

RESOLUTION OF THE CABINET OF MINISTERS OF UKRAINE

dated 15 July 1997, N 765

Kyiv

On Approving the Procedure of State Accreditation of Health Care Institutions

As amended and added under
Resolution of the Cabinet of Ministers of Ukraine
of 21 June 2001 N 678

With the view of improving the quality of health care services provided to the public of Ukraine and pursuant to Article 16 of the Basics of Laws of Ukraine On Health Care, the Cabinet of Ministers of Ukraine herewith **RESOLVES:**

1. To approve the Procedure of State Accreditation of Health Care Institutions attached hereto.
2. The Ministry of Health of Ukraine shall be charged with setting up, within two months, the Chief Accreditation Commission within the structure of the Ministry of Health of Ukraine, and with ensuring the formation of Accreditation Commissions within the structure of the Ministry of Health of the Autonomous Republic of Crimea, Health Care Departments of regional state administrations and Kyiv and Sevastopol city state administrations.

It shall be herewith established that the responsibilities of state accreditation of pharmacies shall be vested in the Chief Accreditation Commission formed under the State Department for Pharmaceuticals and Medical Products Quality, Safety and Fabrication Control, as well as accreditation commissions formed within the structure of the Ministry of Health of the Autonomous Republic of Crimea, Health Care Departments of regional state administrations and Kyiv and Sevastopol city state administrations.

(clause 2 added with paragraph 2 as per
Resolution of the Cabinet of Ministers of Ukraine of 21.06.2001 N 678)

3. The Ministry of Health of Ukraine, the Ministry of Health of the Autonomous Republic of Crimea, Health Care Departments of regional state administrations and Kyiv and Sevastopol city state administrations shall be charged with a responsibility for performing state accreditation of all health care institutions before the year 2000.

The State Department for Pharmaceuticals and Medical Products Quality, Safety and Fabrication Control shall be charged with completing pharmacies accreditation within the year 2001.

(clause 3 added with paragraph 2 as per
Resolution of the Cabinet of Ministers of Ukraine of 21.06.2001 N 678)

4. The oversight of the enforcement hereof shall be vested in the responsibility of Vice-Prime-Minister of Ukraine I.F. Kuras.

Acting Prime-Minister of Ukraine

V. Durdynets

Ind. 28

APPROVED
by Resolution of the Cabinet of Ministers of
Ukraine of 15 July 1997 N 765

PROCEDURE of State Accreditation of Health Care Institutions

1. The state accreditation of a health care institution (hereinafter referred to as Accreditation) shall mean an official recognition of a health care institution's status, its compliance with conditions for provision of an adequate level of health care and sanitation aid and confirmation of its compliance with set criteria and guarantee of high quality professional activity.

2. All health care institutions (hereinafter referred to as Institutions) irrespective of their form of ownership shall be subject to compulsory accreditation.

Accreditation shall be performed once in three years.

3. Health care institutions accreditation shall be performed by the Chief Accreditation Commission formed with the structure of the Ministry of Health of Ukraine whereas pharmacies accreditation shall be a responsibility of the State Department for Pharmaceuticals and Medical Products Quality, Safety and Fabrication Control (hereinafter referred to as Chief Accreditation Commissions), as well as Accreditation Commissions formed within the Ministry of Health of the Autonomous Republic of Crimea, Health Care Departments of regional state administrations and Kyiv and Sevastopol city state administrations (hereinafter referred to as Accreditation Commissions).

(clause 3 as worded under Resolution of the
Cabinet of Ministers of Ukraine of 21.06.2001 N 678)

4. The activity of Chief Accreditation Commissions and Accreditation Commissions shall be governed by the Constitution of Ukraine and other applicable legal acts.

(clause 4 as amended under Resolution of the
Cabinet of Ministers of Ukraine of 21.06.2001 N 678)

5. Chief Accreditation Commissions shall carry out accreditation of state-owned institutions (including those controlled by regional state administrations) and privately-owned institutions.

(clause 5 as amended under Resolution of the
Cabinet of Ministers of Ukraine of 21.06.2001 N 678)

Accreditation Commissions shall accredit communally-owned institutions (except for those within the jurisdiction of regional state administrations).

6. In order to be accredited, an institution shall file documents in accordance with the list (Annex 1) to a respective accreditation commission which must, within three month, complete said accreditation, whereas the state accreditation of a pharmacy shall require submission of documents in accordance with the list compiled by the State Department for Pharmaceuticals and Medical Products Quality, Safety and Fabrication Control.

(clause 6 as amended under Resolution of the
Cabinet of Ministers of Ukraine of 21.06.2001 N 678)

7. Based on an examination of documents filed by an institution and expert examination conclusions, a respective accreditation commission shall make a decision concerning the accreditation and referring the institution in question to a relevant category (first, second, higher category) or a decision to deny same.

Decisions of accreditation commissions shall be approved by a respective chief accreditation commission and communicated to the institution in question within 10 days.

(paragraph 2 of clause 7 as amended under Resolution of the
Cabinet of Ministers of Ukraine of 21.06.2001 N 678)

In case when a decision has been rendered to refer the institution to a respective category, the commission having accredited said institution shall issue an accreditation certificate (Annex 2) to said institution.

The period of effect of the accreditation certificate shall be determined by a respective accreditation commission but may under no circumstances exceed the term of three years.

(paragraph 4 of clause 7 as amended under Resolution of the
Cabinet of Ministers of Ukraine of 21.06.2001 N 678)

8. Extraordinary accreditation may be allowed on an initiative of a health care institution seeking the category elevation which may be granted to institutions not earlier than upon expiration of one year's term following the previous accreditation date.

The same procedure shall also apply to accreditation of institutions whose accreditation was previously declined.

9. Accredited institutions shall be entered in the State Register maintained by the Chief Accreditation Commission.

10. In case of violations of conditions attached to the provision by an institution of quality health care and sanitation aid, as well as in case of provision of inaccurate or false information concerning the institution's activity, the Chief Accreditation Commission may, on the motion of a competent accreditation commission, decide on canceling accreditation or lowering the institution's category.

(paragraph 1 of clause 10 as amended under Resolution of the
Cabinet of Ministers of Ukraine of 21.06.2001 N 678)

Within 10 days following the approval of a decision on accreditation cancellation or category lowering, the institution in question must return its accreditation certificate to the accreditation commission having issued it.

11. The accreditation certificate form is a strict accountancy document bearing an inventory series and number, and shall be fabricated in a professional print-shop. The accreditation certificate shall indicate the name of the issuing accreditation commission, full address of the accredited institution, registration number, date of issue, period of validity and category. Upon the validity period expiration, the accreditation certificate shall be deemed null and void.

12. Inventory, keeping of accreditation certificates shall be a responsibility of Chief Accreditation Commissions and accreditation commissions.

(paragraph 1 of clause 12 as amended under Resolution of the
Cabinet of Ministers of Ukraine of 21.06.2001 N 678)

Documents serving grounds for accrediting the institution shall be kept for the period of 10 years with the accreditation commission having issued the accreditation certificate.

Annex N 1
to the Procedure of State Accreditation of
Health Care Institutions

LIST

OF MANDATORY DOCUMENTS TO BE ATTACHED TO AN APPLICATION REQUESTING STATE ACCREDITATION OF A HEALTH CARE INSTITUTION

Copy of duly notarized Regulations (Articles of Association) of a health care institution

Copy of an order or lease of premises, other documents authorizing the use of assets, including equipment required for treatment and prophylactics purposes

Data concerning the number and qualification profiles of staff employed by the institution

Approved organizational chart of the health care institution

Conclusion of the State Sanitary and Epidemiological Oversight Agency on the epidemic condition of the institution

Conclusion of the State Fire Inspection on the fire safety condition in the institution

Expert conclusion on the condition of safety measures and structures operation in the institution

Financial statement for the preceding year approved by the financial authority having jurisdiction over the institution's place of business

Institution's report on participation in fulfillment of zonal health care programs

Institution's report on therapeutic activities conducted over the past three years

Overview of the institution operation in terms of quality of health care and criteria of quality assessment

Institution's report on academic and teaching activities (if applicable)

Copies of previously issued accreditation certificates (if they had been issued)

NOTE. If need be, the Chief Accreditation Commission under the Ministry of Health of Ukraine may enter additional items on the list of documents.

SAMPLE

Annex N 2
to Procedure of State Accreditation
of Health Care Institution

MINISTRY OF HEALTH OF UKRAINE

series _____ N _____

ACCREDITATION CERTIFICATE

category _____

(name of accreditation commission issuing the certificate)

Name of health care institution

Address of health care institution

Validity of certificate _____

"_____" _____ 19__ .
Date of issue

Registration N _____

Head,
Accreditation Commission

(signed)

Secretary,
Accreditation Commission

(signed)

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