BRITISH COLUMBIA | Ministry of Health

Outpatient Laboratory Facilities Manual of Policies Under the *Laboratory Services Act*

Version 4.0 (February 2025)

Effective February 3, 2025

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REVISION HISTORY

Version 1.0	Approved and posted to Ministry of Health website	October 1, 2015
Version 2.0	Revised to reflect change in accountability for facility approvals; final version posted by Provincial Laboratory Medicine Services	March 8, 2021
Version 3.0	Revised Policy 4.3; added Policy 4.4; revised Policy 5; added/revised (applicable) Definitions	May 12, 2022
Version 4.0	Revised Introduction (Out of scope), Policy 2.1, 2.2, 2.3, 2.4, 3.1, 3.5; Added Policy 3.5.1, 3.5.2, Added Appendix A, Appendix B	February 3, 2025

INTRODUCTION

Authority Under the Laboratory Services Act and Laboratory Services Regulations

Under the authority of the *Laboratory Services Act* and the Laboratory Services Regulation (the Regulation), the Minister of Health (the Minister) is responsible for the administration and provision of Laboratory Service Benefits.

High-level purpose and scope

The Minister may grant to an operator an Approval to provide Benefits through a specified Laboratory Facility pursuant to Section 11 of the *Laboratory Services Act*. Further, the Minister may:

a) add, delete, or amend limits or conditions attached to an Approval, as necessary or advisable (Section 11 of the *Laboratory Services Act)*; and,

b) cancel Approvals (Section 18 of the *Laboratory Services Act*).

The Minister is supported by a designated operational body to oversee, manage, and make recommendations to the Minister in relation to Approvals and other actions related to the provision of community/outpatient Laboratory Services.

The Facilities Policies are intended to assist and guide the work of the designated operational body in performing assigned responsibilities that are related, and incidental, to the Approval of Laboratory Service Benefits to be provided through Laboratory Facilities.

The Facilities Policies bring together the statutory requirements related to Laboratory Facilities and build upon them to provide additional guidance where required. However, these policies are not to be mechanically applied, as they are intended to be a resource when considered appropriate to the particular facts and circumstances of each Application or other Approval related situations. All relevant factors should still be considered, and discretion should be exercised in a manner that conforms to the objectives and scheme of the *Laboratory Services Act* when Applications are assessed for Approval by the Minister.

Applications are assessed – in part – in accordance with Section 8 of the Laboratory Services Regulation, which states that the Minister may grant an Approval, if satisfied, of all of the following:

a) there is sufficient need with respect to 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 (i) provide the proposed Laboratory Services, and (ii) are located within the same Catchment Area of the Laboratory Facility that is the subject of the Application;

b) the quality of Laboratory Services will be maintained at a sufficiently high level;

c) no existing or potential conflicts of interest are identified (except in the situation when the Minister determines that the proposed Laboratory Services cannot reasonably be provided by another approved Laboratory Facility for which an existing or potential Conflict of Interest does not exist as per Subsection 8(2) of the Regulations (refer to Policy 7); and,

d) it would be in the public interest to grant the Approval.

Section 10 of the Laboratory Services Regulation specifies certain (mandatory) criteria for the consideration and Approval of Laboratory Facilities and services-related activities and Applications, including Applications for new facilities to provide Benefits through a specified Laboratory Facility, for the relocation of existing facilities, for a transfer of material financial interest in existing facilities, and for the Expansion of existing facilities including significant changes to their Capacity. 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 Facilities Policies outline additional considerations and provide direction and guidance on how criteria are to be considered and applied by the designated operational body.

A summary of the assessment of each Application will be included in the recommendation from the designated operational body to the Minister to support the recommendation and decision making by the Minister. This summary should include but not be limited to the type of request, reason for the request, information on the facility and its ownership, as well as details on the services the facility will provide.

This document is not a comprehensive guide to, or substitute for, the *Laboratory Services Act* and Laboratory Services Regulation. While the Facilities Policies 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 Facilities Policies will not ensure or constitute compliance with applicable law.

Outside the Scope of the Facilities Policies

The Facilities Policies do not apply in respect of:

a) Physician's office and community-based facilities operating as a private physician-run facility

b) Acute care wards/departments operating as part of a health authority organization; or

c) Long-term care facilities, stand-alone extended care hospitals (designated under the Hospital Act), and seniors' assisted living settings.

The Facilities Policies are not comprehensive of all requirements (including operators' obligations) under the *Laboratory Services Act* and Laboratory Services Regulation, including (but not limited to) the definition of "Benefits" under Section 4 of the *Laboratory Services Act*, payments for providing benefits under Section 14 of the *Laboratory Services Act*, and audits and inspections not in relation to Approvals under Part 4, Division 1 of the *Laboratory Services Act*, etc.

POLICY 1: GUIDING PRINCIPLES AND OBJECTIVES

PURPOSE

To articulate the principles that guide the exercising of the powers and duties under the *Laboratory Services Act*, including use of the Facilities Policies.

POLICY

The duties and functions performed in relation to Laboratory Facility Approvals should be performed with transparency, fairness, consistency, and timeliness.

Duties performed in relation to Laboratory Facility Approvals should 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

POLICY 2.1: NEW APPROVALS, AMENDMENTS TO APPROVALS, AND SERVICE DELIVERY PROPOSALS

PURPOSE

To identify the circumstances where the Minister, upon review of an Operator's application/proposal, may decide to grant an Approval or make changes to an existing Approval, as well as the required timelines to ensure a reasonable opportunity for the Minister to consider applications/proposals and provide appropriate direction.

POLICY

Under the Laboratory Services Regulation, s.10(2), the Minister may decide to grant a new Approval or make amendments to existing Approval(s) if the facility has appropriate accreditation, prescribed criteria are met, and the decision is in the public interest.

In cases where an Operator intends to cease operations or significantly reduce the operations of a Laboratory Facility or the provision of Laboratory Services, the Minister may request more information via a Letter of Intent and, if applicable, a Service Change Proposal. (Refer to Policy 3.5.)

If upon review of a Letter of Intent and/or a Service Change Proposal (see Policies 3.5.1 and 3.5.2), the Minister decides that it is in the public interest to replace the services, the Minister may ask another Operator or Operator(s) to submit a Service Delivery Proposal. (Refer to Policy 2.2.)

OPERATOR REQUIREMENTS

New Approval

The Operator or potential Operator must apply for a new Approval at least 30 days before the requested effective date (or as directed by the Minister) when seeking Approval for any of the following:

a) a new Laboratory Facility (inclusive of facilities that may be subject to an Agreement); or,
b) a change to an existing Approved Laboratory Facility that involves:
    i. the relocation of an existing Approved Laboratory Facility; or,
    ii. a change to the person(s) having a Material Financial Interest in an Approved Laboratory Facility.

Amendment(s) to an Existing Approval

An Operator of a Laboratory Facility (that is subject to an Approval) must apply for an amendment to the existing Approval at least 30 days (or as directed by the Minister) prior to changing any of the following:

a) the Laboratory Services provided through the Approved Laboratory Facility (e.g., downgrading from a Laboratory Facility that provides testing and specimen collection services to only specimen collection services);
b) the limits and conditions stated attached to the existing Facility Approval;
c) a significant change to the capability or capacity of the Approved Laboratory Facility (e.g., significant changes to the physical clinical space of the Laboratory Facility); or

d) the term of the approval expires, if the change is to extend the term of the Facility Approval.

In cases where an Operator intends to cease operations or significantly reduce the operations of a Laboratory Facility or the provision of Laboratory Services, the Operator should refer to Policy 3.5 for more details, including timeline and information requirements.

Service Delivery Proposals

If the Minister has provided approval to an Operator to cease or reduce the operations of a Laboratory Facility or Laboratory Services (as per Policy 3.5.2), another Operator who intends to continue or restore the delivery of Laboratory Services will be asked to provide additional information at least 30 days (or as directed by the Minister) prior to any changes by way of a Service Delivery Proposal. (Refer to Policy 2.2.)

CROSS REFERENCE

Policy 2.2: Required Application Information For an Approval Application or Service Delivery Proposal

Policy 3.3: No Transfer or Assignment of Approvals

Policy 3.5: Ceasing and/or Reducing Operations of a Laboratory Facility or Service

AUTHORITY

Laboratory Services Act, Section 11
Laboratory Services Regulation, Sections 7- 10

POLICY 2.2: REQUIRED INFORMATION FOR A FACILITY APPROVAL APPLICATION OR SERVICE DELIVERY PROPOSAL

PURPOSE

To clarify the information that is required in an application for a new Approval or to amend an existing Approval (hereafter referred to as an "Application"), and a Service Delivery Proposal. This policy also articulates the required timelines to ensure a reasonable opportunity for the Minister to consider Application(s) and/or Service Delivery Proposal(s) and provide appropriate direction.

POLICY

Per the Laboratory Services Regulation, certain details are required from Operator(s) for the Minister to make an informed decision to grant a new Approval, amend an existing Approval, cancel an Approval, and/or provide appropriate direction regarding the recommendation(s) in a Service Delivery Proposal.

OPERATOR REQUIREMENTS

An Operator must provide specific, accurate and complete information within their application(s) for new Approval(s) or amendment(s) to existing Approval(s), and/or their Service Delivery Proposal(s).

New Approval for a New Laboratory Facility (Not Previously Approved)

If an Operator or potential Operator intends to establish a new facility, they must complete and submit an application for a new Approval at least 90 days (or as directed by the Minister) prior to the preferred effective date for the Approval. The application for a new Approval should include the following details:

a) Name: current or proposed name of the facility.
b) Address: current, or, if applicable, the proposed physical location of the facility.
c) Material Financial Interest: names of all persons who have or will have a material financial interest in the laboratory facility, and, if the persons are shareholders, the percentage of the shares that they each own.
d) Name and qualifications of each laboratory medicine physician who will be providing or supervising the provision of benefits through the laboratory facility
e) Approved or proposed Laboratory Services: list of all Laboratory Services that are provided or proposed to be provided through the facility; and the accreditation status of the facility.
f) Capability: description of the capabilities of the major equipment used or to be used in the facility.
g) Capacity: existing or proposed number of phlebotomy chairs and beds; the proposed hours of operation; current or expected average monthly patient throughput; current or expected capacity (e.g., test volumes) of the facility.
h) Proposed hours of operation of the laboratory facility
i) Limits or Conditions: supporting rationale to propose change(s) to the limits and/or conditions on an existing Approval, for example: extending the expiration date of an

Approval or the timeframe for obtaining accreditation for the Laboratory Services stated on the Approval.

j) Conflict of Interest declaration: information about any existing or potential conflicts of interest that the applicant has reason to be aware of, such as in respect of Referring Practitioners who may request Benefits to be provided through the Laboratory Facility (refer to Policy 7). (The applicant may be asked to complete and submit Conflict of Interest and Conflict Declaration Forms.)
k) Foreign ownership: if applicable, information related to foreign ownership (refer to Policy 2.4.6).
l) A list and description of all quality control procedures planned for the laboratory facility, including quality control programs of a formal nature.
m) Any other information or documentation as requested, specified and/or required to assess the Application.

New Approval for a Laboratory Facility (with an Existing Approval)

If an Operator intends to relocate an Approved Facility and/or there is a change to the Material Financial Interest of an Approved Facility, they must submit an application for a new Approval at least 30 days (or as directed by the Minister) prior to the preferred effective date for the new Approval. The Operator may be required to provide any or all of the details that are required for New Laboratory Facility (not previously Approved), applications in addition to relevant supplemental documentation.

Amendment(s) to an Existing Approval

An Operator must submit an application to amend the existing Approval at least 30 days prior to the preferred effective date of the proposed change, if the Operator intends to propose a change or changes to any of the following:

a) A change to the laboratory services to be provided through the approved laboratory facility or the limits and conditions, if any, attached to the approval by the minister.
b) A significant change to the capability or capacity of the approved laboratory facility to provide laboratory services
c) The term of the approval expires, if the change is to extend the term of the approval.

The Operator may be required to provide any or all of the details that are required for New Laboratory Facility (not previously Approved) applications, in addition to relevant supplemental documentation.

Multiple Applications May be Submitted Concurrently

An Operator or potential Operator may concurrently submit multiple Applications for Approval, including Applications for new Approvals and Applications for amendments to an Approval. Multiple concurrent Applications will be considered in accordance with Policy 2.4.7 in particular and the Facilities Policies in general.

Service Delivery Proposal

If upon review of a Letter of Intent and/or a Service Change Proposal (see Policies 3.5.1 and 3.5.2), the Minister decides that it is in the public interest to replace the services, the Minister may ask another Operator or Operator(s) to submit a Service Delivery Proposal.

The Operator must submit the Service Delivery Proposal at least 30 days (or as directed by the Minister) prior to the preferred effective date for the new Approval or amendment to an existing Approval.

Depending on the proposed change(s), the Operator may be required to provide any or all of the information required for a new Approval or an amendment to an existing Approval (see Policy 2.2). In addition, the Operator should provide the following details in their Service Delivery Proposal:

a) Background or context that is relevant to the proposal, including a description of the current or near-future urgent health, safety, and/or business need(s) to be addressed through the proposal (see Appendix A for examples).
b) Details about the proposed service delivery model and of how the proposed model will address the current or near future urgent health, safety, and/or business need(s) and ensure continued access to services.
c) The proposed service delivery effective date and proposed management for continuous service delivery; if the changes are to be phased, describe each phase with a timeline.
d) Population/demographic information and the potential impact of the proposed services for the surrounding community and region; including information about First Nations and Indigenous persons and other underserved or vulnerable populations in the region.
e) Outline of community engagement and communication plans and/or pursued activities.
f) Alignment of the Service Delivery Proposal with the Operator's strategic service delivery planning and/or sustainability plans for laboratory services.

The Operator may consult with other Operator(s), the Ministry and other relevant laboratory system partners in the development of the Service Delivery Proposal. The general details of such consultations (e.g., name of person/organization, consultation date(s), area(s) of expertise, etc.) should be mentioned in the Service Delivery Proposal.

The final version of the Service Delivery Proposal should be reviewed and signed by a member of the Operator's executive or senior management team before being submitted to the Minister or delegate for review.

Refer to Appendix B for more details on the content requirements for a Service Delivery Proposal.

CROSS REFERENCE

Policy 2.1: New Approvals, Amendments to Approvals, and Service Delivery Proposals

Policy 2.3: Approach to Assessing Facility and Approval Applications and Service Delivery Proposals

Policy 2.4.3 Assessment Criteria: Conflict of Interest

Policy 2.4.6: Assessment Criteria: Compliance with Canadian and British Columbia Law For Privately Owned Laboratory Facilities

Policy 2.4.7: Assessment Criteria: Concurrent Like-Applications

Policy 2.5: Approval Decision-Making and Communication

Policy 3.3: No Transfer or Assignment of Approvals

Policy 3.5: Ceasing and/or Reducing Operations of a Laboratory Facility or Service

Policy 4.1: Implementation of an Approval

Policy 7: Conflict of Interest

Appendix B: Service Delivery Proposal Content Recommendations

AUTHORITY

Laboratory Services Act, Section 11(1)
Laboratory Services Regulation, Sections 7-10

POLICY 2.3: APPROACH TO ASSESSING FACILITY APPROVAL APPLCIATIONS AND SERVICE DELIVEY PROPOSALS

PURPOSE

To articulate the general approach taken when assessing applications for a new Approval or applications for changes to an existing Approval (hereafter referred to as an "Application"), and a Service Delivery Proposal.

POLICY

The assessment of an Application or Service Delivery Proposal must include the following:

a) The application of the mandatory criteria and requirements specified in the *Laboratory Services Act* and Laboratory Services Regulation.
b) The documentation of the application of criteria and considerations additional to those specified in the *Laboratory Services Act* and the Laboratory Services Regulation.
c) Consideration of what, if any, limits and conditions are, or might be, necessary or advisable to attach to an Approval, having regard to the *Laboratory Services Act*, Laboratory Services Regulation and Facilities Policies.
d) A consistent approach and incorporation of subject matter expertise to inform decision making by the Minister.

The assessment of an Application or Service Delivery Proposal may include any or all of the following:

a) The application of relevant criteria and considerations in addition to those specific in the *Laboratory Services Act* and Laboratory Services Regulation.
b) The application of 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.
c) Relevant information provided by an advisor or expert to inform deliberations and recommendations regarding the Application and decision making by the Minister.
d) Relevant information and advice provided at any meeting or in any manner and at any time that may inform deliberations, recommendations and/or support decision making by the Minister.

OPERATOR REQUIREMENTS

To ensure that all relevant information is captured for the assessment of an Application or Service Delivery Proposal, Operators may be required to provide supplemental information through written communication and/or meeting deliberations, as appropriate. Upon request, such information should be submitted by the date and time specified by the Minister.

In cases where urgent health or safety or business risk(s) exists, the Operator can request a shortened notification period and should be prepared to provide substantive evidence of the risk(s).

CROSS REFERENCE

Policy 2.1: New Approvals, Amendments to Approvals, and Service Delivery Proposals

Policy 2.2: Required Information for a Facility Approval Application or Service Delivery Proposals

Policy 3.3: No Transfer or Assignment of Approvals

Policy 3.5: Ceasing and/or Reducing Operations of a Laboratory Facility or Service

AUTHORITY

Laboratory Services Act, Section 10-11
Laboratory Services Regulation, Sections 8-10

POLICY 2.4: ASSESSMENT CRITERIA

PURPOSE

To articulate the criteria used to assess an application for a new Approval or an amendment to an existing Approval (hereafter referred to as an "Application") and a Service Delivery Proposal.

POLICY

1. Applications and Service Delivery Proposals will be assessed for evidence of meeting the criteria and requirements set out in:

   a) the *Laboratory Services Act* (in particular, Sections 10-12)

   b) the Laboratory Services Regulation (in particular, Sections 7-9); and,

   c) the Outpatient Laboratory Facilities Manual of Policies Under the *Laboratory Services Act* (in particular, Policies 2.2 and 2.4.1-2.4.7).

   Notwithstanding these criteria, the Minister may, on a case-by-case basis, grant Approval(s) under exceptional circumstances for applications where outpatient laboratory services are required in direct support of a Ministry of Health priority initiative(s), if the Minister is satisfied that the criteria set out in Section 10 of the Laboratory Services Act are met.

2. Service Delivery Proposals, in particular, will be assessed for evidence of meeting the following criteria:
   a) Sufficient details of the services currently provided at the location and how the proposed services delivery model will provide both short- and long-term sustainability planning identifying laboratory stewardship.
   b) Sufficient details about the proposed changes to address and improve identified challenges / critical operational issues and define collaboration with other regional area laboratory operators, including a risk impact assessment (specifically during the transitory period between operators).
   c) Reasonability of the proposed effective date of the proposed services delivery model and/or phased timeline.
   d) Demonstrated awareness of the population demographics in the community(ies) potentially impacted by the proposed services delivery model (e.g., seniors, First Nations and Indigenous persons, other underserved/vulnerable populations).
   e) Evaluation of the potential impacts on the community and/or region, specifying the implications for: patients and their families (e.g., wait times, travel times), underserved or vulnerable populations (e.g., social determinates of health), physicians and other health care providers, local health care facilities, primary care networks (e.g., ordering practices, requisition fulfillment concerns, etc.); other laboratory service providers in the region (e.g., capacity, capability and hours of operation, etc.).

f) The type and level of community engagement and communication plans for patients, health care providers and other system partners.
g) Alignment with the local health authority/ies and the Ministry's strategic goals and planning (e.g., sustainability, service standards, continuum of care, etc.).
h) The feasibility of the proposed services delivery model, including costs, funding sources, and impacts on existing and/or projected budgets.
i) The type and level of consultations described in the Service Delivery Proposal.
j) A clear indication of engagement with and endorsement from local health authority/ies regarding the proposed services delivery model.
k) Approval by the Operator's executive or senior management team.

3. The Minister or delegate will aim to communicate a decision to the Operator, including any limits and conditions to be applied, in a reasonable and timely manner.

CROSS REFERENCE

Facility Policy 2.1: New Approvals, Amendments to Approvals, and Service Delivery Proposals

Facility Policy 2.2: Required Information for a Facility Approval Application or Service Delivery Proposals

Facility Policy 2.3: Approach to Assessment of Facility Approval Applications and Service Delivery Proposals

Facility Policy 2.4.1 – 2.4.7 Assessment Criteria

Facility Policy 3.4: Significant/Material Change Applications

AUTHORITY

Laboratory Services Act, Section 10
Laboratory Services Regulation, Section 8

POLICY 2.4.1: ASSESSMENT CRITERIA: QUALITY

PURPOSE

To ensure Applications are assessed with regard to the quality of Laboratory Services provided in British Columbia.

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

Applications will be assessed based on their fulfillment of the following quality criteria on whether:

a) 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) the physicians (names and qualifications) specified in the Application pursuant to Section 7(2)(d) of the Laboratory Services Regulation are Laboratory Medicine Physicians.

The Minister 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 2.1: Facilities Approvals

Policy 2.3: Approach to Application Assessment

Policy 2.5: Approval Decision-Making and Communications

AUTHORITY

Laboratory Services Act, Section 10
Laboratory Services Regulation, Section 8(1)(b)

POLICY 2.4.2: ASSESSMENT CRITERIA: SUFFICIENT NEED/ACCESSIBILITY

PURPOSE

To ensure the assessment of an Application includes an analysis regarding Access to Laboratory Services, and whether there is sufficient need to support Approval of the proposed Laboratory Services.

POLICY

Sufficient Need

A contextual analysis of the Application is completed to assess:

a) whether there is sufficient need for the proposed service having regard to the Capacity and quality of service, cost, and any other relevant factors (including Agreements-related Capacity);

b) whether or not existing approved Laboratory Facilities that are Like-Facilities to the facility in the Application are meeting Beneficiary and health system needs, and, relatedly, whether existing Approved Like-Facilities are being reasonably utilized and/or have the ability to address the service needs articulated in the Application; and,

c) the Accessibility of Laboratory Service Benefits to beneficiaries.

For the purposes of Policy 2.4.2, the concepts of Catchment Area, Accessibility, and reasonable utilization of existing Laboratory Facilities are explained below.

Catchment Area

The Catchment Area is used to determine the proximity of the facility in the Application to surrounding approved Laboratory Facilities. The Catchment Area used will vary depending on the location of the facility in the Application. For example, a larger Catchment Area may be needed for a Laboratory Facility located in a rural setting as compared to a Laboratory Facility located in an urban area. It may be determined using Community Health Service Areas or a population-density per-square-kilometre radius-based approach consistent with Table 1. It may be decreased or expanded, up to and including the entire Province of British Columbia in some cases, based on the Laboratory Services in the Application.

Table 1

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

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

is assessed by considering:

a) the distances between Like-Facilities within the Catchment Area that has been applied;

b) beneficiaries' travel options/time in relation to the facility and/or Like-Facilities in the identified Catchment Area;

c) Wait times experienced by Beneficiaries in facilities in the Catchment Area; and,

d) other metrics as appropriate/applicable, such as comparing the ratio of beneficiaries to laboratory chairs in the Catchment Area to a provincial ratio.

Use of Existing Facilities

The use of existing Approved Laboratory Facilities is assessed when considering Applications to determine if there is reasonable utilization of existing Approved Like-Facilities (both public and privately-owned) and/or the existing Approved Laboratory Facilities have the Capacity to address the service needs articulated in the Application.

CROSS REFERENCE

Policy 2.1: Facilities Approvals

Policy 2.5: Approval Decision-Making and Communications

Policy 3.4: Significant/Material Change Applications

Policy 4.2: Subsequent Applications and Like-Applications

AUTHORITY

Laboratory Services Regulation, Sections 8-9

POLICY 2.4.3: ASSESSMENT CRITERIA: CONFLICT OF INTEREST

PURPOSE

To ensure that Laboratory Facilities, through which Laboratory Services Benefits are provided to Beneficiaries, are operated in a manner that protects the integrity of publicly-funded Laboratory Services by ensuring that a current or potential Operator'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.

OPERATOR REQUIREMENTS

Current or potential Operators must identify, declare, and communicate actual/existing or potential conflicts of interest in accordance with the Laboratory Facility Conflict of Interest Policy and submit their declaration with the Application.

POLICY

An Application for a new or amended Approval will be considered only if it includes a completed Conflict of Interest declaration form which discloses any existing or potential Conflict of Interest in relation to the Laboratory Facility.

An Application that includes a disclosure of an existing or potential Conflict of Interest will be assessed to determine if the conflict or potential conflict is relevant to the Approval, and, if so, whether the provision of the services in the Application can reasonably be provided by another approved Laboratory Facility within the Catchment Area for which an existing or potential Conflict of Interest does not exist. If the relevant services:

a) can reasonably be provided by another approved Laboratory Facility instead of the applicant with an existing or potential Conflict of Interest, then the Application will be denied by the Minister.

b) cannot reasonably be provided by another approved Laboratory Facility and the Application meets other applicable approval criteria, a recommendation that the Minister approve the Application with any and all limits and conditions deemed necessary or advisable to mitigate the Conflict of Interest will be submitted to the Minister for approval.

If at any time concerns about an actual or potential Conflict of Interest in relation to an approved Laboratory Facility is reported to the designated operational body by the applicant/Operator, the designated operational body will investigate and refer the matter, along with their findings and a recommended course of action, such as adding or alternating any limits and conditions on the Laboratory Facility's Approval or cancelling the Approval, to the Minister for a decision as required.

If a relevant existing or potential Conflict of Interest that has not been self-reported by an applicant is subsequently identified after a Laboratory Facility has been approved, the matter will be referred to the Minister.

CROSS REFERENCE

Policy 2.1: Facilities Approvals

Policy 2.4.4: Assessment Criteria: Changes to the Persons Having a Material Financial Interest in a Facility

Policy 2.5: Approval Decision-Making and Communications

Policy 7: Conflict of Interest

AUTHORITY

Laboratory Services Act, Section 25
Laboratory Services Regulation, Sections 7(2)(f), 8(1)(c), 9(2), 12(4), 17

POLICY 2.4.4: ASSESSMENT CRITERIA: CHANGES TO THE PERSONS HAVING A MATERIAL FINANCIAL INTEREST IN A FACILITY

PURPOSE

To articulate the Approval requirements for changes in the ownership of an Approved Laboratory Facility with a material financial impact.

OPERATOR REQUIREMENTS

An Operator must apply for a new Approval in writing at least 30 days prior to any change to the persons holding a Material Financial Interest in an Approved Laboratory Facility, and, depending on the nature of the interest, provide required information.

POLICY

Applications for a change to the persons having a Material Financial Interest in an Approved Laboratory Facility will be assessed for the following:

a. whether or not there are existing or potential conflicts of interest in relation to the Laboratory Facility in accordance with the *Laboratory Services Act*, Laboratory Services Regulation and Policy 2.4.3; and,

b. if the Application proposes other substantive changes requiring approval, an assessment of the Application using the assessment criteria set out in Policies 2.4-2.4.7 as though it were an Application for a relocation or Expansion of an existing facility or for a new Laboratory Facility.

For clarity, any other relevant factors regarding change to persons having a Material Financial Interest in an Approved Laboratory Facility may be considered.

CROSS REFERENCE

Policy 2.1: Facilities Approvals

Policies 2.4-2.4.7: Assessment Criteria

Policy 2.5: Approval Decision-Making and Communications

Policy 3.1: Notification of Changes

Policy 3.3: No Transfer or Assignment of Approvals

AUTHORITY

Laboratory Services Act, Sections 10 and 11
Laboratory Services Regulation, Sections 2(1), 9(1)(c) and 10(2)

POLICY 2.4.5: ASSESSMENT CRITERIA: PUBLIC INTEREST

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 Laboratory Services Regulation and the Facilities Policies (in particular Policy 1, Policy 2.4.2, and the Introduction).

POLICY

An Application is assessed to determine if it is in the public interest to grant the Approval. Broad discretion and best judgment are used to determine whether approving the Application supports the public interest. The following (non-exhaustive) factors will be assessed in a contextual manner, placing weight on the criteria determined to be the 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 the ability to meet current and future service Capacity/volume requirements, and 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 and/or other Approved Laboratory Facilities;

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

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

CROSS REFERENCE

Policy 2.1: Facilities Approvals

Policy 2.4.2: Assessment Criteria: Sufficient Need/ Accessibility Policy

2.5: Approval Decision-Making and Communications

AUTHORITY

Laboratory Services Act, Section 10(c)
Laboratory Services Regulations, Section 8(1)(d)

POLICY 2.4.6: ASSESSMENT CRITERIA: COMPLIANCE WITH CANADIAN AND BRITISH COLUMBIA LAW FOR PRIVATELY OWNED LABORATORY FACILITIES

PURPOSE

To ensure that a Laboratory Facility with a foreign ownership is operated in a manner that complies with applicable Canadian and British Columbia laws, and that the Province has the necessary protections in place to enable it to collect any debt owing to it in relation to the Laboratory Facility.

OPERATOR REQUIREMENTS

Where there is (or would be) any degree of foreign ownership of a Laboratory Facility and an Approval is sought, the current or potential Operator must satisfactorily demonstrate that it is subject to the applicable laws of British Columbia and Canada with respect to the provision of Laboratory Services in British Columbia, and it must provide the Province with necessary assurances that any debts owing to the Province in relation to the Laboratory Facility will be recoverable.

The current or potential Operator 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) as required and determined to be appropriate during the assessment of the Application.

The current or potential Operator will provide the Province with security where determined to be appropriate during the assessment of the Application. Any and all legal means considered necessary or advisable, including recommending the Minister (or designate) place limits or conditions on Approvals for Laboratory Facilities with any degree of foreign ownership, will be undertaken to ensure that these requirements are met.

The current or potential Operator must provide proof that they are not 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.

POLICY

The following criteria and requirements will be used to assess Applications involving a Laboratory Facility with any degree of foreign ownership:

a) all other requirements of the *Laboratory Services Act*, the Laboratory Services Regulation, applicable privacy policies, and the Facilities Policies are met;

b) documentation is provided that satisfactorily demonstrates that the owner or prospective owner is/will be subject to the applicable laws of British Columbia and Canada with respect to the provision of Laboratory Services in British Columbia – particularly the *Laboratory Services Act*, the Laboratory Services Regulation, and British Columbia privacy laws;

c) the current or potential Operator that is not a publicly owned facility:

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.

CROSS REFERENCE

Policy 2.1: Facilities Approvals

Policy 2.2: Required Application Information

Policy 2.5: Approval Decision-Making and Communications

AUTHORITY

Laboratory Services Regulation Section 11

POLICY 2.4.7: ASSESSMENT CRITERIA: CONCURRENT LIKE APPLICATIONS

PURPOSE

From time to time, Like-Applications may be received for consideration and reviewed at the same time[1]. Following the assessment of each Application against the assessment criteria laid out in Policies 2.4.1-2.4.7, Like-Applications will be comparatively assessed or ranked. Policy 2.4.7 aims to ensure that such Applications are evaluated, and Approvals are recommended on the basis of appropriate, consistently applied, and transparent criteria.

POLICY

Each Application will be assessed independently to ensure it meets all requirements of the *Laboratory Services Act*, the Laboratory Services Regulation, and the Facilities Policies, prior to comparative assessment with concurrent Like-Applications.

The following criteria will be assessed in a contextual manner, placing weight on the criteria determined most appropriate in the circumstances when comparatively assessing or ranking concurrent like Applications in order to determine which (if any) to recommend for Approval and whether there are any necessary or advisable limits or conditions that should be attached to an Approval by the Minister:

a) Beneficiaries' Access to services, including location (or proposed location) of the subject facilities described in the Applications in relation to the Catchment Area and proximity to existing Approved Like-Facilities;

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

    i. the 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,

[1] i.e. received during the same intake period for consideration in the same review period

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

d) the applicant's demonstrated degree of readiness and due diligence, including:

i. the level of detail, accuracy, and quality of the information provided in the Applications;

ii. demonstrated readiness to provide the proposed services, such as plans or arrangements regarding the location, building and infrastructure, equipment, staffing, financing (for Public Laboratory Facilities only), etc. in relation to overall feasibility;

iii. whether there are any substantial suitability concerns relating to past performance or 'track record' (for example, compliance with the *Laboratory Services Act*, the Laboratory Services Regulation, and the Facilities Policies); and,

iv. any other criteria as applicable to the Applications under consideration.

When assessing concurrent Like-Applications, the date and time the Applications were received will, in general, not be considered or weighted in the assessment.

Relevant criteria other than those specified in Policies 2.4-2.4.7 that are used in the assessment of an Application, in a manner consistent with the *Laboratory Services Act*, the Laboratory Services Regulation and the Facilities Policies must be documented along with the rationale for their use in the file for each Application.

The assessment of concurrent Like-Applications may result in one of the following recommendations:

a) the Approval or denial of one or more concurrent like Applications;

b) denial of any or all the concurrent Like-Applications in accordance with the Facilities Policies; or,

c) the Approval of one or more of the concurrent Like-Applications with any limits or conditions on the Approvals – such as conditions relating to facility Capacity and service volumes – they deem necessary or appropriate.

CROSS REFERENCE

Policy 2.1: Facilities Approvals

Policy 2.2: Required Application Information

Policy 2.3: Approach to Application Assessment

Policies 2.4-2.4.7: Assessment Criteria

Policy 2.5: Approval Decision-Making and Communications

AUTHORITY

Laboratory Services Act, Sections 10(2), 11(1)
Laboratory Services Regulation, Section 8(1)

POLICY 2.5: APPROVAL DECISION-MAKING AND COMMUNICATIONS

PURPOSE

To clarify that the Minister makes decisions on granting Approvals, including any limits and conditions to be applied to the Approval, after receiving recommendations based on the assessment of Applications, and to ensure that decisions are communicated clearly, efficiently and in a timely manner.

POLICY

Application Decision-Making

After assessing an Application against the criteria outlined in Policies 2.4-2.4.7, the designated operational body will:

a) recommend the Minister approve or deny the Application;

b) identify any limits or conditions determined to be necessary or advisable having regard to the *Laboratory Services Act*, the Laboratory Services Regulation, and the Facilities Policies, if recommending that the Minister approve the Application.

Communication of Decisions on Applications

Applicants are informed of the Minister's decision on their Application(s) by formal letter sent to the applicant via the email provided by the applicant.

All Application decisions are posted online for public consumption.

CROSS REFERENCE

Policy 2.1: Facilities Approvals

Policy 4.2: Subsequent Applications and Like-Applications

AUTHORITY

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

POLICY 2.5.1: LIMITS AND CONDITIONS

PURPOSE

To ensure that conditions attached to an Approval are relevant, appropriate, and up to date.

POLICY

There will be recommendations to the Minister for limits and conditions to an Approval when necessary or advisable having regard to the *Laboratory Services Act*, the Laboratory Services Regulation, and the Facilities Policies, for example:

a) the effective date of an Approval:
    i. the date that the Application was received, provided that accreditation and credentialing (or other necessary preconditions) have been granted on or before that date;
    ii. the date that all required preconditions of approval have been met for Applications that have been granted with precondition; or
    iii. such other date as determined and specified.
b) the date the Approval will end; or,
c) the extent of the Laboratory Services provided under the Approval.

CROSS REFERENCE

Policy 2.4.2: Assessment Criteria: Sufficient Need/Accessibility

Policy 4.2: Subsequent Applications and Like-Applications

AUTHORITY

Laboratory Services Act, Sections 11
Laboratory Services Regulation, Sections 9, 10, and 20-22

POLICY 2.5.2: DENIAL OF AN APPLICATION FOR INSUFFICIENT NEED

PURPOSE

To articulate the requirements for Applications denied based on insufficient need.

POLICY

Upon completion of the assessment of an Application, the Minister will be provided with a formal recommendation for the Approval or denial of the Application.

If the Minister approves a recommendation to deny an Application on the basis of insufficient need, the denial will be made public by posting a notice that includes the following information online:

a) the Catchment Area for which Applications for specified Laboratory Services will not be accepted;

b) the 18-month time-period for which a moratorium on subsequent or Like-Applications applies; and,

c) any other relevant information.

CROSS REFERENCE

Policy 2.4.2: Assessment Criteria: Sufficient Need/Accessibility

Policy 4.2: Subsequent Applications and Like-Applications

AUTHORITY

Laboratory Services Act, Section 11
Laboratory Services Regulation, Sections 9, 10

POLICY 2.5.3: CANCELLATION OF APPROVAL

PURPOSE

To identify situations when a recommendation to the Minister to cancel an Approval can be made.

POLICY

Recommendations for the cancellation of an Approval can be given to the Minister for the following reasons:

a) laboratory system reasons as specified in Section 18 of the *Laboratory Services Act*;

b) due to a contravention as specified in Section 59(1)(b) of the *Laboratory Services Act* which states.

Enforcement orders

59 (1) The Minister may make an order described in subsection 59 (2) if:

a) following the hearing, the Minister determines that a person has

(i) contravened this *Laboratory Services Act* or a regulation made under it, including failing to comply with a previous order made under this section; or,

(ii) committed an offence under section 64 *[offences]*."

b) when implementation of service provision has not occurred within the required time frame;

c) when there has been a Disruption in Service;

d) when the Approval is void due to provision of false information; or,

e) when a facility has, on its own initiative or accord, ceased operation, its Approval will be cancelled and communicated in writing by email or registered mail, if required, to the facility's Operator, or former Operator, within 90 days of the cancellation.

CROSS REFERENCE

Policy 2.4.2: Assessment Criteria: Sufficient Need/Accessibility

Policy 4.1: Implementation of an Approval

Policy 4.2: Subsequent Applications and Like-Applications

Policy 4.3: Disruptions to Laboratory Services

AUTHORITY

Laboratory Services Act, Sections 11, 18, 59, 61, 64
Laboratory Services Regulation, Sections 9, 10, 21

POLICY 3.1: NOTIFICATION OF CHANGES

PURPOSE

To articulate the three circumstances where an Operator of an Approved Laboratory Facility must submit a notification for a change to its Approval. These circumstances include mere notice, new Approvals, and amendments to an Approval.

OPERATOR REQUIREMENTS

Operators must provide the Minister with notifications for certain intended/proposed changes through the specified notification process and with required information within required timeframes when certain changes are intended/proposed.

POLICY

1) Notice Requirement (in circumstances other than amendment or new approval)

An operator of a Laboratory facility that is subject to an Approval must notify the Minister in writing 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; or,

c) a change in the hours of operation of the Laboratory Facility. If the change of hours is expected to be greater than a 20 percent difference in hours (as reported per Policy 5.0), the Operator is to refer to Policy 3.5 for requirements and guidance.

2) New Approval

An operator of a Laboratory Facility that is subject to an Approval must seek a new Approval at least 30 days before a change to any of the things described in section 9(1) including:

a) the address or addresses of the Approved Laboratory Facility; or,

b) the persons having a material financial interest in the Approved Laboratory Facility.

3) Amendments to an Approval

An Operator of a Laboratory Facility that is subject to an Approval must seek an amendment to the Approval at least 30 days before:

a) a change to the Laboratory Services to be provided through the Approved Laboratory Facility (e.g. withdrawing operational services (categories or tests));

b) changes to the limits and conditions, if any, attached to the Approval by the minister;

c) A significant change to the Capacity of the Approved Laboratory Facility to provide Laboratory Services (e.g. adding or removing beds/stretchers and/or phlebotomy chairs without exceeding the numbers beds/stretchers and/or phlebotomy chairs listed on the facility's Approval); or,

d) the term of the Approval expires, if the change is to extend the term of the Approval.

CROSS REFERENCE

Policy 2.1: Facilities Approvals

Policy 2.5.3: Cancellation of Approval

Policy 3.2: Changes to Limits and Conditions Outside of the Application Process

AUTHORITY

Laboratory Services Act, Sections 10, 11, 13, 14
Laboratory Services Regulation, Section 9(1), 10(1), 10(3), 12(2)

POLICY 3.2: CHANGES TO LIMITS AND CONDITIONS OUTSIDE OF THE APPLICATION PROCESS

PURPOSE

To outline the circumstances when recommendations are ordinarily made to the Minister for modifications/changes to the limits or conditions attached to an existing Approval in the absence of an Application from the Laboratory Facility's Operator to request such changes.

To ensure that limits and conditions attached to an Approval are relevant, appropriate, and up to date, and that the Minister's decisions are communicated to operators clearly, efficiently, and in a timely manner.

POLICY

Recommendation to the Minister to change the limits or conditions attached to an Approval for any reason may be made when appropriate. For example:

a) upon receipt of a notification from the Operator of a situation that would require a change in the limits and conditions of their Approval;

b) identification of a contravention;

c) identification of a laboratory system need of any type;

d) identification of a relevant existing or potential Conflict of Interest that has not been endorsed on or in respect of a Laboratory Facility's Approval, including conflicts identified after the receipt, review, and investigation of reports of or concerns about the Laboratory
Facility; and,

e) when other changes to a Laboratory Facility are determined to make it appropriate to change limits or conditions.

If the Minister decides to change the limits or conditions attached to an existing Approval, the change will be communicated in writing by email or registered mail, if required, to the Laboratory Facility's Operator, or former Operator, within 30 days for a change in the limits and conditions. If the Operator otherwise agrees, however, written notice may be given by a means other than registered mail.

If the Minister is contemplating changes to the limits or conditions attached to an existing Approval, the Laboratory Facility Operator will be given at least 30 days' written notice and a reasonable opportunity to be heard in accordance with Section 11(2) of the *Laboratory Services Act* and Section 22 of the Laboratory Services Regulation.

CROSS REFERENCE

Policy 2.5.1: Limits and Conditions

Policy 3.1: Notification of Changes

AUTHORITY

Laboratory Services Act, Sections 11(2)
Laboratory Services Regulation, Sections 20, 21, 22

POLICY 3.3: NO TRANSFER OR ASSIGNMENT OF APPROVALS

PURPOSE

To emphasize that an Approval is location and owner specific, and it cannot be transferred or assigned.

OPERATOR REQUIREMENTS

As outlined in Policy 2.1, a current or potential owner who wishes to have Benefits provided through a Laboratory Facility must submit an Application for a new Approval.

POLICY

Approvals are location and owner specific. They cannot be transferred or assigned, as per Section 11(3) of the *Laboratory Services Act*.

A new Approval is required if there is a material change in the ownership of an Approved Laboratory Facility.

Ownership of an Approved Laboratory Facility may be monitored from time to time for changes in ownership/any transfer of assignment of ownership of an Approval to a different Operator.

CROSS REFERENCE

Definitions

Policy 2.4.4: Assessment Criteria: Changes to the Persons Having a Material Financial Interest in a Facility

AUTHORITY

Laboratory Services Act, Section 11, and Section 11(3)
Laboratory Services Regulation, Sections 9(1)(a), 9(1)(c) and 10(2)

POLICY 3.4: SIGNIFICANT/MATERIAL CHANGE APPLICATIONS

PURPOSE

To articulate the manner in which a significant/material change to the Approval of an Approved Laboratory Facility is identified and managed.

OPERATOR REQUIREMENTS

As stated in Policy 2.1, a current or potential Operator must submit an Application to amend their Approval before making a significant/material change(s) to a Laboratory Facility's Capacity, including significant/material changes to its physical clinical space. This consideration process includes that a current or potential Operator must submit Capacity related data and other information, if and as required, to the designated operational body.

POLICY

Applications received for a significant/material change will be assessed against the criteria set out in Section 8 of the Laboratory Services Regulation and in accordance with the guiding principles set out in the Facilities Policies. Upon review of a significant change Application, and having regard to the *Laboratory Services Act*, Laboratory Services Regulation and the Facilities Policies, a recommendation for a change to the Laboratory Facility's Approval may be required and submitted to the Minister for Approval (e.g. additions, removals, or alterations to a limit or condition on an Approval). If approval for a change to an existing Approval is required, 30 days' notice and reasonable opportunity to respond is given in accordance with Section 11(2) of the *Laboratory Services Act* and Section 22 of the Laboratory Services Regulation

CROSS REFERENCE

Policy 2.1: Facilities Approvals

Policy 5: Reporting

AUTHORITY

Laboratory Services Act, Section 11
Laboratory Services Regulation, Section 8 and Sections 9(1)(d), 10(3), and 22

POLICY 3.5: CEASING AND/OR REDUCING OPERATIONS OF A LABORATORY FACILITY OR SERVICE

PURPOSE

To articulate how and when the Minister is to be notified of an Operator's intent to cease or significantly reduce the provision of Laboratory Service(s), and the approaches to responding to such notifications to ensure ongoing access to quality Laboratory Services.

OPERATOR REQUIREMENTS

At least 30 days prior to seeking any approval for any of the following actions, the Operator will provide a notice in writing to the Minister by way of a Letter of Intent if the Operator intends to:

a) cease Laboratory Facility operations;
b) cease the provision of a type of Laboratory Services that is specified in the Approval for a Laboratory Facility; or
c) significantly reduce either Laboratory Facility operations or the provision of a type of Laboratory Services that is specified in the Approval for a Laboratory Facility.

In cases where urgent health or safety or business risk(s) exists, the Operator can request a shortened notification period and should be prepared to provide substantive evidence of the risk(s).

In the Letter of Intent outlining the proposed change(s) to operations and/or services, the Operator should include a brief but clear description of the following:

a) The name and location of the impacted facility.
b) The proposed change(s) and the preferred effective date of the proposed change(s).
c) The rationale for ceasing and/or significantly reducing operations or services.
d) The implications for the affected community and region: Basic population/demographic information about the surrounding community and region, and the potential implications for patients, health care providers, other laboratory service providers, etc.
e) Alignment of the proposed change(s) with the Operator's strategic service delivery planning for laboratory services.

The Letter of Intent should be reviewed and signed by a member of the Operator's executive or senior management team before being sent to the Minister or delegate for review.

POLICY

1. Section 10 of the Laboratory Services Regulation requires the Operator of a laboratory facility that is subject to an approval to seek an amendment to the approval at least 30 days before a significant change to the capability or capacity of the laboratory facility to provide laboratory services.

2. Further, under the *Laboratory Services Act*, the Minister may decide to cancel or make changes to Facility Approval(s) if the decision is in the public interest. Thus, the Minister requires advance notification from the Operator to ensure a reasonable opportunity to review the laboratory facility's notification of a reduction in operations (a "Letter of Intent"), make an informed-decision, and provide appropriate direction.

This policy may not be applicable to Operators providing laboratory services under an Agreement, as such Operators would be expected to follow the change management and governance processes set out within the Agreement.

At the discretion of the Minister, the required notification period may be shortened in exceptional circumstances where an Operator has provided substantive evidence that there is an urgent risk to health, safety, or business need.

3. The review of the Letter of Intent may entail the following actions by the Minister or delegate:

    a) Assessing whether the content addresses the Operator's Requirements and if the information provided will be sufficient to either provide further direction to the Operator and/or make a decision under the *Laboratory Services Act*.

    b) Preliminary verification of the data (e.g., volumes, expenditures) if presented in the Letter of Intent.

    c) Consultation(s) with the Operator for clarification and/or additional information.

    d) Consultation(s) with other laboratory system partners to assess support for the proposed change(s) and potential implications for the laboratory system.

    e) Determining if the Letter of Intent, as notification of the proposed change(s), is acceptable to the Minister.

    f) Other actions the Minister or delegate determines to be appropriate in the circumstances.

The Minister or delegate will provide a written response to the Operator to the Letter of Intent. The response will state whether the Operator's Letter of Intent is acceptable to the Minister, a rationale for the assessment, and, if appropriate, direction regarding further actions to be taken by the Operator and/or the Minister.

If the information provided in the Letter of Intent is determined to be sufficient for the Minister to make a decision under the *Laboratory Services Act*, the response to the Letter of Intent will briefly state the decision and the rationale for the decision.

Alternatively, if a more fulsome assessment of the proposed change(s) is required, the Operator may be directed to develop and submit a Service Change Proposal to the Minister or delegate

for review/approval. (Refer to Policy 3.5.1 for more information about the Service Change Proposal.)

CROSS REFERENCE

Policy 3.1: Notification of Changes Policy

Policy 3.3: No Transfer or Assignment of Approvals

Policy 4.3: Disruptions to Laboratory Services

AUTHORITY

Laboratory Services Act: Sections 10 and 18
Laboratory Services Regulation: Sections 7, 8 (1) and (2), 12

POLICY 3.5.1: INFORMATION REQUIRED FOR A SERVICE CHANGE PROPOSAL

PURPOSE

To clarify the information that is required in a Service Change Proposal in support of ceasing and/or significantly reducing the operations of a laboratory facility or service, and to indicate the required timeframes for submitting a Service Change Proposal to the Minister for review and direction.

POLICY

Upon receipt of a notice of an Operator's intention to Cease Operations of an approved Laboratory Facility, an assessment will be conducted to determine the impact of the loss in services may have on the Laboratory Services system, including whether there is a public interest/need to replace the services and how best to replace the services.

OPERATOR REQUIREMENTS

If required by the Minister in response to a Letter of Intent, the Operator is to develop and submit a Service Change Proposal at least 30 days prior to the effective date of the proposed change(s). The Service Change Proposal in regard to ceasing or significantly reducing the operations of a laboratory facility or service must include the following information, in a complete and legible format and manner as required by the Minister:

1. Details about the impacted facility and its current service delivery model:
    a) Name and location of the facility
    b) Hours of operation (as reported and, if different than reported, provide explanation for the change)
    c) Capacity (e.g., phlebotomy chairs and beds)
    d) Capability (i.e., approved services / DAP accredited services)
    e) Average patient throughput per month
    f) Accessibility metrics (e.g., average wait times for walk-ins; if applicable, average time to book an appointment; typical patient travel times to arrive at the facility)

2. Further details about the proposed change(s) and the rationale for ceasing and/or significantly reducing operations or services:
    a) Background or context that is relevant to the proposed change(s) (e.g., historical service disruptions, labour challenges, etc.), including previous or future actions taken by the Operator to alleviate the situation.
    b) Description of the proposed change(s) and effective date of the change(s); if the changes are to be phased, describe each phase with a timeline.

c) Explanation of the reasons for the proposed change(s) and the timing for the change(s).

3. Population/demographic information and the potential impacts of the proposed change(s) for the surrounding community and region:

   a) Description of the community/region population and demographics, including First Nations and Indigenous persons and other underserved or vulnerable populations.

   b) Identification of the potential impacts on the community and/or region:

      i. Patients and their families (e.g., wait times, travel times).

      ii. Underserved or vulnerable populations (e.g., social determinates

      iii. Physicians and other health care providers, local health care facilities, primary care networks (e.g., ordering practices, requisition fulfillment concerns, etc.)

      iv. Other laboratory service providers in the region (e.g., capacity, capability and hours of operation, etc.)

   c) Outline of community engagement and communication plans and/or pursued activities to:

      i. Obtain input from community members on the proposed change(s).

      ii. Ensure that all impacted members of the community and/or region are provided with timely and clear information about the change(s) and how to access other appropriate resources.

4. Alignment of the proposed change(s) with the Operator's strategic service delivery planning for laboratory services:

   a) If applicable, identification of the Operator’s strategic plan or goals that addresses the delivery of laboratory services in the province of British Columbia.

   b) Description of how the proposed change(s) are aligned with the Operator’s strategic plans specifically for the delivery of laboratory services in the impacted community or region.

   c) Description of the Operator’s sustainability plans for the delivery of laboratory services. (Note: This description is especially important if no strategic plan exists, or the proposed change(s) are not aligned with the Operator’s strategic plans.)

5. Proposed course of action or recommendation to ensure continuity of access to laboratory services in the community or region, which could include (but is not limited to):

- Redeployment of staff to the Operator's other facility/ies in the community.
- Request to expand capacity and/or capability for Operator's other facility/ies.
- Pursuit of other service delivery models (e.g. mobile laboratory services).
- Involvement of another laboratory service provider to potentially assume some of or all the patient and/or test volumes.

The Operator may consult with the Ministry and other laboratory system partners in the development of the Service Change Proposal. The general details of such consultations (e.g., name of person/organization, consultation date(s), area(s) of expertise, etc.) should be mentioned in the Service Change Proposal.

The final version of the Service Change Proposal should be reviewed and signed by a member of the Operator's executive or senior management team before being sent to the Minister or delegate for review.

CROSS REFERENCE

Policy 3.1: Notification of Changes Policy

Policy 3.3: No Transfer or Assignment of Approvals

Policy 3.5: Ceasing and/or Significantly Reducing Operators of a Laboratory Facility or Service

Policy 4.3: Disruptions to Laboratory Services

AUTHORITY

Laboratory Services Act: Sections 10 and 18
Laboratory Services Regulation: Sections 7, 8 (1) and (2), 12

POLICY 3.5.2: APPROACH TO ASSESSING SERVICE CHANGE PROPOSALS

PURPOSE

To articulate the general approach taken and the criteria used to assess Service Change Proposals.

POLICY

1. The assessment of a Service Change Proposal will include:
    a) Applying relevant criteria and considerations specified in the *Laboratory Services Act* and the Laboratory Services Regulation;
    b) Documenting the application of criteria and considerations; and,
    c) Consulting with subject matter experts to inform deliberations, recommendations, and/or support decision-making by the Minister.
2. Service Change Proposals will be assessed for evidence of meeting the following criteria:
    a) Sufficient details about the impacted facility and its current service delivery model:
    b) Sufficient details about the proposed change(s) and the rationale for ceasing and/or significantly reducing operations or services, including background/context, actions taken by the Operator to alleviate the situation, and the reason for the timing of the change(s).
    c) Reasonability of the proposed effective date of the change(s) and/or phased timeline.
    d) Demonstrated awareness of the community/region served by the Operator, including but not limited to:
        i. description of population size and demographics (e.g., average age, etc.)
        ii. identification of First Nations and/or Indigenous communities and other underserved/vulnerable populations in the region
        iii. acknowledgement of specific needs or interests that are unique to the community/region.
    e) Evaluation of the potential impacts on the community and/or region, specifying the implications for: patients and their families (e.g., wait times, travel times), underserved or vulnerable populations (e.g., social determinates of health), physicians and other health care providers, local health care facilities, primary care networks (e.g., ordering practices, requisition fulfillment concerns, etc.); other laboratory service providers in the region (e.g., capacity, capability and hours of operation, etc.).
    f) The type and level of community engagement and communication plans and/or pursued activities.

g) Evidence supporting how the proposed change(s) are aligned with the Operator's strategic plans specifically for the delivery of laboratory services in the impacted community or region.

h) The applicability of the Operator's sustainability plans for the delivery of laboratory services.

i) The feasibility of the proposed course of action or recommendation.

j) The Operator's assurance regarding continuity of access to laboratory services in the community or region.

k) The type and level of consultations mentioned in the Service Change Proposal.

l) Approval by Operator's executive or senior management team.

The Minister or delegate will aim to communicate a decision to the Operator, including any limits and conditions to be applied, within 15 business days of receipt of the Service Change Proposal.

OPERATOR REQUIREMENTS

Operators, intending to cease or significantly reduce operations of a laboratory facility or service, must provide and meet specific criteria in order to obtain approval to proceed with the proposed change(s).

CROSS REFERENCE

Policy 3.1: Notification of Changes Policy

Policy 3.3: No Transfer or Assignment of Approvals

Policy 3.5: Ceasing and/or Significantly Reducing Operators of a Laboratory Facility or Service

Policy 3.5.1: Information Required for a Service Change Proposal

Policy 4.3: Disruptions to Laboratory Services

AUTHORITY

Laboratory Services Act: Sections 10 and 18
Laboratory Services Regulation: Sections 7, 8 (1) and (2), 12

POLICY 4.1: IMPLEMENTATION OF AN APPROVAL

PURPOSE

To ensure Benefits that have been approved to be provided through a Laboratory Facility are provided in an efficient and timely manner.

OPERATOR REQUIREMENTS

The Operator must implement the Approval within specified timelines and notify the Minister when the Approval has been implemented.

The Operator may request in writing for a one-time extension to the implementation of Approval for a New Laboratory Facility, relocation of a Laboratory Facility or renovations to an existing Approved Laboratory Facility. When applying, the Operator must include the rationale for the extension request.

POLICY

Approvals are to be operationalized within the timeline (limits and conditions) to minimize any negative impacts on the provision of efficient and timely Access to Benefits for patients and referring health care providers.

a) Applications for amendments to an existing Approval must be operationalized within 6 months of the date of the Approval; and,

b) Applications for a new facility, relocation of an existing facility and renovations to an existing approved Laboratory Facility must be implemented within 18 months of the date of Approval.

A one-time 12-month extension to the 18-month implementation period may be granted if such a request is made at least 60 days prior to its expiry and if the delay in implementing the approved service is the result of extenuating, unforeseeable circumstances.

If the approved service is not implemented within the approved time frame, including any approved extension, the Approval may be cancelled by the Minister.

This policy will not apply to construction or significant physical Expansion of Public Laboratory Facilities that would increase capacity.

CROSS REFERENCE

Policy 2.1: Facilities Approvals

Policy 2.4.2: Assessment Criteria: Sufficient Need/Accessibility

Policy 2.5: Approval Decision-Making and Communications

Policy 6: Moratoriums on Laboratory Facility Approvals Applications

AUTHORITY

Laboratory Services Act Section 11 (1)(c), 11(2), 18
Laboratory Services Regulation Section 9 (e)

POLICY 4.2: SUBSEQUENT APPLICATIONS AND LIKE-APPLICATIONS

PURPOSE

To ensure subsequent and Like-Applications are submitted based on system need, are consistently and fairly assessed, and do not impede the effective and efficient approval of needed facilities.

To ensure the effective oversight and management of the supply of Benefits that are available to beneficiaries.

OPERATOR REQUIREMENTS

The Operator must comply with the specified timelines with respect to the policy for subsequent Applications and Applications for like-services in a Catchment Area.

POLICY

If an applicant has an Application denied, the applicant cannot make another Application in respect of that same location for 18-months, except as provided below.

If during the 18-months period, changes in the Laboratory Services system result in the need for the services in a Catchment Area that had previously been denied (e.g. due to the cancellation of another facility's Approval Applications, or an urgent substantial risk to health or safety or business need) a general notice will be posted online to reflect that Applications will be accepted and the rationale for the change. A subsequent Application from an applicant who was previously denied Approval will not be given priority consideration over a Like-Application.

CROSS REFERENCE

Policy 2.4.2: Assessment Criteria: Sufficient Need/Accessibility

Policy 6: Moratoriums on Laboratory Facility Approvals Applications

AUTHORITY

Laboratory Services Act Section 11(1)
Laboratory Services Regulation Section 8(1)

POLICY 4.3: DISRUPTIONS TO LABORATORY SERVICES

PURPOSE

To ensure the Minister is aware of any Disruption(s) in services being provided at an Approved Laboratory Facility, and that the Laboratory Service(s), if still required, are restored as quickly as possible.

NOTIFICATION REQUIREMENTS

The Operator must notify the Minister of any Disruption in the provision of Laboratory Service(s) at an Approved Laboratory Facility. For a Foreseeable Disruption, the Operator must notify the Minister at least 30 days before the Disruption, or as soon as practicable if the Disruption is not a
Foreseeable Disruption until fewer than 30 days prior to the anticipated Disruption. For an Unforeseeable Disruption, the Operator must notify the Minister as soon as practicable, or two (2) business days after an Unforeseeable Disruption has started, whichever is earlier.

The Operator must provide pertinent details of the Disruption to the Minister, including:

- the extent of the Disruption;
- the anticipated duration of the Disruption;
- what actions are being undertaken to restore services; and
- what plan is in place to provide alternate services, if required during the Disruption.

The Operator must provide the Minister with regular reports on the progress and actions being taken to restore Laboratory Service(s) until the Disruption has ended.

The Operator must communicate the Disruption to Beneficiaries and Referring Practitioners who may use the Approved Laboratory Facility within a period and format that is reasonable to the type of Disruption and its impact on access and quality of services. These communications must include information on what alternative services are available and anticipated duration of the Disruption. Operators must notify Beneficiaries and Referring Practitioners if and when services are going to be restored.

Within 30 days of the end of a Disruption, the Operator is required to provide the Minister with a review of the Disruption.

Additional information pertaining to the cause and resolution of a Disruption, as well as continuity planning, may be requested by the Minister. This could include, but is not limited to, a business continuity plan, details of a maintenance or upgrade project, and long-term and short term strategic plans pertaining to the operations of the Approved Laboratory Facility.

POLICY

Upon receipt of a notification of a Disruption, the Minister will assess impacts, including risks to patient access and quality of services, as well as feasibility of the proposed resolution.

Upon receipt and review of the notification of a Disruption, the Minister will consider the issue and may take one or more actions, including:

a) granting a period of up to 90-days before further action is taken;

b) seeking temporary options to ensure continuity of services, which may include making arrangements with other Operators to perform Laboratory Services;

c) requesting additional information pertaining to the cause and resolution of a Disruption;

d) cancelling the Approval or a component of the Approval;

A one-time extension of up to six (6) months above the initial 90 day period may be granted if:

I. the request for a one-time extension is submitted and received no later than 30 days prior to the expiry of the initial 90 day period; and,

II. in the event of extenuating, unforeseeable circumstances, if the Disruption cannot feasibly be resolved within the original timeline.

The Operator must provide the rationale for the extension, the requested length of the extension, and any additional activities to be taken to rectify the Disruption

If the initial granted period, or extension to this period has ended and an Operator has not restored services, the Minister will take further action including:

a. requesting that the Operator return to pre-Disruption status;

b. cancelling the Approval or a component of the Approval for an approved Laboratory Facility; or,

c. Require that the Operator provide notice (See Policy 3.1: Notification of Changes) that minor changes in hours of operation, with low risks to patient access, are permanent.

A review of the Disruption, and steps taken to resolve and prevent a future Disruption is expected to be submitted by the Operator within 30 days of the end of the Disruption.

The Minister may seek Applications for the provision of Laboratory Service(s) that was/were provided under the cancelled approval from other providers.

The Minister may transfer the provision of the service(s) that was/were provided under the cancelled Approval to another provider if both providers are public providers of Laboratory Services.

The Minster may seek the provision of the service(s) that was/were provided under the cancelled Approval from a provider operating under an agreement, in accordance with the terms of the agreement.

CROSS REFERENCE

Policy 3.1: Notification of Changes

Policy 2.4.2: Assessment Criteria: Sufficient Need/Accessibility

Policy 2.5.3: Cancellation of Approval

Policy 3.4: Significant/Material Change Applications

Policy 4.4: Assessing Impacts of a Disruption

AUTHORITY

Laboratory Services Act Sections 10, 11, 13, 18
Laboratory Services Regulation Sections 10, 12(1), 21

POLICY 4.4: ASSESSING IMPACTS OF A DISRUPTION

PURPOSE

To identify assessment metrics that may be used to determine the severity of impacts to patient access and quality of service stemming from a Disruption in Laboratory Services.

OPERATOR REQUIREMENTS

Operators should provide the requested information to the Minister to assess the severity of an impact when a Disruption is reported (See Policy 4.3: Disruption to Laboratory Services), and determine any required action(s) to ensure continuity of service.

POLICY

The severity of an impact to patient access and quality of service from a Disruption, or potential Disruption, will be assessed by the Minister using the following metrics:

a) The number of alternate facilities in each area and distance to each of these facilities
b) Operational status
c) Reason for the Disruption
d) Challenges in resolving the Disruption and business continuity planning by the Operator
e) Number of hours and days the service will be interrupted
f) Type of facility in terms of capability and capacity, patient volume, and scope of services
g) Social and health needs in the community that are being impacted Other metrics may be considered to enhance this assessment, if required.

The severity of the impact of a Disruption will be classified as low, medium, high, or extreme, and will be reported by the Minister to the Operator along with what actions are required to ensure continuity of service.

A Disruption that is determined to have a low severity of impact on patient access and quality of service may require no additional intervention by an Operator, while those with a high and extreme severity may require extensive intervention by the Operator and Minister.

The impact analysis will occur when a Disruption is reported and if an extension to the initial 90 day period is sought by the Operator (See Policy 4.3: Disruption to Laboratory Services).

CROSS REFERENCE

Policy 2.4.2: Assessment Criteria: Sufficient Need/Accessibility

Policy 2.4.5: Assessment Criteria: Public Interest

Policy 4.3: Disruptions to Laboratory Services

AUTHORITY

Laboratory Services Act Sections 11, 13, 18, 27
Laboratory Services Regulation Sections 10, 12

POLICY 5: REPORTING

PURPOSE

To ensure that up-to-date information regarding the on-going Capacity, and performance of all Approved Laboratory Facilities is available to support decision making and inform system needs in the province.

OPERATOR REQUIREMENTS

An Operator must submit Capacity performance related data and other information if and as required and in accordance with the specified timeframes.

POLICY

Reporting of Capacity, performance related data and other information is required on a biannual basis in October and April of each year, or at other times as determined by the Minister, as appropriate.

Operators will be provided with the required reporting template and must submit the completed template through the designated channel, as directed by the designated operational body which will receive and review the required information and reports that Approved Laboratory Facilities submit.

Operators may be required to report the following information to the designated operational body or persons as stipulated on behalf of the Minister:

a) Capacity related data;

b) Performance related data;

c) Data related to Disruptions that have occurred;

d) the name(s) of the current Medical Director 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 Laboratory Facility; and,

e) any other information required to support, manage and administer the Facility Policies program on behalf of the Minister.

CROSS REFERENCE

Policy 3.4: Significant/Material Change Applications

AUTHORITY

Laboratory Services Act, Sections 31, 27
Laboratory Services Regulation Sections 1

POLICY 6: MORATORIUMS ON LABORATORY FACILITY APPROVALS APPLICATIONS

PURPOSE

To identify the circumstances when the Minister may declare a moratorium on Applications for Laboratory Facility Approvals, and articulate the requirements and processes for considering an Application when there is a moratorium in effect for Laboratory Facility Approvals.

OPERATOR REQUIREMENTS

In the event a moratorium is in effect in relation to application for Laboratory Facility Approvals the Operator or potential Operator must:

a) submit a request for a "Moratorium Exemption" and obtain approval to submit an Application for any Laboratory Service(s) identified in the moratorium prior to submitting an Application for approval; and,

b) include all relevant information required, as determined by the Minister to enable assessment of the Operator's moratorium exemption request based on the relevant moratorium exemption criteria.

POLICY

The Minister may declare a moratorium on Laboratory Facility Applications as needed to ensure appropriate and sustainable delivery of and Access to Laboratory Services.

A moratorium on Laboratory Facility Applications may be implemented for a specific geographic Catchment Area(s) or the entire province, all types of Applications or a specific type of Application (e.g. Applications for new facilities), and any other reason as determined by the Minister.

The Minister will specify criteria for seeking an exemption to the moratorium and will accept requests for exemptions to the moratorium based on these criteria. Criteria for a moratorium exemption may include, but may not be limited to, an urgent health need, safety need, and business need.

Applications for Approval will not be accepted or considered, unless a moratorium exemption approval has first been obtained.

Operators or potential Operators wishing to submit an Application for Approval during a moratorium will be informed of the moratorium and the moratorium exemption process and criteria.

Upon receipt, moratorium exemption requests will be assessed to ensure exemption criteria have been met and, if met, an Approval from the Minister for the moratorium exemption will be sought.

The applicant will be provided with the Minister's decision on the exemption request and subsequent steps as needed.

Information regarding any moratorium that is in effect will be posted on the appropriate website(s), including information on how to request a moratorium exemption.

Denial of a moratorium exception request cannot be appealed at the ministry level.

A moratorium remains in effect until the date specified or until it has been revoked by the Minister.

CROSS REFERENCE

Policy 2.1: Facilities Approvals

Policy 4: Subsequent Applications and Like-Applications

AUTHORITY

Laboratory Services Act, Section 10
Laboratory Services Regulation, Section 8

POLICY 7: CONFLICT OF INTEREST

PURPOSE

The purpose of the Conflict of Interest (COI) Policy is to protect the integrity of publicly-funded outpatient Laboratory Services/Benefits by establishing COI standards in respect of Laboratory Facilities and their operators, and to ensure that personal interests (financial or otherwise) do not conflict with Beneficiaries' interests with respect to medical care/Laboratory Services. The COI Policy aims to ensure that COIs are identified and managed in a timely and proactive manner.

The COI Policy is intended to assist persons who own or intend to own a Laboratory Facility, and operators more generally, to meet their COI obligations in respect of Referring Practitioners who may request Benefits to be provided through an Approved Laboratory Facility. For example, in relation to identifying, declaring, and communicating any relevant existing or potential COI. Despite the intention to assist owners/operators in meeting their COI obligations, the COI Policy is not a comprehensive guide to or substitute for the *Laboratory Services Act* and Laboratory Services Regulation; it should not be used as an Application or compliance checklist. Compliance with the COI Policy will not necessarily ensure or constitute compliance with the *Laboratory Services Act* and Regulations and other applicable law.

SCOPE

A COI arises where there is an existing or potential discrepancy between a person's professional or official duty to act in a beneficiary's interest and the person's own personal interests.

A COI can be existing, potential, or perceived, and may arise in a wide variety of circumstances. Direct financial or material gain is not necessary for a Conflict of Interest to exist. Thus, a COI may occur, for instance, when existing, potential, or perceived benefits accrue or would accrue to the person's Family members or business associate(s).

Section 17 of the Laboratory Services Regulation stipulates that a Referring Practitioner must not refer a Beneficiary, for the purposes of receiving a Benefit, to an approved Laboratory Facility in which the Referring Practitioner has a material or Indirect Financial Interest unless there is no Public Laboratory Facility that:

a) has the same Catchment Area as the Approved Laboratory Facility; and,

b) provides the Benefit.

As prescribed by Section 8 of the Laboratory Services Regulation, an Approval cannot be granted if there is an existing or potential COIs identified under Section 7(2)(f) of the Laboratory Services Regulation (existing or potential Conflict of Interest in respect of referring practitioners), unless another approved Laboratory Facility without existing or potential COI cannot reasonably provide the proposed Laboratory Services.

Section 12 of the Laboratory Services Regulation requires Operators of Approved Laboratory Facilities to ensure Benefits are not provided in respect of a Beneficiary on the request of a

Referring Practitioner who, directly or indirectly, would receive financial profit or a material benefit as a result, unless the Approved Laboratory Facility's Approval authorized the acceptance of requests from that particular Referring Practitioner.

Without limiting the generality or scope of existing or potential COIs, the following circumstances are illustrative of situations which may constitute or give rise to a COI in the context of Laboratory Facilities:

a) a Referring Practitioner with an ownership interest in an Approved Laboratory Facility makes referrals to that Laboratory Facility;

b) a Referring Practitioner makes referrals to an Approved Laboratory Facility, and as a result of making those referrals, receives or could receive, directly or indirectly, financial profit or material benefit; or,

c) a Family member of a Referring Practitioner is the owner of the Approved Laboratory Facility that the Referring Practitioner makes referrals to and as such would directly or indirectly, receive financial or material benefit from making referrals to that Laboratory Facility.

OPERATOR REQUIREMENTS

At time of Application:

Section 12 of the Laboratory Services Regulation requires operators of Approved Laboratory Facilities to ensure that Benefits are not provided in respect of a Beneficiary on the request of a Referring Practitioner who, directly or indirectly, would receive financial profit or a material benefit as a result, unless the approved Laboratory Facility's Approval authorized the acceptance of requests from that particular Referring Practitioner.

Operators applying for a new Approval or an amendment to an existing Approval must complete and submit the:

a) Conflict of Interest Declaration Form; **and,**

b) Conflict of Interest Disclosure Form.

An Approval is void if the applicant fails to disclose a Conflict of Interest.

Ongoing duty:

Additionally, if at any time after an Approval has been granted or after an Application has been submitted but not yet approved or denied by the Minister, circumstances exist or arise that may constitute or give rise to a relevant COI with respect to an Approved Laboratory Facility, the current or potential Operator must:

a) as soon as it is practicable, complete new COI Declaration and COI Disclosure forms to disclose any relevant existing or potential COIs in relation to the Laboratory Facility,

which must be submitted in the manner required by Laboratory Administration Staff; and,

b) ensure that Benefits are not provided in respect of a Beneficiary on the request of a Referring Practitioner who, directly or indirectly, would receive financial profit or material benefit as a result (unless the Approved Laboratory Facility's Approval authorizes the acceptance of requests for that particular Referring Practitioner).

POLICY

If it is determined that relevant circumstances or interests amount to an existing or potential COI in relation to the provision of Benefits by a specific Laboratory Facility for which an Application is being assessed, the Minister will deny the Application in accordance with Section 8 of the Laboratory Services Regulation, unless Section 8(2) of the Laboratory Services Regulation applies.

If there is an existing or potential Conflict of Interest within the meaning of Section 7(2)(f) of the Laboratory Services Regulation, but Section 8(2) of the Laboratory Services Regulation may apply on the basis that the proposed Laboratory Services cannot reasonably be provided by another Approved Laboratory Facility for which an existing or potential COI does not exist, any recommendation to the Minister to approve an Application in such exceptional circumstances will also include a recommendation to attach any and all limits and conditions deemed necessary or advisable to mitigate the COI.

Upon receipt of a COI declaration, or upon learning of an existing or potential COI, the matter will be assessed to determine if there is an existing or potential COI in relation to a specific Laboratory Facility. If it is determined that relevant circumstances or interests amount to an existing or potential COI that has not been previously considered in relation to the provision of Benefits by an Approved Laboratory Facility (whether an Application is being assessed or not), a recommendation will be submitted to the Minister to:

a) add or change the limits and conditions on the Laboratory Facility's Approval; or,

b) cancel the Laboratory Facility's Approval.

CONFIDENTIALITY

The information contained in any declaration or statement respecting a COI shall remain confidential to the designated operating body and the Minister, subject to a legal requirement to disclose the information.

CROSS REFERENCE

Policy 2.1: Facilities Approvals

Policy 2.2: Required Application Information

Policy 2.3: Approach to Application Assessment

Policy 2.4.3: Assessment Criteria: Conflict of Interest

Policy 2.4.4: Assessment Criteria: Changes to the Persons Having a Material Financial Interest in a Facility

Policy 2.5.1: Limits and Conditions

Policy 3.2: Changes to Limits and Conditions Outside of the Application Process

Policy 3.3: No Transfer or Assignment of Approvals

AUTHORITY

Laboratory Services Act, Sections 10, 11, 13,
Laboratory Services Regulation, Sections 7(2)(f), 8,8(2) 9, 9(3) and 12(4), and Section 17

CONFLICT OF INTEREST DECLARATION FORM

To: Designated Operational Body

I have read and understood the Laboratory Facility Conflict of Interest Policy (the "COI Policy"), and I undertake to be bound by its obligations.

I understand that it is my responsibility to report to the designated operational body the information described in the COI Policy, and I undertake to do so.

I acknowledge that an Approval is void if the Application does not fully disclose the information described in the COI Policy.

The information that I disclose (including Personal Information) is being supplied in confidence, although I understand that the information I disclose is being collected under the authority of the *Laboratory Services Act*, and will be used and disclosed for the purpose of administering the *Laboratory Services Act* in accordance with the *Freedom of Information and Protection of Privacy Act*.

I agree to inform the Minister of any change in circumstances that may give rise to a relevant Conflict of Interest with respect to a Laboratory Facility, as soon as is practicable.

ATTENTION: The person completing/signing this Declaration Form (the "Declarant") must be duly authorized to make the declaration on behalf of the person/entity submitting an Application.

Name of Laboratory Facility to which this Conflict of Interest declaration relates:

_____

Declarant

Name: _____

Title: _____

Date: _____

Signature:

_____

To: The Minister of Health

Is there an existing or potential Conflict of Interest to disclose in relation to the Laboratory Facility? Check one:

☐ Yes, there is an existing or potential Conflict of Interest to disclose in relation to the Laboratory Facility.

If yes, provide details of the existing or potential Conflict of Interest in Parts I and II.

☐ I am unsure if the circumstances constitute, or may constitute, an existing or potential Conflict of Interest.

If unsure, provide details of the potential Conflict of Interest in Parts I and II.

☐ No, there is no existing or potential Conflict of Interest to disclose in relation to the Laboratory Facility.

If no existing or potential Conflict of Interest is indicated, the Disclosure Form must be completed by signing and completing the signature block information found at the of end the form.

If applicable, on the following pages, provide full details and circumstances that relate to existing or potential Conflicts of Interest by completing Parts I and II.

ATTENTION: The person completing/signing this Disclosure Form (the “Declarant”) must be duly authorized to make the declaration/disclosure on behalf of the Operator/owner required to make the declaration/disclosure.

Part I

Expand space and/or append additional pages as necessary, to provide all relevant information.

Laboratory Facility Name(s)	The names of all relevant practitioners, Family members, Laboratory Facility owners (including the Declarant) or business associates who hold or may hold a relevant financial or material interest	Any relevant affiliations or relationships with the owner or intended owner of the Laboratory Facility and the details of any interest or benefit that may relate to a Conflict of Interest	Any other information, including dates, that is relevant to understanding and assessing the nature, scope and degree/extent of existing or potential Conflicts of Interest

Part II

In the space below, provide any additional information (not covered in Part I) that is relevant to understanding and assessing the nature, scope, and degree/extent of existing/potential Conflict of Interest. Include any details regarding proposed avoidance or mitigation measures relating to any existing or potential Conflicts of Interest. Expand box/space and/or append additional pages as necessary, to provide all relevant information.

Name of Laboratory Facility to which this Conflict of Interest declaration relates:

_____

Name: _____

Title: _____

Date: _____

Signature: _____

DEFINITIONS

This document is titled "Outpatient Laboratory Facilities Manual: Policies Under the *Laboratory Services Act*" (hereafter referred to in abbreviated form as the "Facilities Policies.") It replaces the previous policy document titled "Approval-Related Policies and Guidelines for Laboratory Facilities Providing Out-patient Laboratory Services on a Fee-For-Service Basis."

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

a) a different, more particular definition is given for the purposes of a specific policy; or,

b) additional modifiers or context require 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*, which is an agreement in relation to the provision of Benefits (see Sections 1 and 12 of the *Laboratory Services Act*).

"Application" means an Application for a new or amended Approval as outlined in Policy 2.1 of this Facilities Policies manual, such as a new Laboratory Facility, a relocation or Expansion of an existing Laboratory Facility, a change to the persons having a Material Financial Interest in a Laboratory Facility, or for any other change or activity for which approval is required under the *Laboratory Services Act* or Section 7 of the Laboratory Services Regulation.

"Approval" means as defined in Section 1 of the *Laboratory Services Act*, which is an approval granted under Section 11 of the *Laboratory Services Act*. Among other things, Section 11 provides that the Minister may "grant to an Operator an approval to provide Benefits through a specified Laboratory Facility."

"Approved Laboratory Facility" means as defined in Section 1 of the *Laboratory Services Act*, which is a Laboratory Facility that is subject to an Approval or to a Laboratory Services Agreement.

"Beneficiary" means as defined in Section 1 of the *Laboratory Services Act*, which is a British Columbia 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.

"Benefit" means as defined in Section 1 of the *Laboratory Services Act*, which is "other than as used in Section 68 of the Act, means a Laboratory Service that is a benefit under Section 4" of the *Laboratory Services Act*. Section 4 of the *Laboratory Services Act* provides that subject to

Section 4(2) of the *Laboratory Services Act*, 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.

Section 4(2) of the *Laboratory Services Act* provides that the Minister may make orders as follows:

a) that a Laboratory Service or a class of Laboratory Services are not benefits; or,

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 a corporation, partnership, limited partnership, or other similar entity that is incorporated or created under the laws of Canada or under the laws of any province of Canada.

"Capacity" means the volume/number of outpatient (Laboratory Services) Benefits and/or Beneficiaries a Laboratory Facility can accommodate, based on the volume of physical and human resources within its hours of operation.

"Catchment Area" means the geographic area that Laboratory Administration Staff consider in assessing an 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 (refer to Policy 2.5.2).

"Cease Operations" means to discontinue providing Benefits that have been approved to be performed through a specified Laboratory Facility.

"Child" as defined in Section 1 of the *Medicare Protection Act*, means a person who:

a) is a child of a Beneficiary or a person in respect of whom a Beneficiary stands in the place of a parent and who is a minor;

b) does not have a spouse; and,

c) is supported by the Beneficiary.

“Conflict of Interest” means any personal interests, financial or otherwise, that may conflict with beneficiaries’ interests with respect to medical care/Laboratory Services and includes Section 2 (2) (3) “Financial interests in a Laboratory Facility” of the Laboratory Services Regulation.

“Declarant” means a person who makes a declaration statement pursuant to the Conflict of Interest (COI) Policy contained within this manual (refer to Policy 7).

“Disruption” means any cessation or reduction in the provision of a Laboratory Service/Benefit (including a decrease in the hours of operation) that a facility is Approved to provide, including a Foreseeable Disruption or an Unforeseeable Disruption.

“Expansion” in relation to an existing Laboratory Facility, means:

a) an addition of Laboratory Services to be provided at an approved Laboratory Facility; or,

c) a significant increase to the Capacity of the approved Laboratory Facility to provide Laboratory Services, which includes increases to the physical clinical space of the Laboratory Facility.

“Family” and **“Family Members”** means as defined in section 2(3) of the Laboratory Services Regulation, which is the person’s:

a) spouse or spouse’s parent;

b) Child, stepchild or grandchild;

c) parent, stepparent or grandparent;

d) sibling or stepsibling; or,

e) the spouse of any of the person listed in paragraphs (a) to (d).

“Foreseeable Disruption” means a planned or reasonably anticipated Disruption to Laboratory Services. This may include but is not limited to: facility maintenance, moving locations, adjustments due to staffing challenges, or supply chain issues.

“Foreign Disclosure Laws” means any laws, statutes, by-laws, treaty, directive, policy having force of law, order, judgment, 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.

“Indirect Financial Interest” means as defined in Subsection 2(2) of the Laboratory Services Regulation, which is that a person has an indirect financial interest in a Laboratory Facility if any of the following circumstances exist:

a) the person, or the person acting on behalf of the person, has a material financial interest in a corporation that has a Material Financial Interest in the Laboratory Facility;

b) the person is a corporate partner of another person that has a Material Financial Interest in the Laboratory Facility;

c) the person is a director or officer of a person or body that has a Material Financial Interest in the Laboratory Facility;

d) the person is an employee of a person or body referred to in paragraph (c); or,

e) the person has a near relative (as defined in Subsection 2(3) of the Laboratory Services Regulation) who has a Material Financial Interest in the Laboratory Facility, and the person has reason to be aware of that interest.

"Laboratory Administration Staff" means staff assigned responsibility by the Ministry of Health to administer the Facilities Policies.

"Laboratory Facility" means as defined in Section 1 of the *Laboratory Services Act*, which is 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; or,

c) a Specimen Collection Station associated with a hospital or facility referred to in paragraph (a) or (b) of this definition.

"Laboratory Medicine Physician" means as defined in Section 1 of the *Laboratory Services Act*, which is "a medical practitioner registered with, and authorized to practice in a prescribed specialty by, the College of Physicians and Surgeons of British Columbia" (see Section 5 of the Laboratory Services Regulation for a list of prescribed specialties.)

"Laboratory Service" means as defined in Section 1 of the *Laboratory Services Act*, which is "subject to the Laboratory Services Regulation:

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."

"Laboratory Services Act" means the legislation pertaining to the provision of a Laboratory Service that is a Benefit in British Columbia.

"Laboratory Services Regulation" means the Laboratory Services Regulation under the *Laboratory Services Act*, as amended from time to time.

“Like-Application” means an Application for 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 Laboratory Facility in the same Catchment Area. Identified like-facilities are used to assess wait times, service need, proximity and Access to services, and utilization of existing facilities.

“Material Financial Interest” means as set out in Subsection 2(1) of the Laboratory Services Regulation, which is that 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 percent of the shares in the corporation or Laboratory Facility.

“Medical Director” means a registrant of the College of Physicians and Surgeons of British Columbia and whose credentials are acceptable to the DAP Committee, and who has been delegated responsibility for the delivery and all matters pertaining to procedures and medical care in the laboratory

“Minister” means the **“Minister (or delegate)”**.

“New Service” means a type of Laboratory Service for which a facility does not have, but seeks, an Approval.

“Operator” means as defined in Section 1 of the *Laboratory Services Act*, which in relation to a Laboratory Facility is the following:

a) the owner;

b) the person having responsibility for the daily operation of the Laboratory Facility; or,

c) a regional health board or Prescribed Agency.

“Personal Information” means as defined in Section 1 of the *Laboratory Services Act*, which is the same meaning as “personal information” in the *Freedom of Information and Protection of Privacy Act.*

“Prescribed Agency” as specified in Section 6 of the Laboratory Services Regulation, for the purposes of the definition of “prescribed agency” in Section 1 of the *Laboratory Services Act* and the Facilities Policies, 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; and,

d) Provincial Health Services Authority.

"Privately-Owned Laboratory Facility" means a facility that:

a) is not a public Laboratory Facility; and,

b) is operating under an Approval or an Agreement under the *Laboratory Services Act* in order to provide Laboratory Services/Benefits through a Specimen Collection Station and/or a laboratory testing site.

"Public Laboratory Facility" means as defined in Section 1 of the Laboratory Services Regulation, which is 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); or,

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

"Referring Practitioner" means as defined in Section 1 of the *Laboratory Services Act*, which is a person who:

a) is either a medical practitioner enrolled under Section 13 of the *Medicare Protection Act*; or,

b) a person within a class of prescribed health care practitioners; and,

c) makes a request for a Beneficiary to receive Benefits.

"Specimen Collection Station" means as defined in Section 1 of the *Laboratory Services Act*, which means a place that is principally equipped for the taking or collecting of specimens.

"Unforeseeable Disruption" means a Disruption to Laboratory Services that occurs for unplanned and unanticipated reasons, including the following:

a) a natural disaster, such as explosion, fire, flood, earthquake, or power failure;
b) catastrophic weather conditions or other elements of nature or acts of God;
c) a war (declared and undeclared), insurrection or act of terrorism or piracy, riot, civil disorder, rebellion, or sabotage;
d) strike, lock-out, work stoppage or other labour disruption;
e) equipment failures, or damage to the functionality of a facility;
f) acute and severe illness that effects staff; or,

anything that is not a Foreseeable Disruption.

APPENDIX A – EXAMPLES OF URGENT HEALTH, SAFETY, AND BUSINESS NEEDS

Urgent Health Need	• The area has a high concentration of vulnerable or underserved populations who have very limited or no access to laboratory services. • In a public health emergency, the province needs to expand laboratory services. • When the scope of existing laboratory services is insufficient or inappropriate in meeting a community's current needs.
Urgent Safety Need	• The physical space and/or its environment poses a safety or accessibility risk for clients or staff (e.g., obstructed access to buildings, washrooms, doorways, etc.). • Surge of criminal activity in a neighborhood or location. • Persistent overcrowding in waiting areas within the facility (e.g., the waiting area does not provide enough space for people to queue for intake, to facilitate confidentiality, to accommodate people with mobility issues, etc.). • To remediate documented WorkSafeBC standards for employee safety will be prohibitively expensive or cannot be adequately resolved in the existing location. • Unavoidable, prolonged constructions activities in a facility or area that poses a safety risk to clients or staff.
Urgent Business Need	• Significant renovations to existing facilities are determined to be unavoidable, such as to accommodate necessary technology or equipment. • The Operator’s head office or a reference laboratory facility requires additional square footage to function more efficiently. • External prolonged construction that significantly impacts the Operator’s ability to conduct business as usual (e.g. drilling or blasting). • The lease for the location is set to expire and cannot be renewed.

APPENDIX B – SERVICE DELIVERY PROPOSAL CONTENT RECOMMENDATIONS

Operator requirements in support of Policy 2.2 Required Information for a Facility Approval Application or Service Delivery Proposal

1. Background or context that is relevant to the proposed change(s) including addressing critical operation issues,
2. Details about the proposed service delivery model, and evidence of how the proposed model will support improve access to services:
    a. Accessibility metrics (e.g., average patient wait times for walk-ins vs booking an appointment) and patient experience
    b. Background or context that is relevant to the proposed change(s) including addressing critical operation issues (e.g., outdated equipment or high operational costs, logistical/transportation requirements, testing turnaround times)
    c. Accreditation in alignment with the Diagnostic Accreditation Program (Policy 2.4.1)
    d. Capacity by service level (CSL) indicating current service level: Calculation is done by dividing current chairs in catchment by current population of catchment and multiplying by 100,000
    CSL = (chairs in LHA/Population in LHA) x 100,000
    e. Target Service Level: identify the number of chairs needed to achieve the target service level of tests per 100,000 people annually. Understanding that one reasonably utilized laboratory chair will operate six days / week throughout the year, minus 10 days for statutory holidays, and that the chair is utilized for XX number of tests per day.
3. Description of the proposed service delivery effective date and proposed management for continuous service delivery; if the changes are to be phased, describe each phase with a timeline
    a. Reasonable utilization (annual operation capacity calculation per chair)
    b. Average monthly utilization at existing approved facilities in the catchment during the preceding 12, 6 and 3-month periods and utilization benchmark of these facilities (per chair, number of tests expected)
4. Population/demographic information and the potential impact management of the proposed change(s) for the surrounding community and region.
    a. Description of the community/region population and demographics, including First Nations and Indigenous persons and other underserved or vulnerable populations.
    b. Identification of the potential impacts on the community and/or region:
        i. Patients and their families (e.g., wait times, travel times).
        ii. Underserved or vulnerable populations (e.g., social determinates)

iii. Physicians and other health care providers, local health care facilities, primary care networks (e.g., ordering practices, requisition fulfillment concerns, etc.)
iv. Other laboratory service providers in the region (e.g., capacity, capability and hours of operation, etc.)

c. Outline of community engagement and communication plans and/or pursued activities to:
    i. Identify closures risk impact assessment, disruptions
    ii. Availability of functional alternative laboratory facilities, including logistical considerations of transportation, within a 1k, 5km, 10km, or beyond 10km, radius.
    iii. Ensure that all impacted members of the community and/or region are provided with timely and clear information about the change(s), timings and how to access other appropriate resources.

5. Alignment of the Service Delivery Proposal with the regional HA's strategic service delivery planning for laboratory services:
    a. If applicable, identification of alignment with the Operator's strategic plan or goals that addresses the delivery of laboratory services in the province of British Columbia.
    b. Description of how the proposed change(s) are aligned with the Operator's strategic plans specifically for the delivery of laboratory services in the impacted community or region (including sustainability and service/continuum of care)
    c. Description of the Operator's sustainability plans for the delivery of laboratory services. (Note: This description is especially important if no strategic plan exists, or the proposed change(s) are not aligned with the Operator's strategic plans.)
        i. identifying both short-and long-term sustainability planning through laboratory stewardship
        ii. identifying capacity to manage clients redirected from other facilities