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Summary

Legal deposit – 1st Quarter 1968
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Table of Contents

Page

Regulations and other acts

Regulations and other acts

Gouvernement du Québec

O.C. 898-2007, 17 October 2007

An Act respecting prescription drug insurance
(R.S.Q., c. A-29.01)

Pharmacists
— Benefits authorized

Regulation respecting benefits authorized for pharmacists

WHEREAS section 78 of the Act respecting prescription drug insurance (R.S.Q., c. A-29.01) provides that, in addition to the regulatory powers otherwise conferred on it by the Act, the Government may, after consulting the Régie de l'assurance maladie du Québec, make regulations for the purposes listed therein;

WHEREAS the third paragraph of section 22 of the Act respecting prescription drug insurance, introduced by section 9 of chapter 40 of the Statutes of 2005, provides that if, after an investigation, the Board believes that a pharmacist has received rebates, gratuities or other benefits not authorized by regulation for pharmaceutical services or medications and the pharmacist is claiming payment for those services or medications or has received payment for them in the preceding 36 months, the Board may deduct an amount corresponding to the value of the rebates, gratuities or other benefits from the payment for those pharmaceutical services or medications or obtain the reimbursement of that amount by way of compensation or otherwise, as the case may be;

WHEREAS it is expedient to determine which benefits are authorized for pharmacists for the purposes of that section;

WHEREAS, in accordance with sections 10 and 11 of the Regulations Act (R.S.Q., c. R-18.1), a draft of the Regulation respecting benefits authorized for pharmacists was published in Part 2 of the *Gazette officielle du Québec* of 20 June 2007 with a notice that it could be made by the Government on the expiry of 45 days following that publication;

WHEREAS, in accordance with section 78 of the Act respecting prescription drug insurance, the Régie de l'assurance maladie du Québec has been consulted on the draft Regulation;

WHEREAS the 45-day period has expired;

WHEREAS it is expedient to make the Regulation with amendments;

IT IS ORDERED, therefore, on the recommendation of the Minister of Health and Social Services:

THAT the Regulation respecting benefits authorized for pharmacists, attached to this Order in Council, be made.

GÉRARD BIBEAU,
Clerk of the Conseil exécutif

Regulation respecting benefits authorized for pharmacists

An Act respecting prescription drug insurance
(R.S.Q., c. A-29.01, s. 22; 2005, c. 40, s. 9)

1. The only benefits authorized within the meaning of the third paragraph of section 22 of the Act respecting prescription drug insurance (R.S.Q., c. A-29.01) are the professional allowances and other authorized benefits provided for in this Regulation.

2. A professional allowance is a reduction as a discount, rebate or premium, good, service, gratuity or any other benefit granted, paid or provided, directly or indirectly, by a generic drug manufacturer to an owner pharmacist, other than the discount referred to in paragraph 2 of section 2 of Schedule I to the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized, made by Minister's Order 92-06 dated 6 July 1992, that is used only for the purposes and before the expiry date and limit set in this section.

The purposes contemplated by this section are

(1) the funding of training and continuing education programs and activities in Québec intended to upgrade the scientific knowledge or professional skills of pharmacists and pharmacy technical assistants. The cost of the programs or activities and their frequency must be reasonable in relation to the nature of the activities offered;

(2) the funding of activities intended for the general public that take place in the pharmacy concerning the promotion or protection of health, disease prevention and the communication of information on diseases or medications, and that are based on scientific grounds. The cost of the activities, their frequency and the number of patients involved per pharmacy must be reasonable in relation to the nature of the activities offered;

(3) the acquisition of educational equipment and material used in the pharmacy and intended to improve the management of chronic diseases and services to train in the reading of devices required for that purpose, in particular devices to measure arterial pressure, glycemia or used for asthma management or anticoagulant therapy, including the relevant software but excluding the purchase or rental of computers. Professional allowances may not be used by an owner pharmacist to purchase an inventory of devices or materials intended for sale at retail;

(4) the acquisition or maintenance of equipment intended to achieve greater quality and safety in the distribution of medications in the pharmacy, in particular devices used for the automated processing of medications. To calculate the professional allowances received by an owner pharmacist, the cost to acquire equipment referred to in this subparagraph may be spread over a reasonable number of years subsequent to the acquisition, taking into account the service life of the equipment; and

(5) the remuneration of pharmacists and pharmacy technical assistants assigned to maintaining or improving the delivery of professional services to promote the optimal use of medications, in particular the preparation and implementation of pharmaceutical care plans.

The limit set in this section is a maximum amount per generic drug manufacturer for a given pharmacy and a given year, corresponding to 20% of the total value of the sales by the manufacturer of generic drugs on the list of medications to an owner pharmacist or, as the case may be, to all the owner pharmacists, for that same year, under the basic prescription drug insurance plan.

The expiry date set in this section is the last day of the sixth month following the end of the year in which the reduction, rebate, discount, premium, good, service, gratuity or other benefit was granted, paid or provided to the owner pharmacist.

For the purposes of the third and fourth paragraphs, "year" means a fiscal year of the pharmacy.

3. For the purposes of this Regulation, the following good or service provided by a manufacturer of innovative drugs to an owner pharmacist or paid by such a manufacturer for the benefit of an owner pharmacist is an authorized benefit other than a professional allowance for the following purposes and under the following conditions:

(1) the carrying out of training and continuing education programs and activities in Québec intended to upgrade the scientific knowledge or professional skills of pharmacists and pharmacy technical assistants. The cost of the programs or activities and their frequency must be reasonable in relation to the nature of the activities offered;

(2) the carrying out of activities intended for the general public that take place in the pharmacy concerning the promotion or protection of health, disease prevention and the communication of information on diseases or medications, and that are based on scientific grounds. The cost of the activities, their frequency and the number of patients involved per pharmacy must be reasonable in relation to the nature of the activities offered;

(3) the educational equipment or material used in the pharmacy and intended to improve the management of chronic diseases and services to train in the reading of devices required for that purpose, in particular devices to measure arterial pressure, glycemia or used for asthma management or anticoagulant therapy, including the relevant software but excluding the purchase or rental of computers. The goods supplied may not constitute an inventory of devices or materials intended for sale at retail;

(4) the device to measure glycemia or the insulin pen given without consideration to a patient by the pharmacist.

4. An owner pharmacist must keep a record of all the professional allowances and other benefits authorized under this Regulation, including any other benefit received by the pharmacist, directly or indirectly, from a manufacturer.

5. This Regulation comes into force on the fifteenth day following the date of its publication in the *Gazette officielle du Québec*.

8354

M.O., 2007

Order number 2007-016 of the Minister of Health and Social Services dated 5 October 2007

An Act respecting prescription drug insurance (R.S.Q., c. A-29.01)

MAKING the Regulation to amend the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized

THE MINISTER OF HEALTH AND SOCIAL SERVICES,

CONSIDERING section 80 of the Act respecting prescription drug insurance (R.S.Q., c. A-29.01);

CONSIDERING that it is necessary to amend the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized, made by Minister's Order 92-06 dated 6 July 1992, to

— make the consequential amendments required by the coming into force of the Controlled Drugs and Substances Act (S.C., 1996, c. 19);

— specify, for the purposes of the basic prescription drug insurance plan (public plan and private plans), what benefits granted by a drug manufacturer to a pharmacist are authorized within the meaning of the Act respecting prescription drug insurance (R.S.Q., c. A-29.01);

CONSIDERING the publication in Part 2 of the *Gazette officielle du Québec* of 20 June 2007, in accordance with sections 10 and 11 of the Regulations Act (R.S.Q., c. R-18.1), of a draft Regulation to amend the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized, with a notice that it could be made by the undersigned on the expiry of 45 days following that publication;

CONSIDERING that it is expedient to make such a regulation with amendments to follow up on the comments received;

ORDERS AS FOLLOWS:

The Regulation to amend the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized, the text of which appears as a Schedule, is hereby made.

Québec, 5 October 2007

PHILIPPE COUILLARD,
Minister of Health and Social Services

Regulation to amend the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized [*]

An Act respecting prescription drug insurance (R.S.Q., c. A-29.01, s. 80)

1. Section 2 of the Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized is amended by replacing paragraph 3 by the following:

"(3) he must hold a permit or licence issued under subsection 55(1) of the Controlled Drugs and Substances Act (S.C. 1996, c. 19) and be an authorized distributor holding a permit for the importation, production or sale of drugs and controlled substances issued under that subsection.".

2. Schedule I is amended in section 1 by replacing the third paragraph by the following:

"The guaranteed selling price is the price that a buyer must pay for a drug. It is reduced by the value of any reduction granted by the manufacturer as a rebate, discount or premium and by the value of any good or service provided without consideration to a buyer by the manufacturer, other than a benefit authorized under the Regulation respecting the benefits authorized for pharmacists [**].".

3. Schedule I is amended in section 2

(1) by replacing paragraph 2 by the following:

"(2) the manufacturer may grant a discount for a payment made within 30 days following the purchase, provided that the discount does not exceed 2% of the net price;";

(2) by replacing paragraph 4 by the following:

[*] The Regulation respecting the conditions on which manufacturers and wholesalers of medications shall be recognized, made by Order 92 06 dated 6 July 1992 (1992, *G.O.* 2, 3263) of the Minister of Health and Social Services, was last amended by the regulation made by Minister's Order 1999 dated 28 April 1999 (1999, *G.O.* 2, 1289). For previous amendments, refer to the *Tableau des modifications et Index sommaire*, Québec Official Publisher, 2007, updated to 1 March 2007.

[**] The Regulation was published on page 2833A

"(4) no reduction in the price of a drug may be granted to a buyer or an intermediary, including a wholesaler, a commercial name or a chain of pharmacies for the attainment of a fixed purchase volume for a given period, and no good or service may be provided without consideration or reduction as a rebate, discount or premium, other than a benefit authorized within the meaning of the Regulation respecting the benefits authorized for pharmacists, or a professional allowance for an owner pharmacist who deals through a wholesaler, a commercial name or a chain of pharmacies that is paid in whole to the owner pharmacist, and other than a discount referred to in paragraph 2;";

(3) by striking out paragraph 5.

4. Schedule I is amended by inserting the following after section 2:

"2.1. The manufacturer undertakes to reimburse to the Board an amount corresponding to the value of any reduction as a rebate, discount or premium, of any good, service or gratuity or of any other benefit granted to an owner pharmacist that is not a benefit authorized within the meaning of the Regulation respecting the benefits authorized for pharmacists or a discount referred to in paragraph 2 of section 2. The manufacturer also undertakes to pay to the Board a sum corresponding to 20% of that amount as administrative expenses.

2.2. The generic drug manufacturer undertakes to send the Board an annual report on or before 1 March for the preceding calendar year giving the detail of the reductions as rebates, discounts or premiums, the gratuities, goods, services or any other benefit, other than the discount referred to in paragraph 2 of section 2, granted by the manufacturer to each owner pharmacist in Québec. The report must also state the value of all the sales of generic drugs on the list of medications that are sold directly to owner pharmacists or indirectly through wholesalers, a commercial name or a chain of pharmacies, under the basic prescription drug insurance plan. If a pharmacist owns more than one establishment, the data must be detailed by establishment. If a pharmacy is owned by a partnership of pharmacists or a joint-stock company, the data must be detailed by partnership or company and, where applicable, by establishment.

The manufacturer agrees to the Board sending the report to the Ministère de la Santé et des Services sociaux, the Conseil du médicament and the Ministère du Revenu du Québec. The manufacturer also undertakes to provide those departments and that body, on request, and the Board with all additional information they may require in relation to the content of the report.".

5. The English text of paragraph 5 of section 1 of Schedule II is replaced by the following:

"(5) no good may be provided without consideration and no reduction as a rebate, discount or premium may be granted to a buyer;".

6. The English text of the title of the Regulation is replaced by the following:

"Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications".

7. This Regulation comes into force on the fifteenth day following the date of its publication in the *Gazette officielle du Québec*.

8357

Index

Abbreviations: **A**: Abrogated, **N**: New, **M**: Modified