COMMONWEALTH OF THE NORTHERN MARIANA ISLANDS
SAIPAN MARIANA ISLANDS

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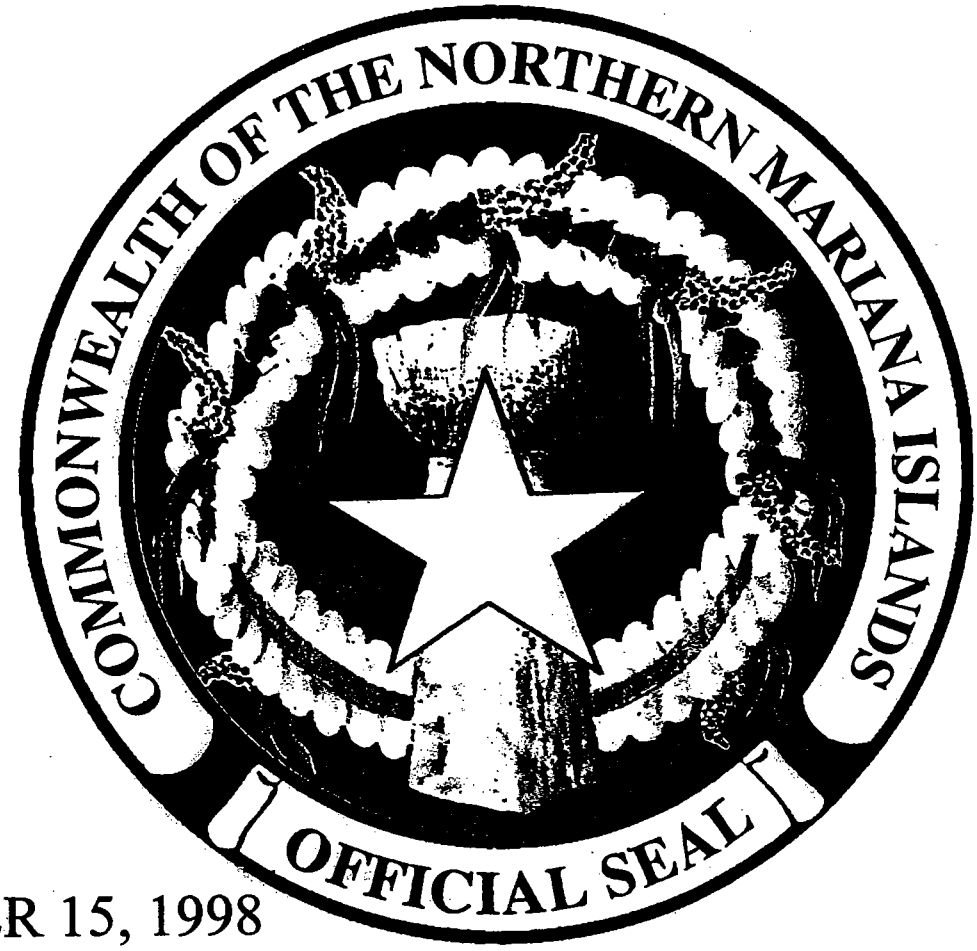

DECEMBER 15, 1998

COMMONWEALTH

REGISTER

COMMONWEALTH REGISTER

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PROPOSED & AMENDMENDS

NOTICE OF ADOPTION

COMMONWEALTH HEALTH CENTER

OFFICE OF THE SECRETARY

GOVERNMENT OF THE NORTHERN MARIANA ISLANDS
DEPARTMENT OF PUBLIC HEALTH-ENVIRONMENTAL SERVICES

DEPARTMENT OF PUBLIC HEALTH
Compliance With Section 504 Of The Rehabilitation Act of 1973 And Title II Of The Americans With Disabilities Act of 1990

GRIEVANCE PROCEDURE

It is the policy of the Department of Public Health to comply with the requirements of Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. §794, and regulations promulgated thereunder at 45 CFR Part 84, and Title II of the Americans With Disabilities Act of 1990, 29 U.S.C. §§ 12131-12134, and regulations promulgated thereunder at 28 CFR Part 35. These regulations provide, in part, that "[n]o qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity which receives or benefits from Federal financial assistance," and that "[n]o qualified individual with a disability shall, on the basis of disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subject to discrimination by any public entity." See 45 CFR §84.4(a), and 28 CFR §35.130(a), respectively.

If any individual has reason to believe that the Department of Public Health is not complying with the requirements of Section 504 of the Rehabilitation Act of 1973 or Title II of the Americans with Disabilities Act of 1990, and their respective regulations, he or she may file a grievance pursuant to the procedure set forth below. Any person wishing to examine the above referenced statutes and regulations may contact Ms. Terrip Tripp, Deputy Secretary for Hospital Administration, at the Commonwealth Health Center (phone: 234-8950). Ms. Tripp is one of the individuals designated to coordinate the efforts of the Department of Public Health in complying with the regulations implementing §504 of the Rehabilitation Act of 1973 and Title II of the Americans with Disabilities Act of 1990.

P.O. BOX 409 CK, SAIPAN, MP 96950
TELEPHONE (670) 234-8950/51/52/53/54 •• TELEX 783-744 PHES SPN

Grievance Procedure

1. Any person who believes he or she has been subjected to discrimination on the basis of disability (the "Complainant"), in contradiction of the policies stated above, may file a grievance under this procedure. It is against the law for the Department of Public Health to retaliate against anyone who files a grievance or cooperates in the investigation of a grievance.

2. The Complainant must submit his or her grievance to Ms. Terri Tripp (the "Compliance Coordinator"), within 30 days from the date the Complainant becomes aware of the alleged discriminatory action.

3. The grievance must be in writing, contain the name and address of the Complainant, provide a complete description of the problem or action alleged to be discriminatory, including any documents to support the claim, and state the remedy or relief sought by the Complainant. The Complainant should also state in the grievance whether he or she would like to present evidence at a hearing.

4. If the Complainant has requested a hearing, the Compliance Coordinator shall schedule a hearing within ten (10) days from the date the grievance is submitted by the Complainant. The Compliance Coordinator and two other Department of Public Health administrators shall preside at the hearing. The Complainant may then present evidence through oral testimony, witnesses, and exhibits. The Complainant shall have the right to be represented by a person of his or her choice at the hearing.

5. The Compliance Coordinator, or his or her designee, shall conduct an investigation of the grievance to determine its validity. This investigation may be informal, but it must be thorough, affording all interested persons an opportunity to submit evidence relevant to the grievance. The Compliance Coordinator shall maintain the files and records of the Department of Public Health relating to such grievances.

6. The Compliance Coordinator shall issue a written decision on the grievance no later than thirty (30) days from the date the written grievance is submitted, or if a hearing is requested, thirty (30) days from the date the hearing is held.

7. The Complainant may appeal the decision of the Compliance Coordinator by filing an appeal with the Deputy Attorney General for Administration, Office of the Attorney General, Administration Building, Second Floor, Capitol Hill, within 15 days of receiving the Compliance Coordinator's decision. The person hearing the appeal shall be impartial as demonstrated by the absence of prior involvement in substantive aspects of the filed grievance.

8. The Deputy Attorney General for Administration shall issue a written decision in response to the appeal no later than thirty (30) days from receipt of the appeal.

9. The availability and use of this grievance procedure does not preclude a person from filing a complaint of discrimination on the basis of disability or any action prohibited by the regulations implementing Section 504 of the Rehabilitation Act of 1973 and Title II of the Americans with Disabilities Act of 1990 with the U.S. Department of Health and Human Services, Office for Civil Rights, 50 United Nations Plaza, Room 322, San Francisco, California, 94102; telephone number (415) 556-8586 - Voice and TDD; FAX (415) 556-5165.

10. The Compliance Coordinator shall be responsible for ensuring that arrangements are made to enable disabled persons to participate in or make use of this grievance process on the same basis as non-disabled individuals. Such arrangements may include, but are not limited to, the provision of interpreters for the deaf, providing taped cassettes of material for the blind, and assuring a barrier-free location for the proceedings.

Villagomez 10/8/98

Joseph K.P. Villagomez
Secretary of Health
Department of Public Health

PUBLIC NOTICE

As required by Title II of the Americans With Disabilities Act of 1990, the Department of Public Health, including the Commonwealth Health Center, hereby notifies the public that it does not discriminate against individuals with disabilities seeking services from, or desiring to participate in programs offered by, the Department of Public Health.

Any person who believes that he or she is being denied services or benefits by the Department of Public Health or is being excluded from participation in programs or activities offered by the Department of Public Health as a result of a disability, or any person who has any questions, concerns, complaints, or requests for additional

information about the Department of Public Health's compliance with the Americans With Disabilities Act may contact any of the following persons:

Terri Tripp, Deputy Secretary for Hospital Administration
Dr. James Hofschneider, Director of Medical Affairs
Ray Guerrero, Assistant Chief of General Support Services
Maria Persson, Director of Vocational Rehabilitation Services
Department of Public Health
Commonwealth Health Center
P.O. Box 409 CK
Saipan, MP 96950
Phone: (670) 234-8950
Fax: (670) 234-8930

Individuals who need auxiliary aids for effective communication in programs or services of the Department of Public Health are invited to make their needs known to any of the individuals listed above.

Office of the Secretary
Department of Finance

P.O. Box 5234 CHRB SAIPAN, MP 96950 TEL. (670) 664-1100 FAX: (670) 664-1115

PUBLIC NOTICE

Title 4, Division 1, Section 1707(i) requires that upon deletion of the names of the taxpayers and any other personal facts that are not essential to the understanding of the ruling, the Department of Finance shall make public any private letter ruling that it issues. The private letter ruling issued on October 14, 1998 by the Department of Finance, regarding the deductibility of amounts that are paid or permanently set aside for a charitable purpose in computing taxable income for the purposes of the NMTIT, is submitted for publication in the Commonwealth Register.

Issued by: _____ 12/9/98
LUCY DLG NIELSEN Date
Secretary of Finance

Received by: _____ 12/14/98
JOSE I. GUERRERO Date
Special Assistant for Admin.

Filed by: _____ 12/14/98
SOLEDAD B. SASMOTO Date
Registrar of Corporations

Pursuant to 1 CMC §2153. As amended by P.L. 10-50, the above has been reviewed and approved as to form and legal sufficiency.

_____ 12/10/98
MAYA B. KARA Date
Attorney General [Acting]
By: Elliott Sattler, AAG

Office of the Secretary
Department of Finance

P.O. Box 5234 CHRB SAIPAN, MP 96950 TEL. (670) 664-1100 FAX: (670) 664-1115

October 14, 1998

SFL: 99-018

Dear

This responds to your letter dated February 13, 1998, requesting rulings under section 642 of the Northern Mariana Territorial Income Tax (NMTIT). The Taxpayer is an estate and a resident of Z. You request a ruling that the Taxpayer may deduct amounts that are paid or permanently set aside for a charitable purpose in computing its taxable income for the purposes of the NMTIT.

The rulings contained in this letter are predicated upon facts and representations submitted by the Taxpayer and accompanied by penalty of perjury statements executed by an appropriate party. This office has not verified any of the material submitted in support of the request for rulings. Verification of the factual information, representations, and other data may be required as part of the audit process.

Facts:

Taxpayer is the Estate of X. X was a citizen of the United States and a resident of Z. The Will of X (the "Will"), was duly admitted to probate in the Z Superior Court. The Will named Y as executor (the "Executor"). In the Will, X left to certain heirs his personal effects and bequests of certain amounts. The Will directed that the residue be given to a charitable trust (the "Trust") which would entitle the Taxpayer to a charitable deduction under IRC §2055. No such trust was created during X's lifetime. The Will provides that if no such trust was created during X's lifetime, the residue is to be given to trustees named in the Will. The Will sets forth in detail the purposes of the Trust (which is referred to both as the "trust" and the "Foundation" in the Will), the use of the trust fund and other aspects of the governance of the Trust. The Will empowers the Trustees to organize a corporation for the uses and purposes provided for the Trust by the Will and to transfer to that corporation all assets of the Trust and all assets to which the Trust becomes entitled.

The Trustees incorporated the foundation and the Trust assigned to the Foundation all "right, title and interest of Trust in and to the Estate of X, and the right of Trust to prosecute, recover, compromise and settle any and all claims seeking to establish its rights, title and interest in the Estate." The Taxpayer has shown that the Foundation has been granted tax-exempt status by the U.S. Internal Revenue Service, and that the Trust has applied for tax-exempt status.

After the Will was admitted to probate, various claimants filed petitions to be adjudicated pretermitted children and heirs of X (collectively "the Heir Claimants"). The Executor opposed the heirship claims of each of the Heir Claimants. The Taxpayer, the Executor, the Trust, the Heir Claimants and the Trustees entered into a settlement agreement. Pursuant to the Settlement Agreement, the Taxpayer's assets will be divided between the Trust and certain Heir Claimants.

The Taxpayer has filed a fiduciary tax return, Form 1041 with the tax authorities of the Z for the fiscal year ended April 30, 1996, claiming a charitable deduction equal to the Taxpayer's income. The Taxpayer will file an amended Form 1041 in the Z for the fiscal year ended April 30, 1996 when the Settlement Agreement becomes final, reducing the charitable deduction to the portion of the Taxpayer's income that is paid to or set aside for the Foundation pursuant to the Settlement Agreement.

Application of NMTIT §642

The Taxpayer may deduct in computing its taxable income any amount of gross income paid or permanently set aside for Foundation, or the Trust once it has been granted tax-exempt status by the Internal Revenue Service.

NMTIT §642(c)(1) and (2) allow an income tax deduction by an estate of amounts paid or permanently set aside for a charitable purpose. NMTIT § 642(c)(1) provides that in the case of an estate or trust (except for trusts which distribute current income only, i.e., simple trusts), there shall be allowed as a deduction in computing its taxable income (in lieu of the deduction allowed by NMTIT §170(a), relating to the deduction for charitable, etc. contributions and gifts) any amount of the gross income, without limitation, which pursuant to the terms of the governing instrument is, during the tax year, paid for purpose specified in NMTIT §170(c) (determined without regard to NMTIT §170(c)(2)(A)). If a charitable contribution is paid after the close of the tax year, then the trustee or administrator may elect to treat the contribution as paid during that tax year. The election shall be made at such time and in such manner as the Secretary prescribes by regulations.

NMTIT §642(c)(2) provides that an estate may claim an unlimited deduction for gross income that is permanently set aside for charitable purposes under the governing instrument during the tax year. The income must be set aside permanently during the tax year for a purpose specified in NMTIT §170(c), or must be used exclusively for religious, charitable, scientific, literary or educational purposes, or for the establishment, acquisition, maintenance or operation of a public cemetery not operated for profit.

NMTIT Reg. §1.642(c)-3(b) provides that if an estate pays, permanently sets aside, or

uses any amount of its income for a purpose specified in NMTIT §642(c)(1) or (2) and the amount includes any items of income not entering into the trust's gross income, the allowable deduction is limited to the gross income so paid, permanently set aside or used.

NMTIT Reg. §1.642(c)-1(a)(2) provides that in determining whether an amount is paid for a purpose specified in NMTIT §170(c)(2), the provisions of NMTIT §170(c)(2)(A) shall not be taken into account. Thus, an amount paid to a corporation, trust, or community chest, fund, or foundation otherwise described in NMTIT §170(c)(2) shall be considered paid for a purpose specified in NMTIT §170(c) even though the corporation, trust, or community chest, fund or foundation is not created or organized in the Z.

The Will, which directs the funding of the Trust and specifies the charitable purpose of the Trust and how it is to be organized and operated, is consistent with the requirement of NMTIT §642(c)(1) and (2) as is the Settlement Agreement which shall take the place of the Will upon the Agreement's execution.

NMTIT Reg. §1.642(c)-3(e) provides for a disallowance of deductions otherwise allowable under NMTIT § 642(c)(1), (2), or (3) in cases where NMTIT §§508(d) and 4948(c)(4) apply.

NMTIT §508(d)(1) provides that no gift or bequest made to an organization upon which the tax provided by NMTIT §507(c) has been imposed (an organization the status of which as a private foundation has been or is being terminated under NMTIT §507(a)) shall be allowed as a deduction under §170, among other sections, if made (A) by any person after notification is made under NMTIT §507(a), or (B) by a substantial contributor (as defined in NMTIT §507(d)(2)) in his tax year which includes the first day on which action is taken by the organization which culminates in the imposition of tax under NMTIT §507(c) and any subsequent tax year.

The Taxpayer represents as a factual matter that NMTIT §508(d)(1) does not apply to the Taxpayer.

NMTIT §508(d)(2) provides that no gift or bequest made to an organization shall be allowed as a deduction under NMTIT §170, among other sections, if made (A) to a private foundation or a trust described in Internal Revenue Code (I.R.C.) §4947 (regarding certain nonexempt trusts) in a tax year for which it fails to meet the requirements of NMTIT §508(e) (determined without regard to NMTIT §508(e)(2)), or (B) to any organization in a period for which it is not treated as an organization described in NMTIT §501(c)(3) by reason of NMTIT §508(a).

NMTIT §508(e)(1) provides that a private foundation shall not be exempt from taxation under NMTIT §501(a) unless its governing instrument includes provisions the effects are (A) to require its income for each year to be distributed at such time and in such manner as not to subject the foundation to tax under I.R.C §4942 (for failure to distribute income), and (B) to prohibit the foundation from engaging in any act of self-dealing (as defined in I.R.C. §4941(d)), from retaining any excess business holdings (as defined in I.R.C. §4943(c)), from making any

investments in such manner as to subject the foundation to tax under I.R.C. §4944, and from making any taxable expenditures (as defined in I.R.C. §4945(d)).

I.R.C. §§ 4941, 4942, 4943, 4944 and 4945 have not been adopted by the CNMI, and therefore are inapplicable in the instant situation. 4 CMC §1702(a).

NMTIT §508(a) provides generally that an organization shall not be treated as an organization described in §501(c)(3); (1) unless it has given notice to the Secretary, in such manner as the Secretary may by regulations prescribe, that it is applying for recognition of such status, or (2) for any period before the giving of such notice, if notice is given after the time prescribed by the Secretary by regulations for giving notice under this subsection.

The Foundation received NMTIT §501(c)(3) status. The Taxpayer has shown that the Trust has given the notice required by NMTIT §508(a). Thus, NMTIT §508(d)(2)(B) will not apply to the Taxpayer.

I.R.C. §4948(c)(4) provides that no gift or bequest shall be allowed as a deduction under I.R.C. (NMTIT) §170, among other sections, if made to a foreign organization described in §4948(b). I.R.C. § 4898 has not been adopted by the CNMI, and therefore is inapplicable in the instant situation. 4 CMC §1702(a).

Application of "paid or permanently set aside"

As discussed previously, NMTIT §642(c) permits an estate to take a deduction for amounts "paid or permanently set aside" for a charitable purpose. The Taxpayer is seeking a deduction for amounts "permanently set aside" for charity pursuant to the Settlement Agreement which has not been finalized at this time. Taxpayer represents that upon receiving a favorable ruling it will execute the Settlement Agreement and amend its filed tax returns to properly deduct any amounts allowed by §642(c). Thus the issue becomes whether the Estate may take a deduction for amounts "set aside" pursuant to a will which has been contested, or under a settlement agreement which has not been executed as of this time but which will ultimately determine the amount that will go to charity, if executed.

The issue of whether litigation prevents a permanent "setting aside" is dependent upon the subject matter of the litigation. That is, a distinction must be made in cases where the provisions of the instrument make it uncertain whether a charitable donee will actually take, and provisions of an instrument make it certain that a charity will take, but the situation is such that due to valid claims against the estate, the time of the taking and the amount of income is uncertain.[1] In *Rockland Oil Co.* v. *Comm'r*[2] the Court held that income set aside during the time of pending creditor's claims was deductible, as the underlying instrument required that income of the estate be set aside for charitable purposes. The Court held "there is nothing in section 162(a)[3] suggesting that its provisions are inapplicable if the estate or trust is threatened by creditor's

1. *C.I.R.* v. *Leon A. Beegley Fund*, 310 F.2d 756 (1962).
2. 22 T.C. 1307 (1954).
3. IRC §162(a) of the 1939 Internal Revenue Code which is the predecessor statute to §642 of the current NMTIT.

claims which might defeat the donor's intentions".[4] The U.S. Congress, in drafting §642 of the code is again, as with other charitable deductions, trying to encourage, rather than limit charitable gifts.[5] As such, in the instant case, the will contest should not affect whether there is a "permanent setting aside". The next issue then becomes whether in a will contest, a settlement agreement relates back to and takes the place of the will.

The issue is significant as it determines whether the Estate will be entitled to a deduction during the time when the will was being contested and the settlement agreement had not yet come into effect. There are two conflicting cases which address this issue, however the case permitting the relation back can be applied to the X case based upon similar facts to those in the instant case.

In the first case, *Emanuelson* v. *U.S.*[6], the Court allowed a settlement agreement to take the place of and relate back to the date on which the contested will was probated. In doing so, it held that "to treat it otherwise would be, in effect, to ignore, in this context, the principal that the compromise agreement takes the place of the will."[7] In a later case, *Genesee Merchants Bank & Trust Co.* v. *U.S.*,[8] the Court held that the relation back doctrine would not apply to two wills subjected to a will contest, and a settlement agreement that took effect before one of the wills was probated. As a result, the Estate was not entitled to a charitable deduction during the time before approval of the settlement agreement. The Court, under those facts held that the relation back doctrine applies only to those cases in which the will was probated and a settlement agreement was later reached; in *Genesee*, however, neither of the contested wills had been probated.

In the instant case, X's Will was probated on July 17, 1995, and at this time, Settlement Agreement has not taken effect; thus the holding in *Emanuelson* should be followed and the Settlement Agreement, once executed, should relate back to the time of the Will's probate. In order for the Estate to claim a charitable deduction it should amend its tax return once the Settlement Agreement is finalized,[9] provided that the statute of limitations has not run.

Based solely on the information submitted and the representations set forth above, it is held as follows:

(1) The Taxpayer may deduct in computing its taxable income any amount of gross income paid or permanently set aside, pursuant to NMTIT §642, for the Foundation or Trust [because it gave notice as provided by NMTIT §508(a)] subject to execution of the Settlement Agreement, and any necessary court approval;

(2) The Estate may amend it's income tax returns to accurately reflect the §642 charitable

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4 *Rockland Oil* v. *Comm'r*, 22 T.C. 1307, 1312 (1954).
5 *C.I.R.* v. *Bonfils Trust*, 115 F. 2d 788 (1940); *Old Colony Trust Co.* v. *C.I.R.*, 57 S. Ct. (1937).
6 159 F.Supp. 34 (D.C. Conn. 1958).
7 Id. at 36.
8 37 AFTR 2d 76-747 (E.D. Mich. 1976).
9 *Ahmanson Foundation* v. *U.S.*, 674 F.2d 761 (C.A. 9 (Cal.) 1981); *Estate of Wright* v. *U.S.*, 677 F2d 53 (9th Cir. 1976).

deduction pursuant to the Settlement Agreement, provided that the statute of limitations has not run on the particular return being amended;

(3) The Estate shall amend its tax returns within 30 days after the execution and any necessary Court approval of the Settlement Agreement.

(4) The Estate is subject to any applicable penalties and interest for amending the return to reflect the proper amount of the charitable deduction.

Except as specifically set forth above, we express no opinion on the federal tax consequences of the facts described above under any other provision of the Code. This ruling is directed only to the Taxpayer who requested it. Under NMTIT §6110(j)(3), this ruling may not be used or cited as precedent by any other Taxpayer.

Attach a copy of this letter to the tax return(s) filed for the Estate. A copy is enclosed for this purpose. Under the power of attorney submitted with the Taxpayer's ruling request, we are sending a copy of this letter to the Taxpayer's authorized representative.

Sincerely yours,

/ s /
Lucy DLG Nielsen
Secretary of Finance

Concurred by: /s/
Deborah L. Covington
Assistant Attorney General

cc: Roman V. Reyes,
Acting Director, Revenue and Tax

COMMONWEALTH OF THE NORTHERN MARIANA ISLANDS
OFFICE OF THE GOVERNOR
OFFICE OF PERSONNEL MANAGEMENT
P.O. Box 5153 CHRB, SAIPAN, MP 96950 - 5153
TEL. NOS.: (670) 234-6925 / 6958 / 8036
FAX NO.: (670) 234-1013

PUBLIC NOTICE OF INTENT TO PROMULGATE A NEW SECTION I.10 TO THE EXCEPTED SERVICE PERSONNEL REGULATIONS

CONTENTS: **PROPOSED NEW SECTION I.10 TO THE EXCEPTED SERVICE PERSONNEL REGULATIONS, Commonwealth Register, Vol. 17, No. 5, at 13414, May 15, 1995:**

Section I.10: **EMPLOYEE OBLIGATIONS, CONDUCT AND COMPLIANCE WITH AFFECTING REGULATIONS.**

(See Attached Proposed Section I.10, which will replace the existing Section I.10 in its entirety.)

PUBLIC COMMENTS: All interested persons may submit written comments about the proposed new section to the Director of Personnel, Office of Personnel Management, Office of the Governor, P.O. Box 5153 CH, Saipan, MP 96950, on or before January 15, 1999.

AUTHORITY: The Governor of the Commonwealth of the Northern Mariana Islands, as the Chief Executive and ultimate Appointing and Contracting Authority for the Executive Branch of the Commonwealth Government, has delegated the authority to develop and promulgate regulations for the Excepted Service Personnel System to the Office of Personnel Management.

MATHILDA A. ROSARIO
Director of Personnel — 12/11/98 Date

Received by:
JOSE I. DELEON GUERRERO
Special Assistant for Administration — 12/14/98 Date

Pursuant to 1CMC §2153, as amended by Public Law 10-50, the rules and regulations attached hereto have been reviewed and approved as to form and legal sufficiency by the CNMI Attorney General's Office.

Dated this 14 day of Dec, 1998.

Attorney General (Acting)
Maya Kara

By:
Assistant Attorney General
Elliot A. Sattler

Filed and recorded by:
SOLEDAD B. SASAMOTO
Registrar of Corporations — Date

COMMONWEALTH OF THE NORTHERN MARIANA ISLANDS
OFFICE OF THE GOVERNOR
OFFICE OF PERSONNEL MANAGEMENT
P.O. Box 5153 CHRB, SAIPAN, MP 96950 - 5153
TEL. NOS.: (670) 234-6925 / 6958 / 8036
FAX NO.: (670) 234-1013

The proposed new Section I.10 to the ***Excepted Service Personnel Regulations*** is submitted for review and publishing in the ***Commonwealth Register*** to solicit public comment. As required by Governor's Directive No. 183, the following information is provided to describe and summarize the proposed new section:

Citation of Statutory Authority: The Office of Personnel Management is authorized to develop and promulgate regulations for the Excepted Service Personnel System by delegated responsibility and authority from the Governor of the Commonwealth of the Northern Mariana Islands.

Short Statement of Goals and Objectives: The proposed new Section I.10 to the ***Excepted Service Personnel Regulations*** will replace the existing section and will update, by promulgation by the Director of Personnel, the regulations regarding the obligations and responsibilities of Excepted Service employees and government management.

Brief Summary of the Proposed New Section: The proposed new Section I.10 to the ***Excepted Service Personnel Regulations*** clarifies the responsibilities of employees and management by providing more specific phrasing and references. The replacement section also updates the ***Excepted Service Personnel Regulations*** by adding new subsections, by referral, that include **Part V.C, The Commonwealth Drug and Alcohol Free Workplace Regulation, Part V.D, Responsibilities of Employees and Management**, and **Part III.G, Grievance Procedure**, of the ***Personnel Service System Rules and Regulations***, as amended.. These additions document, by regulation, obligations and responsibilities relevant to employees and management in these subject areas.

For Further Information Contact: Ms. Mathilda A. Rosario, Director of Personnel, Office of Personnel Management, telephone 234-6925 or facsimile 234-1013.

Citation of Related and/or Affected Statutes, Regulations and Orders: The proposed new Section I.10 will affect only the ***Excepted Service Personnel Regulations.***

I.10 **RESPONSIBILITIES OF EMPLOYEES AND MANAGEMENT.**

A. **EMPLOYEE CONDUCT: GENERAL COMPLIANCE WITH RULES AND REGULATIONS.** The employee and the employee's dependents are subject to the laws, policies, rules and regulations of the Commonwealth that concern personal and work-related conduct and activities while living in the Commonwealth. **Part V.D, Responsibilities of Employees and Management**, of the **Personnel Service System Rules and Regulations** applies equally to Excepted Service employees with the exception that any reference to the Civil Service Commission is amended to read "Director of Personnel."

B. **EMPLOYMENT STATUS AND TAX OBLIGATIONS.** All persons appointed or recruited to Excepted Service employment status are employees of the Commonwealth Government and not the United States Government, even if the position held is federally funded. All Excepted Service employees are subject to applicable CNMI income tax laws.

C. **CODE OF ETHICS:** All persons in government service must comply with the **Code of Ethics** published in the **Commonwealth Register, Volume 6, No. 7** and provided under **Part V.D** of the **Personnel Service System Rules and Regulations.**

D. **COMMONWEALTH ALCOHOL AND DRUG FREE WORKPLACE POLICY**. All persons in government service must comply with the **Alcohol and Drug Free Workplace Policy** published in the **Commonwealth Register, Volume 19, Number 11** and provided under **Part V.C** of the **Personnel Service System Rules and Regulations**. Civil Service adverse action procedures do not apply to Excepted Service employees. Termination of employment, as referenced in **Part V.C4.A(3)**, or otherwise applicable, will be in accordance with **Part I.9B** of this regulation. Reference to the term **Civil Service**, in **Part V.C6.A** and **A(1)**, will be amended to read "Excepted Service" for application to Excepted Service employees.

E. **GRIEVANCE PROCEDURE:** Excepted Service employees are afforded the opportunity to resolve labor-management problems and misunderstandings by means of a grievance procedure similar to the process established for Civil Service employees in **Part III.G** of the **Personnel Service System Rules and Regulations**. The procedure provided therein will apply equally to Excepted Service employees, with the exception that the Director of Personnel will perform any functions assigned to the Civil Service Commission, and will serve as the ultimate appellate level for an Excepted Service grievance. Any other terms or provisions in **Part III.G** relating to the Civil Service System will be interpreted by the Director of Personnel for correct application to Excepted Service employees.

NUTISIAN PUPBLIKU PUT INTENSION-ÑA PARA U FAMATINAS NUEBO NA SEKSIONA L.10 GI REGULASION MAEKSPEPEKTA NA SETBISIUN PETSONAT

SUHETU: **I PRINIPONEN NUEBO NA SEKSIONA L.10 GI REGULASION I MAEKSPEPEKTA NA SETBISIUN PETSONAT,** Rehistran Commonwealth , Baluma 17, No. 5, gi 13414, Mayu 15. 1995:

Seksiona L.10: **OBLIGASION EMPLEAO SIHA, KONDUKTA YAN MATATTIYIN I MANINAFEKTA SIHA NA REGULASION.**

(Atan i chechetton na Priniponen Seksiona L.10, ni para u tulaika i prisenti na Seksiona I.10 enteramente.)

KOMENTON PUPBLIKU: Todu i maninteresante siha na petsona siña matuge' papa komenton-niha put i proponen nuebo na Seksiona ya u masatmiti guatu gi Direktoran Petsonat, Ofisinan Minanehan Petsonat, Ofisinann Gubetno, P.O. Box 5153 CH, Saipan, MP 96950, antes di osino gi Ineru 15, 1999.

ATURIDAT: I Gubetnon Commonwealth i Sangkattan Siha Na Islas Marianas, komu gulya gai Aturidat na Chief Executive yan solamente para Manapunta yan Mangontrata gi Ramas Eksekatibu gi Gubetnamenton Commonwealth, ha aturisa para u macho'gue yan fatinas i regulasion para i Maekspepekta na Setbisiun Sisteman Petsonat para Ofisinan Minanehan Petsonat.

MATHILDA A. ROSARIO
Direktoran Petsonat

12/14/98
Fecha

Rinisibi as: JOSE I. DELEON GUERRERO
Special Assistant for Administration

12/14/98
Fecha

Sigun gi 1 CMC §2153, ni inamendda ni Lai Pupbliku 10-50, i areklamento yan regulasion siha ni chechetton guine esta manmaribisa yan apreba komu fotmat yan sufisente na ligat ni Ofisinan Attorney General giya CNMI.

Mafecha gi mina' 14 na dia guine na mes Dec., 1998.

Attorney General (Acting)
Maya Kara

Ginen: ELLIOTT A. SATTLER
Assistant Attorney General
Elliot A. Sattler

Ma file yan rinikot as: SOLEDAD B. SASAMOTO
Rehistradoran Kotporasion

12/14/98
Fecha

ARONGRONGOL TOULAP REEL IGHA EBWE YOOR LLIIWEL MELLÓL TÁLIL I.10 MELLÓL ALLÉGHÚL PERSONNEL

Autol: Ebwe Ffééř Tálil 1.10 ikka e Ffé bwelle reel Alléghúl Alillis mellól Personnel. Commonwealth Register. Vol. 17. No. 5. mereel 13414. Ghúúw(May) 15, 1995:

Tálil I.10: Obligasionuur Schóól Angaang, Conduct Me Igha Rebwe Attabweey Allégh Kkaal.

(Amweri Pomwol Tálil I. 10 ikka e appasch, iye ebwe liweli Tálil I. 10 ikka eyoor iyeey me alongal kkapasal).

Mángemáng mereer Toulap: Aramas kka re tipeli rebwe ischilong yaar mángemáng bwelle reel ffééréttáál tálil ye e ffé nge rebwe isch ngáli schagh Direktodul Personnel. Bwulasiyol Personnel Management. Bwulasiyol Sów Lemelem, P.O. Box: 5153 CH. Saipan. MP. 96950, nge essóbw aluuw ló Schoow(January) 15, 1999.

Bwángil: Sów Lemelem mellól Commonwealth Metawal Wóól Falúw Kka Marianas, igha i Chief Executive me eyoor bwángil reel mille Appointing me Contracting llól Executive Branch mellól Gobenamentol Commonwealth, e afalafala bwe ebwe arongorong ló allégh kkaal bwelle reel mille Execepted Services Personnel System mellól Bwulasiyol Personnel Management.

Mathilda A. Rosario
Direktodul Personnel

12/11/98
Rál

Bwughiyal:

Josel. Deleon Guerrero
Special Assistan for Administration

12/14/98
Rál

Sángi 1 CMC § 2153, a lliiwel sángi aileewal Alléghúl Toulap(Public Law) 10-50, allégh kkaal ikka e appasch nge atakkal amweri me alúghúlúgh sángi Bwulasiyol Attorney General.

Rál ye 14 llól maramal Dec., 1998.

Attorney General(Acting)
Maya Kara

Mereel: ELLIOTT A. SATTLER
Assistant Attorney General
Elliot A. Sattler

Isáliyal me rekodiyal : _____
Soledad B. Sasamotot
Registrar of Corporation

Rál 12/14/98

Commonwealth of the Northern Mariana Islands
Department of Lands & Natural Resources
Coastal Resources Management
AAA 2852 Box 10001, 2nd Floor Morgen Building,
San Jose, Saipan, MP 96950

COASTAL RESOURCES MANAGEMENT
TELS:(670) 234-6623/7320
FAX: (670) 234-0007

NOTICE OF PROPOSED REGULATIONS TO AMEND THE COASTAL RESOURCES MANAGEMENT JET-SKI REGULATIONS

The CNMI Coastal Resources Management Program hereby notifies the general public of proposed amendments to the jet-ski regulations for the purpose of establishing a jet-ski area for the island of Tinian, Commonwealth of the Northern Mariana Islands and to adjust and clarify the jet-ski launching and landing areas for the island of Saipan, Commonwealth of the Northern Mariana Islands. The Acting Director of Coastal Resources Management is authorized to do so under 2 CMC § 1511 Procedures act, 1 CMC § 1901 et. sig. Interested persons may obtain copies of the proposed amendments from the Coastal Resources Management Office on the second floor of the Morgen Building, San Jose, Saipan.

Section I.102. Exclusion Areas is amended as follows:

I.102.d. Hafa Adai Beach
An area extending two hundred (200) yards seaward from the mean low water line from the drainage channel north of the Carolinian Utt to the southern edge of the Hafa Adai Hotel.

1.102.g. Tachungnya/Kammer
An area extending seventy-five (75) yards seaward from the mean low water line from the southern edge of Tachungnya Beach to the northern edge of Kammer Beach adjacent to the Tinian harbor dock.

I.102.h. Marina/Harbor/Shipping Channel
An area extending from the mean low water line seaward at the Tinian Marina including the entire area within the Tinian harbor breakwater and the Tinian shipping channel.

Section II.202. Launching and Landing is amended as follows:

II.202.f. Off Taga Beach as designated by the Coastal Resources Management Office with jet-skis to be launched from a floating dock.

II.202.g. The public beach adjacent to the Carolinian Utt in Garapan.

Date 15 Oct 1998

Peter J. Barlas
Acting Director, Coastal Resources Management

Date 12/14/98

Jose I. Deleon Guerrero, SAA

Date 12/14/98

Soledad B. Sasamato
Registrar of Corporations

Pursuant to 1 CMC 2153 as amended by PL 10-50 the rules and regulations attached hereto have been reviewed and approved as to form and legal sufficiency by the CNMI Attorney General's Office.

Dated this 10 day of December 1998.

Maya B. Kara
Attorney General (Acting)

By:
Assistant Attorney General
Elliott A. Sattler

Commonwealth of the Northern Mariana Islands
Department of Lands & Natural Resources
Coastal Resources Management
AAA 2852 Box 10001, 2nd Floor Morgen Building,
San Jose, Saipan, MP 96950

COASTAL RESOURCES MANAGEMENT
TELS: (670) 234-6623/7320
FAX: (670) 234-0007

COASTAL RESOURCES MANAGEMENT OFFICE

Citation of Statutory Authority: Pursuant to CNMI P.L. 3-47 § 8 (d) and 9 (c) and 1 CMC § 9115.

Short Statement of Goals & Objectives: To establish a jet-ski operation area on Tinian and to amend the regulations governing jet-ski operation areas on Saipan.

For Further Information Contact: Peter J. Barlas, Acting Director, telephone no. 234-6623, fax no. 234-0007.

Citation of Related and/or Affected Statutes Regulations and Orders: Amended Coastal Resources Management Regulations Volume 8, No. 08 Commonwealth Register, November 17, 1986.

Submitted by: Peter J. Barlas Date: 15 Oct, 1998

Title: Acting Director

ARONGORONGOL POMWOL ALLEGH REEL IGHA EBWE LLIIWEL ALLEGHUL COASTALS RESOURCES MANAGMENT JET-SKI

CNMI Coastal Resources Management Program ekke arongaar aramas toulap reel pomwol lliiwel kkaal reel alléghúl jet-ski reel igha ebwe ayoorátá bwuley ngáli jet-ski Mewóól Falúw Kka Marianas me ebwe affata bwuley reel yááyáál jet-ski mellól Seipél. Acting Director mereel Bwulasiyol Coastal Resources Management eyoor bwángil reel ebwe féérú meta iye e lo faal 1 CMC Tálil 1511(1) B Procedure Act, 1 CMC 9101 et. sig. Aramas kka re tipeli kopiyal pomwol lliiwel kkaal nge emmwal rebwe bweibwogh mereel bwulasiyol Coastal Resources Management iye e lo aruwowal floor Morgen Building, Oleai, Seipél.

Tálil I. 102. Bwuley kka e akkatowow nge a lliiwel ebwe ikkaal:

I.102.d. Hafa Adai Beach
Bwuley yeel nge eyoor ruwabwughúw (200) láláyil mwetewow leeset sángi ppetil schaal iye e mwet mereel drainage channel afángil Utteer Refalúwasch (Carolinian Utt) nweteló éérúl ngáschel Hafa Adai Hotel.

I.102.g. Tachungnya/Kammer
Bwuley yeel nge eyoor fisiigh me limwow (75) láláyil mwetewow leeset sángi ppetil schaal iye e mwet me peighitiwel ngáschel leppiil Tachungnya afang ngáli ngáschel afangil leppiil Kammer iye e ppasch me pantalaanil Tchúliyól.

I.102.h. Marina/Pantalaal/Tóurul Waa
Bwuley yeel nge emwet mereel aghikkillal ppetil schaal iye e lo Tchúliyól marina ebwe schuulong alongal bwuley ikka e lo llól pantalaanil Tchúliyól igha waa e tottoolong iye.

Tálil II.202. Launching me Landing a lliiwel reel ebwe aschuulong:

II.202.f. Leppiil Taga igha a designated mereel bwulasiyol Coastal Resources Management me jet-ski reel igha ebwe bwel mereel floating dock.

II202.g. Reel public beach iye e ppasch me Utteer Refalúwasch (Carolinian Utt) iye e lo Arabwal.

Rál:_____

Peter J. Barlas
Acting Director, Coastal Resources Management

Rál: 12/16/98

Jose I. Deleon Guerrero, SAA

Arongorong reel Pomwol
Schoow September 15, 1998
Peigh 2

Rál: 12/14/98

Soledad B. Sasamoto
Registrar of Corporation

Sángi autol 1 CMC § 2153 igha a lliiwel mereel aileewal P.L. 10-50. Pomwol Lliiwel kkaal ngáli Allégh kkaal ikka e appasch ngáli a takkal amweri me alúghúlúgh reel igha ebwe ffééréló me llégháfisch ló sángi Bwulasiyol Sów Allégh (Attorney general).

Dated this 14th day of Dec., 1998.

Maya B. Kara
Attorney General (Acting)

By: ELLIOTT A. SATTLER
Assistant Attorney General
Elliott A. Sattler

NUTISIA PUT I MAPROPOPONE SIHA NA REGULASION NI PARA U AMNEDA ESTE I REGULASION COASTAL RESOURCES MANAGEMENT PUT JET SKI

I CNMI Coastal Resources Management na Programa ginen este ha nana'e pupbliku henerat nutisia put i priniponen amendasion put regulasion jet-ski put i propositun ma establesin lugat jet-ski para islan Tinian, Commonwealth i Sangkattan Siha Na Islas Marianas para u tmepla yan na klaru i jet-ski launching yan landing siha na lugat Saipan, Commonwealth i Sangkattan Siha Na Islas Marianas. I Acting Director gi Coastal Resources Management ma aturisa gi papa 2 CMC § 1511 (1) B Procedures Act, 1 CMC § 1901 et sig. Hayi interesao na petsona siña ha mañule kopian este i mapropopone na amendasion ginen Coastal Resources Management Office gi mina' dos bibenda, Morgen Building, giya San Jose, Saipan.

Seksiona I. 102. Mana Sahngem i lugat ma amenda para u taiguine:

I.102.d. Hafa Adai Beach
I lugat ni gaige yan maekstende dos (200) sientos yatdas huyong gi tasi desde i mean low water line desde i drainage ni gaige gi kattan i Carolinian Utt guatu luchan i Hafa Adai Hotel.

I.102.g. Tachungnya/Kammer
I lugat ni maekstende sitentai-singko (75) yatdas huyong gi tasi desde mena low water line desde luchan gi kanton Tachungnya Beach asta kattan gi puntan Kammer Beach gi fion Tinian Harbor.

I.102.h. Martina/Segua/Shipping Channel
I lugat ni maekstende desde i mean low water line huyong gi tasi giya Tinian enklusu i enteru lugat gi halom Tinian Harbor breakwater yan i Tinian shipping channel.

Seksiona II. 202. Launching yan Landing para maamenda taiguine:

II.202.f. Gi Taga Beach ni madesikna ni Ofisinan Coastal Resources Managment i para u madispacha ginen floating dock.

II.202.g I public Beach gi fion i Carolinian Utt giya Garapan.

Fecha:_____

Peter J. Barlas
Acting Director, Coastal Resources Management

Fecha: 12/14/98

Jose I. Deleon Guerrero, SAA

Fecha: 12/14/98

Soledad B. Sasamoto
Rehistradoran Kotporasion

Sigun gi 1 CMC § 2153, ni ma amenda gi Lai Pupbliku 10-50, i checheton na Areklamento Regulasion siha man maribisa yan man ma-aprueba nui Ofisinan i Fiskat.

Ma fecha gi dia 14th guine mes Dec., 1998.

Maya B. Kara
Attorney General (Acting)

Ginen as: ELLIOTT A. SATTLER
Assistant Attorney General
Elliott A. Sattler

COMMONWEALTH HEALTH CENTER

Office of the Secretary

GOVERNMENT OF THE NORTHERN MARIANA ISLANDS
DEPARTMENT OF PUBLIC HEALTH SERVICES

PUBLIC NOTICE

PROPOSED RULES AND REGULATIONS GOVERNING THE IMPORTATION, STORAGE, SALES, AND DISTRIBUTION OF DRUG AND PHARMACEUTICAL PRODUCTS

The Secretary of the Department of Public Health and the Chairman of the Medical Profession Licensing Board of the Commonwealth of the Northern Mariana Islands, in accordance with the authority vested in them pursuant to 1 CMC §2605 and Public Law 11-40, and 3 CMC §2214(a), respectively, hereby jointly propose these Rules and Regulations Governing the Importation, Storage, Sales, and Distribution of Drug and Pharmaceutical Products.

It is the intention of the Department of Public Health and the Medical Profession Licensing Board to comply with the requirements of the Administrative Procedures Act, specifically 1 CMC §9104, in proposing these Rules and Regulations. Copies of the proposed Rules and Regulations may be obtained from the Office of the Secretary of Public Health located on the ground floor of the Commonwealth Health Center. Comments on the proposed Rules and Regulations may be sent to the Office of the Secretary of Public Health, Department of Public Health, P.O. Box 409 CK, Saipan, MP, 96950, or the Medical Profession Licensing Board, at the same address. All comments must be received within thirty (30) days from the date this notice is published in the Commonwealth Register.

JOSEPH K.P. VILLAGOMEZ
Secretary of Health
Department of Public Health

Date: 11/12/98

for VICENTE S. ALDAN, M.D.
Vice Chairman
Medical Profession Licensing Board

Date: 11/16/98

P.O. BOX 409 CK. SAIPAN, MP 96950
TELEPHONE (670) 234-8950/51/52/53/54, TELEX 783-744 PHES SPN, FAX (670) 234-8930

Certification by Office of the Attorney General

Pursuant to 1 CMC §2153 as amended by PL 10-50, the proposed rules and regulations attached hereto have been reviewed and approved as to form and legal sufficiency by the CNMI Office of the Attorney General.

Date: 12/10/98

MAYA KARA
Acting Attorney General

Filed By: _____ Date: 12/14/98
SOLEDAD B. SASAMOTO
Registrar of Corporations

Received By: _____ Date: 12/14/98
JOSE I. DELEON GUERRERO
Special Assistant for Administration

Rules and Regulations Governing the Importation, Storage, Sales, and Distribution of Drug and Pharmaceutical Products

Citation of Statutory Authority:	1 CMC §2605 (s), and Public Law 11-40, Section 516, authorize the Department of Public Health to promulgate Rules and Regulations governing the preparation, storing, selling, advertising, and importing of drugs and pharmaceuticals. 3 CMC §2214(a) authorizes the Medical Profession Licensing Board to promulgate rules and regulations governing health care professionals, including pharmacists. 3 CMC §2222(a)(6).
Short Statement of Goals & Objectives:	The Rules and Regulations will establish standards and restrictions on the licensing of pharmacists and pharmacy personnel, pharmacies, and wholesale pharmaceutical distributors, as well as the advertising, labeling, importation, sale, and distribution of drugs and pharmaceuticals, including over-the-counter drugs. The Rules and Regulations are intended to ensure that drugs and pharmaceuticals imported, sold or otherwise distributed in the CNMI have been approved by the Food and Drug Administration, are safe and effective for the purpose intended, are advertised in a direct and honest manner that does not mislead consumers, and are labeled in one of the three official languages of the CNMI and include clear instructions for use as well as necessary warnings.
Brief Summary of the Proposed Rule:	To establish requirements for the licensing of pharmacists and pharmacy personnel, and permiting of pharmacies and wholesale pharmaceutical distributors; establishing the scope of practice for pharmacists and pharmacy personnel; establishing standards for record keeping practices by pharmacies and wholesale pharmaceutical distributors; restricting advertising practices; establishing labeling requirements for drugs and pharmaceuticals; restricting importation of foreign drugs and pharmaceuticals except in limited amounts for personal use; providing for inspections, seizures and forfeitures, and penalties for violations of the Rules and Regulations.
Contact Person(s):	Anthony Raho, Pharmacy Manager, Commonwealth Health Center; Janice Stanley, Member, Medical Profession Licensing Board.

Citation of Related and/or Affected Statutes, Regulations, and Orders:

Medical Profession Licensing Board Regulations, Vol 11, No. 9 Commonwealth Register, 6432-6448 (September 15, 1989), Chapter VIII.

Date: Oct. 30, 1998

Celeste E. Andersen

Celeste E. Andersen, Legal Counsel
Department of Public Health

Commonwealth I Sangkattan Siha na Islas Marianas
Dipatamenton Hinemlo' Pupbliku

Ofisian I Sekretaru

NUTISAN PUPBLIKU

MAPROPONEN AREKLAMENTO YAN REGULASION SIHA PARA U GOBIETNA I MA IMPOTTA, DIPOSITU, BENENDIN, YAN DISTRIBUSION PRODUKTON FINA' AMMOT SIHA

I Sekretariun i Dipatamenton Hinemlo' Pupbliku yan i Chairman i Profesion Lisensian Mediku para i Commonwealth i Sangkattan siha na Islas Marianas, sigun gi aturidat ni mana'e siha ginen 1 CMC §2605 yan i Lai Pupbliku 11-40, yan 3 CMC §2214(a), kon respetu ma propopone este siha na Areklamento yan Regulasion ni para u gobietna i ma impotta, dipositu, benedin, yan distribusion produkton fina' ammot siha.

I intension i Dipatamenton Hinemlo' Pupbliku yan i Profesion Lisensian Mediku, para u akonfotma i nisisidat siha sigun gi Akton Dinirihen Atministrasion (Administration Procedures Act), espesiatmente 1 CMC §9104, ni mapropopone siha na Areklamento yan Regulasion guaha gi Ofisinan i Sekretariun Hinemlo' Pupbliku, ni gaige gi primet bibenda giya Commonwealth Health Center. Komento put i manmapropopone siha na Araklamento yan Regulasion siña ha manmatuge' papa ya u manahanao guato para i Ofisinan i Sekretariun Hinemlo' Pupbliku, Dipatamenton Hinemlo' Pupbliku, P.O. Box 409 CK, Saipan, MP 96950, sino i Profesion Lisensian Mediku gi pareho ha' na saga. Todu i komento siha debi di ufan marisibi gi halom trenta (30) dias desde malaknos este na nutisia gi Rehistran Commonwealth.

Sinettifika as: _____ 11/12/98
JOSEPH KEVIN P. VILLAGOMEZ **FECHA**
Sekretaru
Dipatamenton Hinemlo' Pupbliku

_____
VICENTE S. ALDAN, M.D. **FECHA**
Chairman
Profesion Lisensian Mediku

Settifikasion ginen I Ofisinan I Abugadun Hinerat:

Sigun gi 1 CMC §2153 ni inamenda nui i Lai Pupbliku 10-50, i mapropopone siha na amendasion gi Areklamento yan Regulasion ni chechetton guine, esta manma inan maolek yan apreba para u fotma ligat yan sufisiente ginen i Ofisinan i Abugadun Hinerat giya CNMI.

ELLIOTT A. SATTLER

MAYA KARA
Kuentan Abugadun Hinerat

12/11/98
FECHA

Ma file as:

SOLEDAD B. SASAMOTO
Rehistradoran Kotporasion

12/14/98
FECHA

Rinisibi as:

JOSE I DELEON GUERRERO
Epesiat na Ayudante i Atministrasion

12/14/98
FECHA

Commonwealth of the Northern Mariana Islands
Department of Public Health

Office of the Secretary

PUBLIC NOTICE

PROPOSED RULES AND REGULATIONS GOVERNING THE IMPORTATION, STORAGE, SALES, AND DISTRIBUTION OF DRUG AND PHARMACEUTICAL PRODUCTS

The Secretary of the Department of Public Health and the Chairman of the Medical Profession Licensing Board of the Commonwealth of the Northern Mariana Islands, in accordance with the authority vested in them pursuant to 1 CMC §2605 and Public Law 11-40, and 3 CMC §2214(a) respectively, hereby jointly propose these Rules and Regulations Governing the Importation, Storage, Sales, and Distribution of Drug and Pharmaceutical Products.

It is the intention of the Department of Public Health and the Medical Profession Licensing Board to comply with the requirements of the Administrative Procedures Act, specifically 1 CMC §9104, in proposing these Rules and Regulations. Copies of the proposed Rules and Regulations may be obtained from the Office of the Secretary of Public Health located on the ground floor of the Commonwealth Health Center. Comments on the proposed Rules and Regulations may be sent to the Office of the Secretary of Public Health, Department of Public Health, P.O. Box 409 CK, Saipan, MP 96950, or the Medical Profession Licensing Board, at the same address. All comments must be received within thirty (30) days from the date this notice is published in the Commonwealth Register.

Certified By: _____ 11/12/98
JOSEPH KEVIN P. VILLAGOMEZ **DATE**
Secretary
Department of Public Health

for _____ 11/16/98
VICENTE S. ALDAN, M.D. **DATE**
Vice-Chairman
Medical Profession Licensing Board

Certification by Office of the Attorney General:

Pursuant to 1 CMC §2153 as amended by PL 10-50, the proposed amendments to the rules and regulations attached hereto have been reviewed and approved as to form and legal sufficiency by the CNMI Office of the Attorney General.

ELLIOTT A. SATTLER
MAYA KARA
Acting Attorney General

12/11/98
DATE

Filed By: _____
SOLEDAD B. SASAMOTO
Registrar of Corporations

12/14/98
DATE

Received By: _____
JOSE I. DELEON GUERRERO
Special Assistant for Administration

12/14/98
DATE

RULES AND REGULATIONS GOVERNING THE IMPORTATION, STORAGE, SALES, AND DISTRIBUTION OF DRUGS AND PHARMACEUTICAL PRODUCTS

SECTION

I. Definitions.

For the purposes of these Rules and Regulations, the following terms shall have the meanings set forth below:

1.1. "Adulterated" means a drug or pharmaceutical product: (1) that consists in whole or in part of any filthy, putrid, or decomposed substance; (2) that has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; (3) where the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug or pharmaceutical product meets the requirements of the federal Food, Drug and Cosmetic Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to posses.

1.2. "Advertising" means any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale, distribution, or disposal of any drugs.

1.3. "Automated Data Processing System" or "ADP system" means a system utilizing computer software and hardware for the purpose of record keeping.

1.4. "Board" means the Medical Profession Licensing Board of the CNMI.

1.5. "Commonwealth" or "CNMI" means the Commonwealth of the Northern Mariana Islands, including its municipalities, departments, agencies, and other instrumentalities.

1.6. "Compound" means to combine two or more elements, chemicals, or ingredients in definite proportions necessary to create a drug for dispensing.

1.7. "Controlled Substance" means a drug, substance or immediate precursor controlled pursuant to Federal or CNMI law.

1.8. "Cosmetics", which includes "soap," "dentifrice," and "toilet article" means: (1) articles intended to be rubbed, poured, or sprinkled on, introduced into, or otherwise applied to the human body, or any part thereof, for cleansing, beautifying, or promoting attractiveness; and (2) articles intended for use as a component of any such articles.

1.9. "Department" means the Department Public Health.

1.10. "Dispense" or "Dispensing" means the furnishing of drugs pursuant to a prescription in a suitable container, appropriately labeled for subsequent administration to, or use by, a patient or other individual entitled to receive the drug.

1.11. "Drug" means: (1) articles recognized in the Commonwealth Health Center formulary, official United States Pharmacopoeia, official homeopathic Pharmacopoeia of the United States, or official national formulary, or any supplement to any of them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals; (2)

articles (other than food or clothing) intended to affect the structure or any function of the body of human beings or animals; and (3) articles intended for use as a component of any articles specified in clause (1) or (2), above; provided that the term "drug" shall not include non-prescription medicines, traditional medicines, electrical or mechanical devices, cosmetics, and liquor.

1.12. "Duly Authorized Representative" means an individual appointed by the Board to act in the capacity of the Board for the purpose of fulfilling the duties and responsibilities created by these Rules and Regulations.

1.13. "Encumbered License" means a license issued by any state or territory of the United States for the practice of pharmacy which has been revoked, suspended, or made probationary or conditional by the licensing or registering authority in the respective jurisdiction as a result of disciplinary action.

1.14. "Fill" means the process of preparing a drug for dispensing in accordance with a valid prescription, which includes, but is not limited to, typing a prescription label, entering a prescription into the pharmacy computer, entering information into the patient's file, retrieving medications from stock, placing medications into prescription containers, placing the prescription label on the container, reconstituting oral liquids, and compounding medications for dispensing.

1.15. "Immediate Supervision" means that a pharmacist is physically present in the area or location to insure adequate safety controls, and performs a final assessment of each ingredient and quantity used and the prescription label to insure the correctness and accuracy thereof.

1.16. "Inspectors" means any official designated by the Department through departmental action or through a memorandum of understanding with other CNMI government agencies to act as an inspector for the purpose of enforcement of these Rules and Regulations, specifically to carry out inspections at the CNMI borders and in establishments where drugs are stored, warehoused, distributed, or sold.

1.17. "Institutional Pharmacy" means a pharmacy providing services to an institutional facility.

1.18. "Label" means any legend, word, or mark attached to, included in, belonging to, in close proximity to, or accompanying any drug.

1.19. "Non-Prescription Medicine" means any packaged, bottled, or nonbulk chemical, drug, or medicine which is legally sold without a prescription, and which is labeled with directions for use, and bears the name and address of the manufacturer or distributor; provided that the chemical, drug, or medicine meets the requirements of the pure food and drug laws of the United States and the CNMI.

1.20. "Person" means any individual, sole proprietorship, partnership, corporation, association, joint venture, or division of the CNMI Government.

1.21. "Pharmacist" means a person licensed under these Rules and Regulations to practice pharmacy except where another meaning is clearly manifested by the context.

1.22. "Pharmacy" means every store, shop, or place where: (1) prescription drugs are dispensed or sold at retail, or displayed for sale at retail; or (2) where practitioners' prescriptions or drug preparations are compounded; or (3) which has upon it or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words "pharmacist", "pharmacy", "apothecary", "drug store", "druggist", "drugs", "medicines", "medicine store", "drug sundries", any word or words of similar or like import, or any translation of such words into another language; or (4) any store or shop or other place with respect to which any of the above words or combination of words are used in any advertisement.

1.23. "Pharmacy Technician" means an individual working in a pharmacy who, under the immediate supervision of a licensed pharmacist, assists in various pharmacy activities that do not require the professional judgment of the pharmacist.

1.24. "Physician" means a medical doctor licensed to practice medicine in the CNMI by the Board.

1.25. "Practice of Pharmacy" means the interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and devices (except labeling by a manufacturer, packer, or distributor of non-prescription drugs and prescription drugs and devices); the participation in drug selection and drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records therefor; the responsibility for advising when necessary or where regulated, of therapeutic values, content, hazards, and use of drugs and devices.

1.26. "Practitioner" means a licensed practitioner of medicine, osteopathy, podiatry, dentistry, veterinary medicine, or other health care professional holding a current and valid license by the Board to prescribe prescription drugs.

1.27. "Prescription" means a written, facsimile, or telephone order or formula issued by a practitioner licensed in the CNMI to prescribe prescription drugs within the scope of the practitioner's practice, for the compounding or dispensing of drugs. "Prescription" also includes an order written in the chart of a patient in an institutional facility by a practitioner.

1.28. "Prescription Drug" means any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act.

1.29. "Secretary" means the Secretary of the Department of Public Health.

1.30. "Traditional Medicine" means those foods, drugs, or herbs used by the Chamorro and Carolinian people in the traditional art of healing, including the diagnosis, cure, treatment, mitigation, or prevention of a disease, disorder, or abnormal physical state, or its symptoms, in human beings or animals.

1.31. "Wholesale Distribution" means the distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intra-company sales, defined as any transaction or transfer between an entity and any division, subsidiary, parent, or affiliated or related company under common ownership and control;

(2) The purchase or other acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug for the entity's own use, from the group purchasing organization or from other hospitals or health care entities that are members of the group purchasing organization;

(3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this Section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, working rights by contract, or otherwise;

(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this Section, "emergency medical reasons" includes, but is not limited to, transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any period of twelve consecutive months;

(6) The sale, purchase, or trade of a drug, or an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors' representatives. For purposes of this Section, "drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug; or

(8) The sale, purchase, or trade of blood and blood components intended for transfusion. For purposes of this Section, "blood" means whole blood collected from a single donor and processed either for transfusion or

further manufacturing; and "blood component" means that part of blood separated by physical or mechanical means.

1.32. "Wholesale Distributor" means any person in the CNMI engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; prescription drug repackagers; physicians; dentists; veterinarians; birth control and other clinics; individuals; hospitals; nursing homes and their providers; health maintenance organizations and other health care providers; and retail and hospital pharmacies that conduct wholesale distributions. The term "Wholesale Distributor" shall not include any carrier for hire or person or entity hired solely to transport prescription drugs. For purposes of this Section, "Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

II. Powers and Duties of the Board.

In addition to any other powers and duties authorized by law, the Board shall:

(a) Examine, license, reinstate, and renew the licenses of qualified applicants for pharmacists and wholesale prescription drug distributors, and issue and renew permits to operate pharmacies;

(b) Inspect, or may designate a duly authorized representative to inspect, whether or not in conjunction with an inspector of the Department, any pharmacy or premises in the CNMI where drugs are packed, packaged, compounded, sold, offered for sale, exposed for sale, stored, warehoused, or kept for sale or distribution to ensure compliance with these Rules and Regulations; and

(c) Fine, suspend, or revoke any license or permit for any cause prescribed by these Rules and Regulations, or for any violation of these Rules and Regulations, and refuse to grant or renew any license or permit for any cause which would be grounds for revocation or suspension of a license or permit.

III. Applications For Licensure or Permit

3.1. License or Permit Required. It shall be unlawful for a person who is not licensed to engage in the practice of pharmacy.

3.2 Information To Be Supplied for Pharmacist License.

(a) An application for licensure for a pharmacist shall be made under oath on forms provided by the Board and shall not be considered complete unless accompanied by the required documentation and fees, which shall not be refunded. It shall be each applicant's responsibility to furnish all information and any documentation requested by the Board.

(b) The application form may require the applicant to provide and certify the following:

(1) The applicant's full name;

(2) A statement that the applicant has attained the age of majority;

(3) The applicant's current business or mailing address and telephone number for publication, and the applicant's current residence address and telephone number;

(4) The applicant's social security number;

(5) That the applicant is a graduate of, and received a degree from, a college of pharmacy or department of pharmacy of a university accredited by the American Council on Pharmaceutical Education or other institution approved by the Board;

(6) That the applicant is of good moral character;

(7) The date and place of any conviction of a crime directly related to the practice of pharmacy, drugs, drug samples, wholesale or retail drug distribution, or distribution of controlled substances, unless the conviction has been expunged or annulled or is otherwise precluded from consideration;

(8) The state(s) or United States territories in which the applicant is currently licensed;

(9) Any information regarding any disciplinary proceedings pending or disciplinary actions taken by any state, territory, or jurisdiction against the license;

(10) A photograph of the applicant for identification purposes;

(11) A statement that the applicant is a United States citizen or is lawfully entitled to remain and work in the CNMI;

(12) Whether the applicant has ever submitted false or fraudulent material in connection with any application for the manufacture or distribution of non-prescription medicines or drugs;

(13) Whether the applicant has ever had a license for the manufacture or distribution of any non-prescription medicines or drugs, including controlled substances, suspended or revoked by the CNMI or Federal governments or other foreign jurisdiction in which the applicant has worked;

(14) Whether the applicant has complied with all licensing requirements for previously issued licenses for the manufacture or distribution of non-prescription medicines or drugs, including controlled substances;

(15) Whether the applicant has complied with the requirements of maintaining and supplying the files required by these Regulations to the Board, CNMI, and/or Federal officials authorized to access the files; and

(16) Any other information the Board may require to investigate the applicant's qualifications for licensure.

(c) Any requirement that the Board provide notice to applicants shall be deemed met if notice is sent to the address on file with the Board.

(d) Any change in the application or of any information filed with the Board shall be reported to the Board, in writing, within ten days of the change.

(e) The application shall be valid for a period of six (6) months from the date it is received by the Board unless the Board extends its period of validity.

3.3 Temporary License. An application for a temporary license for pharmacist, which shall not exceed ninety (90) days or other time period approved by the Board, shall be made under oath and shall not be considered complete unless accompanied by the required documentation and application fee which shall not be refunded. Following a determination by the Board that the qualifications for admission listed above in Section 3.2 exist, a temporary license may be issued, provided the applicant:

(a) Submits a photocopy of a current and valid license to practice pharmacy in another state or jurisdiction; and

(b) Submits evidence that the applicant has practiced for at least two thousand hours as a licensed pharmacist within the five years preceding the date of application.

3.4. Application and Requirements for Pharmacist License by Reciprocity.

(a) An application for licensure for a pharmacist by reciprocity shall be made under oath on forms provided by the Board and shall not be considered complete unless accompanied by the required documentation and fees, which shall not be refunded. The applicant shall:

(1) Submit evidence of current and valid licensure to practice pharmacy in another state or jurisdiction with qualifications which equal or exceed those of the CNMI as set forth in Section 3.2 of these Rules and Regulations;

(2) Submit information regarding any disciplinary action taken or any unresolved complaints pending against the applicant;

(3) Submit evidence of having practiced for at least two thousand hours as a licensed pharmacist within the five years preceding the date of application;

(4) Submit evidence that the applicant does not have an encumbered license or a pending disciplinary action or unresolved complaint in the practice of pharmacy in any state or territory of the United States, or if any license has been or is encumbered, the applicant shall provide any information requested by the Board;

(5) Disclose whether the applicant has ever submitted false or fraudulent material in connection with any application for the manufacture or distribution of non-prescription medicines or drugs;

(6) Disclose whether the applicant has ever had a license for the manufacture or distribution of any non-prescription medicines or drugs, including controlled substances, suspended or revoked by the CNMI or Federal governments;

(7) Disclose whether the applicant has complied with all licensing requirements for previously issued licenses for the manufacture or distribution of non-prescription medicines or drugs, including controlled substances;

(8) Disclose any other factors or criteria that the Board considers relevant and consistent with the public safety and welfare.

(b) If an applicant for licensure by reciprocity has a completed official National Association Pharmacy Board (NAPB) licensure transfer application that

was issued within ninety (90) days from the date the applicant submits an application to the Board, the Board may accept the NAPB licensure transfer or require the applicant to comply with the requirements of subsection (a) above.

(c) The Board may deny licensure by reciprocity if the applicant has had any disciplinary action taken or if any unresolved complaints are pending, or if the applicant has failed to comply with, or satisfy the Board with respect to any of the requirements set forth in subsection (a) above.

(d) Any requirement that the Board provide notice to applicants shall be deemed met if notice is sent to the address on file with the Board.

(e) Any change in the application or of any information filed with the Board shall be reported to the Board, in writing, within ten days of the change;

(f) The application shall be valid for a period of six (6) months from the date it is received by the Board unless the Board extends its period of validity.

3.5. Issuance of Licenses For Pharmacists. Licenses for pharmacists shall be issued to qualified applicants in the name of the individual applicant.

3.6 Pharmacy Intern License.

(a) No person shall practice as a pharmacy intern without having first obtained a license from the Board. Any person who is not a licensed pharmacist, but who is employed in the CNMI for the purpose of fulfilling the requirements to become eligible for licensure as a pharmacist, must apply to the Board to be licensed as an intern pharmacist. An applicant, to be eligible for licensure as an intern pharmacist, must have completed a minimum of one (1) year in a college of pharmacy or a department of pharmacy of a university accredited by the American Council on Pharmaceutical Education or other institution approved by the Board, and must provide the Board with a letter of recommendation from that college or university attesting to the applicant's competence to work as a pharmacist intern.

(b) The Board, upon approval of the application submitted by the applicant, shall issue a letter of licensure stating that the applicant is eligible to undergo practical pharmaceutical training under the direct and immediate supervision of a registered pharmacist. Such certification shall be valid for not more than two (2) years from the date of issue, but may be renewed by the Board.

3.7. Registration of Pharmacy Technicians.

(a) All persons wishing to work as Pharmacy Technicians in the CNMI must register with the Board. An application for registration as a Pharmacy Technician shall be made under oath on forms provided by the Board and shall not be considered complete unless accompanied by the required documentation and fees which shall not be refunded. It shall be each applicant's responsibility to furnish all information and any documentation requested by the Board.

(b) The application form may require the applicant to provide and certify the following:

(1) The applicant's full name;

(2) A statement that the applicant has attained the age of majority;

(3) The applicant's current business or mailing address and telephone number for publication, and the applicant's current residence address and telephone number;

(4) The applicant's social security number;

(5) The applicant's education and training related to the work of a Pharmacy Technician;

(6) That the applicant is of good moral character;

(7) The date and place of any conviction of a crime directly related to drugs, drug samples, wholesale or retail drug distribution, or distribution of controlled substances, unless the conviction has been expunged or annulled or is otherwise precluded from consideration.

(8) The state(s), United States territories, or other jurisdictions in which the applicant has worked as a Pharmacy Technician;

(9) A photograph of the applicant for identification purposes;

(10) A statement that the applicant is a United States citizen or an alien authorized to work in the CNMI by the Department of Labor and Immigration; and

(11) Any other information the Board may require to investigate the applicant's qualifications for registration.

(c) Any requirement that the Board provide notice to applicants shall be deemed met if notice is sent to the address on file with the Board.

(d) Any change in the application or of any information filed with the Board shall be reported to the Board, in writing, within ten days of the change.

(e) The application shall be valid for a period of six (6) months from the date it is received by the Board unless the Board extends its period of validity.

3.8 Wholesale Prescription Drug Distributor License.

It shall be unlawful for any person to operate, maintain, open, change location, or establish any wholesale prescription drug distribution business within the CNMI without first having obtained a license from the Board.

3.9 Wholesale Prescription Drug Distributor License Requirements.

(a) Application for a wholesale prescription drug distributor license shall be made under oath on forms provided by the Board, and shall not be considered complete unless accompanied by the required documentation and fees which shall not be refunded. It shall be each applicant's responsibility to furnish all information and any documentation requested by the Board. The applicant shall certify the following information as it pertains to the applicant including any officer, director, manager, or other persons in charge of wholesale drug distribution, storage, or handling:

(1) The name, address, and telephone number of the applicant requesting the license;

(2) The names under which the applicant does business;

(3) The names, addresses, and telephone numbers of the responsible individuals for all of the applicant's facilities used by the applicant in the warehousing, handling, and distribution of wholesale drugs;

(4) The names of the owners of the applicant, such as:

(i) if the applicant is an individual or a sole proprietorship, such individual's name;

(ii) if the applicant is a partnership, the names and addresses of each of the partners;

(iii) if the applicant is a corporation, the names and addresses of the directors and officers of the corporation, and the place of incorporation.

(5) If the applicant is a corporation, a copy of the corporation's articles of incorporation, and a copy of a certificate of good standing with the CNMI Registrar of Corporations;

(6) A copy of the applicant's CNMI business license and a copy of the applicant's Drug Enforcement Agency registration and number;

(7) The names of the managing pharmacist(s), other pharmacists, and pharmacy technicians employed by applicant, and such individuals' license numbers, and a copy of each such individuals' license certificates;

(8) Any convictions under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(9) Any felony conviction under federal, state, or CNMI laws;

(10) Whether the applicant has ever submitted false or fraudulent material in connection with any application for the manufacture or distribution of non-prescription medicines or drugs;

(11) Whether the applicant has complied with all licensing requirements for previously issued licenses for the manufacture or distribution of non-prescription medicines or drugs, including controlled substances;

(12) Whether the applicant has complied with the requirements of maintaining and supplying the files required by these Regulations to the Board, CNMI, and/or Federal officials authorized to access the files;

(13) Any suspension or revocation by any federal, state, or CNMI government agency of any license currently or previously held for the manufacture or distribution of any drugs, including controlled substances;

(14) Verification of at least one year of experience in the distribution or handling of prescription drugs for any person responsible for the distribution of drugs;

(15) A current list of managers and other persons in charge of the wholesale distribution, storage, and handling of prescription drugs, including a description of each person's duties and a summary of each person's qualifications; and

(16) That no CNMI licensed practitioner is owner or part of a corporation that owns a pharmaceutical wholesale distributorship except that they may own a percentage not greater than 7% of the business operation, or own the building in which a pharmaceutical wholesale distributorship is located so long as the sale or lease price of the building is based on the fair market value of the property, and the sale or lease price of the building is not tied to the sale of drugs by the pharmaceutical wholesale distributorship.

(b) A map of the facilities shall also be submitted. The map shall identify:

(1) The storage area for drugs;

(2) The storage area for quarantined drugs; and

(3) The placement of the lighting, ventilation, and temperature control equipment.

(c) No license shall be issued prior to receipt of a satisfactory inspection report from the Department, Division of Public Health. At a minimum, the Department shall insure that:

(1) The facilities are of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) The storage areas are designed to provide adequate ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) A quarantine area is available for prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or whose immediate or sealed outer or sealed secondary containers have been opened;

(4) The facility is maintained in a clean and orderly fashion;

(5) The facility is free from infestation by insects, rodents, birds, or vermin of any kind;

(6) The facility is secure from unauthorized entry;

(7) Access from outside the premises is kept to a minimum and well controlled;

(8) The outside perimeter of the premises is well-lighted;

(9) Entry into areas where prescription drugs are held is limited to authorized personnel;

(10) The facilities are equipped with an alarm system to detect entry after hours, or security guards have been posted on the premises after hours to ensure that only authorized personnel gain access to the facilities;

(11) The facilities are equipped with an internal security system that will provide suitable protection against theft and diversion;

(12) All prescription drugs are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of the drugs, or in accordance with the standards regarding conditions and temperatures for the storage of prescription drugs adopted by the Department.

(A) If no storage requirements are established for a prescription drug, the drug may be held at controlled room temperature, as

defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected;

(B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document the proper storage of prescription drugs;

(13) Upon receipt, each outside shipping container of prescription drugs is examined visually to confirm the identity of the drugs and to prevent the acceptance of contaminated prescription drugs that are unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;

(14) Each outgoing shipment of prescription drugs is inspected carefully to confirm the identity of the drugs and to ensure that no prescription drugs are delivered that have been damaged in storage or held under improper conditions;

(15) Returned, damaged, outdated, deteriorated, mishandled, or adulterated prescription drugs are physically separated from other prescription drugs and stored, in such a way that no cross-contamination or confusion is possible, until they are destroyed or returned to the supplier;

(16) Any prescription drugs whose immediate or sealed outer or sealed secondary containers are found upon arrival to have been opened or used are identified as such, and are physically separated from other prescription drugs and stored in such a way that no cross contamination or confusion is possible, until they are destroyed or returned to the supplier; and

(17) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug is either destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.

(d) Written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for

correcting all errors and inaccuracies in inventories shall be submitted. Written policies and procedures shall include:

(1) A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate;

(2) A procedure for handling recalls and withdrawals of prescription drugs. The procedures shall be adequate to deal with recalls and withdrawals caused by:

(A) Any action initiated at the request of the Department, the Food and drug Administration, or any other federal, or CNMI enforcement or other government agency;

(B) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(C) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(3) A procedure to ensure that the distributor prepares for, protects against, and handles properly any crisis that affects security or operation of any facility in the event of strike, fire, typhoon, or other natural disaster, or in other emergencies; and

(4) A procedure to ensure that all outdated prescription drugs are segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall require written documentation of the disposition of outdated prescription drugs. The documentation shall be maintained for five years after disposition of the outdated drugs.

(e) The Board may deny licensure for a wholesale prescription drug distributor license if the applicant has had any disciplinary action taken or if any unresolved complaints are pending, or if the applicant has failed to comply with, or satisfy the Board of, any of the requirements set forth in subsection (a) above;

(f) Any requirement that the Board provide notice to applicants shall be deemed met if notice is sent to the address on file with the Board.

(g) Any change in the application or of any information filed with the Board shall be reported to the Board, in writing, within ten days of the change.

(h) The application shall be valid for a period of six (6) months from the date it is received by the Board unless the Board extends its period of validity.

3.10. Issuance of Licenses For Wholesale Distributors. Licenses for wholesale distributors shall be issued to qualified applicants in the name of the individual owner, the partnership, corporation, or other organizational entity of the establishment, and will state the business name of the establishment. The license shall also include the name, license number, and a copy of the annual license certificate of the managing pharmacist and the other pharmacists who practice in the establishment.

3.11. Newly Organized Pharmacies and Wholesale Distributors. All newly organized pharmacies and wholesale distributors must obtain a permit from the Board before commencing operations. All applications for newly organized pharmacies and wholesale distributors shall be submitted to the Board no later than sixty (60) days prior to the date the newly organized pharmacy or wholesale distributor will commence operations. The Board shall carry out the inspection required pursuant to these Regulations within thirty (30) days after receiving the application. After the inspection is completed, the Board shall advise the newly organized pharmacy or wholesale distributor of whether its application for licensure has been approved within fifteen (15) business days after the inspection has been completed.

3.12. Permits For Operation Of A Pharmacy.

(a) It shall be unlawful for any person to operate, maintain, open, change location, or establish any pharmacy within the CNMI without first having obtained a permit from the Board.

(b) Application for permits shall be made under oath on a form to be prescribed by the Board. A separate application shall be made and separate permits issued for each separate place at which is carried on any of the operations for which a permit is required. An application for a pharmacy permit must be accompanied by all required documentation and the application fee which shall not be refunded. It shall be each applicant's responsibility to furnish all information and any documentation requested by the Board.

(c) On evidence satisfactory to the Board a permit shall be issued. The application form may require the applicant to provide and certify the following:

(1) The name, address, and telephone number of the applicant requesting the license;

(2) The name(s) under which the applicant does business;

(3) The names, addresses, and telephone numbers of the responsible individuals for all of the applicant's facilities used by the applicant in the warehousing, handling, and distribution of prescription drugs;

(4) The names of the owners of the applicant, such as:

(i) if the applicant is an individual or a sole proprietorship, such individual's name;

(ii) if the applicant is a partnership, the names and addresses of each of the general and/or limited partners;

(iii) if the applicant is a corporation, the names and addresses of the directors and officers of the corporation, and the place of incorporation.

(5) If the applicant is a corporation, a copy of the corporation's articles of incorporation, and a copy of a certificate of good standing with the CNMI Registrar of Corporations;

(6) A copy of the applicant's CNMI business license;

(7) The names of the managing pharmacist(s) and other pharmacists employed by applicant, and such individuals' license numbers, and a copy of each such individuals' license certificates;

(8) Whether the applicant has ever submitted false or fraudulent material in connection with any application for the manufacture or distribution of non-prescription medicines or drugs;

(9) Whether the applicant has ever had a license for the manufacture or distribution of any non-prescription medicines or drugs, including controlled substances, suspended or revoked by either the CNMI or Federal government;

(10) Whether the applicant has complied with all licensing requirements for previously issued licenses for the manufacture or distribution of non-prescription medicines or drugs, including controlled substances;

(11) Whether the applicant has complied with the requirements of maintaining and supplying the files required by these Regulations to the Board, CNMI, and/or Federal officials authorized to access the files;

(12) The documentation demonstrating that the technical equipment required by these Regulations is maintained for the applicant's operations;

(13) A floor plan of the prescription area which shall diagram the space and location of fixtures such as counters, tables, drawers, shelves, storage cabinets including a locked cabinet, library, sink with hot and cold water, proper sewage outlet, and refrigeration storage equipment;

(14) The date the pharmacy will be ready for inspection;

(15) A letter of verification that the pharmacy has been bought with the effective date of sale if the pharmacy was purchased;

(16) Evidence that the trade name, if any, is properly registered with the business registration division, CNMI Department of Commerce;

(17) That the pharmacy for which the permit is sought is, or will be, in full compliance with these Rules and Regulations and any other rules of the Board;

(18) That the location and appointments of the pharmacy are such that it can be operated and maintained without endangering the public health or safety;

(19) That the pharmacy will be under the personal and immediate supervision of a pharmacist;

(20) That no CNMI licensed practitioner is an owner of the pharmacy or of a share of the pharmacy, or an officer, director, or shareholder of a corporation that owns the pharmacy, except that the practitioner may own the building in which a pharmacy is located so long as the sale or lease price of the building is based on the fair market value of the property, and the sale or lease price of the building is not tied to the sale of drugs by the pharmacy; and

(21) In any case where the applicant is a partnership, unincorporated association or corporation which has more than four (4) partners, members, or shareholders, respectively, the application shall state the names of the four (4) partners, members, or shareholders, respectively, who own the largest interests in the applicant entity and state their percentages of interest. Upon request from the Board, the applicant shall furnish information as to partners, members, or shareholders not named in the application or shall refer the Board to an appropriate source of information.

(d) A permit shall not be issued prior to an inspection-report by the Board which indicates that the applicant has the minimum reference materials and technical clinical equipment and supplies.

(1) The minimum reference materials that a pharmacy shall possess are as follows:

(A) United States Pharmacopeia National Formulary, and all supplements;

(B) Federal Drug Enforcement Agency Regulations;

(C) prescription files.

(2) The minimum technical equipment and supplies that a pharmacy shall possess are as follows:

(A) Class A prescription balance or a balance of greater sensitivity and appropriate weights;

(B) Mortar and pestle (glass or porcelain);

(C) Bottles and vials of assorted sizes;

(D) Graduates or other similar measuring devices;

(E) Prescription labels;

(F) Refrigerator;

(G) A sink in the prescription area supplied with hot and cold running water for exclusive use in cleaning pharmaceutical equipment;

(H) A clean and sanitary disposal container for wastes.

(3) Every pharmacy shall be equipped with a wash basin, in addition to that required under subsection (2)(G) above, supplied with soap and paper towels at all times, and kept clean and in order. The washing basin shall not be used for placing, storing, or keeping materials, merchandise, or equipment of any kind.

(e) No permit shall be issued unless all deficiencies, if any, have been corrected and approved by the Board.

(f) The Board may delegate to its executive secretary the authority to issue a permit upon receipt of the inspection report verifying that all requirements have been met.

(g) Any requirement that the Board provide notice to applicants shall be deemed met if notice is sent to the address on file with the Board.

(h) Any change in the application or of any information filed with the Board shall be reported to the Board, in writing, within ten days of the change.

(i) The application shall be valid for a period of six (6) months from the date it is received by the Board unless the Board extends its period of validity.

3.13. Issuance of Permits. Permits shall be issued to qualified applicants in the name of the individual owner, the partnership, corporation, or other

organizational entity of the pharmacy, and will state the pharmacy's business name. The license shall also include the name, license number, and a copy of the annual license certificate of the managing pharmacist and the other pharmacists who practice in the pharmacy.

3.14. Change of Owner or Location. If a pharmacy changes owners or physical locations, the original permit shall become void, and shall be returned to the Board before a new permit is issued. In the case of a change of owner or physical location, the application for a new permit shall comply with Section 3.12 of these Rules and Regulations.

3.15 Other Restrictions On Offers To Sell, Sales, and Distribution of Drugs. It shall be unlawful:

(a) For any person to sell or offer for sale at public auction, or to sell or offer for sale at private sale in a place where public auctions are conducted, any drugs without first obtaining a permit from the Board to do so;

(b) For any person to in any manner distribute or dispense samples of any drugs or medical supplies without first obtaining a permit from the Board to do so; provided that nothing in this paragraph shall interfere with the furnishing of samples or drugs directly to physicians, pharmacists, dentists, veterinarians and other practitioners for use in their professional practice:

(c) For wholesale distributors to sell, distribute, or dispense any drug, except to a pharmacist, physician, dentist, veterinarian, or other practitioner who is allowed to use pharmaceutical agents or to a generally recognized industrial, agricultural, manufacturing, or scientific user of drugs for professional or business purposes;

(d) For wholesale distributors to sell to drugs stores and other retail establishments those medicines that are classified as prescription drugs, unless the drug store or retail establishment has been issued a permit by the Board to operate a pharmacy;

(e) For wholesale distributors to retail drugs and non-prescription medicines directly to the public, unless they have a separate permit from the Board to do so.

(f) For pharmacies and drug stores to sell prescription drugs and non-prescription medicines on a wholesale basis without a wholesale distributor license to conduct such activities;

(g) For any person, as principal or agent, to conduct or engage in the business of preparing, manufacturing, compounding, packing, or repacking any drug without first obtaining a permit from the Board to do so; and

(h) For any out-of-CNMI pharmacy or entity engaging in the practice of pharmacy, in any manner to distribute, ship, mail, or deliver prescription drugs or devices into the CNMI without first obtaining a permit from the Board; provided that the applicant shall:

(1) Provide the location, names, and titles of all principal corporate officers;

(2) Attest that the applicant or any personnel of the applicant has not been found in violation of any CNMI or federal drug laws, including the illegal use of drugs or improper distribution of drugs;

(3) Submit verification of a valid unexpired license, permit, or registration in good standing to conduct the pharmacy in compliance with the laws of the home state and agree to maintain in good standing such license, permit, or registration; and

(4) Have in its employ a pharmacist whose license is current and in good standing.

3.16 Fees for Permits and Licenses. The Board shall collect fees for each permit to operate a pharmacy, including a mail order pharmacy as described in 3.15(h), or for each license to operate as a pharmacist, pharmacy technician, or wholesale prescription drug distributor. The fees for permits and licenses shall be published by the Board in the Commonwealth Register.

3.17 Form of Fee; Dishonored Checks Considered Failure To Meet Requirements. The fees, if in the form of a money order or check, shall be made payable to the CNMI Treasury. The dishonoring of any check upon first deposit shall be considered a failure to meet the requirements for licensure or permit.

3.18. License or Permit Nontransferable; Changes Of Address. Any license or permit issued by the Board shall be valid only in the name issued and shall not be transferable. A permit to operate a pharmacy shall apply only to the physical location of the establishment for which it was issued. All changes of address must be reported to the Board within ten (10) days.

3.19 Criminal Conviction. When an applicant or the applicant's personnel have been convicted of a crime related to the pharmacy profession and it is determined that the conviction may be considered, the Board may request the following documents from the applicant:

(a) Copies of any court records, orders, or other documents that state the facts and statutes upon which the applicant was convicted, the verdict of the court with regard to that conviction, the sentence imposed, and the actual terms of the sentence; and

(b) Affidavits from any parole officer, employer, or other persons who can attest to a firm belief that the applicant has been sufficiently rehabilitated to warrant the public trust.

3.20 Denial or Rejection of Application.

(a) An application for issuance of a license or permit shall be denied when an application is insufficient or incomplete; is not accompanied with the required fees; or when an applicant has failed to provide satisfactory proof that the applicant meets the requirements for the license or permit. In addition, the Board may deny issuance of a license or permit:

(1) When the applicant or the applicant's personnel is known to have committed any of the acts for which a license or permit may be suspended or revoked; or

(2) If the applicant has had any disciplinary action taken in connection with the practice of pharmacy in any jurisdiction, including any federal or CNMI regulatory body.

(b) An application shall be automatically rejected and the applicant shall be denied a license or permit when the applicant, after having been notified to do so:

(1) Fails to pay the appropriate fees within sixty days from notification; or

(2) Fails to submit any of the information or documentation requested to comply with any of the requirements for licensure or permit within sixty days of notification.

(c) Any application which has been denied or rejected shall remain in the possession of the Board and shall not be returned. However, the Board shall notify the applicant by letter of the Board's action which shall include a concise

statement of the reasons therefor. The notice requirement shall be deemed satisfied if notice is sent to the address on file with the Board.

(d) An applicant, whose application has been denied or rejected, may file for an administrative hearing.

3.21. Cancellation of License or Permit. A pharmacy permit, or a license for a pharmacist or wholesale distributor may be cancelled by the Board for any of the following reasons:

(a) If the individual in whose name the license was issued dies. In this circumstance, any new applicant assuming the operations of the deceased shall follow the procedures set forth in Sections 3.2 or 3.9 of these Rules and Regulations for obtaining a new license within sixty (60) days from the date of death of the prior owner of the establishment.

(b) If the pharmacy or wholesale distributorship for which the permit was issued ceases operations.

(c) If the pharmacy or wholesale distributorship for which the permit was issued is sold, leased, or transferred to another person. In this circumstance, the person who purchased, leased, or otherwise assumed the operations of the pharmacy shall be required to submit an application for a new permit as provided in Section 3.12 of these Rules and Regulations.

IV. Renewal of Licenses and Permits

4.1 Renewal of Licenses and Permits.

(a) All licenses and permits issued by the Board, which have not been revoked, suspended, or otherwise encumbered, shall be renewed every two years from the date issued. The standards for renewal of a license or permit shall be the same as those for the initial issuance of a license or permit, as set forth in Sections 3.2, 3.6, 3.9, and 3.12 of these Rules and Regulations. Licensees shall also be required to maintain their license to practice in the jurisdiction in which they were licensed by examination.

(b) Any requirement that the Board provide notice to licensees shall be deemed met if notice is sent to the address on file with the Board.

(c) Any change in the application or of any information filed with the Board shall be reported to the Board, in writing, within ten (10) days of the change.

4.2 Date for filing All licensees and permit holders shall complete and submit a renewal application together with the required fees on or before the 60th day prior to the date of expiration (two years from the date of original or renewal of licensure or permit). A completed renewal application with the required fees sent by the United States mail shall be considered timely filed if the envelope bears a postmark no later than 60 days prior to the expiration date.

4.3 Automatic Forfeiture for Failing to Renew. The failure to timely renew the license or permit, or to pay the applicable fees, or paying fees with a check which is dishonored upon first deposit shall cause the license or permit to be automatically forfeited.

4.4 Restoration of Forfeited License or Permit.

(a) A pharmacist license which has been forfeited may be restored within six months of the forfeiture provided the applicant:

(1) Submits a notarized statement from a licensed pharmacist attesting that the applicant has been employed for a minimum of two thousand hours as a pharmacist within the previous two years; or

(2) If the applicant is licensed out-of-state, a copy of the out-of-state license and a statement signed by the out-of-state licensing official that the out-of-state license is current and in good standing and that the applicant has been employed for a minimum of two thousand hours within the preceding two years; and

(3) Pays the penalty, current biennial, and renewal fees.

(b) A pharmacy permit or a wholesale distributor license which has been forfeited may be restored within one year of the date of forfeiture provided the applicant:

(1) Pays all penalty fees, current biennial, and renewal fees; and

(2) In the case of a pharmacy, passes a pharmacy inspection conducted by the Board; or

(3) In the case of a wholesale distributor, passes a facility inspection conducted by the Department, Division of Public Health.

(c) The Board may deny restoration of a forfeited license or permit against which disciplinary action has been taken since the date of forfeiture of

the license or permit, or if the applicant or applicant's personnel have been convicted of any crime directly related to the practice of pharmacy, drugs, drug samples, wholesale or retail drug distribution, or distribution of controlled substances unless the conviction has been expunged or annulled or is otherwise precluded from consideration.

(d) A person whose license or permit has been forfeited and who fails to restore the license or permit as provided in this section, shall apply as a new applicant.

4.5 Board May Refuse to Renew or Restore.

(a) The Board may refuse to renew or restore a license or permit for failure or refusal of the licensee or permit holder to:

(1) Properly complete or timely submit the renewal application form and submit all fees and required documentation;

(2) Meet and maintain the conditions and requirements necessary to qualify for the issuance of the license or permit.

(b) An applicant whose application has not been renewed or restored for the above reasons may file for an administrative hearing.

V. Scope of Practice

5.1 Display of License or Permit.

(a) The current license or permit shall be conspicuously displayed in the place of business for which the permit or license was granted and the holder of a license shall have the holder's license or evidence of current validation in the holder's possession at all times, provided that a relief pharmacist shall not be required to display a license or permit. In the case of pharmacies, the permit, each pharmacist's license, and a recent photograph of the managing pharmacist of a size no smaller than 3x5 must be prominently displayed.

(b) A licensed pharmacist who is employed or who practices in more than one pharmacy shall post his current certificate of licensure in the pharmacy in which he or she is primarily employed. In addition, the licensed pharmacist shall post a photocopy of his or her current certificate of licensure in every other pharmacy in which he or she practices either part-time or temporarily.

5.2. Pharmacist In Charge; Pharmacy Personnel.

(a) A pharmacist shall be in personal and immediate charge of the pharmacy and personnel employed in the pharmacy. During any absence of the pharmacist, the entire stock of prescription drugs shall be secured from access to unauthorized persons and the means of access shall only be in the possession of the pharmacist; prescriptions may not be dispensed, or received by telephone and no prescription drugs shall be sold; provided that this shall not preclude the sale at those times of things that might be sold were the pharmacy a store not subject to these Rules and Regulations. No person other than a pharmacist or a pharmacy intern under the pharmacist's immediate supervision shall dispense prescriptions.

(b) A pharmacy technician may be employed to assist the pharmacist. The pharmacist shall directly supervise all activities and functions of the pharmacy technicians to insure that all activities and functions are performed in accordance with procedures and the scope of duties of a pharmacy technician and further shall initial all prescriptions filled by pharmacy technicians.

5.3 Physical Presence of a Pharmacist In Institutional Pharmacy.

(a) A pharmacist must be physically present during the hours of operation of a prescription area in an institutional pharmacy.

(b) At any time a pharmacist is not in the prescription area of an institutional pharmacy (except in cases of emergencies), the entire stock of prescription drugs shall be secured from access to unauthorized persons and the means of access shall only be in the possession of the pharmacist.

(c) A pharmacist in an institutional pharmacy shall ensure that written policies and procedures have been established by the institutional facility for provision of drugs to the medical staff and other authorized personnel of the institutional facility by use of night cabinets, and access to the institutional pharmacy and emergency kits when the pharmacist is not in the area. A "night cabinet" is a cabinet, room, or any other enclosure not located within the prescription area. The written policies and procedures shall provide that, a pharmacist shall be "on call" during those periods and shall provide policies and procedures regarding the following:

(1) Security of the night cabinet to ensure that the night cabinet is sufficiently secured to deny access to unauthorized persons by force or otherwise;

(2) The development of an inventory listing of all drugs included in the cabinet and the requirement that the pharmacist ensures, at a minimum, that:

(A) Drugs available therein are properly labeled;

(B) Only prepackaged drugs are available therein in amounts sufficient for immediate therapeutic requirements;

(C) A prescription is attached to the inventory list for any drug that was withdrawn from the cabinet;

(D) All drugs therein are inventoried no less than once per calendar quarter; and

(E) A complete audit of all activity concerning such cabinet is conducted no less than once per month.

(3) Access to the pharmacy. In the event a drug is not available from floor supplies or night cabinets and the drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the institutional pharmacy in accordance with this subsection. Authorized personnel may remove drugs therefrom provided:

(A) The authorized personnel are designated, in writing, by the institutional facility;

(B) The authorized personnel have been instructed by the pharmacist of the proper methods of access, and the records and procedures regarding removal of the drugs; and

(C) The authorized personnel are required to complete a form which shall include the patient's name and room number, the name of drug, drug strength, dosage, date, time, and the signature of the authorized personnel.

(4) Use of drugs that have a "stop date." For purposes of this section, "stop date" in an institutional setting is the length of time to administer a medication as indicated on a drug order. In the absence of such a notation, if an order is necessary or advisable to stop the particular drug, a committee of the institutional facility will have determined by policy, the length of time for administration of the drug.

5.4 Failure to Place Pharmacist In Charge. Any proprietor or manager of a pharmacy who fails or neglects to place a pharmacist in charge thereof or who permits the compounding, filling, or dispensing of prescription drugs, except by or under the immediate supervision of a pharmacist, shall be deemed to have violated these Rules and Regulations. Any person who, not being a pharmacist, compounds, fills, or dispenses prescriptions drugs while not subject to the immediate supervision of a pharmacist shall be deemed to have violated these Rules and Regulations.

5.5 Duties of Pharmacist In Charge. Every pharmacist in charge of a pharmacy shall comply with all laws governing pharmacists and the practice of pharmacy. The pharmacist in charge shall be responsible for the management of the pharmacy; and every activity thereof which is subject to these Rules and Regulations shall be under the pharmacist's complete control.

5.6 Scope of Practice Of a Pharmacy Technician. A pharmacy technician may perform the following tasks, not requiring professional judgment, under the immediate supervision of a pharmacist:

(a) Typing of prescription labels, drug packaging, stocking, delivery, record keeping, pricing, documentation of third party reimbursements, and filling, compounding, and storing medication;

(b) Mixing drugs with parenteral fluids provided that the pharmacy technician:

(1) Has a working knowledge of the pharmaceutical medical terms, abbreviations, and symbols commonly used in the prescribing, dispensing, and charting of medications;

(2) Is able to perform the arithmetic calculations required for the usual dosage determination and solution preparation;

(3) Has a thorough knowledge and understanding of the pharmacy technician's duties and responsibilities, including standards of ethics governing the practice of pharmacy;

(4) Has a working knowledge of drug dosages, route of administration, and dosage forms;

(5) Has a working knowledge of the procedures and operations relating to the manufacturing, packaging, and labeling of drug products; and

(6) Has a working knowledge of the procedures and operations relating to aseptic compounding and parenteral admixture operations.

(c) Pharmacy technicians shall not perform the following functions at any time:

(1) Consultation with the practitioner regarding the patient and his prescription;

(2) Receipt of a verbal prescription other than refill approval or denial from a practitioner;

(3) Consultation with the patient regarding the prescription, both prior to and after the prescription filling and/or regarding any information contained in a patient medication record system;

(4) Interpretation and identification of the contents of the prescription document;

(5) Determination of the product required for the prescription;

(6) Extemporaneous compounding of the prescription whereby the accuracy, correct procedure and preparation, and safety of pharmaceutical constituents cannot be verified by the pharmacist;

(7) Interpretation of data in a patient medication record system;

(8) Dispense prescriptions to patient;

(9) Final checks on all aspects of the completed prescription and assumption of the responsibility for the filled prescription, including but not limited to accuracy of the drug strength, the labeling, and the proper container provided that a pharmacy technician may perform specialized functions as approved by the Board;

(10) Any duty required by law, rule or regulation to be performed only by a pharmacist.

(d) Except for a specialized function approved by the Board for the location, a pharmacy technician shall not release any drug ordered for a specific patient from the pharmacy or satellite pharmacy that has not been checked by a licensed pharmacist.

(e) The employer, the pharmacy manager, and the pharmacist in charge are responsible and liable for the acts performed by a pharmacy technician.

5.7 Adequate Equipment. Every pharmacy compounding drugs shall be equipped with proper pharmaceutical utensils so that the prescriptions can be

properly compounded, as set forth in Section 3.12(d) of these Rules and Regulations.

5.8. Security of Prescription Departments.

(a) The prescription department of every pharmacy shall be separated from the merchandising or public areas of the premises by a barrier extending not less than five (5) feet above the floor level and of sufficient width to make controlled substances, narcotics, poisons, prescription drugs, or restricted devices inaccessible to unauthorized persons. The barrier must be constructed of solid material and contain a gate or door permitting access by the pharmacist. The gate or door must be secured by a deadbolt lock that can be opened from the outside only by a key.

(b) The Board may permit an alternative type of physical security if, in its opinion, the alternative method of security shall be sufficient to make the controlled substances, narcotics, poisons, prescription drugs, or restricted devices inaccessible to unauthorized persons.

5.9. Prescription Record. Every pharmacy or dispensing physician or clinic shall keep a suitable book or file, or a microfilm of such book or file, in which shall be preserved, for a period of not less than five years, every prescription compounded or dispensed at the pharmacy. The book, file, or microfilm of prescriptions shall at all times be open to inspection by the Board.

5.10 Emergency Kits.

(a) A pharmacist may provide emergency kits to emergency medical service units or ambulatory clinics which do not have immediate access to a pharmacy to meet the emergency therapeutic needs of patients.

(b) The pharmacist and the medical staff of the institutional facility shall jointly determine the drugs, and quantity, to be included in the emergency kit.

(c) The exterior of emergency kits shall be labeled by the pharmacist to clearly and unmistakably indicate that the kit is an emergency drug kit and that the kit is for use in emergencies only. In addition, the label shall also contain a listing of the drugs contained therein, including name, strength, quantity, and expiration date of the contents, and the name, address, and telephone number of the supplying pharmacist.

(d) All drugs contained within the emergency kit shall be labeled to identify, at a minimum, the brand or generic name, strength, route, quantity, source, lot number, expiration date, and other information as may be required by the medical staff of the institutional facility to prevent any misunderstanding or risk of harm to the patients of the facility.

(e) On or before the earliest expiration date of any drug contained in the emergency kit, the pharmacist shall replace any expired drugs, re-label, and re-seal the kit.

(f) The pharmacist shall ensure that the institutional facility has established written policies and procedures which shall provide, but not be limited to, policies and procedures covering:

(1) Storage of emergency kits in secured areas which shall be in an environment for preservation of the drugs;

(2) Procedures to ensure that drugs are removed only pursuant to a valid prescription and recordation of any removal; and

(3) Procedures to notify the pharmacist within twenty-four hours of any removal of any drug from the emergency kit.

5.11 Valid Prescriptions.

(a) A pharmacist may fill and dispense prescriptions provided the prescription is valid. A valid prescription shall be legibly written and contain, at the minimum, the following information:

(1) The date of issuance;

(2) The original signature of the practitioner;

(3) The practitioner's name and business address;

(4) The name, strength, quantity, and directions;

(5) The name and address of the person for whom the prescription was filled or the name and address of the owner of the animal for which the drug is prescribed (unless the pharmacy filling the prescription has such address on file);

(6) The room number and route of administration if the patient is in an institutional facility; and

(7) If refillable, the number of allowable refills.

(b) Except where a written prescription is required by law, a phone order is acceptable from practitioners or their authorized agent provided:

(1) Only a pharmacist shall receive the oral prescription;

(2) The oral prescription is promptly reduced to writing and kept on file for five years; and

(3) The oral prescription contains all of the information required under subsection (a).

(c) A faxed prescription for a noncontrolled substance is acceptable from practitioners provided the facsimile is sent by the practitioner or the practitioner's authorized agent, and contains all of the information required under subsection (a) and is kept on file for five years. However, the original prescription must be provided to the dispensing pharmacist within a 72 hour period.

(d) All pharmacists shall comply with any applicable CNMI or federal laws or rules governing the validity of prescriptions.

5.12 Substitution: Drug Product Selection.

(a) It shall be unlawful to dispense a different drug in place of the drug prescribed without the express consent of the practitioner prescribing it. This limitation shall not include generic drug substitutions unless the practitioner restricts such substitution by writing on the prescription "Dispense As Written," or other phrase indicating the same.

(b) Drug product selection shall comply with the federal Food and Drug Administration therapeutic rating (A or B).

5.13 Transfer of Prescriptions. Transfers of prescription information for the purpose of refill dispensing is permissible between pharmacies. At the time of the transfer the transferring pharmacist and receiving pharmacist must provide the following:

(a) The pharmacist transferring the prescription must provide all information necessary for a valid prescription, and write the words "void" and "invalid" on the face of the prescription or in the computer data base in the patient profile and code the data to ensure that there can be no refill of the prescription; and record on the reverse side of the prescription, the name of the pharmacist receiving the prescription information, the date of transfer, and the name of the pharmacist transferring the prescription. The pharmacist transferring the prescription shall indicate on the dispensing record or the ADP system the date of the transfer and the name of the pharmacy and pharmacist to which the prescription was transferred.

(b) The pharmacist receiving the transferred prescription information shall write the word "Transfer" on the face of the valid transferred prescription; and the name of the pharmacist transferring the prescription and pharmacy's name, location, and the date the original prescription was written.

5.14. Prescriptions Subject To Right Of Privacy.

(a) Prescriptions filed and on file in a pharmacy are not a public record. A pharmacist shall not divulge the contents of any prescription or provide a copy of any prescription, except to:

(1) The patient for whom the original prescription was issued;

(2) The practitioner who originally issued the prescription;

(3) A practitioner who is currently treating the patient;

(4) Another licensed pharmacist, upon request by the patient for a transfer of the prescription

(5) A member of the Board, or duly authorized representative, for purposes of Board investigations;

(6) Employees of the Department who are licensed or ancillary health care professionals charged with the responsibility of providing medical care for the patient or charged with the responsibility of handling administrative matters related to the medical care provided for the patient;

(7) An insurance carrier, on receipt of written authorization signed by the patient or his legal guardian, authorizing the release of such information; or

(8) Any person duly authorized by a court order.

(b) Any copy of a prescription for a controlled substance or a prescription drug issued to a person authorized by this section to receive such copy, must contain all of the information appearing on the original prescription and be clearly marked on its face, "Copy, Not Refillable - - - For Reference Purposes Only;" and such a copy must bear the name or initials of the registered pharmacist who prepared the copy.

5.15. Return or Exchange of Drugs Prohibited. No prescription drug shall be accepted for return or exchange by a pharmacy or pharmacist after such drug has been taken from the premises where dispensed or sold by prescription.

VI. Sale of Non-Prescription Medicines

6.1. Sale of Non-Prescription Medicines. Products considered as non-prescription medicines, as set forth in the definitions of these Rules and Regulations, may be sold without the intervention of a pharmacist in permitted pharmacies, by licensed wholesale drug distributors, and those retail dealers selling non-prescription medicines. Only those drugs approved by the United States federal Food and Drug Administration for import into the United States or for over-the-counter sale in the United States may be sold over-the-counter in the CNMI.

6.2. Storage and Dispensing of Non-Prescription Medicines. Non-prescription medicines shall be stored and dispensed in their original containers, with proper labels that indicate the name of the manufacturer, and shall be stored in an environment that avoids deterioration of their quality, purity and potency.

VII. Record Keeping Requirements

7.1 Records of Dispensing.

(a) **Records of dispensing** for original and refill prescriptions are to be made and kept by pharmacies for five years and shall include, but not be limited to, the following:

(1) Quantity prescribed and quantity dispensed;

(2) Date of dispensing;

(3) **Serial number or, if** an institution, equivalent control system;

(4) Identification of the pharmacist responsible for dispensing;

(5) Record of refills to date.

(b) An institutional pharmacy will have fulfilled the requirements of this section if the information required by paragraphs (1) to (4) of subsection (a) is kept on accurate patient profiles or medication administration records showing all drugs administered to the patient for five years; and the institutional facility keeps the original patient charts evidencing the prescription orders and medication administration records in the institutional facility's files for at least five years.

7.2 Automated Data Processing Systems. As an alternative to procedures set forth in Section 7.1, an automated data processing (ADP) system may be employed for the record keeping system provided the following conditions have been met:

(a) The ADP system shall have the capability of producing hard copy documents of all drug orders of original and refilled prescription information. The hard copy produced must be of a print size that is readable without the aid of any special device;

(b) Information to be kept on the ADP system shall include, but not be limited to, the information required in Section 5.11, "Valid Prescriptions," and Section 7.1, "Records of Dispensing";

(c) The pharmacist responsible for pharmacy order entries into the ADP system shall ensure that the information entered into the computer is accurate and complete;

(d) The documentation used to satisfy the above requirements shall be provided to the pharmacy within seventy-two hours of the date of dispensing;

(e) An auxiliary record keeping system shall be established for the dispensing and documentation of refills in the event the ADP system is inoperative for any reason. The auxiliary system shall insure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When the ADP system is restored to operation, the information regarding drug orders and prescriptions filled and refilled during the inoperative period shall be entered in the ADP system within two working days;

(f) Any pharmacy using an ADP system shall comply with all applicable CNMI and federal laws and regulations; and

(g) A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete records for any drug order, prescription, and dispensing if the relationship with such supplier terminates for any reason. The pharmacy shall assure continuity in the maintenance of records.

7.3 Security of Records. To maintain the confidentiality of patient's prescriptions or drug orders, there shall exist adequate safeguards for security of the records whether kept manually or in an ADP system.

7.4 Record Keeping for Wholesale Prescription Drug Distributors.

(a) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

(1) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(2) The identity and quantity of the drugs received and distributed or disposed of; and

(3) The dates of receipt and distribution or other disposition of the drugs;

(b) The wholesale distributor shall also maintain records to reflect:

(1) Storage. That all prescription drugs are stored at appropriate temperatures and under appropriate conditions in accordance with the requirements, if any, in the labeling of the drugs, or in accordance with the standards regarding conditions and temperatures for the storage of prescription drugs.

(A) If no storage requirements are established for a prescription drug, that the drug is held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(B) That appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs are used to document the proper storage of prescription drugs.

(2) Examination of materials.

(A) That each outside shipping container of prescription drugs was examined visually to confirm the identity of the drugs and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(B) That each outgoing shipment of prescription drugs was inspected carefully to confirm the identity of the drugs and to ensure that no

prescription drugs were delivered that have been damaged in storage or held under improper conditions.

(3) Returned, damaged, outdated, deteriorated, misbranded, and adulterated prescription drugs.

(A) That prescription drugs that are damaged, outdated, deteriorated, misbranded, or adulterated are physically separated from other prescription drugs and stored in such a way that no cross-contamination or confusion are possible, until they are destroyed or returned to the supplier.

(B) That any prescription drugs whose immediate or sealed outer or sealed secondary containers are found upon arrival to have been opened or used are identified as such, and are physically separated from other prescription drugs and stored in such a way that no cross-contamination or confusion are possible, until they are destroyed or returned to the supplier.

(C) That if the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug is either destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, quality, or purity, the wholesale distributor considers, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.

(c) Inventories and records shall be made available for inspection and photocopying by the Department or any authorized federal or CNMI law enforcement officials for a period of five years following disposition of the drugs.

(d) Records described in this section that are kept at the inspection site or that can be retrieved immediately by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by the Department or any authorized official of a federal or CNMI law enforcement agency.

VIII. Advertising Practices

8.1. Restrictions on Advertising.

No person may:

(a) (i) display a sign outside an establishment; (ii) advertise in newspapers, on the radio, on television, through printed flyers or other promotional means; or (iii) advertise in an other manner the name of an establishment that includes the words "drug store," "pharmacy," "apothecary," or a combination of these, or whatever related words or phrases; or

(b) display any insignia or emblem that might indicate or imply to the public that the establishment is a drug store, pharmacy, or apothecary;

unless the establishment is actually a permitted pharmacy, or licensed wholesale distributor.

This restriction on advertising shall not apply to retail dealers of non-prescription medicines.

8.2 Procedures to Advertise Prescription Drugs.

(a) Advertising of prescription drugs shall be done for the purpose of providing the public with information in a manner consistent with public health and safety. Prescription drug advertising shall be done for the purpose of providing information, and not to create a demand for drugs. A pharmacy, if it chooses to advertise, shall advertise prescription prices, drugs, and reference to prescription prices and drugs in accordance with this section:

(1) A pharmacy may post its prices for prescription drugs on a prescription price poster. The form of such posting shall be legible.

(2) A pharmacy may advertise prescription prices by publication or display in any media. For purposes of this section, "media" includes, but is not limited to, newspapers, magazines, calling cards, and directories, including all listings in telephone directories.

(3) Any advertisement for prescription drugs shall be made in three commonly prescribed quantities.

(4) Any advertisement for prescription drugs shall contain the brand name of that drug, if it is sold under a brand name.

(5) Any advertisement for prescription drugs or prices shall be truthful, reasonable, fully informative, and understandable to the public and shall not be false or misleading.

(6) Any advertisement for prescription drugs shall state the time period during which the prices advertised will be effective.

(b) The price for prescription drugs advertised shall not be below cost.

(c) A pharmacist or the pharmacist's agent, upon request, however communicated to the pharmacist, shall give the current price for any drug sold at the pharmacist's pharmacy for informational purposes only and such price quoted shall not be false or misleading but must be truthful, reasonable, informative, and understandable to the public.

8.3 Procedures to Advertise Related Pharmacy Services. Advertising of related pharmacy services shall be done for the purpose of providing the public with information in a manner consistent with public health and safety and shall be truthful, reasonable, fully informative, and understandable to the public and shall not be false or misleading. A pharmacy may advertise that it performs the following services:

(a) Personal medication record. To qualify as providing a personal medication record, a system must be maintained which enables the immediate retrieval of information concerning individual pharmacy patients which is of sufficient scope to enable a determination by the pharmacist of rational drug utilization. In accomplishing this purpose the design and use of the system must be to ascertain and record all patient information necessary to assist the pharmacist in avoiding adverse drug reactions, drug-drug interactions, and inappropriate use of drugs.

(b) Professional consultation with patient and physician. The availability of patient consultation means that the pharmacist routinely informs the patient, either directly or indirectly, on what the patient is taking, how to take it, what to expect, what special precautions should be observed, and how the medication is to be properly stored. This service is to assure that the patient understands the proper use of the drug and that the physician's intentions will materialize in a drug regimen of optimal effectiveness, safety, and duration. Physician or practitioner consultation denotes the availability and practice of pharmacists acting as drug information specialists who discuss with practitioners drug effect, interactions, side effects, and drugs of choice for disease conditions.

(c) "Emergency prescription service" means the providing of pharmaceutical services, which includes prescription dispensing, at any time after usual pharmacy hours. This means that a pharmacist is available, can be readily contacted, and will respond with reasonable expediency at any hour, day or night, in a manner consistent with security and personal safety.
Should the pharmacy choose to advertise the performance of the foregoing services, it must conform with the definition of that service as herein set forth.

8.4 Advertising of Controlled Substances Prohibited. No person shall advertise or promote to the public in any manner the sale of a Schedule II, III, IV, or V controlled substance as defined in the Federal Controlled Substances Act, and the rules promulgated thereunder, or as defined in the Commonwealth Controlled Substances Act, 6 CMC §2101 - §2150.

IX. Labeling

9.1. Labels Must Be In Official Language. The minimum label requirements for drugs and non-prescription medicines sold in the CNMI are set forth below. All label information for drugs and non-prescription medicines shall be in at least one of the three official languages of the CNMI.

9.2. Drug Information Sheets. The following minimum information shall be included on all drug information sheets provided to physicians and health-related professionals by the drug manufacturer for prescription medications.

(a) The international nonproprietary name of each active substance;

(b) Pharmacological data, including a brief description of the pharmacological effects and the mechanism of action;

(c) Clinical information, including: (1) indications: whenever appropriate, simple diagnostic criteria should be provided; (2) dosage regimen, including routes of administration, and relevant pharmacokinetics data: (A) average and range of dosage for adults, children, and the elderly; (B) dosage interval; (C) average duration of treatment; (D) special conditions, (i.e., renal, hepatic, cardiac, or nutritional insufficiencies that require either increased or reduced dosages); (3) contraindications; (4) precautions and warnings (i.e., use during pregnancy, lactation, and other special conditions); (5) adverse effects, qualified by category, if possible; (6) drug interactions, but only if clinically

relevant (i.e., interactions with drugs used for self-medication, and with foods.); (7) overdose information, including: (A) brief, clinical description of information; (B) non-drug treatment and supportive therapy; (C) specific antidotes;

(d) Pharmaceutical Information: (1) dosage forms; (2) strength of dosage forms; (3) excipient; (4) storage conditions and shelf-life (expiration date); (5) package sizes; (6) description of the product and the package; (7) legal category (i.e., narcotic or other controlled drug, prescription, or non-prescription); and (8) name and address of manufacturer(s) and/or importer(s).

9.3. Labeling. Labels for drugs and non-prescription medicines shall contain, at minimum, the following information:

(a) Labels for drugs dispensed in their original package must contain the following information: (1) the nonproprietary name (the brand name may also be included); (2) the strength; (3) the name and address of the manufacturer and importer; (4) the storage conditions; (5) the expiration date; (6) the batch identification number; and (7) package size.

(b) Labels for drugs dispensed in other quantities than the package size of the original manufacturer must contain the following information: (1) the brand name and/or nonproprietary name; (2) the patient's name; (3) the strength; (4) the prescriber's name; (5) the manufacturer and importer; (6) the dosage instructions; (7) the expiration date; (8) the storage conditions; (9) the batch identification number: either the manufacturer's code or the pharmacist's prescription number; and (10) the indication (whenever appropriate).

(c) Labels for non-prescription medicines that may be legally sold over-the-counter must contain the following information: (1) the name of the product; (2) the name and address of the manufacturer, packer, or distributor; (3) the net contents of the package; (4) the established name of all active ingredients and the quantity of other ingredients regardless of whether they are active; (5) the name of any habit-forming drug contained in the preparation; (6) cautions and warnings that are needed for the protection of the user; and (7) directions for safe and effective use.

X. Importation of Drugs

10.1. General Prohibition On Importation. Except as provided in Section 10.3 of the Regulations, the importation of any drug or non-prescription medicine

into the CNMI that does not comply with any section of these Rules and Regulations is hereby prohibited. Any person who imports any drug in contravention of these Rules and Regulations shall be guilty of an offense punishable under Section 12.3 herein.

10.2. Seizure and Detention of Imported Drugs.

(a) The Secretary, acting in conjunction with the Department of Finance, Division of Customs, may seize and detain any drugs or non-prescription medicines being imported into the CNMI that the Secretary has reason to believe may contravene any section of these Rules and Regulations. Once seized, the Secretary may order that the drugs and non-prescription medicine be delivered to the Department for identification, and a determination of compliance with these Rules and Regulations.

(b) Upon a finding by the Department that the seized drugs or non-prescription medicines contravene any section of these Rules and Regulations, the owner or person found to be in possession (the "custodian") of the drugs or non-prescription medicines shall be contacted and advised in writing of the Department's determination of violation. The owner or custodian of the drugs or non-prescription medicines shall have the option of sending the contravening drugs or non-prescription medicines back to their country of origin or having them destroyed in the CNMI, however either election shall be at the owner's or custodian's expense.

10.3. Importation of Drugs For Personal Use. The Secretary, or his or her designee, through advisories, may exempt from these Regulations personal shipments of drugs intended for personal use if the following criteria are satisfied:

(a) The intended use of the drug is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means;

(b) There is no known commercialization or promotion to persons residing in the CNMI by those involved in the distribution of the drug at issue;

(c) The drug is not considered to represent an unreasonable risk; and

(d) The individual seeking to import the product affirms in writing that it is for the individual's own use for a period not to exceed three months (90 days), and provides the name and address of the CNMI practitioner responsible for his

or her treatment with the product or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

XI. Inspections, Seizures, and Forfeitures

11.1. Inspection.

(a) Inspectors. The Secretary may designate any person employed by the Department as an inspector for the purpose of enforcing these Rules and Regulations. By Memorandum of Understanding, the Secretary may work in conjunction with the Department of Finance, Division of Customs; Department of Labor & Immigration; the Department of Public Safety, and the Office of the Attorney General to perform inspections for the purpose of enforcing these Rules and Regulations.

(b) Identification badges or credentials to be produced. All individuals designated as inspectors shall be provided identification badges or other evidence of his or her credentials as an inspector. Upon entering any establishment pursuant to Section 11.1(c) of these Rules and Regulations, an inspector shall produce the identification badge or other credentials to the person in charge of such establishment.

(c) Entry and inspection. An inspector may at any reasonable time enter any place of operations where the inspector believes, based on administrative probable cause, any article to which these Rules and Regulations apply is prepared, preserved, packaged, imported, sold, distributed, or stored, and may:

(1) examine any such article and take samples thereof, and examine anything that the inspector believes, based on administrative probable cause, is used or capable of being used for the preparation, preservation, packaging or storing of such article;

(2) enter any conveyance that the inspector believes, based on administrative probable cause, is used to carry any article to which these Rules and Regulations apply, and examine any such article found therein and take samples thereof;

(3) open and examine any receptacle or package that the inspector believes, based on administrative probable cause, contains any article to which these Rules and Regulations apply;

(4) examine and make copies of, or extracts from, any books, documents, or other records found in any place referred to in this subsection 11.1(c) that the inspector believes, based on administrative probable cause, contain any information relevant to the enforcement of these Rules and Regulations with respect to any article to which these Rules and Regulations apply;

(5) seize and detain for such time as may be necessary any article by means of, or in relation to which the inspector believes, based on administrative probable cause, contravenes any provision of these Rules and Regulations.

(d) Warrant required to enter dwelling-house.

(1) Where any place mentioned in subsection 11.1(c) is a dwelling-house, an inspector may not enter that dwelling-house without the consent of the occupant, except under the authority of a warrant issued in accordance with subsection 11.1(d)(2), below.

(2) Where on ex-parte application by an inspector, a judge for the CNMI is satisfied by information on oath that : (i) the conditions for entry described in subsection 11.1(c) exist with respect to a dwelling-house; (ii) entry to the dwelling-house is necessary for any purpose relating to the administration or enforcement of these Rules and Regulations; and (iii) entry to the dwelling-house has been refused or that there are reasonable grounds to believe that entry thereto will be refused, the judge may issue a warrant under his or her hand authorizing the inspector named therein to enter the dwelling-house subject to such conditions as may be specified in the warrant.

(e) Use of force. In executing a warrant issued pursuant to subsection 11.1(d)(2), the inspector named therein shall not use force unless the inspector is accompanied by a police officer, and the use of force has been specifically authorized in the warrant.

(f) Definition of "Article to Which These Rules and Regulations Apply." As used in this Section 11, "article to which these Rules and Regulations apply" shall include: (1) drugs or non-prescription medicines; (2) anything used for the preparation, preservation, packaging, or storing thereof; and (3) any labeling or advertising material.

(g) Assistance and information to be provided inspector.

(1) Cooperation with inspectors. The owner or individual in charge of an establishment being inspected by an inspector pursuant to this

Section 11, and every individual found therein, shall give the inspector all reasonable assistance, and furnish the inspector with any information he or she may require, as provided in these Rules and Regulations.

(2) Obstruction and false statements. No person shall obstruct or hinder, or knowingly make any false or misleading statement, either orally or in writing, to an inspector while the inspector is engaged in carrying out his or her duties and functions under these Rules and Regulations.

(3) Interference. Except pursuant to the approval of the inspector, no person shall remove, alter, or interfere in any way with anything seized pursuant to these Rules and Regulations.

11.2. Analysis.

(a) Analysts. The Secretary may designate any person as an analyst for the purpose of enforcement of these Rules and Regulations.

(b) Analysis and Examination. An inspector may submit to an analyst, for analysis or examination, any article or sample seized by the inspector, or a sample of the article seized.

(c) Certificate or Report. An analyst who has made an analysis or examination may issue a certificate or report setting out the results of the analysis or examination.

11.3. Storage and Removal. Any article seized pursuant to this Section 11 may, at the option of the inspector, be kept or stored in the building or place where it was seized, or at the direction of the inspector, the article may be removed to any other place designated by the Secretary or his designee.

11.4. Release of Seized Articles. An inspector who has seized any article pursuant to this Section 11 shall release it when he or she is satisfied that the owner or other person in charge of the establishment has complied with the provisions of these Rules and Regulations.

11.5. Destruction With Consent; Return To Country Of Origin. Where an inspector has seized an article pursuant to this Section 11, and its owner or the person in whose possession the article was found at the time of seizure consents to its destruction, the article shall thereupon be forfeited to the CNMI, and may be destroyed or otherwise disposed of as the Secretary may direct. The cost of

such disposal shall be born by the owner of the article or the person in whose possession the article was found. At the discretion of the Secretary, the owner of the article or the person in whose possession the article was found may be allowed to send the article back to its country of origin at their own expense. The packaging and shipping of the article shall be subject to the supervision of the Secretary or a designee.

11.6. Forfeiture on Conviction. Where a person is found to have violated the provisions of these Rules and Regulations, the Court may order that any article related to the violation, and anything of a similar nature belonging to, or in the possession of the person, or found with the article, be forfeited, and on the issuance of the order the article and other things be forfeited to the CNMI, and may be disposed of as the Secretary may direct, at the expense of the person.

11.7. Order For Forfeiture On Application of Inspector. Notwithstanding Section 11.6, a Court may, upon the application of the inspector, and on such notice to such persons as the Court directs, order that the article and anything of a similar nature found therewith, be forfeited to the CNMI, and may be disposed of as the Secretary may direct, at the expense of the person, if after inquiry, the Court considers such forfeiture to be necessary to prevent a violation of the Rules and Regulations from the sale, distribution, dispensing, or use of the article.

XII. Disciplinary Sanctions, Hearings, Administrative Procedure

12.1 Disciplinary Action.

(a) In addition to any other actions authorized by law, the Board shall have the power to revoke, suspend, refuse to renew, deny, or condition a license or permit in accordance with these Rules and Regulations, and to fine or otherwise discipline a licensee or permit holder for any cause authorized by law, including but not limited to the following:

(1) Procuring a license or permit through fraud, misrepresentation, or deceit;

(2) Failing to meet or maintain the requirements or conditions necessary to qualify for license or permit;

(3) Conviction of, or pleading *nolo contender* to a crime that is substantially related to the qualifications, functions, or duties of a pharmacist;

(4) Committing any act or omission in the practice of pharmacy or wholesale distribution which constitutes dishonesty, fraud, or misrepresentation with the intent to substantially benefit the pharmacist or wholesale distributor or with the intent to substantially injure another person;

(5) Aiding or abetting an unlicensed person to directly or indirectly evade these Rules and Regulations;

(6) Failing to maintain records or to make accessible any records as required in Sections 7 and 11 of these Rules and Regulations;

(7) Violating any Rules and Regulations of the Department or Department of Public Safety;

(8) Accepting returns or exchanges of prescription drugs after such drugs have been taken from the premises where they were dispensed or sold by a prescription;

(9) Dispensing a different drug or brand in place of the drug or brand prescribed without the express consent of the person prescribing, except as provided in Section 5.12 of these Rules and Regulations;

(10) Interfering with the performance of the functions and duties of the Board or its duly authorized representatives, or any of the Secretary's inspectors.

(11) Professional misconduct, gross carelessness, or manifest incapacity;

(12) Permitting an unlicensed person to perform activities which require a license under these Rules and Regulations;

(13) Violation of any of the provisions of these Rules and Regulations;

(14) Violation of any CNMI or federal drug, controlled substance, or poison law;

(15) False, fraudulent, or deceptive advertising;

(16) Any other conduct constituting fraudulent or dishonest dealings;

(17) Failure to comply with a Board order;

(18) Making a false statement on any document submitted or required to be filed by these Rules and Regulations; or

(19) Habitual intemperance or addiction to the use of habit-forming drugs.

(b) The violation of any condition or limitation on a license or permit may be cause to impose additional sanctions against the licensee or permit holder.

(c) All proceedings for revocation, suspension, refusal to renew, denial, or conditioning of a license or permit on any grounds specified in subsection (a) shall be conducted pursuant to the Medical Practice Act, 3 CMC §2252 and the Administrative Procedures Act, 1 CMC §9101 - §9115. However, the following conditions shall also govern the procedure for hearings.

(1) Default. If a party does not appear at any scheduled settlement conference, is not present at the hearing during any stage of the proceeding, or if the party fails to comply with any provision or order of the examining officer, default may be entered against such party, and the hearing may continue without the party's continued participation. Notice of such default shall be sent to the party's address of record.

(2) Discovery. Within a reasonable time prior to the date scheduled for the hearing, the affected party may request the following information from the Board: (i) all documents in the possession of the Board related to the hearing which the Board proposes to use in the case; and (ii) a list of the witnesses who will appear to testify at the hearing on behalf of the Board. The examining officer may authorize the use of any discovery mechanism, at his or her discretion.

(3) Sanctions and Fines. Any individual who, during the course of the hearing or other proceedings, acts in a disrespectful manner toward the examining officer or toward any of the individuals attending the hearing, or who intentionally interrupts or delays the proceedings without just cause, may be sanctioned with an administrative fine at the discretion of the examining officer, which fine shall not exceed Three Hundred Dollars ($300.00).

12.2. Failure to Correct Cited Violations. When a license or permit has been suspended for violation of these Rules and Regulations, and the licensee or permit holder has failed to take the corrective action cited in the notice of suspension within ninety (90) days, at the expiration of the ninety (90) day time period, the license or permit shall be automatically revoked, unless an extension is granted by the Board.

12.3 Penalties For Violations of These Rules and Regulations. Any person who violates any of the provisions of these Rules and Regulations shall be fined not less than One Hundred Dollars ($100.00) and no more than Five Hundred Dollars ($500.00) for each violation. Each distinct violation of these Rules and Regulations shall be regarded as a separate offense.

12.4. Proceedings of Immediate Action.

(a) The Board may use emergency adjudicative proceedings, including revocation of a license, in a situation where there exists imminent risk to the public health, safety, and welfare, or which otherwise requires immediate action by the Board.

(b) In taking immediate action, the Board shall issue an order or resolution which includes a concise statement of the findings of fact, conclusions of law, and public policy reasons justifying the decision that the Board needs to take immediate action.

(c) The Board shall give whatever notice it deems most appropriate to the persons who are required to comply with the order or resolution. The order shall become effective upon its issuance.

(d) The Board's power to take immediate action shall also include the issuance of a general warning to the public of the existence of a violation of these Rules and Regulations through all available news media, including television, radio, newspaper, and other available means of communication whenever the Board determines that such warning is in the public interest.

12.5. Right of Injunction. The Department may, in addition to any other remedies available, apply to a Court having competent jurisdiction for an injunction to restrain any violation of these Rules and Regulations.

12.6. Cumulative Remedies. The remedies or penalties provided by these Rules and Regulations are cumulative to each other and to the remedies or penalties available under all other laws of the CNMI.

XIII. Application of Law.

These Rules and Regulations shall not apply to any practitioner legally licensed by the CNMI to prescribe prescription drugs within the scope of

the practitioner's practice when the practitioner is handling drugs in the course of the practitioner's professional duties, or prohibit the practitioner from personally supplying the practitioner's own patients with such prescription drugs if the prescription drugs fall within the practitioner's scope of authorized practice. The practitioner shall be required to follow all requirements and restrictions as per labeling, record keeping, dispensing and storage as are required or restricted to a licensed pharmacist.

XIV. Severability

If any provision of these Rules and Regulations or the application of any such provision to any person or circumstance should be held invalid by a court of competent jurisdiction, the remainder of these Rules and Regulations or the application of its provisions to persons or circumstances other than those to which it was held invalid shall not be affected thereby.

XV. Repeal Clause

All other Department Rules and Regulations that conflict with the provisions of these Rules and Regulations are hereby repealed, including Chapter VIII of the Medical Profession Licensing Board Rules and Regulations published in Volume 11, Number 9 of the Commonwealth Register, 6432-6448 (September 15, 1989).

TINIAN CASINO GAMING CONTROL COMMISSION

Municipality of Tinian and Aguiguan
Commonwealth of the Northern Mariana Islands

Commissioners:

Vicente M. Manglona
Chairman

Martin DLG San Nicolas
Vice Chairman

Jose P. San Nicolas
Joaquin H. Borja
Jeffrey M. Hofschneider

Executive Director

Esther H. Barr
Deputy Director

Oscar C. Rasa
Consultant

PUBLIC NOTICE OF PROPOSED AMENDMENTS TO CHAPTER 1 - SUBCHAPTER 8, SECTIONS 1:8.9(a)(b), 1:8.9.01(a)(b) 1:8.10, 1:8.11, 1:8.12, 1:8.12.01 OF THE RULES AND REGULATIONS FOR THE OPERATION OF THE TINIAN CASINO GAMING CONTROL COMMISSION

The Chairman of the Tinian Casino Gaming Control Commission ("TCGCC" or "Commission") hereby gives notice to the general public that the Commission has adopted, and thus hereby proposes to make amendments to its existing TCGCC Rules and Regulations on Operations of the TCGCC: Chapter 1 - Subchapter 8, Sections 1:8.9(a)(b), 1:8.9.01(a)(b), 1:8.10, 1:8.11, 1:8.12, 1:8.12.01. These amendments are made pursuant to Sections 5(8)(c) and Section 121 of the Revised Tinian Casino Gaming Control Act of 1989, also cited at 10 CMC §2521(h)(3) and 10 CMC §25123.

The purpose of these amendments is to increase the fees for the licensing of: (1) all Machine Fees, includes but not limited to slot machines, video poker, video roulette, pachinko machines, and any and all other video combination machines; (2) Gaming Table Fees; (3) Casino Service Industry License Fees; (4) all Casino Employees License Fees; (5) Casino Key Employee's License Fees; and (6) all Hotel Employee's License Fees. It is intended that by these amendments, a much needed additional TCGCC enforcement personnel be added so as to enable the Commission to effectively enforce the provisions and polices of the Casino Act and its TCGCC Rules and Regulations.

The Chairman of the TCGCC solicits comments and recommendations concerning these amendments, which must be received by him within 30 days from the publication of this notice. Copies of the proposed amendments to the regulations may be obtained at the TCGCC main office, P.O. Box 143, San Jose Village, Tinian, MP 96952.

Dated this 19th day of August, 1998

Vicente M. Manglona

Vicente M. Manglona
Chairman of TCGCC

RECEIVED BY:

12/14/98

Jose I. Deleon Guerrero
Special Assistant for Administration
Office of the Governor

FILED BY:

12/14/98

Soledad B. Sasamoto
Registrar of Corporations

Pursuant to 1 CMC 2153 as amended by PL 10-50 the rules and regulations attached hereto have been reviewed and approved as to form and legal sufficiency by the CNMI Attorney General's Office.

Dated this 14th day of Dec., 1998.

Robert E. Dungca
Attorney General

By:

P.O. Box 143 San Jose Village, Tinian, MP 96952 • Tel: (670)433-9292/9288 • Fax: (670)433-9290

TINIAN CASINO GAMING CONTROL COMMISSION

Municipality of Tinian and Aguiguan
Commonwealth of the Northern Mariana Islands

NOTISIAN PUBLIKU

Notisia Pot I Ma Propopone Na Amendasion Para I Kapitulo Uno I Papa Kapitulo Ocho, Secsion 1:8.9(a)(b), 1:8.9.01(a)(b),1:8.10, 1:8.11, 1:8.12, 1:8.12.01

I Kabesan i Tinian Casino Gaming Control Commission ("TCGCC" or "Commission") ha notitisia i henerat publiku na i Commission ha adapta yan ha propopone para u famatinas amendasion para i presente na TCGCC areglo yan regulasion gi i operacion i TCGCC. Kapitulo Uno gi papa Kapitulo Ocho, secsion 1:8.9(a)(b),1:8.9.01(a)(b),1 :8.10, 1:8.11, 1:8.12, 1:8.12.01. Este na amendasion mafatinas sigun i Secsion Sinko(Ocho)(c) yan Secsion Sento bente Uno gi tinulikuan i Tinian Casino Gaming Control Act of 1989, lokue ma indentifica gi dies CMC papa §2521(h)(3) yan dies CMC §25123.

I rason pot este na amendasion put para uma umenta i presion i para ufan ma lisensia gi este siha na patte:(1) Presion todo macheneria incluso Slot Poker, Video Poker, Video Roulette, Pachiko Machines, yan todo otro clasen Video Conbinacion Macheneria; (2) Presion i lamasan huego;(3) Presion i lisensian setvision Casino industria;(4) todo presion lisensia para empleyaon casino; (5) presion i lisensia para i manahante na ampleyao gi casino; yan (6) todo presion i lisensia para empleyao gi hotel. I intension put este na amendasion, put para uma umenta i taotao ni put para u enfuetsa i provision yan i areklun i TCGCC komision segun gi ginaogaogao gi acton i casino yan i TCGCC na regulasion yan areklu.

I kabesan i TCGCC ha notisia todo na ansiakaso na guaha inepe pat recomendasion pot este na amendasion na uma na halom todo inepe guato giya guiya , put mas atrasao gi halom trenta dias ginen ima publikana etsa na notisia. Kopian i man ma propone na amendasion para esta na regulasion sina machule gi principat na ofisinan i TCGCC, osino uma kattage gi P.O. Box 143, San Jose Village, Tinian, MP 96952.

Ginen este na ha'ane dia 19th gi Augusto, 1998.

Vicente M. Manglona
Chairman

RECEIVED BY:

Jose I. Deleon Guerrero
Special Assistant for Administration
Office of the Governor
10/14/98

FILED BY:

Soledad B. Sasamoto
Registrar of Corporations
10/14/98

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TINIAN CASINO GAMING CONTROL COMMISSION

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1. **CITATION OF AUTHORITY:** The Tinian Casino Gaming Control Commission is authorized to promulgate regulations pursuant to the Revised Tinian Casino Gaming Control Commission Act of 1989, Part II, Section (8)©.

2. **STATEMENT OF OBJECTIVES:** The amendments are to allow the international casino service industry provider a simple calculation of the annual fee. The $500.00 fee is pursuant to Part V Section 47 (3) of the Act is for local businesses and entrepreneur who intend to or are doing business with the casino/hotel complex. Other fees are changed to conform towards international standard.

3. **PROPOSED REGULATIONS TINIAN CASINO GAMING CONTROL COMMISSION AMENDMENTS TO RULES AND REGULATIONS**

1:89 Machine Fees

(a) Machines' fees defined in this section shall include all mechanical and video device used as part of the games available for play to patrons of the casino. This includes but not limited to slot machines, video poker, video roulette, pachinko, machines and any and all other video combination machines.

(b) Fees for all machines defined in part (a) of this section shall be imposed on a declining scale on the total number of machines in the casino. As a set rule for all machine fees the following schedule shall apply to all machines in the casino. This fee must be remitted to the Commission by October 1st of each fiscal year.

First 100 machines	$225.00 per machine
Second 100 machines	$200.00 per machine
Third 100 machines	$175.00 per machine
Fourth 100 machines	$150.00 per machine
Remaining machines	$125.00 per machine

1:8.9.01 Gaming Table Fees

(a) All casinos shall have at least one each of the following table games and may be conditioned in their license to have more than this minimum.

1. Craps
2. Roulette
3. Baccarat
4. Black Jack (Twenty-One)
5. Wheel (Wheel of Fortune, Big Six, etc.)
6. Asian Games (Pai Gow, Fan Tan, etc.)

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(b) Fees for each gaming table available for play by the patrons in the casino shall be $500.00 per table. This includes any type of gaming table inside the casino available to the customers.

(c) Table Games are not limited to those outlines in 1:8.9.01 (a) and may include Keno, Bingo, Chemin de Fer, Faro, Chuck-A-Luck, Panguingui, Poker, Red Dog, etc.

1:8.10 Casino Service Industry License Fees

(a) No Casino Service Industry license shall be issued or renewed unless the applicant shall have first paid in full an annual license fee of $500.00 to industries as outlined Part V, Section 47 (1) (a) (b) of the Act. This fee, unlike the casino license fee, shall not be prorated based on the date of issuance in the fiscal year. This fee must be remitted to the Commission by October 1st of each fiscal year.

(b) In addition to the annual license fee of $500.00, no Casino Service Industry license shall be renewed unless a fee in the amount of one half (1/2) of one (1) per cent of the gross income of such services provided to the casino shall be imposed. This fee be remitted to the Commission by October 1st of each fiscal year.

(c) In determining the annual gross of the service industry fee, all taxed imposed by other government agencies shall first be deducted prior to the calculation of the one half (1/2) of one (1) percent. A copy of all documents related to the annual gross income and taxes must be provided to the Commission upon remittance of this fee.

(d) Fees defined in part (a) and (b) above shall not be exempted for license issued in accordance to Section 3-1.12.

(e) 1. Non payment of all fees described in this section shall be sufficient grounds for the revocation or suspension of license for such service industry.

2. All Casino Service Industry license suspended or revoked shall cease its services to the casino immediately upon notification from the Commission.

3. All casino licenses shall terminate its services from such service industry licensee upon notification from the Commission that such service industry's license has been suspended or revoked.

(f) Violation of this section shall result in penalties assess to either the Casino Service Industry Licensee or the Casino Licensee in the amount to be determined by the Commission, but not to exceed $100.00 per day.

1:8.11 Casino Key Employee License Fees

A fee of $500.00 for each and every casino key employee as defined, shall be paid in full to the Commission prior to the employee engaging in any work related to the casino. This fee, unlike the casino license, shall not be prorated based on the date of issuance in the fiscal year and must be remitted to the Commission by October 1st of each fiscal year.

1:8.12 Casino Employee License Fees

A fee of $50.00 for each and every casino employee as defined, shall be paid in full to the Commission prior to the employee engaging in any work related to the hotel. This fee, unlike the casino license fee, shall not be prorated based on the date of issuance in the fiscal year and must be remitted to the Commission by October 1st of each fiscal year.

1:8.12.01Hotel Employee Registration Fees

A fee of $50.00 for each and every hotel employee shall be paid in full to the Commission prior to the employee engaging in any work related to the casino. This fee, unlike the casino license fee, shall not be prorated based on the date of issuance in the fiscal year and must be remitted to the Commission by October 1st of each fiscal year.

4. **CONTACT PERSON:** For further information, you may contact the Executive Director at 433-9288/9292 or write to: Tinian Casino Gaming Control Commission, P.O. Box 143, San Jose Village, Tinian, MP 96952.

5. **CAUSE AND CITATION FOR REGULATION:** Regulations are necessary in the interest of the Tinian Public. In order to maintain continuity in service to the casino industry and to be increasingly consistent with standard Commonwealth fees. The Commission's present fee assessment for gaming devices is very low in comparison with the CNMI Government. The new schedule of fees us consistent with other casino jurisdictions. The public interest requires establishment and adoption of these regulations upon fewer than 30 days notice. The Tinian Casino Gaming Control Commission finds for the reasons given and pursuant to Title 1, CMC, Division 9, Chapter 1, Section 9104 (b) that the public interest requires the adoption of regulations, upon the concurrence of the Governor, to clearly amend the existing Casino Service Industry License Fees 1:8.10 (a) (b) ©, describing the procedures for the Casino Service Industry License Fees.

COMMONWEALTH HEALTH CENTER
Office of the Secretary
GOVERNMENT OF THE NORTHERN MARIANA ISLANDS
DEPARTMENT OF PUBLIC HEALTH SERVICES

PUBLIC NOTICE

PROPOSED AMENDMENTS TO THE RULES AND REGULATIONS GOVERNING THE SCREENING REQUIREMENTS OF ALIEN EMPLOYEES

The Secretary of the Department of Public Health of the Commonwealth of the Northern Mariana Islands, in accordance with the authority vested in him pursuant to 1 CMC §2603 (a) and (b), and 1 CMC §2605 , hereby propose these Amendments to the Rules and Regulations Governing the Screening Requirements of Alien Employees in order to remove employers from direct involvement in the alien health screening process, and to ensure that the health screening process does not violate the alien employees' rights under the Americans with Disabilities Act.

It is the intention of the Department of Public Health to comply with the requirements of the Administrative Procedures Act, specifically 1 CMC §9104, in proposing these amendments to the Rules and Regulations. Copies of the proposed Rules and Regulations may be obtained from the Office of the Secretary of Public Health located on the ground floor of the Commonwealth Health Center. Comments on the proposed Rules and Regulations may be sent to the Office of the Secretary of Public Health, Department of Public Health, P.O. Box 409 CK, Saipan, MP, 96950. All comments must be received within thirty (30) days from the date this notice is published in the Commonwealth Register.

JOSEPH K.P. VILLAGOMEZ
Secretary of Health
Department of Public Health

Date: 12/11/98

P.O. BOX 409 CK, SAIPAN, MP 96950
TELEPHONE (670) 234-8950/51/52/53/54, TELEX 783-744 PHES SPN, FAX (670) 234-8930

Certification by Office of the Attorney General

Pursuant to 1 CMC §2153 as amended by PL 10-50, the proposed rules and regulations attached hereto have been reviewed and approved as to form and legal sufficiency by the GNMI Office of the Attorney General.

for

MAYA KARA
Acting Attorney General

Date: 12/11/98

Filed By: _____
SOLEDAD B. SASAMOTO
Registrar of Corporations

Date: 12/14/98

Received By: _____
JOSE I. DELEON GUERRERO
Special Assistant for Administration

Date: 12/14/98

Proposed Amendments to the Rules and Regulations Governing the Screening Requirements of Alien Employees

Citation of Statutory Authority:	1 CMC §2603 (a) and (b) authorize the Department of Public Health to maintain and improve health conditions and minimize and control communicable disease in the CNMI. 1 CMC §2605 enables the Department of Public Health to adopt regulations in those areas over which it has authority. The current version of the Rules and Regulations Governing the Screening Requirements of Alien Employees is published in Vol. 20, No. 2 of the Commonwealth Register (February 15, 1998).
Short Statement of Goals & Objectives:	The proposed amendments to the Rules and Regulations will remove employers from direct involvement in the alien health screening process and ensure that the health screening process does not violate the alien employees' rights under the Americans with Disabilities Act.
Brief Summary of the Proposed Rule:	Employers of alien employees will no longer be responsible for submitting Physical Examination forms to the Public Health Liaison Office at the Department of Labor & Immigration, and will no longer receive notification that during the health screening process their alien employee was found to have a communicable disease and therefore must comply with the protocols of the Division of Public Health. The monetary penalties previously imposed on employers who failed to ensure that their alien employee complied with the requirements of the health screening regulations have also been deleted.
Contact Person(s):	Dr. Jon Bruss, Medical Director for the Division of Public Health; Connie Guerrero, Public Health Liaison.
Citation of Related and/or Affected Statutes, Regulations, and Orders:	Rules and Regulations Governing the Screening Requirements of Alien Employees, Vol. 20, No. 2 Commonwealth Register (February 15, 1998).

Date: 11/30/98

Celeste E. Andersen

Celeste E. Andersen, Legal Counsel
Department of Public Health

Commonwealth I Sangkattan Siha na Islas Marianas
Dipatamenton Hinemlo' Pupbliku

Ofisian I Sekretaru

NUTISAN PUPBLIKU

MAPROPONEN AREKLAMENTO YAN REGULASION SIHA PARA U GOBIETNA I AFUETSAO NA MARIKONOSEN I TI MAN RESIDENTE (ALIEN) NA EMPLEAO

I Sekretariun i Dipatamenton Hinemlo' Pupbliku i Commonwealth i Sangkattan siha na Islas Marianas, sigun gi aturidat ni mana'e gue' ginen 1 CMC §2603 (a) yan (b), yan 1 CMC §2605, ha propopone este siha na Areklamento yan Regulasion ni para u gobietna i Afuetsao na Marikonesen i Ti Man Residente (Alien) na Empleao ni ha o'otden i mana'suhaña i man empleplea ginen direktamente na inafektan i man marikonosen i ti man residente (alien) na empleao, yan lokkue para u ma na' siguru na i marikonesen hinemlo' ti a kontradisi i direchun i ti man residente (alien) na empleao ni gaige gi papa i Aktun i man Inutet na Amerikano (Americans with Disabilities Act).

I intension i Dipatamenton Hinemlo' Pupbliku para u akonfotma i nisisidat siha sigun gi Akton Dinirihen Atministrasion (Administration Procedures Act), espesiatmente 1 CMC §9104, ni mapropopone siha na Areklamento yan Regulasion guaha gi Ofisinan i Sekretariun Hinemlo' Pupbliku, ni gaige gi primet bibenda giya Commonwealth Health Center. Komento put i manmapropopone siha na Araklamento yan Regulasion siña ha manmatuge' papa ya u manahanao guato para i Ofisinan i Sekretariun Hinemlo' Pupbliku, Dipatamenton Hinemlo' Pupbliku, P.O. Box 409 CK, Saipan, MP 96950. Todu i komento siha debi di ufan marisibi gi halom trenta (30) dias desde malaknos este na nutisia gi Rehistran Commonwealth.

Sinettifika as: _____ _____
JOSEPH KEVIN P. VILLAGOMEZ **FECHA**
Sekretaru, Dipatamenton Hinemlo' Pupbliku

Settifikasion ginen I Ofisinan I Abugadun Hinerat:

Sigun gi 1 CMC §2153 ni inamenda nui i Lai Pupbliku 10-50, i mapropopone siha na amendasion gi Areklamento yan Regulasion ni chechetton guine, esta manma inan maolek yan apreba para u fotma ligat yan sufisiente ginen i Ofisinan i Abugadun Hinerat giya CNMI.

ELLIOTT A. SATTLER — 12/14/98

MAYA KARA — **FECHA**
Kuentan Abugadun Hinerat

Ma file as: — 12/14/98

SOLEDAD B. SASAMOTO — **FECHA**
Rehistradoran Kotporasion

Rinisibi as: — 12/14/98

JOSE I DELEON GUERRERO — **FECHA**
Epesiat na Ayudante i Atministrasion

AMENDMENTS TO THE RULES AND REGULATIONS GOVERNING THE SCREENING REQUIREMENTS OF ALIEN EMPLOYEES

It is the intent of the Department of Public Health to remove employers from direct involvement in the Alien Health Screening process. Pursuant to the amendments set forth below, employers of alien employees will no longer be responsible for submitting Physical Examination forms to the Public Health Liaison Office at the Department of Labor & Immigration, and will no longer receive notification that during the health screening process their alien employee was found to have a communicable disease and therefore must comply with the protocols of the Division of Public Health. The monetary penalties previously imposed on employers who failed to ensure that their alien employee complied with the requirements of the health screening regulations have also been deleted. These amendments to the Rules and Regulations Governing the Screening Requirements of Alien Employees will ensure that the alien health screening process does not violate the alien employees' rights under the Americans with Disabilities Act. The Rules and Regulations Governing the Screening Requirements of Alien Employees are hereby amended as set forth below.

Section III, "Physical Examination," subsection 3.2 is amended as follows:

3.2. Filing of Physical Examination Forms. The Physician performing the Alien Employee's Physical Examination shall provide the ~~Employer~~ **Division** with a copy of the completed Physical Examination form for the Alien Employee in a sealed envelope marked "Confidential" within forty-five (45) days from the date of the Alien Employee's initial Physical Examination, and forty-five (45) days from the date of each annual Physical Examination thereafter. ~~It shall then be the responsibility of the Employer to submit the sealed envelope containing the Alien Employee's Physical Examination form to the Division within ten (10) days from receipt from the Physician~~.

Section IV, "Screening for Communicable Disease," subsection 4.2 is amended as follows:

4.2. Filing of Screening Test Results With The Division. The Alien Employee's Physician shall provide the ~~Employer~~ **Division** with a copy of all screening test results required by this Section 4 and by the Secretary's health advisories within forty-five (45) days from the date of the Alien Employee's initial Physical Examination, and forty-five (45) days from the date of each annual Physical Examination thereafter. The screening test results shall be included in the sealed envelope marked "Confidential" containing the Physical Examination form. ~~It shall then be the responsibility of the Employer to submit the sealed envelope containing the screening test results to the Division within ten (10) days from receipt from the Physician~~.

Section VI, "Division Record Keeping and Tracking Measures," subsection 6.3 is amended as follows:

6.3. Notice of Noncompliance. If a review of the Division's database indicates that an Alien Employee has not been issued a Health Certificate within ninety (90) days from the Alien Employee's date of entry into the CNMI, Division staff shall send written notice to the Alien Employee~~, with a copy provided to the Employer,~~ of noncompliance with these Rules and Regulations. The Alien Employee shall have twenty (20) days from the date of the notice to come into compliance with the requirements of these Rules and Regulations. Failure to respond to the Division's notice shall subject the Alien Employee ~~and the Employer~~ to penalties as set forth in Section 10 of these Rules and Regulations. This Section 6.3 shall not apply to those Alien Employees who have not been issued Health Certificates because they are undergoing treatment for a communicable disease, and who remain fully compliant with the Division's prescribed treatment regimen for the duration of treatment. An Alien Employee undergoing treatment shall be issued a letter by the Division setting forth the date treatment is anticipated to be completed and when a Health Certificate can be issued.

Section IX, "Application of These Rules and Regulations To Alien Employees and Their Dependents Currently Residing In the CNMI," is amended as follows:

Upon the effective date of these Rules and Regulations, all Alien Employees and their Dependents currently residing in the CNMI shall have ninety (90) days to obtain a Health Certificate in order to be in compliance with the requirements of these Rules and Regulations. Those Alien Employees and their Dependents who have already had a Physical Examination or screening tests required by these Rules and Regulations in the CNMI for the year shall not be required to obtain new ones, but the ~~Employer or~~ Alien Employee shall be required to bring the results of the Physical Examination and/or screening test results to the Division for entry into the database and for issuance of the Health Certificate.

Section X, "Penalties For Violations of These Rules and Regulations," is amended by deleting subsection 10.2 in its entirety, and renumbering subsection 10.3 and 10.4 accordingly. Section X shall now read as follows:

10.1. Penalties for Alien Employees. Alien Employees who are found to be in violation of these Rules and Regulations shall be reported to the Division of Immigration, Department of Labor and Immigration and recommended for Deportation back to their country of origin. The costs associated with Deportation shall be the financial responsibility of the Employer.

~~10.2. Penalties for Employers. An Employer found to be employing an Alien Employee who has not been issued a Health Certificate by the Secretary and is not undergoing treatment at the Division, or an Employer otherwise violating the provisions of these Rules and Regulations shall be subject to the following penalties:~~

~~a) For first time violations, the Employer shall receive a warning letter from the Division setting forth a compliance date for obtaining a~~

~~Health Certificate for the Alien Employees who have not obtained Physical Examinations and screening tests;~~

~~b) For second time violations, the Employer shall be subject to a fine of $200 for each Alien Employee who does not have a valid Health Certificate and is not undergoing treatment at the Division;~~

~~c) For repeat violations, the Employer shall be subject to a fine of up to $1,000 for each Alien Employee who does not have a valid Health Certificate and is not undergoing treatment at the Division.~~

10.2. Penalties for Dependents. Dependents age eighteen (18) or older who are found to be in violation of these Rules and Regulations shall be reported to the Division of Immigration, Department of Labor and Immigration and recommended for Deportation back to their country of origin. Dependents under age eighteen (18) who are found to be in violation of these Rules and Regulations shall be reported to the Division of Immigration, Department of Labor and Immigration and recommended for Deportation back to their country of origin along with an adult Dependent, or if there is no adult Dependent legally responsible for the minor in the CNMI, then with the Alien Employee. The costs associated with Deportation shall be the financial responsibility of the Dependent or the Alien Employee.

10.3. Penalties For Other Violations. Any person found by the Department to have obtained a Health Certificate by fraudulent means; forged or altered information on a Physical Examination form or screening test; refused or failed to comply with any order issued by the Secretary or Duly Authorized Representative pursuant to these Rules and Regulations, or violated these Rules and Regulations in any other manner, shall be liable for a civil penalty of up to $1,000.00 for each violation of the Rules and Regulations.

Office of the Secretary
Department of Finance

P.O. Box 5234 CHRB SAIPAN, MP 96950 TEL. (670) 664-1100 FAX: (670) 664-1115

NOTICE AND CERTIFICATION OF ADOPTION OF THE RULES AND REGULATIONS FOR THE VIEWERS TAX

I, Esther A. Calvo, Acting Secretary of Finance, hereby notify the general public of the adoption of the "Viewers Tax Regulations" as published in the CNMI Commonwealth Register on November 15, 1998 (Volume 20, No. 11 at pages 16289 - 16295) with one typographical correction. Section 3.1 should read as follows:

> "Section 3.1. Declaration of Tax. Every person subject to tax under Section ~~3~~ 2 shall make a report and pay the tax to the Secretary of Finance in the manner prescribed in these Regulations, setting forth the number of video tapes rented and the number of admission tapes sold."

By my signature below, I hereby certify that the published Viewers Tax Regulations are a true, correct, and complete copy of the Online Lottery Rules adopted by the Office of the Secretary of Finance, with the exception of the above-referenced typographical correction.

I declare under penalty of perjury that the foregoing is true and correct and that the declaration was executed on the 14th day of December 1998 in Saipan, Commonwealth of the Northern Mariana Islands.

Esther A. Calvo
Secretary of Finance [Acting]

Filed By: _____ 12/14/98
Soledad B. Sasamoto Date
Registrar of Corporations

Received By: _____ 12/14/98
Jose I. DeLeon Guerrero Date
SAA, Office of the Governor

Pursuant to 1 CMC §2153 as amended by P.L. 10-50, the rules and regulations attached hereto have been reviewed and approved as to form and legal sufficiency by the CNMI Attorney General's Office.

Dated this 14th day of December 1998

Maya B. Kara
Attorney General [Acting]

By: _____
Elliott M. Sattler, AAG

Revenue and Taxation
Department of Finance

P.O. Box 5234 CHRB SAIPAN, MP 96950 TEL. (670) 664-1000 FAX. (670) 664-1015

NOTICE AND CERTIFICATION OF ADOPTION OF THE RULES AND REGULATIONS FOR THE RULES OF PLAY FOR THE ONLINE LOTTERY GAMES OF THE CNMI LOTTERY

I, Lucy DLG Nielsen, Secretary of Finance, as successor, pursuant to Section 307(a) of Executive Order 94-3, to the Lottery Commission, hereby notify the general public of the adoption of the "Rules and Regulations for the Rules of Play for the Online Lottery Games of the CNMI Lottery" (hereinafter 'Online Lottery Rules") as published in the CNMI Commonwealth Register on July 15, 1998 (Volume 20, No. 7 at pages 15984 - 15895).

By my signature below, I hereby certify that the published Online Lottery Rules are a true, correct, and complete copy of the Online Lottery Rules adopted by the Office of the Secretary of Finance.

I declare under penalty of perjury that the foregoing is true and correct and that the declaration was executed on the 11th day of December 1998 in Saipan, Commonwealth of the Northern Mariana Islands.

Lucy DLG Nielsen
Secretary of Finance

Filed By: _____ 12/14/98
Soledad B. Sasamoto Date
Registrar of Corporations

Received By: _____ 12/14/98
Jose L. DeLeon Guerrero Date
SAA, Office of the Governor

Pursuant to 1 CMC §2153 as amended by P.L. 10-50, the rules and regulations attached hereto have been reviewed and approved as to form and legal sufficiency by the CNMI Attorney General's Office.

Dated this 11th day of December 1998

Maya B. Kara
Attorney General [Acting]

By: _____
Elliott A. Sattler, AAG

COMMONWEALTH PORTS AUTHORITY

Main Office: SAIPAN INTERNATIONAL AIRPORT
P.O. BOX 1055 • SAIPAN • MP 96950
Phone: (1-670) 664-3500/1 FAX: (1-670) 234-5962
E-Mail Address: cpa.csalas@saipan.com OR cpa.frosario@saipan.com

PUBLIC NOTICE

ADOPTION OF RULES AND REGULATIONS GOVERNING TEMPORARY LAND USE PERMITS

The Commonwealth Ports Authority (CPA), pursuant to its rule-making authority under 2 CMC §2122(j), and in accordance with the provisions of 1 CMC 9102, 9104(a) and 9105, hereby gives notice that the proposed Rules and Regulations Governing Temporary Land Use Permits, published in the Commonwealth Register Volume 20, Number 9, on September 15, 1998 at pages 16137 through and including 16151, were adopted by the CPA Board at its regular meeting on November 13, 1998.

Comments regarding the proposed rules and regulations were received and have been reviewed and were incorporated in the adopted regulations. Because some of the final changes made are different from the proposed rules and regulations, the adopted regulations are hereby published in its entirety. Copies of the rules and regulations may be obtained from the Office of the Executive Director, Commonwealth Ports Authority, Saipan International Airport or request by mail to Post Office Box 1055, Saipan, MP 96950.

The adopted Rules and Regulations Governing Temporary Land Use Permits become effective ten (10) days after publication in the Commonwealth Register.

Issued by: _____ 11/16/98
CARLOS H. SALAS, Executive Director — Date
Commonwealth Ports Authority

Received by: _____ 11/16/98
Jose I. Deleon Guerrero — Date
Special Assistant for Administration

Filed and
Recorded by: _____ 12/14/98
Soledad B. Sasamoto — Date
Registrar of Corporations

Pursuant to 1 CMC 2153 as amended by PL 10-50, the rules and regulations attached hereto have been reviewed and approved as to form and legal sufficiency by the CNMI Attorney General's Office.

Dated this 11th day of Dec., 1998.

By: _____
Attorney General (Acting)
Assistant Attorney General
Elliott A. Sattler

SAIPAN INTERNATIONAL AIRPORT/SEAPORT *P.O. Box 1055, Saipan, MP 96950*
ROTA INTERNATIONAL AIRPORT/SEAPORT *P.O. Box 561, Rota, MP 96951*
WEST TINIAN AIRPORT/SEAPORT *San Jose Village, Tinian, MP 96952*

COMMONWEALTH PORTS AUTHORITY

Main Office: SAIPAN INTERNATIONAL AIRPORT
P.O. BOX 1055 • SAIPAN • MP 96950
Phone: (1-670) 664-3500/1 FAX: (1-670) 234-5962
E-Mail Address: cpa.csalas@saipan.com OR cpa.frosario@saipan.com

NUTISIAN PUPBLIKU

INADAPTAN I AREKLAMENTO YAN REGULASION PUT GINOBETNAN LISENSIAN MAUSAN TANO TEMPURARIU

I Commonwealth Ports Authority (CPA), sigun gi aturidat-na para u famatinas areklamento gi papa 2 CMC §2122(j), yan sigun gi prubinsion siha ginen 1 CMC 9102, 9104(a) yan 9105, ginen este ha nutitisia i put i mapropopone siha na Areklamento yan Regulasion put Ginobetnan Lisensian Ma'usan Tano Tempurariu, ni mapupblika gi Rehistran Commonwealth Baluma 20, Numiru 9, gi Septiembre 15, 1998 gi pahina 16137 asta yan enklusu 16151, esta manma adapta ni CPA Board gi regulat na huntan-niha, Nobembre 13, 1998.

Komento put I manmapropopone siha na areklamento yan regulasion manmarisibi yan ma'inan maolek yan manadanna halom gi I manma adapta siha na regulasion. Put I rason na guaha uttimu siha na tinulaika yan mandiferensiao yan ayu I manmapropopone siha na areklamento yan regulasion, ni manma adapta siha na areklamento yan regulasion esta manma adapta enteramente. Para hayi gai interes guaha kopian I areklamento yan regulasion guatu gi Ofisinan Direktot Eksekatibu, Commonwealth Ports Authority, Saipan International Airport pat sina un fangagao ginen mail ya un nahanao guatu gi Post Office Box 1055, Saipan, MP 96950.

I manma adapta siha na Areklamento yan Regulasion ni para u Ginobetna Lisensian Temporariu na Mausan Tano, u efektibu dies (10) dias despues di mapupblika gi Rehistran Commonwealth.

Linaknos as: _____ 11/16/98
CARLOS H. SALAS, Executive Director — Fecha
Commonwealth Ports Authority

Rinisibi as: _____ 11/14/98
Jose L. Deleon Guerrero — Fecha
Special Assistant for Administration

Ma File yan rekot as: _____ 11/14/98
Soledad B. Sasamoto — Fecha
Rehistradoran Kotporasion

COMMONWEALTH PORTS AUTHORITY

Main Office: SAIPAN INTERNATIONAL AIRPORT
P.O. BOX 1055 • SAIPAN • MP 96950
Phone: (1-670) 664-3500/1 FAX: (1-670) 234-5962
E-Mail Address: cpa.csalas@saipan.com OR cpa.frosario@saipan.com

ARONGORONGOL TOULAP
ADOPTIONUL ALLEGH REEL LEMELEMIL TEMPORARY PERMITS
REEL YAAYAAL FALOW

Commonwealth Ports Authority, sangi bwangil iye e lo faal 2 CMC §2122(j) me ebwe wel me meta kka e lo llol autol 1 CMC §9102, 9104(a) me 9105, sangi milleel ekke arong reel pomwol Allegh kkaal ikka Lemeli mille Temporary Permits reel Yaayaal Faluw, iye e poblikalong Commonwealth Register Volume 20, Number 9, llol maram ye Sarobwel (September) 15, 1998 reel peigh kka 16137 mwet ngali me e bwal toolong 16151, igha re adoptaal llol yaar yeelaghil CPA Board llol maram ye Aremwoy (November) 13, 1998.

Mangemang me tip reel pomwol feerul allegh nge ra bwughil me amwuri fischiiy me aschuwelong llol allegh kka a llugheey lo igha eyoor milikka e lliiwel nge ese weewe tengal me ikka e lo llol pomwol lleerul allegh, nge allegh kka a llugheey lo nge re adoptaali alongal. Kkopiyal aliegh kkaal nge emmwel schagh bwe iyo ye e tipali nge ebwe 1o bweibowgh mellol Bwulasiyol Executive Director Commonwealth Ports Authority, Saipan International Airport me tingor mellol mail reel Post Office Box 1055, Saipan, MP 96950.

Allegh kka a llugheey lo iye ebwe Lemeli Temporary Permits reel Yaayaal Faluw nge ebwe bweleta llol seigh (1) ral sangi igha e toowow mellol Commonwealth Register.

Isaliyalewow: _____ 11/16/98
CARLOS H. SALAS, Executive Director — Ral

Bwughiyal: _____ 11/14/98
Jose I. Deleon Guerrero — Ral
Special Assistant for Administration

Isaliyal me Rekodival: _____ 12/14/98
Soledad B. Sasamoto — Ral
Registrar of Corporations

SAIPAN INTERNATIONAL AIRPORT/ SEAPORT *P.O. Box 1055, Saipan, MP 96950*
ROTA INTERNATIONAL AIRPORT/SEAPORT *P.O. Box 561, Rota, MP 96951*
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COMMONWEALTH PORTS AUTHORITY

Main Office: SAIPAN INTERNATIONAL AIRPORT
P.O. BOX 1055 • SAIPAN • MP 96950
Phone: (1-670) 664-3500/1 FAX: (1-670) 234-5962
E-Mail Address: cpa.csalas@saipan.com OR cpa.frosario@saipan.com

CERTIFICATION OF ADOPTION OF RULES AND REGULATIONS GOVERNING TEMPORARY LAND USE PERMITS

I, CARLOS H. SALAS, Executive Director of the Commonwealth Ports Authority (CPA), the agency which is promulgating Rules and Regulations Governing Temporary Land Use Permits, published in the Commonwealth Register under Volume 20, Number 9, on September 15, 1998 at pages 16137 through and including 16151, by signature below hereby certify that the final rules and regulations were adopted by the CPA Board at its regular meeting on November 13, 1998.

The adopted regulations contain changes suggested by comments received from the public. Because some of the final changes made are different from the proposed rules and regulations, the adopted regulations should be published in its entirety. I further request and direct that this Notice and Certification of Adoption be immediately published in the Commonwealth Register.

I declare under penalty of perjury that the preceding rules and regulations are true and correct and that this declaration was executed on the 16th day of November, 1998, at Saipan, Commonwealth of the Northern Mariana Islands.

CARLOS H. SALAS, Executive Director
Commonwealth Ports Authority

RULES AND REGULATIONS GOVERNING TEMPORARY LAND USE PERMITS

PART I
GENERAL PROVISIONS

1.1 Authority

a. These regulations are hereby promulgated by the Commonwealth Ports Authority ("CPA") in accordance with 2 CMC § 2122(j) and shall have the force and effect of law.

b. The CPA has the duty and responsibility to develop, maintain, operate and manage all air and sea ports within the Commonwealth of the Northern Mariana Islands pursuant to 2 CMC § 2122(a). CPA has certain airport lands under its jurisdiction and ownership, which are being reserved for future port development. These lands are being maintained as unimproved property, but may be used for farming, grazing or other activities so that they remain in a clean and unobstructive state. CPA finds that such lands would best be maintained by farmers and ranchers willing to clean and maintain the lands in return for short-term farming, grazing or short-term non-commercial/commercial purposes under the terms of these regulations and the temporary permit issued. The activities permitted under these regulations shall be deemed "port-connected" pursuant to the requirements of 2 CMC § 2122(e) and as a matter of CPA policy.

1.2 Purpose of the Regulations

a. To establish a uniform land use policy regarding the application, review, and award of agricultural, grazing, and short-term non-commercial or commercial permits to use CPA lands without erecting any permanent improvement thereon.

b. To establish uniform terms and conditions for the use of CPA lands pursuant to temporary land use permits.

c. To ensure that the award of temporary land use permits do not violate any applicable local or federal law, regulation, or policy, and that the mission and best interest of the CPA are carried out and promoted.

1.3 Applicability

These regulations shall apply to all agricultural, grazing and other short-term non-commercial or commercial permits, subject to cancellation at the discretion of the CPA, with or without cause, as provided for under these regulations. These regulations shall not apply to commercial leases and concessions with a term of more than one (1) year, or to other commercial arrangement related to CPA operation of airport and seaport properties.

1.4 Definitions

a. "Application" or "Renewal Application" means the temporary land use permit application made on form provided by the Authority and available to all permit applicants, existing or prospective.

b. "Authority" or "CPA" means the Commonwealth Ports Authority.

c. "Board" or "Board of Directors" means the Board of Directors of the Commonwealth Ports Authority.

d. "CPA Lands," for purposes of these regulations means any unimproved airport land owned by or is under the control of the Authority and which has been designated by CPA for agricultural, grazing or short-term non-commercial or commercial use.

e. "Executive Director" means the Executive Director of the CPA or his designee.

f. "Permanent Improvement" means any permanent or fixed structure, constructed of materials generally associated with permanency such as concrete, hollow block or metal, and incapable of being dismantled or removed upon expiration of the permit except through demolition or destruction of the improvement.

g. "Permit" means the legal instrument issued by the Authority authorizing the agricultural, grazing, short-term commercial or non-commercial use of CPA lands and issued pursuant to these regulations, or were issued prior to these regulations but are now made subject to these regulations.

h. "Permittee" means the person issued a permit to use CPA lands, pursuant to these regulations and the terms and conditions of the permit.

PART II
CANCELLATION OF EXISTING PERMIT AND APPLICATION FOR NEW PERMIT

2.1 Cancellation of Existing Permits

All existing permits for the use of CPA lands issued prior to the adoption of these regulations shall be canceled by the Authority no later than ninety (90) days after the effective date of these regulations. Any existing permittee of CPA lands who fails to file an application for a new permit as set forth in Section 2.2 below shall be deemed a trespasser after such period, and CPA may take any action, legal or equitable, to remove any unlawful occupant who does not have a valid permit to use CPA lands.

2.2 Application for New Permit

Any existing permittee who wishes to obtain a new permit to use CPA land as a result of the proposed termination of an existing permit, must file a completed application for a new permit with the Executive Director within ninety (90) days after the effective date of these regulations. Such person shall obtain an application form from the Authority. Any existing permittee making an application may be allowed to continue the use and occupancy of CPA land described by the canceled permit, pending the final decision of the Authority on the application for a new permit.

PART III
APPLICATION FOR A NEW PERMIT

3.1 Application Form

The Executive Director shall make available uniform application forms for agricultural, grazing, short-term commercial and non-commercial use of CPA lands. Application forms shall be available at the Authority's office at the Saipan International Airport on Saipan and at the office of the Airport manager on Tinian and Rota.

3.2 Application Fee

A non-refundable application fee of twenty-five dollars ($25.00) shall be assessed for each application. The fee shall be used to defray the cost of processing, review, and other administrative costs.

3.3 Renewal

Any permittee who wishes to renew his permit to use CPA land shall file a new application with the Authority no later than sixty (60) days prior to the expiration of the existing permit. All applications for renewal shall be accompanied with the standard application fee and any rental payment due and payable the Authority. No permit may be renewed without payment of the application fee and any outstanding rental due under the existing permit. Any permittee submitting an application for renewal under this section shall continue to use the CPA land he is occupying pending the final decision of the Authority on his application, provided that he pays all rental as the same become due and payable.

3.4 Permit Application for Newly Designated CPA Lands

a. The Authority may designate, for temporary land use permits, other idle lands under its ownership or control and which are being reserved for future port expansion or development by the Authority. The Authority may designate such property, as appropriate, for temporary use under permits issued pursuant to these regulations.

b. In the event the Authority designates for permit issuance any CPA lands, it shall publish a notice of intention to offer for temporary use permitting such CPA lands and shall prescribe in the notice the method for making application. Publication by notice in a newspaper of general circulation in the Commonwealth at least twice within thirty (30) days of CPA designation shall be made by the Authority.

3.5 Review and Award of Permit

(a) The Authority's Airport Facilities Committee shall review each application for a temporary permit to use CPA land. It may, as it deems necessary, provide for a public hearing on the permit applications for newly designated CPA land. If there is a hearing, each applicant shall be entitled to present testimony concerning his/her application and why his/her permit application, if granted, will serve the best interests of the Authority. The Authority may reject any and all application at its sole discretion. Notice of the award or denial of a permit application and the basis for the award or denial shall be given to all applicants.

(b) Where there are several permit applications for the same parcel of land, the Authority's Airport Facilities Committee will base its selection on the applicant's past experience and ability to successfully carry on the farming or cattle grazing activity, the applicant's relative need to support himself and his family, and the applicant's ability to comply with the permit terms and conditions and these regulations. Where all of the applicants appear to qualify for a permit, the Committee shall select the successful applicant by drawing of lots.

3.6 Appeal of Rejection of Application

Any unsuccessful permit applicant may appeal the decision of the Authority denying his application as provided in Section 4.14 below.

3.7 Restrictions on Who May Apply

No director, officer, or employee of the CPA, either personally or as an agent of another shall be permitted to apply or benefit directly or indirectly from a permit issued under these regulations. Any application submitted by a director, officer, employee or an immediate family member shall be summarily rejected. The restrictions imposed by 2 CMC § 2131 and the Ethics in Government Law shall apply.

PART IV
MINIMUM TERMS AND CONDITIONS OF PERMITS

4.1 Uniform Permit

The Authority shall prepare a uniform permit for all permittees. Such permit shall incorporate the terms and conditions of the regulations herein, in addition to other pertinent terms and conditions.

4.2 Term of Permit

All permits issued under these regulations shall be for a period not to exceed one year.

4.3 Other Conditions of Renewal

Any renewal application shall be subject to approval by the Executive Director, after payment of all fees and rentals, as set forth under Section 3.3 above. Any permittee who has complied with the terms of his permit throughout the duration of the permit and is seeking renewal of his permit shall be given priority over other applicants unless the Authority in its best judgment determines otherwise. Any decision to reject a permittee's renewal application and to award a new permit to another applicant must be for good and justifiable reasons and shall not be based on arbitrary or capricious reasons.

4.4 Rentals

Rental rates shall be assessed on a per acreage basis, as stated below. For any land use not stated below, the Authority may impose a different rate, provided it is reasonable.

a. For non-commercial cattle grazing: $30.00 minimum per hectare per year.

b. For non-commercial agriculture (i.e. subsistence farming): $30.00 minimum per hectare per year.

c. For short-term commercial agriculture: $30.00 minimum per hectare per year, plus three percent (3%) of that portion of permittee's Quarterly Business Gross Revenues attributable to the gross income received by permittee from commercial agricultural activity on CPA land covered by the permit. Permittee shall submit a copy of his quarterly BGRT within thirty (30) days after the end of each quarter along with any payment due. Permittee shall, at all times, keep complete books and records evidencing all commercial transactions conducted on the permitted land.

d. For short-term plant nursery activity: $30.00 minimum per hectare per year plus three percent (3%) of that portion of permittee's Quarterly Business Gross Revenues attributable to the gross income received by permittee from commercial agricultural activity on CPA land covered by the permit. Permittee shall submit a copy of his quarterly BGRT within thirty (30) days after the end of each quarter along with any payment due. Permittee shall, at all times, keep complete books and records evidencing all commercial transactions conducted on the permitted land.

e. For other uses (including the use of land by government agencies and non-profit organizations): All applications for use of CPA lands other than for the above purposes shall require approval of the Board of Directors; and the Authority may use any other method to establish rental for such use as it deems fair and would further its best interest and the interest of people of the Commonwealth.

4.5 Security Deposit

Authority shall require each permittee to post a security deposit of $250.00, refundable without interest upon permit expiration on the condition that the permittee has restored the land to the satisfaction of the Authority and permittee has vacated the premises and has paid all due rentals, fees and charges.

4.6 Construction of Improvements

a. Permittee may construct temporary structures only (i.e. non-permanent improvements) on CPA land, only upon obtaining the prior written consent of the Authority, and under the following terms and conditions:

1. Permittee shall not construct any permanent improvement on the land, either concrete, metal, or otherwise. The determination of what is a permanent improvement shall lie with CPA alone.

2. Prior to construction of any temporary improvement on CPA land, a written request describing the proposed improvement and specifications thereto must be approved in advance in writing by Executive Director.

3. Any temporary improvement placed on CPA land shall not create a lien on the land.

4. Upon approval by the Authority, a permittee must obtain any required permits before using the land, from pertinent government agencies, including but not limited to: the Division of Environmental Quality, Department of Lands and Natural Resources, Coastal Resources Management, or Historic Preservation Office, and so forth.

5. Upon expiration of the term of the permit, permittee shall remove all the improvements placed thereon, at his sole expense.

b. The permittee shall not have any right to remain on CPA lands after the expiration or termination of his or her permit; and the Authority shall have the right to remove any improvement, fixture and other property of permittee and dispose of such as it sees fit. In exercising this right, the Authority shall:

1. Not be liable for damages to or loss of any property removed;

2. Have the right to recover costs of removal and/or storage or disposal; and,

3. Recover any attorney's fees or other costs incurred as a result.

4.7(1) Restrictions on Use

The following restrictions shall apply to the use of CPA land covered by a temporary use permit:

a. No employee barracks shall be constructed on CPA land.

b. No residential structure shall be constructed on CPA land.

c. No extension of any business other than agricultural/nursery shall be made, unless specifically approved by the Board of Directors and specifically identified in writing as a variance from these restrictions.

d. No mining, drilling, extraction of land, mineral, or soil shall be made on CPA land.

e. Permittee shall not use CPA land as a waste depositor or landfill.

f. Permittee shall not store explosives, dangerous chemicals, flammable and inflammable liquids or other hazardous materials on CPA land.

g. Permittee shall not conduct any hazardous activities on CPA lands.

h. No permit will be issued for CPA lands within 100 feet from any port perimeter fence.

i. Permittee shall not transplant any permanent trees growing on CPA land, such as coconut trees, fruit trees, breadfruit, etc., except upon the prior written approval of the Authority.

4.7(2) Monitoring for Compliance

To insure that these regulations and the terms and conditions imposed by the land use permit are complied with, CPA's Lease Enforcement and Compliance Office shall conduct regular visual inspections of the permitted premises and take such measures or actions needed to correct any violation of the permit terms and conditions and these regulations. Unannounced inspections shall be conducted and CPA shall not be prohibited by the Permittee or others acting for or on behalf of the Permittee from conducting such inspections. The CPA Comptroller's Office shall monitor and enforce all financial matters relating to the permit issued, including the collection of unpaid fees and charges.

4.8 Proper Maintenance of CPA Lands

All permittees shall properly maintain CPA lands at all times. A permittee shall not commit any waste of the property nor shall he remove any existing trees, or vegetation other than under-brush, shrubs and tangan-tangan. A permittee shall not allow litter, garbage or other refuse to accumulate on the property or allow the property to become an eyesore. Any property of the Authority which is damaged or destroyed by permittee shall be repaired or replaced by permittee.

4.9 Utilities

All electrical, water, telephone or other utility services may be installed but at permittee's expense and in permittee's own name. Permittee shall pay any and all utility bills and invoices as they come due. No utility provider shall be allowed to place any lien or encumbrance on CPA lands or any fixtures attached thereto as a result of a permittee's failure to pay any sums due for such utility services.

4.10 Permit Not Assignable

No permit issued under these regulations shall be assignable to any third party, for any reason. Any permit assigned or transferred to a person other than the named permittee shall be immediately canceled and terminated by the Authority.

4.11 Waiver of Aircraft Noise and Pollution Claims

Any person given a permit to use CPA lands under these regulations shall be deemed to have waived any claim or cause of action for aircraft nuisance, noise pollution, or other nuisance or pollution, for damages suffered for the loss of, or injury to, any crop or livestock against CPA, any airline, or aircraft operator conducting business or operating at any airport under the Authority's control.

4.12 Termination

a. Any permit issued pursuant to these regulations shall be terminable by either party, without cause.

b. A party may terminate a permit, to be effective forty-five (45) days after written notice to the other party.

c. Authority shall not be liable to the permittee for damages suffered due to any early termination of the permit.

d. Any permit issued hereunder shall include a waiver of any claim for assistance which might be afforded under the Federal Relocation Assistance Act.

e. Upon termination, permittee shall be solely responsible for removing any temporary improvements within the time allowed in the notice of termination.

f. Upon termination, permittee shall be responsible for restoring the land to the satisfaction of the Authority.

1. If permittee fails to restore CPA land to the satisfaction of the Authority, the Authority will make such restoration and deduct any and all costs and expenses incurred from the security deposit.

2. If the security deposit is insufficient to pay such expenses and costs, permittee shall reimburse the Authority for the additional expenses incurred by the Authority.

3. In the event the permittee fails to reimburse the Authority for any costs and expenses incurred, the Authority may file suit for damages to recover such costs and expenses. If successful in such suit, it shall be entitled to recover court costs and attorneys fees incurred.

4.13 Indemnification and Release of Liability

Permittee shall indemnify and hold the Authority, directors, officers, employees, and agents free and harmless from any and all liability for any damage to persons or property arising from permittee's activities on CPA land.

4.14 Right to Appeal

Permittee shall have the right to appeal the denial of any permit application, denial of renewal, permit termination, or other grievance within ten days after he knows or should have known the facts giving rise to such grievance. He may also request an extension of time to vacate CPA lands upon the termination of any permit. All appeals and requests for extension of time shall be filed in writing specifying the grounds therefore and addressed to the Executive Director. The CPA Board's Appeals Panel consisting of three Board members appointed by the Chairman shall consider and hear the appeal taken. The panel's decision shall be final and unreviewable.

4.15 Unilateral Modification

The Authority shall have the right to unilaterally amend any of the terms or conditions of any permit issued under these regulations, including any rates and charges stated therein, whether or

not any such amendments conform to these regulations, in order to conform with any applicable federal regulations or directives, or the order of any federal agency including but not limited to the Federal Aviation Administration and the U.S. Department of Transportation.

4.16 Attorney's Fees

In the event the Authority files any civil action with a court of competent jurisdiction to enforce any term or provision of these regulations or any permit issued hereunder, or for breach of any such term or condition, permittee shall pay Authority reasonable attorney's fees and court costs, if Authority is successful.

4.17 Applicable Laws

These regulations and any permit issued hereunder shall be interpreted in accordance with the laws of the Commonwealth of the Northern Mariana Islands.

4.18 Severability

If any of the provisions of these regulations or the terms and conditions of any permit issued hereunder is held invalid or unenforceable by a court of competent jurisdiction, the remainder of these regulations shall not be affected thereby.