Approval-Related Policies and Guidelines for Laboratory Facilities Providing Out-patient Laboratory Services on a Fee-For-Service Basis

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Ministry of Health
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BRITISH COLUMBIA | Ministry of Health

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DEFINITIONS

The following terms as defined here are used throughout the Approval 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.

"access" and "accessibility" means or refers to a beneficiary's ability to secure access, within a reasonable period of time, to outpatient laboratory services that are benefits.

"agreement" means a laboratory services agreement made under Subsection 12(1) of the *Laboratory Services Act* (the "Act"), that is, in relation to the provision of benefits. (See Sections 1 and 12 of the Act.)

"application" means an application for a new laboratory facility, for relocation or expansion of an existing laboratory facility, for a change to persons having a material financial interest in a laboratory facility, or for any other change or activity for which approval is required under the Act or the Laboratory Services Regulation (the "Regulation"). (See also Policy 2.1, Activity Requiring Approval.)

"approval" means an approval granted under section 11 of the Act, which among other things, provides that the Minister may "grant to an operator an approval to provide benefits through a specified laboratory facility". (Defined in Section 1 of the Act.)

"approved laboratory facility" means a laboratory facility that is subject to an approval or to a laboratory services agreement. (Defined in Section 1 of the Act.) Note, however, that the Approval Policies and Guidelines do not apply in respect of agreements or facilities subject to agreements—see Introduction of the Approval Policies and Guidelines.

"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. (Pursuant to Section 1 of the Act and as defined in Section 1 of the *Medicare Protection Act*.)

"benefit", other than as used in section 68 of the Act [no benefit from offence], means a laboratory service that is a benefit under Section 4. (Defined in Section 1 of the Act.) Section 4 provides as follows:

> (1) Subject to subsection (2), a laboratory service is a benefit if it is a medically required service provided

(a) through an approved laboratory facility, and

(b) by or under the supervision of a laboratory medicine physician or a prescribed person who is acting

(i) at the request of a referring practitioner or a prescribed person, and

(ii) in accordance with all applicable protocols approved by the minister.

(2) The minister may make orders as follows:

(a) that a laboratory service or a class of laboratory services are not benefits;

(b) that a laboratory service is a benefit only if provided

(i) on the request of a specified referring practitioner or class of referring practitioners,

(ii) in respect of a specified type of human injury, disease or illness, or

(iii) in a specified laboratory facility or class of laboratory facilities.

“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 outpatient (laboratory service) benefits and/or beneficiaries a laboratory facility can accommodate within a given time period.

“capability” means the ability of a laboratory facility to provide a specific laboratory service by having, for example, appropriately trained staff, appropriate equipment, and appropriate space.

“catchment area” means the geographic area that Laboratory Approval Staff identify for each application and is a factor in determining and assessing service need, access, wait times, reasonable utilization of existing approved facilities, and proximity to other laboratory facilities in that geographic area.

“cease operations” means to discontinue providing one or more, or all, types of benefits that have been approved to be performed through a specified laboratory facility.

"child" means a person who:

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

"expansion" in relation to an existing laboratory facility means a:

- change or addition of laboratory services to be provided at an approved laboratory facility, or
- significant change to the capability or capacity of the approved laboratory facility to provide laboratory services, which includes significant change to the physical clinical space of the laboratory facility.

"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.

"Laboratory Approval Staff" means Ministry of Health staff who has been assigned responsibility to administer the Approval Policies and Guidelines.

"laboratory facility" means the following:

(a) in respect of a hospital within the meaning of paragraph (a) or (e) of the definition of "hospital" in section 1 of the *Hospital Insurance Act*, that part of the hospital that provides laboratory services;

(b) a facility that provides laboratory services;

(c) a specimen collection station associated with a hospital or facility referred to in paragraph (a) or (b) of this definition.

(Defined in Section 1 of the Act.)

"laboratory medicine physician" means a medical practitioner registered with, and authorized to practise in a prescribed specialty by, the College of Physicians and Surgeons of British

Columbia. (Defined in Section 1 of the Act; see also Section 5 of the Regulation for list of prescribed specialties.)

"laboratory service", subject to the Regulation, means

(a) the taking or collecting, or the analysis, of specimens for the purposes of preventing, diagnosing or treating human injury, disease, or illness, or

(b) a prescribed service.

"like-application" means an application for the same laboratory service(s) within the same catchment area.

"like-facility" means a laboratory facility that provides outpatient laboratory services that are benefits of the same type as those provided by another comparator laboratory facility and which is in the same catchment area as the comparator laboratory facility. Identified like-facilities are used to assess wait times, service need, proximity and access to services, and utilization of existing facilities.

"material financial interest**":** a person has a material financial interest in a corporation or a laboratory facility if the person holds an interest

(a) in the corporation or laboratory facility as a sole proprietor or partner, or

(b) of more than 10% of the shares in the corporation or laboratory facility.

(As defined in Section 2(1) of the 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 Medical and Health Care Services Regulation.

"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*.)

"new service" means a type of laboratory service for which a facility does not have, but seeks, an approval.

"operator", in relation to a laboratory facility, means the following:

(a) the owner;

(b) the person having responsibility for the daily operation of the laboratory facility;

(c) a regional health board or prescribed agency.

(Defined in Section 1 of the Act.)

"personal information" has the same meaning as in the *Freedom of Information and Protection of Privacy Act.* (Defined in Section 1 of the Act).

"prescribed agency" for the purposes of the definition of "prescribed agency" in Section 1 of the Act and the Approval Policies and Guidelines, the following bodies are prescribed:

(a) British Columbia Cancer Agency Branch;

(b) British Columbia Centre for Disease Control and Prevention Society Branch;

(c) Children's & Women's Health Centre of British Columbia Branch;

(d) Provincial Health Services Authority.

(As specified/prescribed in Section 6 of the Regulation.)

"privately-owned laboratory facility" means a facility that:

- is not a public laboratory facility and
- must be approved in order to provide laboratory service benefits.

"public laboratory facility" means the following:

(a) in respect of a hospital within the meaning of paragraph (a) or (e) of the definition of "hospital" in section 1 of the *Hospital Insurance Act*, that part of the hospital that provides laboratory services;

(b) a specimen collection station that is associated with a hospital referred to in paragraph (a);

(c) a laboratory that is funded, managed or operated by a regional health board or a prescribed agency.

(Defined in Section 1 of the Regulation.)

"referring practitioner" means a person who

(a) is either

(i) a medical practitioner enrolled under section 13 of the *Medicare Protection Act,* or

(ii) a person within a class of prescribed health care practitioners, and

(b) makes a request for a beneficiary to receive benefits.

(Defined in Section 1 of the Act.)

"specimen collection station" means a place that is principally equipped for the taking or collecting of specimens. (Defined in Section 1 of the Act.)

INTRODUCTION

High-level purpose and scope

This document, Approval-Related Policies and Guidelines for Laboratory Facilities Providing Outpatient Laboratory Services on a Fee-For-Service Basis (the Approval Policies and Guidelines), is intended to assist and guide the work of Ministry of Health ("Ministry") staff/public officers in exercising powers and performing duties within the scope of the Approval Policies and Guidelines—essentially powers and duties related, and incidental, to approval of laboratory services benefits to be provided through laboratory facilities.

The Approval Policies and Guidelines apply to both new facilities and generally to grandparented/existing facilities that continue when the Act and the Approval Policies and Guidelines come into force (October 1, 2015); however, nothing in the Approval Policies and Guidelines derogates from the transitional powers that apply in respect of grandparented facilities, such as those set out in Section 77 of the Act.

Outside the Scope of the Approval Policies and Guidelines

The Approval Policies and Guidelines do not apply in respect of agreements (under the *Laboratory Services Act*, the "Act") or facilities subject to agreements, nor do the Approval Policies and Guidelines apply in respect of inpatient laboratory services or laboratory services that are not funded on a publicly-funded, fee-for-service basis. However, laboratory services provided pursuant to agreements will be considered when assessing applications, for instance, by considering the capability and capacity of facilities subject to relevant agreements and by considering health system impacts and the public interest.

The Approval Policies and Guidelines do not deal with many powers and duties that are set out in the Act and Laboratory Services Regulation (the Regulation); for instance, defining what are "benefits" under the Act (Section 4), entering into "agreements" respecting laboratory services (Section 12), payments for providing benefits (Section 14), and audits and inspections not in relation to approvals (see Part 4, Division 1) are outside the scope of the Approval Policies and Guidelines.

Authority Under the Act and Regulations

Under the authority of the Act and the Regulation, the Minister of Health ("Minister") is responsible for the administration and provision of (laboratory service) benefits. Due to the high volume of approval-related decision-making and related actions, the technical and clinical complexity of the subject matter, and the existence of sufficient resources, expertise and experience within the Ministry, Ministry staff/public officers (hereafter "Laboratory Approval

Staff") will exercise the powers and perform the duties in relation to approvals that are within scope of the Approval Policies and Guidelines for and on behalf of the Minister.
The mandate of Laboratory Approval Staff under the Approval Policies and Guidelines is to consider laboratory facility/services applications, and to exercise or perform approval-related or incidental powers or duties. All duties and powers must be exercised/performed in accordance with the Act, the Regulation, and the Approval Policies and Guidelines.

The Approval Policies and Guidelines bring together the statutory requirements related to laboratory facilities and build upon them, providing additional guidance where required.

In exercising and performing duties, Laboratory Approval Staff do not mechanically apply the Approval Policies and Guidelines, but consider whether they are appropriate to the particular facts and circumstances of each application or other approval-related situation. Laboratory Approval Staff consider all relevant factors in the exercise of their discretion and exercise discretion in a manner that conforms to the objectives and scheme of the Act.

Laboratory Approval Staff assess applications in accordance with the Regulation (Section 8) that requires that:

- there is sufficient need, with respect to capability, capacity, quality of service, cost or other factors to warrant the proposed laboratory services, including that needs are not being met by existing approved laboratory facilities that provide the proposed laboratory services and are located within the same catchment area;
- the quality of laboratory services will be maintained at a sufficiently high level;
- no existing or potential conflicts of interest are identified;* and
- it would be in the public interest to grant the approval.

(*Per Section 8(2) of the Regulation, approval may be granted in exceptional circumstances where a potential conflict of interest exists but it is determined that the services could not reasonably be provided by another laboratory facility.)

Pursuant to Section 11 of the Act, Laboratory Approval Staff have the authority to approve laboratory facilities for the purposes of permitting laboratory services that are benefits to be provided at or through the laboratory facility. Approvals may be temporary, and conditions may be imposed on approvals. Additionally, and subject to the Approval Policies and Guidelines [see, in particular, Policy 2.6], Laboratory Approval Staff may also: (1) add, delete, or amend limits or conditions attached to an approval, as necessary or advisable, and (2) cancel approvals (in one specified administrative circumstance).

The Regulation specifies certain (mandatory) criteria for the consideration and approval of laboratory facilities and services-related activities and applications, including applications for new facilities (that is, to allow an operator to provide benefits through a specified laboratory facility), for the relocation or expansion of existing facilities, for a transfer of material financial

interest, and for significant changes to facility capability or capacity to provide laboratory services. Important considerations such as conflict of interest (existing or potential), need/access (e.g., within a catchment area), and utilization of existing approved laboratory facilities are provided for in the legislation. The Approval Policies and Guidelines outline additional considerations and also provide direction and guidance on how criteria are to be considered and applied by Laboratory Approval Staff.

This document is not a comprehensive guide to or substitute for the Act and Regulation. While the Approval Policies and Guidelines articulate many of the roles, requirements, and obligations of prospective and current laboratory facility operators and applicants, it should not be used as an application or compliance checklist. Compliance with the Approval Policies and Guidelines will not ensure or constitute compliance with applicable law. Applications and other forms related to the Approval Policies and Guidelines are available on the Laboratory Services website linked here.

The Approval 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 Approval Policies and Guidelines are effective October 1, 2015 and replace the prior policies of the Medical Services Commission that relate to the approval of outpatient laboratory services provided on a fee-for-service basis.

PART 1 GUIDING PRINCIPLES AND OBJECTIVES

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To articulate the principles that guide the work of Laboratory Approval Staff under the Approval Policies and Guidelines.

POLICY

Laboratory Approval Staff must perform duties and functions with transparency, fairness, consistency, and timeliness.

Laboratory Approval Staff, in exercising powers and performing duties related to laboratory facility and service approvals, must have regard to the principles expressed in Sections 5.1-5.7 of the *Medicare Protection Act*, namely: public administration; comprehensiveness (in relation to benefits); universality; portability; accessibility; and sustainability.

AUTHORITY

Laboratory Services Act, Section 3.
Medicare Protection Act, Sections 5.1-5.7.

PART 2 APPLICATIONS AND NOTIFICATIONS FOR LABORATORY FACILITIES AND SERVICES

POLICY 2.1 ACTIVITY REQUIRING APPROVAL

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To articulate the types of application that are subject to review and approval by Laboratory Approval Staff.

OWNER/OPERATOR REQUIREMENTS

When an Application for New Approval is Required
The owner or intended/prospective owner (as applicable) must apply for a new approval when seeking any of the following:

- a new laboratory facility;
- the relocation of an existing approved laboratory facility, or
- the transfer of a material financial interest in an approved laboratory facility (that is, change to the persons having a material financial interest in the approved facility).

When an Application for an Amendment to an Approval is Required
An operator must apply for an amendment to an existing approval when seeking any of the following:

- a change or addition of laboratory services to be provided through the laboratory facility;
- a significant change to the capability or capacity of the approved laboratory facility to provide laboratory services (which includes significant change to the physical clinical space of the laboratory facility);
- desired changes to the limits and conditions attached to an approval,
- a change to the date/term the approval expires that is, an extension or renewal of a time-limited approval.

POLICY

The Laboratory Approval Staff will review applications made for approval of:

a) a new laboratory facility,

b) the relocation of an existing approved laboratory facility,

c) a change regarding the persons having a material financial interest in an approved laboratory facility,

d) a change or addition of laboratory services to be provided at an approved laboratory facility,

e) a significant change to the capability or capacity of an approved laboratory facility to provide laboratory services (which includes significant change to the physical clinical space of the laboratory facility),

f) changes to the limits and conditions attached to an approval, or

g) a change to the date/term the approval expires, that is, an extension or renewal of a time-limited approval. [Only relevant to time-limited approvals.]

CROSS REFERENCE

Policy 3.1, Transfer of Ownership Interest (Change to Persons Having a Material Financial Interest in a Facility)
Policy 3.3, Significant Change Applications

AUTHORITY

Laboratory Services Act, Section 11 and Laboratory Services Regulation, Sections 7, 9, and 10.

PART 2 APPLICATIONS AND NOTIFICATIONS FOR LABORATORY FACILITIES AND SERVICES

POLICY 2.2 REQUIRED APPLICATION INFORMATION

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To clarify the information that Laboratory Approval Staff require in an application for a new approval or an amendment to an existing approval and to indicate the required timeframes for submitting an application seeking approval.

OWNER/OPERATOR REQUIREMENTS

The (i) owner or intended/prospective owner or (ii) operator, as applicable, must submit specific and complete information in/with applications for new approvals or amendments to existing approvals.

POLICY

New Approval–In Respect of a New Laboratory Facility Not Previously Approved

Only applications for an approval in respect of a new (not previously approved) laboratory facility that provide the following information, in a complete and legible format (in the manner Laboratory Approval Staff require), at least 90 days[1] prior to the date on which the applicant requests the approval to be effective, will be considered by Laboratory Approval Staff:

a) the (proposed) address or addresses of the laboratory facility or,

b) the name of the owner of the laboratory facility,

c) the name and contact information of the person having responsibility for the daily operation of the laboratory facility,

d) the name and qualifications of each laboratory medicine physician who will be providing or supervising the provision of benefits through the laboratory facility,

e) the names of all persons who have a material financial interest in the laboratory facility and, if the persons are shareholders, the percentage of the shares that they own,

[1] Note exception in Guideline, below.

f) information about any existing or potential conflict of interest that the applicant has reason to be aware of in respect of referring practitioners who may request benefits to be provided through the laboratory facility,

g) a list of all laboratory services that are proposed to be provided through the laboratory facility,

h) a description of the capabilities and capacities of the major equipment to be used in the laboratory facility,

i) the proposed hours of operation of the laboratory facility,

j) a list and description of all quality control procedures of the major equipment planned for the laboratory facility, including quality control programs of a formal nature.

k) if applicable, information related to foreign ownership (see Policy 2.5.5, Compliance with Canadian and B.C. law), and

l) any other information or documentation Laboratory Approval may specify and require that is relevant to performance of Laboratory Approval Staffs' duties and functions.

Changes to Approval—New Approval Required—In Respect of Laboratory Facility with an Existing Approval

Applications for a new approval [See Policy 2.1 Activity Requiring Approval for circumstances in which an approved laboratory facility must apply for a *new* approval], in respect of a laboratory facility with an existing approval, must:

a) be provided at least 30 days prior to the date on which the applicant requests the approval to be effective, and

b) be complete and legible, supplying the information and documentation the Laboratory Approval Staff stipulate and in the manner Laboratory Approval Staff require, which may be any or all elements indicated above [*New Approval –In Respect of a New Laboratory Facility Not Previously Approved*].

Changes to Approval—Amendment to an Approval Required—In Respect of Laboratory Facility with an Existing Approval

Applications for an amendment to an approval [See Policy 2.1 Activity Requiring Approval for circumstances in which an approved laboratory facility must apply for an *amended* approval], in respect of a laboratory facility with an existing approval must:

a) be provided at least:

   i. 30 days before the term of approval expires, if the change is to extend the term of the approval, or

   ii. 30 days prior to the date the applicant requests an approval for any of the following to be effective: (i) a change to the laboratory services to be provided through the laboratory facility, (ii) a change to the limits or conditions attached to the existing approval, (iii) a significant change to the capability or capacity of the laboratory facility to provide laboratory services; and

b) be complete and legible, supplying the information and documentation the Laboratory Approval Staff stipulate and in the manner Laboratory Approval Staff require, which may be any or all elements indicated above [*New Approval –In Respect of a New Laboratory Facility Not Previously Approved*].

Multiple Applications May Be Made Concurrently

Applicants may concurrently submit multiple applications for approval, including applications that require new approvals and those that require amendments to an approval. Laboratory Approval Staff will consider multiple concurrent applications in accordance with Policy 2.6 [Approval, Attaching/Changing Conditions, etc., Denials, Cancellation] in particular and the Approval Policies and Guidelines in general.

GUIDELINE

Regarding applications for a new approval for a new laboratory facility, Laboratory Approval Staff may consider an application received less than 90 days prior to the date on which the applicant requests the approval to be effective, at its discretion.

Regarding applications for changes requiring a *new* approval or an *amendment* to an existing approval, Laboratory Approval Staff may consider an application received less than 30 days prior to the date on which the applicant requests the approval to be effective, at its discretion.

CROSS REFERENCE

Policy 2.1, Activity Requiring Approval
Policy 2.5.3, Conflict of Interest

Policy 2.5.5, Compliance with Canadian and B.C. Law
Policy 2.6, Approval, Attaching and Changing Limits and Conditions of Approval, Cancellation of an Approval, and Denial of an Application

AUTHORITY

Laboratory Services Regulation, Sections 7-9 and *Laboratory Services Act*, Subsection 11(1) and Sections 26 and 27.

PART 2 APPLICATIONS AND NOTIFICATIONS FOR LABORATORY FACILITIES AND SERVICES

POLICY 2.3 ACTIVITY REQUIRING NOTIFICATION

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To describe the circumstances in which operators must provide notice to Laboratory Approval Staff, and the required timeframes for doing so.

OWNER/OPERATOR REQUIREMENTS

Operators must provide Laboratory Approval Staff with notifications, complete with such information as the Laboratory Approval Staff may require, within required timeframes when certain changes are intended/proposed.

POLICY

Operators must notify Laboratory Approval Staff, in writing (in the manner Laboratory Approval Staff require), at least 30 days before a change to any of the following:

a) the laboratory medicine physicians who will be providing or supervising the provision of benefits through the laboratory facility;

b) the contact information of the person having responsibility for the daily operation of the laboratory facility;

c) the hours of operation of the laboratory facility.

Laboratory Approval Staff must

a) receive, review, and document the details of required notification information; and

b) take any action required or advisable in accordance with the Approval Policies and Guidelines.

CROSS REFERENCE

Policy 3.1, Transfer of Ownership Interest (Change to Persons Having a Material Financial Interest in a Facility)
Policy 3.4, Ceasing Operations of a Laboratory Facility

AUTHORITY

Laboratory Services Regulation Subsection 10(1) and *Laboratory Services Act* Sections 26 and 27.

PART 2 APPLICATIONS AND NOTIFICATIONS FOR LABORATORY FACILITIES AND SERVICES

POLICY 2.4 LABORATORY APPROVAL STAFF APPROACH TO APPLICATION ASSESSMENT

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To articulate the general approach that Laboratory Approval Staff take in assessing applications for new approvals or changes to existing approvals.

POLICY

When assessing applications, Laboratory Approval Staff will:

a) apply the mandatory criteria and requirements specified in the Act and the Regulation,

b) document the application of criteria and considerations additional to those specified in the Act and the Regulation,

c) exercise discretion appropriately and use their best judgement, and

d) consider what, if any, limits and conditions are or might be necessary or advisable to attach to an approval, having regard to the Act, the Regulation, and the Approval Policies and Guidelines.

GUIDELINES

Laboratory Approval Staff may, in assessing applications:

a) apply relevant criteria and considerations in addition to those specified in the Act and the Regulation, and

b) apply criteria in a flexible manner by considering all relevant criteria, and according them appropriate weight, in the context of the particular application and relevant circumstances.

Laboratory Approval Staff may:

a) invite any advisor or expert they determine advisable to provide information and advice to inform their deliberations and the exercise of their duties and functions, and

b) receive such information and advice at any meeting or in any manner and at any time Laboratory Approval Staff consider appropriate.

CROSS REFERENCE

Policy 2.1, Activity Requiring Approval
Policy 2.2, Required Application Information
Policy 2.5 - 2.5.6, Assessment Criteria
Policy 2.6, Approval, Attaching and Changing Limits and Conditions of Approval, Cancellation of an Approval, and Recommending Denial of an Application

AUTHORITY

Laboratory Services Regulation, Sections 8-10 and *Laboratory Services Act*, Sections 10 and 11

PART 2 APPLICATIONS AND NOTIFICATIONS FOR LABORATORY FACILITIES AND SERVICES

POLICY 2.5 ASSESSMENT CRITERIA

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To articulate the criteria Laboratory Approval Staff use to assess an application for an approval, that is, for both new approvals and changes to approvals.

OWNER/OPERATOR REQUIREMENTS

Applications (by owners/operators, as required) must meet specific criteria in order to be approved.

POLICY

Laboratory Approval Staff will assess applications for evidence of meeting the criteria and requirements set out in:

a) the Regulation (see Policy 2.2 and 2.4), and

b) the Approval Policies and Guidelines (see Policy 2.5.1-2.5.6 that follow).

CROSS REFERENCE

Policy 2.2, Required Application Information
Policy 2.5-2.5.6, Assessment Criteria
Policy 3.1, Transfer of Ownership Interest (Change to Persons Having a Material Financial Interest in a Facility)
Policy 3.3, Significant Change Applications

AUTHORITY

Laboratory Services Regulation, Section 8.

PART 2 APPLICATIONS AND NOTIFICATIONS FOR LABORATORY FACILITIES AND SERVICES

POLICY 2.5.1 ASSESSMENT CRITERIA: QUALITY

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To ensure that Laboratory Approval Staff assess applications with regard to quality of laboratory services.

OWNER/OPERATOR REQUIREMENTS

Applications must meet specific criteria related to quality of laboratory services in order to be approved. Required accreditation and physician qualifications must be maintained at all times benefits are provided through the laboratory facility.

POLICY

The Laboratory Approval Staff will base their assessment of an application's fulfillment of quality criteria on:

a) whether the laboratory 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 physicians (names and qualifications) specified in the application pursuant to Section 7(2)(d) of the Regulation are in fact laboratory medicine physicians.

Laboratory Approval Staff may approve an application for a laboratory facility that has not yet received the required facility accreditation or does not have requisite laboratory medicine physicians only if, and on condition that, the accreditation and laboratory medicine physician qualification requirements are satisfied prior to benefits being provided through the laboratory facility.

CROSS REFERENCE

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

AUTHORITY

Laboratory Services Regulation, Subsection 8(1)(b).

PART 2 APPLICATIONS AND NOTIFICATIONS FOR LABORATORY FACILITIES AND SERVICES

POLICY 2.5.2 ASSESSMENT CRITERIA: SUFFICIENT NEED/ACCESSIBILITY

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To ensure that Laboratory Approval Staff assess applications with regard to access to laboratory services and whether there is sufficient need in relation to proposed laboratory services.

OWNER REQUIREMENTS

There are no specific owner requirements regarding access and sufficient need additional to the information and other requirements referenced or implicit in Policy 2.2 and Policy 2.5.

POLICY

Sufficient Need

In accordance with the Regulation—in particular, Subsection 8(1)(a)—, Laboratory Approval Staff must undertake a contextual analysis to assess whether there is sufficient need for the (proposed) laboratory services. In so doing, the Laboratory Approval Staff must:

a) consider whether there is sufficient need (for the proposed service) having regard to:

   i. the capability, capacity and quality of service, cost and any other relevant factors (including agreements-related capability and capacity); and

   ii. whether or not existing approved laboratory facilities that are like-facilities (that is, that provide the laboratory services proposed by the applicant and are located within the same catchment area the Laboratory Approval Staff determines appropriate to the application) are not meeting beneficiary and health system needs, and, relatedly, whether existing approved like-facilities are being reasonably utilized; and, relatedly,

b) consider the accessibility of (laboratory service) benefits to beneficiaries.

For the purposes of this Policy (Policy 2.5.2), the concepts of catchment area, accessibility, and reasonable utilization of existing facilities are explained below.

Catchment Area

Laboratory Approval Staff may determine the catchment area that applies to an application by any means they determine appropriate, and, for example, may determine the applicable catchment area by 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

Laboratory Approval Staff may expand the applicable catchment area for all laboratory services, as determined appropriate to the application; Laboratory Approval Staff may determine that the applicable catchment area is the entire Province of British Columbia.

Accessibility—Distance, Travel Time, Ratio of Beneficiaries to Chairs

Laboratory Approval Staff will assess whether the access criteria have been met by considering:

a) the distances between like-facilities, (if applicable, when the catchment area determined appropriate is considered),

b) beneficiaries' travel time, and

c) other metrics, if Laboratory Approval Staff deem appropriate/applicable, for instance, comparing the ratio of beneficiaries to laboratory chairs in the catchment area to the provincial ratio.

Use of Existing Facilities

Laboratory Approval Staff will consider the use of existing approved laboratory facilities when assessing applications by: assessing whether there is reasonable utilization of existing like-facilities (both public and privately-owned).

CROSS REFERENCE

Policy 2.5, Assessment Criteria

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

AUTHORITY

Laboratory Services Regulation, Sections 8 and 9

PART 2 APPLICATIONS AND NOTIFICATIONS FOR LABORATORY FACILITIES AND SERVICES

POLICY 2.5.3 ASSESSMENT CRITERIA: CONFLICT OF INTEREST

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To ensure that laboratory facilities, through which laboratory service benefits are provided to beneficiaries, are operated in a manner that protects the integrity of publicly-funded laboratory services 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/laboratory services.

OWNER/OPERATOR REQUIREMENTS

Operators and owners or prospective owners of a laboratory facility must identify, declare, and communicate actual/existing or potential conflicts of interest to Laboratory Approval Staff in accordance with the Laboratory Facility Conflict of Interest Policy (available to view here).

POLICY

Laboratory Approval Staff will:

a) only consider an application 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 relevant existing or potential conflict of interest in relation to the laboratory facility,

b) not approve an application that includes a disclosure of a relevant existing or potential conflict of interest in relation to the laboratory facility unless the relevant services cannot reasonably be provided by another approved laboratory facility for which an existing or potential conflict of interest does not exist,

   - If Laboratory Approval Staff approve an application in such circumstances, they will attach to the approval any and all limits and conditions they determine 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 laboratory facility, and

d) if a relevant existing or potential conflict of interest that has not been endorsed on or in respect of a laboratory facility's approval is identified by Laboratory Approval Staff after a laboratory facility has been approved, Laboratory Approval Staff may refer the matter to the Minister for determination and action and may recommend a course of action such as adding or altering limits and conditions on the laboratory facility's approval or cancellation of its approval.

CROSS REFERENCE

Policy 2.5.2, Assessment Criteria: Sufficient Need/Accessibility
Policy 2.6, Approval, Attaching and Changing Limits and Conditions of Approval, Cancellation of an Approval, and Recommending Denial of an Application
Policy 3.1, Transfer of Ownership Interest (Change to Persons Having a Material Financial Interest in a Facility)

AUTHORITY

Laboratory Services Regulation, Subsections 7(2)(f), 8(1)(c), 9(2), 12(4), and 17, and *Laboratory Services Act*, Section 35

PART 2 APPLICATIONS AND NOTIFICATIONS FOR LABORATORY FACILITIES AND SERVICES

POLICY 2.5.4 ASSESSMENT CRITERIA: PUBLIC INTEREST

EFFECTIVE OCTOBER 1, 2015

PURPOSE

In order for an approval to be granted, it must be in the public interest to do so, having regard to the mandatory criteria specified in the Regulation, the Approval Policies and Guidelines (in particular this Policy, Policy 2.5.4, and the Introduction, and Guiding Principles and Objectives).

POLICY

Laboratory Approval Staff must not grant an approval (in respect of an application) unless satisfied it is in the public interest to grant the approval. While Laboratory Approval Staff have broad discretion to determine whether the public interest supports the granting of the approval, and are expected to exercise their best judgement in doing so, Laboratory Approval Staff may consider the following (non-exhaustive) factors in a contextual manner, placing weight on the criteria as they determine most appropriate to the application and broader health system:

a) the likely impact on patient access to services (of the type proposed and from a broader health system's perspective), including

    i. ability to meet current and future service capacity/volume requirements;

    ii. impacts on wait times;

b) likely impacts on service quality;

c) impacts on, and other interactions (strategic or operational) with, agreements (respecting laboratory service benefits);

d) impacts on continuity and integration of beneficiary/patient care within the laboratory service system and across the care continuum;

e) impacts on health human resources;

f) service delivery impacts on other catchment areas;

g) impact on, or contribution to, value-added services (for instance, provision of teaching and clinical placements for students);

h) financial, efficiency, and sustainability impacts on the health care system.

CROSS REFERENCE

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

AUTHORITY

Laboratory Services Regulation, Section 8(1)(d).

PART 2 APPLICATIONS AND NOTIFICATIONS FOR LABORATORY FACILITIES AND SERVICES

POLICY 2.5.5 ASSESSMENT CRITERIA: COMPLIANCE WITH CANADIAN AND B.C. LAW

EFFECTIVE OCTOBER 1, 2015

PURPOSE

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

OWNER/OPERATOR REQUIREMENTS

Where there is (or would be) any degree of foreign ownership of a laboratory 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 laboratory services in British Columbia and must provide the province with necessary assurances that any debts owing to the province in relation to the laboratory facility will be recoverable.

POLICY

Laboratory Approval Staff will use the following criteria and requirements to assess applications involving a laboratory 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 Approval 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 laboratory 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 Laboratory Approval Staff to be appropriate, the owner or prospective owner must provide the province 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 Laboratory Approval Staff to be appropriate, the owner or prospective owner will provide the province with security.

Laboratory Approval Staff will undertake any and all legal means they consider necessary or advisable, including placing limits and conditions on approvals for laboratory 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 Laboratory Approval Staff under the authority of the *Laboratory Services Act* and the Laboratory Services Regulation.

PART 2 APPLICATIONS AND NOTIFICATIONS FOR LABORATORY FACILITIES AND SERVICES

POLICY 2.5.6 ASSESSMENT CRITERIA: CONCURRENT LIKE-APPLICATIONS

EFFECTIVE OCTOBER 1, 2015

PURPOSE

From time to time, multiple like-applications may be received within the same Laboratory Approval Staff 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 (Policy 2.5.6) 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, Laboratory Approval Staff will first determine whether each application meets all requirements of the Act, the Regulation, and the Approval Policies and Guidelines.

GUIDELINE

Subsequently, when comparatively assessing or ranking concurrent like-applications in order to determine which (if any) to approve and whether there are any necessary or advisable limits or conditions that should or must be attached to an approval, Laboratory Approval Staff may consider the following criteria in a contextual manner, placing weight on the criteria as they determine most appropriate in the circumstances (that is, applicable laboratory service(s), location(s), and so on):

a) beneficiaries' access to services, including location (or proposed location) of subject facilities described in the applications, in relation to the catchment area, and proximity, if applicable, to existing approved like-facilities;

b) 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 future service capacity/volume requirements; and

    ii. impacts on wait times;

c) other anticipated health system impacts, such as:

    i. impacts on continuity and integration of patient care within the laboratory services system and across the care continuum;

    ii. impacts on, and other interactions (strategic or operational) with, agreements (respecting laboratory service benefits);

    iii. impacts on health human resources;

    iv. service delivery impacts on other catchment areas; and

    v. ability to provide value-added services (for example, provision of teaching and clinical placements for students);

d) 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 laboratory facilities only);

e) whether there are any substantial suitability concerns relating to past performance or 'track record' (for example, compliance with the Act, the Regulation, and the Approval Policies and Guidelines requirements).

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

Laboratory Approval Staff may, in a manner consistent with the Act, the Regulation, and the Approval Policies and Guidelines, use in their assessment of concurrent like-applications relevant criteria other than those specified in this Policy; however, if they do so, they should document those criteria and the rationale for their use.

Following assessment of concurrent like-applications, Laboratory Approval Staff may:

- approve one or more preferred applications and reject one or more (competing) concurrent like-applications;

- deny any or all of the applications in accordance with the Approval Policies and Guidelines; or

- approve one or more of the concurrent like-applications with any conditions on the approvals—such as relating to facility capacity and services volumes—they deem necessary or appropriate.

CROSS REFERENCE

Policy 2.2, Required Application Information
Policy 2.4, Laboratory Approval Staff Approach to Application Assessment
Policy 2.5-2.5.6, Assessment Criteria
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 Laboratory Approval Staff under the authority of the *Laboratory Services Act* and the Laboratory Services Regulation.

PART 2 APPLICATIONS AND NOTIFICATIONS FOR LABORATORY FACILITIES AND SERVICES

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

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To ensure that conditions attached to an approval are relevant, appropriate, and up to date and that Laboratory Approval Staff's approvals, conditions attached to an approval, cancellation of approvals, and application denials are communicated to owners/operators/applicants (as applicable) clearly, efficiently, and in a timely manner.

POLICY

Approval and conditions

Laboratory Approval Staff will:

a) (when considering an application) attach such conditions to an approval that the Laboratory Approval Staff determines are necessary or advisable having regard to the Act, the Regulation, and the Approval Policies and Guidelines;

b) make effective an approval of an application on:

   i. the date that the Laboratory Approval Staff receives that application, provided that accreditation and credentialing (or other necessary preconditions) have been granted on or before that date;

   ii. for applications that have been granted with preconditions, the date that all required preconditions of approval have been met, **or**

   iii. such other date as the Laboratory Approval Staff determine and specify, and;

c) in circumstances other than in response to a contravention, at any time, add, remove, or alter a limit or condition on an approval, either of its own initiative, or following an application, as the Laboratory Approval Staff determines necessary or advisable having regard to the Act, the Regulation, the Approval Policies and Guidelines. If changing the

limits or conditions attached to an existing approval, on the initiative of Laboratory Approval Staff, notice and a reasonable opportunity to be heard must be given in accordance with section 11(2) of the Act and Section 22 of the Regulation, giving at least 30 days' written notice. Laboratory Approval Staff must not add, remove, or alter/change a limit or condition of the approval in response to a contravention.

Denial

Laboratory Approval Staff, after reviewing an application, will decide whether the application must or should be denied.

If Laboratory Approval Staff have denied an application on the basis of insufficient need, Laboratory Approval Staff will make that denial public by posting a notice that includes the following information on the Laboratory Services website:

a) the catchment area for which applications for specified laboratory services will not be accepted,

b) the time-period for which a moratorium on subsequent or like-applications applies, and

c) any other information Laboratory Approval Staff considers relevant.

Cancellation of Approval

Laboratory Approval Staff will not cancel an approval for laboratory systems reasons (see Section 18 of the Act) or due to a contravention (see Section 61 of the Act). However, Laboratory Approval staff may make recommendations to the Minister respecting a (proposed) change to a limit or condition attached to an approval or (proposed) cancellation of an approval, for any reason, including the following:

a) due to a contravention;

b) for laboratory systems reasons of any type, including the following circumstances:

   i. when implementation of service provision has not occurred within the required time frame (see Part 4, Subsequent Applications, Implementation, and Lapse In Service);

   ii. when there has been a lapse in service (see Part 4, Subsequent Applications, Implementation, and Lapse In Service).

Laboratory Approval Staff may cancel an approval (in accordance with the Act and Regulation) in the following administrative circumstance only: when a facility has, on its own initiative or accord, ceased operation.

Communication

Laboratory Approval Staff will communicate in writing to the owner/operator or proposed owner of a laboratory facility (as applicable) an approval, renewal of an approval, an amendment of an approval, or a denial of an application. Written communication on these topics may be by any means Laboratory Approval Staff deem secure and confidential and registered mail, while acceptable, need not be used.

A cancellation of an approval (for administrative reasons) or the change of a limitation or condition on an existing approval, on the initiative of Laboratory Approval Staff, will be communicated in writing by registered mail to an operator or former operator, within the timeframes noted above (pursuant to Section 21 and 22 of the Regulation). If the operator otherwise agrees, however, written notice may be given by a means other than registered mail.

CROSS REFERENCE

Part 4, Subsequent Applications, Implementation, and Lapse in Service Timelines
Part 6, Administrative Matters—Decision/Documentation Requirements; Reconsideration, Audit and Investigation

AUTHORITY

Laboratory Services Regulation, Sections 9, 10, and 20-22 and *Laboratory Services Act*, Sections 11, 18, and 61.

PART 3 OTHER ACTIVITIES

POLICY 3.1 TRANSFER OF OWNERSHIP INTEREST (CHANGE TO PERSONS HAVING A MATERIAL FINANCIAL INTEREST IN A FACILITY, ETC.)

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To ensure that Laboratory Approval Staff are able to monitor ownership of approved laboratory facilities and assess and approve proposed significant ownership changes.

OWNER/OPERATOR REQUIREMENTS

An owner/operator must seek approval prior to any change to persons having a material financial interest in an approved laboratory facility and, depending on the nature of the interest, provide required information.

POLICY

Laboratory Approval Staff will:

a) when considering applications for a change to persons having a material financial interest in an approved laboratory facility that does not propose any other change, assess whether or not there are existing or potential conflicts of interest in relation to the laboratory facility in accordance with Policy 2.5.3, and

b) when considering applications for a change to persons having a material financial interest in an approved laboratory facility that proposes other substantive changes (requiring approval), assess the application using the assessment criteria set out in Policy 2.5. as though it were an application for a relocation or expansion of an existing facility or for a new laboratory facility (as applicable).

GUIDELINES

When considering applications regarding change to persons having a material financial interest in an approved laboratory facility, Laboratory Approval Staff may consider other factors it considers relevant.

CROSS REFERENCE

Policy 2.5, Assessment Criteria
Policy 2.5.3, Conflict of Interest
Policy 3.2, No Transfer and Assignment of Approvals

AUTHORITY

Laboratory Services Regulation, Subsections 9(1)(c) and 10(2).

PART 3 OTHER ACTIVITIES

POLICY 3.2 NO TRANSFER OR ASSIGNMENT OF APPROVALS

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To clarify that an approval is location- and owner-specific and that it cannot be transferred or assigned and to ensure that Laboratory Approval Staff monitor and approve the material ownership of an approved laboratory facility at all times.

OWNER REQUIREMENTS

Approvals are location- and owner-specific and cannot be transferred or assigned. Therefore, a prospective owner must apply to Laboratory Approval Staff for a new approval if he/she wishes to have benefits provided through a laboratory facility.

AUTHORITY

Laboratory Services Regulation, Subsection 9(1)(a) and (c) and 10(2)
Laboratory Service Act, Section 11, and in particular, Subsection 11(3)
Within the general mandate of Laboratory Approval Staff under the authority of the *Laboratory Services Act* and the Laboratory Services Regulation.

PART 3 OTHER ACTIVITIES

POLICY 3.3 SIGNIFICANT CHANGE APPLICATIONS

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To ensure that Laboratory Approval Staff monitor the volume of laboratory services that are *outpatient* benefits provided on a fee-for-service basis.

OWNER/OPERATOR REQUIREMENTS

An operator must seek and receive approval from Laboratory Approval Staff before significant changes to a laboratory facility's capability or capacity to deliver outpatient laboratory service benefits occur, which includes significant change to the physical clinical space of the laboratory facility.

POLICY

Laboratory Approval Staff will:

a) monitor and assess changes in laboratory facilities' outpatient laboratory service billings for each applicable approval for the purposes of determining adherence to the requirement to seek approval in advance of facility changes involving significant change to the capability or capacity of the approved laboratory facility to provide outpatient laboratory services,

b) assess significant change applications against the criteria set out in Section 8 of the Regulation and in accordance with the guiding principles set out in Part 1 of the Approval Policies and Guidelines, and

c) when approving a significant change application, add, remove, or alter a limit or condition on an approval, as the Laboratory Approval Staff determines necessary or advisable having regard to the Act, the Regulation, the Approval Policies and Guidelines. (However, if changing the limits or conditions attached to an existing approval, notice and a reasonable opportunity to be heard must be given in accordance with section 11(2) of the Act and Section 22 of the Regulation, giving at least 30 days written notice.)

GUIDELINES

Laboratory Approval Staff may, at any time, 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.

CROSS REFERENCE

Policy 2.6, Approval, Attaching and Changing Limits and Conditions of Approval, Cancellation of an Approval, and Denial of an Application
Part 4, Subsequent Applications, Implementation, and Lapse In Service

AUTHORITY

Laboratory Services Regulation, Section 8 and Subsections 9(1)(d) and 10(3).

PART 3 OTHER ACTIVITIES

POLICY 3.4 CEASING OPERATIONS OF A LABORATORY FACILITY

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To ensure Laboratory Approval Staff are aware of and assess changes in supply of benefits in a timely manner and ensure that beneficiaries have access to laboratory service benefits.

OWNER/OPERATOR REQUIREMENTS

An operator must inform Laboratory Approval Staff at least 60 days prior to ceasing operations.

POLICY

Laboratory Approval Staff will:

a) receive notice of the intention to cease operations of a laboratory facility, and

b) if applicable, where another owner or prospective owner seeks to provide benefits previously provided through an approved laboratory facility that is ceasing operations, receive and review (in accordance with the Approval Policies and Guidelines) an application relating to the laboratory services/facility for which approval is sought.

CROSS REFERENCE

Part 2, Applications and Notifications For Laboratory Facilities and Services, Policies 2.1 to 2.6

AUTHORITY

Within the general mandate of Laboratory Approval Staff under the authority of the *Laboratory Services Act* and the Laboratory Services Regulation.

PART 4 SUBSEQUENT APPLICATIONS, IMPLEMENTATION, AND LAPSE IN SERVICE

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To ensure that benefits that have been approved to be provided through a laboratory facility are provided in an efficient and timely manner and that Laboratory Approval Staff can effectively manage the supply of benefits available to beneficiaries.

OWNER/OPERATOR 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

Laboratory Approval Staff will not:

a) accept or consider a subsequent application for either a new laboratory service, the relocation of an existing laboratory facility, or the expansion of a laboratory 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 date[2] has elapsed, unless Laboratory Approval Staff determine that extenuating circumstances (such as a substantial risk to health or safety) warrant consideration of the subsequent application;

b) accept or consider a like-application before a period of 18 months from the original application date has elapsed, if the original application was denied due to a determination of insufficient need within the applicable catchment area;

- however, if, within the applicable 18-month moratorium period, Laboratory Approval Staff determine that need for a laboratory service has arisen within the applicable catchment area, Laboratory Approval Staff will lift the moratorium and post a general notice on the Laboratory Services website to reflect that change (see also Policy 2.6).

[2] That is, 18 months from the date when the original application was received by Laboratory Approval Staff.

c) give priority consideration to an application from an applicant who was previously denied approval following the lifting of a moratorium.

Implementation

Laboratory Approval Staff:

a) will ensure that after an application has been approved, a laboratory 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 communication of the approval or another approval date communicated to the applicant,

b) may recommend to the Minister cancellation of the approval of a previously-approved laboratory facility that has not begun providing the new service within this implementation period,

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 Laboratory Approval Staff determine 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 circumstances relating to construction or significant physical expansion of public laboratory facilities.

Lapse In Service

Laboratory Approval Staff:

a) may recommend to the Minister cancellation of the approval of a previously approved laboratory facility/service when there have been no billings for an approved outpatient laboratory service provided on a fee-for-service basis submitted for a period of six consecutive months; 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 Laboratory Approval Staff determine 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 2.5.2, Assessment Criteria: Sufficient Need/Accessibility
Policy 2.6, Approval, Attaching and Changing Limits and Conditions of Approval, Cancellation of an Approval, and Denial of an Application
Policy 3.3, Significant Change Applications

AUTHORITY

Within the general mandate of Laboratory Approval Staff under the authority of the *Laboratory Services Act* and the Laboratory Services Regulation.

PART 5 REPORTING

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To ensure that Laboratory Approval Staff regularly receive the data they require in order to monitor the capability, capacity, and performance of laboratory facilities and services.

OWNER/OPERATOR REQUIREMENTS

An operator must submit capacity- and capability-related data, and other information if and as required by Laboratory Approval Staff, to the Ministry program area or persons stipulated by the Laboratory Approval Staff.

POLICY

Laboratory Approval Staff will:

a) identify and communicate to operators the information elements, and the manner and form, of reports that are required to be submitted biannually to the Ministry program area or persons stipulated by the Laboratory Approval Staff, in November and May of each year, or other times Laboratory Approval Staff determine appropriate, and

b) receive and review the required information and reports that approved laboratory facilities submit.

GUIDELINES

Laboratory Approval Staff may require operators to report the following information to the Ministry program area or persons stipulated by the Laboratory Approval Staff:

a) capacity-related data,

b) capability-related data,

c) the names of the current, relevant laboratory medicine physicians who provide or supervise the provision of benefits through the laboratory facility and/or regional directors or other staff/officials with responsibilities respecting approved laboratory services at the facility, and

d) any other information Laboratory Approval Staff require to perform their duties and functions.

AUTHORITY

Section 27 of the *Laboratory Services Act and* within the general mandate of Laboratory Approval Staff under the authority of the *Laboratory Services Act* and the Laboratory Services Regulation.

PART 6 ADMINISTRATIVE MATTERS—DECISION/DOCUMENTATION REQUIREMENTS; RECONSIDERATION; AUDIT AND INVESTIGATION

EFFECTIVE OCTOBER 1, 2015

PURPOSE

To ensure decisions and actions of Laboratory Approval Staff are appropriately documented and to ensure a transparent and consistent process is in place and utilized in relation to the decisions and actions of Laboratory Approval Staff in order to ensure that the interests and applications of owners/operators and potential owners/operators are treated in a manner consistent with administrative fairness and other administrative law principles.

OWNER/OPERATOR REQUIREMENTS

When requesting a reconsideration of a decision to deny an application for approval, an operator will, in writing, no later than 60 days following the issuance of the decision, submit to Laboratory Approval Staff the following:

- the basis upon which the operator requests reconsideration, that is, the reasons the operator is requesting Laboratory Approval Staff reverse the decision.
- any information, documentation, or operator opinion that is relevant and supportive of the operator's request.

POLICY

Circumstances where Reconsideration may be Available

Decisions to deny approvals may be reconsidered if the Laboratory Approval Staff determine that one or more of the following circumstances exists:

a) a clerical error or an accidental error or omission has occurred;

b) the decision is ambiguous;

c) the decision-maker forgot to deal with an issue he or she should have decided;

d) the decision turned on a finding of fact that was incorrect (for example, due to mistake or omission on the part of the decision-maker or the operator);

e) there has been a significant breach of a principle of administrative fairness in the decision-making process.

Communication and Documenting Decisions and Other Actions

Laboratory Approval Staff will:

a) when undertaking the actions referred to in ii. below, or documenting any decision made pursuant to the Act, the Regulation, and/or the Approval Policies and Guidelines, ensure a notation of "*for and on behalf of the Minister of Health*" prominently accompanies a signature or signature block of a Laboratory Approval Staff member responsible (in whole or in part) for the action or decision. For greater certainty and clarity,

    i. all approvals, including amended approvals, must include a notation of "*for and behalf of the Minister of Health*", prominently accompanying a signature or signature block of a Laboratory Approval Staff member responsible (in whole or in part) for granting the approval.

    ii. decisions or other actions may be documented individually or grouped in a coherent fashion (for example, related decisions or actions occurring at a particular meeting of Laboratory Approval Staff), but in all cases Laboratory Approval Staff will ensure that decisions and actions deriving from the Minister's authority under the Act, the Regulation and these Approval Policies and Guidelines are prominently and clearly signified by the notation "*for and behalf of the Minister of Health*".

Reconsideration of Denial—Internal Ministry Decision Review Process

a) When communicating a denial of an application for approval, Laboratory Approval Staff will provide the owner/operator with a statement in writing advising of the decision, and setting out the basis on which the decision was arrived at, including a short summary of the determinative relevant facts and considerations.

b) No request for reconsideration will be accepted for consideration or acted upon if received more than 60 days after delivery of the decision (to the owner/operator).

c) If Laboratory Approval Staff, receive a request for reconsideration from an owner/operator that meets the requirements of the Approval Policies and Guidelines, Laboratory Approval Staff will review and reconsider the relevant decision rendered.

d) When undertaking a reconsideration, Laboratory Approval Staff will:

   i. consider all new or additional relevant facts and information;

   ii. ensure that irrelevant facts, information, or considerations do not influence or inform reconsideration decision-making;

   iii. ensure reconsideration decision-making conforms to any requirements of the Act, the Regulation, and the Approval Policies and Guidelines, particularly ensuring that the object, purpose/intent, and spirit/scheme of these are taken into account while having regard to the unique circumstances and merits of the reconsideration at hand.

e) At the conclusion of its reconsideration, Laboratory Approval Staff will either:

   i. reverse their previous decision and grant the approval in question; **OR**

   ii. if they determine that the original decision should stand, refer the matter to either the Deputy Minister of Health or the Associate Deputy Minister of Health having responsibility for laboratory facilities and services for final determination.

Audits and Investigations

If Laboratory Approval Staff determine that audit and/or inspection relating to an approval is required or advisable (see Section 42 of the Act in particular, and Part 4, Division 1 [Audits and Inspections] generally), for example, to determine whether a laboratory facility should be approved or to determine whether a facility continues to meet conditions of approval, then Laboratory Approval Staff will do so in accordance with the Act and Regulation.

AUTHORITY

Interpretation Act, Subsection 23(3)
Section 42 of the *Laboratory Services Act* in particular, and Part 4, Division 1 [Audits and Inspections] generally