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Monday, September 22, 2025

RE: Legal justification to remove requirement for BAA.

Dear Hospital Administrator:

This letter serves as California Transplant Services, Inc.'s response to your request for a letter providing legal basis that CTS, as a Health Care Provider, is not required to enter into a Business Associate Agreement with your facility in relationship CTS being provided, collecting, and maintaining Patient Protected Information (PPI) and the proposed skull flap storage agreement between us.

According to Health and Human Services (HHS) CTS is defined as a "Medical Device Company", and is a "Health Care Provider". As such, a covered health care provider is permitted to disclose protected health information to a medical device company for the covered provider's own health care operational purposes. (See Appendix 1; 45 CFR 164.506(c)(1)) The covered provider is permitted to make disclosures without an authorization to a medical device company that is subject to the jurisdiction of the Food and Drug Administration (FDA) for activities related to the quality, safety, or effectiveness of an FDA-regulated product or activity for which the medical device company has responsibility. (See Appendix 1; 45 CFR 164.512(b)(1)(iii)).

CTS is defined by the FDA as a c-GTP manufacturer, is subject to FDA jurisdiction, and registered with the FDA as a Tissue Establishment. The storage, processing, and distribution of autologous tissue performed by CTS is an FDA-regulated activity. In accordance with the HHS Document 490 (See Appendix 1), "When may a covered health care provider disclose protected health information, without an authorization or business associate agreement, to a medical device company representative?", page 3, bullet points 1,3, and 5, MarinHealth Medical Center as a covered provider may disclose protected health information to a medical device manufacturer:

- That is necessary for the device manufacturer to obtain from the health care provider to provide accurate technical information for the operating room staff and surgeon to deliver appropriate patient care regarding instructions for the recovery, handling, packaging, and re-implantation by the surgical staff of autologous tissue.



- To view protected health information, such as films or patient records, to provide consultation, advice or assistance where the provider believes that this will assist with a particular patient's treatment.
- That is subject to FDA jurisdiction to report an adverse event, to track an FDA-regulated product or service. A BAA is therefore not required for the disclosures of patient information by City made to CTS as part of the submission to CTS of the completed request for Autograft Tissue Preservation Service" form (CTS Form 40-2000-1), or for any other related disclosure of protected health information.

HHS Document 490 states, "A business associate agreement would not usually be required for the disclosures noted above."

Tissue Banks are exempt from HIPAA Privacy Rules (See Appendix B).

"OPOs and Tissue Banks are neither covered entities, nor business partners, and are specifically permitted to perform their core function, with stringent confidentiality, but outside the scope of HIPAA."

Tissue banks are therefore not subject to a requirement to enter into a BAA with a covered entity, and are specifically excluded. Furthermore, protected health information can be collected by OPOs and Tissue Banks for a variety of purposes, including those of CTS in conjunction with the proposed agreement including uses and disclosures for which an authorization or opportunity to agree or object is not required. See Appendix B, Section 164.512(b)(1)(iii), (A), (B), (C), and (D).

HHS modified Section 164.512 to permit covered entities to use or disclose protected health information to tissue banks engaged in the procurement, banking, and transplantation of tissues. CTS is currently providing autologous tissue banking for the purpose of re-implantation to the MarinHealth Medical Center, and is included in the proposed agreement.

CTS is provided only with, and only obtains public health patient information for specific patients undergoing craniotomies. The information is documented by surgical staff during the surgical procedure on CTS' "Autograft Tissue Preservation Service" request form (CTS Form 40-2000-1) that documents necessary critical information regarding the recovery, preservation, and banking of the cranial graft that is an FDA regulated activity.

And as California Transplant Services, Inc. is a FDA regulated tissue manufacturing establishment, the information obtained necessary is to satisfy FDA requirements that pertain to CTS' Current Good Tissue Practices (c-GTP) functions, and public health requirements. Patient address information is obtained solely for the purpose of the ability of locating the patient should the patient no longer be associated with the original treating healthcare facility so the cranial flap can be reunited with the patient, and for purposes of notification and possible tissue recall. This information set is exempted from the requirement for patient authorization, and CTS is not considered a Business Associate of the covered entity according to HHS regulations and Document 490.




As a FDA registered and California Department of Public Health licensed Tissue Preservation Laboratory (Tissue Bank) HHS considers these functions to be expressly excluded from HIPAA and its regulations.

California Transplant Services, Inc. does not perform patient billing. CTS does not collect, or maintain any Patient Protected Health Information for sale or commercial purposes, or for any HHS disallowed purposes that would require CTS to enter into a BAA with a covered entity. Protected Health Information is kept in strictest confidence, and is not maintained in or part of any computerized information inter-exchange system.

We have consistently stated our understanding from current federal law promulgated by HHS that we are not a Business Associate as defined by HIPAA. Our relationship with hospitals and the activities we engage in on behalf of the Hospital and its patients are not covered by HIPAA. Therefore, California Transplant Services, Inc. is not required by HHS to enter into business associate agreements.

Please review Appendices 1-5 attached to this letter supporting our position providing official documents issued by HHS and the relevant Code of Federal Regulation.

Sincerely,



Daryl Lirman,

President and CEO
California Transplant Services, Inc.



Appendix 1

Health Information Privacy

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When may a covered health care provider disclose protected health information, without an authorization or business associate agreement, to a medical device company representative?

Answer:

In general, and as explained below, the Privacy Rule permits a covered health care provider (covered provider) without the individual's written authorization, to disclose protected health information to a medical device company representative (medical device company) for the covered provider's own treatment, payment, or health care operation purposes ([45 CFR 164.506\(c\)\(1\)](#)), or for the treatment or payment purposes of a medical device company that is also a health care provider (45 CFR 164.506(c) (2), (3)). Additionally, the public health provisions of the Privacy Rule permit a covered provider to make disclosures, without an authorization, to a medical device company or other person that is subject to the jurisdiction of the Food and Drug Administration (FDA) for activities related to the quality, safety, or effectiveness of an FDA-regulated product or activity for which the person has responsibility. See 45 CFR 164.512(b)(1)(iii) and the frequently asked questions on public health disclosures for more information.

In certain situations, a covered health care provider may disclose protected health information to a medical device company without an individual's written authorization only if the medical device company is a health care provider as defined by the Rule. A medical device company meets the Privacy Rule's definition of "health care provider" if it furnishes, bills, or is paid for "health care" in the normal course of business. "Health care" under the Rule means care, services or supplies related to the health of an individual. Thus, a device manufacturer is a health care provider under the Privacy Rule if it needs protected health information to counsel a surgeon on or determine the appropriate size or type of prosthesis for the surgeon to use during a patient's surgery, or otherwise assists the doctor in adjusting a device for a particular patient. Similarly, when a device company needs protected health information to

provide support and guidance to a patient, or to a doctor with respect to a particular patient, regarding the proper use or insertion of the device, it is providing "health care" and, therefore, is a health care provider when engaged in these services. See 65 FR 82569. By contrast, a medical device company is not providing "health care" if it simply sells its appropriately labeled products to another entity for that entity to use or dispense to individuals.

The following are some examples of circumstances in which a covered provider may share protected health information with a medical device company, without the individual's authorization:

- A covered provider may disclose protected health information needed for an orthopedic device manufacturer or its representative to determine and deliver the appropriate range of sizes of a prosthesis for the surgeon to use during a particular patient's surgery. (This would be a treatment disclosure to the device company as a health care provider. Exchanges of protected health information between health care providers for treatment of the individual are not subject to the minimum necessary standards. 45 CFR 164.502(b).)
- The device manufacturer or its representative may be present in the operating room, as requested by the surgeon, to provide support and guidance regarding the appropriate use, implantation, calibration or adjustment of a medical device for that particular patient. (This would be treatment by the device company as a health care provider. As noted in the prior example, treatment disclosures between health care providers are not subject to the minimum necessary standards.)
- A covered provider may allow a representative of a medical device manufacturer to view protected health information, such as films or patient records, to provide consultation, advice or assistance where the provider, in her professional judgment, believes that this will assist with a particular patient's treatment. (This would also be a treatment disclosure and minimum necessary would not apply.)
- A covered provider may share protected health information with a medical device company as necessary for the device company to receive payment for the health care it provides. (This would be a disclosure for payment of a health care provider and subject to minimum necessary standards.)
- A covered provider may disclose protected health information to a medical device manufacturer that is subject to FDA jurisdiction to report an adverse event, to track an FDA-regulated product, or other purposes related to the quality, safety, or effectiveness of the FDA-regulated product. (This would be a public health disclosure and subject to minimum necessary standards.)

A business associate agreement would not usually be required for the disclosures noted above. For example, a business associate agreement would not be needed for disclosures between health care providers for the treatment of the individual (45 CFR 164.502(e)(1)(ii)(A)). Likewise, a medical device company would not be a business associate of a covered provider with respect to public health disclosures to a device company that is subject to FDA jurisdiction or disclosures to a device company as

a health care provider for that company's payment purposes, as in neither case is the device company performing a function or activity on behalf of, nor providing a specified service to, the Covered provider. See 45 CFR 160.103. In other circumstances, however, a business associate agreement may be required *even* if the disclosure were permitted without an authorization. For example, a business associate agreement would be required if a covered entity asked the medical device company to provide an estimate of the cost savings it might expect from the use of a particular medical device; and to do so, the device company needed access to the covered entity's protected health information. In this case, the medical device company is performing a health care operations function (business planning and development) on behalf of the covered provider, which requires a business associate agreement *even* though the disclosure is permitted without an authorization.

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Appendix 2

Tissue Banks are Exempt from HIPAA Privacy Rules

Background: The HIPAA Privacy Rules grant an exemption to the patient authorization requirements for OPO (Organ Procurement Organization) groups, and tissue banks for the limited purpose of procuring organs --which includes cadaveric organ, eye, tissue donation and transplantation services. With regard to hospital affiliations, OPOs and Tissue Banks are neither covered entities, nor business partners, and are specifically permitted to perform their core function, with stringent confidentiality, but outside the scope of HIPAA.

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required. A covered entity may use or disclose protected health information without the written authorization of the individual, s described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.*

(1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) *Standard: Uses and disclosures for public health activities-*

(1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:

(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;

(B) To track FDA-regulated products;

(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or

(D) To conduct post marketing surveillance;

(h) *Standard: Uses and disclosures for cadaveric organ, eye or tissue donation purposes.* A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or

transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.

In a recent Federal Register from CMS (May-2006):

Comment: Commenters noted that under the organ donation system, information about a patient is disclosed before seeking consent for donation from families. These commenters offered suggestions for ensuring that the system could 1/2 HIPPA- OPO Exception to the Rule continue to operate without consent for information sharing with organ procurement organizations and tissue banks. Commenters suggested that organ and tissue procurement organizations should be "covered entities" or that the procurement of organs and tissues be included in the definition of health care operations or treatment, or in the definition of emergency circumstances.

Response: We agree that organ and tissue donation is a special situation due to the need to protect potential donors' families from the stress of considering whether their loved one should be a donor before a determination has been made that donation would be medically suitable. Rather than list the entities that are "covered entities" or modify the definitions of health care operations and treatment or emergency circumstances to explicitly include organ procurement organizations and tissue banks, we have modified § 164.512 to permit covered entities to use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissues.

Appendix 3

Disclosures for Public Health Activities

45 CFR 164.512(b) [\(Download a COPY in PDF- PDF\)](#)

Background

The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information to carry out their public health mission. The Rule also recognizes that public health reports made by covered entities are an important means of identifying threats to the health and safety of the public at large, as well as individuals. Accordingly, the Rule permits covered entities to disclose protected health information without authorization for specified public health purposes.

How the Rule Works

General Public Health Activities. The Privacy Rule permits covered entities to disclose protected health information, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. This would include, for example, the reporting of a disease or injury; reporting vital events, such as births or deaths; and conducting public health surveillance, investigations, or interventions. See 45 CFR 164.512(b)(1)(i). Also, covered entities may, at the direction of a public health authority, disclose protected health information to a foreign government agency that is acting in collaboration with a public health authority. See 45 CFR 164.512(b)(1)(i). Covered entities who are also a public health authority may use, as well as disclose, protected health information for these public health purposes. See 45 CFR 164.512(b)(2).

A "public health authority" is an agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. See 45 CFR 164.501. Examples of a public health authority include State and local health departments, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, and the Occupational Safety and Health Administration (OSHA). Generally, covered entities are required reasonably to limit the protected health information disclosed for public health purposes to the minimum amount necessary to accomplish the public health purpose. However, covered entities are not required to make a minimum necessary determination for public health disclosures that are made pursuant to an individual's authorization, or for disclosures that are required by other law. See 45 CFR 164.502(b).

For disclosures to a public health authority, covered entities may reasonably rely on a minimum necessary determination made by the public health authority in requesting the protected health information. See 45 CFR 164.514(d)(3)(iii)(A). For routine and recurring public health disclosures, covered entities may develop standard protocols, as part of their minimum necessary policies and procedures, that address the types and amount of protected health information that may be disclosed for such purposes. See 45 CFR 164.514(d)(3)(i).

Other Public Health Activities. The Privacy Rule recognizes the important role that persons or entities other than public health authorities play in certain essential public health activities. Accordingly, the Rule permits covered entities to disclose protected health information, without authorization, to such persons or entities for the public health activities discussed below.

- **Child abuse or neglect.** Covered entities may disclose protected health information to report known or suspected child abuse or neglect, if the report is made to a public health authority or other appropriate government authority that is authorized by law to receive such reports. For instance, the social services department of a local government might have legal authority to receive reports of child abuse or neglect, in which case, the Privacy Rule would permit a covered entity to report such cases to that authority without obtaining individual authorization. Likewise, a covered entity could report such cases to the police department when the police department is authorized by law to receive such reports. See 45 CFR 164.512(b)(1)(ii). See also 45 CFR 512(c) for information regarding disclosures about adult victims of abuse, neglect, or domestic violence.
- **Quality, safety or effectiveness of a product or activity regulated by the FDA.** Covered entities may disclose protected health information to a person subject to FDA jurisdiction, for public health purposes related to the quality, safety or effectiveness of an FDA-regulated product or activity for which that person has responsibility. Examples of purposes or activities for which such disclosures may be made include, but are not limited to:
 - Collecting or reporting adverse events (including similar reports regarding food and dietary supplements), product defects or problems (including problems regarding use or labeling), or biological product deviations;
 - Tracking FDA-regulated products;
 - Enabling product recalls, repairs, replacement or lookback (which includes locating and notifying individuals who received recalled or withdrawn products or products that are the subject of lookback); and
 - Conducting post-marketing surveillance. See 45 CFR 164.512(b)(1)(iii). The "person" subject to the jurisdiction of the FDA does not have to be a specific individual. Rather, it can be an individual or an entity, such as a partnership, corporation, or association. Covered entities may identify the party or

parties responsible for an FDA-regulated product from the product label, from written material that accompanies the product (known as labeling), or from sources of labeling, such as the Physician's Desk Reference.

- Persons at risk of contracting or spreading a disease. A covered entity may disclose protected health information to a person who is at risk of contracting or spreading a disease or condition if other law authorizes the covered entity to notify such individuals as necessary to carry out public health interventions or investigations. For example, a covered health care provider may disclose protected health information as needed to notify a person that (s)he has been exposed to a communicable disease if the covered entity is legally authorized to do so to prevent or control the spread of the disease. See 45 CFR 164.512(b)(1)(iv).
- Workplace medical surveillance. A covered health care provider who provides a health care service to an individual at the request of the individual's employer, or provides the service in the capacity of a member of the employer's workforce, may disclose the individual's protected health information to the employer for the purposes of workplace medical surveillance or the evaluation of work-related illness and injuries to the extent the employer needs that information to comply with OSHA, the Mine Safety and Health Administration (MSHA), or the requirements of State laws having a similar purpose. The information disclosed must be limited to the provider's findings regarding such medical surveillance or work-related illness or injury. The covered health care provider must provide the individual with written notice that the information will be disclosed to his or her employer (or the notice may be posted at the worksite if that is where the service is provided). See 45 CFR 164.512(b)(1)(v).

Please view the [Frequently Asked Questions about the Privacy Rule](#).

OCR HIPAA Privacy

December 3, 2002 Revised April 3, 2003

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Significant Aspects of the Privacy Rule

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- [General Overview](#)
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Appendix 4

Code of Federal Regulations

Title 45 -Public Welfare

Volume: 1

Date: 2003-10-01

Original Date: 2003-10-01

Title: Section 164.502- Uses and disclosures of protected health information: general rules.

Context Title 45- Public Welfare. SUBTITLE A- DEPARTMENT OF HEALTHAND HUMAN SERVICES. SUBCHAPTER C- ADMINISTRATIVE DATA STANDARDS AND RELATED REQUIREMENTS. PART 164- SECURITY AND PRIVACY. Subpart E- Privacy of Individually Identifiable Health Information.

§ 164.502 Uses and disclosures of protected health information: general rules.

(a) *Standard.* A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of§ 164.502(b), § 164.514(d), and§ 164.530(c) with respect to such otherwise permitted or required use or disclosure;

(iv) Pursuant *to* and in compliance with a valid authorization under§ 164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and

(vi) As permitted by and in compliance with this section,§ 164.512, or§ 164.514(e), (f), or (g).

(2) *Required disclosures.* A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by§ 164.524 or§ 164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subpart.

(b) *Standard: Minimum necessary.* (1) *Minimum necessary applies.* When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

(2) *Minimum necessary does not apply.* This requirement does not apply to:

(i) Disclosures to or requests by a health care provider for treatment;

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section or as required by paragraph (a)(2)(i) of this section;

(iii) Uses or disclosures made pursuant to an authorization under§ 164.508;

(iv) Disclosures made to the Secretary in accordance with subpart C of part 160 of this subchapter;

(v) Uses or disclosures that are required by law, as described by § 164.512(a); and

(vi) Uses or disclosures that are required for compliance with applicable requirements of this subchapter.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to § 164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in § 164.522(a).

(d) *Standard: Uses and disclosures of de-identified protected health information.* (1) *Uses and disclosures to create de-identified information.* A covered entity may use protected health information to create information

that is not individually identifiable health information or disclose protected health information only to a business associate for such purpose, whether or not the de-identified information is to be used by the covered entity.

(2) *Uses and disclosures of de-identified information.* Health information that meets the standard and implementation specifications for de-identification under § 164.514(a) and (b) is considered not to be individually identifiable health information, i.e., de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of § 164.514, provided that:

(i) Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information; and

(ii) If de-identified information is re-identified, a covered entity may use or disclose such re-identified information only as permitted or required by this subpart.

(e)(1) *Standard: Disclosures to business associates.* (i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information.

(ii) This standard does not apply:

(A) With respect to disclosures by a covered entity to a health care provider concerning the treatment of the individual;

(B) With respect to disclosures by a group health plan or a health insurance issuer or HMO with respect to a group health plan to the plan sponsor, to the extent that the requirements of § 164.504(f) apply and are met; or

(C) With respect to uses or disclosures by a health plan that is a government program providing public benefits, if eligibility for, or enrollment in, the health plan is determined by an agency other than the agency administering the health plan, or if the protected health information used to determine enrollment or eligibility in the health plan is collected by an agency other than the agency administering the health plan, and such activity is authorized by law, with respect to the collection and sharing of individually identifiable health information for the performance of such functions by the health plan and the agency other than the agency administering the health plan.

(iii) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and § 164.504(e).

(2) *Implementation specification: documentation.* A covered entity must document the satisfactory assurances required by paragraph (e)(1) of this section through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of § 164.504(e).

(f) *Standard: Deceased individuals.* A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual.

(g)(1) *Standard: Personal representatives.* As specified in this paragraph, a covered entity must, except as provided in paragraphs (g)(3) and (g)(5) of this section, treat a personal representative as the individual for purposes of this subchapter.

(2) *Implementation specification: adults and emancipated minors.* If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(3)(i) *Implementation specification: unemancipated minors.* If under applicable law a parent, guardian, or other person acting *in loco parentis* has authority to act on behalf of an individual who is an unemancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation, except that such person may not be a personal representative of an unemancipated minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:

(A) The minor consents to such health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative;

(B) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting in *loco parentis*, and the minor, a court, or another person authorized by law consents to such health care service; or

(C) A parent, guardian, or other person acting in *loco parentis* assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.

(ii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section:

(A) If, and to the extent, permitted or required by an applicable provision of State or other law, including applicable case law, a covered entity may disclose, or provide access in accordance with § 164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting in *loco parentis*;

(B) If, and to the extent, prohibited by an applicable provision of State or other law, including applicable case law, a covered entity may not disclose, or provide access in accordance with § 164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting in *loco parentis*; and

(C) Where the parent, guardian, or other person acting in *loco parentis*, is not the personal representative under paragraphs (g)(3)(i)(A), (B), or (C) of this section and where there is no applicable access provision under State or other law, including case law, a covered entity may provide or deny access under § 164.524 to a parent, guardian, or other person acting in *loco parentis*, if such action is consistent with State or other applicable law, provided that such decision must be made by a licensed health care professional, in the exercise of professional judgment.

(4) *Implementation specification: Deceased individuals.* If under applicable law an executor, administrator, or other person has authority to act on behalf of a deceased individual or of the individual's estate, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(5) *Implementation specification: Abuse, neglect, endangerment situations.* Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative of an individual if:

(i) The covered entity has a reasonable belief that:

(A) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or

(B) Treating such person as the personal representative could endanger the individual; and

(ii) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(h) *Standard: Confidential communications.* A covered health care provider or health plan must comply with the applicable requirements of § 164.522(b) in communicating protected health information.

(i) *Standard: Uses and disclosures consistent with notice.* A covered entity that is required by § 164.520 to have a notice may not use or disclose protected health information in a manner inconsistent with such notice. A covered entity that is required by § 164.520(b)(1)(iii) to include a specific statement in its notice if it intends to engage in an activity listed in § 164.520(b)(1)(iii)(A)-(C), may not use or disclose protected health information for such activities, unless the required statement is included in the notice.

U) *Standard: Disclosures by whistleblowers and workforce member crime victims.* (1) *Disclosures by whistleblowers.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce or a business associate discloses protected health information, provided that:

(i) The workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public; and

(ii) The disclosure is to:

(A) A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity; or

(B) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate with regard to the conduct

described in paragraph U)(1)(i) of this section.

(2) *Disclosures by workforce members who are victims of a crime.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce who is the victim of a criminal act discloses protected health information to a law enforcement official, provided that:

- (i) The protected health information disclosed is about the suspected perpetrator of the criminal act; and
- (ii) The protected health information disclosed is limited to the information listed in § 164.512(f)(2)(i).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53267, Aug. 14, 2002]

Appendix 5

Code of Federal Regulations

Title 45 - Public Welfare

Volume: 1

Date: 2003-10-01

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Title: Section 164.512 - Uses and disclosures for which an authorization or opportunity to agree or object is not required.

Context: Title 45- Public Welfare. SUBTITLE A- DEPARTMENT OF HEALTH AND HUMAN SERVICES. SUBCHAPTER C -ADMINISTRATIVE DATA STANDARDS AND RELATED REQUIREMENTS. PART 164 - SECURITY AND PRIVACY. Subpart E - Privacy of Individually Identifiable Health Information.

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.* (1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) *Standard: uses and disclosures for public health activities.* (1) *Permitted disclosures.* A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:

(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;

(B) To track FDA-regulated products;

(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or

(D) To conduct post marketing surveillance;

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or

(v) An employer, about an individual who is a member of the workforce of the employer, if: