

WSR 24-22-066

PROPOSED RULES

HEALTH CARE AUTHORITY

[Filed October 29, 2024, 11:27 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 22-16-032 and 24-17-080.

Title of Rule and Other Identifying Information: WAC 182-550-1900 Transplant coverage, 182-550-2100 Requirements—Transplant hospitals, 182-550-2200 Transplant requirements—COE, 182-531-0650 Hospital physician-related services not requiring authorization when provided in agency-approved centers of excellence or hospitals authorized to provide the specific services, and 182-531-1750 Transplant coverage for physician-related services.

Hearing Location(s): On December 10, 2024, at 10:00 a.m. The health care authority (HCA) holds public hearings virtually without a physical meeting place. To attend the virtual public hearing, you must register in advance https://us02web.zoom.us/webinar/register/WN_dmXkI7-gTwKhW_NX54cdmA. If the link above opens with an error message, please try using a different browser. After registering, you will receive a confirmation email containing information about joining the public hearing.

Date of Intended Adoption: Not sooner than December 11, 2024.

Submit Written Comments to: HCA Rules Coordinator, P.O. Box 42716, Olympia, WA 98504-2716, email arc@hca.wa.gov, fax 360-586-9727, beginning October 30, 2024, 8:00 a.m., by December 10, 2024, by 11:59 p.m.

Assistance for Persons with Disabilities: Contact Johanna Larson, phone 360-725-1349, fax 360-586-9727, telecommunication relay service 711, email Johanna.Larson@hca.wa.gov, by November 22, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: HCA is amending WAC 182-550-1900 and 182-550-2100 to update which transplant procedures are covered and where the transplants can be performed. HCA is also repealing WAC 182-550-2200 Transplant requirements—COE, as this section will no longer be necessary due to the changes being proposed to WAC 182-550-1900 and 182-550-2100. As a result of these changes, HCA is also amending WAC 182-531-0650 and 182-531-1750.

HCA is also removing diabetes education from WAC 182-531-0650 as a COE is not required. This rule making was filed under WSR 22-16-032 on July 26, 2022.

Reasons Supporting Proposal: See purpose.

Statutory Authority for Adoption: RCW 41.05.021, 41.05.160.

Statute Being Implemented: RCW 41.05.021, 41.05.160.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: HCA, governmental.

Name of Agency Personnel Responsible for Drafting: Valerie Freudenstein, P.O. Box 42716, Olympia, WA 98504-2716, 360-725-1344; Implementation and Enforcement: Joan Chappell, P.O. Box 42716, Olympia, WA 98504, 360-725-1071.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. RCW 34.05.328 does not apply to HCA rules unless requested by the joint administrative rules review committee or applied voluntarily.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(4).

Scope of exemption for rule proposal:

Is fully exempt.

October 29, 2024
Wendy Barcus
Rules Coordinator

OTS-5910.1

AMENDATORY SECTION (Amending WSR 17-04-039, filed 1/25/17, effective 2/25/17)

WAC 182-531-0650 Hospital physician-related services not requiring authorization when provided in agency-approved centers of excellence or hospitals authorized to provide the specific services. The medicaid agency covers the following services without prior authorization when provided in agency-approved centers of excellence. The agency issues periodic publications listing centers of excellence. These services include (~~the following:~~

- ~~(1) All transplant procedures specified in WAC 182-550-1900;~~
- ~~(2) Chronic pain management services, including outpatient evaluation and inpatient treatment, as described under WAC 182-550-2400. See also WAC 182-531-0700;~~
- ~~(3))~~ sleep studies including, but not limited to, polysomnograms for clients one year of age and older. The agency allows sleep studies only in outpatient hospital settings as described under WAC 182-550-6350. See also WAC 182-531-1500 (~~;~~ and
- ~~(4) Diabetes education, in a DOH-approved facility, per WAC 182-550-6300).~~

AMENDATORY SECTION (Amending WSR 17-04-039, filed 1/25/17, effective 2/25/17)

WAC 182-531-1750 Transplant coverage for physician-related services. The medicaid agency covers transplants when performed in (~~an agency-approved center of excellence~~) a facility, as defined in WAC 247-04-020, that has a transplant certificate of need (CON) issued by the department of health. See WAC 182-550-1900 for information regarding transplant coverage.

OTS-5911.2

AMENDATORY SECTION (Amending WSR 15-18-065, filed 8/27/15, effective 9/27/15)

WAC 182-550-1900 Transplant coverage. (1) The medicaid agency pays for medically necessary transplant procedures only for eligible Washington apple health clients who are not otherwise subject to a managed care organization (MCO) plan. Clients eligible under the alien emergency medical (AEM) program are not eligible for transplant coverage.

(2) The agency covers the following transplant procedures when the transplant procedures are performed in a ~~((hospital designated by the agency as a "center of excellence" for transplant procedures and meet that hospital's criteria for establishing appropriateness and the medical necessity of the procedures))~~ health care facility, as defined in WAC 247-04-020, that has a transplant certificate of need from the department of health:

- ~~(a) ((Solid organs involving the heart, kidney, liver, lung, heart-lung, pancreas, kidney-pancreas, and small bowel))~~ Bone marrow;
- ~~(b) ((Bone marrow and peripheral stem cell (PSC))~~ Cornea;
- ~~(c) Skin grafts; ((and))~~
- ~~(d) ((Corneal transplants))~~ Stem cell, autologous and allogeneic;
- ~~(e) Intestine;~~
- ~~(f) Kidney;~~
- ~~(g) Liver or combination liver-kidney;~~
- ~~(h) Heart or combination heart-lung;~~
- ~~(i) Lung, single or bilateral;~~
- ~~(j) Pancreas or combination pancreas-kidney; and~~
- ~~(k) Other transplant services determined to be medically necessary. See WAC 182-501-0165 and 182-500-0070.~~

(3) The agency pays for procedures covered under subsection (2)(a) through (d) of this section, performed at qualified facilities, subject to the limitations in this chapter.

~~(4) For procedures covered under subsection((s)) (2)((a) and (b))~~ (e) through (k) of this section, the agency pays facility charges only to those ~~((hospitals))~~ facilities that meet the standards and conditions:

- ~~(a) Established by the agency; and~~
- ~~(b) Specified in WAC 182-550-2100 ((and 182-550-2200.~~
- ~~(4) The agency pays for skin grafts and corneal transplants to any qualified hospital, subject to the limitations in this chapter)).~~
- (5) The agency ~~((deems))~~ considers organ procurement fees as being included in the payment to the transplant ~~((hospital))~~ facility. The agency may make an exception to this policy and pay these fees separately to a transplant ~~((hospital))~~ facility when an eligible ~~((medical))~~ apple health client is covered by a third-party payer that will pay for the organ transplant procedure itself but not for the organ procurement.

(6) The agency, without requiring prior authorization, pays for up to ~~((fifteen))~~ 15 matched donor searches per client approved for a bone marrow transplant. The agency requires prior authorization for matched donor searches in excess of ~~((fifteen))~~ 15 per bone marrow transplant client.

(7) The agency does not pay for experimental transplant procedures. ~~((In addition, the agency considers as experimental those services including, but not limited to, the following:~~

- ~~(a) Transplants of three or more different organs during the same hospital stay;~~

~~(b) Solid organ and bone marrow transplants from animals to humans; and~~

~~(c) Transplant procedures used in treating certain medical conditions for which use of the procedure has not been generally accepted by the medical community or for which its efficacy has not been documented in peer-reviewed medical publications.)~~

(8) The agency pays for ~~((a solid))~~ an identical organ transplant procedure only once ~~((per client's lifetime, except in cases of organ rejection by the client's immune system during the original hospital stay))~~ for the duration of the specific organ's established viability or as determined medically necessary (see WAC 182-501-0165).

(9) ~~((The agency pays for bone marrow, PSC, skin grafts, and corneal transplants when medically necessary.~~

~~(10))~~ The agency may conduct a postpayment retrospective utilization review as described in WAC 182-550-1700, and may adjust the payment if the agency determines the criteria in this section are not met.

AMENDATORY SECTION (Amending WSR 15-18-065, filed 8/27/15, effective 9/27/15)

WAC 182-550-2100 Requirements—Transplant ~~((hospitals))~~ facilities. This section applies to requirements for ~~((hospitals))~~ facilities that perform the medicaid agency-approved transplants described in WAC 182-550-1900(2).

(1) The agency requires instate transplant ~~((hospitals))~~ facilities to meet the following requirements to be paid for transplant services provided to Washington apple health clients. A ~~((hospital))~~ facility must have:

(a) An approved certificate of need (CON) from the state department of health (DOH) for the type of transplant procedure to be performed ~~((, except that the agency does not require CON approval for a hospital that provides peripheral stem cell (PSC), skin graft or corneal transplant services)); and~~

(b) Approval ~~((from the United Network of Organ Sharing (UNOS) to perform transplants, except that the))~~ as a medicare-certified transplant facility.

(c) The agency does not require ((UNOS)) medicare or department of health approval as a transplant facility for a ((hospital)) facility that provides ((PSC)) stem cell, skin graft, or corneal transplant services ((; and

~~(c) Been approved by the agency as a center of excellence transplant center for the specific organ or procedure the hospital proposes to perform)).~~

(2) The agency requires an out-of-state transplant ~~((center))~~ facility, including bordering city and critical border ~~((hospitals))~~ facilities, to be a medicare-certified transplant ~~((center in a hospital))~~ facility and participating in that state's medicaid program. All out-of-state transplant services ~~((, excluding those provided in agency-approved centers of excellence (COE) in bordering city and critical border hospitals,))~~ must be prior authorized.

(3) ~~((The agency considers a hospital for approval as a transplant center of excellence when the hospital submits to the agency a~~

copy of its DOH-approved CON for transplant services, or documentation that it has, at a minimum:

~~(a) Organ-specific transplant physicians for each organ or transplant team. The transplant surgeon and other responsible team members must be experienced and board-certified or board-eligible practitioners in their respective disciplines, including, but not limited to, the fields of cardiology, cardiovascular surgery, anesthesiology, hemodynamics and pulmonary function, hepatology, hematology, immunology, oncology, and infectious diseases. The agency considers this requirement met when the hospital submits to the agency a copy of its DOH-approved CON for transplant services;~~

~~(b) Component teams which are integrated into a comprehensive transplant team with clearly defined leadership and responsibility. Transplant teams must include, but not be limited to:~~

~~(i) A team-specific transplant coordinator for each type of organ;~~

~~(ii) An anesthesia team available at all times; and~~

~~(iii) A nursing service team trained in the hemodynamic support of the patient and in managing immunosuppressed patients.~~

~~(c) Other resources that the transplant hospital must have include:~~

~~(i) Pathology resources for studying and reporting the pathological responses of transplantation;~~

~~(ii) Infectious disease services with both the professional skills and the laboratory resources needed to identify and manage a whole range of organisms; and~~

~~(iii) Social services resources.~~

~~(d) An organ procurement coordinator;~~

~~(e) A method ensuring that transplant team members are familiar with transplantation laws and regulations;~~

~~(f) An interdisciplinary body and procedures in place to evaluate and select candidates for transplantation;~~

~~(g) An interdisciplinary body and procedures in place to ensure distribution of donated organs in a fair and equitable manner conducive to an optimal or successful patient outcome;~~

~~(h) Extensive blood bank support;~~

~~(i) Patient management plans and protocols; and~~

~~(j) Written policies safeguarding the rights and privacy of patients.~~

~~(4) In addition to the requirements of subsection (3) of this section, the transplant hospital must:~~

~~(a) Satisfy the annual volume and survival rates criteria for the particular transplant procedures performed at the hospital, as specified in WAC 182-550-2200(2).~~

~~(b) Submit a copy of its approval from the United Network for Organ Sharing (UNOS), or documentation showing that the hospital:~~

~~(i) Participates in the national donor procurement program and network; and~~

~~(ii) Systematically collects and shares data on its transplant programs with the network.~~

~~(5)) The agency applies the following specific requirements to a ((PSC)) stem cell transplant ((hospital)) facility:~~

~~(a) A ((PSC)) stem cell transplant ((hospital)) facility must be ((an agency-approved COE)) in compliance with 21 C.F.R. § 1271 to perform any of the following ((PSC)) stem cell services:~~

~~(i) Harvesting, if it has its own apheresis equipment which meets federal or American Association of Blood Banks (AABB) requirements;~~

(ii) Processing, if it meets AABB quality of care requirements for human tissue/tissue banking; and

(iii) Reinfusion, if it meets the criteria established by the Foundation for the Accreditation of (~~Hematopoietic-Cell~~) Cellular Therapy.

(b) A ((PSC)) stem cell transplant (~~hospital~~) facility may purchase ((PSC)) stem cell processing and harvesting services from other agency-approved processing providers.

~~((6))~~ (4) The agency does not pay a ((PSC)) stem cell transplant (~~hospital~~) facility for AABB inspection and certification fees related to ((PSC)) stem cell transplant services.

(5) The agency does not pay for any service that requires consent under RCW 18.130.420.

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 182-550-2200 Transplant requirements—COE.