

WSR 21-09-077

PERMANENT RULES

DEPARTMENT OF HEALTH

[Filed April 20, 2021, 1:36 p.m., effective May 21, 2021]

Effective Date of Rule: Thirty-one days after filing.

Purpose: Chapter 246-50 WAC, Coordinated quality improvement program, coordinated quality improvement program (CQIP) requirements are amended to provide clarification, streamlining of processes, modernization, and updates for compliance with state statutes. The rules include clarification of definitions; a new requirement for mandatory renewal of CQIP programs currently approved by the department; a new requirement for renewal of CQIP programs every five years; and a new fee for processing renewed CQIP. The adopted rule aligns with current statute.

Citation of Rules Affected by this Order: New WAC 246-50-050; and amending WAC 246-50-001, 246-50-005, 246-50-010, 246-50-020, 246-50-030, 246-50-035, 246-50-060, and 246-50-990.

Statutory Authority for Adoption: RCW 43.70.510.

Other Authority: RCW 43.70.250(2).

Adopted under notice filed as WSR 20-21-099 on October 20, 2020.

A final cost-benefit analysis is available by contacting Jovi S. Swanson, P.O. Box 47890, Olympia, WA 98504-7890, phone 360-545-7315, TTY 711, email jovi.swanson@doh.wa.gov.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 1, Amended 8, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 1, Amended 8, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 1, Amended 8, Repealed 0.

Date Adopted: April 12, 2021.

Jessica Todorovich
Chief of Staff
for Umair A. Shah, MD, MPH
Secretary

OTS-1615.2

AMENDATORY SECTION (Amending WSR 06-03-123, filed 1/18/06, effective 2/18/06)

WAC 246-50-001 Purpose ((and scope)). ((+1)) The purpose of ((the)) a coordinated quality improvement program is to improve the quality of health care services ((by identifying and preventing health care)) and identify and prevent medical malpractice under RCW 43.70.510. This chapter establishes the criteria and approval process

for health care entities who choose to apply for a department of health-approved coordinated quality improvement program under RCW 43.70.510. A coordinated quality improvement program((s)) plan must be approved by the department ((are provided discovery limitations under RCW 43.70.510 (3) and (4)). Information and documents specifically created for, collected, and maintained by an approved quality improvement committee are also exempt from disclosure under chapter 42.17 RCW.

~~(2) This chapter allows health care provider groups, professional societies or organizations, health care service contractors, health maintenance organizations, health carriers approved under chapter 48.43 RCW, and any other person or entity providing health care coverage under chapter 48.42 RCW that is subject to the authority and rules of any state agency or any subdivision such as health care institutions and medical facilities other than hospitals, to maintain a department-approved coordinated quality improvement program for the purpose of improving the quality of health care and identifying and preventing health care malpractice.~~

~~(3) This chapter does not apply to hospital quality improvement programs required by RCW 70.41.200)) before the discovery limitations provided in RCW 43.70.510 (3) and (4) and the exemptions under RCW 42.56.360 (1) (c) and 43.70.510(5) shall apply.~~

[Statutory Authority: RCW 43.70.510, 70.41.200, 4.24.250. WSR 06-03-123, § 246-50-001, filed 1/18/06, effective 2/18/06. Statutory Authority: RCW 43.70.510. WSR 96-09-042, § 246-50-001, filed 4/11/96, effective 5/12/96; WSR 94-24-001, § 246-50-001, filed 11/23/94, effective 12/24/94.]

AMENDATORY SECTION (Amending WSR 06-03-123, filed 1/18/06, effective 2/18/06)

WAC 246-50-005 Applicant eligibility. (1) The following health care entities may apply for the coordinated quality improvement program:

(a) ~~((Provider groups of five or more providers;))~~ Health care institutions and medical facilities other than hospitals, that are licensed by the department;

(b) ~~((Health care))~~ Professional societies or organizations ((, including, but not limited to, state or local health care professional associations));

(c) Health care service contractors as defined in RCW 48.44.010;

(d) Health maintenance organizations as defined in RCW 48.46.020;

(e) Health carriers ~~((as defined in RCW 48.43.005;~~

~~(f) Health care institutions or medical facilities other than hospitals; and~~

~~(g))~~ approved pursuant to chapter 48.43 RCW;

(f) Any other person or entity providing ((personal)) health care coverage under chapter 48.42 RCW((, and)) that is subject to the ((authority and rules of any state agency or subdivision)) jurisdiction and regulation of any state or any subdivision thereof; and

(g) Health care provider groups of five or more providers.

(2) This chapter does not apply to hospital coordinated quality improvement programs required by RCW 70.41.200.

[Statutory Authority: RCW 43.70.510, 70.41.200, 4.24.250. WSR 06-03-123, § 246-50-005, filed 1/18/06, effective 2/18/06.]

AMENDATORY SECTION (Amending WSR 14-08-046, filed 3/27/14, effective 4/27/14)

WAC 246-50-010 Definitions. The ~~((words and phrases))~~ definitions in this ~~((chapter have the following meanings))~~ section apply throughout this chapter unless the context clearly ~~((indicates))~~ requires otherwise.

(1) "Alternative program" means a coordinated quality improvement program determined by the department to be substantially equivalent to RCW 70.41.200(1).

(2) "Department" means the Washington state department of health.

(3) "Governing body" means:

(a) The person, persons, or board responsible for the health care entity; or

(b) In the case of a provider group where no person, persons, or board is in charge of all providers ~~((+))~~, the person, persons, or group identified by the provider group is responsible for the coordinated quality improvement program.

(4) ~~((("Health care entity" means a health care institution, medical facility, provider group, professional society or organization, health care service contractors, health maintenance organizations, health carriers approved under chapter 48.43 RCW, and any other person or entity providing health care coverage under chapter 48.42 RCW that is subject to the jurisdiction of any state agency or any subdivision thereof, authorized by RCW 43.70.510 to have a department approved coordinated quality improvement program.~~

~~((5) "Health care institution" or "medical facility" includes the following:~~

~~((a) Adult residential rehabilitation centers regulated under chapter 71.12 RCW;~~

~~((b) Alcohol and drug treatment facilities and hospitals regulated under chapter 70.96A RCW;~~

~~((c) Emergency medical care and transportation services regulated under chapter 18.73 RCW;~~

~~((d) Assisted living facilities regulated under chapter 18.20 RCW;~~

~~((e) Childbirth centers regulated under chapter 18.46 RCW;~~

~~((f) Community mental health centers regulated under chapter 71.05 or 71.24 RCW;~~

~~((g) Home health agencies, home care agencies, hospice care centers, and hospice agencies regulated under chapter 70.127 RCW;~~

~~((h) Medical test sites regulated under chapter 70.42 RCW;~~

~~((i) Nursing homes regulated under chapter 18.51 RCW;~~

~~((j) Pharmacies regulated under chapter 18.64 RCW;~~

~~((k) Private psychiatric hospitals and residential treatment facilities for psychiatrically impaired children and youth regulated under chapter 71.12 RCW;~~

~~((l) Rural health care facilities regulated under chapter 70.175 RCW;~~

~~((m) Organizations that provide designated trauma care services individually or jointly under chapter 70.168 RCW;~~

- ~~(n) Facilities owned and operated by a political subdivision or instrumentality of the state, including, but not limited to:~~
- ~~(i) Public health departments;~~
 - ~~(ii) Fire districts and departments;~~
 - ~~(iii) Soldiers' and veterans' homes;~~
 - ~~(iv) State mental health institutions;~~
 - ~~(v) Health clinics operated by educational institutions;~~
 - ~~(vi) Department of corrections health care facilities;~~
 - ~~(vii) County jail health clinics;~~
 - ~~(viii) County drug and alcohol treatment facilities; and~~
 - ~~(ix) Public hospital districts;~~
 - ~~(o) Facilities required by federal law and implementing regulations, including, but not limited to:~~
 - ~~(i) Native American health facilities; and~~
 - ~~(ii) Veterans' affairs health services; and~~
 - ~~(p) Other facilities that the department determines meet the definition of "health care facility" in RCW 48.43.005.~~
- ~~(6-)) "Health care provider" or "provider" means ((:~~
- ~~(a) A person regulated under Title 18 RCW to practice health or health related services or otherwise practicing health care services in this state consistent with state law; or~~
 - ~~(b) An employee or agent of a person described in (a) of this subsection, acting in the course and scope of the employee's or agent's employment performing health care or auxiliary services.~~
- ~~(7-)) a health care professional licensed under the chapters specified in RCW 18.130.040.~~
- ~~(5) "Health care provider group" or "provider group" means an organized body or consortium of five or more providers in total.~~
- ~~((8-)) (6) "Negative health care outcome" means a patient death or impairment of bodily function other than those related to the natural course of illness, disease, or proper treatment in accordance with generally accepted health care standards.~~
- ~~((9-)) (7) "Professional society or organization" means a group of health care professionals((7)) including, but not limited to, state or local health care professional associations.~~
- ~~((10-)) (8) "Program" means coordinated quality improvement program under RCW 43.70.510.~~

[Statutory Authority: RCW 43.70.510 and 2012 c 10. WSR 14-08-046, § 246-50-010, filed 3/27/14, effective 4/27/14. Statutory Authority: RCW 43.70.510, 70.41.200, 4.24.250. WSR 06-03-123, § 246-50-010, filed 1/18/06, effective 2/18/06. Statutory Authority: RCW 43.70.510. WSR 96-09-042, § 246-50-010, filed 4/11/96, effective 5/12/96; WSR 94-24-001, § 246-50-010, filed 11/23/94, effective 12/24/94.]

AMENDATORY SECTION (Amending WSR 94-24-001, filed 11/23/94, effective 12/24/94)

WAC 246-50-020 Coordinated quality improvement program—Components. A program under the provisions of RCW 43.70.510 shall include, at a minimum:

(1) The following components, as modified and approved by the department to reflect the structural organization of the health care entity:

- (a) A governing body;
- (b) A committee, appointed by the governing body, with a broad representation of the services offered, responsible for:
 - (i) Reviewing services rendered, both retrospectively and prospectively, to improve the quality of health care by measuring key characteristics such as effectiveness, accuracy, timeliness, and cost;
 - (ii) Reviewing categories and methodologies of services rendered and to be rendered with the goal of improving health care outcomes;
 - (iii) Overseeing and coordinating the program;
 - (iv) Ensuring information gathered for the program is reviewed and used to revise health care policies and procedures; and
 - (v) Reporting to the governing body, at least semiannually, on program activities and actions taken as a result of those activities;
- (c) Periodic evaluation of each provider under the purview of the program, including mental and physical capacity, competence in delivering health care, and verification of current credentials;
- (d) A procedure for promptly resolving all complaints pertaining to accidents, injuries, treatment and other events that may result in claims of health care malpractice;
- (e) A method for continually collecting and maintaining information concerning:
 - (i) Experience with negative health care outcomes and injurious incidents; and
 - (ii) Professional liability premiums, settlements, awards, costs for injury prevention and safety improvement activities;
- (f) A method for maintaining information gathered under the purview of the program concerning a provider in that provider's personnel or credential file, assuring patient confidentiality;
- (g) A process for reporting accidents, injuries, negative health outcomes, and other pertinent information to the quality improvement committee;
- (h) A process assuring compliance with reporting requirements to appropriate local, state, and federal authorities;
- (i) A method for identifying documents and records created specifically for and collected and maintained by the quality improvement committee;
- (j) Educational activities for personnel engaged in health care activities including, but not limited to:
 - (i) Quality improvement;
 - (ii) Safety and injury prevention;
 - (iii) Responsibilities for reporting professional misconduct;
 - (iv) Legal aspects of providing health care;
 - (v) Improving communication with health care recipients; and
 - (vi) Causes of malpractice claims; or
- (2) Components determined by the department to be substantially equivalent to those listed in subsection (1) of this section.

[Statutory Authority: RCW 43.70.510. WSR 94-24-001, § 246-50-020, filed 11/23/94, effective 12/24/94.]

AMENDATORY SECTION (Amending WSR 06-03-123, filed 1/18/06, effective 2/18/06)

WAC 246-50-030 Application ((and)) approval and renewal process.

((A)) (1) To obtain department approval of a program, an authorized

representative of the health care entity ((seeking department approval of a program shall submit to the department:

~~(1) An application on forms provided by the department;~~

(2) The program plan, printed on 8 1/2 by 11 inch paper, including)) shall submit to the department a completed application on forms provided by the department. A completed application must include at least the following:

(a) A table of contents clearly denoting, at a minimum, where each component specified in WAC 246-50-020 is located within the program plan; ~~((and))~~

(b) A program plan with detailed description of every aspect of the program including every component of the program required under WAC 246-50-020;

~~((3))~~ (c) The fee specified in WAC 246-50-990; and

~~((4))~~ (d) Other information as may be required by the department.

(2) The department may grant or deny approval of an application. If an application is denied, the health care entity may modify and re-submit its application or request a brief adjudicative proceeding according to RCW 34.05.482.

(3) A health care entity that maintains a department-approved program must renew every five years after the date of initial approval. An application for renewal must meet the requirements of subsection (1) of this section. A program remains approved during the renewal process. A health care entity must apply for renewal on or before the original expired due date, unless it has received written confirmation from the department that the applicant may apply at a later date. Failure to apply for renewal will mean that the approval is expired and no longer valid. A health care entity that does not apply for renewal and the approval expires must reapply for the initial department approval by meeting the requirements of subsection (1) of this section.

(4) The department may grant or deny approval or application for renewal. If an application for renewal is denied, the health care entity may modify and resubmit its application or request a brief adjudicative proceeding according to RCW 34.05.482. A program remains approved while an application for renewal is under review, including the time that a health care entity may use to modify and resubmit its application for renewal, until the adjudicative process is exhausted, or the health care entity indicates it does not intend to seek renewal.

[Statutory Authority: RCW 43.70.510, 70.41.200, 4.24.250. WSR 06-03-123, § 246-50-030, filed 1/18/06, effective 2/18/06. Statutory Authority: RCW 43.70.510. WSR 94-24-001, § 246-50-030, filed 11/23/94, effective 12/24/94.]

AMENDATORY SECTION (Amending WSR 06-03-123, filed 1/18/06, effective 2/18/06)

WAC 246-50-035 Modification of an approved plan. (1) To maintain department approval, a health care entity modifying the scope, components or operation of an approved program, shall submit to the department:

(a) An application package specified in WAC 246-50-030(1), modified as appropriate; and

(b) A detailed description of the modification and how it affects the program.

(2) A health care entity shall modify its approved program to comply with any changes in requirements for program approval adopted by the department or the legislature. Any such modification shall be made using the procedure outlined in subsection (1) of this section.

(3) A health care entity shall notify the department of a change in authorized representative within thirty days of a change. The procedure outlined in subsection (1) of this section does not apply to this subsection. A health care entity shall modify its approved program to comply with any changes in requirements for program approval adopted by the department or the legislature within six months of notice from the department that, unless it has received written confirmation from the department that it may apply at a later date. Any such modification shall be made using the procedure outlined in subsection (1) of this section.

(4) The department shall review each application package submitted under this section((7)) and either:

(a) Send written notification of approval to a health care entity submitting a program with the components specified in WAC 246-50-020; or

(b) Deny the application ((and provide the health care entity an opportunity for)). If denied, the health care entity may modify and resubmit its application package or request a brief adjudicative proceeding according to RCW 34.05.482 ((when the department declines to approve a program)).

((+3)) (5) A program remains approved while an application to modify is under review, including the time that a health care entity may use to modify and resubmit its application under this section or the adjudicative process identified in subsection (4) of this section is exhausted.

(6) The department shall retain a copy of the program plan.

[Statutory Authority: RCW 43.70.510, 70.41.200, 4.24.250. WSR 06-03-123, § 246-50-035, filed 1/18/06, effective 2/18/06.]

NEW SECTION

WAC 246-50-050 One-time mandatory renewal process. All health care entities with currently approved programs must apply for renewal of their programs by December 31, 2021. An application for renewal must meet the requirements of WAC 246-50-030(1). A program remains approved while an application for renewal is under consideration by the department. Failure to apply for renewal by December 31, 2021, will mean the approval is expired and no longer valid.

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AMENDATORY SECTION (Amending WSR 06-03-123, filed 1/18/06, effective 2/18/06)

WAC 246-50-060 Public record disclosure. A program plan and all supplemental material are public records and are subject to the Public

Records (~~(disclosure law)~~) Act, chapter (~~(42.17)~~) 42.56 RCW, once the department receives them. Health care entities submitting material they believe is exempt from public record disclosure should clearly mark the portion or portions as "exempt" and state the specific statutory basis for exemption. The department will notify the health care entity of a public record disclosure request for material the entity marked "exempt" in accordance with this (~~(subsection)~~) section. The department will allow the health care entity ten work days from when it receives department notice to deliver to the department proof that the entity has initiated formal action to secure an injunction under RCW (~~(42.17.330)~~) 42.56.540. Upon receiving such proof, the department will notify the public record requester of the action the health care entity initiated under RCW (~~(42.17.330)~~) 42.56.540, and take no further action pending a decision by the court. The health care entity must notify the department if it withdraws or takes any other action to terminate the judicial process under RCW (~~(42.17.330)~~) 42.56.540. Absent proof from the health care entity that it has initiated action under RCW (~~(42.17.330)~~) 42.56.540, the department will disclose the records consistent with state and federal law.

[Statutory Authority: RCW 43.70.510, 70.41.200, 4.24.250. WSR 06-03-123, § 246-50-060, filed 1/18/06, effective 2/18/06.]

AMENDATORY SECTION (Amending WSR 06-03-123, filed 1/18/06, effective 2/18/06)

WAC 246-50-990 Fees. A health care entity must submit a fee with each application as follows:

Title of Fee	Fee
Original application	\$250.00
Alternative application	40.00
Modification application of a department-approved program	65.00
<u>Renewal application</u>	<u>75.00</u>

[Statutory Authority: RCW 43.70.510, 70.41.200, 4.24.250. WSR 06-03-123, § 246-50-990, filed 1/18/06, effective 2/18/06. Statutory Authority: RCW 43.70.510. WSR 94-24-001, § 246-50-990, filed 11/23/94, effective 12/24/94.]