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For more information concerning the history of these regulations, please see the ***Table of Regulations***.

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CHAPTER D-14

DRUG COST ASSISTANCE ACT

REGULATIONS

Pursuant to section 7 of the *Drug Cost Assistance Act* R.S.P.E.I. 1988, Cap. D-14, the Lieutenant Governor in Council made the following regulations:

1. In these regulations — Definitions

(a) "Act" means the *Drug Cost Assistance Act* R.S.P.E.I. 1988, Cap. D-14; — Act

(b) "Administrator" means such agent as the Minister may designate to administer the Plan; — Administrator

(c) "Association" means the Prince Edward Island Pharmaceutical Association; — Association

(d) "benefit" means a drug, supply or appliance which is listed in the Formulary as a benefit to which an eligible person is entitled under the Plan, according to such conditions as the Formulary may prescribe; — benefit

(e) "Director" means the person designated by the Minister to be the Director of the Drug Cost Assistance Plan; — Director

(f) "drug" means a drug as defined in clause 1(h) of the *Pharmacy Act* R.S.P.E.I. 1988, Cap. P-6; — drug

(g) "eligible person" means a person who, subject to sections 2 and 3, is — eligible person

(i) sixty-five years of age or older,

(ii) legally entitled to remain in Canada,

(iii) resident in the province for six months or more during any year-long period, and

(iv) registered as a person entitled to benefits under the *Health Services Payment Act* R.S.P.E.I. 1988, Cap. H-2 and the *Hospital and Diagnostic Services Insurance Act* R.S.P.E.I. 1988, Cap. H-8,

but does not include a tourist, transient, or a visitor to Prince Edward Island;

(h) "Formulary" means the current formulary published by the Minister to establish the benefits under the Plan and policies for their provision; — Formulary

Minister (i) "Minister" means the Minister of Social Services and Seniors;

participating pharmacy (j) "participating pharmacy" means a pharmacy having a valid permit issued under the *Pharmacy* Act and which has been authorized by the Director to supply benefits to eligible persons;

Plan (k) "Plan" means the Prince Edward Island Drug Cost Assistance Plan;

prescription (l) "prescription" means a direction given by a legally qualified physician or dentist for the preparation and dispensing of a drug;

usual and customary price (m) "usual and customary price" means the price normally charged by a participating pharmacy to any of the pharmacy's customers who are not eligible persons. (EC511/97; 606/05)

Eligible person **2.** The eligibility of a person shall begin

(a) on the day on which the person attains the age of 65; or

(b) on the first day of the month following two calendar months after establishing permanent residence in the province,

whichever is the later. (EC511/97)

Eligibility ceases **3.** A person ceases to be an eligible person

(a) on the day he leaves the province to establish residence in another province or country; or

(b) in the case of an individual who has ceased to be a resident by being absent from the province for more than six months, on the day the person ceases to be an entitled person under the *Health Services Payment Act* and the *Hospital and Diagnostic Services Insurance Act*. (EC511/97)

Production of card **4.** An eligible person requesting benefits from a participating pharmacy shall present his or her health card as referred to in the *Provincial Health Number Act* R.S.P.E.I. 1988, Cap. P-27.01. (EC511/97)

Payment on behalf of eligible person **5.** (1) The Plan will pay to, or on behalf of, an eligible person the cost of a benefit, subject to subsection (2) and any requirements of the Formulary, at a rate determined by such agreement as may be made between the Minister and the Association or, where no such provision exists, by the Minister in accordance with such direction as may be given by Management Board.

Co-payment requirement (2) For any benefit dispensed, the Plan is not responsible for payment of

(a) the professional service fee of the pharmacy;

(b) the first $11 of the material or ingredient cost;

(c) any difference in price between a standard benefit price as determined by the Minister with reference to the Formulary, and the

price of a comparable but more expensive product chosen by the eligible person, unless the more expensive product has been specially authorized under the "No Substitution" provision of the Formulary.

Professional service fee

(3) In dispensing a benefit under the Plan, a participating pharmacy shall not charge a professional service fee higher than the fee set in such agreement as may be made between the Minister and the Association or, where no such provision exists, by the Minister in accordance with such direction as may be given by Management Board. (EC511/97; 310/99; 315/01; 265/04)

Benefits

6. (1) The drugs, supplies and appliances listed in the Formulary constitute the benefits of the Plan subject to such conditions as are prescribed in the Formulary.

Exceptional drug coverage

(2) If a physician or dentist informs the Director that the proper treatment of an eligible person requires a drug which is not a benefit listed in the Formulary, the Director

(a) may determine, taking into account such criteria as may be set by the Advisory Committee established under section 19 or such advice as the Director may receive from it, that there is no satisfactory alternative that is a listed benefit; and

(b) may authorize, subject to any conditions prescribed by the Formulary for this purpose, the supplying of that drug as an exceptional drug for that particular case, as if it were a benefit.

Pharmacy may claim reimbursement

(3) Upon receiving notice from the Director a participating pharmacy may supply, as a benefit, a drug referred to in subsection (2) and may make a claim for reimbursement from the Plan in such manner as the Director may require. (EC511/97)

Participating pharmacy application

7. The holder of a pharmacy permit who wishes to supply benefits to eligible persons shall apply, on the form supplied, to become a participating pharmacy. (EC511/97)

Claim procedure

8. (1) Where a participating pharmacy provides a benefit to an eligible person, the pharmacy shall, within 90 days after providing the benefit, submit a claim to the Plan and supply the following information:

(a) the identification number of the participating pharmacy as assigned by the Plan;

(b) the health number of the eligible person as referred to in the *Provincial Health Number Act*;

(c) the drug identification number of the benefit dispensed;

(d) the quantity dispensed;

(e) the intended duration of the therapy, stated in days;

(f) the date the benefit was dispensed;
(g) the prescription number;
(h) the professional or dispensing fee charged;
(i) the total amount charged for the benefit;
(j) whether the prescription was new or a repeat of a previous prescription;
(k) the identification number of the prescriber, as assigned or confirmed by the Plan;
(l) the identification number of the dispensing pharmacist, as assigned or confirmed by the Plan;
(m) in the case of a claim in printed form, the name and address of the participating pharmacy, and the signature of its authorized agent; and
(n) such further information or other requirements as may be needed in order to assess the claim and make payment.

Re-submission

(2) Where a claim is rejected, a pharmacy may submit it again for reconsideration, with amendment or explanation, but such re-submission must occur not later than 90 days from the date on which the benefit was provided.

Reversing claim for benefit not provided

(3) Where the Plan issues payment for a claim in respect of which the benefit was not actually provided, the claiming pharmacy must within 90 days submit a cancellation of the claim, and the Plan shall reverse the incorrect payment by deduction from payment of other claims. (EC511/97)

Direct reimbursement procedure

9. (1) An eligible person who receives a benefit from a non-participating pharmacy may, within six months of the date of receiving the service, make a direct reimbursement claim to the Plan on a form or in such manner as may be approved by the Director and supply the following information:
(a) the prescription number;
(b) the drug identification number of the benefit dispensed;
(c) the quantity dispensed;
(d) the identity of the prescriber;
(e) the total cost of the prescription;
(f) an itemized receipt from the non-participating pharmacy; and
(g) the health number of the eligible person as referred to in the *Provincial Health Number Act*.

Limit on amount paid

(2) Where a benefit is provided in accordance with subsection (1), the amount payable for the benefit shall be paid directly to the eligible person but shall not exceed the amount which would have been paid by the Plan had the benefit been received from a participating pharmacy.

Participating pharmacy may charge eligible person

(3) Where a participating pharmacy is unable to

(a) confirm the eligibility under the Plan of a client or of the item being dispensed; or

(b) successfully submit a claim to the Plan electronically,

the pharmacy may directly charge the client for the cost of the dispensed item, and the client may submit a claim to the Plan in accordance with subsection (1). (EC511/97)

Amount of payment

10. After deducting the required co-payment, payment to a participating pharmacy for benefits dispensed to an eligible person under the Plan shall be based on the lesser of

(a) the pharmacy's usual and customary price;

(b) the cost price as defined in such agreement as may be made between the Minister and the Association or, where no such provision exists, by the Minister in accordance with such direction as may be given by Management Board. (EC511/97)

Payment is final

11. Where a participating pharmacy submits a claim for benefits in accordance with section 8 and is paid an amount under the Plan, the payment is payment in full of the claim and no other claim, except for the required co-payment, shall be made against any other person or organization. (EC511/97)

Assessment of claims

12. (1) The Administrator acting on behalf of the Minister shall assess claims submitted to the Plan with respect to their validity and determine whether payment should be made under the Plan for claims so submitted.

Audits

(2) The Director or, at his request, the Administrator or other agent, may perform audits on both eligible persons and participating pharmacies who have submitted claims to the Plan.

Examination of documents

(3) A participating pharmacy or an eligible person shall allow an auditor, acting on behalf of the Director or the Administrator, access to prescriptions for which there has been a claim submitted to the Plan and other relevant documentation that may be requested. (EC511/97)

Improper claims

13. Where, after due inquiry, it is the opinion of the Director that a participating pharmacy or any eligible person claiming benefits under the Plan has fraudulently or improperly submitted or assisted in the submission of a fraudulent or improper claim for payment under the Plan, the Director shall report the finding to the Minister and the Minister may in the case of

(a) a participating pharmacy, make an order restricting that pharmacy with respect to providing benefits under the Plan;

(b) an eligible person, make an order restricting that person with respect to receiving benefits under the Plan,

for such period as may be determined by the Minister. (EC511/97)

Quantities

14. Where a participating pharmacy fills a prescription for which a claim is to be submitted to the Plan, it shall dispense the quantity prescribed, subject to any requirements of the Formulary. (EC511/97)

Access to patient information

15. Pursuant to clauses 6(b) and 7(f) of the Act

(a) a physician or dentist who prescribes a drug for an eligible person; or

(b) a pharmacist who fills a prescription as a benefit for an eligible person,

is authorized to have access to or receive information from the eligible person's medication profile in the record-keeping system kept by the Administrator, regardless of the person's consent, for the purpose of determining the person's drug utilization and better assuring drug safety and efficacy. (EC511/97)

Refusal to fill prescription

16. (1) A participating pharmacy may refuse to fill a prescription if it is the professional judgment of the pharmacist that the prescription should not be dispensed.

Reasons

(2) If a participating pharmacy refuses to fill a prescription, the pharmacist shall notify the eligible person and the prescriber of the decision and the reason therefor. (EC511/97)

Prescriptions refill limits

17. Prescriptions which are more than a year old shall not be filled or refilled without reference to the prescriber. (EC511/97)

Manner of invoice

18. A participating pharmacy must submit any claim under the Plan

(a) in accordance with the Formulary; and

(b) in such electronic manner as the Director requires or authorizes, or in such other manner as the Director considers necessary for special circumstances. (EC511/97)

Extemporaneous preparations

19. Extemporaneous preparations when prescribed by a physician or dentist may be benefits, subject to any requirements of the Formulary, when compounded by a pharmacist and when the compound does not duplicate the formulation of a manufactured drug product. (EC511/97)

Advisory Committee

20. The Minister may establish an Advisory Committee which may, in addition to such other duties as may be assigned,

(a) review and make recommendations on the Formulary;

(b) provide criteria and advice on determining benefits, exceptional drug approvals, and special authorizations; and

(c) in general make suggestions on any matter which may contribute to the better operation of the Plan. (EC511/97)

Policy

21. The Minister or the Director may establish, amend or cancel procedures, policies and interpretive guidelines for the effective operation of the Plan by means of publication in the Formulary, Pharmacist's Guide or other written form distributed to participating pharmacies. (EC511/97)