

Attachment H

Health Insurance Portability and Accountability Act (HIPAA) Business Associate Requirements

DEFINITIONS

Terms used, but not otherwise defined, in this Schedule shall have the same meaning as those terms are defined in 45 Code of Federal Regulations (CFR) sections 160.103, 164.304, and 164.501. All regulatory references in this Schedule are to Title 45 of the Code of Federal Regulations unless otherwise specified.

- a. **Business Associate.** "Business Associate" shall generally have the same meaning as the term "business associate" at 45 CFR 160.103, and in reference to the parties to this agreement shall mean Verily.
- b. **Covered Entity.** "Covered entity" shall generally have the same meaning as the term "covered entity" at 45 CFR 160.103, and in reference to the party to this agreement shall mean County.
- c. **HIPAA Rules.** "HIPAA rules" shall mean the Privacy, Security, Breach Notification and Enforcement Rules at 45 CFR part 160 and part 164, as amended and supplemented by Subtitle D of the Health Information Technology for Economic and Clinical Health Act provisions of the American Recovery and Reinvestment Act of 2009.
- d. **Designated Record Set.** "Designated Record Set" shall have the same meaning as the term "designated record set" in Section 164.501.
- e. **Electronic Protected Health Information.** "Electronic Protected Health Information" (EPHI) means individually identifiable health information that is transmitted or maintained in electronic media; it is limited to the information created, received, maintained or transmitted by Business Associate from or on behalf of Covered Entity.
- f. **Individual.** "Individual" shall have the same meaning as the term "individual" in Section 164.501 and shall include a person who qualifies as a personal representative in accordance with Section 164.502(g).
- g. **Privacy Rule.** "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E.
- h. **Protected Health Information.** "Protected Health Information" (PHI) shall have the same meaning as the term "protected health information" in Section 160.103 and is limited to the information created or received by Business Associate from or on behalf of County.
- i. **Required By Law.** "Required by law" shall have the same meaning as the term "required by law" in Section 164.103.
- j. **Secretary.** "Secretary" shall mean the Secretary of the United States Department of Health and Human Services or his or her designee.
- k. **Breach.** The acquisition, access, use, or disclosure of PHI in violation of the Privacy Rule that compromises the security or privacy of the PHI and subject to the exclusions set forth in Section 164.402. Unless an exception applies, an impermissible use or disclosure of PHI *is presumed* to be a breach, unless it can be demonstrated there is a low

probability that the PHI has been compromised based upon, at minimum, a four-part risk assessment:

1. Nature and extent of PHI included, identifiers and likelihood of re-identification;
 2. Identity of the unauthorized person or to whom impermissible disclosure was made;
 3. Whether PHI was actually viewed or only the opportunity to do so existed;
 4. The extent to which the risk has been mitigated.
- l. **Security Rule.** "Security Rule" shall mean the Security Standards for the Protection of Electronic Protected Health Information at 45 CFR Part 160 and Part 164, Subparts A and C.
- m. **Unsecured PHI.** "Unsecured PHI" is protected health information that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary in relevant HHS guidance.
- n. **Security Incident.** "Security Incident" shall mean the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with systems operations in an information system. "Security Incident" includes all incidents that constitute breaches of unsecured protected health information.

OBLIGATIONS AND ACTIVITIES OF VERILY AS BUSINESS ASSOCIATE

- a. Business Associate agrees to not use or further disclose Protected Health Information other than as permitted or required by the Agreement, inclusive of this Schedule, or as Required by Law.
- b. Business Associate agrees to use appropriate safeguards to comply with Subpart C of 45 CFR part 164 with respect to EPHI and PHI, and to prevent the use or disclosure of the Protected Health Information other than as provided for by this Agreement.
- c. Business Associate agrees to make uses and disclosures of, and requests for, Protected Health Information consistent with minimum necessary policy and procedures.
- d. Business Associate may not use or disclose protected health information in a manner that would violate subpart E of 45 CFR part 164.504 if used or disclosed by Covered Entity.
- e. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.
- f. Business Associate agrees to report to County any use or disclosure of Protected Health Information not authorized by this Agreement.
- g. Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of County, agrees to adhere to similarly legally required restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.
- h. If Business Associate has Protected Health Information in a Designated Record Set, Business Associate agrees to provide access, at the request of County, and in the time and manner designated by County, to Protected Health Information in a Designated

Record Set, to County or, as directed by County, to an Individual in order to meet the requirements under Section 164.524.

- i. If Business Associate has Protected Health Information in a Designated Record Set, Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the County directs or agrees to make pursuant to Section 164.526 at the request of County or an Individual, and in the time and manner designed by County.
- j. Business Associate agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of County, available to the County at the request of County or the Secretary, in a time and manner designated by the County or the Secretary, for purposes of the Secretary determining County's compliance with the Privacy Rule.
- k. Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for County to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with Section 164.528.
- l. Business Associate agrees to provide to County in the time and manner designated by County, information collected in accordance with Section (k) of this Schedule, in order to permit County to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with Section 164.528.
- m. Business Associate shall implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of EPHI that Business Associate creates, receives, maintains, or transmits on behalf of County.
- n. Business Associate shall conform to generally accepted system security principles and the requirements of the final HIPAA rule pertaining to the security of health information.
- o. Business Associate shall ensure that any agent to whom it provides EPHI, including a subcontractor, agrees to implement reasonable and appropriate safeguards to protect such EPHI.
- p. Business Associate shall report to County any Security Incident that is not an Unsuccessful Security Incident (as defined below) within ten (10) business days of becoming aware of such incident. Business Associate shall also facilitate breach notification(s) to the appropriate governing body (i.e. HHS, OCR, etc.) as required by law. As appropriate and after consulting with County, Business Associate shall also notify affected individuals and the media of a qualifying breach. Business Associate hereby notifies County of pings and other broadcast attacks on a firewall, denial of service attacks, port scans, unsuccessful login attempts, interception of encrypted information where the encryption key is not compromised, and other Unsuccessful Security Incident. Business Associate will provide additional information about Unsuccessful Security Incidents on a reasonable basis, orally or in writing, if requested by County. **“Unsuccessful Security Incident”** means a Security Incident that does not involve unauthorized access, use, disclosure, modification or destruction of EPHI or interference with an information system in a manner that poses a material threat to the confidentiality, integrity, or availability of the EPHI.

- q. Business Associate understands that it is directly liable under the HIPAA rules and subject to civil and, in some cases, criminal penalties for making uses and disclosures of Protected Health Information that are not authorized by this Attachment, the underlying contract as or required by law.

PERMITTED USES AND DISCLOSURES BY VERILY AS BUSINESS ASSOCIATE

Except as otherwise limited in this Schedule, Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, County as specified in the Agreement; provided that such use or disclosure would not violate the Privacy Rule if done by County.

Without limiting the foregoing and notwithstanding anything in the Agreement or this Attachment H to the contrary, Business Associate may do the following:

- a. ***Use and Disclosure for Management and Administration and Public Health Purposes.*** Use and disclose PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate, provided that such disclosures are required by law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and will be used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies Business Associate of any instances of which it is aware that the confidentiality of the information has been breached. For clarity, the Services performed for SMC, as well as the management and administration of those services, and use of PHI for public health purposes, involve the processing of PHI to produce analytics and research that is anticipated to be of use to public health authorities and Verily in their conduct of the testing program.
- b. ***Provision of Data Aggregation Services.*** Use PHI to provide data aggregation services to SMC and other local and state health authorities. Data aggregation means the combining of PHI created or received by Business Associate on behalf of SMC with PHI received by Business Associate in its capacity as Business Associate of another covered entity, to permit data analyses that relate to the successful operation and continuous improvement of the Services conducted for SMC.
- c. ***De-identification of PHI.*** Business Associate may use PHI to create de-identified health information. Such data de-identification shall be performed in accordance with the California Health and Human Services Agency Data De-Identification Guidelines (Sept. 23, 2016), and otherwise in accordance with the HIPAA de-identification requirements. Business Associate may use de-identified data for purposes of developing COVID-19-related products and services.
- d. ***Contact for Research; Research and Analytics.*** Business Associate may use Participant contact information to contact Participants to obtain their authorization to use and disclose such Participants' PHI for research purposes and to conduct further outreach to such Participants based on the public health need for rapid recruitment into clinical trials and other research; Business Associate may base such outreach on the results of a Participant's COVID-19 test results and other Participant data and may conduct research

and analytics based on Participant Data: (i) if directed by the State of California, (ii) at the request of a County, the federal government, or other relevant governmental authorities for such purpose, (iii) as required by law, or (iv) as otherwise legally authorized by Participants. Business Associate may further use or disclose PHI for public health purposes to the extent such activities would be permitted as a disclosure for public health purposes under 45 C.F.R. § 164.512(b)(1).

OBLIGATIONS OF COUNTY

- a. County shall provide Business Associate with the notice of privacy practices that County produces in accordance with Section 164.520, as well as any changes to such notice.
- b. County shall provide Business Associate with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect Business Associate's permitted or required uses and disclosures.
- c. County shall notify Business Associate of any restriction to the use or disclosure of Protected Health Information that County has agreed to in accordance with Section 164.522.

PERMISSIBLE REQUESTS BY COUNTY

County shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if so requested by County, except to the extent that Business Associate will use or disclose Protected Health Information for data aggregation or management and administrative activities of Business Associate.

DUTIES UPON TERMINATION OF AGREEMENT

- a. Upon termination of the Agreement, for any reason, Business Associate shall retain only that PHI which is necessary for Business Associate to continue its proper management and administration (e.g., contacting participants as required or authorized in connection with the conduct of the testing program; use of PHI for public health purposes and to produce analytics and research that is anticipated to be of use to public health authorities and Verily in their conduct of the testing program), or to carry out its legal responsibilities. Business Associate shall return or destroy all remaining Protected Health Information received from County, or created, maintained, or received by Business Associate on behalf of County, that Business Associate still maintains in any form. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate.
- b. In the event that Business Associate determines that returning or destroying Protected Health Information is infeasible, Business Associate shall provide to County notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of Protected Health Information is infeasible, Business Associate shall extend the protections of the Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protection Health Information.

MISCELLANEOUS

- a. **Regulatory References.** A reference in this Schedule to a section in the HIPAA Privacy Rule means the section as in effect or as amended, and for which compliance is required.
- b. **Amendment.** The Parties agree to take such action as is necessary to amend this Schedule from time to time as is necessary for County to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act, Public Law 104-191.
- c. **Survival.** The respective rights and obligations of Business Associate under this Schedule shall survive the termination of the Agreement.
- d. **Interpretation.** Any ambiguity in this Schedule shall be resolved in favor of a meaning that permits County to comply with the Privacy Rule.
- e. **Security Audit.** Verily agrees that County shall have the right to review and to copy any records and supporting documentation evidencing Verily's compliance with the security requirements in this Attachment H. Verily agrees to maintain such records for possible audit for a minimum of three (3) years after expiration or termination of the Agreement. Verily agrees to allow County access to such records during normal business hours.