Secretary of State

NOTICE OF PROPOSED RULEMAKING HEARING*

A Statement of Need and Fiscal Impact accompanies this form

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Oregon Health Authority, Health Policy and Analytics — 409

Agency and Division — Administrative Rules Chapter Number

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Rules Coordinator — Telephone

Oregon Health Authority, Health Policy and Analytics, 500 Summer St. NE, E-65, Salem, OR 97301

Address

RULE CAPTION

Amendment of Health Evidence Review Commission Rule

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

Hearing Date	Time	Location	Hearings Officer
12-19-16	10:00 a.m.	500 Summer St NE, Room 554, Salem, Oregon 97301	Zarie Haverkate

RULEMAKING ACTION

Secure approval of rule numbers with the Administrative Rules Unit prior to filing.

ADOPT:

AMEND:
OAR 409-060-0110, 409-060-0120, 409-060-0140, and 409-060-0150

REPEAL:

RENUMBER: Secure approval of new rule numbers with the Administrative Rules Unit prior to filing.

AMEND AND RENUMBER: Secure approval of new rule numbers with the Administrative Rules Unit prior to filing.

Statutory Authority:
ORS 414.695 and 413.042

Other Authority:

Statutes Implemented:
ORS 414.695 and 414.698

RULE SUMMARY

The Oregon Health Authority is amending the rule to align with the Health Evidence Review Commission's request to streamline its coverage guidance process.

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

12-21-2016 5:00 p.m.	Zarie Haverkate	zarie.haverkate@state.or.us
Last Day *(m/d/yyyy)* and Time for public comment	Rules Coordinator Name	Email Address

*The Oregon Bulletin is published on the 1st of each month and updates the rule text found in the Oregon Administrative Rules Compilation.

Secretary of State

STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing accompanies this form.

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Oregon Health Authority, Health Policy and Analytics — 409

Agency and Division — Administrative Rules Chapter Number

Amendment of Health Evidence Review Commission Rule

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

In the Matter of:

The amendment of OAR 409-060-0110, 409-060-0120, 409-060-0140, and 409-060-0150.

Statutory Authority:

ORS 414.695 and 413.042

Other Authority:

Statutes Implemented:

ORS 414.695 and 414.698

Need for the Rule(s):

The Oregon Health Authority is amending the rule to align with the Health Evidence Review Commission's request to streamline its coverage guidance process.

Documents Relied Upon, and where they are available:

ORS 414.695 and 414.698 available at http://www.oregon.gov/oha/ohpr/Pages/Statutes-HERC.aspx.

Fiscal and Economic Impact:

Amending these rules will have no fiscal impact on the Authority or state agencies, local government, clients, the public, or 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 business and types of businesses and industries with small businesses subject to the rule:

None.

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

N/A

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

N/A

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

No impact to small businesses.

Administrative Rule Advisory Committee consulted?: Yes

If not, why?:

12-21-2016 5:00 p.m.	Zarie Haverkate	zarie.haverkate@state.or.us
Last Day (m/d/yyyy) and Time for public comment	Printed Name	Email Address

CHAPTER 409
OREGON HEALTH AUTHORITY, HEALTH POLICY AND ANALYTICS

DIVISION 60
HEALTH EVIDENCE REVIEW COMMISSION

Evidence-based Reports

409-060-0110
Definitions

The following definitions apply to OAR 409-060-0100 to 409-060-0150:

(1) "Ad hoc expert" means an individual identified by the Commission as having particular expertise in a technology or its application.

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

(3) "Commission" means the Health Evidence Review Commission.

(4) "Coverage guidance" means a report approved by the Commission on a health service or technology which makes coverage recommendations for insurers and health care purchasers in furthering the use of evidence-based healthcare.

(5) "Evidence-based guideline" means an evidence-based report on a health service or technology, for use by health care providers in encouraging the use of the safest and most effective care possible.

(6) "Evidence-based report" means a medical technology assessment, evidence-based guideline or coverage guidance which includes conclusions and recommendations based on the information in the source documents, and which incorporates the clinical context necessary for the information to be properly interpreted by policymakers.

(7) "EbGS" means the Evidence-based Guidelines Subcommittee.

(8) "HTAS" means the Health Technology Assessment Subcommittee

(9) "Medical technology" or "technology" means medical equipment and devices, medical or surgical procedures and other techniques used or prescribed by health care providers in delivering health care to individuals, and the organizational or supportive systems within which health care is delivered.

(10) "Medical technology assessment" means an evidence-based report on the use, clinical effectiveness and risks, and cost of a technology in comparison with its alternatives.

(11) "Subcommittee" means a subcommittee established by the Commission.

~~(12) "Trusted source" means a source designated by the Commission for use in developing an evidence-based report.~~

(12) "Scientific evidence" means scientific studies found in peer-reviewed medical literature, printed in journals or other publications that publish original manuscripts only after the manuscripts have been critically reviewed by unbiased independent experts for scientific accuracy, validity and reliability. Such evidence will be evaluated by the Commission for evidence of bias based on the current principles of evidence-based medicine.

Stat. Auth.: ORS 413.042 & 414.695
Stats. Implemented: 414.695 & 414.698

409-060-0120
Health Evidence Review Commission Process for Evidence-based Reports

(1) The Commission shall ~~develop evidence-based reports or may direct a Subcommittee to prepare these reports~~base its reports on scientific evidence, taking into account the strength of the evidence, including an assessment of any biases present. ~~The Commission shall identify reports from trusted sources to serve as the basis for these reports.~~ Meetings shall be public and conducted in a manner consistent with the Commission's policies and procedures.

(2) Topics for review shall be publicly identified at least ~~30~~28 days prior to the initial Subcommittee meeting at which a draft evidence-based report is reviewed. In this notice, the Subcommittee shall make publicly available the primary evidence source documents to be used in creating the initial draft report, except when source documents are proprietary. If additional sources are added to the initial draft report after this notice, the Subcommittee shall publicly identify them no later than 14 days prior to the Subcommittee meeting where they will be discussed. In lieu of proprietary source documents, the Subcommittee shall make publicly available a citation of the evidence source. In the case of a proprietary evidence source, a full listing of citations from the proprietary source shall be made available when allowed by the source. If providing the citations is not allowed or not otherwise feasible, a summary of the evidence findings will be provided at least 14 days in advance of the meeting at which the initial draft report will be discussed.

(3) When developing an evidence-based report other than a coverage guidance, the Commission or its designated Subcommittee shall consult with two or more ad hoc experts on the subject matter of the evidence-based report. Subcommittee shall publicly solicit ad hoc experts at least ~~30~~28 days prior to the meeting at which it reviews the initial draft evidence-based report. One of the ad hoc experts must be a provider who manages patients who would potentially receive the treatment, service or device in question. Candidates wishing to serve as ad hoc experts shall disclose conflicts of

interest according to HERC bylaws. The Authority shall appoint ad hoc experts that best meet the needs of the state, considering any conflicts of interest, and shall not be limited to those who have volunteered to serve.

(4) After the Subcommittee reviews the initial draft report, the subcommittee may revise the initial draft report. The Subcommittee shall then solicit public comment on this version of the draft report over a 30-day period. Draft reports posted for comment shall include citations for all sources used in developing the report and a summary of evidence findings. The Subcommittee shall publicly disclose written comments received during the 30-day period, draft responses and additional revisions (if any) to the draft report at least seven days before the Subcommittee meeting at which the Subcommittee reviews public comments. After discussing the available evidence and considering public comment, including additional verbal testimony, the Subcommittee shall make conclusions as to the overall importance of beneficial effects versus potential harms and approve its final draft evidence-based report reflecting these conclusions.

(5) Before an evidence-based report is reviewed at a Commission meeting, a final draft report approved by the Subcommittee, along with all written public comments received during the public comment period and the Subcommittee's responses to these public comments shall be made publicly available ~~for a period of at least~~ 14 days prior to the meeting. At the meeting, the Commission shall consider the Subcommittee's approved draft report and accept further public comment.

(6) After evaluating the report and public comments the Commission may take one of three actions:

(a) Accept the report as written.

(b) Make edits to the report and accept as modified.

(c) Return the report to the Subcommittee with recommendations for further work.

(7) The Commission or its Subcommittees may revise evidence-based reports when additional information relevant to the report ~~becomes available or if~~is presented to the ~~findings of one or more of the source reports change~~Commission or its Subcommittees. The Commission or its Subcommittees may initiate a review of evidence-based reports at the request of interested parties who provide information or interpretations not considered in developing an existing evidence-based report. ~~At a minimum, the HERC or one of its Subcommittees shall review the need to update each report within two years after its adoption or most recent revision.~~ The Commission may also elect to retire a coverage guidance based on an assessment of the importance of the coverage guidance and the resources that would be required to update it. HERC shall annually solicit requests to revise its coverage guidances and any requests shall be presented to HERC at a regular meeting along with the results of staff research on the topic and any recommendations related to the request.

Stat. Auth.: ORS 414.695 & 413.042
Stats. Implemented: 414.695 & 414.698

409-060-0140
Evidence-based Guidelines

The EbGS shall develop evidence based guidelines based on one or more existing guideline ~~from trusted sources~~, which may involve the consideration of additional research. Evidence-based guidelines shall be developed according to the process described in OAR 409-060-0120 except as described in this section.

Stat. Auth.: ORS 414.695 & 413.042
Stats. Implemented: 414.695 & 414.698

409-060-0150
Coverage Guidances

(1) A Subcommittee shall develop coverage guidances ~~which shall be based on reports developed by trusted sources, and may cite supplemental evidence which is more recent or beyond the scope of the report~~ based on evidence searches using scope statements approved by the EbGS or HTAS after a seven-day public comment period. These evidence searches may be supplemented as necessary to provide additional contextual, economic, clinical or policy information based on questions which arise during the development of the coverage guidance. Coverage guidances shall be developed according to the process described in OAR 409-060-0120 except as described in this section.

(2) OAR 409-060-0120(3) does not apply to this section. Instead, if the Subcommittee responsible for development of the report determines that it lacks sufficient expertise in the relevant field, or a request is received from an interested outside party, the Subcommittee shall solicit ~~an~~ one or more ad hoc experts to provide additional information. Requests from interested parties to appoint ad hoc experts must be submitted within fourteen days after the public notice announcing the subcommittee's first review of the initial draft coverage guidance. The subcommittee may solicit ad hoc experts at any time thereafter if the committee determines such expertise is necessary. Candidates wishing to serve as ad hoc experts shall disclose conflicts of interest according to HERC bylaws. Ad hoc experts, if needed, shall be appointed by the Authority. The Authority shall select experts that best meet the needs of the state, considering any conflicts of interest, and shall not be limited to those who have volunteered to serve. Ad hoc experts shall answer technical questions and provide clinical context during the review of the evidence.

Stat. Auth.: ORS 414.695 & 413.042
Stats. Implemented: 414.695 & 414.698