

## LABORATORY FACILITY CONFLICT OF INTEREST POLICY

### 1. DEFINITIONS

In this Laboratory Facility Conflict of Interest Policy:

“application” means an application for a new laboratory facility, for relocation or expansion of an existing laboratory facility, for a change to persons having a material financial interest in a laboratory facility, or for any other change or activity for which approval is required under the *Laboratory Services Act* (the “Act”) or the Laboratory Services Regulation (the “Regulation”).

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

“approved laboratory facility” means, for the purpose of the Laboratory Facility Conflict of Interest Policy (the “Policy”), a laboratory facility that is subject to an approval, but does not include a laboratory facility that is subject to a laboratory services agreement (that is, an agreement referred to in Section 12 of the Act).

“beneficiary” means a B.C. resident who is enrolled in accordance with section 7.2 of the *Medicare Protection Act*, and includes the resident's child if the child is enrolled under section 7.2. (Pursuant to Section 1 of the Act and as defined in Section 1 of the *Medicare Protection Act*.)

“benefit”, means a laboratory service that is a benefit under Section 4. (Defined in Section 1 of the Act.) Section 4 provides as follows:

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

(a) through an approved laboratory facility, and

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

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

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

(2) The minister may make orders as follows:

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

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

- (i) on the request of a specified referring practitioner or class of referring practitioners,
- (ii) in respect of a specified type of human injury, disease or illness, or
- (iii) in a specified laboratory facility or class of laboratory facilities.

“declarant” means a person who makes a declaration statement pursuant to this Policy.

“family” and “family members” means or refers to:

- (a) a spouse;
- (b) a son or daughter;
- (c) a step-son or step-daughter;
- (d) a parent or step-parent;
- (e) a mother-in-law or father-in-law;
- (f) a grandparent;
- (g) a grandchild;
- (h) a brother or sister;
- (i) a step-brother or step-sister; or
- (j) a spouse of a person referred to in paragraphs (b) to (i).

“indirect financial interest”: 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);
- (e) the person has a near relative [as defined in Section 2(3) of the Regulation] who has a material financial interest in the laboratory facility, and the person has reason to be aware of that interest.

(Defined in Section 2(2) of the Regulation.)

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

“laboratory facility” means the following:

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

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

(Defined in Section 1 of the Act.)

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

- (a) in the corporation or laboratory facility as a sole proprietor or partner, or
- (b) of more than 10% of the shares in the corporation or laboratory facility.

(As defined in Section 2(1) of the Regulation.)

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

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

- (a) the owner;
- (b) the person having responsibility for the daily operation of the laboratory facility;
- (c) a regional health board or prescribed agency.

(Defined in Section 1 of the Act.)

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

“privately-owned laboratory facility” means a facility that:

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

“public laboratory facility” means the following:

- (a) in respect of a hospital within the meaning of paragraph (a) or (e) of the definition of “hospital” in section 1 of the *Hospital Insurance Act*, that part of the hospital that provides laboratory services;
- (b) a specimen collection station that is associated with a hospital referred to in paragraph (a);
- (c) a laboratory that is funded, managed or operated by a regional health board or a prescribed agency.

(Defined in Section 1 of the Regulation)

“referring practitioner” means a person who

- (a) is either
- (i) a medical practitioner enrolled under section 13 of the *Medicare Protection Act*, or
  - (ii) a person within a class of prescribed health care practitioners, and
- (b) makes a request for a beneficiary to receive benefits.

(Defined in Section 1 of the Act.)

## 2. PURPOSE OF THE POLICY

The purpose of this Laboratory Facility Conflict of Interest Policy (the “Policy”) is to protect the integrity of publicly-funded out-patient laboratory services/benefits by establishing conflict of interest 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. This Policy aims to ensure that conflicts of interest are identified and managed in a timely and proactive manner.

The Policy is intended to assist persons who own or intend to own a laboratory facility, and operators more generally, to meet their conflict of interest obligations in respect of referring practitioners who may request benefits to be provided through a laboratory facility, for example in relation to identifying, declaring and communicating any relevant existing or potential conflicts of interest. Despite the intention to assist owners/operators in meeting their conflict of interest obligations, this Policy document is not a comprehensive guide to or substitute for the Act and Regulation; it should not be used as an application or compliance checklist. Compliance with the Policy will not necessarily ensure or constitute compliance with applicable law.

## 3. SCOPE OF CONFLICT OF INTEREST

A conflict of interest 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 conflict of interest can be real (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 conflict of interest may occur, for instance, where the real, potential, or perceived benefits accrue or would accrue to the person’s family members or business associate(s).

As prescribed by Section 8(1)(c) of the Laboratory Services Regulation, B.C. Reg. 52/2015 (the “Regulation”), an approval may be granted only if no existing or potential conflicts of interest are identified under Section 7(2)(f) [*application for approval*]. Section 8(2) allows an approval to be granted if existing or potential conflicts of interest are identified but another approved laboratory facility [as defined in Section 1 of the Act, rather than as this Policy] without existing

or potential conflicts of interests cannot reasonably provide the proposed laboratory services. For the purposes of Section 8 of the Regulation and this Policy a relevant conflict of interest is any existing or potential conflict of interest that the applicant has reason to be aware of in respect of referring practitioners who may request benefits to be provided through the laboratory facility (see section 7(2)(f) and 8(1)(c) of the Regulation.)

Section 12(4) of the Regulation [*operational requirements*] requires that an operator of an approved laboratory facility must 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.

Section 17 of the Regulation [*prohibition on referrals*] 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.

Without limiting the generality or scope of existing or potential conflicts of interest, the following circumstances are illustrative of situations which may constitute or give rise to conflicts of interest in the context of laboratory facilities:

- a practitioner with an ownership interest in a laboratory facility could make referrals to that laboratory facility;
- a practitioner could make referrals to a laboratory facility, and as a result of making those referrals, receives or could receive, directly or indirectly, financial profit or material benefit;
- ownership of a privately-owned laboratory facility includes family members of a referring practitioner who, directly or indirectly, would receive financial or material benefit from making referrals to that facility.

#### 4. DISCLOSURES OF CONFLICTS OF INTEREST

*At time of application:*

In accordance with Sections 7(2)(f), 8(1)(c), 9(3), and 12(4) of the Regulation, Section 25 of the *Laboratory Services Act*, and Policies 2.2, 2.5 and 2.5.3 of the Approval Policies and Guidelines for Laboratory Facilities<sup>1</sup>, an operator/person who owns or intends to own a laboratory facility must complete and submit both a Conflict of Interest Declaration Form (**Appendix A**) and a

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<sup>1</sup> The full title of this policy document is the Approval-Related Policies and Guidelines for Laboratory Facilities Providing Out-patient Laboratory Services on a Fee-For-Service Basis.

Conflict of Interest Disclosure Form (**Appendix B**) with any application; the Conflict of Interest Disclosure Form (**Appendix B**) must disclose to the Laboratory Approval Staff any relevant existing or potential conflict of interest that arises or may arise in relation to a laboratory facility.

*Ongoing duty:*

Additionally, at any time after an approval has been granted, if circumstances exist or arise that may constitute or give rise to a relevant conflict of interest with respect to a laboratory facility, an operator/person who owns or intends to own a laboratory facility must:

- complete and submit a new Conflict of Interest Disclosure Form (**Appendix B**) to the Laboratory Approval Staff as soon as it is practicable; and
- 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).

## 5. DETERMINING EXISTENCE OF, AND RESPONSE TO, CONFLICT OF INTEREST

Upon receipt of a Conflict of Interest Disclosure Form or learning of an existing or potential conflict of interest by any other means, the Laboratory Approval Staff will determine if there is a conflict of interest (existing or potential) in relation to a specific laboratory facility.

If it is determined that the relevant circumstances or interests amount to an existing or potential conflict of interest in relation to the provision of benefits by a specific laboratory facility, the Laboratory Approval Staff must deny an application in accordance with Subsection 8(1)(c) of the Regulation, that is, unless the exceptional circumstances described in Section 8(2) apply. Laboratory Approval Staff may attach limits or conditions to an approval they deem necessary to avoid or mitigate a conflict of interest.

Pursuant to Section 8(2) of the Regulation, in exceptional circumstances, Laboratory Approval Staff may approve an application in respect of which an existing or potential conflict of interest is identified, where 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; if Laboratory Approval Staff approve an application in such exceptional circumstances, they will place an appropriate endorsement on the approval in question and attach any and all limits and conditions they deem necessary or advisable to mitigate the conflict of interest.

If Laboratory Approval Staff find an existing or potential conflict of interest that has not been endorsed in relation to the approval of the laboratory facility in question, they may refer the matter to the Minister for determination and action and may recommend a course of action



such as adding or altering limits and conditions on the laboratory facility's approval or cancellation of its approval.

## 6. CONFIDENTIALITY

The information contained in any declaration or statement, respecting a conflict of interest shall remain confidential to Laboratory Approval Staff subject to any requirement to disclose, as may be required by law.



**APPENDIX A - CONFLICT OF INTEREST DECLARATION FORM**

**To: The Laboratory Approval Staff**

I have read and understood the Laboratory Facility Conflict of Interest Policy (the “Policy”), and I undertake to be bound by the obligations contained therein.

I understand that it is my responsibility to report to the Laboratory Approval Staff the information described in the Policy, and I undertake to do so.

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

I agree to inform the Laboratory Approval Staff 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:

\_\_\_\_\_

## APPENDIX B - CONFLICT OF INTEREST DISCLOSURE FORM

### To: The Laboratory Approval Staff

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 of **Appendix B**.

- 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 of **Appendix B**.

- No, there is no existing or potential conflict to interest to disclose in relation to the laboratory facility.

If no existing or potential conflict of interest is indicated, **Appendix B** must be completed by signing and completing the signature block information found at the end of this **Appendix B** Disclosure 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 an 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 detail 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:

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### Declarant

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Signature:

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