

**MERCER COUNTY**

**PRIVACY POLICY**

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## **Introduction**

It is every employee's responsibility to be familiar with this Privacy and Security Policy and to be sensitive to and report any situations that may violate it. Claims of ignorance, good intentions and bad advice are not acceptable as excuses for noncompliance.

Individuals in supervisory/managerial positions ("Managers") at Mercer County (the "County") have the additional ongoing responsibility to verify that employees whom they supervise understand and comply with the standards of conduct set forth in this Policy.

## **Goal**

To assure the privacy, security and confidentiality of all patients treated at the County. These policies govern the conduct of the County as a health care provider, employees of the County, all non-employed physicians with privileges at the County, all agents, representatives and volunteers of the County. The County, and all of the foregoing individuals, are hereafter simply referred to as the "County".

To comply with state and federal laws and regulations, especially the applicable general administrative requirements of the Health Insurance Portability and Accountability Act (HIPAA) and the applicable standards, requirements, and implementation specifications of the regulations created under HIPAA and state regulations governing privacy of Patient Information.

## **Purpose**

To maintain the privacy and security of Patient Information.

## **Policy**

In order to achieve the Purpose of this Policy, County leaders and managers shall implement Procedures consistent with this Policy by: exercising all due diligence in the maintenance, use, storage, and sharing of Patient Information; designing and maintaining the environment to support the privacy and security of Patient Information; training and supervising employees and imposing sanctions for inappropriate behavior; and maintaining and submitting such records as are necessary to comply with federal and state laws and regulations.

The County-wide, Patient Information privacy and security policy is as follows:

(Note: Section references are to the HIPAA regulations, 45 C.F.R. §160.100, et seq. and §164.500, et seq.)

## **Select Definitions**

### **§160.103 Definitions. / § 164.501 Definitions.**

***Disclosure*** means the release, transfer, provision of access to, or divulging in any other manner of information outside the County.

***Health information*** means any information, whether oral or recorded in any form or medium, that: (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

***Individually identifiable health information*** is information that is a subset of health information, including demographic information collected from an individual, and: (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) That identifies the individual; or (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

***Organized Health Care Arrangement*** means a clinically integrated environment, such as the County, in which individuals typically receive health care from more than one health care provider.

***Patient Information*** is all information created or maintained by the County that pertains, refers or relates to a patient. This includes both health information and other information.

***Use*** means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

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### **General Procedures:**

#### **§160.310 Responsibilities of The County**

The County shall maintain and submit such compliance records, in the time, manner and format required by the Secretary (the “Secretary” or “Secretary of HHS”) of Health and Human Services (HHS) to enable the Secretary to ascertain whether the County has complied, or is complying with, the HIPAA regulations.

The County will cooperate with the Secretary of HHS, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of the County to determine whether it is complying with the applicable HIPAA regulations.

The County shall permit access by the Secretary of HHS during normal business hours to its facilities, books, records, accounts, and other sources of information, including health information, that are pertinent to ascertaining compliance with the HIPAA regulations. The

County shall permit access by the Secretary at any time and without notice if the Secretary determines that an exigent circumstance exists.

The County shall certify, if applicable, that information required of the County is in the exclusive possession of another agency, institution, or person and the agency, institution, or person fails or refuses to furnish the information.

### **§164.502 Uses And Disclosures Of Patient Information: General Rules**

The County shall not use or disclose Patient Information except as permitted by this Policy. The following is an overview of the general rules contained in this Policy, with references to the HIPAA regulations and corresponding County policies, when such regulations and policies contain additional or more specific directives with respect to the particular circumstances.

#### Permitted and Required Disclosures

The County is ***permitted*** to use or disclose Patient Information as follows:

- 1) to the individual;
- 2) for treatment, payment, or health care operations (See §164.506);
- 3) incident to a use or disclosure otherwise permitted or required by this section provided that the County has made reasonable efforts to limit Patient Information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. (See §164.502(b), §164.514(d) and §164.530(c)).
- 4) pursuant to and in compliance with a HIPAA-compliant authorization (See §164.508);
- 5) pursuant to an agreement by the individual to use or disclose Patient Information to the facility's directory or to a family member, friend or caregiver, or as otherwise permitted by the HIPAA regulations (*see* §164.510);
- 6) as otherwise permitted by and in compliance with the HIPAA regulations or other, more restrictive law.

The County is ***required*** to disclose Patient Information:

- 1) to an individual, provided the disclosure of such information would not be detrimental to the patient; and
- 2) when required by the Secretary during an authorized investigation or to determine the County's compliance with the HIPAA regulations.

### Minimum Necessary Standard

When using or disclosing Patient Information or when requesting Patient Information from another covered entity (such as a hospital, healthcare provider or health plan), the County must make reasonable efforts to limit the information used or disclosed to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

The "minimum necessary" standard does not apply to:

- 1) disclosures to, or requests by, a health care provider for treatment;
- 2) uses or disclosures made to the individual;
- 3) uses or disclosures made pursuant to a HIPAA-compliant authorization (See §164.508);
- 4) disclosures made to the Secretary in accordance with the HIPAA regulations;
- 5) uses or disclosures that are required by law, such as: disclosures for public health activities; disclosures about victims of abuse, neglect or domestic violence; uses or disclosures for health oversight activities; disclosures for judicial and administrative proceedings; disclosures for law enforcement purposes; uses and disclosures about decedents; uses and disclosures for cadaveric organ, eye or tissue donation purposes; uses and disclosures for research purposes; uses and disclosures to avert a serious threat to health or safety; uses and disclosures for specialized government functions and disclosures for workers' compensation (*see* §164.512); and
- 6) uses or disclosures that are required for compliance with applicable requirements of the HIPAA regulations.

The minimum necessary standard is more fully discussed at § 164.514(d).

### Restrictions Requested by the Individual

The County may agree to a restriction on the use or disclosure of Patient Information as set forth at § 164.522.

### De-identified Patient Information

The County may use Patient Information to create information that is not individually identifiable or disclose Patient Information to a "business associate" (a person or entity that performs a function *on behalf of* the County) for such purpose as set forth at § 164.514. The information is not considered to be "de-identified" if the County discloses a code or other means to re-identify the Patient Information. If de-identified information is subsequently "re-identified," the County may only disclose it in accordance with these policies.

### Business Associates

The County may disclose Patient Information to a business associate, provided that the County first obtains “satisfactory assurance” from the business associate through a written contract or other written agreement or arrangement that meets the requirements set forth at § 164.504. The County does not need to obtain a business associate agreement from a provider in order to disclose Patient Information for purposes of treatment of the individual. If the County is a business associate of another County and violates the “satisfactory assurances” it provided to the County, it will be in violation of HIPAA.

### Deceased Individuals

The County must comply with the requirements of these policies with respect to the Patient Information of a deceased individual as set forth at § 164.512.

### Personal Representatives

The County will treat a personal representative as the individual for purposes of the HIPAA Privacy Regulations with respect to Patient Information relevant to such personal representation, except as otherwise provided in this Policy.

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, the County will treat such person as a personal representative for purposes of the HIPAA Regulations, with respect to Patient Information relevant to such personal representation. However, such person may not be treated as a personal representative of an unemancipated minor when the minor has the authority to act as an individual, with respect to Patient Information pertaining to a health care service, if:

- 1) The minor consents to such health care service, no other consent is required by law, and the minor has not requested that such person be treated as the personal representative;
- 2) 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
- 3) 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.

Notwithstanding the foregoing, if, and to the extent, permitted or required by an applicable provision of State or other law, including applicable case law, the County may disclose or provide access in accordance with the HIPAA Privacy Regulations to protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*. Where the parent, guardian, or other person acting *in loco parentis*, is not the personal

representative and where there is no applicable access provision under State or other law, including case law, the County may provide or deny access under the HIPAA Privacy Regulations 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.

#### Executors/Administrators—Treatment as a Personal Representative

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, the County will treat such person as a personal representative as set forth at § 164.510.

#### Situations Involving Abuse, Neglect or Endangerment—Treatment of Others as Personal Representatives

The County may elect not to treat a person as the personal representative of an individual if the County has a reasonable belief that:

- 1) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or
- 2) Treating such person as the personal representative could endanger the individual; and the County, 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.

See also § 164.512 for additional restrictions on the reporting of abuse to law enforcement officials.

#### Request for Restrictions and/or Confidential Communications

The County shall comply with reasonable requests by individuals to receive communications of Patient Information by alternate means or at alternate locations as set forth at § 164.522.

#### Communicating Limits on Use or Disclosure of Patient Information

The County may not use or disclose Patient Information in a manner inconsistent with County's "Notice of Privacy Practices" and must distribute the Notice as set forth at § 164.520.

#### Whistleblower Provisions

The County is not considered to have violated the restrictions contained in these policies if a member of its workforce or a business associate discloses Patient Information as part of a "whistleblower" report provided that the individual:

- 1) Believes in good faith that the County has engaged in conduct that is unlawful or otherwise violates professional or clinical standards,

or that the care, services or conditions provided by the County potentially endanger one or more patients, workers or the public; and

- 2) The disclosure is to:
  - a) A health oversight agency or public health authority authorized to investigate or otherwise oversee the relevant conduct or conditions of the County 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 County; or
  - b) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining his or her legal options.

#### Disclosures by Workforce Members Who are Victims of a Crime

The County is not considered to have violated the requirements of these policies if a member of its workforce who is the victim of a criminal act discloses Patient Information to a law enforcement official provided that:

- 1) The Patient Information disclosed is about the suspected perpetrator of the criminal act; and
- 2) The Patient Information that is disclosed is limited to the information listed in § 164.512.

#### **§164.504 Uses And Disclosures: Organizational Requirements**

##### Responsibility for Business Associate Conduct

The County may disclose information to a “business associate.” A “business associate” is a person who, on behalf of the County, performs or assists in the performance of a function or activity involving the use or disclosure of Patient Information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management or repricing, legal, actuarial, accounting, consulting, management, administrative, accreditation or financial services to the County. It does not include members of the County’s workforce.

The County must enter into a contract with each of its business associates, which must:

- 1) Establish the permitted and required uses and disclosures of Patient Information by the business associate. The contract may not authorize the business associate to use or further disclose Patient Information in a manner that would violate the requirements of these policies, if done by the County, except that:

- a) The contract may permit the business associate to use and disclose Patient Information for the proper management and administration of the business associate, as provided by these policies; and
- b) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the County.

Elements of a Business Associate Agreement

- 2) Provide that the business associate will:
  - a) Not use or further disclose the information other than as permitted or required by the contract or as required by law;
  - b) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by its contract;
  - c) Report to the County any use or disclosure of the information not provided for by its contract of which it becomes aware;
  - d) Ensure that any agents, including a subcontractor, to whom it provides Patient Information received from, or created or received by the business associate on behalf of, the County agrees to the same restrictions and conditions that apply to the business associate with respect to such information;
  - e) Make available Patient Information in accordance with these policies;
  - f) Make available Patient Information for amendment and incorporate any amendments to Patient Information in accordance with these policies;
  - g) Make available the information required to provide an accounting of disclosures in accordance with these policies;
  - h) Make its internal practices, books, and records relating to the use and disclosure of Patient Information received from, or created or received by the business associate on behalf of, the County available to the Secretary for purposes of determining the County's compliance with these policies; and
  - i) At termination of the contract, if feasible, return or destroy all Patient Information received from, or created or received by the business associate on behalf of, the County

that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information unfeasible.

- 3) Authorize termination of the contract by the County, if the County determines that the business associate has violated a material term of the contract.

#### Business Associates' Use of Patient Information

The contract or other arrangement between the County and the business associate may permit the business associate to use the information received by the business associate in its capacity as a business associate to the County, if necessary:

- 1) For the proper management and administration of the business associate; or
- 2) To carry out the legal responsibilities of the business associate.

#### Business Associate Disclosures

The contract or other arrangement between the County and the business associate may permit the business associate to disclose the information received by the business associate in its capacity as a business associate for the purposes described in these policies, if:

- 1) The disclosure is required by law; or
- 2) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and 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 the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

#### County Responsibility for Breaches of Business Associate Agreement

If the County learns of, or knows of, a pattern of activity or practice of a business associate that constitutes a material breach or violation of the business associate's obligation under its contract with the County, the County will take reasonable steps to cure the breach or end the violation, as applicable, and, if such steps are unsuccessful:

- 1) Terminate the contract or arrangement, if feasible; or

- 2) If termination is not feasible, report the problem to the Secretary.

### **§164.506 Uses and Disclosures to Carry Out Treatment, Payment, or Health Care Operations**

#### Standard: Permitted Uses and Disclosures

**The County may use or disclose protected health information without patient authorization for treatment, payment, or health care operations as follows:**

- 1) For use by the County in its own treatment, payment or health care operations;
- 2) For treatment activities of a health care provider;
- 3) To another covered entity or health care provider for the payment activities of the entity that receives the information;
- 4) To another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:
  - a) For the purposes of conducting quality assessment and improvement activities or reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing or credentialing activities; or
  - b) For the purpose of health care fraud and abuse detection or compliance.
- 5) As an Organized Health Care Arrangement, to another covered entity that participates in the Organized Health Care Arrangement for any health care operations activities of the Organized Health Care Arrangement.

#### Consent for Uses and Disclosures (Optional)

Although not required to do so, the County may, in its discretion, obtain the consent of an individual to use or disclose protected health information to carry out treatment, payment, or health care operations. However, such consent shall not be effective to permit a use or disclosure

of protected health information if an authorization is required or when another condition must be met for such use or disclosure.

### **§164.508 Uses And Disclosures For Which An Authorization Is Required**

**Except for uses and disclosures by the County for purposes of treatment, payment or healthcare operations and uses and disclosures under a few, select circumstances explained in these policies (e.g., in emergencies, as required by law, in order to locate family, etc.) the County may not use or disclose Patient Information without an authorization.** The HIPAA regulations specify the elements that are necessary for a valid authorization. These are set forth below. When the County obtains or receives a valid authorization for its use or disclosure of Patient Information, the use or disclosure must be consistent with the authorization.

#### Psychotherapy Notes

Notwithstanding the requirements of any other County policy, the County must obtain an authorization for any use or disclosure of psychotherapy notes, except to carry out the following treatment, payment, or health care operations:

- 1) Use by originator of the psychotherapy notes for treatment;
- 2) Use or disclosure by the County in training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling;
- 3) Use or disclosure by the County to defend a legal action or other proceeding brought by the individual; or
- 4) A use or disclosure that is to an individual; as required by law; to a health oversight agency with respect to the oversight of the originator of the psychotherapy notes; to coroners or medical examiners; or to avert a serious threat to health or safety.

#### Marketing

Notwithstanding the requirements of any other County policy, the County must obtain an authorization for any use or disclosure of protected health information for marketing, except if the communication is in the form of:

- 1) A face-to-face communication made by the County to an individual; or
- 2) A promotional gift of nominal value provided by the County.

If the marketing involves direct or indirect remuneration to the County from a third party, the authorization must state that such remuneration is involved.

## Valid Authorizations

A valid authorization must contain the following:

- 1) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion;
- 2) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;
- 3) The name or other specific identification of the person(s), or class of persons, to whom the County may make the requested use or disclosure;
- 4) A description of each purpose of the requested use or disclosure. The statement “At the request of the individual” is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose;
- 5) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure;
- 6) A statement setting forth the individual’s right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization and reference to the County’s notice;
- 7) A statement regarding the ability or inability to condition treatment, payment, enrollment or eligibility for benefits on authorization;
- 8) A statement that information used or disclosed pursuant to the authorization may be subject to another disclosure by the recipient and no longer be protected by this rule;
- 9) A reference to the notice provided to the individual concerning the uses and disclosures of protected health information that may be made by the County, and of the individual’s rights and the County’s legal duties with respect to the protected health information (See § 164.520);
- 10) Signature of the individual and date; and
- 11) If the authorization is signed by a personal representative of the individual, a description of such representative’s authority to act for the individual;
- 12) If the authorization is initiated at the County’s request for “marketing” purposes and direct or indirect remuneration is

involved, the authorization must contain such a statement. In addition, the authorization must be written in easy to understand language that the County staff and patients can comprehend.

An authorization may contain additional, but not contradictory, elements or information as deemed necessary by the County.

#### Invalid Authorizations

An authorization is invalid if the document has any of the following defects:

- 1) The expiration date has passed or the expiration event is known by the County to have occurred;
- 2) The authorization has not been filled out completely;
- 3) The authorization is known by the County to have been revoked;
- 4) The authorization lacks an element required by the compound authorization paragraph of this section, as applicable;
- 5) The authorization violates the prohibition on conditioning of authorizations in this section; or
- 6) A material provision in the authorization is known by the County to be false.

A sample “approved” authorization is attached to this Policy.

#### Compound Authorizations

An authorization for use or disclosure of Patient Information may not be combined with any other document to create a compound authorization, except as follows:

- 1) An authorization for the use or disclosure of Patient Information for a research study may be combined with any other type of written permission for the same research study;
- 2) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes;
- 3) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes may be combined with any other such authorization under this section, except when the County has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under the Prohibition on Conditioning of Authorizations paragraph of this section on the provision of one of the authorizations.

### Prohibition on Conditioning of Authorizations

The County may not condition treatment or payment on the provision of an authorization, except as follows:

- 1) The provision of research-related treatment may be conditioned on the provision of an authorization for the use or disclosure of protected health information for such research; and
- 2) The provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party may be conditioned on provision of an authorization for the disclosure of the protected health information to such third party.

### Revocation of Authorizations

An individual may revoke an authorization at any time, provided that the revocation is in writing, except to the extent that the County has taken action in reliance thereon.

### Documentation

The County must document and retain any signed authorization for a period of six years.

### Copy to the Individual

If the County seeks an authorization from an individual for a use or disclosure of protected health information, the County must provide the individual with a copy of the signed authorization.

### **§164.510 Uses And Disclosures Requiring An Opportunity For The Individual To Agree Or To Object**

Provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, the County may use or disclose Patient Information for the purposes of maintaining a facility directory and/or disclosing to a family member, other relative or a close personal friend of the individual (or any other person identified by the individual), the Patient Information directly relevant to such person's involvement with the individual's care or payment related to the individual's health care and only under the following circumstances.

### For Facility Directories

- 1) The County may use the following Patient Information to maintain a directory of individuals in its facility:
  - a) The individual's name;

- b) The individual's location in the covered health care provider's facility;
  - c) The individual's condition described in general terms that does not communicate specific medical information about the individual; and
  - d) The individual's religious affiliation.
- 2) The County may disclose the directory information:
- a) To members of the clergy; or
  - b) Except for religious affiliation, to other persons who ask for the individual by name.
- 3) Opportunity to Object. The County must inform an individual of the Patient Information that may be included in a directory and the persons to whom the County may disclose the information (including disclosures to clergy of information regarding religious affiliation) and provide the individual with the opportunity to restrict or prohibit some or all of the approved uses or disclosures permitted by this policy.
- 4) In Emergency Circumstances. If the opportunity to object to uses or disclosures cannot practicably be provided because of the individual's incapacity or an emergency treatment circumstance, the County may use or disclose some or all of the Patient Information permitted for the facility's directory, if such disclosure is:
- a) Consistent with a prior expressed preference of the individual, if any, that is known to the County; and
  - b) In the individual's best interest as determined by the County, in the exercise of professional judgment.
  - c) When it becomes practical to do so, the County must inform the individual of the opportunity to object to the County's use of his/her information in the directory.

#### To Family Members, Relatives or Friends

The County may use or disclose protected health information, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this section.

- 1) Notification of Family Members. The County may use or disclose Patient Information to notify, or assist in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the

individual's location, general condition, or death. Any such use or disclosure of Patient Information for notification purposes must be in accordance with appropriate policies in this section.

- 2) Uses and Disclosures with the Individual Present. If the individual is present for, or otherwise available prior to, a use or disclosure permitted to a family member, other relative or other person identified by the individual, and has the capacity to make health care decisions, the County may use or disclose the Patient Information if it:
  - a) Obtains the individual's agreement;
  - b) Provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or
  - c) Reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure.
- 3) Limited Uses and Disclosures When the Individual is Not Present or Incapable of Communicating. If the individual is not present for, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the County may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the Patient Information that is directly relevant to the person's involvement with the individual's health care. The County may use professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of Patient Information.

#### Uses and Disclosures for Disaster Relief Purposes

The County may use or disclose Patient Information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities. The requirements identified above under "uses and disclosures with the individual present" and "limited uses and disclosures when the individual is not present" apply to such uses and disclosure to the extent that the County, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

#### **§164.512 Uses And Disclosures For Which An Authorization Or Opportunity To Agree Or Object Is Not Required**

For all situations covered by this section, the County may use or disclose Patient 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. When the County 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 County's information and the individual's agreement may be given orally.

#### As Required by Law

- 1) The County may use or disclose Patient 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) The County must meet the requirements described in the paragraph relating to disclosures about victims of abuse, neglect or domestic violence;

#### For Public Health Activities

- 1) The County may disclose Patient Information for the public health activities and purposes described in this paragraph to:
  - a) 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;
  - b) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;
  - c) 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:
    - i) To collect or report adverse events (or similar reports 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;
    - ii) To track FDA-regulated products;
    - iii) 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

- iv) To conduct post marketing surveillance.
- d) 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 County 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
- e) An employer, about an individual who is a member of the workforce of the employer, if:
  - i) The County is a covered health care provider who is a member of the workforce of such employer or who provides health care to the individual at the request of the employer:
    - a) To conduct an evaluation relating to medical surveillance of the workplace; or
    - b) To evaluate whether the individual has a work-related illness or injury;
  - ii) The Patient Information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;
  - iii) The employer needs such findings in order to comply with its obligations, under 29 C.F.R. parts 1904 through 1928, 30 C.F.R. parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and
  - iv) The County provides written notice to the individual that Patient Information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:
    - a) By giving a copy of the notice to the individual at the time the health care is provided; or
    - b) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.

## Disclosures About Victims of Abuse, Neglect or Domestic Violence

- 1) Except for reports of child abuse or neglect permitted under the “As Required by Law” Section of this Policy, the County may disclose Patient Information about an individual whom the County reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence:
  - a) To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;
  - b) If the individual agrees to the disclosure; or
  - c) To the extent the disclosure is expressly authorized by statute or regulation and:
    - i) The County, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or
    - ii) If the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the Patient Information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.
- 2) Informing the individual. When the County makes a disclosure permitted by this section it must promptly inform the individual that such a report has been or will be made, except if:
  - a) The County, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or
  - b) The County would be informing a personal representative, and the County reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the County, in the exercise of professional judgment.

For Health Oversight Activities

- 1) The County may disclose Patient Information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:
  - a) The health care system;
  - b) Government benefit programs for which health information is relevant to beneficiary eligibility;
  - c) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or
  - d) Entities subject to civil rights laws for which health information is necessary for determining compliance.
- 2) For the purpose of the disclosures permitted by this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:
  - a) The receipt of health care;
  - b) A claim for public benefits related to health; or
  - c) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.
- 3) Notwithstanding paragraph (2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of this section.

For Judicial or Administrative Proceedings

- 1) The County may disclose Patient Information in the course of any judicial or administrative proceeding:
  - a) In response to an order of a court or administrative tribunal, provided that the County discloses only the Patient Information expressly authorized by the order; or

- b) In response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if:
  - i) The County receives “satisfactory assurance,” as described in paragraph (c) of this section, from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the Patient Information that has been requested has been given notice of the request; or
  - ii) The County receives satisfactory assurance from the party seeking the information that reasonable efforts have been made by the party to secure a “qualified protective order” that meets the requirements of this section.
- c) “Satisfactory Assurances”. The County will be deemed to have received satisfactory assurances from a party seeking Patient Information if the County receives from such party a written statement and accompanying documentation demonstrating that:
  - i) The party requesting such information has made a good faith attempt to provide written notice to the individual (or, if the individual’s location is unknown, to mail a notice to the individual’s last known address);
  - ii) The notice included sufficient information about the litigation or proceeding in which the Patient Information is requested to permit the individual to raise an objection to the court or administrative tribunal; and
  - i) The time for the individual to raise objections to the court or administrative tribunal has elapsed, and:
    - a) No objections were filed; or
    - b) All objections filed by the individual have been resolved by the court or the administrative tribunal and the disclosures being sought are consistent with such resolution.
- d) “Qualified Protective Orders”. The County will also be deemed to have received satisfactory assurances from a party seeking Patient Information, if the County receives from such party a written statement and accompanying documentation demonstrating that:
  - i) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and

have presented it to the court or administrative tribunal with jurisdiction over the dispute; or

- ii) The party seeking the Patient Information has requested a qualified protective order from such court or administrative tribunal.
- iii) A “qualified protective order” means, an order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that:
  - a) Prohibits the parties from using or disclosing the Patient Information for any purpose other than the litigation or proceeding for which such information was requested; and
  - b) Requires the return to the County or destruction of the Patient Information (including all copies made) at the end of the litigation or proceeding.
- e) The County may disclose Patient Information in response to a subpoena or other request without receiving satisfactory assurances, if the County makes reasonable efforts to provide notice to the individual or seeks a qualified protective order.
- 2) The provisions of this paragraph do not supersede other provisions of this section that otherwise permit or restrict uses or disclosures of Patient Information.

#### Disclosures for Law Enforcement Purposes

The County may disclose Patient Information for a law enforcement purpose to a law enforcement official if the following conditions are met, as applicable.

- 1) Pursuant to process and as otherwise required by law. The County may disclose Patient Information:
  - a) As required by law including laws that require the reporting of certain types of wounds or other physical injuries, except: (i) for laws subject to section 2 or 3 of this section; or (ii) In compliance with and as limited by the relevant requirements of:
    - i) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;
    - ii) A grand jury subpoena; or
    - iii) An administrative request, including an administrative subpoena or summons, a civil or an authorized

investigative demand, or similar process authorized under law, provided that:

- a) The information sought is relevant and material to a legitimate law enforcement inquiry;
- b) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and
- c) De-identified information could not reasonably be used.

2) Disclosure of limited information for identification and location purposes. Except for disclosures required by law as permitted of this section, the County may disclose Patient Information in response to a law enforcement official's request for information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that:

- a) The County may disclose only the following information:
  - i) Name and address;
  - ii) Date and place of birth;
  - iii) Social security number;
  - iv) ABO blood type and rh factor;
  - v) Type of injury;
  - vi) Date and time of treatment;
  - vii) Date and time of death, if applicable; and
  - viii) A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.
- b) The County may not disclose for the purposes of identification or location any Patient Information related to the individual's DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissue.

3) Regarding victims of a crime. Except for disclosures required by law as permitted by this section, the County may disclose Patient Information in response to a law enforcement official's request for such information about an individual who is, or is suspected to be, a victim of a crime, other

than disclosures that are to public health authorities or to law enforcement officials to report victims of abuse, neglect or domestic violence, if:

- a) The individual agrees to the disclosure; or
  - b) The County is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:
  - c) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;
  - d) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and
  - e) The disclosure is in the best interests of the individual as determined by the County, in the exercise of professional judgment.
- 4) About decedents. The County may disclose Patient Information about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the death of the individual if the County has a suspicion that such death may have resulted from criminal conduct.

#### Reporting Crime on Premises

The County may disclose to a law enforcement official Patient Information that the County believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the County.

#### Reporting Crime in Emergencies

- 1) When the County provides emergency health care in response to a medical emergency, other than such emergency on the premises of the County, it may disclose Patient Information to a law enforcement official if such disclosure appears necessary to alert law enforcement to:
  - a) The commission and nature of a crime;
  - b) The location of such crime or of the victim(s) of such crime; and
  - c) The identity, description, and location of the perpetrator of such crime.
- 2) If the County believes that the medical emergency described in this section is the result of abuse, neglect, or domestic violence of the

individual in need of emergency health care, this section does not apply and any disclosure to a law enforcement official for law enforcement purposes is subject to the requirements of this section or disclosures about victims of abuse, neglect or domestic violence.

#### Uses and Disclosures About Decedents

- 1) To Coroners and Medical Examiners. The County may disclose Patient Information to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. If the County also performs the duties of a coroner or medical examiner it may use Patient Information for the purposes described in this paragraph.
- 2) To Funeral Directors. The County may disclose Patient Information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. If necessary for funeral directors carry out their duties, the County may disclose the Patient Information prior to, and in reasonable anticipation of, the individual's death.

#### Uses and Disclosures for Cadaveric Organ, Eye or Tissue Donation Purposes

The County may use or disclose Patient 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.

#### Uses and Disclosures for Research Purposes

- 1) Permitted uses and disclosures. The County may use or disclose Patient Information for research, regardless of the source of funding of the research, provided that:
  - a) The County obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization for use or disclosure of Patient Information has been approved by:
    - i) An Institutional Review Board (IRB), established in accordance with 7 C.F.R. 1c.107, 10 C.F.R. 745.107, 14 C.F.R. 1230.107, 15 C.F.R. 27.107, 16 C.F.R. 1028.107, 21 C.F.R. 56.107, 22 C.F.R. 225.107, 24 C.F.R. 60.107, 28 C.F.R. 46.107, 32 C.F.R. 219.107, 34 C.F.R. 97.107, 38 C.F.R. 16.107, 40 C.F.R. 26.107, 45 C.F.R. 46.107, 45 C.F.R. 690.107, or 49 C.F.R. 11.107; or
    - b) The County obtains from the researcher representations that:

- i) Use or disclosure is sought solely to review Patient Information as necessary to prepare a research protocol or for similar purposes preparatory to research;
    - ii) No Patient Information is to be removed from the County by the researcher in the course of the review; and
    - iii) The Patient Information for which use or access is sought is necessary for the research purposes.
  - c) The County obtains from the researcher:
    - i) Representation that the use or disclosure is sought is solely for research on the Patient Information of decedents;
    - ii) Documentation, at the request of the County, of the death of such individuals; and
    - iii) Representation that the Patient Information for which use or disclosure is sought is necessary for the research purposes.
- 2) For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under this section, the documentation must include all of the following:
  - a) Identification and date of action. A statement identifying the IRB and the date on which the alteration or waiver of authorization was approved;
  - b) Waiver criteria. A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:
    - i) The use or disclosure of Patient Information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;
      - (a) An adequate plan to protect the identifiers from improper use and disclosure;
      - (b) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

- (c) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted under HIPAA;
  - ii) The research could not practicably be conducted without the waiver or alteration; and
  - iii) The research could not practicably be conducted without access to and use of protected health information.
- c) Patient Information needed. A brief description of the Patient Information for which use or access has been determined to be necessary by the IRB.
- d) Review and approval procedures. A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:
  - i) An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 C.F.R. 1c.108(b), 10 C.F.R. 745.108(b), 14 C.F.R. 1230.108(b), 15 C.F.R. 27.108(b), 16 C.F.R. 1028.108(b), 21 C.F.R. 56.108(b), 22 C.F.R. 225.108(b), 24 C.F.R. 60.108(b), 28 C.F.R. 46.108(b), 32 C.F.R. 219.108(b), 34 C.F.R. 97.108(b), 38 C.F.R. 16.108(b), 40 C.F.R. 26.108(b), 45 C.F.R. 46.108(b), 45 C.F.R. 690.108(b), or 49 C.F.R. 11.108(b)) or the expedited review procedures (7 C.F.R. 1c.110, 10 C.F.R. 745.110, 14 C.F.R. 1230.110, 15 C.F.R. 27.110, 16 C.F.R. 1028.110, 21 C.F.R. 56.110, 22 C.F.R. 225.110, 24 C.F.R. 60.110, 28 C.F.R. 46.110, 32 C.F.R. 219.110, 34 C.F.R. 97.110, 38 C.F.R. 16.110, 40 C.F.R. 26.110, 45 C.F.R. 46.110, 45 C.F.R. 690.110, or 49 C.F.R. 11.110);
- e) Required signature. The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.

Uses and Disclosures to Avert a Serious Threat to Health or Safety

- 1) Permitted disclosures. The County may, consistent with applicable law and standards of ethical conduct, use or disclose Patient Information, if the County, in good faith, believes the use or disclosure:
  - a) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and
  - b) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or
    - i) Is necessary for law enforcement authorities to identify or apprehend an individual:
      - a) Because of a statement by an individual admitting participation in a violent crime that the County reasonably believes may have caused serious physical harm to the victim; or
      - b) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody.
- 2) The County may not use or disclose Patient Information to avert or lessen a serious and imminent threat to the health or safety of a person or the public if the Patient Information is learned by the County:
  - a) In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure or counseling or therapy; or
  - b) Through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy.
- 3) A disclosure made to assist law enforcement authorities to identify or apprehend an individual (as allowed in (1)(B)(i)(a) above) shall contain only the statement made by the individual admitting participation in the violent crime and the following Patient Information: name and address, date and place of birth, social security number, ABO blood type and rh factor, type of injury, date and time of treatment, date and time of death (if applicable) and a description of distinguishing characteristics.
- 4) When the County uses or discloses Patient Information in order to avert a serious threat to health or safety, it is presumed to have acted in good faith with regard to the belief that the disclosures is necessary to prevent or lessen the threat or ensure the safety of a person or the public or is

necessary for law enforcement authorities to identify or apprehend an individual if the belief is based upon the County's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.

#### Uses and Disclosures for Specialized Government Functions

- 1) Military and veterans activities.
  - a) Armed Forces personnel. The County may use and disclose Patient Information of individuals who are Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the **Federal Register** the following information:
    - i) Appropriate military command authorities; and
    - ii) The purposes for which the Patient Information may be used or disclosed.
  - b) Foreign military personnel. The County may use and disclose Patient Information of individuals who are foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for Armed Forces personnel under notice published in the **Federal Register**.
- 2) National security and intelligence activities. The County may disclose Patient Information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, *et seq.*) and implementing authority (e.g., Executive Order 12333).
- 3) Protective services for the President of the United States and others. The County may disclose Patient Information to authorized federal officials for the provision of protective services to the President of the United States or to foreign heads of state or other similar persons or for the conduct of investigations authorized by 18 U.S.C. 871 (regarding threats against the President and successors to the Presidency) and 18 U.S.C. 879 (regarding threats against former presidents and certain other persons).
- 4) Correctional institutions and other law enforcement custodial situations.
  - a) The County may disclose Patient Information about an inmate to a correctional institution or a law enforcement official having lawful custody of an inmate if the

correctional institution or such law enforcement official represents that such Patient Information is necessary for:

- i) The provision of health care to such individuals;
  - ii) The health and safety of such individual or other inmates;
  - iii) The health and safety of the officers or employees of, or others at, the correctional institution;
  - iv) The health and safety of such individuals and officers or other persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another;
  - v) Law enforcement on the premises of the correctional institution; and
  - vi) The administration and maintenance of the safety, security, and good order of the correctional institution.
- b) No application after release. For the purposes of this provision, an individual is no longer an inmate when released on parole, probation, supervised release, or otherwise is no longer in lawful custody.

#### Disclosures for Workers' Compensation

The County may disclose Patient Information as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs that provide benefits for work-related injuries or illness.

#### **§164.514 Other Requirements Relating To Uses And Disclosures Of Patient Information**

##### De-Identification

Patient Information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information and is considered "de-identified".

- 1) In order to "de-identify" patient data, the following information relating to the individual, his/her relatives, employers, or household members shall be removed:
  - a) Names;

- b) All geographic subdivisions smaller than a State, including street address, city, county, and zip code. The first three digits of a zip code may be used if, according to the current census data:
  - i) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
  - ii) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;
- c) All dates (except year) including birth date, admission date, discharge date, and date of death. For anyone over the age of 89, the birth date year must also be removed and replaced with “90 and over”;
- d) Telephone numbers;
- e) Fax numbers;
- f) E-mail addresses;
- g) Social security numbers;
- h) Medical record numbers;
- i) Health plan beneficiary numbers;
- j) Account numbers;
- k) Certificate/license numbers;
- l) Vehicle identifiers and serial numbers, including license plate numbers;
- m) Device identifiers and serial numbers;
- n) Web Universal Resource Locators (URLs);
- o) Internet Protocol (IP) address numbers;
- p) Biometric identifiers, including finger and voice prints;
- q) Full face photographic images and any comparable images; and
- r) Any other unique identifying number, characteristic, or code, except as permitted by this section.

**Even if the foregoing are removed, the Patient Information is not de-identified if the County has actual knowledge that the information could be used alone or in combination with other information to identify the individual.**

Re-Identification

- 2) The County may assign a code or other means of record identification to allow de-identified information to be re-identified by the County, provided that:
  - a) The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and
  - b) The County does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.
- 3) Minimum Necessary Rule. The County must take reasonable efforts to ensure that any use or disclosure that it, or anyone acting on its behalf, makes with respect to Patient Information follows the “minimum necessary” rule. (See § 164.502)
  - a) Minimum necessary uses of Patient Information.
    - i) The County shall identify:
      - a) Those persons (or titles of persons, as appropriate), in its workforce who need access to Patient Information to carry out their duties; and
      - b) The category of Patient Information to which access is needed by these persons and the conditions appropriate to such access.
    - ii) The County shall make reasonable efforts to limit the access of Patient Information consistent with this section.
  - b) Minimum necessary disclosures of Patient Information.
    - i) The County shall implement policies and procedures (which may be standard protocols) relating to routine and recurring disclosures that limit the Patient Information disclosed to the amount reasonably

necessary to achieve the purpose of the disclosure.

- ii) For all non-routine disclosures, the County shall:
  - a) Develop criteria designed to limit the Patient Information disclosed to the information reasonably necessary to accomplish the purpose for which disclosure is sought; and
  - b) The Privacy Officer shall review requests for disclosure on an individual basis in accordance with this criteria.
- iii) The County may rely, if the reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when:
  - a) The request is made by a public official as long as the public official represents that the information requested is the minimum necessary for the stated purpose(s) (see § 164.512 for standards relating to disclosures by public officials);
  - b) The information is requested by a hospital, provider, health plan or healthcare clearinghouse;
  - c) The information is requested by a professional who is a member of the County's workforce or is a business associate of the County for the purpose of providing professional services to the County, if the professional represents that the information requested is the minimum necessary for the stated purpose(s); or
  - d) The request is for research (see § 164.512 for the requirements relating to research).

- c) Minimum necessary requests for Patient Information.
  - i) When requesting Patient Information from other hospitals, providers, health plans or healthcare clearinghouses, the County shall limit any request for Patient Information to that which is reasonably necessary to accomplish the purpose for which the request is made.
  - ii) For requests that are made on a routine and recurring basis, the County must implement policies and procedures (which may be standard protocols) that limit the Patient Information requested to the amount reasonably necessary to accomplish the purpose for which the request is made.
  - iii) For all other requests, the County must:
    - (a) Develop criteria designed to limit the request for protected health information to the information reasonably necessary to accomplish the purpose for which the request is made; and
    - (b) Review requests for disclosure on an individual basis in accordance with such criteria.
- d) Other Content Requirement. The County may not use, disclose or request an entire medical record, unless the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure, or request.

#### Uses and Disclosures of Limited Data Set

A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- 1) Names;
- 2) Postal address information, other than town or city, State and zip code;
- 3) Telephone numbers;
- 4) Fax numbers;

- 5) Electronic mail addresses;
- 6) Social Security numbers;
- 7) Medical record numbers;
- 8) Health plan beneficiary numbers;
- 9) Account numbers;
- 10) Certificate/license numbers;
- 11) Vehicle identifiers and serial numbers, including license plate numbers;
- 12) Device identifiers and serial numbers;
- 13) Web Universal Resource Locators (URLs);
- 14) Internet Protocol (IP) address numbers;
- 15) Biometric identifiers, including finger and voice prints; and
- 16) Full face photographic images and any comparable images.

The County may use or disclose a limited data set only for the following purposes of research, public health, or health care operations. The County may use protected health information to create a limited data set that meets the requirements of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the County. However, to use or disclose a limited data set, the County must enter into a data use agreement with the limited data set recipient.

The data use agreement between the County and the limited data set recipient must:

- 1) Establish the permitted uses and disclosures of such information by the limited data set recipient (which must be limited to research, public health or health care operations). The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of these policies if done by the County;
- 2) Establish who is permitted to use or receive the limited data set; and
- 3) Provide that the limited data set recipient will:

- a) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
- b) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
- c) Report to the County any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
- d) Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
- e) Not identify the information or contact the individuals.

If the County becomes aware of a pattern of activity or Practice of the limited data set recipient that constitutes a material breach or violation of the data use agreement, the County must take reasonable steps to cure the breach or end the violation. If such steps are unsuccessful, the County must discontinue disclosure of protected health information to the recipient; and report the problem to the Secretary of Health and Human Services or any other officer or employee of Health and Human Services to whom authority has been delegated.

#### Uses and Disclosures for Fundraising

- 1) The County may use, or disclose to a business associate, the following Patient Information for the purpose of raising funds for its own benefit, without an authorization:
  - a) Demographic information relating to an individual; and
  - b) Dates of health care provided to an individual.
- 2) Fundraising requirements.
  - a) The County may not use or disclose Patient Information for fundraising purposes unless a statement to this effect is included in the County's notice;
  - b) The County must include in any fundraising materials it sends to an individual a description of how the individual may opt out of receiving any further fundraising communications.
  - c) The County must make reasonable efforts to ensure that individuals who decide to opt out of receiving future

fundraising communications are not sent any additional communications.

### Verification Requirements

Prior to making any disclosure of Patient Information, the County must:

#### General

- 1) Verify the identity of a person requesting Patient Information and the authority of any such person to have access to Patient Information.
  - a) This does not pertain to disclosures under §164.510; or
  - b) In cases where the identity or authority of the person is known to the County.
- 2) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the Patient Information when the documentation, statement, or representation is a condition of the disclosure under these policies.
  - a) The County may rely, if such reliance is reasonable under the circumstances, on documentation, statements, or representations that, on their face, meet the applicable requirements, including:
    - i) Subpoenas or by a separate written statement that, on its face, demonstrates that the applicable requirements set forth in section 164.512 have been met.
    - ii) Where documentation is required (e.g. § 164.512) the verification requirement is satisfied by one or more written statements, provided that each is appropriately dated and signed.

#### Reliance on Documents

- a) Identity of public officials. The County may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of Patient Information is to a public official or a person acting on behalf of the public official:

- i) If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;
  - ii) If the request is in writing, the request is on the appropriate government letterhead; or
  - iii) If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate government letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person is acting on behalf of the public official.
- b) Authority of public officials. The County may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of Patient Information is to a public official or a person acting on behalf of the public official:
- i) A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority;
  - ii) If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.
- c) Exercise of professional judgment. The verification requirements of this paragraph are met if the County relies on the exercise of professional judgment or acts on good faith in making a use or disclosure.

## **§164.520 Notice Of Privacy Practices For Patient Information**

### Notice of Privacy Practices

- a) Right to notice. An individual has a right to notice of the uses and disclosures of Patient Information that may be made by the County, and of the individual's rights and the County's legal duties with respect to Patient Information.

- b) Exception for inmates. An inmate does not have a right to notice under this section.

### Content of Notice

- a) Required elements. The County must provide a notice that is written in plain language and that contains the elements required by this paragraph.
  - i) Header. The notice must contain the following statement as a header or otherwise prominently displayed: “THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.”
  - ii) Uses and disclosures. The notice must contain:
    - a) A detailed description, including at least one example, of the types of uses and disclosures that County is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations. The description must reflect the most stringent law.
    - b) A detailed description of each of the other purposes for which the County is permitted or required by this subpart to use or disclose Patient Information without the individual’s written authorization.
    - c) A statement that other uses and disclosures will be made only with the individual's written authorization and that the individual may revoke such authorization.
  - iii) Separate statements for certain uses or disclosures. If the County intends to engage in any of the following activities, the notice must include a separate statement, as applicable, that:
    - a) The County may contact the individual to provide appointment reminders or information about treatment alternatives or other health-related benefits and services that may be of interest to the individual; or
    - b) The County may contact the individual to raise funds for the County.

- iv) Individual rights. The notice must contain a statement of the individual's rights with respect to Patient Information and a brief description of how the individual may exercise these rights, as follows:
  - a) The right to request restrictions on certain uses and disclosures of Patient Information, including a statement that the County is not required to agree to a requested restriction;
  - b) The right to receive confidential communications of Patient Information, as applicable;
  - c) The right to inspect and copy Patient Information;
  - d) The right to amend Patient Information;
  - e) The right to receive an accounting of disclosures of Patient Information; and
  - f) The right of an individual, including an individual who has agreed to receive the notice electronically to obtain a paper copy of the notice from County upon request.
- v) The County's duties. The notice must contain:
  - a) A statement that the County is required by law to maintain the privacy of Patient Information and to provide individuals with notice of its legal duties and privacy practices with respect to Patient Information;
  - b) A statement that the County is required to abide by the terms of the notice currently in effect; and
  - c) A statement that the County reserves the right to change the terms of its notice and to make the new notice provisions effective for all Patient Information that it maintains. The statement must also describe how it will provide individuals with a revised notice.
- vi) Complaints. The notice must contain a statement that individuals may complain to the County and to the Secretary if they believe their privacy rights have been

violated, a brief description of how the individual may file a complaint with the County, and a statement that the individual will not be retaliated against for filing a complaint.

vii) Contact. The notice must contain the name, or title, and telephone number of a person or office to contact for further information.

viii) Effective date. The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.

b) Optional elements.

i) The County may adopt uses and disclosures that are more limited than required by law. If the County elects to further limit the uses or disclosures, the County must describe its more limited uses or disclosures in its notice. The County may not limit uses or disclosures that are required by law or permitted by § 164.512.

ii) The County may only apply a change in its more limited uses and disclosures to Patient Information created or received prior to issuing a revised notice, if the notice includes a statement to this effect.

### Revisions to the Notice

The County shall promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the County's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.

### Provision of Notice

- a) The County shall provide the notice no later than the date of the first service delivery, including service delivered electronically, to such individual after April 14, 2003.
- b) In an emergency treatment situation, the County shall provide the notice as soon as reasonably practicable after the emergency treatment situation.
- c) Except in an emergency treatment situation, the County shall make a good faith effort to obtain a written acknowledgement of receipt of the notice provided in accordance with these policies, and if not obtained, document

its good faith efforts to obtain such acknowledgement and the reason why the acknowledgement was not obtained;

d) The County shall:

- i) Have the notice available at all sites for individuals to request to take with them; and
- ii) Post the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the County to be able to read the notice; and
- iii) Whenever the notice is revised, make the notice available upon request on or after the effective date of the revision and promptly post the notice.

e) Specific requirements for electronic notice.

- i) The County must prominently post its notice on its web site and make the notice available electronically through the web site.
- ii) The County may provide the notice to an individual by e-mail, if the individual agrees to electronic notice and such agreement has not been withdrawn. If the County knows that the e-mail transmission has failed, a paper copy of the notice must be provided to the individual.
- iii) If the first service delivery to an individual is delivered electronically, the County must provide electronic notice automatically and contemporaneously in response to the individual's first request for service. Except in an emergency treatment situation, the County must make a good faith effort to obtain a written acknowledgement of receipt of the notice provided in accordance with these policies, and if not obtained, document its good faith efforts to obtain such acknowledgement and the reason why the acknowledgement was not obtained.
- iv) An individual retains the right to obtain a paper copy of the notice from a County upon request.

### Documentation

The County shall document compliance with the notice requirements by retaining copies of each of the notices issued by the County for a period of six years, and, if applicable, any written acknowledgments of receipt of the notice or documentation of good faith efforts to obtain such written acknowledgment.

## **§164.522 Right To Request Privacy Protection For Patient Information**

### The Right of an Individual to Request Restriction of Uses and Disclosures

- a) The County must permit an individual to request that the County restrict:
  - i) Uses or disclosures of Patient Information to carry out treatment, payment, or health care operations; and
  - ii) Disclosures permitted under § 164.510.
- b) The County is not required to agree to a restriction.
- c) If the County agrees to a restriction, the County may not use or disclose Patient Information in violation of such restriction, except that, if the individual who requested the restriction is in need of emergency treatment and the restricted Patient Information is needed to provide the emergency treatment, the County may use the restricted Patient Information, or may disclose such information to a health care provider, to provide such treatment to the individual.
- d) If restricted Patient Information is disclosed to a health care provider for emergency treatment, the County must request that such health care provider not further use or disclose the information.
- e) A restriction agreed to by the County under paragraph (A) of this section is not effective under this subpart to prevent uses or disclosures permitted or required under §§ 164.502, 164.510 or 164.512.

Terminating a Restriction. The County may terminate its agreement to a restriction, if:

- a) The individual agrees to or requests the termination in writing;
- b) The individual orally agrees to the termination and the oral agreement is documented; or
- c) The County informs the individual that it is terminating its agreement to a restriction, except that such termination is only effective with respect to Patient Information created or received after it has so informed the individual.

Documentation. If the County agrees to a restriction, it must document the restriction and retain it for six years.

The Right of an Individual to Request Confidential Communications

- a) The County must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of Patient Information from the County by alternative means.
- b) Conditions on providing confidential communications.
  - i) The County may require the individual to make a request for a confidential communication in writing.
  - ii) The County may condition the provision of a reasonable accommodation in the following circumstances:
    - a) When appropriate, information as to how payment, if any, will be handled; and
    - b) Specification of an alternative address or other method of contact.
  - iii) The County may not require an explanation from the individual as to the basis for the request as a condition of providing communications on a confidential basis.

**§164.524 Access Of Individuals To Patient Information**

1) Right of Access

An individual has a right of access to inspect and obtain a copy his/her Patient Information that is contained in the records of the County, for as long as the Patient Information is maintained by the County, except for:

- a) Psychotherapy notes;
- b) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and
- c) Patient Information maintained by a County that is:
  - i) 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
  - ii) Exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 C.F.R. 493.3(a)(2).

Unreviewable grounds for denial. The County may deny an individual access without providing the individual an opportunity for review, in the following circumstances.

- a) The Patient Information is excepted from the right of access by paragraph 1) of this section.
- b) If the Patient Information was created or obtained by the County in the course of research that includes treatment. In this case, access may be temporarily suspended 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 and the County has informed the individual that the right of access will be reinstated upon completion of the research.
- c) If the records are subject to the Privacy Act, 5 U.S.C. § 552a and the denial of access under the Privacy Act would meet the requirements of that law.
- d) An individual's access may be denied if the Patient Information was obtained from someone other than the County under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

Reviewable grounds for denial. The County may deny an individual access under the following circumstances, provided that the individual is given a right to have such denials reviewed by a licensed health care professional who is designated by the County to act as a reviewing official and who did not participate in the individual decision to deny.

- a) 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;
- b) The Patient Information makes reference to another person 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
- c) 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.

### Requests for Access and Timely Action

- a) Individual's request for access. The County must permit an individual to request access to inspect or to obtain a copy of the Patient Information about the individual that is maintained by the County. The County may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.
- b) Timely action by the County.
  - i) Unless the information is stored offsite, the County must act on a request for access no later than 30 days after receipt of the request as follows:
    - a) If the County grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested as set forth below.
    - b) If the County denies the request, in whole or in part, it must provide the individual with a written denial as set forth below.
  - ii) For Patient Information that is not maintained or accessible to the County on-site, the County must act on a request no later than 60 days from the receipt of such a request.
  - iii) If the County is unable to act on a request within the time allotted, the County may extend the time by no more than 30 days, provided that:
    - a) Within the time allotted, the County provides the individual with a written statement of the reasons for the delay and the date by which the County will complete its action on the request; and
    - b) The County is only permitted one such extension of time for action on a request for access.

### Provision of Access

If the County provides an individual with access, in whole or in part, to Patient Information, the County shall comply with the following requirements.

- a) Providing the access requested. The County must provide the access requested by individuals, including inspection or obtaining a copy, or both. The County must ensure that it produces all relevant information, no matter what department the records are located in. If the same Patient Information that is the subject of a request for access is maintained at more than one location, the County need only produce the Patient Information once in response to a request for access.
- b) Form of access requested.
  - i) The County must provide the Patient Information to the individual accessing the Patient Information in the form or format requested by the individual, if it is readily producible in such form or format; or, if not, in a readable hard copy form or such other form or format as agreed to by the County and the individual.
  - ii) The County may provide the individual with a summary of the Patient Information requested, in lieu of providing access to the Patient Information or may provide an explanation of the Patient Information to which access has been provided, 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 County for such summary or explanation.
- c) Time and manner of access. The County must provide access as requested by the individual in a timely manner, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the Patient Information, or mailing the copy of the Patient Information at the individual's request. The County 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.
- d) Fees. If the individual requests a copy of the Patient Information or agrees to a summary or explanation of such information, the County may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:
  - i) Copying, including the cost of supplies for and labor of copying, the Patient Information requested by the individual;

- ii) Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and
- iii) Preparing an explanation or summary of the Patient Information, if agreed to by the individual in advance.

### Denial of Access

If the County denies access, in whole or in part, to Patient Information, the County must comply with the following requirements.

- a) Making other information accessible. The County must, to the extent possible, give the individual access to any other Patient Information requested, given the Patient Information the County has the right to prohibit access.
- b) Denial. The County 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 including a description of how the individual may exercise such review rights; and
  - iii) A description of how the individual may complain to the County or to the Secretary. The description must include the name, or title, and telephone number of the contact person or office designated for this purpose.
- c) Other responsibility. If the County does not maintain the Patient Information that is the subject of the individual's request for access, and the County knows where the requested information is maintained, the County must inform the individual where to direct the request for access.
- d) Review of denial requested. If the individual has requested a review of a denial, the County must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The County 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 set forth herein. The County 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.
- e) Documentation. The County must document the following and retain the documentation for a period of six years:

- i) The records that are subject to access by individuals; and
- ii) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.

### **§164.526 Amendment Of Patient Information**

#### Right to Amend

An individual has the right to have the County amend Patient Information maintained by the County in its records.

#### Denial of Amendment

The County may deny an individual's request for amendment, if it determines that the Patient Information:

- 1) Was not created by the County, unless the individual provides a reasonable basis to believe that the originator of Patient Information is no longer available to act on the requested amendment;
- 2) Is not part of the County's records;
- 3) Would not be available for inspection under the principles set forth at §164.524; or
- 4) Is accurate and complete.

#### Requests for Amendment and Timely Action

The County must permit an individual to request that the County amend the Patient Information that is maintained by the County in its records. The County may require an individual to make a request for amendment in writing and to provide a reason to support the request, provided that it informs individuals in advance of such requirements.

#### Timely Action by the County

- 1) The County must act on the individual's request for an amendment no later than 60 days after receipt of such a request.
- 2) If the County is unable to act on the amendment within 60 days, the County may extend the time for such action by no more than 30 days, provided that:
  - a) Within the 60 day period, it provides the individual with a written statement of the reasons for the delay and

the date by which the County will complete its action on the request; and

- b) The County may have only one such extension of time for action on a request for an amendment.

### Accepting the Amendment

If the County accepts the requested amendment, in whole or in part, the County must comply with the following requirements.

- 1) Making the amendment. The County must make the appropriate amendment to the Patient Information or record by, at a minimum, identifying the records that are affected by the amendment and appending or otherwise providing a link to the location of the amendment.
- 2) Informing the individual. The County must timely inform the individual that the amendment is accepted and obtain the individual's identification of and agreement to have the County notify the relevant persons with which the amendment needs to be shared.
- 3) Informing others. The County must make reasonable efforts to inform and provide the amendment within a reasonable time to:
  - i) Persons identified by the individual as having received Patient Information about the individual and needing the amendment; and
  - ii) Persons, including business associates, that the County knows have the Patient Information that is the subject of the amendment and that may have relied, or could foreseeably rely, on such information to the detriment of the individual.

### Denying the Amendment

If the County denies the requested amendment, in whole or in part, the County must comply with the following requirements.

- 1) Denial. The County must provide the individual with a timely, written denial. The denial must use plain language and contain:
  - i) The basis for the denial;
  - ii) The individual's right to submit a written statement disagreeing with the denial and how the individual may file such a statement;

- iii) A statement that, if the individual does not submit a statement of disagreement, the individual may request that the County provide the individual's request for amendment and the denial with any future disclosures of the Patient Information that is the subject of the amendment; and
  - iv) A description of how the individual may complain to the County or to the Secretary. The description must include the name, or title, and telephone number of the contact person or office designated by the County.
- 2) Statement of disagreement. The County must permit the individual to submit to the County a written statement disagreeing with the denial of all or part of a requested amendment and the basis of such disagreement. The County may reasonably limit the length of a statement of disagreement.
  - 3) Rebuttal statement. The County may prepare a written rebuttal to the individual's statement of disagreement. Whenever such a rebuttal is prepared, the County must provide a copy to the individual who submitted the statement of disagreement.
  - 4) Recordkeeping. The County must, as appropriate, identify the record or Patient Information contained in the County's records that is the subject of the disputed amendment and append or otherwise link the individual's request for an amendment, the County's denial of the request, the individual's statement of disagreement, if any, and the County's rebuttal, if any, to the designated record set.
  - 5) Future disclosures. If a statement of disagreement has been submitted by the individual, the County must include the request for an amendment, the County's denial of the request, the individual's statement of disagreement and the County's rebuttal or, at the election of the County, an accurate summary of any such information, with any subsequent disclosure of the Patient Information to which the disagreement relates.
    - i) If the individual has not submitted a written statement of disagreement, the County must include the individual's request for amendment and its denial, or an accurate summary of such information, with any subsequent disclosure of the Patient Information only if the individual has requested such action.
    - ii) If a subsequent disclosure is made using a standard transaction that does not permit the additional material to be included with the disclosure, the County may separately transmit the amendment, denial, statement of disagreement and rebuttal as applicable, to the recipient of the standard transaction.

### Actions on Notices of Amendment

When the County is informed by hospital, provider, health plan or healthcare clearinghouse of an amendment to an individual's Patient Information, the County must amend the Patient Information in its records.

### Documentation

The County must document the titles of the persons or offices responsible for receiving and processing requests for amendments by individuals and retain the documentation for six years.

## **§164.528 Accounting Of Disclosures Of Patient Information**

### Right to an Accounting of Disclosures of Patient Information

- 1) An individual has a right to receive an accounting of disclosures of Patient Information made by the County for any period during the six years prior to the date on which the accounting is requested, except for disclosures:
  - a) To carry out treatment, payment and health care operations;
  - b) To individuals of Patient Information about them;
  - c) For the County's directory or to persons involved in the individual's care or other notification purposes;
  - d) That were incident to a use or disclosure otherwise permitted or required;
  - e) Pursuant to a written authorization;
  - f) For national security or intelligence purposes;
  - g) To correctional institutions or law enforcement officials;
  - h) As part of a limited data set in accordance with these policies; or
  - i) That occurred prior to April 14, 2003 for the County.
- 2) The County must temporarily suspend an individual's right to receive an accounting of disclosures made to a health oversight agency or law enforcement official for the time specified by such agency or official, if such agency or official provides the County with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.

- a) If the agency or official statement is made orally, the County must:
  - i) Document the statement, including the identity of the agency or official making the statement;
  - ii) Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and
  - iii) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement is submitted during that time.

### Content of the Accounting

The County must provide the individual with a written accounting that meets the following requirements.

- 1) The accounting must include disclosures of Patient Information that occurred during the six years (or such shorter time period at the request of the individual) prior to the date of the request for an accounting, including disclosures to or by business associates of the County.
- 2) The accounting must include for each disclosure:
  - a) The date of the disclosure;
  - b) The name of the entity or person who received the Patient Information and, if known, the address of such entity or person;
  - c) A brief description of the Patient Information disclosed; and
  - d) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure.
- 3) If, during the period covered by the accounting, the County has made multiple disclosures of Patient Information to the same person or entity for a single purpose, or pursuant to a single authorization, the accounting may, with respect to such multiple disclosures, provide:
  - a) The information required by this policy for the first disclosure during the accounting period;

- b) The frequency, periodicity, or number of the disclosures made during the accounting period; and
  - c) The date of the last such disclosure during the accounting period.
- 4) If, during the period covered by the accounting, the County has made disclosures of protected health information for a particular research purpose for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide:
- a) The name of the protocol or other research activity;
  - b) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
  - c) A brief description of the type of protected health information that was disclosed;
  - d) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;
  - e) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and
  - f) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.
- 5) If the County provides an accounting for research disclosures and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the County shall, at the request of the individual, assist in contacting the entity that sponsored the research or the researcher.

Provision of the Accounting

- 1) The County must act on the individual's request for an accounting, no later than 60 days after receipt of such a request, as follows.
  - a) The County must provide the individual with the accounting requested; or

- b) If the County is unable to provide the accounting within 60 days, the County may extend the time to provide the accounting by no more than 30 days, provided that:
  - i) The County, within the time limit set by this section, provides the individual with a written statement of the reasons for the delay and the date by which the County will provide the accounting; and
  - ii) The County may have only one such extension of time for action on a request for an accounting.
- 2) The County must provide the first accounting to an individual in any 12-month period without charge. The County may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12-month period, provided that the County informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.

#### Documentation

The County must document the following and retain the documentation for a period of six years:

- 1) The information required to be included in an accounting for disclosures of Patient Information that are subject to an accounting;
- 2) The written accounting that is provided to the individual under this section; and
- 3) The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals.

#### **§164.530 Administrative Requirements**

##### Privacy Officer

- a) The County must designate a Chief Privacy Officer (CPO). The CPO is responsible for the development of these Privacy and Security Policies for the County and to advise and assist the County leadership in the development and implementation of necessary procedures and action to assure compliance with the regulations.

- b) The CPO shall be responsible for receiving complaints under this section and must be able to provide further information about matters covered by the notice. The County shall document any changes to the CPO and retain such documentation for six years.

### Training

The County will train all members of the workforce on the policies and procedures, as necessary and appropriate for the members of the workforce to carry out their function within the County.

- a) The County shall provide training, as follows:
  - i) To each member of the County's workforce by no later than April 14, 2003;
  - ii) Thereafter, to each new member of the workforce within a reasonable period of time after the person joins the County's workforce; and
  - iii) To each member of the County's workforce whose functions are affected by a material change in the policies or procedures, within a reasonable period of time after the material change becomes effective.
- b) The County shall document that all training has been provided and retain it for a period of six years.

### Safeguards

The County shall have in place appropriate administrative, technical, and physical safeguards to protect the privacy of Patient Information.

- a) The County shall reasonably safeguard Patient Information from any intentional or unintentional use or disclosure that is in violation of the policies and procedures.
- b) The County shall reasonably safeguard protected health information to limit incidental uses or disclosures made pursuant to an otherwise permitted or required use or disclosure.

### Complaints to the County

The County shall provide a process for individuals to make complaints concerning the County's policies and procedures or its compliance with its policies and procedures. The County shall document all complaints received, and their disposition, if any. The County shall maintain this documentation for a period of six years.

### Sanctions

The County shall have and apply appropriate sanctions against members of its workforce who fail to comply with the privacy policies and procedures of the County or the requirements of this subpart. This standard does not apply to a member of the County's workforce with respect to whistleblower actions or complaints to or against the County. The County shall document the sanctions that are applied, if any and retain it for a period of six years.

### Mitigation

The County shall mitigate, to the extent practicable, any harmful effect that is known to the County of a use or disclosure of Patient Information in violation of its policies and procedures by the County or its business associate.

### Refraining from Intimidating or Retaliatory Acts

The County shall not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against:

- a) Individuals. Any individual for the exercise by the individual of his or her rights including the filing of a complaint under this section;
- b) Individuals and others. Any individual or other person for:
  - i) Filing of a complaint with the Secretary;
  - ii) Testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing; or
  - iii) Opposing any unlawful act or practice provided the individual or person has a good faith belief that the practice is unlawful, and the manner of the opposition is reasonable and does not involve an unlawful disclosure of Patient Information.

### Waiver of Rights

The County shall not require individuals to waive their rights as a condition of the provision of treatment.

### Policies and Procedures

The County shall implement policies and procedures with respect to Patient Information that are designed to comply with the standards, implementation specifications, or other requirements of federal and state law and regulations. The policies and procedures must be reasonably designed, taking into account the size of and the type of activities that relate to Patient Information undertaken by the County, to ensure such compliance.

- a) Changes to policies or procedures.

- i) The County shall change its policies and procedures as necessary and appropriate to comply with changes in the law.
  - ii) When the County changes a privacy County as stated in its notice and makes corresponding changes to its policies and procedures, it may make the changes effective for Patient Information that it created or received prior to the effective date of the notice revision, if the County has a statement in its notice reserving its right to make such a change in its privacy practices; or
  - iii) The County may make any other changes to policies and procedures at any time, provided that the changes do not materially affect the content of the notice, the changes comply with federal and state law and the changes are retained for six years.
- b) Changes in law. Whenever there is a change in law that necessitates a change to the County's policies or procedures, the County must promptly document and implement the revised policy or procedure. If the change in law materially affects the content of the notice, the County shall promptly make the appropriate revisions to the notice. Nothing in this paragraph may be used by the County to excuse a failure to comply with the law.

#### Documentation

The County must:

- a) Maintain its policies and procedures in written or electronic form;
- b) If a communication is required to be in writing, maintain such writing, or an electronic copy, as documentation; and
- c) If an action, activity, or designation is required by this subpart to be documented, maintain a written or electronic record of such action, activity, or designation.

#### Retention Period

The County shall retain the documentation required by these policies for six years from the date of its creation or the date when it last was in effect, whichever is later.

#### **§164.532 Transition Provisions**

The County may use or disclose Patient Information pursuant to authorization, or other express legal permission obtained from an individual permitting the use or disclosure of Patient

Information, informed consent of the individual to participate in research, or a waiver of informed consent by an IRB.

#### Effect of Prior Authorization for Purposes Other than Research

The County may use or disclose Patient Information that it creates or receives prior to April 14, 2003 pursuant to an authorization or other express legal permission obtained from an individual prior to April 14, 2003, provided that the authorization or other express legal permission specifically permits such use or disclosure and there is no agreed-to restriction.

#### Effect of Prior Permission for Research

The County may, to the extent allowed by one of the following permissions, use or disclose, for research, Patient Information that it creates or receives either before or after April 14, 2003, provided that there is no agreed-to restriction, and the County obtains, prior to April 14, 2003, either:

- a) An authorization or other express legal permission from an individual to use or disclose protected health information for the research;
- b) The informed consent of the individual to participate in the research; or
- c) A waiver, by an IRB, of informed consent for the research in accordance with 7 C.F.R. 1c.116(d), 10 C.F.R. 745.116(d), 14 C.F.R. 1230.116(d), 15 C.F.R. 27.116(d), 16 C.F.R. 1028.116(d), 21 C.F.R. 50.24, 22 C.F.R. 225.116(d), 24 C.F.R. 60.116(d), 28 C.F.R. 46.116(d), 32 C.F.R. 219.116(d), 34 C.F.R. 97.116(d), 38 C.F.R. 16.116(d), 40 C.F.R. 26.116(d), 45 C.F.R. 46.116(d), 45 C.F.R. 690.116(d), or 49 C.F.R. 11.116(d). However, if informed consent is sought from an individual participating in the research after April 14, 2003, the County must obtain a written authorization (See §164.508).

#### Effect of Prior Contracts or Other Arrangements with Business Associates

The County may disclose Patient Information to a business associate and may allow a business associate to create, receive, or use protected health information on its behalf pursuant to a written contract or other written arrangement with such business associate that does not comply with these policies, if:

- a) Prior to October 15, 2002, the County has entered into and is operating pursuant to a written contract or other written arrangement with a business associate to perform functions or activities or provide services that make the entity a business associate; and

- b) The contract or other arrangement is not renewed or modified from October 15, 2002, until April 14, 2003.

A prior contract or other arrangement that meets the foregoing qualification requirements, shall be deemed compliant until the earlier of:

- a) The date such contract or other arrangement is renewed or modified on or after April 14, 2003; or
- b) April 14, 2004.