

Policies and Guidelines of the Medical Services Commission's Advisory Committee on Diagnostic Facilities

**British Columbia Medical Services Commission
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DEFINITIONS

The following terms as defined here are used throughout the Policies and Guidelines, except in situations where:

- a different, more particular definition is given for the purposes of a specific policy or
 - additional modifiers or context requires a different interpretation.
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Access means a beneficiary's ability to secure access, within a reasonable period of time, to medically-required outpatient diagnostic services that are benefits.

Advisory Committee on Diagnostic Facilities (the Committee) means a committee of the Medical Services Commission (the Commission), established as a panel and delegated powers pursuant to Sections 5 and 6 of the *Medicare Protection Act*, that provides advice and assistance to the Commission on diagnostic facilities and services and exercises certain powers and duties that the Commission has delegated to it.

Application means an application for a new diagnostic facility, for relocation or expansion of an existing diagnostic facility, or for transfer of a material financial interest in a diagnostic facility. (Defined in Subsection 38(2) of the Medical and Health Care Services Regulation.)

Approved baseline means the volume of Medical Services Plan diagnostic service benefits that the Committee has approved and communicated to an owner as an approved baseline for the diagnostic facility; approved volumes are set in relation to each Certificate of Approval held by a diagnostic facility.

Approved diagnostic services means the following diagnostic services that have been approved by the Commission for Medical Services Plan billing:

- diagnostic radiology (including, computerized axial tomography—CT/CAT)
- diagnostic ultrasound
- nuclear medicine scanning
- pulmonary function
- polysomnography
- electromyography
- electroencephalography

Beneficiary means a B.C. resident who is enrolled in accordance with section 7.2 of the *Medicare Protection Act*, and includes the resident's child if the child is enrolled under section 7.2. (Defined in Section 1 of the *Medicare Protection Act*.)

Benefits are medically required services performed:

- in an approved diagnostic facility, and
- by or under the supervision of an enrolled medical practitioner who is acting on order of a person in a prescribed category of persons, or in accordance with protocols approved by the Commission. (Defined in Section 1 of the *Medicare Protection Act*.) unless determined by the Commission under Section 5 of the *Medicare Protection Act* not to be benefits.

Canadian entity means corporations, partnerships, limited partnerships, or other similar entities that are incorporated or created under the laws of Canada or under the laws of any province of Canada.

Capacity means the number of diagnostic service benefits and/or beneficiaries a diagnostic facility can accommodate within a given time period.

Capability means the ability of a diagnostic facility to provide a specific diagnostic service by having, for example, appropriately trained staff, appropriate equipment, appropriate space for x-ray machine.

Catchment area means the geographic area that the Committee identifies for each application and is a factor in determining and assessing medical need, access, wait times, reasonable utilization of existing approved facilities, and proximity to other diagnostic facilities in that geographic area.

Cease operations means to discontinue providing one or more, or all, types of benefits that have been approved by the Committee/Commission to be performed at a diagnostic facility.

Certificate of Approval means the document in which the Commission, or the Committee under delegation from the Commission, formally documents approval for a diagnostic facility to provide specific diagnostic services as benefits.

Child means a person who:

- is a minor,
- is a child of a beneficiary or a person in respect of whom a beneficiary stands in the place of a parent,
- does not have a spouse, and
- is supported by the beneficiary. (Defined in Section 1 of the *Medicare Protection Act*.)

Conflict of interest means an actual or potential discrepancy between a person's duty to act in someone else's interest and the personal interest of that person. A conflict of interest can be real, potential, or perceived. Direct financial or material gain is not necessary for a conflict of interest to exist. Indirect financial interest or other benefit may also give rise to a conflict of interest.

Diagnostic Facilities Administration means staff of the Ministry of Health who provide administrative, research, and operations support to the Commission and the Committee in the processing and administration of diagnostic facility applications and support other functions within the Commission's and Committee's mandate and authority.

Diagnostic facility means a facility, place or office principally equipped for performing prescribed diagnostic services.

Foreign disclosure laws means any laws, statutes, by-laws, treaty, directive, policy having force of law, order, judgement, injunction, award, decree or other similar matter of any government, legislature (or similar body), court, governmental department, commission, board, bureau, agency, instrumentality, province, state, territory, association, county, municipality, city, town, or other political or governmental jurisdiction, whether not or in the future constituted, outside of Canada, that may require, request, or otherwise demand access, use or disclosure of personal information, whether to intercept or obstruct terrorism, or for any other reason.

Like-application means an application for the same service(s) within the same catchment area.

Like-facility means a diagnostic facility that provides outpatient diagnostic services that are benefits of the same type as those provided by another approved diagnostic facility. Identified like-facilities are used to assess wait times, medical need, proximity and access to services, and utilization of existing facilities.

Material financial interest means the interest of a sole proprietor, the interest of a partner, or an interest of more than 10 per cent of the shares in the corporation. (Defined in Subsection 38(2) of the Medical and Health Care Services Regulation.)

Medical Services Commission (the Commission) means the statutory body that manages the Medical Services Plan on behalf of the Government of British Columbia in accordance with the *Medicare Protection Act* and Regulations.

Medical Services Plan (MSP) means the Medical Services Plan continued under Section 3 of the *Medicare Protection Act*. (Defined in Section 1 of the *Medicare Protection Act*.)

Mobile diagnostic service means a non-fixed unit that travels to communities such as rural areas to provide diagnostic services.

New diagnostic equipment means any net new equipment, in addition to that which the diagnostic facility has previously used in providing benefits, but not including replacement equipment.

New service means a type of diagnostic service for which a facility does not have, but seeks, an approval.

Practitioner means, as defined in Section 1 of the *Medicare Protection Act*, a medical practitioner or a health care practitioner who is enrolled under Section 13 of the *Medicare Protection Act*.

Privately-owned diagnostic facility means a facility that:

- is not a public diagnostic facility and
- must be approved by the Commission in order to provide diagnostic service benefits.

Public diagnostic facility means:

- as defined in Section 38 of the Medical and Health Care Services Regulation, a hospital as defined in Section 1 of the *Hospital Act*, or an establishment which has been designated a diagnostic and treatment centre under the *Hospital Insurance Act*, and which provides (or seeks to provide) diagnostic service benefits that must be approved by the Commission or
- a publicly-owned diagnostic facility that is otherwise under the direct authority of a health authority and which provides (or seeks to provide) diagnostic service benefits that must be approved by the Commission.

Replacement equipment means diagnostic equipment that:

- has been or will be introduced to replace existing equipment and
- may increase the capacity or capability of an approved diagnostic facility.

Significant change means:

- bringing into use new diagnostic equipment or
- a volume increase or decrease of 20 percent or more in a 12-month period compared with the approved baseline or

- a volume increase or decrease of 30 percent or more in a 36-month period compared with the approved baseline.

Telemetry means the electronic transmission of diagnostic images from one site to another for interpretation.

INTRODUCTION

This document, *Policies and Guidelines of the Medical Services Commission's Advisory Committee on Diagnostic Facilities* (the Policies and Guidelines), is intended to assist and guide the work of the Advisory Committee on Diagnostic Facilities and its members in the exercise of their duties and functions in relation to diagnostic facilities.

Under the authority of the *Medicare Protection Act*¹ (the Act) and the Medical and Health Care Services Regulation (the Regulation),² the Medical Services Commission (the Commission) regulates aspects of diagnostic facilities that provide publicly-funded diagnostic services. The mandate of the Advisory Committee on Diagnostic Facilities (the Committee) is to provide advice and assistance to the Commission with respect to diagnostic services and diagnostic facilities, to consider certain applications, and to exercise or perform certain related or incidental powers or duties delegated by the Commission. The Commission refers applications regarding existing and proposed diagnostic facilities and diagnostic services to the Committee, which the Committee reviews in accordance with the Act, the Regulation, the terms of any delegation from the Commission to the Committee, and the Commission-approved Policies and Guidelines.

The Policies and Guidelines bring together the statutory requirements related to diagnostic facilities and build upon them in terms of the mandate of the Committee, providing additional guidance where required.

The Commission has delegated authority to the Committee to consider, and where appropriate, approve applications for diagnostic facilities and services and to provide advice and assistance to the Commission related to diagnostic facilities that provide or intend to provide the following outpatient³ diagnostic services:

- diagnostic radiology (including, computerized axial tomography—CT/CAT)
- diagnostic ultrasound
- nuclear medicine scanning
- pulmonary function
- polysomnography
- electromyography
- electroencephalography

¹ Particularly, but not exclusively, Parts 6, 7, and 8

² Particularly, but not exclusively, Part 7 and 8

³ Note: Prior Commission/Committee approval is required in relation to professional fees for practitioners providing CT services (which includes some CT services provided on an *inpatient* basis); however, with that exception, the Commission and Committee's mandate and role to consider and approve diagnostic services relates exclusively to *outpatient* diagnostic services, and the Policies and Guidelines is to be understood and interpreted in that context.

The Committee assesses applications in accordance with the Regulation that requires that:

- there is sufficient medical need,
- the quality of the proposed diagnostic services is sufficiently high,
- there is reasonable utilization of existing approved diagnostic facilities which provide the same services for which approval is sought and which are located within the catchment area under consideration, and
- the person applying for the approval/Certificate of Approval does not have a potential conflict of interest. (However, approval may be granted in exceptional circumstances where a potential conflict of interest exists but the services could not reasonably be provided by another diagnostic facility.⁴)

In the exercise of its delegated authority, the Committee does not mechanically apply the Policies and Guidelines, but considers whether they are appropriate to the particular facts of each case. The Committee considers all relevant factors in the exercise of its delegated discretion and exercises its discretion in a manner that conforms to the objectives and scheme of the Act.

The Committee's work accords with the Commission's mandate to advance the principle of facilitating reasonable access throughout B.C. to quality medically necessary outpatient diagnostic services for beneficiaries.

The majority of the requirements of the Act and the Regulation with respect to diagnostic services and diagnostic facilities is located in Part 6 of the Act and in Part 7 of the Regulation.

Under Section 33 of the Act, the Commission has the authority to approve diagnostic facilities for the purposes of permitting services that are benefits to be delivered there. Approvals may be temporary, and conditions may be imposed on approvals. The Commission has delegated authority to the Committee to consider applications and make Section 33 approvals, as well as to attach, add, delete, or amend conditions as necessary or advisable. Moreover, the Commission has delegated certain limited authority to the Committee to cancel approvals pursuant to Section 33 of the Act.

The legislation specifies certain criteria for the consideration and approval of diagnostic facilities and services-related activities and applications, including applications for new facilities, for the relocation or expansion of existing facilities, for a transfer of material

⁴ Medical and Health Care Services Regulation, Subsections 40(1) and (2)

financial interest, and for significant changes in its capability or capacity to perform diagnostic services. Important considerations such as conflict of interest (real or potential), medical need/access (e.g., within a catchment area), and reasonable utilization of existing approved diagnostic facilities are provided for in the legislation. The Policies and Guidelines outline additional considerations and also provide direction and guidance on how criteria are to be considered and applied by the Committee in its work.

This document is not a comprehensive guide to or substitute for the Act and Regulation. While the Policies and Guidelines articulate many of the roles, requirements, and obligations of prospective and current diagnostic facility owners and applicants, it should not be used as an application or compliance checklist. Compliance with the Policies and Guidelines will not ensure or constitute compliance with applicable law. Information and assistance, application forms, other forms, Frequently Asked Questions, and a User Guide are available to view/download/print at: <http://www.gov.bc.ca/diagnosticfacilities>.

The Policies and Guidelines should be read and understood with reference to the following interpretative rules:

- words in the singular include the plural, and words in the plural include the singular, and
- if a word or expression is defined, other parts of speech and grammatical forms of the same word or expression have corresponding meanings.

The Policies and Guidelines is effective June 1, 2014 and replace the prior policies of the Medical Services Commission that relate to the approval of diagnostic facilities or other functions within the Committee's mandate and authority.

PART 1 GUIDING PRINCIPLES AND OBJECTIVES

EFFECTIVE JUNE 1, 2014

PURPOSE

To articulate the principles and objectives that guide the work of the Committee.

POLICY

The Committee, in exercising delegated powers of the Commission, and in providing the Commission with advice and assistance, must act in accordance with and advance the intentions of the preamble and the guiding principles, purpose, and objectives of the *Medicare Protection Act* which are as follows:

WHEREAS the people and government of British Columbia believe that medicare is one of the defining features of Canadian nationhood and are committed to its preservation for future generations;

WHEREAS the people and government of British Columbia wish to confirm and entrench universality, comprehensiveness, accessibility, portability, public administration and sustainability as the guiding principles of the health care system of British Columbia and are committed to the preservation of these principles in perpetuity;

WHEREAS the people and government of British Columbia are committed to building a public health care system that is founded on the values of individual choice, personal responsibility, innovation, transparency and accountability;

WHEREAS the people and government of British Columbia are committed to developing an efficient, effective and integrated health care system aimed at promoting and improving the health of all citizens and providing high quality patient care that is medically appropriate and that ensures reasonable access to medically necessary services consistent with the Canada Health Act;

WHEREAS the people and government of British Columbia wish to ensure that all publicly funded health care services are responsive to patients' needs and designed to foster improvements in individual and public health outcomes and ongoing value-for-money for all taxpayers;

WHEREAS the people and government of British Columbia recognize a responsibility for the judicious use of medical services in order to maintain a fiscally sustainable health care system for future generations;

AND WHEREAS the people and government of British Columbia believe it to be fundamental that an individual's access to necessary medical care be solely based on need and not on the individual's ability to pay.

Purpose: The purpose of the Act is to preserve a publicly managed and fiscally sustainable health care system for British Columbia in which access to necessary medical care is based on need and not an individual's ability to pay.

Public administration: The plan is publicly funded and operated on an accountable basis.

Comprehensiveness: The plan includes as benefits

- all medically required services provided by enrolled medical practitioners;
- all required services provided by enrolled health care practitioners and prescribed as benefits under section 51 of the Act;
- benefits that are performed in approved diagnostic facilities; and
- any benefits that are performed by practitioners in a health facility that has entered into an agreement with one or more regional health boards designated under the *Health Authorities Act* or with the Provincial Health Services Authority, in accordance with the agreement.

Universality: The plan applies to 100% of beneficiaries on uniform terms and conditions.

Portability: The plan applies to the following individuals:

- beneficiaries who are temporarily absent from British Columbia or moving to another province;
- eligible individuals who are moving to British Columbia;
- eligible individuals visiting British Columbia from another province that has entered into a reciprocal agreement with British Columbia for medical and health care services, in accordance with that agreement.

Accessibility: The plan provides benefits on uniform terms and conditions on a basis that does not impede or preclude reasonable access to benefits by beneficiaries; and

Sustainability: The plan is administered in a manner that is sustainable over the long term, providing for the health needs of the residents of British Columbia and assuring that annual health expenditures are within taxpayers' ability to pay without compromising the

ability of the government to meet the health needs and other needs of current and future generations.

The Committee must:

- act in accordance with and, where possible, advance the mandate of the Commission to facilitate reasonable access throughout B.C. to quality medical care, health care, and diagnostic facility services for B.C. residents under the MSP, and
- perform its duties and functions with transparency, fairness, consistency, and timeliness.

CROSS REFERENCE

Policy 2.3, Committee's Approach to Application Assessment
Policies 2.4.1-2.4.6, Assessment Criteria

AUTHORITY

Medicare Protection Act, Preamble, Sections 2 and 5.1-5.7.

PART 2 APPLICATIONS FOR DIAGNOSTIC FACILITIES AND SERVICES

POLICY 2.1 ACTIVITY REQUIRING APPROVAL

**EFFECTIVE JUNE 1, 2014 (For updates see Appendix 2 – Version/Revision
History)**

PURPOSE

To articulate the types of application that are subject to the review and approval of the Commission and the Committee.

OWNER REQUIREMENTS

The owner or prospective owner must apply to the Commission for approval of new diagnostic facilities, the relocation or expansion of existing facilities, the transfer of a material financial interest in a diagnostic facility, changes to conditions attached to an approval, or renewal of a time-limited approval.

POLICY

The Committee will review applications made to the Commission for approval of:

- a) a new diagnostic facility,
- b) the relocation of an existing diagnostic facility when such relocation is within the same geographic catchment area,
- c) the expansion of an existing diagnostic facility if:
 - a physical expansion of the diagnostic facility is planned,
 - a new service, not previously approved in relation to a diagnostic facility, is planned to be delivered at that diagnostic facility, or
 - a significant change will or may occur,
- d) the transfer of a material financial interest in a diagnostic facility,
- e) changes to conditions attached to an approval, and
- f) renewal of a time-limited approval, that is, renewal before a time-limited approval expires.

except where the Policies and Guidelines indicate that the Committee may take other action (e.g., referring a matter directly to the Commission).

CROSS REFERENCE

Policy 2.5, Referral of Applications To the Medical Services Commission

Policy 3.1, Transfer of Ownership Interest

Policy 3.4, Significant Change Applications

AUTHORITY

Medical and Health Care Services Regulation, Subsections 39(2), 40(1), 43(e)(iii).

PART 2 APPLICATIONS FOR DIAGNOSTIC FACILITIES AND SERVICES

POLICY 2.2 REQUIRED APPLICATION INFORMATION

EFFECTIVE JUNE 1, 2014

PURPOSE

To clarify the information that the Committee requires in an application for a new diagnostic facility, relocation or expansion of an existing diagnostic facility, transfer of a material financial interest in a diagnostic facility, changes to conditions attached to an approval, or renewal of a time-limited approval.

OWNER REQUIREMENTS

The owner or prospective owner must submit specific and complete information in/with their applications for approval of new facilities, the relocation or expansion of existing facilities, transfer of a material financial interest in a diagnostic facility, changes to conditions attached to an approval, or renewal of a time-limited approval.

POLICY

The Committee will consider only those applications that provide the following information, in a complete and legible format, at least 60 days⁵ prior to the date on which the applicant requests the approval to be effective:

- a) the proposed address of the diagnostic facility or, if it will be a mobile diagnostic service, the specific addresses for the proposed services and the address of the base facility,
- b) appropriate descriptions of the capabilities and capacities of the major equipment which is intended to be used in the diagnostic facility,
- c) the square footage of the clinical area to be used to provide approved diagnostic services,
- d) the proposed hours of operation of the diagnostic facility,

⁵ Note exception in Guideline below.

- e) leasing or building ownership details and deadlines related to the physical premises,
- f) the names of the owner and the medical director of the diagnostic facility,
- g) the names of all persons who have a material financial interest in the diagnostic facility and, if the persons are shareholders, the percentage of the shares which they own,
- h) information about any actual or potential conflict of interest,
- i) the names and qualifications of all medical, scientific, technical and supervisory staff employed by or providing services (that is, providing services on any basis, for instance, on a full-time, part-time, locum, or occasional basis) at the diagnostic facility,
- j) a list and description of all quality control procedures planned for the facility, including quality control programs of a formal nature,
- k) if applicable, information related to foreign ownership (see Policy 2.4.5, Compliance with Canadian and B.C. law), and
- l) any other information or documentation the Committee may specify and require that is relevant to performance of the Committee's duties and functions.

GUIDELINE

The Committee may consider an application received less than 60 days prior to the date on which the applicant requests the approval to be effective, at its discretion or as directed by the Commission.

CROSS REFERENCE

Policy 2.4.4, Conflict of Interest

Policy 2.4.5, Compliance with Canadian and B.C. Law

Policy 2.6, Approval, Attaching and Changing Conditions of Approval, Cancellation of an Approval, and Recommending Denial of an Application

AUTHORITY

Medical and Health Care Services Regulation, Subsection 39(1) and *Medicare Protection Act*, Subsection 33(1) and within the general mandate of the Medical Services Commission under the authority of the *Medicare Protection Act* and the Medical and Health Care Services Regulation.

PART 2 APPLICATIONS FOR DIAGNOSTIC FACILITIES AND SERVICES

POLICY 2.3 COMMITTEE'S APPROACH TO APPLICATION ASSESSMENT

EFFECTIVE JUNE 1, 2014

PURPOSE

To articulate the general approach that the Committee takes in assessing an application for a new diagnostic facility, relocation or expansion of an existing diagnostic facility, transfer of a material financial interest in a diagnostic facility, changes to conditions attached to an approval, or renewal of a time-limited approval.

POLICY

When assessing applications, the Committee will:

- a) apply the mandatory criteria and requirements specified in the Act and the Regulation,
- b) document its application of criteria and considerations in addition to those specified in the Act and the Regulation,
- c) exercise discretion appropriately and use its best judgment, and
- d) consider what if any conditions are or might be necessary or advisable to attach to an approval, having regard to the Act, the Regulation, the Policies and Guidelines and its mandate.

GUIDELINES

The Committee may, in assessing applications:

- apply criteria and considerations in addition to those specified in the Act and the Regulation, and
- apply criteria in a flexible manner by considering all relevant criteria in the context of the particular application and relevant circumstances.

The Committee may:

- invite any advisor or expert it determines advisable to provide information and advice to inform its deliberations and the exercise of its duties and functions, and
- receive such information and advice at any Committee meeting or in any manner and at any time the Committee considers appropriate.

CROSS REFERENCE

Policy 2.1, Activity Requiring Approval

Policy 2.2, Required Application Information

Policy 2.4 - 2.4.6, Assessment Criteria

Policy 2.6, Approval, Attaching and Changing Conditions of Approval, Cancellation of an Approval, and Recommending Denial of an Application

AUTHORITY

Medical and Health Care Services Regulation, Section 40 and *Medicare Protection Act*, Subsection 33(1)

PART 2 APPLICATIONS FOR DIAGNOSTIC FACILITIES AND SERVICES

POLICY 2.4 ASSESSMENT CRITERIA

EFFECTIVE JUNE 1, 2014

PURPOSE

To articulate the criteria the Committee uses to assess an application for a new diagnostic facility, relocation or expansion of an existing diagnostic facility, transfer of a material financial interest in a diagnostic facility, changes to conditions attached to an approval, or renewal of a time-limited approval.

OWNER REQUIREMENTS

The owner or prospective owner's application must meet specific criteria for the approval of their applications for a new diagnostic facility, relocation or expansion of an existing diagnostic facility, transfer of a material financial interest in a diagnostic facility, changes to conditions attached to an approval, or renewal of a time-limited approval.

POLICY

The Committee will assess an application for a new diagnostic facility, for relocation or expansion of an existing diagnostic facility, or for transfer of a material financial interest in a diagnostic facility for evidence of meeting the criteria set out in:

- a) the Medical and Health Care Services Regulation (see Policy 2.2 and 2.3), and
- b) the Policies and Guidelines (see Policy 2.4.1-2.4.6 that follow).

Notwithstanding these criteria, the Committee may, on a case-by-case basis, recommend the Commission grant approval under exceptional circumstances for applications where outpatient diagnostic services are required in direct support of a Ministry of Health priority initiative(s) (i.e. service provision directly related to Primary Care Networks, including Urgent Primary Care Centres, or Specialized Community Service Programs for target populations). Privately-owned facilities affiliated with a Ministry of Health priority initiative must have an existing contractual arrangement with a health authority to provide services, and this relationship must be identified within the facility's application.

CROSS REFERENCE

Policy 2.2, Required Application Information
Policy 2.4.1-2.4.6, Assessment Criteria
Policy 3.1, Transfer of Ownership Interest

AUTHORITY

Medical and Health Care Services Regulation, Section 40

PART 2 APPLICATIONS FOR DIAGNOSTIC FACILITIES AND SERVICES

POLICY 2.4.1 ASSESSMENT CRITERIA: QUALITY

EFFECTIVE JUNE 1, 2014

PURPOSE

To ensure that the Committee assesses applications for diagnostic facilities/services with regard to quality.

OWNER REQUIREMENTS

The owner or prospective owner's application must meet specific criteria related to quality for approval of their new facilities or for the relocation or expansion of existing facilities. The owner must maintain required accreditation and physician credentials at all times diagnostic service benefits requiring approval are provided at the facility.

POLICY

The Committee will base its assessment of an application's fulfillment of quality criteria on:

- a) whether the diagnostic facility has received applicable and required accreditation from the Diagnostic Accreditation Program of the College of Physicians and Surgeons of British Columbia, and
- b) whether the physicians specified in the application possess all the appropriate, applicable credentials (that is, relevant to the diagnostic services proposed). For physicians who solely work at, or are affiliated exclusively with, privately-owned diagnostic facilities, the applicable/required credential is that provided by the College of Physicians and Surgeons of British Columbia. For physicians who have any affiliation with, or privileging at, public diagnostic facilities (even if they also work in, or are affiliated with, privately-owned diagnostic facilities), the applicable/required credential is that provided by a health authority.

The Committee may approve an application for a diagnostic facility that has not yet received the required facility accreditation and physician credentialing only if, and on condition that, the accreditation and credentialing requirements are satisfied prior to benefits being delivered at the diagnostic facility.

CROSS REFERENCE

Policy 2.6, Approval, Attaching and Changing Conditions of Approval, Cancellation of an Approval, and Recommending Denial of an Application

AUTHORITY

Medical and Health Care Services Regulation, Subsections 39(1)(i) and 40(1)(e)

PART 2 APPLICATIONS FOR DIAGNOSTIC FACILITIES AND SERVICES

POLICY 2.4.2 ASSESSMENT CRITERIA: ACCESSIBILITY

EFFECTIVE JUNE 1, 2014 (For updates see Appendix 2 – Version/Revision History)

PURPOSE

To ensure that the Committee assesses applications for diagnostic facilities with regard to access to services and gives priority consideration to public diagnostic facilities when appropriate.

OWNER REQUIREMENTS

While there are no specific owner requirements regarding access in addition to those outlined in Policy 2.4, with respect to public diagnostic facilities that will provide diagnostic service benefits requiring approval, owners or prospective owners must submit plans and annual status reports on progress respecting construction or significant physical expansion of those public diagnostic facilities, in order to receive the priority consideration specified in this Policy (Policy 2.4.2).

POLICY

Catchment Area

The Committee will determine the catchment area that applies to an application for all services, except polysomnography, using a population-density-per-square-kilometre radius-based approach consistent with the following table:

population density per square km. (permanent residents only)	catchment area radius
1 – 399 persons	75 Kilometres
400 – 999 persons	35 Kilometres
1000 or more persons	15 Kilometres

The Committee will determine the catchment area that applies for applications for polysomnography using the area within the geographic boundaries of the Health Service Delivery Areas, as defined by the Ministry of Health and BC Stats, of the health authority where the diagnostic facility that is the subject of the application is located.

The Committee will expand the applicable catchment area for all diagnostic services including polysomnography, as required, in order to include a minimum of three like-facilities in its assessment.

Wait Times, Distance, and Travel Time

The Committee will assess whether the access criteria have been met by considering:

- a) Commission-endorsed provincial wait time benchmarks, if applicable to the service (see Appendix 1: Medical Services Commission-Endorsed Provincial Wait Time Benchmarks),
- b) the distances between like-facilities, and
- c) beneficiaries' travel time.

Use of Existing Facilities

The Committee will consider the use of existing facilities when assessing applications by:

- a) assessing whether there is reasonable utilization of existing like-facilities (both public and privately-owned) that provide the services for which approval is sought and which are located within the catchment area that applies to the application in question,
- b) giving priority consideration to existing approved public diagnostic facilities where the approved public diagnostic facility has already been approved to provide the services proposed in an application seeking approval of a new facility or relocation of an existing facility,
- c) first approaching all existing public diagnostic facilities in the catchment area to enquire whether they are willing and able to provide the service,
- d) not considering an application from a privately-owned facility seeking approval for expansion for a new service if an existing public diagnostic facility states that it is willing and able to provide the service and has submitted an application to the Committee within 90 days of making that representation to the Committee, and
- e) if an existing public diagnostic facility has not stated that it is willing and able to provide the service or has not submitted an application to the Committee within 90 days of making a representation that it is willing and able to provide the service, then

proceeding to consider the application from the privately-owned facility seeking approval for expansion for a new service.

Construction/Significant Physical Expansion of Public Diagnostic Facilities

The Committee will have regard to future plans for the construction or significant physical expansion of public diagnostic facilities in the catchment area or other geographic area defined by the Committee, when considering an application by:

- a) not considering or approving like-applications if there is a firm plan for implementation of a new or significantly expanded existing public diagnostic facility within the next five years, unless there is a current shortage of one or more medically-necessary outpatient diagnostic services and the like-application proposes to address that shortage,
- b) reviewing annual status reports on progress in implementing new or expanded public diagnostic facilities which must include the estimated date of service implementation, and
- c) considering applications without regard to any future plans of public diagnostic facilities if annual status reports on progress with estimated dates of implementation are not provided.

GUIDELINE

The Committee may, notwithstanding future plans for the construction or significant physical expansion of public diagnostic facilities in the catchment area or other area defined by the Committee:

- approve applications from existing approved or prospective new like-facilities by issuing a time-limited approval/Certificate of Approval if there is an identified gap in services, that is, a current shortage of one or more medically necessary outpatient diagnostic services, and the like-application proposes to address that gap,
- extend a time-limited approval/Certificate of Approval if a new or significantly expanded public diagnostic facility is not implemented by the estimated service implementation date.

CROSS REFERENCE

Policy 2.4, Assessment Criteria

Policy 3.4, Significant Change Applications

Policy 4, Subsequent Applications, Implementation, and Lapse In Service

AUTHORITY

Medical and Health Care Services Regulation, Subsections 39(1) and 40(1)

PART 2 APPLICATIONS FOR DIAGNOSTIC FACILITIES AND SERVICES

POLICY 2.4.3 ASSESSMENT CRITERIA: SERVICE-SPECIFIC CRITERIA

**EFFECTIVE JUNE 1, 2014 (For updates see Appendix 2 – Version/Revision
History)**

PURPOSE

To articulate additional assessment criteria applicable to applications for specific diagnostic services.

OWNER REQUIREMENTS

The owner or prospective owner's application must meet criteria related to specific diagnostic services for approval of their new facilities or for the relocation or expansion of existing facilities.

POLICY

The Committee will use, in addition to the other assessment criteria set out in Policy 2.4, the following criteria to assess applications for specific diagnostic services or manner of service provision:

Electroencephalography (EEG)

- a) the diagnostic facility is to be operated as, or as part of, a public diagnostic facility, and
- b) the service is to be provided to a beneficiary on an outpatient basis.

Electromyography (EMG)

- a) If an individual is seeking a privately-owned *Certificate of Approval* to be operated within a publicly-owned diagnostic facility, the application must include an appropriate letter of support from the representative, or authorized delegate, of the owner of the publicly-owned diagnostic facility, and
- b) the service is to be provided to a beneficiary on an outpatient basis.

Mobile Diagnostic Services

- a) all the facilities indicated in the application are hospitals⁶ and a base location is specified, and
- b) the application is for a public diagnostic facility.

Nuclear Medicine

In vivo Radioisotope

- a) the diagnostic facility is operated as, or as part of, a public diagnostic facility, and
- b) the service is to be provided to a beneficiary on an outpatient basis.

Polysomnography

Facilities applying for a Polysomnography Certificate of Approval must provide for a minimum capacity of three (3) beds appropriate for the purpose of overnight sleep testing.

Pulmonary Function Testing In Privately-Owned Facility

- a) only pulmonary function tests that are benefits listed as Category IIA and Category IIB services are proposed to be approved and delivered (see Pulmonary Function Category List <http://www.gov.bc.ca/diagnosticfacilitiesfeitems>), and
- b) the service is to be provided to a beneficiary on an outpatient basis.

Radiology

CT Scans

⁶ See first bullet under definition of *public diagnostic facility* in this document.

- a) the diagnostic facility is to be operated as, or as part of, a public diagnostic facility, and
- b) the service is to be provided to a beneficiary on an outpatient or an inpatient basis.

CT Colography and Cardiac CT/CT Coronary Angiography

- a) the diagnostic facility is to be operated as, or as part of, a public diagnostic facility, and
- b) the service is to be provided to a beneficiary on an outpatient basis.

Ultrasound

Ultrasound in privately-owned facility

- a) the diagnostic facility has one or more radiologists who are appropriately credentialed, and
- b) the diagnostic facility already holds a Certificate of Approval that permits radiology Category IV services (see Radiology Category List: <http://www.gov.bc.ca/diagnosticfacilitiesfeeitems>)

Doppler Studies

- a) the diagnostic facility is operated as, or as part of, a public diagnostic facility, and
- b) the service is to be provided to a beneficiary on an outpatient basis.

Doppler Studies in a privately-owned facility

- a) Only non-cardiac Doppler studies may be approved in a privately-owned facility,
- b) the diagnostic facility holds both Category IV radiology and Category IV ultrasound Certificates of Approval, and
- c) the diagnostic facility holds a mutually satisfactory clinical placement agreement

with a Ministry of Advanced Education recognized (ultrasound) Diagnostic Medical Sonography training institution in British Columbia.

GUIDELINES

- a) Until otherwise indicated, applications will not be accepted for non-cardiac Doppler studies in a privately-owned facility. Instead, the Medical Services Commission will determine which facilities are approved to perform and bill the Medical Services Plans for non-cardiac Doppler studies.

Echocardiography

- a) the diagnostic facility is operated as, or as part of, a public diagnostic facility,
- b) the service is to be provided to a beneficiary on an outpatient basis, and
- c) the proposed service is:
 - (i) an expansion of echocardiography capacity beyond that provided onsite at a public diagnostic facility to another public diagnostic facility that is located at a different site **or**
 - (ii) an expansion of echocardiography capacity beyond that provided onsite at a public diagnostic facility through the use of a privately-owned diagnostic facility that is located offsite, and there is a contractual arrangement concerning provision of diagnostic services by a privately-owned facility and a health authority.

Distance-Reading (Diagnostic Ultrasound Telemetry)

Medical Services Commission (MSC) Payment Schedule Definition: The electronic transmission of diagnostic ultrasound images from one site to another for interpretation. See page 38-1 <http://www2.gov.bc.ca/assets/gov/health/practitioner-pro/medical-services-plan/msc-payment-schedule-july-2017.pdf>

- a) Both public and privately-owned facilities may apply for Distance-Reading (Diagnostic Ultrasound Telemetry) for ultrasound services they are approved to perform.

- b) Both sending (transmitting) and receiving sites must hold an ultrasound Certificate of Approval from the Committee or the Commission.
- c) Applications will be assessed based on patient access needs and the general and specific criteria in the *Policies and Guidelines of the Medical Services Commission's Advisory Committee on Diagnostic Facilities*.
- d) An application must be submitted and approval received prior to any change in a facility's Distance Reading approval, including the type of ultrasound services transmitted or any change in receiving sites. Applications must include the addresses of all current and proposed sites.

GUIDELINES

- a) When assessing patient access needs, the Committee may consider various factors, including but not limited to: facility location; community size; population density; and distance and driving time to the nearest approved ultrasound facility that offers on-site radiologists for ultrasound interpretation.
- b) When assessing applications, the Committee may consider the number of appropriately credentialed radiologists in the community and the distance between transmitting and receiving sites.
- c) Facilities seeking to apply for both an ultrasound service and Distance Reading for that service must complete separate applications for the service and Distance Reading approval. Both applications may be assessed at the same Committee meeting.

AUTHORITY

Within the general mandate of the Medical Services Commission under the authority of the *Medicare Protection Act* and the Medical and Health Care Services Regulation.

PART 2 APPLICATIONS FOR DIAGNOSTIC FACILITIES AND SERVICES

POLICY 2.4.4 ASSESSMENT CRITERIA: CONFLICT OF INTEREST

EFFECTIVE JUNE 1, 2014

PURPOSE

To ensure that diagnostic facilities delivering diagnostic service benefits to beneficiaries are operated in a manner that protects the integrity of the MSP by ensuring that an owner's or prospective owner's or referring practitioner's personal interests, financial or otherwise, do not conflict or appear to conflict with beneficiaries' interests with respect to medical care/diagnostic services.

OWNER REQUIREMENTS

The owner or prospective owners of a diagnostic facility must identify, declare, and communicate actual or potential conflicts of interest to the Committee in accordance with the *Diagnostic Facility Conflict of Interest Policy* (see: <http://www.gov.bc.ca/diagnosticfacilities>).

POLICY

The Committee will:

- a) only consider an application from an applicant for approval of a new diagnostic facility, for the relocation or expansion of an existing facility, or for the transfer of a material interest in a diagnostic facility that includes both a completed *Conflict of Interest Declaration Form* and a completed *Conflict of Interest Disclosure Form* regarding the absence or presence of any actual or potential conflict of interest in relation to the diagnostic facility,
- b) not approve an application for a new diagnostic facility, for the relocation or expansion of an existing facility, or for the transfer of a material interest in a diagnostic facility that includes a disclosure of an actual or potential conflict of interest in relation to the diagnostic facility unless the relevant services could not reasonably be provided by another diagnostic facility for which a potential conflict of interest does not exist,
 - If the Committee approves an application in such circumstances, it will attach to the approval any and all conditions it determines necessary or advisable to mitigate the conflict of interest.

- c) receive, review, and investigate reports of or concerns about actual or potential conflicts of interest in relation to an approved diagnostic facility, and
- d) if an actual or potential conflict of interest that has not been endorsed on a diagnostic facility's Certificate(s) of Approval is identified by the Committee after a diagnostic facility has been approved, the Committee may:
 - (i) add, delete, or alter a condition on a diagnostic facility's approval, and/or
 - (ii) refer the matter to the Commission.

CROSS REFERENCE

Policy 2.4.2, Assessment Criteria: Accessibility

Policy 2.5, Referral of Applications to the Medical Services Commission

Policy 2.6, Approval, Attaching and Changing conditions of Approval, Cancellation of an Approval, and Recommending Denial of an Application

Policy 3.1, Transfer of Ownership Interest

AUTHORITY

Medical and Health Care Services Regulation, Subsections 39(1)(f), 40(1)(g), 40(2), 40(3), and 43(1)(b) and *Medicare Protection Act*, Section 35

PART 2 APPLICATIONS FOR DIAGNOSTIC FACILITIES AND SERVICES

POLICY 2.4.5 ASSESSMENT CRITERIA: COMPLIANCE WITH CANADIAN AND B.C. LAW

**EFFECTIVE June 1, 2014 (For updates see Appendix 2 – Version/Revision
History)**

PURPOSE

Where there is any degree of foreign ownership of a diagnostic facility, to ensure that the diagnostic facility is operated in a manner that complies with applicable Canadian and B.C. laws and the Commission has the necessary protections in place to enable it to collect any debt owing to it in relation to the diagnostic facility.

OWNER/OPERATOR REQUIREMENTS

Where there is (or would be) any degree of foreign ownership of a diagnostic facility and an approval is sought, the owner or prospective owner must satisfactorily demonstrate that it is subject to the laws of British Columbia and Canada applicable in British Columbia with respect to the provision of diagnostic services in British Columbia and must provide the Commission with necessary assurances that any debts owing to the Commission in relation to the diagnostic facility will be recoverable.

POLICY

The Committee will use the following criteria and requirements to assess applications involving a diagnostic facility with any degree of foreign ownership:

- a) all other requirements of the Act, the Regulation, applicable privacy policies (see http://www.cio.gov.bc.ca/cio/priv_leg/index.page for more information), and the Policies and Guidelines are met;
- b) documentation is provided that satisfactorily demonstrates that the owner or prospective owner is/will be subject to the laws of British Columbia and Canada applicable in British Columbia with respect to the provision of diagnostic services in British Columbia, particularly the Act, the Regulation, and BC privacy laws;
- c) the owner or prospective owner:

- i. must provide corporate organization charts or information relating to all ownership or shareholdings of the owner/prospective owner, including indirect ownership or shareholdings,
 - ii. will be required to provide updates on any future ownership changes, and
 - iii. will be and remain under the direct control of a Canadian entity;
- d) the owner or prospective owner must not be subject to any foreign disclosure laws or any directions or requests relating to personal information from any foreign affiliate, and limits and conditions on an approval and/or assurance provided by the prospective owner or owner ensuring this requirement must exist;
- e) where determined by the Committee to be appropriate, the owner or prospective owner must provide the Commission with a performance guarantor (such as from a parent corporate entity) and/or a financial guarantor (such as from a foreign direct owner);
- f) where determined by the Committee to be appropriate, the owner or prospective owner will provide the Commission with security.

The Committee will undertake any and all legal means it considers necessary or advisable, including placing limits and conditions on approvals for diagnostic facilities with any degree of foreign ownership, to ensure that these requirements are met.

CROSS REFERENCE

Policy 2.2, Required Application Information
Policy 2.6, Approval, Attaching and Changing Limits and Conditions of Approval, Cancellation of an Approval, and Recommending Denial of an Application

AUTHORITY

Within the general mandate of the Medical Services Commission under the authority of the *Medicare Protection Act* and the Medical and Health Care Services Regulation.

PART 2: APPLICATIONS FOR DIAGNOSTIC FACILITIES AND SERVICES

POLICY 2.4.6 ASSESSMENT CRITERIA: CONCURRENT LIKE-APPLICATIONS

EFFECTIVE: February 26, 2015 (For updates see Appendix 2 – Version/Revision History)

PURPOSE

From time to time, multiple like-applications may be received within the same Committee decision-making period. Following the assessment of each application against the standard criteria/requirements, like-applications will be comparatively assessed or ranked. This policy and guideline aims to ensure that such applications are evaluated, and approvals are made, on the basis of appropriate, consistently-applied, and transparent criteria.

POLICY

Before undertaking a comparative assessment of concurrent like-applications, the Committee will first determine whether each application meets all requirements of the Act, the Regulation, and the Policies and Guidelines.

GUIDELINES

Subsequently, when comparatively assessing or ranking concurrent like-applications in order to determine which (if any) to approve, as well as necessary or appropriate approval conditions, the Committee may consider the following criteria in a contextual manner, placing weight on the criteria as it determines most appropriate in the circumstances (that is, applicable service(s), location(s), and so on):

- a) Comparative assessment of each application with respect to beneficiaries' access to services, including location (or proposed location) of subject facilities described in the applications, in relation to the catchment area, and proximity to existing approved like-facilities.

- b) Comparative degree to which the proposed supply of services parallels or approximates actual or anticipated health system needs, including consideration of:

- i. Ability to meet current and near-future (that is, less than three years out) service capacity/volume requirements; and
 - ii. Impacts on wait times.
- c) Other comparative anticipated health system impacts, such as:
 - i. Impacts on continuity and integration of patient care within the diagnostic services system and across the care continuum;
 - ii. Impacts on health human resources;
 - iii. Service delivery impacts on other catchment areas; and
 - iv. Ability to provide value-added services (for example, provision of teaching and clinical placements for students).
- d) Comparative degree of readiness and due diligence demonstrated, including:
 - i. The level of detail, accuracy, and quality of the information provided in the applications; and
 - ii. Demonstrated readiness to provide the proposed services, for example, in relation to overall feasibility and plans or arrangements regarding: location, building and infrastructure, equipment, staffing, and financing (financing to be considered for public diagnostic facilities only).
- e) Comparative application characteristics, including:
 - i. Whether the application is from a public diagnostic facility or a privately-owned diagnostic facility (status as a public diagnostic facility will be one factor in favour of an application, relative to an application from a privately-owned facility, though it is not determinative in and of itself and the other guidelines/factors will be comparatively assessed and considered as well); and
 - ii. Whether there are any substantial suitability concerns relating to past performance or 'track record' (for example, compliance with the Act, the Regulation, and the Policies and Guidelines requirements).

When assessing concurrent like-applications, the Committee generally should not consider or place weight on the respective date and time the applications were received.

The Committee may, in a manner consistent with the Act, the Regulation, and the Policies and Guidelines, use in its assessment of concurrent like-applications relevant criteria other than those specified in this Policy; however, if it does so, it should document those criteria and the rationale for their use.

Following its assessment of concurrent like-applications, the Committee may:

- approve one or more preferred applications and reject one or more (competing) concurrent-like applications;
- recommend denial all of the applications in accordance with the Policies and Guidelines;
- approve one or more of the concurrent like-applications with any conditions on the approvals—such as relating to facility capacity and services volumes—it deems appropriate; or
- refer the concurrent like-applications to the Commission, typically with a recommendation.

CROSS REFERENCE

Policy 2.2, Required Application Information

Policy 2.3, Committee's Approach to Application Assessment

Policy 2.4.1-2.4.5, Assessment Criteria

Policy 2.5, Referral of Applications to the Medical Services Commission

Policy 2.6, Approval, Attaching and Changing Conditions of Approval, Cancellation of an Approval, and Recommending Denial of an Application

AUTHORITY

Within the general mandate of the Medical Services Commission under the authority of the *Medicare Protection Act* and the Health Care Services Regulation.

PART 2 APPLICATIONS FOR DIAGNOSTIC FACILITIES AND SERVICES

**POLICY 2.5 REFERRAL OF APPLICATIONS TO THE MEDICAL SERVICES
COMMISSION**

EFFECTIVE JUNE 1, 2014

PURPOSE

To ensure that applications are thoroughly, efficiently, and fairly assessed.

POLICY

The Committee will refer an application to the Commission when the Committee has determined that the application is outside of its delegated powers and mandate.

The Committee will refer an application to the Commission, accompanied by its recommendation that the application be denied, when it has considered an application and determined that it cannot or should not be approved.

GUIDELINE

The Committee may refer any application or other matter related to diagnostic facilities and the Policies and Guidelines directly to the Commission at any time the Committee considers it appropriate, having regard to the nature, magnitude, complexity, and significance of an application or other matter at issue.

CROSS REFERENCE

Policy 2.4.4, Conflict of Interest

Policy 2.4.6, Concurrent Like-Applications

Policy 2.6, Approval, Attaching and Changing Conditions of Approval, Cancellation of an Approval, and Recommending Denial of an Application

Policy 3.1, Transfer of Ownership Interest

Policy 3.2, No Transfer and Assignment of Approvals/Certificates of Approval

Policy 3.3, Setting Approved Baselines

Policy 3.4, Significant Change Applications

AUTHORITY

Within the general mandate of the Medical Services Commission under the authority of the *Medicare Protection Act* and the Medical and Health Care Services Regulation.

PART 2 APPLICATIONS FOR DIAGNOSTIC FACILITIES AND SERVICES

POLICY 2.6 APPROVAL, ATTACHING AND CHANGING CONDITIONS OF APPROVAL, AND RECOMMENDING DENIAL OF AN APPLICATION

EFFECTIVE HISTORY JUNE 1, 2014 (For updates see Appendix 2 – Version/Revision History)

PURPOSE

To ensure that conditions attached to an approval are relevant, appropriate, and up to date and that the Committee's approvals, conditions attached to an approval, and recommendations for denial are communicated to owners/applicants clearly, efficiently, and in a timely manner.

POLICY

Approval and conditions

The Committee will:

- a) attach such conditions to an approval/Certificate of Approval that the Committee determines are necessary or advisable having regard to the Act, the Regulation, the Policies and Guidelines, and its mandate,
- b) make effective an approval of an application on:
 - (i) the date that the Diagnostic Facilities Administration receives that application, provided that accreditation and credentialing (or other necessary preconditions) have been granted on or before that date or
 - (ii) for applications that have been granted with conditions, the date that all required conditions of approval have been met, or on a date specified as a condition of the approval, and
- c) at any time, add, remove, or alter a condition on an approval/Certificate of Approval, either of its own initiative, or following an application, as the Committee determines necessary or advisable having regard to the Act, the Regulation, the Policies and Guidelines.

Denial

The Committee must, after reviewing an application and deciding that it should be denied, refer the matter and its recommendation to the Commission for decision.

The Committee, if the Commission has denied an application on the basis of insufficient medical need, will make public that denial by posting a notice that includes the following information on the Diagnostic Facilities Administration website:

- a) the catchment area for which applications for specified services will not be accepted,
- b) the time-period for which a moratorium on subsequent or like-applications applies, and
- c) any other information the Commission or the Committee considers relevant.

Communication

The Committee will communicate in writing to the owner of a diagnostic facility an approval, renewal of an approval, an amendment of an approval/Certificate of Approval, and a recommendation for denial of an application.

CROSS REFERENCE

Policy 2.5, Referral of Applications To the Medical Services Commission
Policy 4, Subsequent Applications, Implementation, and Lapse in Service Timelines

AUTHORITY

Medical and Health Care Services Regulation, Section 41 and *Medicare Protection Act*, Section 33

PART 3 OTHER ACTIVITIES

POLICY 3.1 TRANSFER OF OWNERSHIP INTEREST

EFFECTIVE JUNE 1, 2014

PURPOSE

To ensure that the Committee and the Commission are able to monitor ownership of diagnostic facilities and assess and approve proposed significant ownership changes.

OWNER REQUIREMENTS

An owner or prospective owner must seek approval prior to a transfer of a material financial interest in an approved diagnostic facility and, depending on the nature of the interest, provide required information. Also, before the transfer of an ownership interest which is less than a material financial interest, the owner must notify the Committee in writing, in the manner the Committee requires.

POLICY

The Committee will:

- a) when considering applications for transfer of a material financial interest in an approved diagnostic facility that does not propose any other change, assess whether or not there are potential conflicts of interest in relation to the diagnostic facility in accordance with Policy 2.4.4,
- b) when considering applications for transfer of an ownership interest involving a material financial interest in an approved diagnostic facility that proposes other substantive changes to the diagnostic facility, assess the application using the assessment criteria set out in Policy 2.4. as though it were an application for a relocation or expansion of an existing facility or for a new diagnostic facility (as applicable), and
- c) when the transfer involves an ownership interest that is not a material financial interest:
 - (i) receive, review, and document the details of the required transfer of ownership interest notification before the transfer is completed, and
 - (ii) take any action required or advisable in accordance with Policy 2.4.

GUIDELINES

When considering applications regarding transfer of a material financial interest in a diagnostic facility, the Committee may:

- consider other factors it considers relevant, and
- refer the application directly to the Commission for consideration.

CROSS REFERENCE

Policy 2.4, Assessment Criteria

Policy 2.4.4, Conflict of Interest

Policy 2.5, Referral of Applications to the Medical Services Commission

Policy 3.2, No Transfer and Assignment of Approvals/Certificates of Approval

AUTHORITY

Medical and Health Care Services Regulation, Subsections 38(2), 39(2), and 43(1)(e)(iii)

PART 3 OTHER ACTIVITIES

**POLICY 3.2 NO TRANSFER OR ASSIGNMENT OF APPROVALS/CERTIFICATES
OF APPROVAL**

EFFECTIVE JUNE 1, 2014

PURPOSE

To clarify that an approval/Certificate of Approval is location- and owner-specific and that it cannot be transferred or assigned and to ensure that the Committee and the Commission monitor and approve the ownership of an approved diagnostic facility at all times.

OWNER REQUIREMENTS

Approvals/Certificates of Approval are location- and owner-specific and cannot be transferred or assigned. Therefore, a prospective owner must apply to the Commission for a new approval/Certificate of Approval if he/she wishes to have benefits provided at a diagnostic facility.

GUIDELINE

The Committee may refer a new application related to or arising from the transfer or assignment of assets directly to the Commission for consideration.

CROSS REFERENCE

Policy 2.5, Referral of Applications to the Medical Services Commission

AUTHORITY

Medical and Health Care Services Regulation, Subsection 43(1)(e)
Medicare Protection Act, Subsection 33(3), (5), and (7)

Within the general mandate of the Medical Services Commission under the authority of the *Medicare Protection Act* and the Medical and Health Care Services Regulation.

PART 3 OTHER ACTIVITIES

POLICY 3.3 SETTING APPROVED BASELINES

EFFECTIVE JUNE 1, 2014

PURPOSE

To ensure that diagnostic facilities are delivering appropriate and efficient services.

OWNER REQUIREMENTS

A prospective owner must provide the Committee with projected monthly volume and projected maximum monthly volume in relation to each approval/Certificate of Approval sought.

POLICY

The Committee will set and communicate to new and approved diagnostic facilities approved baselines for volume that continue in effect for a period of 36 months from the date set or for another time period identified by the Committee as appropriate.

New Facilities

The Committee will set approved baselines for new diagnostic facilities, at the level it determines appropriate, based on:

- a) the applicant's projected monthly volume in relation to each Certificate of Approval sought,
- b) the applicant's projected maximum monthly volume in relation to each Certificate of Approval sought,
- c) a comparison of the applicant's projected volumes with actual volumes of approved like-facilities in the catchment area, and if there are fewer than three like-facilities in the initially-identified-catchment area that are comparable to the application, in comparison to a minimum of three like-facilities in closest proximity to the proposed new facility, and
- d) any other relevant considerations.

Approved Facilities

The Committee will set approved baselines for (existing) approved diagnostic facilities based on:

- a) for diagnostic facilities that have been in operation for more than 36 months: the highest 12-consecutive-month volume period from the most recent 36-month period for which MSP billing data is available, or
- b) for diagnostic facilities that have been in operation for less than 36 months: the highest 12-consecutive-month volume period for which MSP billing data is available.

New Baselines After Significant Change

The Committee, when a significant change has been approved, will set a new approved baseline that will continue in effect for 36 months unless a further significant change application is approved during that time.

Communication

The Committee will communicate to owners the approved baseline in relation to each Certificate of Approval that applies to each diagnostic facility:

- a) when it approves a new facility,
- b) in a timely manner, for approved facilities that exist and continue at the time the Policies and Guidelines become effective,
- c) when an existing facility's approved baseline expires, and
- d) when a significant change application has been approved.

Monitoring

The Committee will monitor and assess changes in diagnostic facilities' MSP diagnostic services billings, based on applicable Certificates of Approval, to determine their performance measured against established baselines.

CROSS REFERENCE

Policy 2.4.2, Assessment Criteria: Accessibility

Policy 3.4, Significant Change Applications

AUTHORITY

Within the general mandate of the Medical Services Commission under the authority of the *Medicare Protection Act* and the Medical and Health Care Services Regulation.

PART 3 OTHER ACTIVITIES

POLICY 3.4 SIGNIFICANT CHANGE APPLICATIONS

EFFECTIVE JUNE 1, 2014

PURPOSE

To ensure that the Committee monitors the volume of diagnostic services that are benefits as defined in the Act.

OWNER REQUIREMENTS

An owner must seek and receive approval from the Committee before significant changes to a diagnostic facility's capability or capacity to deliver diagnostic service benefits occur.

POLICY

The Committee will:

- a) monitor and assess changes in diagnostic facilities' MSP diagnostic services billings for each applicable Certificate of Approval for the purposes of determining diagnostic facility adherence to the requirement to seek the Commission's approval in advance of facility changes that involve significant change in volume,
- b) assess significant change applications against the criteria set out in Policy 2.4 and in accordance with the guiding principles set out in Part 1 of the Policies and Guidelines,
- c) assess and approve a significant change application before the facility brings into use any new diagnostic equipment,
- d) assess and approve increases or decreases in MSP billing volume above or below approved baseline to a degree constituting significant change before the significant change occurs, and
- e) when a significant change application has been approved, set and communicate a new approved baseline that will continue in effect for 36 months or for another time

period identified by the Committee as appropriate unless a further significant change application is approved during that time.

GUIDELINES

The Committee may at any time:

- add, delete, or amend a condition of a diagnostic facility's approval,
- alter the approved baseline for a diagnostic facility,
- stipulate an approved maximum capacity,
- enquire into the nature and extent of a significant change and its internal and external causes if a significant change occurs but a significant change application has not been submitted and approved,
- at the level it considers appropriate, approve a new baseline for each Certificate of Approval held by the subject diagnostic facility and communicate the new-approved baseline to the diagnostic facility, and
- refer a matter related to significant change to the Commission for consideration and regulatory action authorized under the Act and Regulation.

CROSS REFERENCE

Policy 2.4, Assessment Criteria

Policy 2.5, Referral of Applications to the Medical Services Commission

Policy 2.6, Approval, Attaching and Changing Conditions of Approval, Cancellation of an Approval, and Recommending Denial of an Application

Policy 3.3, Setting Approved Baselines

Part 4, Subsequent Applications, Implementation, and Lapse In Service

AUTHORITY

Medical and Health Care Services Regulation, Subsections 40(1) and 43(1)(e)(ii) and
Medicare Protection Act, Subsection 33(2)

PART 3 OTHER ACTIVITIES

POLICY 3.5 CEASING OPERATIONS OF A DIAGNOSTIC FACILITY

EFFECTIVE JUNE 1, 2014

PURPOSE

To ensure the Committee and Commission are aware of and assess changes in supply of diagnostic service benefits in a timely manner and ensure that beneficiaries have reasonable access to diagnostic service benefits.

OWNER REQUIREMENTS

An owner must inform the Committee at least 60 days prior to ceasing operations.

POLICY

The Committee will:

- a) receive notice of the intention to cease operations of a diagnostic facility, and
- b) if applicable, where another owner or prospective owner seeks to provide diagnostic service benefits that were previously provided by a diagnostic facility that is ceasing operations, receive and review (in accordance with the Policies and Guidelines) an application relating to the diagnostic services/facility for which approval is sought.

CROSS REFERENCE

Part 2, Applications for Approval of Diagnostic Facilities/Services, Policies 2.1 to 2.6

AUTHORITY

Within the general mandate of the Medical Services Commission under the authority of the *Medicare Protection Act* and the Medical and Health Care Services Regulation.

PART 3 OTHER ACTIVITIES

POLICY 3.6 RELOCATION

EFFECTIVE April 5, 2017

PURPOSE

To articulate the required criteria for how the Committee and Commission assess applications for relocation of diagnostic facilities to ensure that beneficiaries are able to maintain reasonable access to diagnostic services in a given geographic catchment area.

OWNER REQUIREMENTS

The facility owner must apply to the Committee and Commission for approval to relocate an existing approved diagnostic facility.

POLICY

The Committee will assess an application for a relocation of an existing diagnostic facility for evidence of meeting the criteria set out in the Medical and Health Care Services Regulation (see Policy 2.2 and 2.3), and the Policies and Guidelines of the Medical Services Commission's Advisory Committee on Diagnostic Facilities (see Policy 2.4.1-2.4.6). In addition, the Committee will assess applications on the following criteria:

- a) that the relocation of an existing diagnostic facility is within the same geographic catchment area,
- b) that the relocation does not unduly impact existing facilities in the proposed new location and the delivery and management of services as previously approved will be maintained at the proposed new site of the applicant facility,
- c) current patient access is not compromised and the quality of service delivery remains consistent or improves in the proposed new location,
- d) that utilization of services at the proposed new location are within the parameters of the facility's current approval,

- e) there is reasonable utilization of existing approved diagnostic facilities which provide the same services for which approval is sought and which are located within the catchment area under consideration,
- f) if the application is requesting relocation and expansion, that there is sufficient medical need to warrant any increase in proposed services, and
- g) the applicant seeking approval does not have a potential conflict of interest.

GUIDELINES

The Committee may (as per policy 2.3), in assessing applications:

- apply criteria and considerations in addition to those specified in the Act and the Regulation, and
- apply criteria in a flexible manner by considering all relevant criteria in the context of the particular application and relevant circumstances.

The Committee (as per policy 2.3) may:

- invite any advisor or expert it determines advisable to provide information and advice to inform its deliberations and the exercise of its duties and functions, and
- receive such information and advice at any Committee meeting or in any manner and at any time the Committee considers appropriate.

CROSS REFERENCE

Policy 2.1, Activity Requiring Approval

Policy 2.2, Required Application Information

Policy 2.3, Committee's Approach to Application Assessment

Policy 2.4 – 2.4.6, Assessment Criteria

Policy 2.6, Approval, Attaching and Changing Conditions of Approval, Cancellation of an Approval, and Recommending Denial of an Application

AUTHORITY

Medical and Health Care Services Regulation, Subsection 39(1) and 40(1) and within the general mandate of the Medical Services Commission under the authority of the *Medicare Protection Act* and the Medical and Health Care Services Regulation.

PART 4 SUBSEQUENT APPLICATIONS, IMPLEMENTATION, AND LAPSE IN SERVICE

EFFECTIVE JUNE 1, 2014

PURPOSE

To ensure that diagnostic service benefits that have been approved to be provided at a diagnostic facility are provided in an efficient and timely manner and that the Committee can effectively manage the supply of approved diagnostic services to beneficiaries.

OWNER REQUIREMENTS

The owner or prospective owner must comply with specific timelines with respect to subsequent applications, applications for like services in a catchment area, implementation of approved services, and lapse in services.

POLICY

Subsequent Applications and Like-Applications

The Committee will:

- a) not accept or consider a subsequent application for either a new diagnostic service, the relocation of an existing diagnostic facility, or the expansion of a diagnostic facility (including a significant change expansion) from the same applicant in respect of the same location before a period of 18 months from the original application date⁷ has elapsed, unless the Commission directs consideration of the subsequent application,
- b) not accept or consider a like-application before a period of 18 months from the original application date has elapsed if the Commission has denied the original application due to a determination of insufficient medical need within the applicable catchment area, and,
 - if, within the applicable 18-month moratorium period, the Commission determines that medical need for a diagnostic service has arisen within the

⁷ That is, 18 months from the date when the original application was received by the Diagnostic Facilities Administration.

applicable catchment area, lift the moratorium and post a general notice on the Diagnostic Facilities Administration website to reflect that change (see also Policy 2.6).

- c) not give priority consideration to an application from an applicant who was previously denied approval following the lifting of a moratorium.

Implementation

The Committee:

- a) will ensure that after an application has been approved, a diagnostic facility has begun providing the new service and/or begun providing services at a new location (as applicable) within 18 months of the date of the letter of approval or another approval date communicated to the applicant by other means, whichever occurs first,
- b) may cancel the approval of a previously-approved diagnostic facility that has not begun providing the new service within this implementation period, or alternatively, refer and recommend to the Commission cancellation of the approval,
- c) will consider, on a one-time only basis, applications for extension that are submitted no later than 60 days prior to the expiry of the 18-month implementation period and grant an extension:
 - i) if the Committee determines the delay in implementing new services is the result of extenuating, unforeseeable circumstances, and
 - ii) for up to 12 months beyond the initial 18-month implementation period
- d) Will not apply this implementation policy to situations involving construction or significant physical expansion of public diagnostic facilities (see Policy 2.4.2).

Lapse In Service

The Committee:

- a) may cancel the approval of a previously-approved service when there have been no MSP billings for an approved diagnostic service submitted for a period of six consecutive months, or alternatively, refer and recommend to the Commission cancellation of the approval; and

- b) will consider, on a one-time only basis, applications for extension that are submitted no later than 30 days prior to the expiry of the 6-month lapse in service period and grant an extension:
 - i) if the Committee determines the lapse in services is the result of extenuating, unforeseeable circumstances, and
 - ii) for up to 6 months beyond the initial 6-month lapse in service period.

CROSS REFERENCE

Policy 2.4.2, Assessment Criteria: Accessibility (re: catchment area and expansion of public diagnostic facilities)

Policy 2.6, Approval, Attaching and Changing Conditions of Approval, Cancellation of an Approval, and Recommending Denial of an Application

Policy 3.4, Significant Change Applications

AUTHORITY

Medicare Protection Act, Subsection 33(7) and within the general mandate of the Medical Services Commission under the authority of the *Medicare Protection Act* and the Medical and Health Care Services Regulation.

PART 5 REPORTING

EFFECTIVE: JUNE 1, 2014

PURPOSE

To ensure that the Committee regularly receives the data it requires to monitor the capability, capacity, and performance of diagnostic facilities and services.

OWNER REQUIREMENTS

An owner must submit capacity-related data, wait times-related data, and other information if and as required by the Committee, to the Diagnostic Facilities Administration.

POLICY

The Committee will:

- a) identify and communicate to owners the information elements, and the manner and form, of reports that are required to be submitted to the Diagnostic Facilities Administration biannually, in November and May of each year, or other times the Committee determines appropriate, and
- b) receive and review the required information and reports that approved diagnostic facilities submit.

GUIDELINES

The Committee may require owners to report the following information to the Diagnostic Facilities Administration:

- capacity-related data,
- wait time-related data,
- the name of the current, relevant medical directors and/or regional directors or other staff/officials with responsibilities respecting approved diagnostic services at the facility,

- information related to replacement equipment, and
- any other information the Committee requires to perform its duties and functions.

AUTHORITY

Within the general mandate of the Medical Services Commission under the authority of the *Medicare Protection Act* and the Medical and Health Care Services Regulation.

APPENDIX 1: MEDICAL SERVICES COMMISSION-ENDORSED PROVINCIAL WAIT TIME BENCHMARKS

The following table contains provincial wait time benchmark's endorsed by the Medical Services Commission for the purposes of considering and assessing applications in accordance with Committee Policy 2.4.2.

Service Category:	Wait Time Benchmark:
Polysomnography	<ul style="list-style-type: none"> ▪ Priority 1⁸: 2-4 weeks ▪ Priority 2⁹: 2 months ▪ Priority 3¹⁰: 6 months
Bone Densitometry	(Approximately) 1 month
Echocardiography	15 working days
Urgent, Non-emergency Ultrasound	10 working days

⁸ Priority 1 (Urgent)

Patients with:

- suspected sleep disorder; and
- major daytime sleepiness (ESS 10 or greater); and
- one or more of the following
 - co-morbid disease (ischemic heart disease, cerebrovascular disease, congestive heart failure, obstructive/restrictive lung disease, pulmonary hypertension, hypercapnic respiratory failure) or,
 - high risk occupation (truck, taxi, bus drivers; railway engineers, airline pilots, car drivers who admit to have fallen asleep while driving within the last two years (all patients who are considered high risk should be told to cease their occupation and personal driving until after their polysomnogram has been reviewed and/or appropriate treatment has commenced) or,
 - overnight home oximetry which reveals >10/hour 4% desaturations.

⁹ Priority 2

Patients with:

- suspected sleep disorder; and
- major daytime sleepiness (ESS 10 or greater); but
- with no co-morbid disease or high risk occupation.

¹⁰ Priority 3

Patients with:

- suspected sleep disorder; but without
 - major daytime sleepiness (i.e., ESS <10); or
 - co-morbid diseases; or high risk occupation

APPENDIX 2:
VERSION/REVISION HISTORY

Date Approved by Commission	Policy	Comments/Summary of Changes
February 26, 2015	2.4.6 Concurrent Like-Applications	Guidelines for Committee members to utilize when assessing Like-Applications at the same ACDF meeting.
February 1, 2016	2.4.5 Compliance with Canadian and B.C. Law	Amended policy and removed 7 year term-limit.
April 27, 2016	2.4.3 Service-Specific Criteria	Added general requirements for Polysomnography.
June 29, 2016	2.6 Approval, Attaching and Changing Conditions of Approval, and Recommending Denial of an Application	Removed Committee's powers to cancel an Approval/Certificate of Approval
December 7, 2016	2.4.3 Assessment Criteria: Service Specific Criteria Ultrasound (Distance-Reading Telemetry)	Added revised policy and guidelines for Ultrasound (Distance-Reading) Telemetry
April 5, 2017	2.1 Activity Requiring Approval and 3.6 Relocation	Added in general requirements for Relocation.
April 5, 2017	2.4: Assessment Criteria: 2.4.2 Accessibility	Expanded catchment area for Polysomnography from health authority boundaries to health service delivery areas.
April 5, 2017	2.4: Assessment Criteria: 2.4.3 Service-Specific Criteria	Amended minimum bed requirement to 3 for Polysomnography.
May 17, 2017	2.4: Assessment Criteria: 2.4.3 Service-Specific Criteria	Added criteria for Privately-owned facilities to submit a letter of support from the representative, or authorized delegate, of the owner of the publicly-owned diagnostic facility when submitting an application for a Certificate of Approval.
October 25, 2017	2.4: Assessment Criteria: 2.4.3 Service-Specific Criteria	Added non-cardiac Doppler studies policy for privately-owned facilities.
February 14, 2018	n/a	Removed electrocardiography as a restricted modality.
June 27, 2018	2.4: Assessment Criteria	Added additional criteria for

		approval(s) under exceptional circumstances for applications where outpatient diagnostic services are required in direct support of a Ministry of Health priority initiative(s).
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