

Nontransplant Anatomical Research Recovery Organization (NARRO)

House Bill 3345

FACT SHEET for NARRO Oregon Administrative Rules (OARs)

Background:

The Healthcare Regulation and Quality Improvement program ensures that a safe and healthy environment is provided by over 500 health related facilities and agencies. HB 3345 was passed by the 2013 Oregon Legislature, to establish rules regarding licensure of NARROs. Permanent administrative rules have been filed to address the provisions of HB 3345.

Summary of Rules:

These rules establish licensing requirements for NARROs, including application, licensing fee, surveys, complaints, investigations, record keeping requirements, notice requirements, NARRO duties, informal and formal enforcement.

What is a NARRO (OAR 333-081-0005(6)(a))?

“Nontransplant anatomical research recovery organization” or “NARRO” means:

A person that engages in the recovery or distribution of anatomical material from a donor for research or education purposes other than transplanting the anatomical material or therapy.

A NARRO does not include (OAR 333-081-0005(6)(b)):

- A hospital or other health care facility as those terms are defined in ORS 442.015;
- A public corporation as defined in ORS 353.010;
- A public or private institution of higher education; or
- A clinical laboratory, as defined in ORS 438.010, that is:
 - Licensed under ORS 438.010 to 438.510; and
 - Owned or controlled by, or under common ownership with, a hospital described in paragraph (A) of this subsection.

1. Application and Licensure

What is required for NARRO licensure?

A NARRO administrator must read and understand all the Oregon Administrative Rules, Chapter 333 Division 081, found online at www.healthoregon.org/hcrqi.

NARROs have record requirements listed in OAR 333-081-0070. Those requirements include

record documentation for donors, requirements for the documentation, and record retention. See the OAR for a complete listing for record requirements.

NARROs have notice requirements listed in OAR 333-081-0075. Those requirements include the donation notice and requirements for the documentation and disclosure notice. See the OAR for a complete listing for notice requirements.

NARROs have Duty Requirements listed in OAR 333-081-0080. Those requirements include the disposal of unreturned anatomical material. See the OAR for a complete listing of duty requirements.

Important Application Information:

- Application information changes must be submitted on an application within 30 calendar days of the change (OAR 333-081-0010(4)).
- Certain changes require notification 30 calendar day **PRIOR** to the change. These changes include: ownership (including mergers), change in facilities due to expansion, relocation, renovations or structural changes, and change in the scope of operations (OAR 333-081-0010(5)). HCRQI may request additional documentation related to these changes in order to ensure compliance with the rules (OAR 333-081-0010(6)).
- After HCRQI receives a completed application and fee, they will contact the administrator about the initial licensure survey (OAR 333-081-0015).
- HCRQI will notify the applicant in writing, including a copy of the license, if they are approved. The license must be posted in a conspicuous location, viewable by the public (OAR 333-081-0020).
- HCRQI will issue a Notice of Proposed Denial of License Application, if they intend to deny a license application (OAR 333-081-0025).
- The license will expire two (2) years after the date of issuance, and must be renewed 45 days prior to the expiration date (OAR 333-081-0030).

How do you apply to get licensed as a NARRO (OAR 333-081-0010)?

Fill out the NARRO application available online at www.healthoregon.org/hcrqi. Make sure to sign, date and include the fee of \$1750.00. Send the completed application to:

HCRQI – NARRO
PO Box 14260
Portland, OR 97293-0260

NARRO Fees (OAR 333-081-0035)

Effective July 1, 2014 new fees are in effect for licensing of NARROs:

- \$1,750.00 for initial, renewal, and change of ownership.

All fees are non-refundable.

Denial, Suspension or Revocation of License (OAR 333-081-0040)

A license may be denied, suspended or revoked by HCRQI, if a licensed NARRO fails to comply with the rules. The license must be returned immediately when it is suspended or revoked (OAR 333-081-0045).

2. Surveys

What is a state survey (OAR 333-081-0050(1))?

A survey is an on-site inspection to review and determine compliance with the Oregon Administrative Rules. The Division must conduct at least one survey of each NARRO prior to licensure and once every two years thereafter as a requirement of licensing.

What is an accreditation survey (OAR 333-081-0050(2))?

In lieu of an on-site inspection for initial or ongoing licensing, the Division may accept proof of accreditation by an accrediting body approved by the Division if the NARRO:

- Gives the Division sufficient advance notice to allow the Division to participate in any exit interviews conducted by the accrediting body; and
- Provides the Division with a copy of all the accreditation survey results report.

At this time there are no approved accrediting bodies to conduct NARRO accreditation surveys. The requirements to apply to be an accrediting body are located in OAR 333-081-0055.

What is a complaint survey (OAR 333-081-0060)?

A complaint survey is an on-site investigation of allegations of non-compliance with the OARs. Any person may make a complaint to HCRQI regarding violations of the rules by a licensed NARRO. If the complaint involves allegations of criminal contact, HCRQI will refer the matter to the proper authorities. Investigations include, but are not limited to: Interviews of staff, on-site observations, and a review of documents, records and other materials (OAR 333-081-0065).

Important Survey Information:

- A NARRO must permit Division staff access to its premises during a survey (OAR 333-081-0050(3)).
- A survey may include, but is not limited to:
 - Interviews of NARRO management and staff;
 - On-site observations of the NARRO premises, staff performance and activities; and
 - Review of documents, records and other materials required to be kept.
- A NARRO shall make all requested documents and records available to the surveyor for review and copying (OAR 333-081-0050(5)).
- Following a survey, Division staff may conduct an exit conference with a NARRO agency owner, administrator, or designee. During an exit conference, Division staff must:

- Inform the NARRO owner, administrator or designee of the preliminary findings of the inspection; and
- Give the owner, administrator or designee a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings (OAR 333-081-0050(6)).
- Following a survey, Division staff must prepare and provide the NARRO owner or administrator specific and timely written notice of the findings (OAR 333-081-0050(7)).
- If no deficiencies are found during a survey, the Division must issue written findings to the NARRO owner or administrator indicating that fact (OAR 333-081-0050(8)).
- Upon conclusion of a survey the Division must, upon request, publicly release the written documents described above in accordance with the Oregon Public Records Act (OAR 333-081-0050(9)).
- If deficiencies are found, the Division must take informal or formal enforcement action (OAR 333-081-0050(10)). See section 4 of this document, entitled “Enforcement” for more details on this subject.
- Licensing survey and complaint investigation reports are public record.

3. Enforcement

What is enforcement?

Enforcement is the action taken by HCRQI, when a NARRO is found to have violated the rules. Enforcement can either be informal or formal, depending on the survey findings.

Informal Enforcement (OAR 333-081-0085)

Informal enforcement includes the report written by HCRQI, which lists the organization’s deficiencies. This report requires a response from the organization, which is detailed under this rule. See the OAR for a complete list of informal enforcement requirements.

Formal Enforcement (OAR 333-081-0090)

Formal enforcement includes suspension, revocation, and civil penalties. See the OAR for a complete list of formal enforcement requirements.

Questions? Contact the HCRQI program at 971-673-0540 or by email at mailbox.hclc@state.or.us