The Medical Imaging Facilities Licensing Regulations

being

Chapter P-4.11 Reg 1 (effective February 28, 2017) as amended by Saskatchewan Regulations 70/2019.

NOTE:

This consolidation is not official. Amendments have been incorporated for convenience of reference and the original statutes and regulations should be consulted for all purposes of interpretation and application of the law. In order to preserve the integrity of the original statutes and regulations, errors that may have appeared are reproduced in this consolidation.

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CHAPTER P-4.11 REG 1

The Patient Choice Medical Imaging Act

Title

1 These regulations may be cited as *The Medical Imaging Facilities Licensing Regulations*.

Interpretation

- 2 In these regulations:
 - "Act" means The Patient Choice Medical Imaging Act;
 - "Category I licence" means a licence described in clause 12(2)(a);
 - "Category II licence" means a licence described in clause 12(2)(b);
 - "CT services" includes:
 - (a) the production of an image from a computerized tomography imaging machine;
 - (b) the medical interpretation of the image mentioned in clause (a);
 - (c) the digital transcription of the results;
 - (d) communication of the results to the appropriate persons involved in the care or treatment of the individual to whom the services were provided;
 - (e) digital storage of the image as required by section 7; and
 - (f) any further consultation required on the image or interpretation of the image for clarification purposes;
 - "eHealth Saskatchewan" means eHealth Saskatchewan created by the Lieutenant Governor in Council as a Crown corporation pursuant to *The Crown Corporations Act, 1993*;

"medical imaging services" includes the following:

- (a) CT services;
- (b) MRI services;

"MRI services" includes:

- (a) the production of an image from a magnetic resonance imaging machine:
- (b) the medical interpretation of the image mentioned in clause (a);
- (c) the digital transcription of the results;

- (d) communication of the results to the appropriate persons involved in the care or treatment of the individual to whom the services were provided;
- (e) digital storage of the image as required by section 7; and
- (f) any further consultation required on the image or interpretation of the image for clarification purposes;

"referring practitioner" means:

- (a) a health care professional who has been granted privileges or given specific authority by a regional health authority to order the specific medical imaging service from facilities operated by the regional health authority or an affiliate within the meaning of The Regional Health Services Act; or
- (b) a physician who holds a current licence to practise medicine in a Canadian jurisdiction outside Saskatchewan and who is a member in good standing of a body that is responsible for the licensing and regulating of physicians in that jurisdiction;

"second scan service" means the provision of medical imaging services by a licensee to an individual who is identified by the regional health authority pursuant to subsection 14(5).

3 Mar 2017 cP-4.11 Reg 1 s2.

Medical imaging facility exemption

2.1 A place or facility where an oral maxillofacial surgeon or oral radiologist authorized to do so by the College of Dental Surgeons of Saskatchewan provides only cone beam computed tomography imaging services is not a medical imaging facility for the purposes of the Act.

 $20~{\rm Sep}~2019~{\rm SR}~70/2019~{\rm s2}.$

Application fees

- **3** Every applicant for a licence or renewal of a licence shall pay a fee to the accreditation program operator in the amount required to reimburse the accreditation program operator for the reasonable costs incurred by or on behalf of it with respect to:
 - (a) reviewing and processing the application and accompanying information and material;
 - (b) determining if the medical imaging facility conforms to the standards of the accreditation program; and
 - (c) any other services provided by the accreditation program operator that are necessary or incidental to the matters mentioned in clauses (a) and (b).

3 Mar 2017 cP-4.11 Reg 1 s3.

Accreditation program

- 4(1) The CT/MRI Facilities Accreditation Program established by the College of Physicians and Surgeons of the Province of Saskatchewan is the accreditation program for medical imaging facilities.
- (2) A licensee of a medical imaging facility shall participate in the accreditation program and shall comply with the standards of the accreditation program.

3 Mar 2017 cP-4.11 Reg 1 s4.

Medical director

- **5**(1) A licensee shall ensure that medical imaging services provided in a medical imaging facility are under the continuous supervision of a medical director.
- (2) In order for a person to act as a medical director of a licensee, he or she must be a duly qualified medical practitioner who:
 - (a) has a specialty practice in radiology recognized by the College of Physicians and Surgeons of the Province of Saskatchewan; and
 - (b) meets the requirements set out by the accreditation program operator.
- (3) A medical director is responsible for all aspects of the operation of the medical imaging facility and, without limiting the generality of the foregoing, is responsible for:
 - (a) ensuring that the medical imaging facility is operated in accordance with the requirements of the accreditation program; and
 - (b) the control and safekeeping of the medical imaging records of the medical imaging facility, as described in section 7.

3 Mar 2017 cP-4.11 Reg 1 s5.

Employment of staff

- **6** A licensee shall ensure that:
 - (a) all physicians who provide or assist in providing medical imaging services are duly qualified medical practitioners and meet any requirements for those services set by the College of Physicians and Surgeons of the Province of Saskatchewan for physicians to provide services in medical imaging facilities;
 - (b) all medical radiation technologists practising in the medical imaging facility are practising members within the meaning of *The Medical Radiation Technologists Act, 2006* and meet any requirements set by the Saskatchewan Association of Medical Radiation Technologists;
 - (c) any other individual involved or assisting in providing medical imaging services at the medical imaging facility who is required to be licensed pursuant to an Act in order to provide those services has a current licence to practise and meets any requirements set by the governing body responsible for the licensing and regulating of those services;

- (d) an up-to-date record of the qualifications of the persons mentioned in clauses (a) to (c), as applicable, is kept in the medical imaging facility;
- (e) it employs a sufficient number of staff members in order to provide medical imaging services in a safe and appropriate manner; and
- (f) each staff member is appropriately trained and proficient in the proper use of any equipment that may be used by the staff member in providing medical imaging services at the medical imaging facility.

3 Mar 2017 cP-4.11 Reg 1 s6.

Medical imaging records

7(1) A licensee shall keep a medical imaging record for each individual who receives medical imaging services at the medical imaging facility in which the medical imaging services were provided.

(2) A licensee shall:

- (a) transmit a copy of all images that result from the provision of medical imaging services to individuals at the licensee's medical imaging facility to eHealth Saskatchewan for storage in the provincial diagnostic information system approved by the minister; or
- (b) maintain all images that result from the provision of medical imaging services to individuals at the licensee's medical imaging facility in a format suitable to eHealth Saskatchewan and, when directed by the minister, transmit a copy of those images to eHealth Saskatchewan for the storage by eHealth Saskatchewan of those images in the provincial diagnostic information system approved by the minister.
- (3) A record mentioned in subsection (1) must include:
 - (a) any information collected for the purpose of providing a medical imaging service to the individual; and
 - (b) all information related to the medical imaging services provided to the individual, including orders for and particulars of any examination, test, interpretation, consultation and treatment.
- (4) A licensee shall keep an individual's medical imaging record for the longer of:
 - (a) a period of 6 years after the date on which the individual last attended the medical imaging facility to receive medical imaging services; and
 - (b) a period that ends when the individual attains, or would have attained, the age of 20 years.
- (5) Subsection (4) continues to apply if the licensee ceases to operate or has its licence cancelled.

- (6) No licensee or person employed by a licensee shall disclose any information concerning an individual who receives medical imaging services at the medical imaging facility or information contained in an individual's medical imaging record, except:
 - (a) as may be required for the purposes of administering the Act or these regulations, including information requested by an inspector, the accreditation program operator or the minister; or
 - (b) as may be permitted pursuant to $\it The\ Health\ Information\ Protection\ Act.$

$3~\mathrm{Mar}~2017~\mathrm{cP}\text{-}4.11~\mathrm{Reg}~1~\mathrm{s}7.$

Standards

- **8**(1) A licensee shall ensure that all aspects of the medical imaging services provided in the medical imaging facility are provided in accordance with generally accepted standards and the standards of the accreditation program.
- (2) A licensee shall ensure that all equipment used in the provision of medical imaging services at the medical imaging facility:
 - (a) is appropriate for the medical imaging services being provided at the medical imaging facility;
 - (b) is in a safe operating condition and meets any requirements of the accreditation program; and
 - (c) is serviced at regular intervals in accordance with manufacturers' recommendations to ensure that it performs all of its functions within the manufacturers' specifications.
- (3) A licensee shall ensure that the medical imaging services being provided at the medical imaging facility result in images that are clinically acceptable for the purposes of medical interpretation.

3 Mar 2017 cP-4.11 Reg 1 s8.

Business records

9 A licensee shall keep all business records, including financial statements, for a medical imaging facility at that facility for a period of not less than 3 years after the date on which those records were created.

3 Mar 2017 cP-4.11 Reg 1 s9.

Annual returns

10(1) For the purposes of subsection 14(2) of the Act, a licensee shall provide the minister with an annual return within 90 days after the end of the fiscal year of the medical imaging facility for which the licence was issued.

- (2) The following must be included with the annual return mentioned in subsection (1):
 - (a) any changes in the information:
 - (i) that has been provided to the minister in the licence application submitted by the licensee or, if it has submitted an annual return, in its previous annual return; and
 - (ii) for which notice has not already been provided to the minister;
 - (b) a confirmation that all of the other information that has been provided to the minister in the licence application submitted by the licensee or, if it has submitted an annual return, in its previous annual return is accurate;
 - (c) any other information required by the minister for the purposes of administering the Act and these regulations.

3 Mar 2017 cP-4.11 Reg 1 s10.

Reporting

- 11(1) A Category II licensee shall provide a report, in a form specified by the minister, of all medical imaging services that were referred to the Category II licensee's medical imaging facility and that were provided by the medical imaging facility during each month to the minister and to the regional health authority in which the medical imaging facility is located within 14 days after the end of that month.
- (2) The report mentioned in subsection (1) must include:
 - (a) the name of the medical imaging facility providing the medical imaging services;
 - (b) the code for the type of examination, the name of the type of examination and the examination order status related to the medical imaging services provided with respect to an individual;
 - (c) the name of the referring practitioner;
 - (d) the date on which the individual was referred for medical imaging services;
 - (e) the priority level assigned by the referring practitioner;
 - (f) if applicable, the date on which the medical imaging services were provided;
 - (g) if applicable, the number assigned to an image in the provincial diagnostic information system mentioned in subsection 7(2); and
 - (h) if applicable, the person billed for payment.
- (3) A Category II licensee shall provide any information to the regional health authority in which the medical imaging facility is located regarding referrals for medical imaging services or medical imaging services that were provided that the regional health authority determines is necessary to ensure the accuracy of the list of individuals awaiting medical imaging services in that health region.

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Categories of licences

- 12(1) Every applicant shall indicate on his or her application the category of licence he or she wishes to obtain.
- For the purposes of subsection (1), the following are the categories of licence:
 - (a) Category I licence, permitting publicly funded medical imaging service delivery, in the case of an applicant who intends to provide medical imaging services under a contract for services with a regional health authority, the minister or other public funding source;
 - (b) Category II licence, permitting privately paid medical imaging service delivery, in the case of an applicant who intends to provide medical imaging services to individuals and to accept private payment for those services directly.
- (3) An applicant may request, and the minister may issue, more than one category of licence with respect to a single medical imaging facility.
- (4) An applicant for a Category I licence shall include with the application a copy of the contract with the regional health authority or evidence of the other public funding it is receiving to provide the medical imaging services.
- (5) A licensee shall not provide medical imaging services other than those authorized by the category of licence the licensee holds.

3 Mar 2017 cP-4.11 Reg 1 s12.

Terms and conditions of licence

- **13**(1) The following terms and conditions apply to all licences:
 - (a) the licensee must:
 - (i) provide to the minister a copy of, and have in place at all times during the term of its licence, a prepaid contract with an information management service provider as defined in clause 2(j) of The Health Information Protection Act that is acceptable to the minister to accept the licensee's medical imaging records and to fulfil the licensee's obligations to maintain and make available those medical imaging records in accordance with section 7 of these regulations and The Health Information Protection Act, in the event that the licensee ceases to operate or has its licence cancelled; or
 - (ii) provide financial security in a form satisfactory to the minister in the amount of \$25,000, redeemable by the minister;
 - (b) the licensee may not offer employment or contracts for services to individuals to provide imaging or technical services to the licensee if those individuals are under contract with or employed by a regional health authority, an affiliate or the Saskatchewan Cancer Agency and if the licensee's action would have a sustained adverse effect on the ability of the regional health authority, the affiliate or the Saskatchewan Cancer Agency to provide publicly funded medical imaging services.

- (2) A licensee may only provide medical imaging services:
 - (a) that are ordered by a referring practitioner; or
 - (b) in the case of services to be provided to a worker as defined in *The Workers' Compensation Act, 201*3 as a result of an injury, if those services are requested by and paid for by the Workers' Compensation Board pursuant to that Act.
- (3) The licensee shall maintain general liability insurance in an amount not less than \$5 million per occurrence, against liability arising from injury to or the death of persons and loss of or damage to property occurring in medical imaging facilities owned by the licensee.

3 Mar 2017 cP-4.11 Reg 1 s 13.

Conditions of licence - privately paid service delivery

- **14**(1) A medical imaging facility with respect to which a Category II licence has been issued is subject to the conditions set out in this section.
- (2) The medical imaging facility shall not accept an order to provide medical imaging services, other than second scan services, from a referring practitioner:
 - (a) if that referring practitioner has any proprietary interest, or practises, in that medical imaging facility; or
 - (b) if a member of that referring practitioner's family has any proprietary interest, or practises, in that medical imaging facility.
- (3) Subject to the Act and these regulations, a licensee may charge for a medical imaging service that the licensee provides under the authority of a Category II licence.
- (4) Subject to section 16, for each privately paid medical imaging service purchased from the licensee, the licensee is required to provide a second scan service of similar complexity to an individual identified by the regional health authority pursuant to subsection (5), at no charge or fee, except as may be permitted by section 17.
- (5) The licensee is responsible for the following, with respect to providing the second scan service mentioned in subsection (4):
 - (a) within 7 days after having provided the privately paid medical imaging services purchased pursuant to subsection (3), requesting from the regional health authority mentioned in subsection (4) the names of individuals from among whom the next individual awaiting medical imaging services that would otherwise be provided by a Category I licensee or a regional health authority is to be identified;
 - (b) contacting the individual who is to receive the second scan service as soon as is reasonably practicable after receiving the names of individuals mentioned in clause (a);

- (c) offering the individual mentioned in clause (b) two opportunities to receive the second scan service within a period that is commensurate with the priority level assigned by the referring practitioner, to a maximum of 14 days;
- (d) within 7 days after providing the second scan service, notifying the regional health authority mentioned in clause (a) that the second scan service was completed.

3 Mar 2017 cP-4.11 Reg 1 s14.

Provision of information

- **15**(1) A regional health authority may disclose personal health information and personal information of individuals to licensees as may be required to permit licensees to provide medical imaging services and second scan services pursuant to these regulations.
- (2) A licensee may disclose personal health information and personal information of individuals to the regional health authority in which the licensee's medical imaging facility is located as may be required to ensure the accuracy of the list of individuals awaiting medical imaging services in that health region.

3 Mar 2017 cP-4.11 Reg 1 s15.

Regional health authority may identify next most appropriate individual

16 If the regional health authority, after making reasonable efforts, is not able to identify an individual who requires a second scan service of similar complexity for the purposes of subsection 14(5), the regional health authority may identify the next most appropriate individual to receive second scan services.

3 Mar 2017 cP-4.11 Reg 1 s 16.

Addressing disparity re complexity between privately paid and second scan services

- 17(1) If a Category II licensee determines that, with respect to providing second scan services to an individual, unforeseen additional imaging services are necessary on an emergent basis to address health issues unrelated to the purpose of the second scan services in order to fulfil medical, professional, ethical or legal obligations, the licensee shall provide the necessary additional medical imaging services at no charge or fee, except as permitted by this section.
- (2) After providing the additional medical imaging services mentioned in subsection (1), the Category II licensee shall provide the regional health authority with a report containing the information reasonably requested by the regional health authority, in a form and manner acceptable to that authority, with respect to those additional services provided.
- (3) The regional health authority shall reimburse the Category II licensee for the value of the additional medical imaging services provided pursuant to subsection (1) in accordance with the applicable valuation method set out in subsection (4).

- (4) For the purposes of subsection (3), the value of additional medical imaging services is:
 - (a) if the Category II licensee holds a Category I licence and the regional health authority has a contract for the provision of medical imaging services under that Category I licence, the cost of the additional medical imaging services under that contract;
 - (b) if the Category II licensee does not hold a Category I licence with a contract for the provision of medical imaging services with the regional health authority:
 - (i) the lowest cost of the additional medical imaging services under any contract that the regional health authority has with a Category I licensee; or
 - (ii) if the regional health authority does not have a contract for the provision of medical imaging services with any Category I licensee, the lowest cost of the additional medical imaging services under any contract that any other regional health authority has with a Category I licensee.

 $3~{\rm Mar}~2017~{\rm cP}\text{-}4.11~{\rm Reg}~1~{\rm s}17.$

No recovery of costs re services provided by Category II licensees

- 18(1) Any person who chooses to pay for medical imaging services offered by a Category II licensee is not entitled, in any circumstances, to recover from the minister, a regional health authority, an affiliate or the Saskatchewan Cancer Agency any costs incurred with respect to the medical imaging services provided.
- (2) Before providing any medical imaging services mentioned in subsection (1), a Category II licensee shall obtain from the person paying for those services a signed acknowledgement, on a form approved by the minister, that any costs incurred with respect to the medical imaging services provided are not recoverable.
- (3) The signed acknowledgement form mentioned in subsection (2) is part of a medical imaging record for the purposes of section 7.

 $3~{\rm Mar}~2017~{\rm cP}\text{-}4.11~{\rm Reg}~1~{\rm s}18.$

Critical incidents

- **19**(1) The Saskatchewan Critical Incident Reporting Guideline, 2004 published by the ministry is prescribed as a guideline for the purposes of clause (b) of the definition of "critical incident" in subsection 13(1) of the Act.
- (2) The minister shall:
 - (a) cause the guideline mentioned in subsection (1) to be made available to the public in any form or manner that the minister considers appropriate; and
 - (b) take any steps that the minister considers appropriate to bring the guideline, and the manner or form in which it is available, to the attention of the public.

3 Mar 2017 cP-4.11 Reg 1 s19.

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Forfeiture of financial security

- **20**(1) The financial security provided pursuant to subclause 13(1)(a)(ii) is forfeited if:
 - (a) the licensee ceases to operate or has its licence cancelled; and
 - (b) the minister is satisfied that the financial security is necessary to pay for costs associated with assuming the control and safekeeping of patient records of the licensee.
- (2) The minister may pay any money realized pursuant to a forfeited financial security to any person that the minister is satisfied is entitled to payment for the costs mentioned in clause (1)(b).
- (3) The minister shall pay any money not paid pursuant to subsection (2) to the following after the payment of any expenditures incurred by the minister in connection with the realization on the financial security:
 - (a) in the case of a bond, the surety or obligor under the bond;
 - (b) in the case of a letter of credit, the obligor under the letter of credit;
 - (c) in the case of any financial security other than that mentioned in clause (a) or (b), any person who the minister is satisfied is entitled to the money.

3 Mar 2017 cP-4.11 Reg 1 s20.

RRS c M-23.001 Reg 1 repealed

21 The MRI Facilities Licensing Regulations are repealed.

3 Mar 2017 cP-4.11 Reg 1 s21.

Coming into force

- **22**(1) Subject to subsection (2), these regulations come into force on the day on which section 1 of *The Patient Choice Medical Imaging Act* comes into force.
- (2) If these regulations are filed with the Registrar of Regulations after the day on which section 1 of *The Patient Choice Medical Imaging Act* comes into force, these regulations come into force on the day on which they are filed with the Registrar of Regulations.

 $3~{\rm Mar}~2017~{\rm cP}\text{-}4.11~{\rm Reg}~1~{\rm s}22.$