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PERSONAL AND CONFIDENTIAL

MEMORANDUM

To: AJRR Participating Sites

From: Rob Portman
AJRR General Counsel

Date: January 7, 2013

Re: AJRR HIPAA/Common Rule Compliance Strategy

The American Joint Replacement Registry ("AJRR" or "Registry") will collect and utilize data derived from information submitted by physicians, hospitals and manufacturers related to joint replacements. Some of this data will qualify as protected health information ("PHI") under the Health Information Portability and Accountability Act of 1996 ("HIPAA") Privacy and Security rules ("HIPAA Rules").[1] This memorandum briefly describes AJRR's HIPAA compliance strategy. It also addresses the applicability of the Common Rule.[2]

HIPAA Background

PHI is individually identifiable health information that requires patient authorization for use and disclosure unless such disclosure falls within one of many exceptions.[3] HIPAA applies to "covered entities," defined to include health care providers, health plans, and health care clearinghouses that handle electronic claims, as well "business associates," defined as entities that provide services for or perform functions on behalf of covered entities. The HIPAA Privacy Rule allows for the disclosure of PHI without patient authorization for the purposes of treatment, payment or health care operations.[4] Health care operations include quality assurance and improvement activities.

The extent to which HIPAA will apply to the activities of the AJRR will depend on the nature of the data being collected, the purpose of the collection, and whether AJRR is actually

[1] 45 C.F.R. Pt. 164.
[2] 45 C.F.R. Pt. 46.
[3] 45 C.F.R. § 164.502.
[4] 45 C.F.R. § 164.506; 45 C.F.R. § 164.508(a)(2)-(3).

physically receiving the data. For example, the AJRR would not be subject to HIPAA limitations when handling de-identified information, which is information that contains no personal identifiers or unique identifying numbers, characteristics or codes.[5] Similarly, if the AJRR collected "limited data sets," it would not need to obtain patient authorization or a waiver of such authorization from an Institutional Review Board ("IRB").[6] A limited data set is information that is partially de-identified by removing specific identifiers but retains certain information, such as addresses, gender, and date of birth.[7] The limited data set exception applies only to the use of data for research, health care operations and certain public health purposes. This exception requires the covered entity to enter into a data use agreement with the limited data set recipient to preserve the confidentiality of the data and restrict its use.

The HIPAA rules allow covered entities to disclose only the "minimum necessary" information.[8] They also permit covered entities to share PHI with "business associates" if they enter into business associate agreements that meet regulatory requirements.

AJRR HIPAA Compliance Strategy

AJRR will be aggregating and analyzing data and providing participants[9] with reports on their performance relative to other registry participants. Participants are covered entities under HIPAA. To the extent that the purpose of such reports relates to health care operations, such as quality improvement, the AJRR will be performing data aggregation services for the participants and would qualify as a business associate.[10] As such, it will be entering into business associate agreements with each participant prior to receiving the participant's PHI. While it will receive and analyze each participant's data and report back aggregate results to all participants, it will not share the PHI of any one participant with other sites, except that data on patients treated by more than one hospital will be shared with just those hospitals. As a business associate, AJRR has adopted HIPAA-compliant policies and procedures necessary to protect the privacy and security of PHI received from participants.

To the extent that AJRR plans to collect PHI primarily for research purposes, where research is defined as "a systematic investigation, including research, development, testing and evaluation designed to develop or contribute to generalizable knowledge,"[11] the business associate agreement will not protect the data. Instead, AJRR has obtained a waiver of the HIPAA patient authorization requirement for the submission of PHI for research purposes from Western Institutional Review Board (WIRB) (http://www.wirb.com).[12] The AJRR will also obtain separate IRB approval or waiver of authorization for any disclosure of PHI for specific research purposes.

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[5] 45 C.F.R. § 164.514.
[6] 45 C.F.R. § 164.512(i).
[7] 45 C.F.R. § 164.514.
[8] 45 C.F.R. § 164.502(b).
[9] The term "participants" for the purposes of this memorandum, is defined as providers, hospitals, and any other entities submitting data to the AJRR.
[10] 45 C.F.R. § 164.501.
[11] 45 C.F.R. §164.501.
[12] 45 C.F.R. 164.512(i).

The (U.S. Department of Health and Human Services (HHS) Office for Civil Rights (http://www.hhs.gov/ocr/) has clearly stated that the HIPAA rules do not require each site participating in a data registry to obtain a waiver from its local IRB:

> The Privacy Rule permits covered entities reasonably to rely upon a researcher's documentation that a waiver was properly granted by a single IRB or Privacy Board, even if the IRB or Privacy Board is not affiliated with the covered entity. Under the Privacy Rule, one IRB or Privacy Board's documentation of waiver of Authorization suffices.[13]

Therefore, sites submitting PHI to AJRR do not need to obtain local IRB waivers of the HIPAA patient authorization requirement.

Common Rule

The Common Rule does not apply to AJRR activities as that rule relates to research that is "conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research."[14] The Common Rule defines "research subject to regulation" as:

> [R]esearch activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).[15]

Where the Common Rule applies, it covers research involving human subjects, which includes the collection of identifiable patient information.[16] The Common Rule does not apply to privately-funded research activities such as the AJRR that are not otherwise subject to federal regulation.

The Common Rule also does not apply to participants that submit data to the AJRR. The HHS Office for Human Research Protections (http://www.hhs.gov/ohrp/) has clearly stated that data collected in the course of clinical care that is submitted to external researchers is not human subjects research and therefore is not subject to the Common Rule. Specifically, "Institutions whose employees or agents release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research" are not engaged in human subjects research.[17] Thus, hospitals that submit PHI collected in the

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[13] See http://privacyruleandresearch.nih.gov/healthservicesprivacy.asp; see also http://privacyruleandresearch.nih.gov/research_repositories.asp.
[14] 45 C.F.R. §46.101(a).
[15] 45 C.F.R. §46.102(e).
[16] 45 C.F.R. §46.101(b).
[17] HHS Office for Human Research Protection, Guidance on Engagement of Institutions in Human Subjects Research, Section III.B.6., http://www.hhs.gov/ohrp/policy/engage08.html. OHRP also has had correspondence

course of clinical care to national registries for research purposes are not engaged in human subjects research.

Nonetheless, AJRR has obtained a waiver of the Common Rule informed consent requirement from WIRB to cover the collection of patient information for research purposes. The Office for Human Rights Protections, like OCR, strongly supports the use of central IRB review for multicenter clinical research,[18] including research conduct or facilitated by clinical data registries.[19]

with the registry sponsored by the American Association of Neurological Surgeons in which it has applied this principle to clinical registries. Copies of that correspondence are available from AJRR upon request.

[18] See http://www.hhs.gov/ohrp/policy/Correspondence/cirb20100430.html.
[19] See OHRP correspondence described in FN. 17 herein.