Act (2002:160) on Pharmaceutical Benefits, etc.

Issued 11 April 2002
Amendments incorporated up to and including SFS 2003:76
- -

General provisions

Section 1 This Act contains provisions on pharmaceutical benefits, price controls of products included on the Pharmaceutical Benefits Scheme and other related matters.

Section 2 For the purposes of this Act, ”drug” refers to a medicinal product intended to be given to humans to prevent, identify, alleviate or cure disease or symptoms of disease, or to be used for a similar purpose.

Section 3 That said in this Act pertaining to county councils shall apply also to municipalities that are not part of a county council.

Persons entitled to benefits

Section 4 The following persons shall be entitled to benefits pursuant to this Act:

1. Residents of Sweden, and

2. Persons who do not reside in Sweden but are entitled to sickness and maternity care benefits in Sweden pursuant to Council Regulation (EEC) No 1408/71 of 14 June 1971 on application of social security systems when employed persons, self-employed persons or members of their families move within the Community.[1]

Persons who are otherwise employed in Sweden but not residing in Sweden shall be entitled to benefits pursuant to Sections 5 and 20, except for products referred to in Section 18, Clause 2.

Special provisions on free drugs shall apply to persons receiving care in hospitals as referred to in Section 5 of the Health and Medical Services Act (1982:763) or Chap. 2, Section 4 of the National Insurance Act (1962:381), as well as persons receiving home health care as referred to in Section 3 e or 18 d of the Health and Medical Services Act, and persons living in special accommodation as referred to in Section 18 d of the same Act. **Act 2002:1145.**

Content of the Pharmaceutical Benefits Scheme

Section 5 "Pharmaceutical Benefits" according to this Act refers to protection against high costs upon purchase of such products referred to in Sections 15 and 18. The Pharmaceutical Benefits Scheme entails a subsidised reduction of the individual’s costs for such products.

The subsidy is calculated based on the total cost of products that the person entitled to benefits buys in one year, commencing on the date of the first purchase. The subsidy is granted upon each purchase, based on the total cost of products purchased prior to that date and the products purchased on that occasion.

[1] EGT L 149, 5.7.1971, p. 416 (Celex 31971R1408)

No subsidy shall be granted as long as the total cost does not exceed SEK 900. When the total cost exceeds that amount, a subsidy shall be granted as follows:

1. 50 percent of the portion exceeding SEK 900 but less than SEK 1,700

2. 75 percent of the portion exceeding SEK 1,700 but less than SEK 3,300

3. 90 percent of the portion exceeding SEK 3,300 but less than SEK 4,300

4. 100 percent of total cost exceeding SEK 4,300

That stated in the second and third paragraphs shall not apply to such products as referred to in Section 18, Clause 3, which are free of cost pursuant to Section 19.

If a parent has, or parents together have, more than one child under the age of 18 in their care, the provisions in the second and third paragraphs shall apply commonly to the children. The subsidy shall also apply for one year commencing on the date of the first purchase for children who turn 18 during that period. ”Parents” refers also to foster parents. A person with whom a parent permanently lives and is, or has been married to, or who has, or has had, children with the parent is also considered to be a parent. **Act 2003:76**.

Section 6 The provisions in Section 5 shall be applied to a drug included on the Pharmaceutical Benefits Scheme if prescribed for human use by a doctor, dentist, nurse, midwife, or licensed dental hygienist for the purpose of preventing, identifying, alleviating or curing disease or symptoms of disease, or for a similar purpose, and provided that the prescription is labelled with a code which identifies the prescriber’s place of work (workplace code).

Pharmaceutical Benefits Board

Section 7 The Pharmaceutical Benefits Board shall determine whether a drug or product as referred to in Section 18 shall be included on the Pharmaceutical Benefits Scheme and shall set the price for that drug or product.

Section 8 Sellers of a drug or product as referred to in Section 18 may apply for the drug or product to be included on the Pharmaceutical Benefits Scheme pursuant to this Act. The applicant shall demonstrate that the terms and conditions according to Section15 have been fulfilled and shall produce the supporting documentation required for a price to be set.

Section 9 Before the Pharmaceutical Benefits Board issues a decision in matters referred to in Section 7, the applicant and the county councils shall be given an opportunity to participate in deliberations with the Board.

Section 10 The Pharmaceutical Benefits Board may at its own volition decide that a drug or other product included on the Pharmaceutical Benefits Scheme shall no longer be included on the scheme.

Section 11 If there are special reasons, the Pharmaceutical Benefits Board may decide that a drug or other product shall be included on the Pharmaceutical Benefits Scheme only for a particular use.

Other special terms and conditions may be attached to the decisions of the Pharmaceutical Benefits Board.

Section 12 If requested to do so by the seller of a drug or product as referred to in Section 18, the Pharmaceutical Benefits Board shall decide that the drug or product shall no longer be included on the scheme.

Section 13 A question of changing a previously set price may, not only at the volition of the Pharmaceutical Benefits Board, be addressed by the Board at the request of the seller of the drug or product, or the request of a county council. The party that requests the change shall also be entitled to participate in deliberations with the Board. If deliberations are not requested, the Board may set the new price based on available information.

Section 14 An established price for a drug or product as referred to in Section 18 shall no longer apply if the approval for sale of the drug or product becomes invalid or if the Pharmaceutical Benefits Board decides that the drug or product shall no longer be included on the scheme.

Drugs included on the Pharmaceutical Benefits Scheme

Section 15 Prescription drugs shall be included on the Pharmaceutical Benefits Scheme and the price for the drug shall be set provided:

1. that the costs of using the drug, with observation of the provisions of Section 2 of the Health and Medical Services Act (1982:763), appear reasonable from the medical, humanitarian and economic aspects, and

2. that there are no other available drugs or treatment methods which after overall consideration of the intended effects and harmful effects as referred to in Section 4 of the Medicinal Products Act can be judged as significantly more suitable for the purpose.

Section 16 If the Pharmaceutical Benefits Board so decides, after having applied the conditions stated in Section 15, a drug that has been approved in accordance with Section 5, first paragraph, second sentence of the Medicinal Products Act (1992:859), or which is licensed in accordance with the third paragraph of the same section, shall be included on the Pharmaceutical Benefits Scheme even if no price has been set for the drug.

Section 17 The Government or agency designated by the Government shall issue regulations on the conditions under which a certain non-prescription drug, or a certain group of such drugs, shall be included on the Pharmaceutical Benefits Scheme.

Other products included on the Pharmaceutical Benefits Scheme

Section 18 When so decided in accordance with Section 7, the Pharmaceutical Benefits Scheme shall include:

1. Products to which Section 3 of the Medicinal Products Act (1992:859) is applicable and which are prescribed by physicians or midwives solely for contraceptive purposes,

2. Consumables required for stoma care and which are prescribed by a physician or other professional authorised to do so by the National Board of Health and Welfare, and

3. Consumables required to administer a drug to the body or for self-checking of medication. **Act 2003:76.**

Special provisions on certain products

Section 19 Consumables as referred to in Section 18, Clause 3 shall be provided free of cost if prescribed due to sickness by a physician, dentist or other professional authorised to do so by the National Board of Health and Welfare. **Act 2003:76**.

Section 20 If the Government so prescribes, persons under 16 years of age shall be entitled to a subsidy of the costs exceeding SEK 120 for each purchase of foodstuffs as referred to in Section 20 of the Food Act (1971:511) if prescribed by a physician.

The Government or agency designated by the Government shall determine the conditions upon which subsidies for such foodstuffs shall be granted.

The costs for foodstuffs shall not be added to the costs of purchases of such drugs, contraceptives and consumables as referred to in Sections 15 and 18.

Substitutions of drugs by the pharmacy

Section 21 If a drug included on the Pharmaceutical Benefits Scheme has been prescribed and there is one or more less expensive, substitutable drug available at the pharmacy where the prescription is dispensed, the drug shall, except as stipulated in the third paragraph, be substituted with the least expensive drug available.

A drug is not substitutable if it differs from the prescribed drug to such an extent that it cannot be considered equivalent. The Government or agency designated by the Government shall decide which drugs are substitutable.

A drug shall not be substituted if the prescriber has objected to the substitution on medical grounds. Nor shall the drug be substituted if the patient pays the difference between the price set for the prescribed drug and the corresponding price for the least expensive substitutable drug available. If another substitutable drug is available, the drug may be substituted with that drug if the patient pays the difference between the price set for that drug and the corresponding price for the least expensive substitutable drug.

When relevant the pharmacy shall inform the patient about the substitution and of the patient’s right to obtain the prescribed drug if the patient pays the difference in price. When a substitution is made, the pharmacy shall inform the prescriber in writing.

Costs of benefits, etc.

Section 22 The costs of benefits pursuant to this Act shall be paid by the county council within whose district the person entitled to benefits resides.

If the person entitled to benefits does not reside within a county council district, the county council within whose district the person entitled to benefits works or, if the person is unemployed, the county council within whose district the person is registered as a job seeker, shall pay the costs of benefits pursuant to this Act. With respect to persons entitled to benefits pursuant to this Act in their capacity as a member of the family of an employed or self-employed person in accordance with Council Regulation (EEC) No 1408/71, the costs of benefits shall instead by borne by the county council within whose district the employed or self-employed person works or is registered as a job seeker.

In cases other than as referred to in the first and second paragraphs, costs shall be paid by the county council within whose district the prescriber of a product included on the Pharmaceutical Benefits Scheme works.

Section 23 Entitlement to benefits pursuant to this Act shall be determined by the county council required to pay the costs of benefits in accordance with Section 22.

Disclosure of information

Section 24 The Medical Products Agency shall upon request of the Pharmaceutical Benefits Board provide information on a drug to the Board if the information is necessary for review in accordance with this Act.

Credit

Section 25 Credit extended by Apoteket Aktiebolag for purchase of drugs and other products in accordance with this Act and which does not exceed SEK 1,800 shall be exempt from the provisions in Sections 6, 7 and 9 of the Consumer Credit Act (1992:830).

Appeals

Section 26 Decisions in individual cases rendered by the Pharmaceutical Benefits Board or a county council pursuant to this Act or pursuant to a regulation issued based upon the Act may be appealed in a public administrative court.

Leave to appeal is required for appeals to the administrative court of appeal.

Entry into force and transitional provisions

1. This Act shall enter into force on 1 October 2002, on termination of the Purchase Cost Maximisation (Medicinal and Other Products) Act (1996:1150).

2. Prescription drugs and other products for which the National Social Insurance Board has set prices pursuant to the older law shall be included on the Pharmaceutical Benefits Scheme.

However, this does not apply to drugs and products not covered by the cost maximisation scheme.

3. Applications pertaining to the setting of prices that are pending at the National Social Insurance Board when this Act enters into force shall thereafter be processed by the Pharmaceutical Benefits Board. Such an application shall be considered a request that the drug or product be included on the Pharmaceutical Benefits Scheme.

4. Upon appeal of a decision by the National Social Insurance Board issued prior to the entry into force of this Act, the older law shall be applied. If a price is set, the drug or product shall be included on the Pharmaceutical Benefits Scheme.

5. Benefits for individuals that arose pursuant to Section 4 of the older law shall be considered to be Pharmaceutical Benefits pursuant to the new Act.

6. A prescription issued prior to the entry into force of this Act may be dispensed within the Pharmaceutical Benefits Scheme even though it lacks a workplace code.