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PHYSICIAN CLINICAL REGISTRY COALITION

January 6, 2016

Jerry Menikoff, M.D., J.D.
Director, Office for Human Research Protections
Department of Health and Human Services
ATTN: HHS-OPHS-2015-0008
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

[Submitted online at: http://www.regulations.gov/#!docketDetail;D=HHS-OPHS-2015-0008]

Re: HHS-OPHS-2015-008, Federal Policy for the Protection of Human Subjects Notice of Proposed Rulemaking

Dear Dr. Menikoff:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition) appreciate the opportunity to comment on the "Federal Policy for the Protection of Human Subjects," otherwise known as the "Common Rule," Notice of Proposed Rulemaking (NPRM).[1] The Coalition is a group of more than 20 medical societies and other physician-led organizations that sponsor clinical data registries that collect and analyze clinical outcomes data to identify best practices and improve patient care. The Coalition's mission is to advocate for public policies that encourage or facilitate the development of clinical data registries.

The Coalition commends the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) for its continued dedication to balancing the need to protect the rights of human research subjects with reducing barriers to research and avoiding confusion between human subjects research and quality improvement activities. The focus of our comments is on the effect of the proposed changes in the Common Rule on clinical data registries. In particular, we urge OHRP to implement the following changes in the Common Rule: 1) expand the exclusion for quality improvement activities to cover comparative benchmarking; 2) modify the proposed exclusion for data collection activities covered by the HIPAA Rules (as defined herein) to include business associates and researchers that comply with those rules; and 3) modify the proposed exemption for the use of identifiable private information for secondary research by removing the notice requirement for clinical data registries.

[1] 80 Fed. Reg. 53933 (Sept. 8, 2015), *available at* http://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf.

The Coalition also supports OHRP's proposal to mandate central Institutional Review Board (IRB) review and harmonize the Common Rule with other agency guidance. In addition, the Coalition urges OHRP to expand its harmonization efforts by ensuring that the Common Rule is consistent in all material respects with the regulations issued under the Health Information Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act (collectively, the HIPAA Rules).

1. **OHRP's Proposed Exclusion for Quality Assurance/Improvement Activities Should Be Expanded to Include Benchmarking Activities Undertaken for Quality Improvement Purposes**

The NPRM proposes to create an exclusion (at § __.101 (b)(1)(iv)) for quality assurance/improvement activities that are designed to alter the use of an accepted practice and collect identifiable patient data to evaluate the effects of the practice on utilization.[2] OHRP intends for this exclusion to improve the delivery or quality of accepted treatments or services. The exclusion does not cover evaluation of the accepted practice itself, as OHRP considers the evaluation of an accepted practice to be research.

The Coalition generally supports this proposed exclusion as quality improvement activities that are focused on disseminating or measuring the use of accepted or best practices by specific health care providers, rather than on the safety and efficacy of the practices themselves, do not promote generalizable knowledge and therefore are not research. Measuring the use of these activities merely helps ensure that providers are implementing accepted or best practices in the most efficient and effective way possible. Excluding these activities from the Common Rule will help ensure that providers do not mistakenly assume they must obtain IRB approval or a waiver of informed consent requirements for pure quality assurance programs.

The Coalition is not comfortable with the NPRM's blanket statement that the exclusion does not cover the evaluation of an accepted practice. Whether or not the evaluation of an accepted practice is best treated as research or quality improvement will generally depend on the facts and circumstances. We, therefore, urge OHRP to consider qualifying this language to take into account circumstances in which the evaluation of an accepted practice may be conducted solely or primarily as part of a quality improvement process, and not designed to promote generalizable knowledge.

The Coalition also urges OHRP to expand this exclusion to cover quality improvement activities that allow providers to compare their outcomes to generalized statistics on the outcomes of a group of providers. For instance, clinical data registries typically engage in benchmarking that involves the aggregation of data collected from participating providers (usually hospitals, physicians, or other health care providers) and reporting statistics on that data to the participants so they can compare their performance to the overall performance of the entire group of registry participants. While registries may also engage in studies to evaluate the effectiveness of

[2] *Id.* at 54045; *Id.* at 53948-49.

particular practices (whether accepted, evolving, or experimental), most benchmarking by clinical data registries simply involves providing participants with general statistics. These statistics allow providers to compare their performance to their peers. For example, clinical data registries routinely provide participating hospitals with data on their mortality rates from various types of surgical procedures. Each individual hospital would then compare its own data to the general statistics provided by the clinical data registry. This type of quality improvement benchmarking is clearly not research, but simply statistical comparison. Therefore, these types of quality improvement activities should be excluded from the Common Rule.

2. OHRP's Proposal to Exclude Quality Improvement and Research Activities Conducted by Covered Entities Pursuant to the HIPAA Privacy Rule Sufficiently Protects Human Subjects, But Should Be Expanded to Include Business Associates and Researchers that Comply with HIPAA

The Coalition strongly supports OHRP's proposed exclusion for certain activities that are covered by HIPAA. However, the exclusion should be expanded to include business associates and researchers who are collecting protected health information (PHI as defined by the HIPAA Privacy Rule) from covered entities and therefore are also required to comply with HIPAA.

Clinical data registries collect and aggregate PHI from health care providers primarily for purposes of improving the quality of the procedures or treatments covered by the registry. In collecting this information, registries typically act as business associates (as defined by the HIPAA Privacy Rule) of their participant/covered entities, and, as such, are required to comply with the same HIPAA Rules as their participants. Thus, registries must enter into HIPAA-compliant business associate agreements with each of their participating hospitals and medical practice groups to ensure that they protect the PHI they collect in accordance with the HIPAA Rules.

The HHS Office of Civil Rights (OCR) has clarified that covered entities and business associates, including clinical data registries, may use de-identified PHI for secondary research purposes without seeking an IRB waiver of authorization as long as such use is consistent with the registries' business associate agreements.[3] Likewise, OHRP has provided the Coalition with guidance that the Common Rule does not apply to institutions that release PHI obtained in the course of clinical care to a clinical data registry for research purposes.[4]

Despite OHRP's guidance, many hospitals and other data sources will not submit their data to a registry that engages in some research without obtaining local IRB approval and proof that the registry has obtained an IRB waiver of the Common Rule consent requirement. Some hospitals even insist on receiving informed consent from patients before they will participate in a registry

[3] *See* United States Dep't of Health and Human Servs., *Frequently Asked Questions: Health Information Privacy* (Dec. 15, 2008), http://www.hhs.gov/ocr/privacy/hipaa/faq/health_information_technology/544.html.
[4] Letter from Jerry Menikoff, Director, Office for Human Research Protections to Rob Portman, Principal, Powers, Pyles, Sutter & Verville, P.C., June 25, 2015, *available at* http://www.hhs.gov/ohrp/policy/Correspondence/toportman25jun2015.html.

that conducts research on their data. These mistaken applications of the Common Rule have created significant barriers to the development of clinical data registries and demonstrate the need for the exclusion of certain research activities covered by the HIPAA Rules.

Therefore, the Coalition strongly supports the proposed exception to the Common Rule (at § __.101 (b)(2)(iv)) for activities that are regulated under the HIPAA Privacy Rule.[5] Specifically, OHRP proposes to exclude research, as defined in the NPRM, using PHI conducted by "covered entities" for "health care operations," "public health activities," or "research," as those terms are defined under the HIPAA Rules. This is a significant step forward in facilitating data-based research by reducing duplicative regulations without sacrificing patient privacy.

The HIPAA Rules are stricter, more detailed, and generally more protective than the Common Rule of the privacy and security of PHI. Requiring entities covered by the HIPAA Rules to comply with duplicative and redundant privacy laws creates unnecessary burdens on the quality improvement and research activities of clinical data registries. This proposed exclusion will go a long way towards preventing confusion by health care providers otherwise covered by the Common Rule and assure them that they need only comply with the HIPAA Rules when conducting research on PHI. Without this exclusion, some hospitals and academic medical centers may be dissuaded from participating in clinical data registries or delay that decision.

However, the Coalition urges OHRP to clarify that the proposed exclusion would not just apply to covered entities; it must also apply to their business associates who are engaging in quality improvement and research activities on their behalf. The HITECH Act and its implementing rules mandate that business associates must comply with the HIPAA Rules with respect to the use or disclosure of PHI they receive from or on behalf of covered entities. The rationale of the exclusion for activities covered by HIPAA—*i.e.*, that covered entities already must comply with the HIPAA Rules in conducting health care operations, research, and public health activities using PHI—applies with equal force to business associates that are engaged in quality improvement activities on behalf of covered entities that OHRP considers to be research. For example, a clinical data registry may be engaged in benchmarking activities that OHRP considers to be research, but because the benchmarking is conducted for quality improvement purposes the activities are covered by the HIPAA business associate rules. The Common Rule should not apply in such a case.

Likewise, the proposed exclusion should apply to business associates and other entities, including clinical data registries, that conduct research on PHI or limited data sets (partially de-identified PHI as defined by the HIPAA Rules) collected from covered entities in compliance with the HIPAA Rules. Specifically, if a clinical data registry collects PHI from a covered entity pursuant to a business associate agreement, de-identifies the data as part of its business associate duties, and then conducts research on the de-identified data, these activities should not be subject to the Common Rule. Similarly, if the registry obtains patient authorizations or a waiver of the HIPAA authorization requirement from an IRB to use or disclose PHI for research purposes, but

[5] 80 Fed. Reg. 53933, 54045-46; *Id.* at 53953-54.

does not have any direct interaction with patients, the Common Rule should not apply.[6] Or if the registry receives or creates limited data sets from the PHI it collects as a business associate and/or enters into a data use agreement with the covered entity(ies) that provided the data, it should be able to perform research on those limited data sets without having to comply with the Common Rule. In such cases, the patient's privacy rights in his or her data are more than adequately protected by the HIPAA Rules for research or limited data sets.

Again, the rationale for the exception is that data collection activities that are subject to the more comprehensive privacy and security protections of the HIPAA Rules should not also be subject to the duplicative, but less rigorous protections of the Common Rule. All of the scenarios described above meet this standard. Whether the researchers involved are covered entities, business associates, or individuals or entities collecting data from covered entities should not matter, as long as the research is being conducted in compliance with the HIPAA Rules and the PHI was collected from covered entities. The last factor is critical because as long as the data is collected from covered entities, those entities and their business associates have a legal obligation to ensure that any research conducted on that data complies with the HIPAA Rules.

In sum, the Coalition strongly supports the creation of an exclusion for covered entities conducting research on PHI pursuant to the HIPAA Rules. However, this exclusion should be expanded to business associates and other researchers to the extent they are collecting PHI from covered entities and therefore are required (directly or indirectly) to comply with the HIPAA Rules for research. The Common Rule protections are simply not necessary for entities that are business associates or researchers required (by law or contract) to follow the HIPAA Rules for research involving PHI collected from covered entities. Thus, just as OHRP has done for the exemption for secondary research (discussed below), the agency could modify this exclusion to apply to business associates and other researchers collecting data from covered entities in compliance with the HIPAA Rules.

[6] In this respect, the NPRM statement that the proposed exclusions to the Common Rule will not require entities conducting research activities to "receive any form of determination or IRB approval–including expedited review," 80 Fed. Reg. at 53950, is incorrect. In many cases, covered entities, business associates, and other researchers collecting PHI from covered entities, including clinical data registries, will be required by the HIPAA Rules to obtain patient authorization or IRB waivers of authorization in order to use the PHI for research purposes. Such waivers would only be granted if the researcher has protections in place that the IRB deems adequate to protect the data. This is another example of how the HIPAA Rules provide equal or greater protection of patient privacy rights than the Common Rule.

3. OHRP's Proposed Exemption for the Secondary Research Use of Identifiable Private Information Should be Modified by Removing the Notice Requirement for Clinical Data Registries

The NPRM proposes a new exemption from IRB review (at § __.104(e)(2)) for the use of PHI for secondary research where the PHI has been or will be collected or generated for non-research purposes.[7] The proposed exemption will only apply if 1) prior notice has been given to the individuals to whom the PHI pertains that such information may be used in research; 2) the privacy safeguards under § __.105 are met; and 3) the PHI is used only for the purposes of the specific research for which the investigator or recipient entity requested access to the information. The NPRM states that the exemption would enable beneficial secondary research to occur without being impeded by administrative or IRB review, but with privacy safeguards to avoid harm and a notice requirement to show respect for patient choice.[8]

The Coalition supports the proposed IRB exemption for the secondary research use of PHI that is collected for non-research purposes. This exemption is necessary to allow clinical data registries to perform research on information that does not fall under the HIPAA exclusion, especially if OHRP does not make the modifications to the HIPAA exclusion that the Coalition has requested. Without this proposed exception, clinical data registries may still be subject to duplicative Common Rule requirements for secondary research on PHI they collect for quality improvement purposes. The proposed exemption also has adequate privacy protections, as clinical data registries conducting research must follow the privacy protections specified in § __.105(b). These privacy protections consist of compliance with either the specified HIPAA Rules or a list of specific measures that the Secretary of HHS shall establish that will be deemed to constitute the necessary privacy safeguards.

However, the patient notice requirement under this exemption completely defeats its utility for clinical data registries. Requiring prior notice to individuals that their information may be used in future research is unduly burdensome for clinical data registries. Many clinical data registries will find it difficult to utilize this exemption if the notice requirement remains. Clinical data registries collect information from thousands of patient encounters and it would be incredibly burdensome to notify each patient that his or her data could be used for research purposes. In effect, it means only data collected pursuant to a patient authorization or consent that includes the required notice would qualify for this exemption. The Coalition appreciates OHRP's mission to respect patient wishes and balance autonomy with beneficence, but the notice requirement could make this exemption functionally unavailable to most clinical data registries.

Moreover, the notice requirement is not necessary to protect patient rights for entities that are required to comply with the HIPAA Rules. As discussed in connection with the proposed HIPAA exclusions, the HIPAA Rules for research provide more protection for patient rights than the Common Rule. Thus, this proposed exemption would be not a viable alternative to the

[7] 80 Fed. Reg. 53933, 54409; *Id.* at 53963-66.
[8] *Id.* at 53963.

proposed HIPAA exclusion for clinical data registries unless OHRP removes the patient notice requirement for cases where the researcher is complying with the HIPAA research rules.

4. OHRP's Proposal to Mandate Central IRB Review for Cooperative Research Will Reduce Delays and Increase Efficiency of Review

The NPRM (at § __.114) requires institutions in the United States engaged in cooperative research to rely upon approval by a single IRB for all research conducted in the United States, with limited exceptions.[9] The reviewing IRB will be selected by the Federal department or agency supporting or conducting the research or, if there is no funding agency, by the lead institution conducting the research. The NPRM defines cooperative research as projects that involve more than one institution.[10]

The Coalition supports OHRP's proposal to mandate central IRB review for cooperative research. In the Advanced Notice of Proposed Rulemaking (ANPRM) for revisions to the Common Rule, as well as in guidance provided to the Coalition, OHRP has clearly stated that sites participating in a multi-center research study may rely on central IRB review and are not required to also obtain separate local IRB review and approval.[11] Clinical data registries often obtain a central waiver of the HIPAA authorization and Common Rule consent requirements allowing them to conduct secondary research on PHI collected from participants. However, notwithstanding OHRP's clear guidance in favor of central IRB review, many hospitals that participate in clinical data registries take the position that they must also obtain separate approval and waivers from their local IRBs before they can submit data to a registry for research purposes.

Without central IRB review, participants' involvement in clinical data registries can be significantly delayed due to processing time for local IRB approval and/or waivers. IRBs vary in processing time, and if an institution's IRB is extremely backlogged, that may substantially delay the hospital's ability to participate in the registry. Mandating central IRB review and approval will allow many hospitals to join clinical data registries without these undue delays.

In addition, mandating central IRB review will help decrease administrative burdens and costs of joining clinical data registries. If hospitals can rely on a registries' central IRB waiver of authorization and consent, they will save both time and money. If you multiply these savings over thousands of hospitals and scores of clinical data registries, the decrease in administrative costs is enormous.

The Coalition also supports the proposed three-year compliance date and believes three years is a sufficient amount of time to coordinate the implementation of the central IRB mandate.

[9] *Id.* at 54052; *Id.* at 53981-84.
[10] *Id.* at 54052.
[11] *See* "ANPRM for Revision of Common Rule," 76 Fed. Reg. 44412, 44521 (July 26, 2011).

5. OHRP's Proposal to Harmonize Agency Guidance is Necessary, But Should Be Modified to Require Harmonization Between the Common Rule and the HIPAA Rules

The NPRM (at §__.101(j)) states that the final guidance on the Common Rule shall only be issued after consultation, for the purpose of harmonization, with other Federal departments and agencies that have adopted the Common Rule, unless the consultation is not feasible.[12] The Coalition supports this provision, but requests that this provision be modified to also require consultation with OCR prior to harmonizing the Common Rule with the HIPAA Rules.

The HIPAA Rules and Common Rule overlap in numerous critical ways. Therefore, modifications to the Common Rule must be developed in consultation with OCR, which develops and oversees the HIPAA Rules.

In addition, wherever possible, OHRP should avoid creation of other non-HIPAA privacy or security rules or standards. For example, the NPRM at §__.105(b) requires researchers that collect, store, or use PHI to implement data security safeguards by following a list developed by the Secretary of HHS or through complying with the specified HIPAA Rules. The Coalition advocates for such data security standards to follow the HIPAA Rules as applicable, rather than encouraging the creation of yet another set of parallel privacy or security rules.

Conclusion

The Coalition appreciates this opportunity to comment on OHRP's proposed modifications to the Common Rule and its special efforts to accommodate the interests of clinical data registries. We strongly support the expansion of the quality assurance/improvement activities exclusion to include certain benchmarking activities undertaken for quality improvement purposes. We urge that OHRP adopt the HIPAA exclusion and the exemption for secondary research with our suggested revisions. We also support the proposed mandate for central IRB review and the harmonization of the Common Rule with the HIPAA Rules. These changes will reduce burdens on clinical data registries with no loss of protection for patient autonomy, privacy, or decision-making. Please contact Rob Portman at Powers Pyles Sutter & Verville PC if you have any questions (rob.portman@ppsv.com or (202) 872-6756).

Sincerely,

AMERICAN ACADEMY OF NEUROLOGY
AMERICAN ACADEMY OF OPHTHALMOLOGY
AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION
AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS/NEUROPOINT ALLIANCE
AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
AMERICAN COLLEGE OF SURGEONS

[12] 80 Fed. Reg. 53933, 54046; *Id.* at 53980-81.

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