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The CLIA/HIPAA Conundrum of Returning Test Results to Research Participants



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Introduction

Whether and under what circumstances individualized research results should be returned to study participants—and, in particular, whether test results from research laboratories should be returned—has drawn considerable attention from industry, academia and the larger research and data privacy communities. Research subjects who participate in research involving the testing of drugs and devices are typically in a physician-patient relationship with at least one of the study investigators. As a result, these research participants are often given real-time access to the results of tests conducted during research studies. In clinical trials, tests required by protocols are typically validated, widely supported by peer-reviewed clinical literature and performed in laboratories certified under the Clinical Laboratory Improvement Amendments (“CLIA”) that meet specific quality control/assurance standards, and there is consensus

about the desirability of returning the test results to the research participants. This consensus breaks down in the context of research laboratories that are not CLIA-certified and in regard to tests, whether performed in CLIA-certified or non-CLIA-certified laboratories, that are “research” in nature and not validated. Moreover, many research tests—such as genome and exome sequencing—are performed not only in the context of clinical trials, but in numerous later studies using banked biospecimens and data collected either in clinical care or clinical trials.

It has become increasingly common for academic and industry-sponsored studies to conduct tests in non-CLIA-certified research laboratories. These tests are performed as part of institutional review board (“IRB”)-approved research protocols, frequently using banked biospecimens and associated phenotypic data, and are conducted in non-CLIA-certified research laboratories, often with methods that are cutting-edge yet not fully validated. For these reasons, the clinical meaning of test results may be unclear. This can be the case with innovative genome or exome sequencing tests that are performed as part of an attempt to identify and understand the genetic markers of different types of diseases. Returning research test results to research participants is

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more complicated than returning validated tests because of various ethical and legal considerations. First, if performed in non-CLIA-certified research laboratories, research tests may lack the indicia of quality and reliability that are the hallmark of tests conducted in CLIA-certified settings. Second, regardless of the CLIA-certification status of the laboratory where tests are conducted, research tests that are not themselves validated may produce at best only equivocal meanings in regard to diagnosis, prognosis, and treatment. At the same time, some investigators and institutions have seen increasing interest by participants in their personal study results, even if there is no currently known value to the results; and when confronted with these requests, investigators and institutions have struggled with whether there is an ethical duty to provide them.

As a legal and regulatory matter, returning to participants the results of research tests performed in non-CLIA-certified laboratories constitutes a violation of CLIA regulations, according to the CLIA enforcement authorities' current regulatory interpretations. At the same time, if a non-CLIA-certified laboratory is subject to the Health Insurance Portability and Accountability Act ("HIPAA") or is part of a HIPAA-covered entity (such as a hospital, medical center or medical school), or if the entire research record is held by a HIPAA-covered entity, then research participants have a legal right to seek and receive their laboratory test results (including research results) if they are deemed to be part of the participant's "designated record set." Although it is arguable that such research test results were subject to individual right of access under HIPAA from the first enactment of the Privacy Rule, recent amendments to HIPAA have been widely interpreted as expanding this right of access to include research test results contained in a designated record set, thus effectively enabling a research participant to obtain the results of research tests performed in all laboratories that are subject to HIPAA, including those performed in non-CLIA-certified research laboratories. Significantly, the expanded right of access likely guarantees access to all of the raw data in a person's designated record set

upon request by the individual, even though the amendments contain no requirements or guidelines for provision of interpretive assistance. If regulators interpret the HIPAA term "designated record set" broadly—as they seem to do now—then a research participant may, as a result of his or her exercise of this right of access, receive masses of uninterpreted medical or genomic data without any guidance as to the data's clinical meaning or contextual significance. While this outcome may be consistent with the Department of Health and Human Services' ("HHS") intent, the practical consequences are impractical and ethically challenging.

Most importantly, the expanded right of access to research test results conflicts with the cognizant agency interpretation of CLIA requirements, under which test results (including their interpretation) may not be provided at all if the tests were performed in a non-CLIA-certified laboratory. This conflict between the legal requirements of CLIA and HIPAA—the regulations and interpretations of two offices within HHS—has therefore further complicated an already difficult set of ethical calculations regarding the return of research tests' results to research participants. In this article, we explore the inconsistencies in these laws, regulations and interpretations and recommend ways in which they may be more appropriately interpreted and applied.

This article will begin with an overview of some of the most important changes introduced by HHS's most recent regulation concerning the return of test results to individuals, followed by a detailed look at the potential implications for research laboratories, and finally, recommendations aimed at reconciling regulatory mandates regarding patients' and research participants' rights of access to their own health data.

Broadened Rights of Access to Personal Health Data, including the Results of 'Research Tests'

On Feb. 6, 2014, HHS adopted a new regulation regarding patients' right of access to laboratory test reports. The regulation, "*CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports*" (the "Regulation"), amends two regulatory regimes: (1) the existing Laboratory Requirements contained in Part 493 of regulations promulgated under CLIA, and (2) the Privacy Rule promulgated under HIPAA (the "Privacy Rule").¹ The Regulation's amendments became effective on April 7, 2014, and the deadline for compliance with amendments to the Privacy Rule was Oct. 6, 2014.² The Privacy Rule amendments are particularly significant because they expand patients' right of access to records in the "designated record set" to include laboratories that were previously exempt from such requirements.³ These regulatory changes could have a major

¹ CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. 7290 (Feb. 6, 2014) (amending 42 C.F.R. § 493.1291; 45 C.F.R. § 164.524).

² *Id.* at 7290, 7292.

³ *Id.* (explaining that "this final rule amends the . . . HIPAA Privacy Rule to provide individuals . . . with the right to access test reports directly from laboratories subject to HIPAA . . . by removing the exceptions for CLIA-certified laboratories and CLIA-exempt laboratories from the provision that provides individuals with the right of access to their protected health in-

impact on laboratories that perform testing for research subjects, including genome-sequencing and exome-sequencing studies.

One of the driving forces behind the Regulation was to increase patients' rights of access to their own health information—specifically in the context of laboratory test reports—to empower patients “to take a more active role in managing their health” and “take action to prevent and control disease.”⁴ While the Regulation contains provisions that could increase patient access to test reports and potentially empower patients to take health-related actions based on the reports, the Regulation's ultimate impact remains an open issue with respect to research laboratories that are not subject to CLIA-certified requirements. These laboratories include genomic testing laboratories and other research laboratories belonging to larger academic medical centers, which have not traditionally been subject to CLIA. The Regulation's ultimate impact on research laboratories will be determined by how HHS responds to persistent questions regarding regulatory intent and enforcement.

First, regarding regulatory intent, it remains unclear whether the Centers for Medicare and Medicaid Services (“CMS”), the HHS office that administers CLIA, intended to subject research laboratories to the Privacy Rule's right-of-access obligations or whether the imposition of this legal obligation was an unintended consequence of past regulatory guidance. Second, regarding regulatory enforcement, it is unclear whether CMS or the Office for Civil Rights (“OCR”), the HHS office responsible for enforcing HIPAA, will exercise their enforcement discretion in regard to those research laboratories on which the Regulation has imposed an obligation of making records available to patients and research participants who request them. Third, multiple critical factors that are still unknown will determine the Regulation's impact on research laboratories. These factors include the extent to which individuals (including research participants) actually submit requests for access to their test reports; the position that OCR takes with respect to which specific genomic data or research results form part of the HIPAA-covered entity's “designated record set” to which persons have a right of access; the potential development and marketing of tools to analyze and interpret genomic data; and how different research laboratories, investigators, privacy offices and IRBs respond to these new legal obligations.

Most significantly for institutions subject to legal requirements under CLIA and HIPAA, the Regulation appears to create several inconsistencies between (i) the obligations that the Regulation imposes on all laboratories to provide access to laboratory test reports upon an individual's request,⁵ and (ii) CMS's broad interpretation that CLIA prohibits the return of test results produced in non-CLIA-certified laboratories.⁶ The Regulation's mandate that research test results in a designated record set be provided to participants who seek those results also challenges research protocols and institutional practices that prohibit the return of unvalidated and non-actionable research test results.

formation”) (amending 45 C.F.R. § 164.524). For further discussion, see footnote 20 and accompanying text.

⁴ *Id.*

⁵ See *id.*; see also 45 C.F.R. § 164.524 (2015).

⁶ See 42 C.F.R. § 493.3(b)(2) (2015); see also footnote 36 and accompanying text for further discussion.

Access to Test Results under CLIA and HIPAA

The Regulation enhances patients' right of access to certain laboratory results by amending provisions in two separate federal regulatory regimes: CLIA and HIPAA. In the case of CLIA, the Regulation's amendment provides for *permissive* access to test reports upon request by a patient (or the patient's personal representative) as long as the following conditions are met: (i) the laboratory from which the test reports are requested must be subject to CLIA under the law's definitional provisions⁷; (ii) test reports must be “completed”⁸; (iii) test reports must be capable of being “identified” as belonging to an individual patient through use of the laboratory's authentication process; and (iv) the request must be made by a patient or the patient's personal representative.⁹ Under CLIA, a CLIA-certified laboratory is not required to provide access or return such test reports to a patient or research participant,¹⁰ but instead is *permitted* to provide access upon request by the patient (or his or her personal representative).¹¹

The Privacy Rule, on the other hand, provides that HIPAA-covered entities *must* allow access to *all* of the protected health information (the “PHI”) about an individual maintained in the individual's “designated record set,”¹² including laboratory test reports, upon request by an individual (or the individual's personal representative),¹³ if the following conditions are met: (i) the entity from which the PHI is requested must be a “covered entity” under HIPAA's general definitional provisions (the “HIPAA-covered entity” or “covered entity”)¹⁴; (ii) the information being requested must be contained in the designated record set and actually retained by the covered entity; and (iii) the covered entity

⁷ See 42 C.F.R. § 493.2 (2015) (defining a “Laboratory” as a facility that examines “materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings”).

⁸ As discussed below, HHS has indicated that a test becomes “complete” when “all results associated with an ordered test are finalized and ready for release.” CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7295.

⁹ 42 C.F.R. § 493.1291(i) (2015).

¹⁰ *Id.* (allowing for the provision of test reports to other “designated” persons so long as the designation procedure specified in 45 C.F.R. § 164.524(c)(3)(ii) is followed).

¹¹ *Id.*; see also CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7292 (explaining that “With respect to CLIA regulations, this final rule *allows* laboratories subject to CLIA . . . to provide access” (emphasis added); see also 79 Fed. Reg. at 7291 (“[w]hile we proposed to use the word ‘may,’ we highlighted the importance of reading the proposed amendments to the CLIA regulation in concert with the proposed changes to the HIPAA Privacy Rule . . . which would require covered entity laboratories to provide patients with access to test reports”).

¹² See 45 C.F.R. § 164.501 (2015) for the HIPAA definition of “designated record set,” discussed below.

¹³ 45 C.F.R. § 160.103 (2015) (defining an “individual” as “the person who is the subject of protected health information”).

¹⁴ 45 C.F.R. § 160.103 (defining a “covered entity” as “[a] health plan, [a] health care clearinghouse, [or a] health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter”).

must verify the identity and access authority of the person requesting the PHI.¹⁵

Before the Regulation's compliance deadline of Oct. 6, 2014, the Privacy Rule's access provisions contained a specific exception for "CLIA-certified" and "CLIA-exempt" laboratories, thus allowing these entities to refuse to honor individuals' requests for access to their test results.¹⁶ The Regulation's amendment to the Privacy Rule removed this exception. As a result, every laboratory that is, or is part of, a HIPAA-covered entity is now subject to the Privacy Rule's access requirements. As explained below, this currently appears to include laboratories that meet the CLIA definition of "research laboratories," despite a contradictory CMS interpretation that CLIA prohibits such laboratories from providing access to test reports to patients or research participants.¹⁷

Research Laboratories

The Regulation has significant implications for research laboratories that have not traditionally been subject either to CLIA¹⁸ or the Privacy Rule's individual access obligations, based on the interpretation offered in the preamble to the original Privacy Rule.¹⁹ These include genomic testing laboratories that perform next-generation sequencing ("NGS") and research laboratories that are part of health-care and research entities (such as academic medical centers) that are subject to HIPAA requirements. If a research laboratory is part of a HIPAA-covered entity, it must now comply with the Privacy Rule's access requirements²⁰ even though its return of laboratory test reports (or research results) to patients or research participants would be inconsistent with CMS's broad interpretation of CLIA as barring the return of results unless the laboratory is CLIA-certified or CLIA-exempt.²¹

Part of the confusion may stem from the Privacy Rule's use of terms that are defined in CLIA. These include the terms "CLIA-certified laboratory" and "CLIA-exempt laboratory." CLIA defines a "CLIA-exempt laboratory" as "a laboratory that has been licensed or approved by a State where CMS has determined that the State has enacted laws relating to laboratory re-

quirements that are equal or more stringent than CLIA requirements."²² This currently includes laboratories located in the states of New York and Washington, which maintain state laboratory licensure regimes that are deemed to be at least equivalent to CLIA requirements. CLIA also contains a definition for "research laboratories," defining them as "laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, individual patients."²³ While "research" and "CLIA-exempt" laboratories are both *functionally exempt* from CLIA certification requirements, "research laboratories" are not technically included in CLIA's definition of "exempt" laboratories. "Research laboratories" and "CLIA-exempt" laboratories are different types of laboratories with different definitions. Therefore, based on a purely textual reading of the Regulation, it would appear that its modifications to the Privacy Rule to require access to results generated by "CLIA-certified" and "CLIA-exempt" laboratories would not implicate "research laboratories," since such laboratories do not fit within CLIA's definition of "CLIA-certified" or "CLIA-exempt" laboratories.

However, longstanding OCR commentary regarding the Privacy Rule has interpreted the term "CLIA-exempt" to include "research laboratories" for purposes of the Privacy Rule even though, as explained above, this interpretation differs from the specific definitions that CLIA gives to these terms.²⁴ Accordingly, when the Regulation modified the Privacy Rule to require provision of access to test results by "CLIA-exempt" laboratories that are part of HIPAA-covered entities, under existing OCR guidance that change swept "research laboratories" subject to HIPAA into the category of laboratories now subject to the Privacy Rule's right of access obligations.²⁵ It therefore appears that CLIA "research laboratories" that are part of HIPAA-covered entities must fully comply with the Privacy Rule's access obligations, which puts institutions at risk of violating CMS's interpretation of the CLIA "research laboratory" provision as prohibiting return of results unless laboratories become CLIA-certified and forfeit their "research laboratory" status in the process. While such a result seems contradictory, the Regulation and its accompanying preamble do not mention the term "research laboratories" even once, and neither OCR nor CMS has issued written guidance to clarify the obligations of "research laboratories" under the Regulation or the amended Privacy Rule.

Additional uncertainty and potential for inconsistent practices is created by the fact that the right of access under HIPAA extends only to records that are held as part of a covered entity's "designated record set." HIPAA defines the term "designated record set" to include (1) medical records, (2) billing records and (3) in-

¹⁵ See 45 C.F.R. § 164.514(h) (2015) for verification requirements that apply prior to any disclosure being permitted.

¹⁶ CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7290.

¹⁷ Remarks of Penelope Meyers, Technical Director, CLIA, CMS, delivered at March 25, 2015, meeting of HHS Secretary's Advisory Committee on Human Research Protections ("SACHRP"), pp. 19-21, accessible at <http://www.perma.cc/EY3W-BYTB>.

¹⁸ *Id.*

¹⁹ See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,485 (Dec. 28, 2000) ("[W]e have also excluded covered entities that are exempt from CLIA under that rule [the exception from CLIA-certification requirements for 'research laboratories'] from the access requirement of this regulation").

²⁰ 45 C.F.R. § 164.524; see also CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7290 (explaining that "[w]e do not believe it is appropriate to only permit rather than require HIPAA-covered laboratories to provide individuals with access to their test reports").

²¹ Remarks of Penelope Meyers, Technical Director, CLIA, CMS, delivered at March 25, 2015, meeting of HHS SACHRP at pp. 19-21.

²² 42 C.F.R. § 493.2.

²³ 42 C.F.R. § 493.3(b)(2).

²⁴ See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. at 82,485 ("[W]e have also excluded covered entities that are exempt from CLIA under that rule [the exception from CLIA-certification requirements for 'research laboratories'] from the access requirement of this regulation"). Presumably, this statement was an attempt to avoid conflict between CLIA and the new Privacy Rule.

²⁵ *Id.*

formation that may be used, in whole or in part, by or for the covered entity to make decisions about individuals.²⁶ Accordingly, covered entities have generally believed that PHI that is generated during research could be excluded from the designated record set if such PHI were (i) excluded from the research participant's medical or billing records and (ii) not otherwise available to make treatment or other decisions about the individual or others. However, the preamble to the Regulation states that "[l]aboratory test reports that are maintained by or for a laboratory that is a covered entity are part of a designated record set."²⁷ In response to a comment, the Regulation also states that "[f]or purposes of this final rule . . . we do not consider test reports to be part of the designated record set until they are complete,"²⁸ and that a test becomes "complete" when "all results associated with an ordered test are finalized and ready for release."²⁹ These statements suggest that laboratory test reports typically become part of a covered entity's designated record set and therefore accessible as long as they are maintained by or for the laboratory and are "complete;" there is, therefore, no obvious path for a covered entity to exclude such results from its designated record set. OCR could provide greater clarification on this point by issuing guidance indicating that a laboratory may exclude tests results from its designated record set if the tests are part of a research study and have uncertain clinical significance or if the clinical significance of the tests is so uncertain that the tests should not be considered "complete." Alternatively, in line with its preference for broader personal rights of access to data, OCR could indicate through guidance that broader access to records, including research test results, is indeed intended, regardless of the clinical significance of the data.

In its current form, the Regulation creates an uncertain regulatory framework for research laboratories. Members of the research community have analyzed with a great level of detail the impact that the Regulation could have on research laboratories that conduct genome and exome sequencing and NGS studies.³⁰ First, regarding the requirement that test reports become part of the designated record set once "complete," some have noted that CMS's commentary addresses when, but not what types of, test-related data laboratories must add to an individual's designated record set pursuant to the amended Privacy Rule.³¹ As a result of the Regulation, because nothing in CLIA or the Privacy Rule requires that genetic testing results be provided together with interpretation of the results, laboratories with data-only business models that supply uninterpreted variant data as their final work product may now be required to return uninterpreted genetic findings in data-only form to research participants upon their request.³² As interpreted by some members of the research community, the type of data that genomic test-

ing laboratories may be required to add to the designated record set could vary for different genomic testing file types. Second, the "potential use" criterion for the "designated record set," which requires that the designated record set include information that may be wholly or partially used by or for the covered entity to make decisions about individuals, could mean that information about a genetic marker for a congenital disorder must be included in the designated record set even if the subject does not have a diagnosis for the disorder.³³ As anticipated by some, the potential use requirement places NGS findings in a "Pandora's Box" due to the ongoing development and marketing of genomic analyses tools notwithstanding the uncertainties surrounding the clinical relevance of many of the genomes and genetic markers involved.³⁴

Potential Solutions to the Perceived Conflict between the Regulation and CMS's Interpretation that CLIA Prohibits Return of Research Results

CLIA prohibits "research laboratories" from returning or otherwise reporting patient-specific results for treatment or health assessment purposes.³⁵ One might think that a quick, practical compliance solution for research laboratories that are now subject to the Privacy Rule's right of access obligations would be to return research results to subjects with a disclaimer that explains that the results are not for treatment or health assessment purposes and that subjects should seek treatment through their regular health care provider. This "quick fix" would potentially enable research laboratories to comply with the Privacy Rule's access obligations—i.e., a release required by law—and simultaneously avoid violating CLIA by not returning results "for treatment or health assessment purposes."

However, CMS removed this compliance option when it took the position that it would regard any return of research results—even the use of results to decide to counsel patients or research participants that they should seek additional testing from a CLIA-certified laboratory—as being for "treatment purposes."³⁶ As a result, research laboratories subject to HIPAA are now caught in a double-bind: either they are fully compliant with the Privacy Rule and CLIA, which would entail obtaining CLIA certification and forfeiting the laboratory's CLIA "research" status, or they run the risk of violating the Privacy Rule in order to remain CLIA-compliant.³⁷ With criminal penalties available

³³ *Id.*

³⁴ *Id.*

³⁵ See 42 C.F.R. § 493.3(b)(2).

³⁶ Remarks of Penelope Meyers, Technical Director, CLIA, CMS, delivered at March 25, 2015, meeting of HHS SACHRP, p. 21, accessible at <http://www.perma.cc/EY3W-BYTB>.

³⁷ CMS has publicly suggested that if non-CLIA-certified research laboratories wish to be able to return test results to research participants, then such laboratories should obtain CLIA certification; this way, CMS has asserted, the return of research test results to participants would present no compliance problems because the laboratories would be complying with both regulations by fulfilling their obligations under HIPAA and becoming CLIA-certified. Remarks of Penelope Meyers, Technical Director, CLIA, CMS, delivered at March 25, 2015, meeting of HHS SACHRP at p. 19.

²⁶ 45 C.F.R. § 164.501.

²⁷ CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7291.

²⁸ *Id.* at 7295.

²⁹ *Id.*

³⁰ See, e.g., B. Evans et al., *Regulatory changes raise troubling questions for genomic testing*, Am. College of Med. Genetics and Genomics (November 2014).

³¹ *Id.*

³² *Id.*

and civil monetary penalties for Privacy Rule violations running as high as \$50,000 or more per violation, and amounts depending on factors like the covered entity's intent,³⁸ obtaining CLIA certification could be perceived as necessary for research laboratories that are covered entities and that seek to assure compliance with both HIPAA and CLIA.

Obtaining CLIA certification simply in order to be able to comply with the Privacy Rule's right of access would, however, be a costly venture. It generally involves an application; certification fees that vary per certificate; documentation of policies and procedures for the different tests administered in the laboratory; CMS audits and on-site inspections to assess program compliance; proficiency testing; specific education, training and experience requirements for laboratory staff; and additional requirements. While CMS has publicly suggested that research laboratories that wish to be able to return results to research participants, even if on a case-by-case basis, should obtain CLIA certification to avoid compliance problems,³⁹ this is not a realistic alternative given the magnitude of the transaction costs involved in becoming and remaining CLIA-certified, although it theoretically would be the most compliant strategy. Indeed, a research laboratory's obtaining CLIA certification would be costly and infeasible, and obtaining CLIA certification would be a nearly insurmountable barrier to entry for new research laboratories, thus potentially stifling innovation. For all these reasons, other alternatives must be considered.

First, to avoid triggering the Privacy Rule's obligations that covered entities allow persons access to their "designated record set," research laboratories might be carved out of a HIPAA-covered entity. For example, if a research laboratory is part of a larger entity that constitutes a covered entity, such as an academic medical center, a research laboratory might be placed into an affiliated non-covered entity, although such a solution would impose high transaction costs as well as ongoing complications of sharing information between covered and non-covered entities. An academic medical center might also choose to become a "hybrid entity" under HIPAA, carving out the research laboratories from the covered entity portion, but this would entail breaking down the corporate entity into "covered" and "non-covered" components, also imposing high transaction and ongoing compliance costs.⁴⁰ Further, because a health care provider's status as a covered entity depends on whether the provider conducts any of HIPAA's standard electronic transactions, most of which are tied to reimbursement claims submissions, the few free-standing research laboratories could cease billing insurers for experimental, unvalidated tests and for other tests and services, thus avoiding covered-entity status altogether.

One should also recall that research participants' right to access test results or other information may be suspended during the course of research, but only if such a suspension is specified in the research protocol

³⁸ See 45 C.F.R. § 160.404 (2015).

³⁹ Remarks of Penelope Meyers, Technical Director, CLIA, CMS, delivered at March 25, 2015, meeting of HHS SACHRP at p. 19.

⁴⁰ See 45 C.F.R. § 164.105 (2015) (establishing requirements for a "hybrid entity").

and informed consent/authorization form.⁴¹ This is, however, a solution that lasts only as long as the research is in progress or for the duration of the trial itself; the right of access must be reinstated upon completion of the research.⁴² Alternatively, an institution might define a "designated record set" as not including test results from non-CLIA-certified laboratories and/or as not including results from unvalidated tests, resulting in a situation in which HIPAA access rights would not require provision of the results. In addition, only "completed" test results are subject to HIPAA access rights. However, because of a lack of specific OCR guidance, the definitions of a "designated record set" or of a "completed" test result remain unclear.

Ethical Issues

The Regulation specifies that, in general, a HIPAA-covered entity may deny an individual access to his or her health information "only with respect to endangerment of the life or physical safety of the individual or another person."⁴³ HHS recognized the narrowness of the grounds for denial when, in responding to comments, it indicated that this is "a very limited exception" and that "concerns about psychological or emotional harm are not sufficient to justify denial of access."⁴⁴ HHS made clear that "covered entities may not deny an individual access to his or her health information based on the information's sensitive nature or potential for causing distress to the individual."⁴⁵

The ethical foundation for providing access to research results includes a desire to provide recognition and appreciation for the subject's autonomous and altruistic decision to participate in research. The ethical foundation for access also recognizes that some research results may prove valuable to guide the behavior and health-related decision-making process of participants and their families. Returning such potentially actionable research results to participants may be useful to them and may lead to greater public trust in research and a higher level of individual willingness to participate in studies.

However, some ethicists argue that providing access becomes less compelling as the information loses its clinical value and thus its usefulness to guide or help inform health-related actions of research participants. Indeed, the value of individual results to subjects often has depended on the validity and degree to which the individual may reasonably rely on the information to guide his or her health behaviors. This position informs general research protocols and institutional policies that prohibit or prevent the return of unproven and non-actionable results.⁴⁶ This concern for the validity and reliability of research test results also underlies CLIA's

⁴¹ 45 C.F.R. § 164.524(a)(2)(iii) (2015).

⁴² *Id.*

⁴³ CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7296 (citing 45 C.F.R. § 164.524(a)(3)(i)).

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ See, e.g., B. Evans et al., *Regulatory changes raise troubling questions for genomic testing*, Am. College of Med. Genetics and Genomics (November 2014); see also Burke et al., *Return of results: ethical and legal distinctions between re-*

prohibition on non-CLIA-certified laboratories' provision of access to test reports.

The access right that the amended Privacy Rule affords raises genuine concerns, in that research participants exercising that right may receive research test results—especially genetic testing results—that may be unreliable, non-actionable and/or of ambiguous clinical meaning. Some have argued that providing research participants with results from unvalidated tests, especially those not performed in the quality-controlled CLIA setting, is a disservice to these participants, who may make personal choices based on flawed or uncertain information. At the same time, research participants may prefer—and arguably should have the right to prefer—receiving even flawed or ambiguous information to receiving no information at all. Although non-scientific laypersons may not have the tools that are necessary to comprehend the data fully or against the appropriate contextual baseline, the solution here would lie in allowing researchers and physicians to counsel research participants about test results. Indeed, in issuing the Regulation theoretically to empower patients “to take a more active role in managing their health”⁴⁷ yet simultaneously failing to provide guidelines that would be instrumental in assessing the value of test results, HHS arguably has not fully empowered research participants. The Regulation would have better served patient and research participant interests if it had taken into account the wide variety of research tests conducted by CLIA-certified and non-CLIA-certified laboratories. A more nuanced approach to assuring access rights to laboratory data would have included interpretive assistance guidelines, under which researchers and laboratorians could, with impunity, counsel research participants on the context or clinical value (or lack thereof) of the research information.

Because the Regulation fails to address access rights specifically in the context of research laboratories, HIPAA-covered entities (including their research laboratories), IRBs, privacy offices and investigators will wrestle with difficult ethical and legal dilemmas, weighing rights of access to research information against the harm that could come from the disclosure, and weighing the mandate to share certain results upon an individual's request against CMS's interpretation of CLIA as prohibiting the sharing of results generated in non-CLIA-certified laboratories. Genomic testing laboratories that are within HIPAA-covered entities will have to decide, among other things, whether they would like to

provide interpretive assistance for research participants to help them understand test reports or research results, especially when data-only genomic files are requested. Although in issuing the Regulation, HHS considered but declined to impose or recommend interpretive assistance requirements or guidelines despite interested parties' requests to the contrary,⁴⁸ genomic testing laboratories and investigators may find that they have an ethical imperative to provide such assistance. Further, IRBs, investigators and research institutions will need to decide whether studies involving especially sensitive reports or findings should be conducted in non-HIPAA-covered laboratories that are not subject to the Privacy Rule's right of access provision.

Conclusion

The Regulation represents a step forward in increasing patients' and research participants' access to laboratory test reports. However, CMS should consider a more nuanced approach for research laboratories that (i) takes into account their conflicting obligations under the Privacy Rule, as amended by the Regulation, and CLIA, as currently interpreted by CMS, and (ii) that addresses the variety of test results in terms of their data sensitivity, clinical utility, reliability and the ethical obligations of investigators.

In the face of these uncertain ethical and legal obligations to research participants, and the conflicting interpretations of two of its own divisions, HHS must clarify whether the Regulation indeed expands the Privacy Rule's right of access to apply fully to non-CLIA-certified research laboratories that are within HIPAA-covered entities. In the meantime, OCR could exercise enforcement discretion not to take action against non-CLIA-certified research laboratories if the laboratories decline to provide access while OCR and CMS resolve what appear to be conflicting compliance directives. OCR should also provide guidance on how covered entities should define an individual's “designated record set” and “completed” test results in the context of research laboratories and research test results; optimally, these definitions should afford to covered entities some limited discretion to define “designated record set” and “completed” test results as calibrated to their clinical or personal utility and potential “actionability.” Moreover, as the CLIA enforcement authority, CMS could relieve some of the immediate ethical and legal anxiety in the research laboratory community by not regarding as a CLIA violation the counseling of a patient/research participant with a clinically significant research test result produced by a non-CLIA-certified laboratory to seek retesting in a CLIA-certified laboratory.

search and clinical care, Am. J. Med. Genet. C. Semin. Med. Genet. 2014 Mar; 166C(1): 105-11.

⁴⁷ CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. at 7290.

⁴⁸ *See id.* at 7302-03.