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LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF
THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative text.

FEDERAL REPUBLIC OF GERMANY

Communicated by the Government of the Federal Republic of Germany

NOTE BY THE SECRETARIAT

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

ORDER
CONCERNING THE PRESCRIPTION, DISPENSING AND ISSUE, AND PROOF OF THE STORAGE LOCATION OF NARCOTIC DRUGS (NARCOTIC DRUGS PRESCRIPTION ORDER - BtMVV)[, 1993]

V.97-24358

Order
Concerning the Prescription, Dispensing and Issue, and Proof of the Storage Location of Narcotic Drugs (Narcotic Drugs Prescription Order - BtMVV) [, 1993]

§ 1
Principle of prescription

The narcotic drugs designated in Annex III of the Narcotic Drugs Act[1/] may be prescribed only as preparations. The provisions of this Order shall also apply to the salts and molecular compounds of narcotic drugs that are used according to the state of medical science by physicians, dentists, or veterinarians. Unless otherwise provided in individual cases, the maximum quantities determined for a narcotic drug shall also apply to its salts and molecular compounds.

§ 2
Prescription by a physician

(1) For one patient, a physician may prescribe on one day:

(a) One, or, in the context of a special therapy plan, two of the following narcotic drugs, adhering to the maximum quantities in respect of requirements for up to 30 days determined below, but not more than one-tenth of such quantities per day of treatment:

1.	Buprenophine	150 mg,
2.	Fentanyl	120 mg,
3.	Hydrocodone	1 200 mg,
4.	Hydromorphone	600 mg,
5.	*l*-Methadone	1 500 mg,
6.	Methadone	3 000 mg,
7.	Morphine	20 000 mg,
8.	Pentazocine	15 000 mg,
9.	Pethidine	10 000 mg,
10.	Piritramide	6 000 mg,

or

(b) One of the following narcotic drugs, adhering to the maximum quantities determined below:

1.	Amphetamine	200 mg,
2.	Amfetaminil	200 mg,
3.	Fenetyllin	2 500 mg,
4.	Methamphetamine	100 mg,
5.	Methaqualone	6 000 mg,
6.	Methylphenidate	400 mg,
7.	Nabilone	36 mg,
8.	Normethadone	200 mg,
9.	Opium, standardized	4 000 mg,
10.	Opium extract	2 000 mg,
11.	Tincture of opium	40 000 mg,
12.	Papaver somniferum, calculated as morphine	200 mg,

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13.	Phenmetrazine	600 mg,
14.	Secobarbital	1 200 mg,
15.	Tilidine	1 050 mg,

or

(c) One of the narcotic drugs designated in Part B (except pentazocine and pentobarbital) and Part C of Annex III of the Narcotic Drugs Act.

(2) In justified individual cases and observing the necessary security of the administration of narcotic drugs, the physician, notwithstanding the provisions of paragraph (1), and for a patient who is under his long-term care, may on one day:

1. Prescribe more than one narcotic drug;
2. Exceed the quantities of narcotic drugs determined in paragraph (1), subparagraphs a and b;
3. Prescribe narcotic drugs for a period longer than that determined in paragraph (1), subparagraph a.

Prescription pursuant to the first sentence of this paragraph must be reported in writing to the competent *Land* agency within three days.

(3) For the needs of his practice, a physician may prescribe the narcotic drugs listed in paragraph (1), as well as alfentanil and cocaine, only for operations on the eye, the larynx, the nose or the ear, the pharynx or the jaw, in the form of a solution with a content of up to 20 per cent or an ointment with a content of up to 2 per cent, as well as pentobarbital and sufentanil up to the quantity of his average fortnightly requirements, but at least the smallest package unit. The supplies of each narcotic drug kept in store should not exceed the physician's monthly requirements.

(4) Only the physician who is in charge of a hospital or of a subsidiary unit of a hospital or is supervising it in the absence of its head may issue prescriptions for the needs of hospital wards. He may prescribe the narcotic drugs designated in paragraph (3), adhering to the limitations determined in that paragraph concerning purpose, content, and form of administration. This also applies to a private practitioner who has a contractual arrangement for the hospitalization of his patients if the beds assigned to him are separated physically and organizationally from those in other units.

§ 2a
Prescription for substitution purposes

"(1) For substitution purposes in the context of drug-dependency treatment, the physician may prescribe only *l*-methadone, methadone or a narcotic drug authorized for substitution treatment. Prescription shall be admissible only if and for as long as the narcotic drug is used subject to the requirements of § 13 (1) of the Narcotic Drugs Act, and in particular in accordance with the rules of medical science."

(2) In the interests of the purpose of treatment, namely, abstinence from narcotic drugs, the attending physician must endeavour to ensure that drug-dependent persons who undergo substitution treatment also take part continuously in psychological and/or social therapy.

(3) Physicians who prescribe narcotic drugs for drug-dependent persons for substitution purposes pursuant to paragraph (1) may only present the prescription in person to the pharmacy for filling or have it presented by reliable auxiliary staff authorized by them, except in the cases mentioned in paragraph (7).

(4) Except in the cases mentioned in paragraph (7), drug-dependent persons shall be supplied with each individual dose in a form not suitable for parenteral use only under the supervision of the prescribing physician or of his locum tenens for immediate consumption.

(5) At weekends or on public holidays as well as in cases in which home care is required, the narcotic drug pursuant to paragraph (1), in the form mentioned in paragraph (4), can also be supplied to a drug-dependent person for immediate consumption by a qualified nurse or male nurse from a social welfare centre or other institution recognized by the competent *Land* agency, acting on the instructions of the attending physician. To enable them to carry out their tasks, social welfare centres or other institutions recognized by the competent *Land* agency shall be permitted to store in their premises the narcotic drugs required pursuant to the first sentence of this paragraph. The relevant security measures must be guaranteed.

(6) The attending physician must ensure, by means of suitable diagnostic laboratory tests carried out at irregular intervals, that the use of substances that jeopardize the purpose of substitution can be detected.

(7) With the written consent of the competent *Land* agency, the physician may issue a patient once a week with a prescription for the quantity of the narcotic drug pursuant to paragraph (1) needed for up to three days if the patient has been taking part in successful substitution treatment for at least 12 months and if, over a sufficiently long period, neither the use of substances jeopardizing the purpose of substitution nor any other indications of renewed narcotic drug abuse have been detected in his case. In that context, the physician must prescribe the narcotic drug in the form of a preparation not suitable for parenteral use and in separate individual doses for the relevant days of use. The days of treatment must be stated on the prescription form and indicated by the pharmacy on the individual doses. The physician must enter the annotation "With the consent of the *Land* agency" on the prescription form. The narcotic drug pursuant to paragraph 1 may be supplied only personally to the patient undergoing substitution treatment, against presentation of his or her identity document or passport.

(8) Patients who cannot visit the attending physician for a certain period and can credibly adduce grave and weighty reasons for this can receive confirmation from the physician on a narcotic drug prescription form that they are undergoing regular substitution treatment (substitution certificate). The following particulars must be stated on the substitution certificate:

1. The family name, given name and address of the patient for whom the substitution certificate is intended;
2. The date of issue;
3. The quantity of the narcotic drug to be prescribed and to be supplied for immediate consumption pursuant to paragraph (1);
4. Validity: from/to (at most 30 days);
5. The name of the issuing physician, his professional designation and address, including his telephone number;
6. The signature of the issuing physician.

The substitution certificate must bear the notation "Only for presentation to a physician". Part I of the substitution certificate is issued to the patient, and Part II is sent by the physician without delay to the *Land* agency responsible for the supervision of his administration of narcotic drugs. Part III is retained by the issuing physician. After presentation of Part I of the substitution certificate and verification of the personal particulars by comparison with the patient's identity document or passport, a physician can

take over the patient's substitution treatment subject to the rules determined in paragraphs (1) to (4). The physician taking over temporary substitution treatment shall inform the attending physician in writing of the action taken, immediately after the conclusion of substitution treatment.

(9) The implementation of the measures required in the above paragraphs, including participation in accessory therapy pursuant to paragraph (2), must be documented by the attending physician for every patient and reported to the competent agency. The documentation must be presented to the competent *Land* agency on demand for inspection and evaluation.

§ 3
Prescription by a dentist

(1) For one patient, a dentist may prescribe on one day:

(a) One of the following narcotic drugs, adhering to the maximum quantities determined below:

1.	Amphetamine	200 mg,
2.	Buprenorphine	10 mg,
3.	Fenetyllin	2 500 mg,
4.	Hydrocodone	200 mg,
5.	Hydromorphone	30 mg,
6.	*l*-Methadone	60 mg,
7.	Methamphetamine	100 mg,
8.	Methaqualone	6 000 mg,
9.	Methylphenidate	200 mg,
10.	Morphine	200 mg,
11.	Opium, standardized	2 000 mg,
12.	Opium extract	1 000 mg,
13.	Tincture of opium	20 000 mg,
14.	Pentazocine	1 350 mg,
15.	Pethidine	1 000 mg,
16.	Phenmetrazine	600 mg,
17.	Piritramide	220 mg,
18.	Tilidine	1 050 mg,

or

(b) One of the narcotic drugs designated in Part B (except pentazocine and pentobarbital) or Part C of Annex III of the Narcotic Drugs Act.

(2) For the requirements of his practice, a dentist may prescribe the narcotic drugs listed in paragraph (1), as well as alfentanil, fentanyl, and sufentanil up to the quantity of his average fortnightly requirements, but at least the smallest package unit. The amount of each narcotic drug kept in store should not exceed the dentist's monthly requirements.

(3) Only the dentist who is in charge of a hospital or of a subsidiary unit of a hospital or who is supervising it in the absence of the dentist in charge may issue prescriptions for the needs of hospital wards. He may prescribe the narcotic drugs designated in paragraph (2), adhering to the limitations determined in that paragraph concerning purpose, content, and form of administration. This also applies to a private dentist who has a contractual arrangement for the hospitalization of his patients if the beds assigned to him are separated physically and organizationally from those in other units.

§ 4
Prescription by a veterinarian

(1) For an animal a veterinarian may prescribe on one day:

(a) One of the following narcotic drugs, adhering to the maximum quantities determined below:

1.	Amphetamine	1 000 mg,
2.	Buprenorphine	10 mg,
3.	Hydrocodone	200 mg,
4.	Hydromorphone	30 mg,
5.	*l*-Methadone	250 mg,
6.	Methamphetamine	100 mg,
7.	Morphine	500 mg,
8.	Normethadone	200 mg,
9.	Opium, standardized	12 000 mg,
10.	Opium extract	6 000 mg,
11.	Tincture of opium	120 000 mg,
12.	Pentazocine	1 350 mg,
13.	Pethidine	1 000 mg,
14.	Piritramide	220 mg,
15.	Tilidine	1 050 mg

or

(b) The narcotic drugs designated in Part B (except pentazocine and pentobarbital) or Part C of Annex III of the Narcotic Drugs Act.

(2) A veterinarian may prescribe for an animal on one day in a particularly serious case of illness one of the following narcotic drugs in a quantity up to twice the maximum determined in paragraph (1), subparagraph a, in respect of requirements for up to seven days: buprenorphine, hydromorphone, *l*-methadone, morphine, standardized opium, opium extract, tincture of opium, pentazocine, pethidine, piritramide.

(3) For the requirements of his practice, the veterinarian may prescribe the narcotic drugs listed in paragraph (1), as well as alfentanil and cocaine, only for operations on the eyes and in the form of a solution with a content of up to 20 per cent or an ointment with a content of up to 2 per cent; etorphine only for the immobilisation of animals kept in a zoo, a circus, or game enclosure, when administered by or in the presence of the prescribing veterinarian; fentanyl and pentobarbital only for premedication and anaesthesia as well as for putting animals to sleep; and sufentanil up to the quantity of his average fortnightly requirements, but at least the smallest package unit. Supplies of each narcotic drug kept should not exceed the veterinarian's monthly requirements.

(4) Only the veterinarian in charge of an animal hospital or a subsidiary unit of an animal hospital or who supervises it in the absence of its head may prescribe drugs for ward requirements. He may prescribe the narcotic drugs designated in paragraph (3), except etorphine, adhering to the limitations determined in that paragraph concerning purpose, content, and form of administration.

§ 5
Narcotic drug prescription forms

(1) Narcotic drugs for patients, the requirements of a practice and animals may be prescribed only on a three-part official form (narcotic drug prescription form). This form may be used for the prescription of other pharmaceutical products only if such products are prescribed in addition to a narcotic drug. Parts I and II of the completed narcotic drug

prescription form are intended for presentation to a pharmacy; Part III is retained by the physician, dentist or veterinarian to whom the narcotic drug prescription form was issued.

(2) Narcotic drug prescription forms are issued on request by the Federal Health Office to individual physicians, dentists or veterinarians. The Federal Health Office can refuse issue if there is justified suspicion that the narcotic drug prescription forms are not being used in accordance with legal regulations on narcotic drugs.

(3) The numbered narcotic drug prescription forms, bearing the date of issue by the Federal Health Office and the Federal Health Office number of the individual physician, dentist or veterinarian are intended only for their use and may be transferred only to a locum tenens. Unused narcotic drug prescription forms must be returned to the Federal Health Office when the physician, dentist or veterinarian retires from practice.

(4) Physicians, dentists or veterinarians must protect narcotic drug prescription forms against theft. Loss must be reported immediately, stating the serial numbers of the forms, to the Federal Health Office, which shall inform the competent supreme *Land* agency.

(5) Physicians, dentists or veterinarians must keep Part III of the completed narcotic drug prescription forms and Parts I to III of incorrectly completed narcotic drug prescription forms on file by date of issue for three years(§ 6 (1), subparagraph 2) and must send them on demand to the *Land* agency competent according to § 19 (1), subparagraph 3, of the Narcotic Drugs Act or present them to authorized representatives of that agency.

§ 6
Particulars to be stated on narcotic drug prescription forms

(1) The following particulars must be stated on narcotic drug prescription forms:

1. The name, given name and address of the patient for whom the narcotic drug is intended; in the case of prescription by a veterinarian, the species of animal and the family name, given name and address of the animal owner;
2. The date of issue;
3. With regard to the preparation prescribed:
   (a) In the case of off-the-shelf drugs, the pharmacopoeia name or designation of the narcotic drug component, form of administration, weight of the narcotic drug content per package unit, and, in the case of dosage units, the above particulars per dosage unit, and the number of units;
   (b) In the case of a prescription, the components, weight of the narcotic drug content, form of administration; in the case of dosage units, the number of units;
   (c) In the case of an off-the-shelf homoeopathic drug or of a homoeopathic prescription, the designation of the pharmaceutical preparation or designation of the narcotic drug component, the form of administration, the degree of dilution of the narcotic drug component and the weight of the package unit; in the case of preparations divided into dosage units, the number of units, and in the case of a mixture of several preparations in addition the percentage by weight of the dilution containing the narcotic drug;

   weights in grammes or milligrammes, and the number of units repeated in words;
4. The instructions for use with the individual or daily dose or in the event that the patient was given written instructions for use, the annotation "According to written instructions";
5. In the cases covered by § 2 (2), the letter "A" in a circle, in the cases covered by § 2a (7), the annotation "With the consent of the *Land* agency", and, in the cases covered by § 4 (2) the annotation "Serious illness";

6. The name of the prescribing physician, dentist or veterinarian, his professional designation and address as well as telephone number;

7. In the cases covered by § 2 (3), § 3 (2) and § 4 (3), the annotation "For requirements of the practice" instead of the particulars in subparagraphs 1 and 4;

8. The signature of the prescribing physician, dentist or veterinarian, or if represented by a locum tenens, in addition the annotation "As locum tenens".

(2) The particulars according to paragraph (1) must be entered indelibly and must appear consistently on all parts of the narcotic drug prescription form. In this context, the particulars according to subparagraphs 3, 4, and 8 must be entered in writing by the prescribing physician, dentist or veterinarian. In the event of an alteration of the prescription in respect of the particulars according to paragraph (1), subparagraphs 2 to 6, the prescribing physician, dentist or veterinarian must make the alteration in writing on all parts of the narcotic drug prescription form and confirm this by his signature.

(3) In the case of liquid preparations, the weight of the narcotic drug represented by the overfilling of the dispensing container which is necessary for technical reasons shall not be taken into account:

1. In respect of the maximum quantity determined in each particular case (§§ 2 to 4); and

2. On the narcotic drug prescription forms and narcotic drug requisition forms as well as in the records on storage location and stocks (§ 9).

§ 6a
Narcotic drug requisition forms

(1) Narcotic drugs for ward requirements according to § 2 (4), § 3 (3) and § 4 (4) may be prescribed only on a narcotic drugs requisition form. Narcotic drugs requisition forms are three-part official forms. Parts I and II of the completed narcotic drug requisition forms are intended for presentation to a pharmacy, and Part III is retained by the physician, dentist or veterinarian entitled to prescribe the drugs.

(2) Narcotic drug requisition forms are issued by the Federal Health Office on request to the physician or dentist in charge of a hospital or a subsidiary unit of a hospital, or to the veterinarian in charge of an animal hospital. The numbered narcotic drug requisition forms are intended only for use in the institution of which the requesting physician, dentist or veterinarian is in charge. They may be passed on by the requesting physician, dentist or veterinarian to the heads of subsidiary units of the institution. Records must be kept concerning such forms passed on. The records must be kept on file for three years, counting from the last entry, and must be sent on demand to the Federal Health Office or to the *Land* agency competent according to § 19 (1), third sentence, of the Narcotic Drugs Act or presented to authorized representatives of that agency.

(3) The following particulars must be stated on the narcotic drug requisition form:

1. The name or designation and address of the institution for which the ward requirements are intended;

2. The date of issue;

3. The preparations prescribed according to § 6 (1), subparagraph 3;

4. The name of the prescribing physician, dentist or veterinarian, including the telephone number, and, if represented by a locum tenens, also the annotation "locum tenens";

5. The signature of the prescribing physician, dentist or veterinarian.

The particulars according to subparagraphs 1 to 5 must be entered indelibly and must appear consistently on all parts of the form. Particulars according to subparagraphs 1 to 4 may be entered by a person other than the prescribing physician, dentist, or veterinarian.

(4) Part III of completed narcotic drug requisition forms and Parts I to III of incorrectly completed narcotic drug requisition forms must be kept on file for three years in the institution of which the requesting physician, dentist or veterinarian is in charge and must be sent on demand to the *Land* agency competent pursuant to § 19 (1), third sentence, of the Narcotic Drugs Act, or presented to authorized representatives of that agency.

§ 7
Supply and dispensing

(1) Narcotic drugs may not be dispensed, subject to paragraphs (2) and (3):

1. Against a narcotic drugs prescription form:

   (a) The completion of which can be recognized by the dispensing pharmacist as not being permissible under a rule in §§ 1 to 4 or § 8 (2);

   (b) In the completion of which a rule under § 5 (1), first and second sentences, § 6 or § 8 (1), second sentence, was disregarded or

   (c) That was completed more than seven days previously; and

2. Against a narcotic drug requisition form:

(a) The completion of which can be recognized by the dispensing pharmacist as not being permissible under a rule in §§ 1 to 4, § 6a (2) or § 8a (1) and (2);

(b) In the completion of which a rule under § 6a (1) and (3) was disregarded.

(2) In the case of narcotic drug prescriptions that contain an error recognizable by the dispensing pharmacist, that are illegible or do not fully comply with the rules under § 6, subparagraphs 1, 2, 3, 4 and 6, the dispensing pharmacist is entitled to make changes after consultation with the prescribing physician, dentist or veterinarian. Missing particulars according to § 6 (1), subparagraph 1, can be supplemented by the dispensing pharmacist if the person presenting the narcotic drug prescription produces evidence of or gives a credible assurance regarding such particulars.

(3) On narcotic drug prescriptions in which a change according to paragraph (2) is not possible, the prescribed narcotic drugs or fractions thereof may be dispensed if the person presenting the prescription gives a credible assurance or it is recognizable in other ways that the case is urgent and requires the immediate use of the narcotic drug. In such cases, the manager of the pharmacy must immediately inform the prescribing physician, dentist or veterinarian that the drug has been dispensed.

(4) An annotation regarding consultation pursuant to paragraph (2) and dispensing pursuant to paragraph (3) must be entered by the prescribing physician, dentist or veterinarian on Parts I and II of the narcotic drug prescription form, but on Part III in the case covered by the second sentence of paragraph (2).

(5) The dispensing pharmacist must enter the following particulars indelibly on the reverse of the narcotic drug prescription form or the narcotic drug requisition form:

1. The name or company name and address of the pharmacy and the Federal Health Office number assigned to the manager of the pharmacy;

2. The date of issue; and

3. The signature of the dispensing pharmacist.

(6) The manager of the pharmacy must keep Part 1 of the narcotic drugs prescription forms and narcotic drug requisition forms on file by date of issue for three years and send them on demand to the Federal Health Office or to the *Land* agency competent pursuant to § 19 (1). third sentence, of the Narcotic Drugs Act or present them to authorized representatives of those authorities. Part II is intended for accounting purposes

(7) A veterinarian may issue narcotic drugs from his medicine cabinet only for use on an animal being treated by him and only in conformity with the rules under § 1 and § 4 (1) and (2) applicable to prescription.

§ 8

Prescription and dispensing for supply to merchant ships

(1) The provisions of § 1, of § 5 to § 7, paragraphs (1) to (3), apply to the prescription and dispensing of narcotic drugs for supply to merchant ships. The particulars mentioned in paragraph (4), subparagraphs 3 to 5 below must be entered on the narcotic drug prescription forms instead of those determined under § 6 (1) and (4).

(2) Only a physician authorized by the competent agency may prescribe narcotic drugs for supply to merchant ships; for this purpose he may prescribe only the narcotic drug hydromorphone.

(3) As an exception, narcotic drugs may be supplied by a pharmacy, initially without a prescription, to merchant ships that fly the federal flag if:

1. The physician designated in paragraph (2) cannot be contacted in time before the ship leaves harbour;
2. The drugs are of a type and quantity provided in the Order on medical care on merchant ships and are supplied only to replace narcotic drugs that:
   (a) Have been used up;
   (b) Have become unusable; or
   (c) Were obtained outside the area of application of the Narcotic Drugs Act and have to be replaced;
3. The dispensing pharmacist has previously satisfied himself that stocks of narcotic drugs on hand conform in type and quantity to the entries in the ship's dangerous drugs register; and
4. The dispensing pharmacist obtains certification of receipt from the person responsible for the proper organization of medical care.

(4) The certification pursuant to paragraph (3), subparagraph 4, must contain the following particulars:

1. The type and quantity of the narcotic drugs issued (§ 6 (1), subparagraph 3);
2. The date of issue;
3. The name of the ship;
4. The name of the ship-owner;
5. The ship's home port; and
6. The signature of the person in charge of medical care.

(5) The dispensing pharmacist must present the certification pursuant to paragraph (3), subparagraph 4, without delay to the physician authorized by the competent *Land* agency for subsequent prescription. The physician must make out the prescription if the requirements of paragraph (3), subparagraphs 1 and 2 were met, or otherwise inform the competent agency.

§ 8
Prescription for ambulance service institutions

(1) The provisions concerning prescription for ward requirements pursuant to § 2 (4) shall apply *mutatis mutandis* to the prescription of narcotic drug requirements for ambulance service institutions and their subsidiary units.

(2) The ambulance service agency or organizer must authorize a physician to prescribe the necessary narcotic drugs pursuant to § 2 (4) and to carry out the monthly verification pursuant to § 9 (3).

(3) The keeping of records on the storage location and stocks of narcotic drugs in the ambulance service institutions and their subsidiary units pursuant to § 9 shall be the responsibility of the attending physician in each case. Dangerous drugs registers must be kept in accordance with § 9 (1), third sentence.

(4) The ambulance service agency or organizer must authorize a pharmacist to supply narcotic drugs against prescriptions and to verify stocks of narcotic drugs in ambulance service institutions or their subsidiary units at least once every half year, and in particular to verify that the drugs are in good condition and are properly kept in a safe place. The authorized pharmacist must set the ambulance service agency or organizer an appropriate time limit for the correction of any shortcomings noted, and must inform the *Land* agency competent pursuant to § 19 (1), third sentence, of the Narcotic Drugs Act in the event of non-compliance.

§ 9
Proof of storage location and stocks

(1) Continuous records must be kept on file cards in the official form concerning the storage location and stocks of narcotic drugs:

1. In pharmacies;
2. In veterinarians' medicine cabinets;
3. Required for medical, dental and veterinary practices;
4. Required for wards of hospitals and animal hospitals;

stating, for each narcotic drug, the designation, form of administration and weight and, in the case of homoeopathic preparations, the degree of dilution of the narcotic drug contained therein, instead of the weight. If the institutions mentioned in subparagraph 4 have subsidiary units, the records must be kept in those subsidiary units. Registers with serially numbered pages in the official form (dangerous drugs registers) can also be kept in subsidiary units, instead of file cards. The records can also be kept by electronic data processing methods, provided that the printout of the stored data pursuant to paragraph (2) is guaranteed in the same sequence as on the official forms.

(2) Permanent records of each receipt and issue [of narcotic drugs] must be kept on the file cards or in the dangerous drugs registers, stating:

1. Date of receipt or issue;
2. Quantity received or issued and the resultant stocks at the end of a calendar month; in the case of substances and preparations not divided into dosage units, the weight in grammes or milligrammes, and, in preparations divided into dosage units, the number of units; in the case of liquid preparations that are used for treatment in the institutions mentioned in paragraph (1), subparagraphs 3 or 4, also the quantity in millilitres;
3. The name or company name and address of the supplier or of the recipient or an indication of other origin or location;

4. In pharmacies, in the case of issue against prescription, in hospitals and animal hospitals in the case of purchase against prescription, the name and address of the prescribing physician, dentist or veterinarian and the serial number of the narcotic drug prescription form or narcotic drug requisition form.

(3) The entries concerning receipt, issue and stocks of narcotic drugs as well as the consistency of stocks on hand with the records kept must be verified at the end of each calendar month by:

1. The pharmacist, for the pharmacy operated by him;
2. The veterinarian for the veterinary medicine cabinet managed by him; and
3. The physician, dentist or veterinarian authorized to prescribe and designated in §§ 2 to 4 in respect of the requirements of a practice or ward requirements;

if there has been a change in the stocks, such change must be confirmed by signature and statement of the date of verification. In the event that records are computerized, they must be verified on the basis of printouts made at the end of the month.

(4) The file cards, dangerous drugs registers or computer printouts pursuant to paragraph (3), second sentence, must be kept by the persons mentioned in paragraph (3), first sentence, or in the institutions supervised by the latter (§ 2 (4), § 3 (3) and § 4 (4)), for three years, counting from the date of the last entry. In the event of a change in the management of an institution or a hospital pharmacy, the persons in question must record the date of hand-over as well as the stocks handed over and confirm such record by their signature.

(5) The file cards, dangerous drugs registers and computer printouts pursuant to paragraph (3), second sentence, must be sent on demand to the *Land* agency competent pursuant to § 19 (1), third sentence, of the Narcotic Drugs Act or presented to authorized representatives of that agency. In the interim, provisional records must be kept and the particulars recorded therein must be entered on the file cards and dangerous drugs registers after the return of the latter.

§ 10
Criminal offences

Pursuant to § 29 (1), subparagraph 11, of the Narcotic Drugs Act, any person shall be punished. who:

1. Contrary to the provisions of § 1, does not prescribe a narcotic drug as a preparation;
2. (a) Infringes the provisions of § 2 (1) or (2), § 2a (1) or § 3 (1), [by prescribing] for a patient narcotic drugs other than those designated in this Order or more than one narcotic drug on one day or a narcotic drug in excess of the determined maximum quantity or without complying with other restrictions;

   (b) Infringes the provisions of § 2 (3), first sentence, § 3 (2), first sentence or § 4 (3), first sentence, [by prescribing] for the needs of his practice [narcotic drugs as set forth in (a) above]; or

   (c) Infringes the provisions of § 4 (1) or (2), [by prescribing] for an animal [narcotic drugs as set forth in (a) above],
3. Infringes the provisions of § 2 (4), also in conjunction with § 8 a (1), § 3 (3) or § 4 (4), by prescribing:

   (a) Narcotic drugs for institutions other than those designated in those passages of this Order;

   (b) Narcotic drugs other than those designated in those passages of this Order; or

(c) Narcotic drugs designated in those passages of this Order, without adhering to the restrictions mentioned therein; or

4. Infringes the provisions of § 8 (2) in prescribing narcotic drugs for supply to merchant ships.

Any person who issues narcotic drugs [for supply to a merchant ship] in the context of the operation of a pharmacy, other than in the exceptional circumstances provided in § 8 (3), shall be punishable pursuant to § 29 (1), subparagraph 1, of the Narcotic Drugs Act.

§ 11
Administrative offences

The following acts or omissions, whether intentional or negligent, shall constitute administrative offences within the meaning of § 32 (1), subparagraph 6, of the Narcotic Drugs Act:

1. Failure to use a narcotic drug prescription form in prescribing for patients, the needs of his practice and animals, contrary to the provisions of § 5 (1), first sentence;

2. Transfer of narcotic drug prescription forms intended for his own use, except to a locum tenens, or failure to return them to the Federal Health Office on retirement from practice, contrary to the provisions of § 5 (3);

3. Failure to protect narcotic drug prescription forms against theft or to report their loss without delay, contrary to the provisions of § 5 (4);

4. Failure to keep or to keep in accordance with regulations parts of narcotic drug prescription forms or narcotic drug requisition forms, contrary to the provisions of § 5 (5), § 6a (4), or § 7 (6), first sentence;

5. Failure to state particulars, or statement of particulars incorrectly, incompletely or not in the required form, contrary to the provisions of §§ 6, 6a (3), § 7 (5), § 8 (1), second sentence, or § 8 (4),

6. Failure to keep records of narcotic drug requisition forms passed on, contrary to the provisions of § 9 (2), fourth sentence, or

7. Infringement of a rule under § 9 on the keeping, verification and storage of records.

§ 12
Forms

The Federal Health Office shall issue the official forms for prescription (narcotic drugs prescription forms and narcotic drugs requisition forms) and for recording their storage location (file cards and dangerous drugs registers) and shall publish information thereon in the Federal Gazette.

§ 13
(Entry into force, abrogation)