# Mandatory Disclosures of Protected Health Information in Oregon

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#### **Background, Intent, and Miscellany**

Under the HIPAA Privacy Regulations, a disclosure of protected health information is permitted without patient authorization when required by law. Such a disclosure must be in compliance with and limited to the relevant requirements of such law (See 45 CFR 164.512).

This document is intended to provide a comprehensive listing of mandatory disclosures of protected health information in the state of Oregon. It was developed by the OAHHS Compliance Advisory Committee and may be used freely by OAHHS member organizations.

As the Compliance Advisory Committee becomes aware of statutory and regulatory changes affecting this document, it will be updated. However, the reader is hereby put on notice that the content of this document is not guaranteed to be complete or accurate. Statutory and regulatory citations are provided so the reader can research specific requirements. In some cases it may be advisable to seek legal counsel.

## Infants and Vital Statistics

#### Birth

Mandate to disclose applies to• Person in charge of Institution or designee. • For a birth outside institution (such as a home birth), in order of priority: physician, midwife, any person in attendance, parent, or person in charge of premises. • Any person having knowledge of the facts, upon demand of the State Registrar of the Center for Health Statistics See OAR 333-011-0225 for whom the mandate to disclose applies to in special situations such as delayed reporting.Disclosure to be made toCounty registrar of the county in which the birth occurred or with the Center for Health Statistics, or as otherwise directed by the State Registrar of the Center for Health Statistics, or as otherwise directed by the State Registrar of the Center for Health StatisticsRequirements: form of report, components, etc.Reports to be made via the Oregon Vital Events Registration System (OVERS). http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/over s/Pages/index.aspxCitation of AuthorityORS 432.089; OAR 333-011-0225; ORS 432.075OrmentsORS states within 5 days General information on registering birth records: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Pag es/InstructionsBirth.aspxTo gain access to OVERS: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Pag es/InstructionsBirth.aspxTo gain access to OVERS: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/over s/Pages/NewUsers.aspxDefinitions of live birth, fetal death, and induced termination of pregnancy: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Doc uments/DefLiveBirthFetalDeathITOP.pdfDefinitions of live birth, fetal death, and i		
made toHealth Statistics, or as otherwise directed by the State Registrar of the Center for Health StatisticsRequirements; form of report, components, etc.Reports to be made via the Oregon Vital Events Registration System (OVERS). http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/over s/Pages/index.aspxGeneral information on how to register birth records: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Pag es/InstructionsBirth.aspxCitation of AuthorityORS states within 5 days General information on registering birth records: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Pag es/InstructionsBirth.aspxComments or gain access to OVERS: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Deag es/InstructionsBirth.aspxTo gain access to OVERS: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Deag es/InstructionsBirth.aspxDefinitions of live birth, fetal death, and induced termination of pregnancy: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Doc uments/DefLiveBirthFetalDeathITOP.pdfKeywordsBirth registration; Home birth; Registration of birth	disclose applies	<ul> <li>For a birth outside institution (such as a home birth), in order of priority: physician, midwife, any person in attendance, parent, or person in charge of premises.</li> <li>Any person having knowledge of the facts, upon demand of the State Registrar of the Center for Health Statistics</li> <li>See OAR 333-011-0225 for whom the mandate to disclose applies to in special</li> </ul>
form of report, components, etc.http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/over s/Pages/index.aspxGeneral information on how to register birth records: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Pag es/InstructionsBirth.aspxCitation of AuthorityORS 432.088; OAR 333-011-0225; ORS 432.075Comments General information on registering birth records: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Pag es/InstructionsBirth.aspxTo gain access to OVERS: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/over s/Pages/NewUsers.aspxDefinitions of live birth, fetal death, and induced termination of pregnancy: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Doc uments/DefLiveBirthFetalDeathITOP.pdfKeywordsBirth registration; Home birth; Registration of birth		Health Statistics, or as otherwise directed by the State Registrar of the Center for
Authority         Comments       ORS states within 5 days         General information on registering birth records: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Pag es/InstructionsBirth.aspx         To gain access to OVERS: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/over s/Pages/NewUsers.aspx         Definitions of live birth, fetal death, and induced termination of pregnancy: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Doc uments/DefLiveBirthFetalDeathITOP.pdf         Keywords       Birth registration; Home birth; Registration of birth	form of report,	http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/over s/Pages/index.aspx General information on how to register birth records: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Pag
General information on registering birth records:         http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Pag         es/InstructionsBirth.aspx         To gain access to OVERS:         http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/over         s/Pages/NewUsers.aspx         Definitions of live birth, fetal death, and induced termination of pregnancy:         http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Doc         wments/DefLiveBirthFetalDeathITOP.pdf         Birth registration; Home birth; Registration of birth	-	ORS 432.088; OAR 333-011-0225; ORS 432.075
	Comments	General information on registering birth records: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Pag es/InstructionsBirth.aspx To gain access to OVERS: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/over s/Pages/NewUsers.aspx Definitions of live birth, fetal death, and induced termination of pregnancy: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Doc
Last reviewed 10/27/2015	Keywords	Birth registration; Home birth; Registration of birth
	Last reviewed	10/27/2015

#### **Infants and Vital Statistics Fetal Death** (Fetal death of 350 grams or more, or, if weight is unknown, of 20 completed weeks gestation or more, calculated from the date last normal menstrual period began to the date of delivery) Mandate to • When a fetus is delivered in an institution, the person in charge of the disclose applies institution or a designated representative shall prepare and file the report. When a fetus is delivered outside an institution, the physician in attendance at • to or immediately after delivery shall prepare and file the report. Any person having knowledge of the facts, upon demand of the State Registrar • of the Center for Health Statistics Center for Health Statistics Disclosure to be made to Within 5 days of death *Requirements;* Reports to be made via the Oregon Vital Events Registration System (OVERS). form of report, http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/over components, etc. s/Pages/index.aspx ORS 432.143; ORS 432.075 Citation of Authority *Comments* General Information on Registering Fetal Death Records: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecor ds/Pages/InstructionsFetalDeath.aspx To gain access to OVERS: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecor ds/overs/Pages/NewUsers.aspx Definitions Of Live Birth, Fetal Death, And Induced Termination Of Pregnancy: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Doc uments/DefLiveBirthFetalDeathITOP.pdf *Keywords* Fetal death; Certificate of Death; Stillbirth; Death, fetal

*Last reviewed* 10/27/2015

#### **Infants and Vital Statistics**

#### Abortion

(not disclosing name or identity of parents)

Mandate to disclose applies to	<ul> <li>Supervisor of institution, or physician if did not occur in institution.</li> <li>Any person having knowledge of the facts, upon demand of the State Registrar of the Center for Health Statistics</li> </ul>
Disclosure to be made to	Center for Health Statistics
Requirements; form of report, components, etc.	Special form no sooner than two weeks but within 30 days of abortion: https://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Do cuments/ITOP/45-113.pdf
	As of February 2015 reports may be made via OVERS . General information on how to register induced termination of pregnancy: https://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Pag es/ITOPInstruct.aspx
Citation of Authority	ORS 435.496; ORS 432.075
Comments	Although no patient name is required, the report contains PHI because it includes information that does not meet the de-identification standard 45 CFR §164.514. Definitions Of Live Birth, Fetal Death, And Induced Termination Of Pregnancy: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Doc uments/DefLiveBirthFetalDeathITOP.pdf
Keywords	Termination of pregnancy; Abortion; Pregnancy, termination
Last reviewed	10/27/2015

#### Infants and Vital Statistics

#### Infant/Child Hearing Screening Test Results

Mandate to disclose applies to	Hospitals and birthing centers with more than 200 live births per year, diagnostic facilities performing screening, public and private educational institutions that provide early intervention services
Disclosure to be made to	OHA/Public Health: Oregon EHDI Program
Requirements; form of report, components, etc.	Within 10 days of birth conducting the hearing screen test Reports to be made via the Oregon Vital Events Registration System (OVERS). http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/over s/Pages/index.aspx
Citation of Authority	ORS 433.321
Comments	General information, forms, protocols, etc.: http://public.health.oregon.gov/HealthyPeopleFamilies/Babies/HealthScreening/ HearingScreening/Pages/index.aspx To gain access to OVERS: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/over s/Pages/NewUsers.aspx
Keywords	Hearing screening; Infant Hearing Screening; Child Hearing Screening; Screening, hearing (infant/child)
Last reviewed	10/27/2015

#### Death and Cause of Death

Mandate to disclose applies to	The physician, physician assistant practicing under the supervision of a person licensed to practice medicine under ORS chapter 677 or certified nurse practitioner in charge of the care of the patient for the illness or condition that resulted in death.
Disclosure to be made to	Funeral service practitioner or person acting as a funeral service practitioner
Requirements; form of report, components, etc.	The above medical professional must complete, sign and return the medical certificate of death to the funeral service practitioner or person acting as a funeral service practitioner within 48 hours after receipt of the certificate of death.
Citation of Authority	ORS 432.133(5)-(6); ORS 432.075
Comments	When a death occurs in a hospital where 10 deaths occurred in the previous calendar year the hospital shall require the medical certification to be reported via OVERS and the report of death to include the electronic signature of the medical certifier.
	<ul> <li>When death occurs in a hospital described above and the death is not under the jurisdiction of a medical examiner, the person in charge of the hospital or the designated representative of the person in charge of the hospital shall enter the following information on the report of death within 48 hours of death: <ul> <li>If the report of death does not exist in the state electronic reporting system, the name of the decedent, the date of the decedents birth, the date of the decedents death and the county in which the decedent died; and</li> <li>The medical certification of death, accompanied by the signature or electronic signature of the person completing the cause of death as described in subsection (3) of this section.</li> </ul> </li> </ul>
	The partially completed report of death prepared shall be made available to the funeral service practitioner or person acting as a funeral service practitioner within 48 hours of death.
	For general information on how to register death records: https://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecords/Pag es/InstructionsDeath.aspx
	To gain access to OVERS: http://public.health.oregon.gov/BirthDeathCertificates/RegisterVitalRecor ds/overs/Pages/NewUsers.aspx
Keywords	Death; Certificate of death; Death certificate

*Last reviewed* 10/27/2015

### <u>Deaths</u>

	Deaths
	<b>Deaths Requiring Investigation</b> (and all deaths of persons admitted to hospital or institution for less than 24 hours)
Mandate to disclose applies to	Any person having knowledge
Disclosure to be made to	District Medical Examiner or designated assistant medical examiner for county in which death occurs
Requirements; form of report, components, etc.	When inquiry is required by ORS chapter 146, the Medical Examiner shall determine the cause of death and shall complete and sign the medical certification of death within 48 hours after taking charge of the case.
Citation of Authority	ORS 146.090-146.100
Comments	<ol> <li>Deaths requiring investigation are:         <ol> <li>Apparently homicidal, suicidal, or occurring under suspicious or unknown circumstances,</li> <li>resulting from the unlawful use of controlled substances or use or abuse of chemicals or toxic agents,</li> <li>occurring while incarcerated in any jail or correction facility or in police custody,</li> <li>apparently accidental or following an injury,</li> <li>by disease, injury, or toxic agent during or arising from employment,</li> <li>while not in the care of a physician during the period immediately previous to death,</li> <li>Related to disease that might threaten public health, or</li> <li>In which the human body apparently has been disposed of in an offensive manner.</li> </ol> </li> </ol>
Keywords	Death; Death requiring investigation; Homicide; Suicide; Accidental death; Reportable death; Medical examiner case
Last reviewed	10/27/2015

### **Deaths**

#### **Toy-Related Injury or Death**

Mandate to disclose applies to	Physician who determines or reasonably suspects
Disclosure to be made to	Director of the Oregon Health Authority
Requirements; form of report, components, etc.	
Citation of Authority	ORS 677.491
Comments	ORS 677.491 calls for the Director of the Oregon Health Authority to adopt rules to implement the statutory reporting requirement. However, the legislature did not supply funding to create a reporting program; no rules have been promulgated and no reporting program currently exists.
Keywords	Death; Injury; Toy-Related Injury or Death; Death, toy-related; Injury, toy-related
Last reviewed	10/27/2015

	<u>Mental or Physical Impairment</u> <u>Cognitively or Functionally Impaired Driver</u> (A person whose cognitive or functional impairment affects that person's ability to safely operate a motor vehicle.)
Mandate to disclose applies to	Physicians and health care providers
Disclosure to be made to	DMV
Requirements; form of report, components, etc.	Mandatory Impairment Referral, DMV Form 7230 http://www.odot.state.or.us/forms/dmv/7230.pdf
Citation of Authority	ORS 807.710; OAR 735-074-0050, et seq.
Comments	OAR 735-074-0110 and 735-074-0130 provide details on conditions requiring a report
Keywords	Cognitive impairment; Functional impairment; Impaired driver; Mental impairment; Physical impairment; Driver, impaired; Motor vehicle operation, impaired
Last reviewed	12/7/2015

#### **Mental or Physical Impairment Mentally Impaired Driver** (mentally ill or mentally retarded, who, because of condition should not drive, in opinion of superintendent of hospital) Mandate to Superintendent of hospital for mentally ill or mentally retarded upon release of patient with driver's license disclose applies to Disclosure to be **Department of Transportation** made to None specified *Requirements;* form of report, components, etc. ORS 807.700 Citation of Authority *Comments* May be applicable to those hospitals that have an inpatient psychiatry unit. *Keywords* Mental impairment; Mentally ill; Mentally retarded; Developmentally disabled; Impaired driver; Driver, impaired; Motor vehicle operation, impaired Last reviewed 12/7/2015

#### **Mental or Physical Impairment**

# Suicide Attempts of Persons under Age 18 (statistics only, no name)

Mandate to disclose applies to	Hospitals
Disclosure to be made to	OHA/Public Health
Requirements; form of report, components, etc.	Special form, <u>Teen Suicide Attempt Report Form 45-119</u> <u>http://public.health.oregon.gov/DiseasesConditions/InjuryFatalityData/Document</u> <u>s/ASADForm.pdf</u>
	Send by 15 <sup>th</sup> of each month for previous month's suicide attempts; fax the form to 971-673-0990
Citation of Authority	ORS 441.750(1)(b)
Comments	Patient name not required by law, but is requested; form requires other PHI. Oregon Public Health Division, Teen Suicide Attempt: Zero Attempts Form 45-120 will be used by the hospital to inform the Center for Health Statistics that no patients were treated under ORS Chapter 189 during the current reporting period. This eliminates call-backs from the Public Health Division to verify reporting procedures.
Keywords	Suicide attempts, minors; Minors' suicide attempts
Last reviewed	12/7/2015

### Mental or Physical Impairment

	<b>Intoxicated Driver</b> (a person reasonably believed to be the operator of a motor vehicle involved in an accident with blood alcohol level at or above the legal limit, or blood containing a controlled substance)
Mandate to disclose applies to	Any health care facility that provides medical care immediately after a motor vehicle accident to a person reasonably believed to be the operator of a motor vehicle involved in the accident
Disclosure to be made to	Any law enforcement officer who is present and acting in an official capacity with respect to the accident. If no law enforcement officer is present, notification shall be made to the county in which the accident occurred, or an Oregon State Police dispatch center, as soon as possible but no more than 72 hours after becoming aware of the blood test.
Requirements; form of report, components, etc.	Notice required if the health care facility becomes aware, as a result of any blood test performed in the course of that treatment, that: (a) The person's blood alcohol level meets or exceeds the percent specified in ORS 813.010 (0.08%); or (b) The person's blood contains a controlled substance as defined in ORS 475.005 (a drug or its immediate precursor classified in Schedules I through V under the federal Controlled Substances Act). Notice must consist of: (a) The name of the person being treated; (b) The blood alcohol level and name and level of any controlled substance disclosed by the test; and (c) The date and time of the administration of the test.
Citation of Authority	ORS 676.260
Comments	
Keywords	MVA; Motor vehicle accident; Driver under the influence; DUI; Under the influence; Impaired driver; Driver, impaired; Drunk driver; ETOH; Alcohol; Controlled substance
Last reviewed	12/7/2015

#### **Mental or Physical Impairment**

#### Disabled Child Not Enrolled in a Special Education Program

Mandate to disclose applies to	<ul> <li>Public or private official (ORS 419b.005)</li> <li>"Public or private official" means: <ul> <li>(a) Physician or physician assistant licensed under ORS chapter 677 or</li> <li>naturopathic physician, including any intern or resident.</li> <li>(b) Dentist.</li> <li>(c) Licensed practical nurse, registered nurse, nurse practitioner, nurse's aide,</li> <li>home health aide or employee of an in-home health service.</li> <li>(g) Psychologist.</li> <li>(i) Regulated social worker.</li> <li>(j) Optometrist.</li> <li>(k) Chiropractor.</li> <li>(t) Physical, speech or occupational therapist.</li> <li>(u) Audiologist.</li> <li>(v) Speech-language pathologist.</li> <li>(x) Pharmacist.</li> </ul> </li> </ul>
Disclosure to be made to	Superintendent of Public Instruction
Requirements; form of report, components, etc.	No form specified Report must include the child's name and the facts leading the official to the belief that the child has a disability and is eligible for but not enrolled in a special education program
Citation of Authority	ORS 343.193
Comments	"Child with a disability" is defined by ORS 343.035.
	Legal Specialist for the Dept. of Education advised that such reports be made to the local school district special education director or directly to the Department at 503-947-5600 (fax 503-378-5156).
	Requirement may change in the future; as part of an education overhaul, a 2011 state law eliminated the elected office of Superintendent and made the Governor the Superintendent, with the responsibility of appointing a Deputy Superintendent of Public Instruction.
Keywords	Disabled child; Special education; School; Child, disabled
Last reviewed	12/7/2015

#### **Reporting to protect health Disease Reporting** (All cases or suspected cases of diseases, infections, microorganisms and conditions specified in current lists maintained by Oregon Public Health Division) Mandate to Health care providers, licensed laboratories disclose applies to Disclosure to be Local Public Health Authority (LCPA) http://public.health.oregon.gov/ProviderPartnerResources/LocalHealthDepartme made to ntResources/Pages/lhd.aspx **Requirements;** Conditions required to be reported immediately, within 24 hours, and 1 working day: form of report, http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/Repor components, etc. tingCommunicableDisease/Pages/reportable.aspx#immed Form: http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/Repor tingCommunicableDisease/ReportingForms/Documents/morbrpt.pdf **Caution**: The above lists and forms are updated from time to time. It is strongly recommended that you *not* print lists or forms; go directly to the website for current information. ORS 433.004; OAR 333-018-0010 and 333-018-0015(5) **Citation of** Authority *Comments* Civil penalties may be imposed for a violation of reporting and failure to cooperate with local and state public health authorities in their investigation and control of reportable diseases. Reportable diseases includes animal bites (Humans) within one Local Public Health Authority working day Diseases; Infections; Microorganisms; Medical conditions; Animal bites; Bites, **Keywords** animal *Last reviewed* 12/1/2015

#### **Reporting to protect health**

Newborn Metabolic Testing/Screening (Submission of identifiable blood specimens to the state public health laboratory)

Mandate to disclose applies to	In order of responsibility: (A) The hospital, alternate birthing facility, or other health care facility licensed under ORS 441, or if the infant is not in such a facility; (B) The practitioner, or if no practitioner is in attendance; (C) The parent or legal guardian.
Disclosure to be made to	Oregon state public health laboratory
Requirements ; form of report, components, etc.	Instructions for submitting specimens: https://public.health.oregon.gov/LaboratoryServices/NewbornScreening/Pages/index.as px
Citation of Authority	ORS 433.285; OAR 333-024-0210, et seq.
Comments	ORS 433.295 requires physicians, public health nurses and the administrators of hospitals to report the discovery of cases of phenylketonuria to the Oregon Health Authority. Web-Rad Results for all infants born in your facility or under care in your practice can now be accessed online through the OSPHL's website. Contact Oregon State Public Health Laboratory, Newborn Screening Section by phone (503-693-4174) or e-mail to sign up and obtain a user ID and password.
Keywords	Infant, metabolic testing; Newborn, metabolic testing; Baby, metabolic testing; Metabolic testing, newborn; Newborn screening; Screening, newborn metabolic
Last reviewed	12/1/2015

### **<u>Reporting to protect health</u>**

#### Phenylketonuria

Mandate to disclose applies to	Physicians, public health nurses and the administrators of hospitals
Disclosure to be made to	Oregon Health Authority
Requirements; form of report, components, etc.	<ol> <li>All physicians, public health nurses and the administrators of hospitals shall report the discovery of cases of phenylketonuria to the Oregon Health Authority.</li> <li>The authority shall furnish forms that all physicians, public health nurses, and hospitals shall use to report to the authority the test results for phenylketonuria.</li> </ol>
Citation of Authority	ORS 433.285 and ORS 433.295
Comments	No rules have been promulgated to implement this requirement; no forms for this purpose found. See preceding entry regarding newborn metabolic testing/screening.
Keywords	Phenylketonuria
Last reviewed	12/1/2015

#### **Reporting to protect health**

#### Reporting of Medical Devices Related to Injury, Death

Mandate to disclose applies to	-	ry surgical facilities, n nt diagnostic facilitie		
Disclosure to be made to	<ul> <li>Deaths: FDA and Manufacturer</li> <li>Serious Injuries: Manufacturer; FDA only if manufacturer is unknown</li> </ul>			
Requirements; form of report,	WHAT TO REPORT	REPORT FORM #	то wном	WHEN
components, etc.	Death	Form FDA 3500A	FDA & Manufacturer	Within 10 work days
	Serious injury	Form FDA 3500A	Manufacturer FDA only if manufacturer unknown	Within 10 work days
	Annual reports of death & serious injury	Form FDA 3419	FDA	January 1
	Forms and instructic http://www.fda.gov	ons: /MedicalDevices/Safe	ety/ReportaProblen	<u>1/default.htm</u>
Citation of Authority	Section 519(a) of the <u>Federal Food Drug &amp; Cosmetic (FFD&amp;C) Act</u> <sup>8</sup> ; 21 CFR 803.30, et seq.			
Comments	A medical device is any item that is used for the diagnosis, treatment, or prevent of a disease, injury or other condition, NOT a drug or biologic.			
	(Note: Clinical trials require separate reporting)			
Keywords	Medical device, injury or death; Death, medical device; Injury, medical device; FDA, reporting of medical devices related to injury, death; Device, medical: injury or death			
Last reviewed	12/1/2012			

#### **Reporting to protect health**

### **Reporting of Vaccine Adverse Events**

Mandate to disclose applies to	Health care providers
Disclosure to be made to	Vaccine Adverse Event Reporting System (VAERS) which is managed by the U.S. Centers for Disease Control and Prevention and the U.S. Food and Drug Administration.
Requirements; form of report, components, etc.	Forms and instructions: <u>http://vaers.hhs.gov/esub/index</u>
Citation of Authority	42 USC 300aa-25
Comments	List of reportable events: http://vaers.hhs.gov/resources/VAERS Table of Reportable Events Following Va ccination.pdf
Keywords	VAERS
Last reviewed	12/1/2015

#### **Crime or Abuse Reporting Suspected Child Abuse** (Assault, mental injury, rape, sexual abuse, sexual exploitation, negligent treatment or maltreatment of a child, unlawful exposure to a controlled substance; see ORS 419B(1) for the complete definition of child abuse.) Public or private official (ORS 419B.005) Mandate to disclose applies to Disclosure to be DHS or law enforcement within the county where the person making the report is located at the time of the contact made to **Requirements**; Immediate oral communication by telephone or otherwise The report shall contain, if known: form of report, 1.the names and addresses of the child and the parents of the child or other components, etc. persons responsible for care of the child 2.the child's age 3.the nature and extent of the abuse, including any evidence of previous abuse 4.the explanation given for the abuse; and 5.any other information that the person making the report believes might be helpful in establishing the cause of the abuse and the identity of the perpetrator ORS 419B.010, 419B.015 Citation of ORS 419B.025 Authority includes Domestic violence if minor was present *Comments* Anyone participating in good faith in the making of a report of child abuse and who has reasonable grounds for the making thereof shall have immunity from any liability, civil or criminal, that might otherwise be incurred or imposed with respect to the making or content of such report. Any such participant shall have the same immunity with respect to participating in any judicial proceeding resulting from such report. *Kevwords* Child abuse; Abuse reporting, child; Abuse, child; Neglect, child Last reviewed 8/16/2012

#### **Child Abuse Investigation**

Mandate to disclose applies to	Health care provider as defined in ORS 192.556
Disclosure to be made to	The law enforcement agency, DHS, the member agency of the county multidisciplinary child abuse team or the member of the county multidisciplinary child abuse team investigating the abuse
Requirements; form of report, components, etc.	Must permit the inspection and copying of medical records, including, but not limited to, prenatal and birth records, of the child involved in the investigation without the consent of the child, or the parent or guardian of the child
Citation of Authority	ORS 419B.050
Comments	A health care provider who in good faith disclosed medical records under this section is not civilly or criminally liable for the disclosure.
Keywords	Child abuse; Abuse investigation, child; Investigation, child abuse
Last reviewed	8/16/2012

### <u>Crime or Abuse</u>

	<b>Reporting Suspected Elder Abuse</b> (65 years of age or older; Any physical injury caused by other than accidental means, neglect, abandonment, verbal abuse, financial exploitation; see ORS 124.050 for the complete definition of abuse.)
Mandate to disclose applies to	Public or private official (ORS 124.060) having reasonable cause to believe that any person 65 years of age or older with whom the official comes in contact, while acting in an official capacity, has suffered abuse, or that any person with whom the official comes in contact while acting in an official capacity has abused a person 65 years of age or older shall report or cause a report to be made in the manner required in ORS 124.065
Disclosure to be made to	DHS or law enforcement within the county where the person making the report is at the time of contact
Requirements; form of report, components, etc.	<ul> <li>Immediate oral communication by telephone or otherwise</li> <li>The report shall contain, If known:</li> <li>1. the names and addresses of the elderly person and any persons responsible for the care of the elderly person</li> <li>2. the nature and the extent of the abuse (including any evidence of previous abuse)</li> <li>3. the explanation given for the abuse; and</li> <li>4. any other information which the person making the report believes might be helpful in establishing the cause of the abuse and the identity of the perpetrator.</li> </ul>
Citation of Authority	ORS 124.050-124.095; OAR 411-020-0020
Comments	Anyone participating in good faith in the making of a report of elder abuse and who has reasonable grounds for making the report shall have immunity from any civil liability that might otherwise be incurred or imposed with respect to the making or content of such report. Any such participant shall have the same immunity with respect to participating in any judicial proceeding resulting from such report.
Keywords	Elder abuse; Abuse reporting, elder; Abuse, elder
Last reviewed	8/16/2012

#### **Elder Abuse Investigation**

Mandate to disclose applies to	Health care provider as defined in ORS 192.556
Disclosure to be made to	Law enforcement agency investigating report of abuse under ORS 124.070
Requirements; form of report, components, etc.	Must: (a) Permit the law enforcement agency to inspect and copy, or otherwise obtain, PHI of the named elderly person; and (b) Upon request of the law enforcement agency, consult with the agency about the PHI.
Citation of Authority	ORS 124.050 -124.095; OAR 411-020-0123
Comments	Information must be provided without the consent of the named elderly person or of the named elderly person's caretaker, fiduciary or other legal representative. A health care provider who in good faith discloses PHI under this section is not civilly or criminally liable under state law for the disclosure. APS may seek to obtain PHI directly from a health care provider or indirectly through law enforcement under procedures set forth in OAR 411-020-0123; however, while such disclosure may be permitted under 45 CFR 164.512(c) or 164.512(j), it is not mandated.
Keywords	Elder abuse; Abuse investigation, elder; Investigation, elder abuse
Last reviewed	11/26/2012

	<u>Crime or Abuse</u>
	Reporting Suspected Abuse of Mentally III or Developmentally Disabled Persons (Abandonment, any physical injury caused by other than accidental means, willful infliction of physical pain or injury, sexual abuse, neglect, verbal abuse, financial exploitation; see ORS 430.735 for the complete definition of abuse.)
Mandate to disclose applies to	Public or private official who has reasonable cause to believe that any adult with whom the official comes in contact while acting in an official capacity, has suffered abuse, or that any person with whom the official comes in contact while acting in an official capacity has abused an adult shall report or cause a report to be made in the manner required in ORS 430.743.
Disclosure to be made to	DHS or law enforcement within the county where the person making the report is at the time of contact
Requirements; form of report, components, etc.	<ul> <li>Immediately by telephone or otherwise. If known, the report shall include:</li> <li>1. The name, age and present location of the allegedly abused adult;</li> <li>2. The names and addresses of persons responsible for the adult's care;</li> <li>3. The nature and extent of the alleged abuse, including any evidence of previous abuse;</li> <li>4. Any information that led the person making the report to suspect that abuse has occurred plus any other information that the person believes might be helpful in establishing the cause of the abuse and the identity of the perpetrator; and</li> <li>5. The date of the incident.</li> </ul>
Citation of Authority	ORS 430.743, 430.765
Comments	Anyone participating in good faith in making a report of abuse of mentally ill or developmentally disabled persons and who has reasonable grounds for making the report, shall have immunity from any civil liability that might otherwise be incurred or imposed with respect to the making or content of the report. The participant shall have the same immunity with respect to participating in any judicial proceeding resulting from the report. Under current Oregon law, there is no mandated disclosure of PHI in connection with an investigation into suspected abuse of a mentally disabled person. Disclosure of PHI to DHS or law enforcement may be permitted under 45 CFR
	164.512(c) or 164.512(j).
Keywords	Abuse reporting, mentally ill or developmentally disabled persons; Mental impairment; Mentally ill; Mentally retarded; Developmentally disabled
Last reviewed	11/26/2012

#### Abandoned Baby

	Abandoned Baby (A parent may leave an infant at an authorized facility in the physical custody of an agent, employee, physician or other medical professional working at the authorized facility if the infant is 30 days of age or younger as determined to a reasonable degree of medical certainty and has no evidence of abuse.)
Mandate to disclose applies to	The authorized facility (hospital, freestanding birthing center, physician's office) shall notify DHS that an infant has been left at the facility no later than 24 hours after receiving the infant. The authorized facility shall release the infant to DHS when release is appropriate considering the infant's medical condition and shall provide the department with all information the facility has regarding the infant.
Disclosure to be made to	DHS
Requirements; form of report, components, etc.	
Citation of Authority	ORS 418.017
Comments	If acting in good faith in receiving an infant, an authorized facility receiving an infant under this section and any agent, employee, physician or other medical professional working at the authorized facility are immune from any criminal or civil liability that otherwise might result from their actions relating to receiving the infant.
Keywords	Abandoned baby; Baby, abandoned; Infant, abandoned; Newborn, abandoned
Last reviewed	8/16/2012

	<b>Reporting Abuse of Patient in Long-Term Care Facility</b> (Any physical injury to a resident of a long term care facility which has been caused by other than accidental means, failure to provide basic care or services, sexual contact with a resident, Illegal or improper use of a resident's resources, verbal or mental abuse, corporal punishment; see ORS 441.630 for complete definition of abuse.)
Mandate to disclose applies to	Public or private official having reasonable cause to believe that any resident in a long term care facility, with whom the official comes in contact while acting in an official capacity, has suffered abuse, or that any person with whom the official comes in contact while acting in an official capacity has abused a resident in a long term care facility, shall report or cause a report to be made in the manner required in ORS 441.645.
Disclosure to be made to	Local office of the area agency on aging; DHS, SDS; or to a law enforcement agency within the county where the person making the report is at the time of contact
Requirements; form of report, components, etc.	<ul> <li>Immediate oral communication by telephone or otherwise. If known, such reports shall contain:</li> <li>1. the names and addresses of the resident and any persons responsible for the care of the resident,</li> <li>2. the nature and the extent of the abuse, including any evidence of previous abuse,</li> <li>3. the explanation given for the abuse and</li> <li>4. any other information which the person making the report believes might be helpful in establishing the cause of the abuse and the identity of the perpetrator.</li> </ul>
Citation of Authority	ORS 441.630-441.655; OAR 411-020-0020
Comments	Anyone participating in good faith in the making of a report of abuse of a patient in a long-term care facility and who has reasonable grounds for the making thereof, shall have immunity from any liability, civil or criminal, that might otherwise be incurred or imposed with respect to the making or content of such report. Any such participant shall have the same immunity with respect to participating in any judicial proceeding resulting from such report.
Keywords	Abuse reporting, long-term care facility patient; Patient abuse, long-term care facility; Long-term care facility patient abuse
Last reviewed	8/16/2012

# Investigations into suspected abuse of patient in long-term care facility

Mandate to disclose applies to	Health care provider as defined in ORS 192.556
Disclosure to be made to	Law enforcement agency investigating report of abuse under ORS 441.650
Requirements; form of report, components, etc.	Must: (a) Permit the law enforcement agency to inspect and copy, or otherwise obtain, PHI of the named resident; and (b) Upon request of the law enforcement agency, consult with the agency about the PHI.
Citation of Authority	ORS 441.630 – 441.680; OAR 411-020-0123
Comments	Information must be provided without the consent of the named resident or of the named resident's caretaker, fiduciary or other legal representative. A health care provider who in good faith discloses PHI under this section is not civilly or criminally liable under state law for the disclosure. APS may seek to obtain PHI directly from a health care provider or indirectly through law enforcement under procedures set forth in OAR 411-020-0123; however, while such disclosure may be permitted under 45 CFR 164.512(d), it is not mandated.
Keywords	Abuse investigation, long-term care facility patient; Patient abuse, long-term care facility; Long-term care facility patient abuse
Last reviewed	11/26/2012

#### **Crime or Abuse Reporting Unlawful or Unsatisfactory Nursing Home Conditions** (Not conducted or operated under the supervision of a nursing home administrator who holds a valid license.) Mandate to Health care facility licensed under ORS 441.015, licensee licensed by the Oregon Health Licensing Agency, physician licensed by the OMB, licensed professional disclose applies nurse and licensed pharmacist to **Oregon Health Licensing Agency** Disclosure to be made to **Requirements;** Conditions to be reported: Nursing homes not conducted or operated under the supervision of a nursing form of report, • home administrator who holds a valid license issued under the provisions of components, etc. ORS 678.710 to 678.820. Individuals who do not hold a valid license issued under the provisions of ORS 678.710 to 678.820 and are: • Practicing or offering to practice as a nursing home administrator; or 0 Using in connection with the name of the individual the words or letters "nursing home administrator," "NHA" or any other words, letters or abbreviations or insignia tending to indicate that the individual is a licensed nursing home administrator. Form not specified. ORS. 678.725 Citation of Authority Any person who reports or provides information in good faith may not be subject *Comments* to an action for civil damages as a result of making the report or providing the information. Nursing home administrator; Licensure, nursing home administrator; **Keywords** Administrator, nursing home; Unlawful or unsatisfactory nursing home conditions; Nursing home conditions, unlawful or unsatisfactory *Last reviewed* 8/16/2012

# Non-Accidental Physical Injury Caused By a Deadly Weapon (knife, gun, pistol or other dangerous or deadly weapon)

Mandate to disclose applies to	Physicians, residents, interns and registered nurse licensed under ORS 678.010 to 678.410
Disclosure to be made to	Appropriate law enforcement agency
Requirements; form of report, components, etc.	Immediate oral communication by telephone or otherwise; followed by written report ASAP
Citation of Authority	ORS 146.710-146.780
Comments	Anyone participating in good faith in the making of a report and who has reasonable grounds for the making thereof shall have immunity from any liability, civil or criminal, that might otherwise be incurred or imposed with respect to the making of such report. Any such participant shall have the same immunity with respect to participation in any judicial proceeding resulting from such report.
Keywords	Injury; Injury, deadly weapon; Non-accidental injury; Deadly weapon injury; Injury, non-accidental
Last reviewed	8/16/2012

	Missing Person, Identifying Information
Mandate to disclose applies to	Dentist, denturist, physician, optometrist, or other medical practitioner
Disclosure to be made to	Law enforcement agency
Requirements; form of report, components, etc.	Upon receipt of a written request from a law enforcement agency for identifying information, shall furnish to the agency such information known to the practitioner upon the request forms provided by the agency.
Citation of Authority	ORS 146.184
Comments	Information obtained under this section is restricted to use for the identification of missing persons or the identification of unidentified human remains and may not be made available to the public. Compliance with a written request for information under this law does not constitute a breach of confidentiality.
Keywords	Missing person, identification; Identification, missing person
Last reviewed	8/16/2012

#### Inpatient Data Reporting

	inpatient Data Reporting
Mandate to disclose applies to	Oregon licensed general acute care hospitals
Disclosure to be made to	OAHHS via COMPdata http://compdatainfo.com/data-submission-services/oregon.aspx
Requirements; form of report, components, etc.	Electronic submission; what to report: -Hospital ID -Patient zip code -DRG -Type of procedures performed -Total charges -DOB -Admit and discharge dates -Type of discharge -Sex of the patient
Citation of Authority	ORS 442.120; OAR 409-022-0005
Comments	General information: http://cms.oregon.gov/oha/OHPR/RSCH/Pages/databank.aspx Resource for hospital data submission: http://compdatainfo.com/data- submission-services/oregon.aspx Resource for training: http://compdatainfo.com/Training/Data- Submission/Training-Self-Tutorials.aspx
Keywords	Data, hospital; Hospital data; Inpatient data; Data, inpatient
Last reviewed	8/17/2012

	Outpatient Surgical Data Reporting
Mandate to disclose applies to	Oregon licensed general acute care hospitals and ambulatory surgical facilities
Disclosure to be made to	OAHHS via COMPdata http://compdatainfo.com/data-submission-services/oregon.aspx
Requirements; form of report, components, etc.	Electronic submission; what to report: -DOB -Sex of the patient -Patient zip code -Service date -Type of discharge -Diagnosis -Procedure type -Hospital ID -Total charges -Expected source of pay, if available
Citation of Authority	ORS 442.120; OAR 409-022-0005
Comments	General information: http://cms.oregon.gov/oha/OHPR/RSCH/Pages/Ambulatory Surgery Reporting.a spxResource for hospital data submission: <a href="http://compdatainfo.com/data-submission-services/oregon.aspx">http://compdatainfo.com/data-submission-services/oregon.aspx</a> Resource for training: <a href="http://compdatainfo.com/Training/Data-Submission/Training-Self-Tutorials.aspx">http://compdatainfo.com/Training/Data-Submission/Training-Self-Tutorials.aspx</a>
Keywords	Data, outpatient surgery; Data, ambulatory surgery; Ambulatory surgery data; Outpatient surgery data; Surgery, outpatient data; Surgery, ambulatory data
Last reviewed	5/17/2012

#### Cancer

Mandate to disclose applies to	-Clinical labs -Healthcare providers
Disclosure to be made to	Oregon State Cancer Registry (OSCaR) , 800 N.E. Oregon, Suite 730, Portland, OR 97232
Requirements; form of report, components, etc.	<ul> <li>What to report:</li> <li>Reportable cancer or non-malignant conditions within 180 days of dx or 1<sup>st</sup> treatment</li> <li>Cancer dx</li> <li>Treatment</li> <li>Patient demographics</li> <li>Health provider contact info</li> </ul> General information, instructions, and forms: <a href="http://public.health.oregon.gov/DiseasesConditions/ChronicDisease/Cancer/osca">http://public.health.oregon.gov/DiseasesConditions/ChronicDisease/Cancer/osca</a>
Citation of Authority	ORS 432.500 - 432.900; OAR 333-010-0000 – 333-010-0080
Comments	OSCaR sometimes notifies patients of the disclosure to them of the patient's cancer, but not always.
Keywords	OSCaR; Registry, cancer; Cancer registry
Last reviewed	8/16/2012

#### Trauma

Mandate to disclose applies to	Hospitals with OHA Accredited Trauma Center (Levels I-III)
Disclosure to be made to	Oregon Trauma Registry Oregon Health Division EMS & Systems 800 NE Oregon St, Suite 465 Portland, OR 97293
Requirements; form of report, components, etc.	Data to be submitted electronically using the Trauma Registry database, Trauma One
Citation of Authority	ORS 431.623 – 431.635; OAR 333-200-0000 – 333-200-0090
Comments	General information: http://public.health.oregon.gov/ProviderPartnerResources/EMSTraumaSystems/ TraumaSystems/Pages/registry.aspxData submission instructions: http://public.health.oregon.gov/ProviderPartnerResources/EMSTraumaSystems/ TraumaSystems/Documents/corner/AbstractManualVersion16.pdf
Keywords	Registry, trauma; Trauma registry
Last reviewed	8/17/2012

#### Immunizations

	minumzations
Mandate to disclose applies to	Any healthcare provider that administers vaccines, including pharmacists.
Disclosure to be made to	Oregon Immunization Alert 800 NE Oregon Street, Suite 370 Portland, OR 97232
Requirements; form of report, components, etc.	OIA report form: <u>http://www.immalert.org/new/</u>
Citation of Authority	ORS 433.090-433.104; OAR 333-049-0010 to 333-049-0120
Comments	
Keywords	Registry, immunization; Immunization registry
Last reviewed	8/16/2012

#### Juvenile Onset Diabetes

Mandate to disclose applies to	Physicians who make the initial diagnosis.
Disclosure to be made to	Childhood Diabetes Database, Department of Human Services State of Oregon, 500 Summer St. NE, Salem, OR 97301
Requirements; form of report, components, etc.	<ul> <li>Applies to children 18 years of age and younger.</li> <li>Report cases to the CDD within 30 days of diagnosis or 1<sup>st</sup> treatment.</li> <li>Report forms and general information available at http://public.health.oregon.gov/DiseasesConditions/ChronicDisease/Diabetes/ /ChildhoodDiabetes/Pages/practitioners.aspx</li> </ul>
Citation of Authority	ORS 444.300-444.330; OAR 333-010-0600 to 333-010-0640
Comments	
Keywords	Diabetes (juvenile onset) registry; Juvenile onset diabetes registry; Registry, diabetes (juvenile onset)
Last update	8/16/2012

#### **Other Required Disclosures**

#### Physician Orders for Life-Sustaining Treatment (POLST)

Mandate to disclose applies to	Physicians, nurse practitioners, and physician assistants are required to submit or cause to be submitted
Disclosure to be made to	Oregon POLST Registry OHSU Center for Ethics in Health Care 3181 SW Sam Jackson Park Road Portland, Oregon 97239 Fax: (503) 418-2161 Documents may be submitted by fax or mail.
Requirements; form of report, components, etc.	<ul> <li>Requires submission of the following documents to the POLST registry, unless the patient has requested to opt out of the registry:</li> <li>(A) A copy of each POLST. In order for a POLST form to be considered complete, the form (and any supporting documentation) shall include, but is not limited to: <ul> <li>(1) The patient's full name;</li> <li>(2) The patient's date of birth;</li> <li>(3) Orders related to cardiopulmonary resuscitation;</li> <li>(4) The legible, printed name and the signature of the physician, nurse practitioner or physician assistant; and</li> <li>(5) The date the order was signed.</li> </ul> </li> <li>(B) A copy of a revised POLST; and</li> <li>(C) Notice of any known revocation of a POLST</li> </ul>
Citation of Authority	ORS 127.663-127.684; OAR 333-270-0010 et seq.
Comments	A POLST form may be submitted by fax or mail. If the Registry develops a secure method of accepting POLST forms electronically, POLST forms may be submitted electronically.
Keywords	POLST registry; Registry, POLST; Physician Orders for Life-Sustaining Treatment (POLST) Registry
Last reviewed	12/7/2015

#### **Other Required Disclosures**

#### Inpatient Psychiatric Admissions

Mandate to disclose applies to	Regional acute care psychiatric service providers
Disclosure to be made to	Addictions and Mental Health Division (AMHD) of the Oregon Health Authority using the Oregon Patient/Resident Client System (OPRCS)
Requirements; form of report, components, etc.	Requires submission of information about persons admitted to and discharged from a regional acute care psychiatric service through the Oregon Patient/Resident Client System (OPRCS). Such information shall include the patient's name, DSM diagnosis, admission date, discharge date, legal status, Medicaid eligibility, Medicaid Prime Number, and various patient demographics. Such information shall be entered on the day of admission and updated on the day of discharge.
Citation of Authority	ORS 430.6300AR 309-32-0870(4)
Comments	OPRCS User Manuals http://www.oregon.gov/oha/amh/Pages/Data-Systems.aspx
Keywords	Inpatient Psychiatric Admissions; Admissions, inpatient psychiatric; Psychiatric, inpatient admissions
Last reviewed	12/7/2015

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