

# **Ordinance (2002:687) on Pharmaceutical Benefits, etc.**

Issued 4 July 2002

Amendments incorporated up to and including SFS 2003:187

-----

## **Introductory provision**

**Section 1** This ordinance contains regulations on execution of the Act (2002:160) on Pharmaceutical Benefits, etc. The terms and designations used in the Act have the same meaning in this ordinance.

That said about county councils in this ordinance shall also apply to municipalities that are not part of a county council.

## **Restrictions to the Pharmaceutical Benefits Scheme**

**Section 2** The Pharmaceutical Benefits Scheme in accordance with Section 5 of the Act (2002:160) on Pharmaceutical Benefits, etc., and cost-exemption pursuant to Section 19 of the same Act shall not apply to quantities of drugs or other products greater than the estimated need for 90 days or, if an appropriate package size for 90 days is not available, the next larger package. However, this shall not apply to products referred to in Section 18 Clause 1 of the act cited.

A drug that has been prescribed shall not be prescribed again as long as the prescription is still valid if the sole reason for doing so is to get the prescription dispensed on more favourable terms. **Ordinance 2002:726.**

**Section 3** A new one-year period in accordance with Section 5 of the Act (2002:160) on Pharmaceutical Benefits, etc., cannot be commenced until the preceding one-year period has ended.

## **Workplace code**

**Section 4** All persons who have a workplace and are authorised to prescribe drugs have the right to a workplace code as referred to in Section 6 of the Act (2002:160) on Pharmaceutical Benefits, etc.

The county council may otherwise decide the design and distribution of workplace codes for prescribers whose workplaces are within the county council's district.

If the county council finds that the applicant does not have the right to a workplace code, the matter shall be submitted to the National Board of Health and Welfare for review.

A workplace code shall remain valid only as long as the conditions stipulated in the first paragraph are fulfilled.

## Non-prescription drugs

**Section 5** The Pharmaceutical Benefits Board may issue regulations on the conditions under which a non-prescription drug or a certain group of such drugs shall be included on the Pharmaceutical Benefits Scheme. **Ordinance 2003:**

### Products other than drugs

**Section 6** The subsidy of the costs of certain foodstuffs prescribed in Section 20 of the Act (2002:160) on Pharmaceutical Benefits, etc. shall apply when a child is suffering from any of the conditions stipulated in the appendix to this ordinance.

The Medical Products Agency shall prepare a list of the foodstuffs covered by the subsidy. The Agency shall also stipulate the specialist expertise that shall be required for a physician to be authorised to prescribe such foodstuffs.

**Section 7** Prescriptions for foodstuffs as referred to in Section 20 of the Act (2002:160) on Pharmaceutical Benefits, etc. shall be written on a "food prescription form" (*"livsmedelsanvisning"*).

The food prescription form shall state how many times the prescription may be dispensed. For each time it is dispensed, the prescription shall be for no more than the amount of food equal to the estimated need for 90 days.

**Section 8** Prescriptions for consumables as referred to in Section 18, Clause 2 and Section 19 of the Act (2002:160) on Pharmaceutical Benefits, etc. and Sections 3 d and 18 c of the Medical Services Act (1982:763) shall be written on a "medical devices prescription form" (*"hjälpmedelskort"*).

The medical devices prescription form shall state how many times the prescription may be dispensed.

### Processing, etc.

**Section 9<sup>1</sup>** The Pharmaceutical Benefits Board shall issue a decision within 180 days of receiving a complete application for inclusion of a drug or product on the Pharmaceutical Benefits Scheme.

A decision to increase a previously set price shall be issued within 90 days of the date upon which the Board received the application. If the information provided in support of the application is insufficient, the Board shall immediately inform the applicant of the additional information required and make a decision within 90 days of receiving the additional information. If the number of applications is very large, the processing deadline may be extended once by an additional 60 days. The applicant shall be informed of such an extension prior to the original deadline.

If a decision is not issued within the time or times stipulated in the second paragraph, the applicant shall have the right to put the requested price increase into effect.

---

<sup>1</sup> EGT L 40, 11.2.1989, p. 8 (Celex 31989L0105)

A decision to lower a previously set price shall be issued as soon as possible.

**Section 10<sup>1</sup>** The Pharmaceutical Benefits Board shall publish a list of the drugs included on the Pharmaceutical Benefits Scheme as well as the prices that may be charged for those products. The list and price information shall be submitted to the European Commission at least once a year.

### **Validity of prescriptions, etc.**

**Section 11** A written prescription shall be valid for one year from date of issue unless the prescriber specifies a shorter period of validity. The number of times that the prescription may be dispensed shall be specified on the prescription form.

Prescriptions as referred to in Sections 7 and 8 shall be valid for one year from date of issue.

Each time the prescription is dispensed, the name of the pharmacy and the date on which the prescription was dispensed shall be noted on the prescription form. For products to be included on the Pharmaceutical Benefits Scheme pursuant to Section 5 of the Act (2002:160) on Pharmaceutical Benefits, etc., or free of cost pursuant to Section 19 of the same Act, the prescription shall not be dispensed again until at least two thirds of the time that the previously dispensed drug or other product was intended to cover. However, the prescription may be dispensed prior to that date if there is special reason for doing so.

When a prescription is dispensed a verification shall be prepared, after which the prescription form shall be returned to the customer. When the prescription is dispensed for the last time, the pharmacy may keep the prescription form or a copy of it as its verification.

### **Substitutable drugs**

**Section 12** The Medical Products Agency shall decide which drugs are substitutable pursuant to Section 21 of the Act (2002:160) on Pharmaceutical Benefits, etc.

### **Dispensing of prescriptions from the pharmacy**

**Section 13** Drugs or other products as referred to in Sections 5, 19 or 20 of the Act (2002:160) on Pharmaceutical Benefits, etc. may in urgent cases be dispensed even though the prescription was not written on the prescribed form. In such case, the prescriber shall certify that the case is urgent and provide the information that should have been provided had the prescribed form been used.

A prescription as referred to in this section shall be dispensed only once. The pharmacy shall retain the document as its verification or document the information and retain it as its verification.

**Section 14** Upon dispensation of a prescription that is retained by the pharmacy, the pharmacy shall, if the customer so requests, give the customer a certified copy of the document. It shall be noted on the copy that it is not valid for dispensation.

---

<sup>1</sup> EGT L 40, 11.2.1989, p. 8 (Celex 31989L0105)

**Section 15** Each time a prescription is dispensed, the pharmacy shall provide a separate receipt for the amount the customer has paid for products covered by the Pharmaceutical Benefits Scheme.

If the customer has purchased products covered by the Pharmaceutical Benefits Scheme in such an amount that the subsidy then equals the entire cost of further purchases, the pharmacy shall issue a "free card" (*"frikort"*). The pharmacy shall also take other measures required to ensure that the customer receives pharmaceutical benefits.

### **The pharmacy's right to reimbursement**

**Section 16** If a drug or other product as referred to in the Act (2002:160) on Pharmaceutical Benefits, etc. has been dispensed free or at a subsidised cost from the pharmacy against a prescription, Apoteket Aktiebolag shall have the right to be reimbursed by the county council referred to in Section 22 of the same Act in an amount equal to the full price or prescribed subsidy.

Reimbursement shall be paid in arrears, meaning that reimbursement attributable to a certain month shall be paid on the first weekday other than a Saturday of the second month thereafter. In other respects, reimbursement shall be paid in the manner agreed between the county councils and Apoteket Aktiebolag.

### **Verifications**

**Section 17** The documents which, according to this ordinance, constitute the pharmacy's verifications shall be kept on file for three years from the date upon which Apoteket Aktiebolag requested reimbursement for them.

The verifications shall upon request of a county council be submitted to such county council for review.

**Section 18** The county council shall be permitted to audit claims for reimbursement pursuant to Section 16 and to confirm that drugs and other products dispensed free or at a subsidised price are covered by the Act (2002:160) on Pharmaceutical Benefits, etc.

### **Adoption of forms**

**Section 19** The Medical Products Agency shall, following consultation with the Pharmaceutical Benefits Board and county councils, adopt forms as referred to in Sections 7 and 8.

### **Appeals**

**Section 20** Provisions on appeals to a public administrative court are found in Section 22 a of the Administrative Procedure Act (1986:223).

## **Additional regulations**

**Section 21** The Pharmaceutical Benefits Board may issue additional regulations on execution of the Act (2002:160) on Pharmaceutical Benefits, etc. However, the National Board of Health and Welfare may issue regulations on workplace codes as well as execution of Section 18, Clause 2 and Section 19 of the same Act.

---

This Ordinance shall enter into force on 1 October 2002. By this Ordinance the Purchase Cost Maximisation (Medicinal and Other Products) Ordinance (1996:1294) is repealed.

-----

### Appendix

List of conditions that entitle covered persons to subsidised foodstuffs pursuant to Section 20 of the Act (2002:160) on Pharmaceutical Benefits, etc.

Chron's Disease

Phenylketonuria

Galactosemia

Gluten Intolerance

Cow's Milk Protein Intolerance

Short Bowel Syndrome

Lactose Intolerance (congenital and secondary)

Chronic Renal Insufficiency

Soy Protein Intolerance

Ulcerative Colitis