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Health (Miscellaneous Provisions) Act 2024

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Number 23 *of* 2024

HEALTH (MISCELLANEOUS PROVISIONS) ACT 2024

An Act to amend the Health Act 1970, the Irish Medicines Board Act 1995; the Pharmacy Act 2007; the Health (Pricing and Supply of Medical Goods) Act 2013 and the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023; and to provide for related matters. [15*th July*, 2024]

Be it enacted by the Oireachtas as follows:

PART 1

Preliminary and General

Short title and commencement

1. (1) This Act may be cited as the Health (Miscellaneous Provisions) Act 2024.

(2) This Act shall come into operation on such day or days as the Minister for Health may by order or orders appoint either generally or with reference to any particular purpose or provision and different days may be so appointed for different purposes or different provisions.

Definitions

2. In this Act—

"Act of 1970" means the Health Act 1970;

"Act of 1995" means the Irish Medicines Board Act 1995.

PART 2

Amendment of Act of 1970

Amendment of section 45 of Act of 1970

3. Section 45 of the Act of 1970 is amended—

(a) in subsection (2), by the substitution of "Subject to subsection (2A), in deciding" for "In deciding", and

(b) by the insertion of the following subsection after subsection (2):

"(2A) In having regard under subsection (2) to a person's overall financial situation, the Health Service Executive shall disregard any relevant sums (within the meaning of section 216A of the Taxes Consolidation Act 1997) arising to the person (or the person's spouse or civil partner within the meaning of the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010) where the relevant sums qualify for relief under section 216A of the Taxes Consolidation Act 1997.".

Amendment of section 45A of Act of 1970

4. Section 45A of the Act of 1970 is amended—

(a) by the substitution of the following subsection for subsection (5):

"(5) In the calculation of the gross income of a person for the purposes of this section and section 45(5A), all gross income from all sources is to be included except for the gross income arising from the following sources of income and any subsequent income from the investment of the monies arising from the sources referred to in paragraphs (a) to (e):

(a) compensation awards to persons under the Hepatitis C Compensation Tribunal Acts 1997 to 2006;

(b) compensation awards by way of the Residential Institutions Redress Board established under section 3 of the Residential Institutions Redress Act 2002;

(c) prescribed repayments referred to in section 8(2) of the Health (Repayment Scheme) Act 2006;

(d) *ex-gratia* awards approved by the Lourdes Hospital Redress Board under the terms of the Lourdes Hospital Redress Scheme 2007;

(e) such other awards and payments prescribed in regulations made under subsection (7);

(f) relevant sums (within the meaning of section 216A of the Act of 1997) arising to the person (or the person's spouse or civil partner) which qualify for relief under section 216A of the Act of 1997.",

(b) in subsection (6), by the substitution of "Subject to subsection (5)(f), in the calculation of" for "In the calculation of", and

(c) in subsection (8), by the insertion of the following definition:

" 'Act of 1997' means the Taxes Consolidation Act 1997.".

Amendment of section 58 of Act of 1970

5. Section 58 of the Act of 1970 is amended—

(a) in subsection (2), by the substitution of "Subject to subsection (2A), in deciding" for "In deciding", and

(b) by the insertion of the following subsection after subsection (2):

"(2A) In having regard to a person's overall financial situation under subsection (2), the Health Service Executive shall disregard any relevant sums (within the meaning of section 216A of the Taxes Consolidation Act 1997) arising to the person (or the person's spouse or civil partner within the meaning of the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010) which qualify for relief under section 216A of the Taxes Consolidation Act 1997.".

Amendment of section 59 of Act of 1970

6. Section 59 of the Act of 1970 is amended in subsection (1A), by the substitution of "a registered medical practitioner, registered dentist or registered pharmacist" for "a registered medical practitioner or registered dentist".

General practitioner medical and surgical service for certain persons over 70 years of age

7. The Act of 1970 is amended by the substitution of the following section for section 58A:

"General practitioner medical and surgical service for certain persons over 70 years of age

58A. (1) The Health Service Executive shall make available without charge a general practitioner medical and surgical service for a person who is ordinarily resident in the State, who is not a person who comes within a category mentioned in subsection (1) of section 58, and who is in one of the following categories:

(a) persons who have attained the age of 70 years;

(b) dependants of qualifying persons where the Health Service Executive has, in accordance with subsection (5)(a), confirmed that a condition specified in subsection (2) is met by the qualifying person concerned, for so long as that condition is met.

(2) A qualifying person meets a condition referred to in subsection (1)(b) where—

(a) in the case of a qualifying person who is not married, is not living together with another person as a married couple and does not have a civil partner, his or her gross income does not exceed the gross income limit specified in subsection (3)(a),

(b) in the case of a qualifying person who is married, the combined gross income of the person and his or her spouse does not exceed the gross income limit specified in subsection (3)(b),

(c) in the case of a qualifying person who is living together with another person as a married couple, the combined gross income of the person and that other person does not exceed the gross income limit specified in subsection (3)(b), or

(d) in the case of a qualifying person who has a civil partner, the combined gross income of the person and his or her civil partner does not exceed the gross income limit specified in subsection (3)(b).

(3) Subject to subsection (9)—

(a) for the purposes of subsection (2)(a), the gross income limit shall be €700 per week, not including the income from the portion of the person's savings or similar investments whose capital value does not exceed €36,000, and

(b) for the purposes of subsection (2)(b), (c) and (d), the gross income limit shall be €1,400 per week, not including the income from the portion of the persons' savings or similar investments whose capital value does not exceed €72,000.

(4) A qualifying person may, for the purposes of subsection (1)(b), make an application to the Health Service Executive, in such form as it considers appropriate, for confirmation that a condition specified in subsection (2) is met by him or her.

(5) The Health Service Executive shall, on receipt of an application under subsection (4), consider the application, together with any information furnished to it pursuant to a request under subsection (6), and—

(a) if it is satisfied that a condition specified in subsection (2) is met by the qualifying person concerned, provide the qualifying person with confirmation in writing that the condition is met by him or her, or

(b) if it is not so satisfied, provide the qualifying person with a notice in writing stating that the application has been refused and the reasons for such refusal.

(6) A person shall, when requested to do so by the Health Service Executive, furnish to the Health Service Executive such information as the Health Service Executive considers necessary for it to establish that the person, or his or her dependant, as the case may be, is, or continues to be, entitled under subsection (1) to the service referred to in that subsection.

(7) Where a person fails or refuses to furnish the information requested by the Health Service Executive under subsection (6) within such reasonable period as is specified in the request, the Health Service Executive may—

(a) if the information requested relates to the person's entitlement under subsection (1)(a) to the service referred to in that subsection, treat the person concerned as if he or she was not entitled under subsection (1)(a) to the service referred to in that subsection, and

(b) if the information requested relates to the entitlement of the person's dependant under subsection (1)(b) to the service referred to in that subsection, treat the dependant concerned as if he or she was not entitled under subsection (1)(b) to the service referred to in that subsection.

(8) The Health Service Executive shall provide any necessary assistance to any person in the making of an application under subsection (4) or the furnishing of information requested under subsection (6), as the case may be, where, by reason of any incapacity, such person requests such assistance.

(9) The Minister shall, on 1 September of every year, review the most recent information on the consumer price index made available by the Central Statistics Office and may, with the consent of the Minister for Public Expenditure, National Development Plan Delivery and Reform, by regulations to take effect on 1 January next following that review, increase or decrease the gross income limits specified in subsection (3) to reflect any increase or decrease in that index.

(10) In the calculation of the gross income of a person for the purposes of this section, all gross income from all sources shall be included other than the gross income arising from the following sources of income, and any subsequent income from the investment of the monies arising from the sources referred to in paragraphs (a) to (e):

(a) compensation awarded under the Hepatitis C Compensation Tribunal Acts 1997 to 2006;

(b) compensation awarded by the Residential Institutions Redress Board established under section 3 of the Residential Institutions Redress Act 2002;

(c) prescribed repayments referred to in section 8(2) of the Health (Repayment Scheme) Act 2006;

(d) *ex-gratia* awards approved by the Lourdes Hospital Redress Board under the terms of the Lourdes Hospital Redress Scheme 2007;

(e) such other awards and payments prescribed in regulations made under subsection (12);

(f) relevant sums (within the meaning of section 216A of the Act of 1997) arising to the person (or the person's spouse or civil partner) which qualify for relief under section 216A of the Act of 1997.

(11) Subject to subsection (10)(f), in the calculation of the gross income of a person for the purposes of this section, income shall not be imputed from property comprising an interest in land (whether a family home, a holiday home or any other property) other than any net rental income (calculated as gross rental income less any cost necessarily incurred and associated with the rental of the property).

(12) The Minister may make regulations prescribing a class or classes of awards or payments not coming within paragraphs (a) to (d) of subsection (10) but which the Minister considers to be made for a similar purpose as those made under those paragraphs.

(13) Insofar as it is considered practicable by the Health Service Executive, a choice of medical practitioner shall be offered under the general practitioner medical and surgical service made available under this section.

(14) In this section—

'Act of 1997' means the Taxes Consolidation Act 1997;

'civil partner' has the same meaning as it has in the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010;

'dependants' means dependants who have not attained the age of 70 years;

'qualifying person' means a person who has attained the age of 70 years and is entitled to the service referred to in subsection (1).".

PART 3

Amendment of Act of 1995

Amendment of section 1 of Act of 1995

8. Section 1 of the Act of 1995 is amended by the insertion of the following definitions:

" 'authorised medicinal product' means a medicinal product that is authorised under the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) or Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004[1], as amended;

'medicinal product shortage' means where the current or anticipated supply of an authorised medicinal product or products that is placed on the market does not meet the current or, as the case may be, anticipated demand for that medicinal product or products;

'medicinal product that is in short supply' means, in relation to a medicinal product shortage, the authorised medicinal product or products that is the subject of the medicinal product shortage;

'protocol' means a protocol issued by the Minister under section 32G;

'registered pharmacist' means a person registered in the register of pharmacists established under section 13 of the Pharmacy Act 2007;

1 OJ No. L136, 30.4.2004, p. 1

'substitutable medicinal product' means the medicinal product or products that registered pharmacists are authorised under a protocol to supply in substitution for the medicinal product that is in short supply;".

Amendment of section 32 of Act of 1995

9. Section 32 of the Act of 1995 is amended—

(a) in subsection (2)—

(i) in paragraph (k), by the substitution of the following subparagraph for subparagraph (i):

"(i) by a registered pharmacist, or a person, or class of persons, specified in the regulations, being a suitably qualified person or class of persons—

(I) concerned in the provision of a health service, whether the health service is provided in a hospital, nursing home, clinic, retail pharmacy business (within the meaning of the Pharmacy Act 2007) or otherwise,

(II) registered with a relevant professional body, and

(III) trained in the administration of the medicinal product,

and",

and

(ii) in paragraph (l)—

(I) in subparagraph (ii), by the substitution of "thereto," for "thereto, or", and

(II) by the insertion of the following subparagraphs after subparagraph (iii):

"(iv) subject to subsection (11A), such medicinal product or class of medicinal products as may be used for the purpose of treating mild or moderate illnesses or ailments, pursuant to a prescription issued by a registered pharmacist—

(I) who has reached the required standard of education and training in relation to prescribing medicinal products in accordance with the rules of the Council of the Pharmaceutical Society of Ireland made under section 11(3A) of the Pharmacy Act 2007,

(II) where the prescription is issued under the governance of a retail pharmacy business (within the meaning of the Pharmacy Act 2007) in accordance with regulations made under section 18 of the Pharmacy Act 2007, and

(III) in accordance with such other rules made, and codes of conduct drawn up by the Council of the Pharmaceutical

Society of Ireland under sections 7(2)(a)(iii) and 11 of the Pharmacy Act 2007,

or

(v) subject to subsection (11A), by a registered pharmacist, in accordance with such conditions as are specified in the regulations in relation thereto,",

(b) by the insertion of the following subsection after subsection (11):

"(11A) Before making regulations under section 32(2)(l)(iv) or (v), the Minister shall consult the Health Service Executive and the Council of the Pharmaceutical Society of Ireland, and may consult any other person or body as he or she considers appropriate.",

and

(c) by the substitution of the following subsection for subsection (14):

"(14) In this section—

'relevant profession' means—

(a) for the purposes of subsection (2)(k), any profession a member of which may, before the commencement of section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006, and in his or her capacity as such member, have lawfully administered a medicinal product,

(b) for the purposes of subsection (2)(l), any profession a member of which may, before the commencement of section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006, and in his or her capacity as such member, have lawfully issued a prescription for a medicinal product;

'relevant professional body' means—

(a) the Dental Council established under section 6 of the Dentists Act 1985,

(b) the Nursing and Midwifery Board of Ireland referred to in section 6 of the Nurses and Midwives Act 2011,

(c) the Optical Registration Board established by section 26 of the Health and Social Care Professionals Act 2005,

(d) the Physiotherapists Registration Board established by section 26 of the Health and Social Care Professionals Act 2005,

(e) the Podiatrists Registration Board established by section 26 of the Health and Social Care Professionals Act 2005,

(f) the Radiographers Registration Board established by section 26 of the Health and Social Care Professionals Act 2005, or

(g) the Pre-Hospital Emergency Care Council established by the Pre-Hospital Emergency Care Council (Establishment) Order 2000 (S.I. No. 109 of 2000).".

Insertion of sections 32G to 32I into Act of 1995

10. The Act of 1995 is amended by the insertion of the following sections after section 32F:

"Substitution by pharmacists in case of medicinal product shortage

32G. (1) Where the Minister, having consulted with the Health Service Executive and the Health Products Regulatory Authority, is of the opinion that—

(a) there is a medicinal product shortage,

(b) arising from that shortage, there is likely to be a negative impact on the health service or the health needs of patients that cannot be addressed via other mechanisms, and

(c) a protocol under this section would assist in addressing the impacts referred to in paragraph (b),

he or she may prepare and issue a protocol to registered pharmacists authorising registered pharmacists to supply such alternative medicinal product or products as are specified in the protocol for the medicinal product that is in short supply under such conditions as are specified in the protocol and without the need for a further prescription.

(2) In the preparation and issuing of a protocol under this section, the Minister shall act in accordance with regulations made under section 32H and shall consult with the bodies referred to in subsection (1) in relation to the content of the protocol.

(3) A protocol prepared and issued under this section shall specify—

(a) the medicinal product that is in short supply,

(b) the substitutable product,

(c) the circumstances in which the registered pharmacist may supply the substitutable product,

(d) the time period for which the protocol is in place, and

(e) such other conditions or information in respect of the supply by a registered pharmacist of the substitutable medicinal product as the Minister considers appropriate.

(4) The Minister may, where appropriate and following consultation with the Health Products Regulatory Authority and the Health Service Executive, amend the time period during which the protocol is in place or any conditions specified in the protocol.

(5) The Minister shall publish or cause to be published each protocol issued (or amended) under this section in such form and manner, including on a website maintained by or on behalf of the Minister, as the Minister considers appropriate.

Regulations governing protocol

32H. (1) The Minister shall make regulations providing for the issuing and operation of a protocol.

(2) Without prejudice to the generality of subsection (1), such regulations shall include—

(a) the procedures for the preparation and review of a protocol including in relation to—

(i) the assessment of the impact of the medicinal product shortage on the provision of a health service and the health needs of patients,

(ii) the assessment of existing mechanisms to address the negative impacts of a medicinal product shortage, including the availability of appropriate alternatives,

(iii) the identification of a substitutable medicinal product and any conditions that should apply in accordance with its supply, and

(iv) the persons who shall be consulted in relation to the preparation and review,

(b) the procedure for the notification of a protocol (including any amendment made to the protocol) to registered pharmacists,

(c) the procedure for the operation of a protocol, and

(d) the requirements in relation to the notification of the supply of a substitutable medicinal product under a protocol to the person who prescribed the medicinal product that is in short supply.

Reporting of information to support the security of supply of medicines

32I. (1) The Health Products Regulatory Authority may require a relevant person to provide to the Authority, in such form and manner and within such period as may be prescribed by regulations made by the Minister, such information in relation to medicinal products within the possession or control of the relevant person as the Authority considers necessary for the purpose of the management of the availability of medicinal products in the State, including—

(a) the monitoring of the current and future supply of medicinal products, and

(b) the identification and management of medicinal product shortages.

(2) A relevant person shall comply with a requirement set out in regulations made under subsection (1).

(3) In this section, 'relevant person' means the following persons involved in the manufacture or supply of a medicinal product:

(a) the holder of a manufacturer's authorisation granted under Regulation 8 of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007);

(b) the holder of a marketing authorisation granted in accordance with the Medicinal Products (Control of Placing on the Market) Regulations 2007;

(c) the holder of a community marketing authorisation within the meaning of the Medicinal Products (Control of Placing on the Market) Regulations 2007;

(d) the holder of a wholesaler's authorisation granted under Regulation 9 of the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007);

(e) a retail pharmacy business within the meaning of the Pharmacy Act 2007;

(f) a hospital;

(g) such other persons or legal entities, being persons or entities authorised or entitled to supply medicinal products, as may be prescribed in regulations made by the Minister.".

PART 4

Amendment of Pharmacy Act 2007

Amendment of Pharmacy Act 2007

11. The Pharmacy Act 2007 is amended—

(a) in section 7(1)—

(i) by the substitution of the following paragraph for paragraph (a):

"(a) to regulate the profession of pharmacy in the State, including prescribing by pharmacists, having regard to the need to protect, maintain and promote the health and safety of the public,",

and

(ii) in paragraph (d), by the insertion of "in relation to prescribing and" after "including",

(b) in section 11—

(i) by the insertion of the following subsections after subsection (3):

"(3A) The Council shall make rules specifying the education and training which a registered pharmacist must receive to enable him or her to prescribe medicinal products in accordance with regulations made under section 32(2)(l)(iv) of the Irish Medicines Board Act 1995.

(3B) Rules made under subsection (3A) shall include—

(a) the standard of education and training required to be reached by a registered pharmacist in order to prescribe medicinal products in accordance with regulations made under section 32(2)(l)(iv) of the Irish Medicines Board Act 1995, taking into account any practical professional experience of prescribing which the registered pharmacist may have, and

(b) any other relevant continuing professional education.",

and

(ii) in subsection (5), by the substitution of "subsection (2), (2A), (2B), (3) or (3A)" for "subsection (2), (2A), (2B) or (3)",

and

(c) in section 18(1)—

(i) in paragraph (g), by the substitution of "prepared, supplied, sold or prescribed" for "sold or supplied",

(ii) in paragraph (i), by the substitution of "supplied, sold or prescribed" for "sold or supplied",

(iii) in paragraph (j), by the substitution of "to whom medicinal products are being sold, supplied or prescribed" for "being sold or supplied with medicinal products",

(iv) in paragraph (k), by the substitution of "sold, supplied or prescribed" for "sold or supplied", and

(v) by the substitution of the following paragraph for paragraph (l):

"(l) the keeping of records of and in connection with the preparation, prescribing, sale and supply of medicinal products and the preparation and dispensing of medicinal prescriptions;".

PART 5

Amendment of Health (Pricing and Supply of Medical Goods) Act 2013

Amendment of Health (Pricing and Supply of Medical Goods) Act 2013

12. The Health (Pricing and Supply of Medical Goods) Act 2013 is amended in section 2—

(a) in the definition of "prescriber", by the substitution of "(a), (b), (c) or (d)" for "(a), (b) or (c)", and

(b) in the definition of "prescription"—

(i) in paragraph (b)(iii), by the substitution of "order," for "order, or",

(ii) in paragraph (c), by the substitution of "Nurses and Midwives Act 2011, or" for "Nurses and Midwives Act 2011;", and

(iii) by the insertion of the following paragraph after paragraph (c):

"(d) a registered pharmacist who is for the time being registered in the register of pharmacists established under section 13(1)(a)(i) of the Pharmacy Act 2007;".

PART 6

Amendment of Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

Amendment of Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

13. The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 is amended—

(a) in section 19(7), by the substitution of "the patient or the relevant person (or both of them) may" for "the patient may", and

(b) in section 50(7), by the substitution of "the patient or the relevant person (or both of them) may" for "the patient may".