter format, including all relevant USCDI data.

     Whereas a hospital might be required to proactively share real-time lab and ADT data, and share patient CCDAs, including all relevant USCDI data, in response to queries.

   - Clarify which data must be shared proactively in real-time and which data can be shared in response to queries. Note that some use cases can be satisfied by query. But others—such as encounter alerts—require proactive and real-time data sharing.

2. **Require data exchange for all HIPAA purposes**
   The agreement and the related binding policies should require data sharing for all HIPAA treatment, payment, and operations (TPO), purposes as established by AB 133.

   > On or before January 31, 2024, the entities listed in subdivision (f), except those identified in paragraph (2), shall exchange health information or provide access to health information to and from every other entity in subdivision (f) in real time as specified by the California Health and Human Services Agency pursuant to the California Health and Human Services Data Exchange Framework data sharing agreement for treatment, payment, or health care operations.

   This means that any entity signing the agreement should be required to share data in response to any request from another signatory or their qualified intermediary that falls under TPO.

   The current "requirement to respond" section of the draft language includes a confusing sub-set of these HIPAA TPO purposes. Requiring exchange for some purposes and not others will make it more difficult

for participants to rely on the framework for their exchange needs and will undermine the goals of AB 133 by continuing to perpetuate the fragmented exchange environment we have today.

Requiring data sharing for all allowable TPO purposes also aligns with the direction of federal policy. For instance, the Information Blocking rule requires data sharing when allowable by law. And TEFCA is likely to require data sharing for all payment and operations use cases, rather than the subset originally proposed. It is highly advisable for California to align with this federal direction.

3. **Reduce the burden of exchange by defining the role of qualified intermediaries**
Many organizations will want to rely on HIEs or other intermediaries to satisfy their data exchange requirements under AB 133. To facilitate this process, and avoid confusion and substantial unintentional non-compliance, the following should be added to the agreement and policies:

- The state should establish criteria and a process for naming qualified intermediaries
- A provider, health plan or other entity covered by AB 133 should be able to meet the law's requirements in two ways:
    - By sharing data directly
    - By sharing data with a qualified intermediary that will share on its behalf
- All "direct sharing" organizations and all qualified intermediaries must share required data with each other for all TPO purposes.
- Every entity covered by AB 133 should be required to publicly register whether it will be sharing data directly or will do so through a specified qualified intermediary. The state should maintain a public and available listing of these decisions.

In the absence of this approach, a small practice may choose to join and share data with a particular HIE or network, but other providers that have not selected the same HIE will still come to them directly requesting data. This will be an unworkable and unsustainable situation for the practice. The data exchange framework needs to establish a process for providers or plans to join a single qualified network, and for those qualified networks to share on their behalf.

The agreement includes this language, which is consistent with above intent but is not sufficient to clearly lay out how this designation process will work: "The parties intend that each individual party shall be entitled to choose which method of exchange best suits that individual party. However, each party shall engage in meaningful health and social services information exchange either through execution of an agreement with an entity that provides data exchange or through use of their own technology."

4. **Simplify and edit the agreement so that it can be signed by thousands of providers and plans**.
The draft language that has been shared to date is mostly pulled or adapted from the California DURSA. Simpler and more direct language is needed to 1) clarify the obligations of the signatories 2) ensure the agreement can be understood and signed by the broad range of entities covered by AB 133.

We also strongly recommend that the full draft agreement and related binding policies be shared with and reviewed by the Stakeholder Advisory Group – the body established by AB 133 to advise on the data exchange framework and data sharing agreement – before it is shared for comment with the public.

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