BRITISH COLUMBIA

Laboratory Services Act

LABORATORY SERVICES REGULATION

B.C. Reg. 52/2015

Deposited March 30, 2015 and effective October 1, 2015
Last amended September 4, 2018 by B.C. Reg. 152/2018

Consolidated Regulations of British Columbia

This is an unofficial consolidation.

Consolidation current to September 27, 2018

B.C. Reg. 52/2015 (O.C. 132/2015), deposited March 30, 2015 and effective October 1, 2015, is made under the *Laboratory Services Act*, S.B.C. 2014, c. 8, ss. 71, 72 (1), (2) and (3), 74 and 75 (3), (5) and (6).

This consolidation includes any amendments deposited and in force as of the currency date at the bottom of each page. See the end of this regulation for any amendments deposited but not in force as of the currency date. Any amendments deposited after the currency date are listed in the B.C. Regulations Bulletins. All amendments to this regulation are listed in the *Index of B.C. Regulations*. Regulations Bulletins and the Index are available online at www.bclaws.ca.

See the User Guide for more information about the *Consolidated Regulations of British Columbia*. The User Guide and the *Consolidated Regulations of British Columbia* are available online at www.bclaws.ca.

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PART 1 – INTERPRETATION

Definitions

1 In this regulation:

"Act" means the *Laboratory Services Act*;

"identity number" means the identity number referred to in section 8 of the Act;

"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;

"requisition form" means the form, whether paper or electronic, on which a request for benefits from a referring practitioner is made or recorded.

[am. B.C. Reg. 225/2016, Sch. 3, s. 1.]

Financial interests in laboratory facilities

2 (1) For the purposes of this regulation, 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.

(2) For the purposes of this regulation, a person has an indirect financial interest in a laboratory facility if any of the following circumstances exist:

(a) the person, or a 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 who has a material financial interest in the laboratory facility, and the person has reason to be aware of that interest.

(3) For the purposes of subsection (2) (e), a person is a near relative of another person if the person is

(a) the other person's spouse or a parent of the other person's spouse,

(b) the other person's child, stepchild or grandchild,

(c) the other person's parent, stepparent or grandparent,

(d) the other person's sibling or stepsibling, or

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

PART 2 – REFERRING PRACTITIONERS

Referring practitioners

3 (1) A health care practitioner is prescribed as a referring practitioner for the purposes of the Act if the health care practitioner is enrolled as a practitioner under section 13 of the *Medicare Protection Act* and is a member of at least one of the following classes:

(a) a registrant of the College of Dental Surgeons of British Columbia who is authorized to use the title "dentist", "dental surgeon", "surgeon" or "doctor";

(b) a registrant of the College of Midwives of British Columbia who is authorized to use the title "midwife";

(c) a registrant of the College of Podiatric Surgeons of British Columbia who is authorized to use the title "podiatrist", "podiatric surgeon", "surgeon" or "doctor";

(d) a registrant of the British Columbia College of Nursing Professionals who is authorized to use the title "nurse practitioner" or "registered nurse practitioner".

(2) A health care practitioner is prescribed as a referring practitioner for the purposes of the Act if the health care practitioner is enrolled as a practitioner under section 13 of the *Medicare Protection Act* and

(a) is a registrant of the British Columbia College of Nursing Professionals who is authorized to use the title "registered nurse", and

(b) has successfully completed a certification program as described in section 8 (2) (b) (ii) of the Nurses (Registered) and Nurse Practitioners Regulation.

(3) The minister may establish, by order, schedules in respect of the benefits that may be requested by one or more classes of referring practitioners.

(4) In referring a beneficiary to an approved laboratory facility for the purposes of receiving benefits, a referring practitioner may request benefits only in accordance with the schedule established under subsection (3) for the class to which the referring practitioner belongs.

(5) A person is prescribed for the purposes of section 4 (1) (b) (i) of the Act as a person who may request benefits if the person is, at the time a laboratory service

is requested, authorized in another jurisdiction of Canada to practise a health profession equivalent to that of a medical practitioner.

[am. B.C. Regs. 225/2016, Sch. 3, ss. 2 and 3; 152/2018, s. 6.]

4 Repealed. [B.C. Reg. 225/2016, Sch. 3, s. 4.]

PART 3 – LABORATORY FACILITIES

Laboratory medicine physicians

5 For the purposes of the definition of "laboratory medicine physician" in section 1 of the Act, a medical practitioner must be authorized by the College of Physicians and Surgeons of British Columbia to practise in one or more of the following specialties, as recognized by the Royal College of Physicians and Surgeons of Canada:

(a) general, anatomical or hematological pathology;

(b) medical biochemistry;

(c) medical genetics;

(d) medical microbiology;

(e) neuropathology.

Prescribed agencies

6 For the purposes of the definition of "prescribed agency" in section 1 of the Act, the following bodies are prescribed:

(a) British Columbia Cancer Agency Branch;

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

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

(d) Provincial Health Services Authority.

Application for approval

7 (1) An application for approval in respect of a laboratory facility, including a proposed laboratory facility, may be made

(a) only by the owner or intended owner of the laboratory facility, and

(b) no later than 90 days before the date on which the applicant requests the approval to be effective.

(2) An application for approval must include all of the following:

(a) the address or addresses of the laboratory facility;

(b) the name of the owner of the laboratory facility;

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

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

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

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

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

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

(i) the proposed hours of operation of the laboratory facility;

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

Criteria for approval

8 (1) The minister may grant an approval if satisfied of all of the following:

(a) there is sufficient need with respect to capability, capacity, quality of service, cost or other factors to warrant the proposed laboratory services, including that needs are not being met by existing approved laboratory facilities that

(i) provide the proposed laboratory services, and

(ii) are located within the 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 under section 7 (2) (f) *[application for approval]*;

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

(2) Subsection (1) (c) does not apply if 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.

Granting approval

9 (1) An approval must identify at least the following information:

(a) the address or addresses of the approved laboratory facility;

(b) the laboratory services to be provided through the approved laboratory facility;

(c) the persons having a material financial interest in the approved laboratory facility;

(d) the capability or capacity of the approved laboratory facility to provide laboratory services;

(e) the limits and conditions, if any, attached to the approval by the minister.

(2) The term of an approval begins and ends on the dates specified by the minister in the approval.

(3) An approval is void, and laboratory services provided during the term of the approval are not benefits, if the applicant for the approval

(a) provided information with the application that the applicant knew or ought to have known to be false or misleading, or

(b) failed to provide information with the application that the applicant knew or ought to have known was relevant to the consideration of the application by the minister.

Changes to approval

10 (1) 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;

(c) the hours of operation of the laboratory facility.

(2) 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) (a) or (c) *[granting approval]*.

(3) 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 any of the things described in section 9 (1) (b) or (e),

(b) a significant change to any of the things described in section 9 (1) (d), or

(c) the term of the approval expires, if the change is to extend the term of the approval.

(4) This section does not apply in respect of a change that

(a) results from the exercise by the minister of a power under the Act, or

(b) has been agreed to previously by the minister as a condition of an approval.

(5) Despite subsection (1), the minister may waive the 30-day notice requirement under that subsection if the minister is of the opinion that the operator could not reasonably comply with that requirement.

Criteria for agreements

11 The minister may enter into a laboratory services agreement if satisfied of all of the following:

(a) there is sufficient need with respect to capability, capacity, quality of service, cost or other factors to warrant the proposed laboratory services;

(b) the quality of laboratory services will be maintained at a sufficiently high level;

(c) the agreement, if implemented according to the terms of that agreement, will support the sustainability of the health care system;

(d) it would be in the public interest to enter into the agreement.

Operational requirements

12 (1) An operator of an approved laboratory facility must ensure that all of the following are maintained to the satisfaction of the minister:

(a) the number of skilled and qualified personnel employed by the approved laboratory facility;

(b) the level of supervision provided by laboratory medicine physicians who are supervising the provision of benefits through the approved laboratory facility;

(c) the laboratory services provided through the approved laboratory facility;

(d) the capability or capacity of the approved laboratory facility to provide laboratory services;

(e) the standards of testing and analysis used in the approved laboratory facility.

(2) Persons who provide benefits through an approved laboratory facility must consider all relevant guidelines established by the minister.

(3) An operator of an approved laboratory facility must not give to a referring practitioner a requisition form other than one made by the minister under section 36 (1) of the Act.

(4) 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 authorizes the acceptance of requests from that particular referring practitioner.

Clinical record-keeping requirements

13 (1) An operator of an approved laboratory facility must keep, in accordance with this section, a clinical record for each benefit provided through the approved laboratory facility.

(2) A clinical record must include at least the following:

(a) the names of both the beneficiary and the referring practitioner;

(b) the beneficiary's identity number;

(c) the referring practitioner's practitioner number;

(d) a description of the injury, disease or illness, or the diagnosis, that gave rise to the request for the benefit to be provided;

(e) each specific laboratory service requested by the referring practitioner;

(f) the requisition form;

(g) the date on which, and the location at which, relevant specimens were collected from the beneficiary;

(h) each specific laboratory service provided;

(i) if a laboratory service was provided but was not requested by a referring practitioner, the name of the laboratory medicine physician who authorized the non-requested service;

(j) the results and diagnostic interpretations of each laboratory service provided.

(3) For the purposes of subsection (2) (f), the requisition form must be one of the following:

(a) the original requisition form;

(b) a copy or electronic reproduction of the original requisition form;

(c) a record of a verbal request made by a referring practitioner, showing the name of the person who recorded the request and the information that would have been required had a requisition form been completed by the referring practitioner.

(4) Despite subsection (2) (a) and (b), the clinical record must not include the name or identity number of a beneficiary who has

(a) been provided a service in relation to voluntary testing for human immunodeficiency virus, and

(b) requested anonymity for the purposes of a report made under the *Public Health Act* by a medical practitioner in respect of the person's infection with or exposure to human immunodeficiency virus.

General record-keeping requirements

14 (1) An operator of an approved laboratory facility must keep the financial records, including the books, accounts and financial transactions, of the approved laboratory facility in the form required by the minister.

(2) An operator of an approved laboratory facility must keep all of the following in a readily retrievable manner:

(a) the clinical records referred to in section 13 *[clinical record-keeping requirements]*,

(b) the financial records referred to in subsection (1) of this section, and

(c) records of internal protocols and results of internal reviews in relation to quality assurance and adverse events.

(3) An operator of an approved laboratory facility must keep the records referred to in this section for at least 6 years unless

(a) the minister agrees in writing to a shorter period, or

(b) an audit or investigation is in process at the end of the 6-year period, in which case the records must be kept until the audit or investigation is complete.

PART 4 – REQUESTING AND RECEIVING BENEFITS

Services excluded from being benefits

15 (1) A service is not a laboratory service that is a benefit for the purposes of the Act if the person receiving the service is entitled to have the service paid for on the person's behalf, or to be reimbursed for the cost of the service, under any of the following Acts:

(a) *Insurance (Vehicle) Act*;

(b) *Workers Compensation Act*.

(2) A service is not a laboratory service that is a benefit for the purposes of the Act if the person receiving the service is entitled to have the service paid for on the person's behalf, or to be reimbursed for the cost of the service, under any of the following Acts of Canada:

(a) *Aeronautics Act*;

(b) *Canadian Forces Members and Veterans Re-establishment and Compensation Act*;

(c) *Civilian War-related Benefits Act*;

(d) *Corrections and Conditional Release Act*;

(e) *Department of Veterans Affairs Act*;

(f) *Government Employees Compensation Act*;

(g) *Merchant Seamen Compensation Act*;

(h) *National Defence Act*;

(i) *Pension Act*;

(j) *Royal Canadian Mounted Police Pension Continuation Act*;

(k) *Royal Canadian Mounted Police Superannuation Act*.

Electronic requests for benefits

16 A referring practitioner may make a request for benefits by submitting a requisition form to an approved laboratory facility electronically only if submitted in the manner required by the minister.

Prohibition on referrals

17 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.

Duty to verify enrolment

18 (1) Before providing benefits to a person, an operator must take reasonable steps to verify whether the person is or is not a beneficiary, including by doing all of the following:

(a) requiring the person to provide, in accordance with subsection (2), information and documentation respecting the person's identity;

(b) disclosing the information collected under paragraph (a) to the commission;

(c) obtaining confirmation from the commission as to whether the person is or is not a beneficiary.

(2) For the purposes of subsection (1) (a), a person must provide

(a) the person's services card or, before February 10, 2018, the person's CareCard, as those terms are defined in the Medical and Health Care Services Regulation, B.C. Reg. 426/97,

(b) the person's identity number, accompanied by

(i) one piece of identification showing the person's photograph and legal name, or

(ii) two pieces of identification showing the person's legal name, or

(c) if the information or documentation referred to in paragraphs (a) and (b) is not available, the information necessary to verify whether the person is or is not a beneficiary, including the person's legal name, date of birth, address and gender.

Benefits rendered outside British Columbia

18.1 If a beneficiary receives, outside British Columbia, laboratory services that the minister determines are medically required, the beneficiary is entitled to payment for the cost of the laboratory services as follows:

(a) without the minister's prior approval if the beneficiary resides in British Columbia and the nearest convenient location for receiving the laboratory services is outside British Columbia but within Canada;

(b) with prior approval of the minister if the laboratory services are elective, non-emergency laboratory services and are provided outside Canada;

(c) without the minister's prior approval if

(i) the laboratory services are provided in respect of emergency services that are not available in Canada, and

(ii) the British Columbia Patient Transfer Network operated by British Columbia Emergency Health Services coordinates the transfer of the beneficiary outside Canada for the purpose of receiving the emergency services.

[en. B.C. Reg. 229/2017, Sch.]

Misuse of identity numbers

19 The following persons are prescribed as persons who must make a report under section 8 of the Act:

(a) an operator or employee of an approved laboratory facility;

(b) a person who provides medical, scientific, technical or administrative services under contract to an approved laboratory facility.

PART 5 – ADMINISTRATIVE MATTERS

Notices

20 (1) If the minister is required under the Act to give notice to a person, the minister must give the notice

(a) in writing, and

(b) by registered mail to,

(i) in the case of an operator or a former operator, the address of the operator's or former operator's approved laboratory facility as specified under section 9 (1) (a) *[granting approval]*, or

(ii) in the case of a person other than an operator or a former operator, the last known address of the person.

(2) Despite subsection (1) (b), the minister and the intended recipient may agree in writing that notice may be given in an alternative manner or to an alternative address.

(3) A notice sent by registered mail as required under subsection (1) is deemed to have been received on the date the notice is delivered.

Cancellation of approvals for laboratory system reasons

21 The minister must give at least 90 days' written notice before cancelling an approval under section 18 of the Act.

Notice and hearings

22 (1) The minister must give at least 30 days' written notice of the following before taking an action under any of sections 11 (2), 52 (2), 59 (2) and 61 (2) of the Act:

(a) the action the minister proposes to take;

(b) the reason for taking the action;

(c) the time and manner in which the recipient of the notice may respond to the proposed action;

(d) that a failure to respond to a proposed action will result in the action being taken without further notice or an opportunity to be heard.

(2) For the purposes of subsection (1) (c), responses to proposed actions may be as follows:

(a) an operator, a former operator, an employee of an operator or a person who provided a benefit may respond to a proposed action either

(i) in writing, by delivering the response to the minister within 30 days of receiving the notice under subsection (1), or

(ii) in person and with or without legal counsel, by delivering a written request to appear in person to the minister within 21 days of receiving the notice under subsection (1);

(b) a person other than one referred to in paragraph (a) may respond to a proposed action in writing, by delivering the response to the minister within 30 days of receiving the notice under subsection (1).

(3) A response to a proposed action may do one or more of the following:

(a) provide reasons why the minister should not take or should delay taking the proposed action;

(b) propose that the minister take an alternative action;

(c) include information, evidence or supporting documentation.

(4) On considering a response received under subsection (2) or further information or evidence received under paragraph (b) of this subsection, the minister may do any of the following:

(a) determine that the proposed action should not be taken;

(b) request further information or evidence and, for this purpose, the minister may delay taking the proposed action;

(c) without further notice or opportunity to be heard, proceed with the proposed action or a modification of the proposed action.

(5) If no response is received under subsection (2) within the time or in the manner required under that subsection, the recipient of the notice is deemed to agree with the proposed action and the minister may proceed without further notice or opportunity to be heard.

Recovery of non-entitled amounts

23 (1) In addition to the information required under section 22 (1) *[notice and hearings]* of this regulation, the minister must include in a notice given under section 52 (3) of the Act

(a) the amount of the non-entitled amount owing,

(b) the amount of the surcharge owing, and

(c) information respecting the calculation of interest owing.

(2) The prescribed surcharge for the purposes of section 52 (2) (b) of the Act is 5% of the non-entitled amount.

Advisory committees

24 If an advisory committee is established under section 35 of the Act, Treasury Board Directive 3/11 applies for the purpose of determining

(a) the remuneration of members, and

(b) the payment of members' reasonable and necessary travel and out-of-pocket expenses incurred in carrying out the work of the committee.