

Secretary of State
NOTICE OF PROPOSED RULEMAKING*
A Statement of Need and Fiscal Impact accompanies this form.

Department of Human Services	407	
Agency and Division	Administrative Rules Chapter Number	
Jennifer Bittel	250 Winter St NE, Salem, OR 97301	(503) 947-5250
Rules Coordinator	Address	Telephone

RULE CAPTION

Privacy Rules Setting Forth General Procedures Governing the Collection, Use and Disclosure of Protected Information

Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

RULEMAKING ACTION

Secure approval of new rule numbers (Adopted or Renumbered rules) with the Administrative Rules Unit prior to filing

ADOPT: OAR 407-014-0015

AMEND: OAR 407-014-0000, 407-014-0020, 407-014-0030, 407-014-0040, 407-014-0050, 407-014-0060, 407-014-0070

REPEAL: OAR 407-014-0000(T), 407-014-0015 (T), 407-014-0020(T), 407-014-0030(T), 407-014-0040(T), 407-014-0050(T), 407-014-0060(T), 407-014-0070(T)

Stat. Auth.: **ORS 409.050**

Other Auth.: **HB 2009, enacted in 2009 OR Laws, chapter 595, sections 19-25 & 45 CFR parts 160-164**

Stats. Implemented: **ORS 409.010 & 433.045**

RULE SUMMARY

These rules govern the collection, use and disclosure of protected information by the Department about individuals and to explain the rights and specific actions that individuals may take or request to be taken regarding the uses and disclosures of their protected information. The proposed adoption and amendment of these rules also set forth Department requirements governing the use and disclosure of protected health information for purposes of HIPAA, 42 USC 1320-d through 1320d-8, Pub L 104-191, sec. 262 and 264, and the implementing HIPAA privacy rules, 45 CFR parts 160 and 164. Adoption of these proposed rules will repeal the temporary rules, currently in effect through December 27, 2011.

Proposed rules are available on the DHS Website: <http://www.oregon.gov/DHS/admin/dwssrules/index.shtml>.
For hardcopy requests, call: (503) 947-5250.

The agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing the negative economic impact of the rule on business.

November 22, 2011; 5:00pm

Last Day for Public Comment (Last day to submit written comments to the Rules Coordinator)

	Jennifer Bittel, Rules Coordinator	10/14/11
Signature	Printed name	Date

*Rulemaking Notices published in the Oregon Bulletin must be submitted by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a weekend or legal holiday, upon which the deadline is 5:00 pm the preceding workday. A public rulemaking hearing may be requested in writing by 10 or more people, or by an association with 10 or more members, within 21 days following the publication of the Rulemaking Notice in the Oregon Bulletin or 28 days from the date Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing. ARC 923-2005

STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

Department of Human Services

407

Agency and Division

Administrative Rules Chapter Number

In the Matter of:

The proposed adoption of OAR 407-014-0015, the proposed amendment of OAR 407-014-0000, 407-014-0020, 407-014-0030, 407-014-0040, 407-014-0050, 407-014-0060, 407-014-0070 and the proposed repeal of OAR 407-014-0000(T), 407-014-0015 (T), 407-014-0020(T), 407-014-0030(T), 407-014-0040(T), 407-014-0050(T), 407-014-0060(T), 407-014-0070(T).

Rule Caption:

Privacy Rules Setting Forth General Procedures Governing the Collection, Use and Disclosure of Protected Information

Statutory Authority: ORS 409.050

Other Authority: HB 2009, enacted in 2009 OR Laws, chapter 595, sections 19-25 & 45 CFR parts 160-164

Stats. Implemented: ORS 409.010 & 433.045

Need for the Rule(s):

These rules govern the collection, use and disclosure of protected information by the Department about individuals and to explain the rights and specific actions that individuals may take or request to be taken regarding the uses and disclosures of their protected information. The proposed adoption and amendment of these rules also set forth Department requirements governing the use and disclosure of protected health information for purposes of HIPAA, 42 USC 1320-d through 1320d-8, Pub L 104-191, sec. 262 and 264, and the implementing HIPAA privacy rules, 45 CFR parts 160 and 164. Adoption of these proposed rules will repeal the temporary rules, currently in effect through December 27, 2011.

Documents Relied Upon, and where they are available:

Federal HIPAA privacy rules, 45 CFR parts 160 and 164, available from the Office for Civil Rights at <http://www.hhs.gov/ocr/>.

Fiscal and Economic Impact:

Adopting these rules will have no fiscal impact on the Authority, other state agencies, local governments, clients, the public and businesses, including small businesses.

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):

None.

2. Cost of compliance effect on small business (ORS 183.336):

a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule:

None.

b. Projected reporting, record keeping and other administrative activities required for compliance, including costs of professional services:

None.

c. Equipment, supplies, labor and increased administration required for compliance:

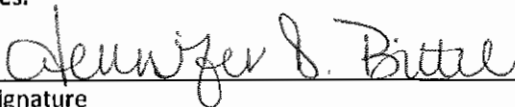
None.

How were small businesses involved in the development of this rule?

Access to the draft rules was made available via a public meeting announcement.

Administrative Rule Advisory Committee consulted? If not, why?:

Yes.



Jennifer Bittel, Rules Coordinator

10/14/11

Signature

Printed name

Date

**CHAPTER 407
DEPARTMENT OF HUMAN SERVICES**

**DIVISION 14
PRIVACY AND CONFIDENTIALITY**

Privacy of Protected Information

407-014-0000

Definitions

The following definitions apply to OAR 407-014-0000 to 407-014-0070:

(1) "Administrative Hearing" means an oral proceeding before an administrative law judge in a contested case hearing.

~~(2) "Authority" means the Oregon Health Authority.~~

(3) "Authorization" means permission from an individual or his or her personal representative giving the Department of Human Services (Department) authorization to obtain, release or use information about the individual from third parties for specified purposes or to disclose information to a third party specified by the individual.

~~(4) "Business Associate" means an individual or entity performing any function or activity on behalf of the Authority, including the Department, involving the use or disclosure of protected health information (PHI) and is not a member of the ~~Department's~~Authority's workforce.~~

~~(a) "Function" (a) For purposes of the definition of "Business Associate" "function or activity" includes but is not limited to program administration, claims processing or administration, data analysis, utilization review, quality assurance, billing, legal, actuarial, accounting, consulting, data processing, management, administrative, accreditation, financial services, and similar services for which the ~~Department~~Authority may contract or obtain by interagency agreement, if access to PHI is involved.~~

(b) Business associates do not include licensees or providers unless the licensee or provider also performs some function or activity on behalf of the ~~Department~~Authority.

(45) "Client" means an individual who requests or receives services from the Department. This includes but is not limited to applicants for or recipients of public assistance, minors and adults receiving protective services, ~~Oregon Health Plan members or enrollees, individuals who apply for or are admitted to a state training center or a state hospital or individuals~~ who are committed to the custody of the Department, children in the custody of the Department receiving services on a voluntary basis, and children committed to the custody of the Department.

- | (56) “Client Information” means personal information relating to a client that the Department may maintain in one or more locations and in various forms, reports, or documents, or stored or transmitted by electronic media.
- | (67) “Collect” or “Collection” means the assembling of personal information through interviews, forms, reports, or other information sources.
- | (78) “Contract” means a written agreement between the Department and a person or entity setting forth the rights and obligations of the parties including but not limited to contracts, licenses, agreements, interagency agreements, and intergovernmental agreements.
- | (89) “Correctional Institution” means any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by contract with the federal government, a state, or an Indian tribe for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. “Other persons held in lawful custody” include juvenile offenders, adjudicated delinquents, aliens detained awaiting deportation, witnesses, or others awaiting charges or trial.
- | (910) “Corrective Action” means an action that a ~~Department~~ business associate must take to remedy a breach or violation of the business associate’s obligations under the business associate’s contractual requirement, including but not limited to reasonable steps that must be taken to cure the breach or end the violation.
- | (~~1011~~) “Covered Entity” means health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form in connection with a transaction that is subject to federal Health Insurance Portability and Accountability Act (HIPAA) requirements, as those terms are defined and used in the HIPAA regulations, 45 CFR parts 160 and 164.
- | (~~1112~~) “De-identified Data” means client information from which the Department or other entity has deleted, redacted, or blocked identifiers so the remaining information cannot reasonably be used to identify an individual.
- | (~~1213~~) “Department” means the Department of Human Services.
- | (~~1314~~) “Department Workforce” means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for the Department, is under the direction and control of the Department, whether or not they are paid by the Department.
- | (~~1415~~) “Disclose” means the release, transfer, relay, provision of access to, or conveying of client information to any individual or entity outside the Department.

~~(15)~~

(16) "Health Care" means care, services, or supplies related to the health of an individual. Health care includes but is not limited to preventive, diagnostic, therapeutic, rehabilitative, maintenance, palliative care, counseling services, assessment, or procedures with respect to the physical or mental condition, or functional status of an individual, or that affects the structure or function of the body and the sale or dispensing of a drug, device, equipment, or other prescribed item.

~~(1617)~~ "Health Care Operations" means any activities of ~~the Department~~ covered entity to the extent that the activities are related to health care, Medicaid, or any other health care related programs, services, or activities administered by the ~~Department~~ covered entity and includes:

(a) Conducting quality assessment and improvement activities, including income evaluation and development of clinical guidelines;

(b) Population-based activities related to improving health or reducing health care costs, protocol development, case management and care coordination, contacting health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(c) Reviewing the competence of qualifications of health care professionals, evaluating practitioner, provider, and health plan performance; and conducting training programs in which students and trainees in areas of health care learn under supervision to practice or improve their skills, accreditation, certification, licensing, or credentialing activities;

(d) Underwriting, premium rating, and other activities relating to the creation, renewal, or replacement of a contract for Medicaid or health care related services;

(e) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs, and disclosure to the Medicaid Fraud Unit pursuant to 43 CFR part 455.21;

(f) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the ~~Department~~ covered entity, including administration, development, or improvement of methods of payments or health care coverage; and

(g) Business management and general administrative activities of the ~~Department~~ covered entity, including but not limited to:

(A) Management activities relating to implementation of and compliance with the requirements of HIPAA;

(B) Customer service, including providing data analysis;

(C) Resolution of internal grievances, including administrative hearings and the resolution of disputes from patients or enrollees regarding the quality of care and eligibility for services; and

(D) Creating de-identified data or a limited data set.

| ~~(1718)~~ “Health Oversight Agency” means an agency or authority of the federal government, a state, territory, political subdivision of a state or territory, Indian tribe, or a person or entity acting under a grant of authority from or by contract with the public agency, including employees or agents of the public agency or its contractors or grantees that is authorized by law to oversee the health care system or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant. When performing these functions, the Department acts as a health oversight agency for the purposes of these rules.

| ~~(1819)~~ “HIPAA” means the Title II, Subtitle F of the Health Insurance Portability and Accountability Act of 1996, 42 USC 1320d et seq, and the federal regulations adopted to implement the Act.

| ~~(1920)~~ “Individual” means the person who is the subject of information collected, used, or disclosed by the Department.

| ~~(2021)~~ “Individually Identifying Information” means any single item or compilation of information or data that indicates or reveals the identity of an individual, either specifically (such as the individual’s name or social security number), or from which the individual’s identity can be reasonably ascertained.

| ~~(2122)~~ “Information” means personal information relating to an individual, a participant, or a Department client.

| ~~(2223)~~ “Inmate” means a person incarcerated in or otherwise confined in a correctional institution. An individual is no longer an inmate when released on parole, probation, supervised release, or is otherwise no longer in custody.

| ~~(2324)~~ “Institutional Review Board (IRB)” means a specially constituted review body established or designated by an entity in accordance with 45 CFR part 46 to protect the welfare of human subjects recruited to participate in biomedical or behavioral research. The IRB must be registered with the Office for Human Research Protection.

| ~~(2425)~~ “Law Enforcement Official” means an officer or employee of any agency or authority of the federal government, a state, territory, political subdivision of a state or territory, or Indian tribe who is empowered by law to:

(a) Investigate and conduct an official inquiry into a potential violation of law; or

(b) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

(~~2526~~) "Licensee" means a person or entity that applies for or receives a license, certificate, registration, or similar authority from the Department to perform or conduct a service, activity, or function.

(~~2627~~) "Minimum Necessary" means the least amount of information, when using or disclosing confidential client information, that is needed to accomplish the intended purpose of the use, disclosure, or request.

(~~2728~~) "Participant" means individual's participating in Department population-based services, programs, and activities that serve the general population, but who do not receive program benefits or direct services received by a client. Examples of participants include ~~but are not limited to an individual whose birth certificate is recorded with Department of Vital Statistics, the subjects of public health studies, immunization or cancer registries, newborn screening, and other public health services, and~~ individuals who contact Department hotlines or the ombudsman for general public information services.

(~~2829~~) "Payment" means any activities undertaken by ~~the Department~~ a covered entity related to a client to whom health care is provided in order to:

(a) Obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the Medicaid program or other publicly funded health care services; and

(b) Obtain or provide reimbursement for the provision of health care.

(~~c~~-30) "Payment activities include" means:

(~~Aa~~) Determinations of eligibility or coverage, including coordination of benefits or the determination of cost sharing amounts, and adjudication of health benefit or health care claims;

(~~Bb~~) Risk adjusting amounts due which are based on enrollee health status and demographic characteristics;

(~~Cc~~) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance, and related health care data processing;

(~~Dd~~) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(~~Ee~~) Utilization review activities, including pre-certification and pre-authorization of services, concurrent and retrospective review of services; and

(~~Ff~~) Disclosure to consumer reporting agencies relating to collection of premiums or reimbursement including name and address, date of birth, payment history, account number, and name and address of the health care provider or health plan.

(~~2931~~) “Personal Representative” means a person who has authority to act on behalf of an individual in making decisions related to health care.

(~~3032~~) “Protected Health Information (PHI)” means any individually identifiable health information, whether oral or recorded in any form or medium, that 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 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. Any data transmitted or maintained in any other form or medium by covered entities, including paper records, fax documents, all oral communications, or any other form, such as screen prints of eligibility information, printed e-mails containing identified individual’s health information, claim or billing information, or hard copy birth or death certificates. PHI does not include school records that are subject to the Family Educational Rights and Privacy Act and employment records held in the Department’s role as an employer.

(~~3133~~) “Protected Information” means any participant or client information that the Department may have in its records or files that must be safeguarded pursuant to ~~Department policy~~ federal or state law. This includes but is not limited to individually identifying information.

(~~3234~~) “Provider” means a person or entity that may seek reimbursement from the Department as a provider of services to Department clients pursuant to a contract. For purposes of these rules, reimbursement may be requested on the basis of claims or encounters or other means of requesting payment.

(~~3335~~) “Psychotherapy Notes” mean notes recorded in any medium by a health care provider who is a mental health professional documenting or analyzing the contents of conversations during a private counseling session, or group, joint, or family counseling session, when the notes are separated from the rest of the individual’s record. Psychotherapy notes do not include medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of diagnosis, functional status, treatment plan, symptoms, prognosis, or progress to date.

(~~3436~~) “Public Health Agency” means a public agency, ~~including the Department~~, or a person or entity acting under a grant of authority from or by contract with the ~~Department or~~ public

agency that performs or conducts one or more of the following essential functions that characterize public health programs, services, or activities:

- (a) Monitor health status to identify community health problems;
- (b) Diagnose and investigate health problems and health hazards in the community;
- (A) Inform, educate, and empower people about health issues;
- (B) Mobilize community partnerships to identify and solve health problems;
- (C) Develop policies and plans that support individual and community health efforts;
- (D) Enforce laws and regulations that protect health and ensure safety;
- (E) Direct individuals to needed personal health services and assure the provision of health care when otherwise unavailable;
- (F) Ensure a competent public health and personal health care workforce;
- (G) Evaluate the effectiveness, accessibility, and quality of personal and population-based health services; and
- (H) Perform research for new insights and innovative solutions to health problems.

~~(3537) “Public Health Authority” means an agency or authority of the federal government, a state, territory, political subdivision of a state or territory, Indian tribe, or a person or entity acting under a grant of authority from or by contract with the public agency, including the employees or agents of the public agency, or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. When performing functions as a public health agency, the Department acts as a public health authority for purposes of these rules.~~

~~(3638) “Re-disclosure” means the disclosure of information to a person, a Department program, a Department subcontracted entity, or other entity or person other than what was originally authorized.~~

~~(3739) “Research” means systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge.~~

~~(3840) “Required by Law” means a duty or responsibility that federal or state law specifies that a person or entity must perform or exercise. Required by law includes but is not limited to court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the~~

production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or rules that require the production of information, including statutes or rules that require such information if payment is sought under a government program providing public benefits.

(~~3941~~) “Treatment” means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party, consultation between health care providers relating to a patient, or the referral of a patient for health care from one health care provider to another.

(~~4042~~) “Use” means the sharing of individual information within a Department program or the sharing of individual information between program staff and administrative staff that support or oversee the program.

Stat. Auth.: ORS 409.050

Stats. Implemented: ORS 409.010

407-014-0015

Information Governed by the HIPAA Privacy Rules

(1) These rules address information that, among other things, may be PHI that is protected by the HIPAA Privacy Rules. For purposes of HIPAA Privacy Rules, the Authority is a covered entity, primarily because of its role as the state Medicaid and Children’s Health Insurance Program.

(2) The Authority administers many aspects of the medical assistance program with the assistance of the Department, including but not limited to eligibility determinations for the medical assistance program and supervising the long-term and community-based services for seniors and people with disabilities. The Department also provides certain health care operations services for the Authority. In doing so, the Department is a business associate of the Authority. As a business associate of the Authority, the Department is authorized to use and disclose protected health information to perform or assist the Authority in the performance of its covered functions, in a manner consistent with these rules.

(3) These rules only apply to information maintained by the Department as a business associate of the Authority.

Stat. Auth.: ORS 409.050

Stats. Implemented: ORS 409.010

407-014-0020

Uses and Disclosures of Client or Participant Protected Information

(1) Uses and disclosures with individual authorization. The Department must obtain a completed and signed authorization for release of information from the individual, or the individual’s personal representative, before obtaining or using protected information about an

individual from a third party or disclosing protected information about the individual to a third party.

(a) Uses and disclosures must be consistent with what the individual has approved on the signed authorization form approved by the Department.

(b) An individual may revoke an authorization at any time. The revocation must be in writing and signed by the individual, except that substance abuse treatment patients may orally revoke an authorization to disclose information obtained from substance abuse treatment programs. No revocation shall apply to information already released while the authorization was valid and in effect.

(2) Uses and disclosures without authorization. The Department may use and disclose information without written authorization in the following circumstances:

(a) The Department may disclose information to individuals who have requested disclosure to themselves of their information, if the individual has the right to access the information under OAR 407-014-0030(6).

(b) If the law requires or permits the disclosure, and the use and disclosure complies with, and is limited to, the relevant requirements of the relevant law.

(c) For treatment, payment, and health care operations the Department may disclose the following information:

(A) Activities involving the current treatment of an individual, for the Department or health care provider;

(B) Payment activities, for the Department, covered entity, or health care provider;

(C) Protected health information for the purpose of health care operations; and

(D) Substance abuse treatment information, if the recipient has a Qualified Service Organization Agreement with the Department.

(d) Psychotherapy notes. The Department may only use and disclose psychotherapy notes in the following circumstances:

(A) In the Department's supervised counseling training programs;

(B) In connection with oversight of the originator of the psychotherapy notes; or

(C) To defend the Department in a legal action or other proceeding brought by the individual.

(e) Public health activities.

(A) The Department may disclose an individual's protected information to appropriate entities or persons for governmental public health activities and for other purposes including but not limited to:

(i) A governmental public health authority that is authorized by law to collect or receive protected information for the purpose of preventing or controlling disease, injury, or disability. This includes but is not limited to reporting disease, injury, and vital events such as birth or death; and the conducting of public health surveillance, investigations, and interventions;

(ii) An official of a foreign government agency that is acting in collaboration with a governmental public health authority;

(iii) A governmental public health authority, or other government authority that is authorized by law to receive reports of child abuse or neglect;

(iv) A person subject to the jurisdiction of the federal Food and Drug Administration (FDA), regarding an FDA-regulated product or activity for which that person is responsible for activities related to the quality, safety, or effectiveness of an FDA-regulated product or activity; or

(v) A person who may have been exposed to a communicable disease, or may be at risk of contracting or spreading a disease or condition, ~~if the Department or other public health authority is authorized to notify the person as necessary in conducting a public health intervention or investigation.~~

(B) Where state or federal law prohibits or restricts use and disclosure of information obtained or maintained for public health purposes, the Department shall deny the use and disclosure.

(f) Child abuse reporting and investigation. If the Department has reasonable cause to believe that a child is a victim of abuse or neglect, the Department may disclose protected information to appropriate governmental authorities authorized by law to receive reports of child abuse or neglect (including reporting to the Department protective services staff if appropriate). If the Department receives information as the child protective services agency, the Department may use and disclose the information consistent with its legal authority and in compliance with any applicable state and federal regulations.

(g) Adult abuse reporting and investigation. If the Department has reasonable cause to believe that a vulnerable adult is a victim of abuse or neglect, the Department may disclose information, as required by law, to a government authority or regulatory agency authorized by law to receive reports of abuse or neglect including but not limited to a social service or protective services agency (which may include the Department) authorized by law to receive such reports. Vulnerable adults are adults age 65 or older and persons with disabilities. If the

Department receives information as the social services or protective services agency, the Department may use and disclose the information.

(h) Health oversight activities. The Department may disclose information without authorization for health oversight activities, including audits; civil, criminal, or administrative investigations, prosecutions, licensing or disciplinary actions; Medicaid fraud; or other necessary oversight activities.

(i) Administrative and court hearings, grievances, investigations, and appeals.

(A) The Department may use or disclose information for an investigation, administrative or court hearing, grievance, or appeal about an individual's eligibility or right to receive Department benefits or services.

(B) If the Department has obtained information in performing its duties as a health oversight agency, ~~public health authority~~, protective service entity, or public benefit program, the Department may use or disclose that information in an administrative or court hearing consistent with the other privacy requirements applicable to that program, service, or activity.

(j) Court orders. The Department may disclose information for judicial or administrative proceedings in response to a court order, subpoena, discovery request, or other legal process. If a court orders the Department to conduct a mental examination pursuant to ORS 161.315, 161.365, 161.370, or 419B.352, or orders the Department to provide any other report or evaluation to the court, the examination, report, or evaluation shall be deemed to be required by law for purposes of HIPAA.

(k) Law enforcement purposes. For limited law enforcement purposes, the Department may report certain injuries or wounds; provide information to identify or locate a suspect, victim, or witness; alert law enforcement of a death as a result of criminal conduct; and provide information which constitutes evidence of criminal conduct on Department premises.

(A) The Department may provide client information to a law enforcement officer in any of the following situations:

(i) The law enforcement officer is involved in carrying out any investigation, criminal, or civil proceedings connected with administering the program from which the information is sought;

(ii) A Department employee may disclose information from personal knowledge that does not come from the client's interaction with the Department;

(iii) The disclosure is authorized by statute or administrative rule;

(iv) The information informs law enforcement of a death as a result of criminal conduct;

(v) The information constitutes evidence of criminal conduct on Department premises; or

(vi) The disclosure is necessary to protect the client or others, and the client poses a threat to his or her safety or to the safety of others.

(B) Except as provided in section (2)(k)(C) of this rule, the Department may give a client's current address, Social Security number, and photo to a law enforcement officer if the law enforcement officer makes the request in the course of official duty, supplies the client's name, and states that the client:

(i) Is a fugitive felon or is violating parole, probation, or post-prison supervision;

(ii) For all public assistance programs, has information that is necessary for the officer to conduct official duties, and the location or apprehension of the client is within the officer's official duties; or

(iii) For clients only in the ~~Food Stamp~~SNAP program, has information that is necessary to conduct an official investigation of a fugitive felon or person violating parole, probation, or post-prison supervision.

(C) If domestic violence has been identified in the household, the Department may not release information about a victim of domestic violence unless a member of the household is either wanted as a fugitive felon or is violating parole, probation, or post-prison supervision.

(D) For purposes of this subsection, a fugitive felon is a person fleeing to avoid prosecution or custody for a crime, or an attempt to commit a crime, that would be classified as a felony.

(E) For purposes of this section, a law enforcement officer is an employee of the Oregon State Police, a county sheriff's department, or a municipal police department, whose official duties include arrest authority.

(I) Use and disclosure of information about deceased individuals.

(A) The Department may disclose individual information to a coroner or medical examiner for the purpose of identifying a deceased individual, determining cause of death, or other duties authorized by law.

(B) The Department may disclose individual information to funeral directors as needed to carry out their duties regarding the decedent. The Department may also disclose individual information prior to, and in anticipation of, the death.

(m) Organ or tissue donation. The Department may disclose individual information to organ procurement organizations or other entities engaged in procuring, banking, or transplanting cadaver organs, eyes, or tissue for the purpose of facilitating transplantation.

(n) Research. The Department may disclose individual information without authorization for research purposes, as specified in OAR 407-014-0060.

(o) Threat to health or safety. To avert a serious threat to health or safety the Department may disclose individual information if:

(A) The Department believes in good faith that the information is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and

(B) The report is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat.

(p) National security and intelligence. The Department may disclose information to authorized federal officials for lawful intelligence, counterintelligence, and other national security activities.

(q) Correctional institutions and law enforcement custody situations. The Department may disclose information to a correctional institution or a law enforcement official having lawful custody of an inmate or other person, for the limited purpose of providing health care or ensuring the health or safety of the person or other inmates.

(r) Emergency treatment. In case of an emergency, the Department may disclose individual information to the extent needed to provide emergency treatment.

(s) Government entities providing public benefits. The Department may disclose eligibility and other information to governmental entities administering a government program providing public benefits.

(3) Authorization not required if opportunity to object given. The Department may use and disclose an individual's information without authorization if the Department informs the individual in advance and gives the individual an opportunity to either agree or refuse or restrict the use and disclosure.

(a) These disclosures are limited to disclosure of information to a family member, other relative, close personal friend of the individual, or any other person named by the individual, subject to the following limitations:

(A) The Department may disclose only the protected information that directly relates to the person's involvement with the individual's care or payment for care.

(B) The Department may use and disclose protected information for notifying, identifying, or locating a family member, personal representative, or other person responsible for care of the individual, regarding the individual's location, general condition, or death. For individuals who

had resided at one time at the state training center, OAR 411-320-0090(6) addresses family reconnection.

(C) If the individual is present for, or available prior to, a use and disclosure, the Department may disclose the protected information if the Department:

(i) Obtains the individual's agreement;

(ii) Provides the individual an opportunity to object to the disclosure, and the individual does not object; or

(iii) Reasonably infers from the circumstances that the individual does not object to the disclosure.

(D) If the individual is not present, or the opportunity to object to the use and disclosure cannot practicably be provided due to the individual's incapacity or an emergency situation, the Department may disclose the information if, using professional judgment, the Department determines that the use and disclosure is in the individual's best interests.

(b) Exception. For individuals referred to or receiving substance abuse treatment, mental health, or vocational rehabilitation services, the Department shall not use or disclose information without written authorization, unless disclosure is otherwise permitted under 42 CFR part 2, [38 CFR 361.38](#), or ORS 179.505.

(c) Personal representative. The Department must treat a personal representative as the individual for purposes of these rules, except that:

(A) A personal representative must be authorized under state law to act on behalf of the individual with respect to use and disclosure of information. The Department may require a personal representative to provide a copy of the documentation authorizing the person to act on behalf of the individual.

(B) The Department may elect not to treat a person as a personal representative of an individual if:

(i) The Department has a reasonable belief that the individual has been or may be subjected to domestic violence, abuse, or neglect by the person;

(ii) The Department, 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.

(4) Rediscovery. The Department must inform the individual that information held by the Department and authorized by the individual for disclosure may be subject to rediscovery and no longer protected by these rules.

(5) Specific written authorization. If the use or disclosure of information requires an authorization, the authorization must specify that the Department may use or disclose vocational rehabilitation records, alcohol and drug records, HIV/AIDS records, genetics information, and mental health or developmental disability records held by publicly funded providers.

(a) Pursuant to federal regulations at 42 CFR part 2 and 34 CFR 361.38, the Department may not make further disclosure of vocational rehabilitation and alcohol and drug rehabilitation information without the specific written authorization of the individual to whom it pertains.

(b) Pursuant to ORS 433.045 and OAR 333-012-0270, the Department may not make further disclosure of individual information pertaining to HIV/AIDS.

(c) Pursuant to ORS 192.531 to 192.549, the Department may not make further disclosure pertaining to genetic information.

(6) Verification of person or entity requesting information. The Department may not disclose information about an individual without first verifying the identity of the person or entity requesting the information, unless the Department workforce member fulfilling the request already knows the person or has already verified identity.

(7) Whistleblowers. The Department may disclose an individual's protected health information under the HIPAA privacy rules under the following circumstances:

(a) The Department workforce member ~~or business associate~~ believes in good faith that the Department has engaged in conduct that is unlawful or that otherwise violates professional standards or Department policy, or that the care, services, or conditions provided by the Department could endanger Department staff, individuals in Department care, or the public; and

(b) The disclosure is to a government oversight agency or public health authority, or an attorney of a Department workforce member ~~or business associate~~ retained for the purpose of determining the legal options of the workforce member ~~or business associate~~ with regard to the conduct alleged under section (7)(a) above; and

(c) Nothing in this rule is intended to interfere with ORS 659A.200 to 659A.224 describing the circumstances applicable to disclosures by ~~Department~~the Department's workforce ~~or business associates~~.

Stat. Auth.: ORS 409.050

Stats. Implemented: ORS 409.010, 433.045

407-014-0030
Client Privacy Rights

(1) Rights of clients to access their information. Clients may access, inspect, and obtain a copy of information on their own cases in Department files or records, consistent with federal and state law.

(a) A client may request access by completing the Access to Records Request form, or by providing sufficient information to accomplish this request.

(b) Clients may request access to their own information that is kept by the Department by using a personal identifier such as the client's name or Department case number.

(c) If the Department maintains information in a record that includes information about other people, the client may see information only about himself or herself.

(d) If a person identified in the file is a minor child of the client, and the client is authorized under Oregon law to have access to the minor's information or to act on behalf of the minor for making decisions about the minor's care, the client may obtain information about the minor.

(e) If the requestor of information is recognized under Oregon law as a the client's guardian or custodian and is authorized under Oregon law to have access to the client's information or to act on behalf of the client for making decisions about the client's services or care, the Department shall release information to the requestor.

(f) For individuals with disabilities or mental illnesses, the named system in ORS 192.517, to protect and advocate the rights of individuals with developmental disabilities under Part C of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6041 et seq.) and the rights of individuals with mental illness under the Protection and Advocacy for Individuals with Mental Illness Act (42 U.S.C. 10801 et seq.), shall have access to all records defined in ORS 192.515.

(g) The Department may deny a client's access to their own PHI if federal law prohibits the disclosure. Clients may access, inspect, and obtain a copy of health information on their own case in Department files or records except for the following:

(A) Psychotherapy notes;

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

(C) Information that is subject to the federal Clinical Labs Improvement Amendments of 1988, or exempt pursuant to 42 CFR 493.3(a)(2);

(D) Information that the Department believes, in good faith, can cause harm to the client, participant, or to any other person; and

(E) Documents protected by attorney work-product privilege.

(h) The Department may deny a client access to information that was obtained under a promise of confidentiality from a person other than a health care provider to the extent that access would reveal the source of the information.

(i) The Department may deny a client access to information, if the Department gives the client a right to have the denial reviewed when:

(A) A licensed health care professional (for health information) or other designated staff (for other information) has determined, in the exercise of professional judgment, that the information requested may endanger the life or physical safety of the client or another person;

(B) The information makes reference to another person, and a licensed health care professional (for health information) or other designated staff (for other information) has determined, in the exercise of professional judgment, that the information requested may cause substantial harm to the client or to another person; or

(C) The request for access is made by the client's personal representative, and a licensed health care professional (for health information) or other designated staff (for other information) has determined, in the exercise of professional judgment, that allowing the personal representative access to the information may cause substantial harm to the client or to another person.

(j) If the Department denies access under section (1)(i) of this rule, the client may have the decision reviewed by a licensed health care professional (for health information) or other designated staff (for other information) not directly involved in making the original denial decision.

(A) The Department must promptly refer a client's request for review to the designated reviewer.

(B) The reviewer must determine, within the 30 or 60-day time limits stated in section (1)(k)(A) and (B) of this rule, whether to approve or deny the client's request for access.

(C) Based on the reviewer's decision, the Department shall:

(i) Promptly notify the client in writing of the reviewer's determination; and

(ii) If approved, take action to carry out the reviewer's determination.

(k) The Department must act on a client's request for access no later than 30 days after receiving the request, except as provided in this section and in the case of written accounts under ORS 179.505, which must be disclosed within five days.

(A) In cases where the information is not maintained or accessible to the Department on-site, and does not fall under ORS 179.505, the Department must act on the client's request no later than 60 days after receiving the request.

(B) If the Department is unable to act within the 30 or 60-day limits, the Department may extend this time period a maximum of 30 additional days, subject to the following:

(i) The Department must notify the client in writing of the reasons for the delay and the date by which the Department shall act on the request.

(ii) The Department shall use only one 30-day extension.

(l) If the Department grants the client's request, in whole or in part, the Department must inform the client of the access decision and provide the requested access.

(A) If the Department maintains the same information in more than one format or at more than one location, the Department may provide the requested information once.

(B) The Department must provide the requested information in a form or format requested by the client, if readily producible in that form or format. If not readily producible, the Department shall provide the information in a readable hard-copy format or other format as agreed to by the Department and the client.

(C) The Department may provide the client with a summary of the requested information, in lieu of providing access, or may provide an explanation of the information if access has been provided, if:

(i) The client agrees in advance; and

(ii) The client agrees in advance to pay any fees the Department may impose, under section (1)(L)(E) of this rule.

(D) The Department shall arrange with the client for providing the requested access in a time, place, and manner convenient for the client and the Department.

(E) If a client, or legal guardian or custodian, requests a copy, written summary, or explanation of the requested information, the Department may impose a reasonable cost-based fee, limited to the following:

(i) Copying the requested information, including the costs of supplies and the labor of copying;

(ii) Postage; and

(iii) Staff time for preparing an explanation or summary of the requested information.

(m) If the Department denies access, in whole or in part, to the requested information, the Department must:

(A) Give the client access to any other requested client information, after excluding the information to which access is denied; and

(B) Provide the client with a timely written denial. The denial must:

(i) Be provided within the time limits specified in section (1)(k)(A) and (B) of this rule;

(ii) State the basis of the denial in plain language;

(iii) If the Department denies access under section (1)(i) of this rule, explain the client's review rights as specified in section (1)(j) of this rule, including an explanation of how the client may exercise these rights; and

(iv) Provide a description of how the client may file a complaint with the Department, and if the information is PHI, with the United States Department of Health and Human Services (DHHS), Office for Civil Rights, pursuant to section (7) of this rule.

(n) If the Department does not maintain the requested information, in whole or in part, and knows where the information is maintained (such as by a medical provider, insurer, other public agency, private business, or other non-Department entity), the Department must inform the client where to direct the request for access.

(2) Department Notice of Privacy Practices. The Department shall send clients notice about the Department's privacy practices as follows:

(a) The Department shall make available to each client a notice of Department privacy practices that describes the duty of the Department to maintain the privacy of PHI and include a description that clearly informs the client of the types of uses and disclosures the Department is permitted or required to make;

(b) The Department shall provide all clients in direct care settings a notice of Department privacy practices and shall request the client's signature on an acknowledgement of receipt form;

(c) If the Department revises its privacy practices, the Department shall make the revised notice available to all clients;

(d) The Department shall post a copy of the Department's Notice of Privacy Practices for public viewing at each Department worksite and on the Department website; and

(e) The Department shall give a paper copy of the Department's Notice of Privacy Practices to any individual upon request.

(3) Right to request restrictions on uses or disclosures. Clients may request restrictions on the use or disclosure of their information.

(a) The Department may deny the client's request or limit its agreement to a request.

(A) The Department may not agree to restrict uses or disclosures of information if the restriction would adversely affect the quality of the client's care or services.

(B) The Department shall not agree to restrict uses or disclosures of information that would limit or prevent the Department from making or obtaining payment for services.

(b) The Department may not deny a client's request to restrict the sharing of records of alcohol and drug treatment or records relating to vocational rehabilitation services with another Department program.

(c) The Department shall document the client's request, and the reasons for granting or denying the request, in the client's Department case file.

(d) If the client needs emergency treatment and the restricted protected information is needed to provide the treatment, the Department may use or disclose the restricted protected information to a provider, for the limited purpose of providing treatment. However, once the emergency situation subsides the Department shall ask the provider not to redisclose the information.

(e) The Department may terminate its agreement to a restriction if:

(A) The client agrees to or requests the termination in writing;

(B) The client orally requests or agrees to the termination, and the Department documents the oral request or agreement in the client's Department case file; or

(C) With or without the client's agreement, the Department informs the client that the Department is terminating its agreement to the restriction. Information created or received while the restriction was in place shall remain subject to the restriction.

(4) Rights of clients to request to receive information from the Department by alternative means or at alternative locations. The Department must accommodate reasonable requests by clients to receive communications from the Department by alternative means, such as by mail, e-mail, fax, or telephone, and at an alternative location.

- (a) The client must specify the preferred alternative means or location.
- (b) The client may submit the request for alternative means or locations either orally or in writing.
 - (A) If the client makes a request in-person, the Department shall document the request and ask for the client's signature.
 - (B) If the client makes a request by telephone or electronically, the Department shall document the request and verify the identity of the client.
- (c) The Department may terminate its agreement to an alternative location or method of communication if:
 - (A) The client agrees to or requests termination of the alternative location or method of communication in writing or orally. The Department shall document the oral agreement or request in the client's Department case file; or
 - (B) The Department informs the client that the Department is terminating its agreement to the alternative location or method of communication because the alternative location or method of communication is not effective. The Department may terminate its agreement to communicate at the alternative location or by the alternate method if:
 - (i) The Department is unable to contact the client at the location or by the method requested; or
 - (ii) The client fails to respond to payment requests, if applicable.
- (5) Right of clients to request amendment of their information. Clients may request that the Department amend information about themselves in Department files.
 - (a) For all amendment requests, the Department shall have the client complete the approved Department form.
 - (b) The Department may deny the request or limit its agreement to amend.
 - (c) The Department must act on the client's request no later than 60 days after receiving the request. If the Department is unable to act within 60 days, the Department may extend this time limit by a maximum of 30 additional days, subject to the following:
 - (A) The Department must notify the client in writing, within 60 days of receiving the request, of the reasons for the delay and the date by which the Department shall act on the request; and
 - (B) The Department shall use only one 30-day extension.

(d) The program's medical director, a licensed health care professional designated by the program administrator, or a Department staff person involved in the client's case must review the request and any related documentation prior to making a decision to amend a health or medical record.

(e) A staff person designated by the Department shall review the request and any related documentation prior to making a decision to amend any information that is not a health or medical record.

(f) If the Department grants the request, in whole or in part, the Department shall:

(A) Make the appropriate amendment to the information or records, and document the amendment in the client's Department file or record;

(B) Provide notice to the client that the amendment has been granted, pursuant to the time limits under section (5)(c) of this rule;

(C) Obtain the client's agreement to notify other relevant persons or entities with whom the Department has shared or needs to share the amended information; and

(D) Inform and provide the amendment within a reasonable time to:

(i) Persons named by the client who have received the information and who need the amendment; and

(ii) Persons, ~~including business associates of the Department,~~ that the Department knows have the information that are the subject of the amendment and who may have relied, or could foreseeably rely, on the information to the client's detriment.

(g) The Department may deny the client's request for amendment if:

(A) The Department finds the information to be accurate and complete;

(B) The information was not created by the Department;

(C) The information is not part of Department records; or

(D) The information would not be available for inspection or access by the client, pursuant to section (1)(g) and (h) of this rule.

(h) If the Department denies the amendment request, in whole or in part, the Department must provide the client with a written denial. The denial must:

(A) Be sent within the time limits specified in section (5)(c) of this rule;

(B) State the basis for the denial, in plain language; and

(C) Explain the client's right to submit a written statement disagreeing with the denial and how to file the statement. If the client files a statement:

(i) The Department shall enter the written statement into the client's Department case file;

(ii) The Department may also enter a Department written rebuttal of the client's written statement into the client's Department case file. The Department shall send a copy of any written rebuttal to the client;

(iii) The Department shall include a copy of the statement and any Department written rebuttal with any future disclosures of the relevant information;

(iv) If a client does not submit a written statement of disagreement, the client may ask that if the Department makes any further disclosures of the relevant information that the Department shall also include a copy of the client's original request for amendment and a copy of the Department written denial; and

(v) The Department shall provide information on how the client may file a complaint with the Department and, if the information is PHI, with DHHS, Office for Civil Rights.

(6) Rights of clients to request an accounting of disclosures of PHI. Clients may receive an accounting of disclosures of PHI that the Department has made for any period of time, not to exceed six years, preceding the request date for the accounting.

(a) For all requests for an accounting of disclosures, the client ~~shall~~ may complete the authorized Department form ~~(DHS 2096, "Request for Accounting of Disclosures of Health Records")~~, or provide sufficient information to accomplish this request.

(b) The right to an accounting of disclosures does not apply when the request is:

(A) Authorized by the client;

(B) Made prior to April 14, 2003;

(C) Made to carry out treatment, payment, or health care operations, unless these disclosures are made from an electronic health record;

(D) Made to the client;

(E) Made to persons involved in the client's care;

(F) Made as part of a limited data set in accordance with OAR 407-014-0070;

(G) Made for national security or intelligence purposes; or

(H) Made to correctional institutions or law enforcement officials having lawful custody of an inmate.

(c) For each disclosure, the accounting must include:

(A) The date of the disclosure;

(B) The name and address, if known, of the person or entity who received the disclosed information;

(C) A brief description of the information disclosed; and

(D) A brief statement of the purpose of the disclosure that reasonably informs the client of the basis for the disclosure, or, in lieu of a statement, a copy of the client's written request for a disclosure, if any.

(d) If, during the time period covered by the accounting, the Department has made multiple disclosures to the same person or entity for the same purpose, the Department may provide the required information for only the first disclosure. The Department need not list the same identical information for each subsequent disclosure to the same person or entity if the Department adds the following information:

(A) The frequency or number of disclosures made to the same person or entity; and

(B) The date of the most recent disclosure during the time period for which the accounting is requested.

(e) The Department must act on the client's request for an accounting no later than 60 days after receiving the request. If the Department is unable to act within 60 days, the Department may extend this time limit by a maximum of 30 additional days, subject to the following:

(A) The Department must notify the client in writing, within 60 days of receiving the request, of the reasons for the delay and the date by which the Department shall act on the request; and

(B) The Department shall use only one 30-day extension.

(f) The Department shall provide the first requested accounting in any 12-month period without charge. The Department may charge the client a reasonable cost-based fee for each additional

accounting requested by the client within the 12-month period following the first request, if the Department:

(A) Informs the client of the fee before proceeding with any additional request; and

(B) Allows the client an opportunity to withdraw or modify the request in order to avoid or reduce the fee.

(g) The Department shall document the information required to be included in an accounting of disclosures, as specified in section (6)(c) of this rule, and retain a copy of the written accounting provided to the client.

(h) The Department shall temporarily suspend a client's right to receive an accounting of disclosures that the Department has made to a health oversight agency or to a law enforcement official, for a length of time specified by the agency or official, if the agency or official provides a written or oral statement to the Department that the accounting would be reasonably likely to impede their activities. If the agency or official makes an oral request, the Department shall:

(A) Document the oral request, including the identity of the agency or official making the request.

(B) Temporarily suspend the client's request to an accounting of disclosures; and

(C) Limit the temporary suspension to no longer than 30 days from the date of the oral request, unless the agency or official submits a written request specifying a longer time period.

(7) Filing a complaint. Clients may file a complaint with the Department or, if the information is PHI, with DHHS, Office for Civil Rights.

(a) Upon request, the Department shall give clients the name and address of the specific person or office of where to submit complaints to DHHS.

(b) The Department ~~shall~~ may not intimidate, threaten, coerce, discriminate against, or take any other form of retaliatory action against any individual filing a complaint or inquiring about how to file a complaint.

(c) The Department may not require clients to waive their rights to file a complaint as a condition of providing treatment, payment, enrollment in a health plan, or eligibility for benefits.

(d) The Department shall designate staff to review and determine action on complaints filed with the Department.

(e) The Department shall document, in the client's Department case file all complaints, the findings from reviewing each complaint, and the Department's actions resulting from the complaint. For each complaint the documentation shall include a description of corrective action that the Department has taken, if any are necessary, or why corrective action is not needed.

Stat. Auth.: ORS 409.050

Stats. Implemented: ORS 409.010

407-014-0040

Minimum Necessary Standards

(1) The Department shall limit the use and disclosure of protected information to that which is reasonably necessary to accomplish the intended purpose of the use or disclosure which is referred to in these rules as the minimum necessary standard.

(2) This minimum necessary standard is not intended to impede ~~the~~ essential Department activities ~~of treatment, payment, health care operations, or service delivery.~~

(3) The minimum necessary standard applies:

(a) When using protected information within the Department;

(b) When disclosing protected information to a third party in response to a request; or

(c) When requesting protected information from another covered entity.

(4) The minimum necessary standard does not apply to:

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

(b) Disclosures made to the individual, including disclosures made in response to a request for access or an accounting;

(c) Disclosures made with a valid authorization;

(d) Disclosures made to DHHS for the purposes of compliance and enforcement of federal regulations under 45 CFR part 160 and required for compliance with 45 CFR part 164.; or

(e) Uses and disclosures required by law;

(5) When requesting protected information about an individual from another entity, the Department shall limit requests to those that are reasonably necessary to accomplish the purposes for which the request is made. The Department shall not request a person's entire

medical record unless the Department can specifically justify the need for the entire medical record.

Stat. Auth.: ORS 409.050

Stats. Implemented: 409.010

407-014-0050

Business Associate

(1) The Department is a business associate of the Authority. The Authority is the single State Medicaid agency but the Department performs or assists in the performance of key components of the medical assistance program under the supervision of the Authority including but not limited to eligibility determinations for the medical assistance program and supervising the long-term and community-based services for seniors and people with disabilities. The Department also provides certain health care operations services for the Authority. In doing so, the Department is a business associate of the Authority. As a business associate of the Authority, the Department is authorized to use and disclose protected health information to perform or assist the Authority in the performance of its covered functions. However, as a business associate, the Department is subject to the privacy requirements described in these rules.

(2) As a business associate of the Authority implementing the requirements of the medical assistance program, the Department may disclose an individual's PHI to ~~a business associate~~its contractors or providers, and may allow ~~a business associate~~its contractors or providers to create or receive an individual's PHI on behalf of the Department if the ~~Department and the business associate first enter into a~~ contract or agreement that complies with applicable federal and state law. In some limited circumstances, the Department may determine that the Department is a business associate of a covered entity. A business associate relationship with the Department requires additional contractual disclosure and privacy provisions that must be incorporated into the contract pursuant to 45 CFR part 164-504 (e)(1)

(~~23~~) A contract with a business associate must comply with OAR 125-055-0100 to 125-055-0130 and the qualified service organization requirements in 42 CFR part 2.11.

Stat. Auth.: ORS 409.050

Stats. Implemented: 409.010

407-014-0060

Uses and Disclosures of Protected Information for Research Purposes

The Department may use and disclose an individual's information for research purposes as specified in this rule.

(1) All research disclosures are subject to applicable requirements of federal and state laws and rules including but not limited to 45 CFR part 46 and 21 CFR part 50.0 to 50.56, relating to the protection of human research subjects.

(2) The Department may use and disclose de-identified information or a limited data set for research purposes, pursuant to OAR 407-014-0070.

(3) The Department may use and disclose information regarding an individual for research purposes with the specific written authorization of the individual. The authorization must meet all requirements in OAR 407-014-0030, and may indicate an expiration date with terms such as “end of research study” or similar language. An authorization for use and disclosure for a research study may be combined with other types of written authorization for the same research study. If research includes treatment, the researcher may require an authorization for use and disclosure for the research as a provision of providing research related treatment.

(4) Notwithstanding section (3) of this rule, the Department may use and disclose an individual’s information for research purposes without the individual’s written authorization, regardless of the source of funding for the research, provided that:

(a) The Department obtains documentation that a waiver of an individual’s authorization for release of information requirements has been approved by an IRB registered with the Office for Human Research Protection. Documentation required of an IRB when granting approval of a waiver of an individual’s authorization for release of information must include all criteria specified in 45 CFR part 164.512(i)(2).

(b) A researcher may request access to individual information maintained by the Department in preparation for research or to facilitate the development of a research protocol in anticipation of research. The Department may determine whether to permit such use or disclosure, without individual authorization or use of an IRB, pursuant to 45 CFR part 164.512(i)(1)(ii).

(c) A researcher may request access to individual information maintained by the Department about deceased individuals. The Department may determine whether to permit such use or disclosure of information about decedents, without individual authorization or use of an IRB, pursuant to 45 CFR part 164.512(i)(1)(iii).

(5) The Department, ~~as a public health authority, may obtain and use individual information without authorization for the purpose of preventing injury or controlling disease and for the conduct of public health surveillance, investigations, and interventions. The Department may also~~ may collect, use, or disclose information, without individual authorization, to the extent that the collection, use, or disclosure is required by law. When the Department uses information to conduct studies as ~~a public health authority~~ required by law, no additional individual authorization is required nor does this rule require an IRB or privacy board waiver of authorization based on the HIPAA privacy rules.

(6) The Department may use and disclose information without individual authorization for studies and data analysis conducted for the Department’s own quality assurance purposes or to

comply with reporting requirements applicable to federal or state funding requirements in accordance with the definition of “Health Care Operations” in 45 CFR part 164.501.

Stat. Auth.: ORS 409.050

Stats. Implemented: ORS 409.010

407-014-0070

De-identification of Client Information and Use of Limited Data Sets under Data Use Agreements

(1) The Department may use and disclose information as appropriate for the work of the Department, without further restriction, if the Department or another entity has taken steps to de-identify the information pursuant to 45 CFR part 164.514(a) and (b).

(2) The Department may assign a code or other means of record identification to allow the Department to re-identify the de-identified information provided that:

(a) The code or other means of record identification is not derived from or related to information about the individual and cannot otherwise be translated to identify the individual; and,

(b) The Department 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) The Department may use and disclose a limited data set if the Department enters into a data use agreement with an entity requesting or providing the Department with a limited data set subject to the requirements of 45 CFR part 164.514(e).

(a) The Department may use and disclose a limited data set ~~only~~ for the purposes of research, ~~public health, or health care operations.~~ The Department may use limited data set for its own activities or operations if the Department has obtained a limited data set that is subject to a data use agreement.

(b) If the Department knows of a pattern of activity or practice of a limited data set recipient that constitutes a material breach or violation of a data use agreement, the Department shall take reasonable steps to cure the breach or end the violation. If such steps are unsuccessful, the Department shall discontinue disclosure of information to the recipient and report the problem to the ~~Secretary of DHHS~~ appropriate authority.

Stat. Auth.: ORS 409.050

Stats. Implemented: ORS 409.010