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Joining of 2013 164.524 with the 2021 proposed changes

Draft by Sue Miller, June 2023

Changes noted in red and ~~strike through~~

This is a DRAFT document! It attempts to join together the current HIPAA Access of Individuals to Protected Health Information (PHI) regulation ([45 CFR § 164.524](#)), and proposed changes to this regulation. ([Federal Register :: Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement](#))

For more information on the new HIPAA Notice for Proposed Rulemaking (NPRM) [visit Susan Miller's Blog featuring a Primer about the New NPRM!](#) The drafter suggests this document be used for planning purposed only; you can reach Sue Miller at HIPAASuccess@connectinghealthcare.com

§ 164.524 Access of individuals to protected health information.

(a) Standard: Access to protected health information.

(1) Right of access. (i) Except as otherwise provided in paragraph (a)(2) or ~~(a)~~(3) of this section, an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for:

(A) Psychotherapy notes;

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(B) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding;

(ii) An individual's right to inspect protected health information about the individual in a designated record set includes the right to view, take notes, take photographs, and use other personal resources to capture the information, except that a covered entity is not required to allow an individual to connect a personal device to the covered entity's information systems and may impose requirements to ensure that an individual records only protected health information to which the individual has a right of access.

(iii) Protected health information maintained by a covered entity that is:

(A) Subject to the Clinical Laboratory Improvements Amendments of 1988, 42 U.S.C. 263a, to the extent the provision of access to the individual would be prohibited by law; or

(B) Exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 CFR 493.3(a)(2).

(2) Unreviewable grounds for denial. A covered entity may deny an individual access under paragraph (a)(1) of this section, without providing the individual an opportunity for review, in the following circumstances.

~~(2) Unreviewable grounds for denial. A covered entity may deny an individual access without providing the individual an opportunity for review, in the following circumstances.~~

(i) The protected health information is excepted from the right of access by paragraph (a)(1) of this section.

(ii) A covered entity that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to obtain a copy of protected health information, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate.

(iii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of

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access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.

(iv) An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law.

(v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

(3) Reviewable grounds for denial. A covered entity may deny an individual access under paragraph (a)(1) of this section, provided that the individual is given a right to have such denials reviewed, as required by paragraph (e)(4) of this section, in the following circumstances:

~~(3) Reviewable grounds for denial. A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed, as required by paragraph (a)(4) of this section, in the following circumstances:~~

(i) A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;

(ii) The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or

(iii) The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.

(4) Review of a denial of access. If access is denied on a ground permitted under paragraph (a)(3) of this section, the individual has the right to have the denial reviewed by a licensed health care professional who is designated by the covered entity to act as a reviewing official and who did not participate in the original decision to deny. The covered entity must provide or deny access

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in accordance with the determination of the reviewing official under paragraph (d)(4) of this section.

(b) Implementation specifications: Requests for access and timely action.

(1) Individual's request for access.

(i) The covered entity must permit an individual to request access to inspect or to obtain a copy of the protected health information about the individual that is maintained in a designated record set.

~~The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.~~

(ii) The covered entity may require an individual to make a request for access in writing (in electronic or paper form), provided that it informs the individual of such a requirement and does not impose unreasonable measures that impede the individual from obtaining access when a measure that is less burdensome for the individual is practicable for the entity. For example, requiring individuals to complete a standard form containing only the information the covered entity needs to process the request is a reasonable measure because it does not cause an individual to expend unnecessary effort or expense. In contrast, examples of unreasonable measures include requiring an individual to do any of the following when a measure that is less burdensome for the individual is practicable for the entity: fill out a request form with extensive information that is not necessary to fulfill the request; obtain notarization of the individual's signature on a request form; or submit a written request only in paper form, only in person at the entity's facility, or only through the covered entity's online portal.

(2) Timely action by the covered entity.

(i) Except as provided in paragraph (b)(2)(ii) of this section, the covered entity must act on a request for access no later than **15 calendar** days after receipt of the request as follows.

(A) If the covered entity grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (c) of this section.

(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (e) of this section.

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(ii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) of this section, as applicable, the covered entity may extend the time for such actions by no more than **15 calendar** days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for access; **and**

(C) The covered entity has implemented a policy to prioritize urgent or otherwise high priority requests (especially those relating to the health and safety of the individual or another person), so as to limit the use of a 15 calendar-day extension for such requests.

(iii) Where another federal or state law requires a covered entity to provide an individual with access to the protected health information requested in less than 15 calendar days, that shorter time period is deemed practicable under paragraph (b)(2)(i) of this section.

(c) Implementation specifications: Provision of access. If the covered entity provides an individual with access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) Providing the access requested. The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the protected health information about them in designated record sets. If the same protected health information that is the subject of a request for access is maintained in more than one designated record set or at more than one location, the covered entity need only produce the protected health information once in response to a request for access.

(2) Form of access requested.

(i) The covered entity must provide the individual with access to the protected health information in the form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable hard copy form or such other form and format as agreed to by the covered entity and the individual.

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(ii) Notwithstanding paragraph (c)(2)(i) of this section, if the protected health information that is the subject of a request for access is maintained in one or more designated record sets electronically and if the individual requests an electronic copy of such information, the covered entity must provide the individual with access to the protected health information in the electronic form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual.

(iii) Where another federal or state law applicable to the covered entity requires the provision of access in a particular electronic form and format, the protected health information is deemed readily producible in such form and format under paragraphs (c)(2)(i) and (ii) of this section.

(iv)(A) The covered entity may provide the individual with a summary of the protected health information requested, in lieu of providing access to the protected health information or may provide an explanation of the protected health information to which access has been provided, if:

(1) The individual agrees in advance to such a summary or explanation; and

(2) The individual agrees in advance to the fees imposed, if any, by the covered entity for such summary or explanation.

(B) The covered entity must inform any individual to whom it offers to provide a summary in lieu of a copy of protected health information that the individual retains the right to obtain a copy of the requested protected health information if the individual does not agree to receive such summary. This requirement does not apply if a covered entity is offering to provide a summary in lieu of a copy of protected health information because the covered entity is denying an individual's request for a copy; however, the covered entity still must follow the denial procedures under § 164.524(e).

(3) Time and manner of access. -The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or **at the individual's request** mailing **or electronically transmitting** the copy of the protected health information **to** the individual, **including by email or to or through the individual's personal health application (if a copy is readily producible to or through such application).** When protected health information is readily available at the point of care in conjunction with a health care appointment, a covered health care provider is not permitted to

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delay the right to inspect. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access; **however such discussion shall not extend the time allowed for the covered entity to provide access.**

(4) Fees. **(i)** If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:

~~(ii) If an individual's request for access directs the covered entity to transmit directly to another person designated by the individual, the covered entity must provide the copy to the person designated by the individual. The individual's request must be in writing, signed by the individual, and clearly identify the person designated, and where to send the copy of protected health information.~~

(A) Labor for copying the protected health information requested by the individual, whether in **non-electronic (e.g., paper, film)** or electronic form;

(B) Supplies for creating ~~(the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media)~~ **a non-electronic copy;**

(C) Postage, when the individual has requested **a non-electronic** copy, or the summary or explanation, be mailed; and

(D) Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(iii) of this section.

(ii) A covered entity may not impose a fee when:

(A) an individual inspects the protected health information about the individual, as described at (a)(1)(ii) of this section, or

(B) an individual accesses electronic protected health information maintained by or on behalf of the covered entity using an internet-based method such as a personal health application.

(d) Standard: Right to direct the transmission of certain protected health information in an electronic format to a third party—(1) An individual has a right of access to direct a covered health care provider to transmit an electronic copy of protected health information in an electronic health

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record directly to another person designated by the individual (a “third party”). The covered health care provider must provide access under this paragraph when the individual’s request to exercise the right of access is clear, conspicuous, and specific, which may be orally or in writing (including electronically), except for:

(i) Psychotherapy notes; and

(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

(2) *Unreviewable grounds for denial.* A covered entity may deny an individual’s request to exercise the right of access to direct a covered health care provider to transmit an electronic copy of protected health information in an electronic health record directly to a third party under paragraph (d)(1) of this section, without providing an opportunity for review, in the following circumstances:

(i) The protected health information is excepted from the right of access by paragraph (d)(1) of this section.

(ii) A covered entity that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate’s request to exercise of the right of access, if transmitting such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional

institution or responsible for the transporting of the inmate.

(iii) An individual’s ability to exercise of the right of access may be temporarily suspended by a covered health care provider in the course of research that includes treatment for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.

(iv) An individual’s request to exercise the right of access may be denied if the protected health information is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, and if the denial of access under the Privacy Act would meet the requirements of that law.

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(v) An individual's request to exercise the right of access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and providing the copy to the third party would be reasonably likely to reveal the source of the information.

(3) *Reviewable grounds for denial of a request to direct an electronic copy of protected health information in an electronic health record.* A covered entity may deny an individual's request under paragraph (d)(1) of this section, provided that the individual is given a right to have such denials reviewed, as required by paragraph (e)(4) of this section, in the following circumstances:

(i) A licensed health care professional has determined, in the exercise of professional judgment, that the access is reasonably likely to endanger the life or physical safety of the individual or another person; or

(ii) The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access is reasonably likely to cause substantial harm to such other person.

(4) *Implementation specification: Summary or explanation prepared by covered health care provider.* (i) A covered health care provider may transmit, to a third party designated by an individual, a summary of requested protected health information in an electronic health record, in lieu of transmitting a copy of the protected health information, or may transmit an explanation of the requested protected health information in an electronic health record in addition to such protected health information, if:

(A) The individual agrees in advance to such a summary or explanation; and (B) The individual agrees in advance to the fees imposed, if any, by the covered health care provider for such summary or explanation.

(ii) A covered health care provider must inform any individual to whom it offers to transmit a summary in lieu of a copy of protected health information that the individual retains the right to direct an electronic copy of the requested protected health information in an EHR if the individual does not agree to receive such summary. This requirement does not apply if a covered entity is offering to provide a summary in lieu of a copy of protected health information because the covered entity is denying an individual's request for a copy; however, the covered entity still must follow the denial procedures under § 164.524(e).

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(5) *Implementation specification: Timely action by the covered entity.* (i) Except as provided in paragraph (d)(5)(ii) of this section, a covered health care provider is required to provide the copy requested under paragraph (d)(1) of this section as soon as practicable but no later than 15 calendar days after receipt of the individual's request.

(A) If the covered entity grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (d) of this section.

(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (e)(2) of this section.

(ii) If the covered entity is unable to take an action required by paragraph (d)(5)(i)(A) or (B) of this section within the time required by paragraph (d)(5)(i) of this section, as applicable, the covered entity may extend the time for such actions by no more than 15 calendar days, provided that:

(A) The covered entity, within the time limit set by paragraph (d)(5)(i) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request.

(C) The covered entity has implemented a policy to prioritize urgent or otherwise high priority requests (especially those relating to the health and safety of the individual or another person), so as to limit the use of a 15 calendar-day extension for such requests.

(iii) Where another federal or state law requires a covered entity to provide an individual with an electronic copy of the protected health information in an electronic health record in less than 15 calendar days, that shorter time period is deemed practicable under paragraph (d)(5)(i) of this section.

(6) *Fees.* A covered health care provider may impose a reasonable, cost-based fee for an access request to direct an electronic copy of protected health information in an electronic health record to a third party, provided that the fee includes only the cost of:

(i) Labor for copying the protected health information requested by the individual in electronic form; and

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(ii) Preparing an explanation or summary of the protected health information, if agreed to by the individual as provided in paragraph (d)(4) of this section.

(7) Right to direct covered health care providers or plans to submit an access request.

(i) An individual has a right of access to direct a covered health care provider or health plan ("Requester-Recipient") to submit to a covered health care provider ("Discloser") a request for an electronic copy of the individual's protected health information in an electronic health record maintained by or on behalf of the Discloser.

(ii) A Requester-Recipient must submit to the Discloser a request made by the individual, orally or in writing (including electronically), and that is clear, conspicuous, and specific, if the individual is:

A. a current or prospective new patient of the Requester-Recipient health care provider, or

B. a current enrolled member (or dependent) of the Requester-Recipient health plan.

(iii) The Requester-Recipient must submit the access request to the identified Discloser as soon as practicable, but no later than 15 calendar days after receiving the individual's direction and any information needed to submit the request. An extension is not available for submitting the request. The Discloser must respond to the access request within the time limits in paragraph (d)(5) of this section.

(e) Implementation specifications: Denial of access. If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) Making other information accessible. The covered entity must, to the extent possible, give the individual access to any other protected health information requested, after excluding the protected health information as to which the covered entity has a ground to deny access.

(2) Denial. The covered entity must provide a timely, written denial to the individual. The denial must be in plain language and contain:

(i) The basis for the denial;

(ii) If applicable, a statement of the individual's review rights under paragraph (e)(a)(4) of this section, including a description of how the individual may exercise such review rights; and

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(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in § 164.530(d) or to the Secretary pursuant to the procedures in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in § 164.530(a)(1)(ii).

(3) Other responsibility. If the covered entity **(or its business associate on the covered entity's behalf)** does not maintain the protected health information that is the subject of the individual's request for access, and the covered entity knows where the requested information is maintained, the covered entity must inform the individual where to direct the request for access.

(4) Review of denial requested. If the individual has requested a review of a denial under paragraph (a)(3) **or (d)(3)** of this section:

(i) the individual has the right to have the denial reviewed by ~~the covered entity must designate~~ a licensed health care professional, who **is designated by the covered entity and who did not participate in the original decision to deny access. **The covered entity must provide or deny access in accordance with the determination of the reviewing official under paragraph (e)(4)(i) of this section.****

(ii) If the individual has requested a review of a denial under paragraph (e)(4)(i) of this section, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards in paragraph (a)(3) or (d)(3) of this section, whichever is applicable, of this section. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.

~~The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards of paragraph (a)(3) of this section. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.~~

(f) Implementation specification: Documentation. A covered entity must document the following and retain the documentation as required by § 164.530(j):

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- (1) The designated record sets that are subject to access by individuals **under paragraph (a) of this section;**
- (2) **The electronic health records that are subject to the right of access to direct the transmission of an electronic copy of protected health information in an electronic health record under paragraph (d) of this section; and**
- (3) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.

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