HIPAA Compliance Issues in Contracting with Data Registries

HIPAA Summit West

Austin O'Flynn, Esq.
Senior Counsel, IT/IP, Privacy, eCom,
Web Services & eDiscovery

Oct 10-12, 2012

Dignity Health

Issues Covered:

- Purpose of Data Registries (DRs)
- Examples of Data Registries
- Types of Data Registry
- Big Data as Big Oil
- Four Main Categories of Datasets
- Typical Reports Produced by Registry
- Increasing Difficulty in Finalizing Contracts
- Some DRs Demanding that DUAs (Data Use Agreement) becoming Data Sale Agreements
- Need for National Template for DUA (Data Use Agreement)
- Recommended Provision for DUA with DRs

Map of US Hospitals' Outcome Metrics

- by Mortality rates and Re-admission rates

Yellow – US Avg.

Red – Worse

Green – Better

Blue – no data reported

Image Source: *CustomerThink.com 2012*

Data source: *Medicare claims and enrollment data.*

Dignity Health

Purpose of Data Registries

From the Data Provider's Perspective:

- Receive outcome comparison reports
  - Certifying Body for the particular service line requires participation and the data – often owns the Data Registry.
  - Use them to improve quality of care
  - If good reports – marketing advantage
  - No so good – discretion of provider to be made public
  - Often tolerated as a data monopoly

Purpose of Data Registries

From the Data Registry's Perspective:

- Create and distribute outcome comparison reports
- Use the reports to push for improvement in quality of care
- Opportunity to collect a huge volume of data:
  - Independent Research
    - Common Rule
    - IRB of Provider?
  - Public Reports
  - Other Uses

Examples of Hospital Related Data Registries (DRs) - some have multiple registries

- ACS - American College of Surgeons ($ to $$$)
- CAP – College of American Pathologists (0)
- ACCF - American College of Cardiology ($ to $$)
  - Medicare requires TVT Registry ($25K first year)
- ACR – American College of Radiology ($)
- AHA – American Hearth Association ($)
- STS – Society of Thoracic Surgeons
- STS and ACCF jointly operates the TVT Registry ($$$$)
  - Required by Medicare for hospitals performing TAVR (Transcatheter Aortic Valve Replacement) procedure.

Types of Data Registries

- Types of Data Registries
  - Non-Governmental:
    - Certifying Professional Body
    - Payer – non governmental
  - Governmental
    - Medicare Required
    - State

Big Data as the New Oil – Big Oil

"How Big Data Became So Big" - NY Times Article - August 11, 2012

Big Data is no longer confined to database silos.

With Digitization of Data and XML, "Big Data" finally begins to flow like "black gold from them 'er hills."

Big Data IS the Model

"*All models are wrong, and increasingly you can succeed without them.*" Speaking at the O'Reilly Emerging Technology Conference this past March 2008, Peter Norvig, Google's research director.

"This is a world where massive amounts of data and applied mathematics replace every other tool that might be brought to bear. Out with every theory of human behavior, from linguistics to sociology. Forget taxonomy, ontology, and psychology. Who knows why people do what they do? The point is they do it, and we can track and measure it with unprecedented fidelity. With enough data, the numbers speak for themselves." Wired.com 23June08

Four Types of Datasets under HIPAA submitted to a Data Registries

1. De-identified Data
2. LDS – Limited Dataset
3. PHI plus other data

   - but the PHI is used only by Data Registry;

4. Full PHI, which may include SSN for longitudinal record matching

(*Note: important to get representation that DR will only seek dataset agreed under the contract terms. Sometimes website may have additional data fields*.)

Typical Reports Produced by Data Registry

- Hospital-only Reports
- Hospital vs. System Reports
- Hospital vs. State Reports
- Hospital vs. National Reports

Increasing Difficulty Negotiating Data Use Agreements with DRs

Data Provider's View:

Provide the data to the DR for two purposes:

1. Use license to permit the DR to create the Reports

2. Permit DR to share the reports with others providers who submitted the same dataset.

From the Data Registry's View:

1. Aggregate the data
2. Produce the reports AND
3. Trust us on anything else we might like to do with your Data
    - Research
    - Resell the raw data

Increasing Difficulty in Finalizing Contracts

- Dictated terms and conditions
- Often puts all risk on the provider of the data in the event of a privacy breach by the Data Registry.
- Not clear that Data Registries with millions of records containing PHI have the necessary security skills to secure the PHI submitted by the hospitals across the country.
- Permitted Uses of Data
  - Produce the agreed reports
  - Improve the Data Registry
- Ownership and Use License of Data

Some Data Use Agreements becoming Data Sale Agreements?

Basic contract question from a Hospital to Data Registry

Question: Can the DR aggregate the data and produce the reports with a *use license* rather then seeking to take ownership of the hospital's data?

Answer: Always yes . . . BUT, we the DR want to do all these other things too.

It may be that the hospital has similar uses. Regardless, it's not reasonable that the DR should be able to operate as a monopoly: "*give up ownership of your data or you don't get to participate*."

Ownership should have nothing to do with the DR purpose.

Need for a National Date Registry Contract Template

1. No commercialization of the hospitals’ data by the DR
2. Limit the use of the data to the purpose of aggregating the submitted data
3. Creating the reports
4. Sharing the reports with the data submitter and similarly situated submitters submitting the same dataset.

Monopolies need Transparency if not Regulation:

<u>Transparency by standard DUA template</u>: Healthcare industry sorely needs straight forward template for use by DRs and Hospitals.

<u>Reduce Costs</u>: Too many lawyer hours required in negotiating what should be standard terms for data use and data security.

Recommended Provision in Data Use Agreements between Hospitals and Data Registries.

"Subject to the licenses granted by Participant in this Section XYZ, all intellectual property rights and title to the Data relating to individual patients submitted by Participant shall remain the exclusive property of Participant, subject to the rights, if any, of the Participant's patients in Individually Identifiable health Information. Participant hereby agrees the return of the Data is not feasible to the extent that it has been integrated into the registry and aggregated. Participant hereby grants to the Data Registry a perpetual, royalty-free license, that is worldwide and in all forms and all media (including derivative works), to use and retain the Data as long as it's being used only for the following purposes: (i) to create reports for Participant, and (ii) to permit the creation of similar reports for other similarly situated participants submitting substantially similar data as Participant has submitted Data Registry, in such manner that is consistent with this Agreement and the HIPAA BAA."

Thank You

Austin O’Flynn, Esq.

Senior Counsel, IT/IP, Privacy, eCom, Web Services & eDiscovery

Austin.O’Flynn@DignityHealth.org

Dignity Health