

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

Oregon Health Authority		943
Agency and Division		Administrative Rules Chapter Number
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Rules Coordinator	Address	Telephone

RULE CAPTION

Informed Consent Requirements for Health Care Providers Participating in Electronic Health Information Exchange
Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

August 22, 2011	Time 2pm-3pm	TBD	Staff
Hearing Date	Time	Location	Hearings Officer

Auxiliary aids for persons with disabilities are available upon advance request.

RULEMAKING ACTION

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

ADOPT: OAR 943-015-0000, 943-015-0010, 943-015-0015

AMEND:

REPEAL:

RENUMBER:

AMEND & RENUMBER:

Stat. Auth. : **ORS 413.300- 413.308; 413.042**

Other Auth.: **Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5 (Feb. 17, 2009).**

Stats. Implemented: **ORS 413.300- 413.308**

RULE SUMMARY

These rules ensure that standardized information is provided to patients about electronic health information exchange (HIE), and that all providers participating in HIE offer a standardized choice to provide patients an informed opportunity to decide whether to participate in HIE.

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.

August 24, 2011

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

Signature		Suzanne Hoffman	7-14-11
	Printed name		Date

*Hearing 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. ARC 920-2005

STATEMENT OF NEED AND FISCAL IMPACT

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

Oregon Health Authority**943**

Agency and Division

Administrative Rules Chapter Number

In the Matter of: **The adoption of OAR 943-015-0000, 943-015-0010, 943-015-0015**

Rule Caption: (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

Informed Consent Requirements for Health Care Providers Participating in Electronic Health Information Exchange.Statutory Authority: **ORS 413.300- 413.308; 413.042**Other Authority: **Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5 (Feb. 17, 2009)**Stats. Implemented: **ORS 413.300-413.308**

Need for the Rule(s): **The Authority needs to adopt these rules to ensure that standardized information is provided to patients about electronic health information exchange (HIE), and that all providers participating in HIE offer a standardized choice to provide patients an informed opportunity to decide whether to participate in HIE.**

Documents Relied Upon, and where they are available: **The policy being implemented by this rule was developed through an extensive stakeholder engagement process involving multiple public meetings, including meetings of the Health Information Technology Oversight Council (HITOC), the HITOC Legal and Policy Workgroup and the HITOC Consumer Advisory Panel, over the course of a year. The materials for and summaries of those meetings can be found on the website of the Health Information Technology Oversight Council: <http://www.oregon.gov/OHA/OHPR/HITOC/>**

Fiscal and Economic Impact: **It is estimated that these rules will have a small negative fiscal/economic impact on those provider organizations participating in electronic health information exchange, in terms of the costs of compliance as outlined below**

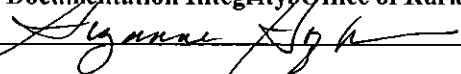
Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)): **There will be no cost to state agencies or units of local government, except those providing direct healthcare services. Healthcare providers participating in electronic health information exchange will be required to provide information in writing to their patients. This cost could include the cost of printing paper and ink, and associated costs of administering and filing the forms. It is not possible to estimate what the total cost to the public will be, because participating in health information exchange is a voluntary activity, so it is currently unknown how many providers will be impacted by these rules**
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: **Small, independent medical practice clinics will be subject to the rule if they are participating in electronic health information exchange. It is not possible to estimate the number of these small businesses that will be subject to the rule because participating in health information exchange is a voluntary activity.**
 - b. Projected reporting, record keeping and other administrative activities required for compliance, including costs of professional services: **Record-keeping and other administrative activities required for compliance include: printing or otherwise providing in writing to the patient the Notification, "HIE Opt Out" form, and "Revocation of Prior HIE Opt Out form; administering these with the patient; and filing them when the patient has completed them.**
 - c. Equipment, supplies, labor and increased administration required for compliance: **Paper, printer ink (if applicable; a provider may choose to provide this information and administer these forms electronically to the patient.**

How were small businesses involved in the development of this rule? **The policy being implemented by this rule was developed through an extensive stakeholder engagement process involving multiple workgroups, advisory panels, and public meetings. Small businesses have been represented on the workgroups and advisory panels that were involved in this process, and also attended the meetings as members of the public to provide public testimony.**

Administrative Rule Advisory Committee consulted?: **Yes, a RAC was held 7/6/11; Participants represented ACLU of ORE, ORE Patient Safety Commission, Providence Health & Services, ORE Medical Association, Advantage Dental, ODS, DHS, Stoel Rives, Multnomah County Health Information Services, Deschutes County Behavioral Health, OCHIN, PSU, Acumentra Health, Greater ORE Behavioral Health, Inc., ORE Optometric Physicians Association, OEBC, Association for Healthcare Documentation Integrity, Office of Rural Health**

Signature



Suzanne Hoffman

7/14/2011

Printed name

Date

Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310. ARC 925-2007

NEW RULE

DIVISION 15 HIE Consent

943-015-0000

Scope

The purpose of these rules is to ensure that standardized information is provided to patients about health information exchange (HIE), and that all providers participating in HIE offer a standardized choice to patients about whether to participate in HIE for the purposes of their health care.

943-015-0010

Definitions

For the purposes of these rules the following definitions apply:

(1) "Health Information Exchange (HIE)" means the sending of patient health information from one health care provider to another health care provider for the purposes of treatment using computerized hardware and software.

(2) "Health care provider" includes but is not limited to:

(a) A psychologist, occupational therapist, regulated social worker, professional counselor or marriage and family therapist licensed or otherwise authorized to practice under ORS chapter 675 or an employee of the psychologist, occupational therapist, regulated social worker, professional counselor or marriage and family therapist;

(b) A physician, podiatric physician and surgeon, physician assistant or acupuncturist licensed under ORS chapter 677 or an employee of the physician, podiatric physician and surgeon, physician assistant or acupuncturist;

(c) A nurse or nursing home administrator licensed under ORS chapter 678 or an employee of the nurse or nursing home administrator;

(d) A dentist licensed under ORS chapter 679 or an employee of the dentist;

- (e) A dental hygienist or denturist licensed under ORS chapter 680 or an employee of the dental hygienist or denturist
- (f) A speech-language pathologist or audiologist licensed under ORS chapter 681 or an employee of the speech-language pathologist or audiologist
- (g) An emergency medical technician certified under ORS chapter 682
- (h) An optometrist licensed under ORS chapter 683 or an employee of the optometrist
- (i) A chiropractic physician licensed under ORS chapter 684 or an employee of the chiropractic physician;
- (j) A naturopathic physician licensed under ORS chapter 685 or an employee of the naturopathic physician;
- (k) A massage therapist licensed under ORS 687.011 (Definitions) to 687.250 (Enforcement) or an employee of the massage therapist
- (l) A direct entry midwife licensed under ORS 687.405 ("Licensed direct entry midwife" defined) to 687.495 (Collection of data on births) or an employee of the direct entry midwife
- (m) A physical therapist licensed under ORS 688.010 (Definitions for ORS 688.010 to 688.201) to 688.201 (Disposition of receipts) or an employee of the physical therapist
- (n) A medical imaging licensee under ORS 688.405 (Definitions for ORS 688.405 to 688.605) to 688.605 (Duty to report violation) or an employee of the medical imaging licensee
- (o) A respiratory care practitioner licensed under ORS 688.800 (Definitions for ORS 688.800 to 688.840) to 688.840 (Immunity from civil liability) or an employee of the respiratory care practitioner
- (p) A dietitian licensed under ORS 691.405 (Definitions) to 691.585 (Confidential information) or an employee of the dietitian

(q) A funeral service practitioner licensed under ORS chapter 692 or an employee of the funeral service practitioner

(r) A health care facility as defined in ORS 442.015 (Definitions)

(s) A home health agency as defined in ORS 443.005 (Definitions for ORS 443.005 to 443.105)

(t) A hospice program as defined in ORS 443.850 (Definitions for ORS 443.850 to 443.869)

(u) A diabetes self-management program as defined in ORS 743A.184 (Diabetes self-management programs); an

(v) Any other person or entity that furnishes, bills for or is paid for health care in the normal course of business

(3) Health care providers do not include pharmacies, laboratories, or health plans.

(4) "Treatment" has the meaning provided in ORS 192.519.

943-015-0015

Patient HIE Notification and Opt Out Requirements

(1) All health care providers participating in HIE must provide or cause to be provided written notification to their patients using substantially the following language (contained in subsections (1)(a) - (1)(i)):

(a) <Insert name of provider> participates in electronic health information exchange (HIE); and

(b) HIE is a computer-based, secure method of sending your health information to other medical professionals that provide health care to you.

(c) Benefits of HIE:

(A) Helps coordinate your care among all your health care providers because they all have the same information

(B) Cuts down on repeated tests and their costs.

(C) Can improve the quality and safety of your health care by providing faster, more complete information to your health care providers.

(D) Protects the privacy of your health care information through encryption, authentication, access controls, and other security mechanisms. Only those who are authorized will be able to see your record.

(E) Allows you to get a copy of your health information more easily.

(d) You may opt out of electronic health information exchange

(A) Your health information will be automatically included in electronic health information exchange unless you choose to opt out of the exchange by completing an opt out form (available upon request)

(B) If you choose to opt out, your health information will not be disclosed through electronic health information exchange, even in the case of an emergency, but it will continue to be disclosed through such traditional methods as fax, phone and United States postal mail, unless your health care provider has agreed, at your request, not to disclose the information.

(e) We are required to disclose certain information even if you opt out

(A) Certain information is required by Oregon state public health law to be shared with the county, state, and/or federal public health agencies. This information may be transmitted through electronic health information exchange even if you opt out of your health information being sent via HIE to your other health care providers.

(f) Authorization still required in some circumstances

(A) Some health information is subject to special privacy protections in state and federal law. Even if you do not opt out of disclosure of your health information through electronic health information exchange, we will continue to obtain authorization from you to disclose information that is subject to special protection.

(g) You may change your mind

(A) You may change your decision to participate or not participate in HIE at any time by requesting and completing the appropriate form from <insert name of provider>

(h) Questions?

(A) If you have any questions or concerns about your health information being disclosed via HIE, you may contact <insert person's name> at <insert person's contact information>.

(i) Acknowledgment

(A) I have received and reviewed this HIE notification.

(B) <Signature of Patient or Authorized Representative, Date>

(2) If requested by the patient, provide an "HIE Opt Out" form using substantially the following language (contained in subsections (2)(a)-(2)(d)):

(a) I received and reviewed the HIE notification from <insert name of provider> and have chosen to opt out of my health information being sent via HIE to my other health care providers by <insert name of provider>, even in the case of a medical emergency.

(b) I understand that my health information will continue to be sent via "traditional" methods, such as fax, phone, and United States postal mail, unless my health care service provider has agreed, at my request, not to disclose the information.

(c) I understand that I may change my decision to not participate in HIE at any time by requesting and completing a "Revocation of Prior HIE Opt Out" form from <insert name of provider>;

(d) <Signature of Patient or Authorized Representative, Date>

(3) If requested by the patient, provide a "Revocation of Prior HIE Opt Out" form using substantially the following language (contained in subsection (3)(a)):

(a) 1. I WISH TO REVOKE (change) my prior decision to Opt-Out of <insert name of provider> sending my health information via electronic health information exchange (HIE) and now I specifically AUTHORIZE my information to be sent via HIE for my health care treatment.

(b) 2. I UNDERSTAND that this Revocation can only be changed if I specifically submit a new HIE Opt-Out form; and

(c) 3. I have had an opportunity to ask and receive answers to my questions regarding this “Revocation of Prior HIE Opt-Out”.

(d) <Signature of Patient or Authorized Representative, Date>

(4) All health care providers participating in HIE must:

(a) Comply with the terms set forth in these rules;

(b) Provide the notification to the patient at or before the patient’s first visit to that provider's office; or if the patient is an already established patient, provide this notification at the patient’s next visit;

(c) Post the notification in the provider's office in a location visible to patients;

(d) Insert the same provider name in the HIE Notification, HIE Opt Out form, and Revocation of Prior HIE Opt Out form.

(e) Become compliant with these rules no later than March 1, 2012.

(5) Health care providers participating in HIE may choose to provide additional informational resources to their patients about HIE. One source of consumer education and engagement materials, including materials that address the benefits and risks of HIE, can be found on the website of the Office of the National Coordinator for Health Information Technology, of the US Department of Health and Human Services:

<http://healthit.hhs.gov/portal/server.pt?open=512&objID=1280&PageID=16051&mode=2&cached=true>