



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do **NOT** use for expedited rule making

Agency: Health Care Authority, Washington Apple Health

- Preproposal Statement of Inquiry was filed as WSR 16-17-094; or
- Expedited Rule Making--Proposed notice was filed as WSR _____; or
- Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).

- Original Notice
- Supplemental Notice to WSR _____
- Continuance of WSR _____

Title of rule and other identifying information:

WAC 182-531-0050 Physician-related services definitions
WAC 182-531-0550 Experimental and investigational services

Hearing location:

Health Care Authority
Cherry Street Plaza Building; Sue Crystal Conf Rm 106A
626 - 8th Avenue, Olympia WA 98504

Metered public parking is available street side around building. A map is available at:
http://www.hca.wa.gov/documents/directions_to_csp.pdf
or directions can be obtained by calling: (360) 725-1000

Date: **January 10, 2017** Time: **10:00 a.m.**

Date of intended adoption: Not sooner than January 11, 2017 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: HCA Rules Coordinator
Address: PO Box 45504, Olympia WA, 98504-5504
Delivery: 626 – 8th Avenue, Olympia WA 98504
e-mail arc@hca.wa.gov
fax (360) 586-9727

by **5:00 pm on January 10, 2017**

Assistance for persons with disabilities: Contact Amber Lougheed by January 6, 2017
e-mail: amber.lougheed@hca.wa.gov or (360) 725-1349
TTY (800) 848-5429 or 711

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

The agency is revising WAC 182-531-0050 to remove the definition of “ADSA,” clarify the definitions of “experimental” and “investigational,” and align the definition of “peer-reviewed medical literature” with other agency rules. WAC 182-531-0550 is being updated to strike redundant subsections and clarify information regarding experimental and investigational services. These revisions do not change current policy. Housekeeping changes were also made in these WACs.

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

Is rule necessary because of a:

- Federal Law? Yes No
 - Federal Court Decision? Yes No
 - State Court Decision? Yes No
- If yes, CITATION:

DATE
December 2, 2016

NAME
Wendy Barcus

SIGNATURE

TITLE
HCA Rules Coordinator

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: December 02, 2016

TIME: 10:34 AM

WSR 16-24-055

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: N/A

Name of proponent: Health Care Authority

- Private
 Public
 Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Katie Pounds	PO Box 42716, Olympia, WA 98504-2716	(360) 725-1346
Implementation.... Shana Johnson	PO Box 45506, Olympia, WA 98504-5506	(360) 725-1668
Enforcement..... Shana Johnson	PO Box 45506, Olympia, WA 98504-5506	(360) 725-1668

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

Yes. Attach copy of small business economic impact statement or school district fiscal impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone ()

fax ()

e-mail

No. Explain why no statement was prepared.

The agency has determined that the proposed filing does not impose a disproportionate cost impact on small businesses or nonprofits.

Is a cost-benefit analysis required under RCW 34.05.328?

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name:

Address:

phone ()

fax ()

e-mail

No: Please explain:

RCW 34.05.328 does not apply to Health Care Authority rules unless requested by the Joint Administrative Rules Review Committee or applied voluntarily.

WAC 182-531-0050 Physician-related services definitions. The following definitions and abbreviations and those found in chapter 182-500 WAC, apply to this chapter.

"Acquisition cost" - The cost of an item excluding shipping, handling, and any applicable taxes.

"Acute care" - Care provided for clients who are not medically stable. These clients require frequent monitoring by a health care professional in order to maintain their health status. See also WAC 246-335-015.

"Acute physical medicine and rehabilitation (PM&R)" - A comprehensive inpatient and rehabilitative program coordinated by a multi-disciplinary team at an agency-approved rehabilitation facility. The program provides twenty-four hour specialized nursing services and an intense level of specialized therapy (speech, physical, and occupational) for a diagnostic category for which the client shows significant potential for functional improvement (see WAC 182-550-2501).

"Add-on procedure(s)" - Secondary procedure(s) that are performed in addition to another procedure.

"Admitting diagnosis" - The medical condition responsible for a hospital admission, as defined by the ICD diagnostic code.

"Advanced registered nurse practitioner (ARNP)" - A registered nurse prepared in a formal educational program to assume an expanded health services provider role in accordance with WAC 246-840-300 and 246-840-305.

~~(**"Aging and disability services administration (ADSA)"** - The administration that administers directly or contracts for long term care services including, but not limited to, nursing facility care and home and community services. See WAC 388-71-0202.)~~

"Allowed charges" - The maximum amount reimbursed for any procedure that is allowed by the agency.

"Anesthesia technical advisory group (ATAG)" - An advisory group representing anesthesiologists who are affected by the implementation of the anesthesiology fee schedule.

"Bariatric surgery" - Any surgical procedure, whether open or by laparoscope, which reduces the size of the stomach with or without bypassing a portion of the small intestine and whose primary purpose is the reduction of body weight in an obese individual.

"Base anesthesia units (BAU)" - A number of anesthesia units assigned to a surgical procedure that includes the usual preoperative, intraoperative, and postoperative visits. This includes the administration of fluids and/or blood incident to the anesthesia care, and interpretation of noninvasive monitoring by the anesthesiologist.

"Bundled services" - Services integral to the major procedure that are included in the fee for the major procedure. Bundled services are not reimbursed separately.

"Bundled supplies" - Supplies (~~which~~) that are considered to be included in the practice expense RVU of the medical or surgical service of which they are an integral part.

"By report (BR)," see WAC 182-500-0015.

"Call" - A face-to-face encounter between the client and the provider resulting in the provision of services to the client.

"Cast material maximum allowable fee" - A reimbursement amount based on the average cost among suppliers for one roll of cast material.

"Center of excellence (COE)" - A hospital, medical center, or other health care provider that meets or exceeds standards set by the agency for specific treatments or specialty care.

"Centers for Medicare and Medicaid Services (CMS)," see WAC 182-500-0020.

"Certified registered nurse anesthetist (CRNA)" - An advanced registered nurse practitioner (ARNP) with formal training in anesthesia who meets all state and national criteria for certification. The American Association of Nurse Anesthetists specifies the national certification and scope of practice.

"Children's health insurance plan (CHIP)," see chapter 182-542 WAC.

"Clinical Laboratory Improvement Amendment (CLIA)" - Regulations from the U.S. Department of Health and Human Services that require all laboratory testing sites to have either a CLIA registration or a CLIA certificate of waiver in order to legally perform testing anywhere in the U.S.

"Conversion factors" - Dollar amounts the agency uses to calculate the maximum allowable fee for physician-related services.

"Covered service" - A service that is within the scope of the eligible client's medical care program, subject to the limitations in this chapter and other published WAC.

"CPT," see "current procedural terminology."

"Critical care services" - Physician services for the care of critically ill or injured clients. A critical illness or injury acutely impairs one or more vital organ systems such that the client's survival is jeopardized. Critical care is given in a critical care area, such as the coronary care unit, intensive care unit, respiratory care unit, or the emergency care facility.

"Current procedural terminology (CPT)" - A systematic listing of descriptive terms and identifying codes for reporting medical services, procedures, and interventions performed by physicians and other practitioners who provide physician-related services. CPT is copyrighted and published annually by the American Medical Association (AMA).

"Emergency medical condition(s)," see WAC 182-500-0030.

"Emergency services" - Medical services required by and provided to a patient experiencing an emergency medical condition.

"Estimated acquisition cost (EAC)" - The agency's best estimate of the price providers generally and currently pay for drugs and supplies.

"Evaluation and management (E&M) codes" - Procedure codes ((which)) that categorize physician services by type of service, place of service, and patient status.

"Expedited prior authorization" - The process of obtaining authorization that must be used for selected services, in which providers use a set of numeric codes to indicate to the agency which acceptable indications, conditions, diagnoses, and/or criteria are applicable to a particular request for services.

"Experimental" - A term to describe a ~~((procedure, or course of treatment, which))~~ health care service that lacks sufficient scientific evidence of safety and effectiveness. ~~((See WAC 182-531-0550.))~~ A service is not "experimental" if the service:

(1) Is generally accepted by the medical profession as effective and appropriate; and

(2) Has been approved by the ((FDA)) federal Food and Drug Administration or other requisite government body, if such approval is required.

"Federally approved hemophilia treatment center" - A hemophilia treatment center (HTC) ((which)) that:

(1) Receives funding from the U.S. Department of Health and Human Services, Maternal and Child Health Bureau National Hemophilia Program;

(2) Is qualified to participate in 340B discount purchasing as an HTC;

(3) Has a U.S. Center for Disease Control (CDC) and prevention surveillance site identification number and is listed in the HTC directory on the CDC web site;

(4) Is recognized by the Federal Regional Hemophilia Network that includes Washington state; and

(5) Is a direct care provider offering comprehensive hemophilia care consistent with treatment recommendations set by the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation in their standards and criteria for the care of persons with congenital bleeding disorders.

"Fee-for-service," see WAC 182-500-0035.

"Flat fee" - The maximum allowable fee established by the agency for a service or item that does not have a relative value unit (RVU) or has an RVU that is not appropriate.

"Geographic practice cost index (GPCI)" - As defined by medicare, means a medicare adjustment factor that includes local geographic area estimates of how hard the provider has to work (work effort), what the practice expenses are, and what malpractice costs are. The GPCI reflects one-fourth the difference between the area average and the national average.

"Global surgery reimbursement," see WAC 182-531-1700.

"HCPCS Level II" - Health care common procedure coding system, a coding system established by Centers for Medicare and Medicaid Services (CMS) to define services and procedures not included in CPT.

"Health care financing administration common procedure coding system (HCPCS)" - The name used for the Centers for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration) codes made up of CPT and HCPCS level II codes.

"Health care team" - A group of health care providers involved in the care of a client.

"Hospice" - A medically directed, interdisciplinary program of palliative services which is provided under arrangement with a Title XVIII Washington licensed and certified Washington state hospice for terminally ill clients and the clients' families.

"ICD," see "International Classification of Diseases."

"Informed consent" - That an individual consents to a procedure after the provider who obtained a properly completed consent form has done all of the following:

(1) Disclosed and discussed the client's diagnosis; and

(2) Offered the client an opportunity to ask questions about the procedure and to request information in writing; and

(3) Given the client a copy of the consent form; and

(4) Communicated effectively using any language interpretation or special communication device necessary per 42 C.F.R. Chapter IV 441.257; and

(5) Given the client oral information about all of the following:

(a) The client's right to not obtain the procedure, including potential risks, benefits, and the consequences of not obtaining the procedure; and

(b) Alternatives to the procedure including potential risks, benefits, and consequences; and

(c) The procedure itself, including potential risks, benefits, and consequences.

"Inpatient hospital admission" - An admission to a hospital that is limited to medically necessary care based on an evaluation of the client using objective clinical indicators, assessment, monitoring, and therapeutic service required to best manage the client's illness or injury, and that is documented in the client's medical record.

"International Classification of Diseases (ICD)" - The systematic listing that transforms verbal descriptions of diseases, injuries, conditions, and procedures into numerical or alphanumeric designations (coding).

"Investigational" - A term to describe a ~~((procedure, or course of treatment, which))~~ health care service that lacks sufficient scientific evidence of ~~((benefit))~~ safety and effectiveness for a particular condition. A service is not "investigational" if the service:

(1) Is generally accepted by the medical professional as effective and appropriate for the condition in question; or

(2) Is supported by an overall balance of objective scientific evidence, ~~((in which))~~ that examines the potential risks and potential benefits ~~((are examined, demonstrating))~~ and demonstrates the proposed service to be of greater overall benefit to the client in the particular circumstance than another ~~((r))~~ generally available service.

"Life support" - Mechanical systems, such as ventilators or heart-lung respirators, which are used to supplement or take the place of the normal autonomic functions of a living person.

"Limitation extension," see WAC 182-501-0169.

"Long-acting reversible contraceptive (LARC)" - Subdermal implants and intrauterine devices (IUDs).

"Maximum allowable fee" - The maximum dollar amount that the agency will reimburse a provider for specific services, supplies, and equipment.

"Medically necessary," see WAC 182-500-0070.

"Medicare clinical diagnostic laboratory fee schedule" - The fee schedule used by medicare to reimburse for clinical diagnostic laboratory procedures in the state of Washington.

"Medicare physician fee schedule data base (MPFSDB)" - The official CMS publication of the medicare policies and RVUs for the RBRVS reimbursement program.

"Medicare program fee schedule for physician services (MPFSPS)" - The official CMS publication of the medicare fees for physician services.

~~((**"Medicare clinical diagnostic laboratory fee schedule"** - The fee schedule used by medicare to reimburse for clinical diagnostic laboratory procedures in the state of Washington.))~~

"Mentally incompetent" - A client who has been declared mentally incompetent by a federal, state, or local court.

"Modifier" - A two-digit alphabetic and/or numeric identifier that is added to the procedure code to indicate the type of service performed. The modifier provides the means by which the reporting physician can describe or indicate that a performed service or procedure has been altered by some specific circumstance but not changed in

its definition or code. The modifier can affect payment or be used for information only. Modifiers are listed in fee schedules.

"Outpatient," see WAC 182-500-0080.

"Peer-reviewed medical literature" - (~~Medical literature published in professional journals that submit articles for review by experts who are not part of the editorial staff. It does not include publications or supplements to publications primarily intended as marketing material for pharmaceutical, medical supplies, medical devices, health service providers, or insurance carriers.~~) A research study, report, or findings regarding a medical treatment that is published in one or more reputable professional journals after being critically reviewed by appropriately credentialed experts for scientific validity, safety, and effectiveness.

"Physician care plan" - A written plan of medically necessary treatment that is established by and periodically reviewed and signed by a physician. The plan describes the medically necessary services to be provided by a home health agency, a hospice agency, or a nursing facility.

"Physician standby" - Physician attendance without direct face-to-face client contact and which does not involve provision of care or services.

"Physician's current procedural terminology," see "current procedural terminology (CPT)."

"PM&R," see acute physical medicine and rehabilitation.

"Podiatric service" - The diagnosis and medical, surgical, mechanical, manipulative, and electrical treatments of ailments of the foot and ankle.

"Pound indicator (#)" - A symbol (#) indicating a CPT procedure code listed in the agency's fee schedules that is not routinely covered.

"Preventive" - Medical practices that include counseling, anticipatory guidance, risk factor reduction interventions, and the ordering of appropriate laboratory and diagnostic procedures intended to help a client avoid or reduce the risk or incidence of illness or injury.

"Prior authorization," see WAC 182-500-0085.

"Professional component" - The part of a procedure or service that relies on the provider's professional skill or training, or the part of that reimbursement that recognizes the provider's cognitive skill.

"Prognosis" - The probable outcome of a client's illness, including the likelihood of improvement or deterioration in the severity of the illness, the likelihood for recurrence, and the client's probable life span as a result of the illness.

"Prolonged services" - Face-to-face client services furnished by a provider, either in the inpatient or outpatient setting, which involve time beyond what is usual for such services. The time counted toward payment for prolonged E&M services includes only face-to-face contact between the provider and the client, even if the service was not continuous.

"Provider," see WAC 182-500-0085.

"Radioallergosorbent test" or "RAST" - A blood test for specific allergies.

"RBRVS," see resource based relative value scale.

"RBRVS RVU" - A measure of the resources required to perform an individual service or intervention. It is set by medicare based on three components - Physician work, practice cost, and malpractice expense. Practice cost varies depending on the place of service.

"Reimbursement" - Payment to a provider or other agency-approved entity who bills according to the provisions in WAC 182-502-0100.

"Reimbursement steering committee (RSC)" - An interagency work group that establishes and maintains RBRVS physician fee schedules and other payment and purchasing systems utilized by the agency and the department of labor and industries.

"Relative value guide (RVG)" - A system used by the American Society of Anesthesiologists for determining base anesthesia units (BAUs).

"Relative value unit (RVU)" - A unit (~~which~~) that is based on the resources required to perform an individual service or intervention.

"Resource based relative value scale (RBRVS)" - A scale that measures the relative value of a medical service or intervention, based on the amount of physician resources involved.

"RSC RVU" - A unit established by the RSC for a procedure that does not have an established RBRVS RVU or has an RBRVS RVU deemed by the RSC as not appropriate for the service.

"RVU," see relative value unit.

"Stat laboratory charges" - Charges by a laboratory for performing tests immediately. "Stat" is an abbreviation for the Latin word "statim," meaning immediately.

"Sterile tray" - A tray containing instruments and supplies needed for certain surgical procedures normally done in an office setting. For reimbursement purposes, tray components are considered by CMS to be nonroutine and reimbursed separately.

"Technical advisory group (TAG)" - An advisory group with representatives from professional organizations whose members are affected by implementation of RBRVS physician fee schedules and other payment and purchasing systems utilized by the agency and the department of labor and industries.

"Technical component" - The part of a procedure or service that relates to the equipment set-up and technician's time, or the part of the procedure and service reimbursement that recognizes the equipment cost and technician time.

AMENDATORY SECTION (Amending WSR 11-14-075, filed 6/30/11, effective 7/1/11)

WAC 182-531-0550 Experimental and investigational services. (1) When the (~~department makes a determination as to whether~~) medicaid agency determines a proposed service is experimental or investigational, the (~~department~~) agency follows the procedures in this section. (~~The policies and procedures and any criteria for making decisions are available upon request.~~)

(2) The determination of whether (~~a service is~~) to authorize an experimental (~~and/or~~) or investigational service is subject to a case-by-case review under the provisions of WAC (~~388-501-0165 which relate to medical necessity. The department~~) 182-501-0165. The agency also considers the following criteria:

(a) Evidence in **peer-reviewed medical literature**, as defined in WAC (~~388-531-0050, and preclinical and clinical data reported to the National Institute of Health and/or the National Cancer Institute~~) 182-531-0050, concerning the probability of the service maintaining or

significantly improving the enrollee's length or quality of life, or ability to function, and whether the benefits of the service or treatment are outweighed by the risks of death or serious complications;

(b) Whether evidence indicates the service or treatment is more likely than not to be as beneficial as existing conventional treatment alternatives for the treatment of the condition in question;

(c) Whether the service or treatment is generally used or generally accepted for treatment of the condition in the United States;

(d) Whether the service or treatment is under continuing scientific testing and research;

(e) Whether the service or treatment shows a demonstrable benefit for the condition;

(f) Whether the service or treatment is safe and ~~((efficacious))~~ effective;

(g) Whether the service or treatment will result in greater benefits for the condition than another generally available service; and

(h) If approval is required by a regulating agency, such as the federal Food and Drug Administration, whether such approval has been given before the date of service.

~~(3) ((The department applies consistently across clients with the same medical condition and health status, the criteria to determine whether a service is experimental. A service or treatment that is not experimental for one client with a particular medical condition is not determined to be experimental for another enrollee with the same medical condition and health status. A service that is experimental for one client with a particular medical condition is not necessarily experimental for another, and subsequent individual determinations must consider any new or additional evidence not considered in prior determinations.~~

~~(4) The department does not determine a service or treatment to be experimental or investigational solely because it is under clinical investigation when there is sufficient evidence in peer reviewed medical literature to draw conclusions, and the evidence indicates the service or treatment will probably be of greater overall benefit to the client in question than another generally available service.~~

~~(5))~~ All determinations that a proposed service or treatment is "experimental" or "~~((investigation))~~ investigational" are subject to the review and approval of a physician who is:

(a) Designated by the agency's medical director to issue such approvals;

(b) Licensed under chapter 18.57 RCW or an osteopath licensed under chapter 18.71 RCW(~~(+~~

~~(b) Designated by the department's medical director to issue such approvals))~~; and

(c) Available to consult with the client's treating physician by telephone.