COMMONWEALTH OF THE NORTHERN MARIANA ISLANDS
SAIPAN, TINIAN, ROTA and NORTHERN ISLANDS

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TABLE OF CONTENTS

TINIAN CASINO GAMING CONTROL COMMISSION
Municipality of Tinian and Aguiguan
Commonwealth of the Northern Mariana Islands

Esther Hofschneider Barr
Chairman

Jose P. Kiyoshi
Vice Chairman

Lydia F. Barcinas
Member

Patrick H. San Nicolas
Member

Charlene M. Lizama
Member

William M. Cing
Executive Director

PUBLIC NOTICE OF CERTIFICATION AND ADOPTION OF AMENDMENTS TO THE TCGCC PERSONNEL RULES AND REGULATIONS REGARDING PART 500 SUBSECTION 170-30.5-520 OTHER LEAVE OF THE TINIAN CASINO GAMING CONTROL COMMISSION

PRIOR PUBLICATION IN THE COMMONWEALTH REGISTER AS PROPOSED REGULATIONS
VOLUME 39, NUMBER 04, PAGES 39594-39602
OF APRIL 28, 2017

ACTION TO ADOPT THESE PROPOSED RULES AND REGULATIONS: The Tinian Casino Gaming Control Commission (TCGCC) finds that:

INTENDED ACTION TO ADOPT THESE PROPOSED RULES AND REGULATIONS: The Tinian Casino Gaming Control Commission HEREBY ADOPTS AS PERMANENT REGULATIONS the Proposed Regulations which were published in the Commonwealth Register at the above-referenced pages, pursuant to the procedures of the Administrative Procedure Act, 1 CMC § 9104(a). The Tinian Casino Gaming Control Commission announced that it intended to adopt them as permanent, and now does so. I also certify by signature below that:

> as published, such adopted regulations are a true, complete and correct copy of the Referenced Proposed Regulations, and that they are being adopted without modification or amendment.

PRIOR PUBLICATION: The prior publication was as stated above.

MODIFICATIONS FROM PROPOSED REGULATIONS, IF ANY: None.

AUTHORITY: The proposed Regulations are promulgated pursuant to the Commission's authority as provided by Part II Section 5(8)c of the Revised Tinian Casino Gaming Control Act of 1989 to establish regulations and the CNMI Administrative Procedures Act.

EFFECTIVE DATE: Pursuant to the Administrative Procedures Act, 1 CMC §9105(b), these adopted Regulations are effective 10 days after compliance with the Administrative Procedures Act, 1 CMC §9102 and §9104(a) or (b), which in this instance, is 10 days after this publication in the Commonwealth Register.

P.O. Box 520143 Tinian, MP 96952 * Tel: (670) 433-9288 * Fax:(670) 433-9290 *

COMMENTS AND AGENCY CONCISE STATEMENT: Pursuant to the Administrative Procedures Act, 1CMC §9104(a)(2), the agency has considered fully all written and oral submissions respecting the proposed regulations. Upon this adoption of the regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against its adoption. Please see the following pages for this agency's concise statement, if there are any, in response to filed comments.

I declare under penalty of perjury that the foregoing is true and correct copy and that this declaration was executed on the 30th day of May 2017, at Tinian, Commonwealth of the Northern Mariana Islands.

Certified and ordered by:

Esther Hofschneider Barr
Chairman

5/30/17
Date

Filed and recorded by:

Esther SN. Nesbitt
Commonwealth Registrar

06.19.2017
Date

Commonwealth Healthcare Corporation
Commonwealth of the Northern Mariana Islands
1 Lower Navy Hill Road Navy Hill, Saipan, MP 96950

PUBLIC NOTICE OF PROPOSED REVISION TO THE CHCC HUMAN RESOURCES RULES AND REGULATIONS

INTENDED ACTION TO ADOPT THESE PROPOSED REVISIONS TO THE RULES AND REGULATIONS: The Commonwealth Healthcare Corporation (CHCC) intends to adopt as permanent the attached Proposed Revision to the Rules and Regulations, pursuant to the procedures of the Administrative Procedure Act,1 CMC § 9104(a). The CHCC Human Resources Rules and Regulations were initially published in November, 2016 in Volume 38, Number 11 of the Commonwealth Register. They were adopted in February, 2017 in Volume 39, Number 2 of the Commonwealth Register. The Revision to the CHCC Human Resources Rules and Regulations will become effective 10 days after adoption and publication in the Commonwealth Register. (1 CMC § 9105(b))

AUTHORITY: CHCC is authorized to adopt rules and regulations as may be necessary for the implementation of this chapter. 3 CMC Section 2824(l). Furthermore, CHCC has developed and adopted a personnel system independent of the civil service system in accordance with the law. 3 CMC Section 2824(k).

THE TERMS AND SUBSTANCE: The CHCC Human Resources Rules and Regulations provide guidance on all aspects of the employment relationship between CHCC and its permanent, provisional, temporary, and contract employees.

THE SUBJECTS AND ISSUES INVOLVED: This Revision is to remove the Travel Policy from the CHCC Human Resources Rules and Regulations.

THE REVISION IS AS FOLLOWS:

Section 7.8 Travel Regulations: The entire section is removed. The numbering for the sections following it shall remain unchanged. Section 7.8 shall appear as [Removed].

DIRECTIONS FOR FILING AND PUBLICATION: These Notice of Proposed Revision to the Regulations shall be published in the Commonwealth Register in the section on proposed and newly adopted regulations (1 CMC § 9102(a)(1)) and posted in convenient places in the civic center and in local government offices in each senatorial district, both in English and in the principal vernacular. (1 CMC § 9104(a)(1)) Copies are available upon request from Clarinda Ngirausui, Human Resources Director.

P.O. Box 500409 CK, Saipan, MP 96950
Telephone: (670) 234-8950 FAX: (670) 236-8930

TO PROVIDE COMMENTS: Send or deliver your comments to Esther Muna, *Attn: Revision to CHCC HR Rules and Regulations*, at the above address, fax or email address, with the subject line "Travel Policy Revision." Comments are due within 30 days from the date of publication of this notice. Please submit your data, views or arguments. (1 CMC § 9104(a)(2)).

This proposed revision was approved by the CEO on 23rd of May, 2017.

Submitted by: _____ 05/23/17
ESTHER MUNA, CEO Date

Received by: _____ 5/31/17
SHIRLEY CAMACHO-OGUMURO Date
Governor's Special Assistant for Administration

Filed and
Recorded by: _____ 06.19.2017
ESTHER SN. NESBITT Date
Commonwealth Register

Pursuant to 1 CMC § 2153(e) (AG approval of regulations to be promulgated as to form) and 1 CMC § 9104(a)(3) (obtain AG approval) the proposed regulations attached hereto have been reviewed and approved as to form and legal sufficiency by the CNMI Attorney General and shall be published, 1 CMC § 2153(f) (publication of rules and regulations).

Dated the 19 day ~~of~~ June, 2017.

_____
EDWARD E. MANIBUSAN
Attorney General

P.O. Box 500409 CK, Saipan, MP 96950
Telephone: (670) 234-8950 FAX: (670) 236-8930

Commonwealth Healthcare Corporation
Commonwealth gi Sangkattan na Islas Mariånas
1 Lower Navy Hill Road, Saipan, MP 96950

NUTISIAN PUPBLIKU NI MANMAPROPONI NA TINILAIKA PARA I AREKLAMENTU YAN REGULASION I HUMAN RESOURCES GI CHCC

I AKSION NI MA'INTENSIONA PARA U MA'ADÅPTA ESTI I MANMAPROPONI NA AREKLAMENTU YAN REGULASION SIHA: I Commonwealth Healthcare Center (CHCC) ha intensiona para u ma´adåpta komu petmanienti i regulasion siha i mañechetton i Manmaproponi na Tinilaika para i Areklamentu yan Regulasion siha, sigun gi manera siha gi Åkton Atministrasion Procedure, 1 CMC § 9104(a). **I Areklamentu yan Regulasion i Human Resources giya CHC ginin manmapupblika gi hålom Nubembri, 2016 hålom Baluma 38, Numiru 11 gi Rehistran Commonwealth. Manma´adåpta gi hålom Fibreru, 2017 hålom Baluma 39, Numiru 2 gi Rehistran Commonwealth.** I Tinilaika para i Areklamentu yan Regulasion i Human Resources gi CHCC mu ifektibu gi hålom dies (10) dihas dispues di adåptasion yan pupblikasion gi hålom i Rehistran Commonwealth. (1 CMC § 9105(b))

ÅTURIDÅT: I CHCC ma´aturisa ni para u adåpta i areklamentu yan regulasion siha komu nisisåriu para i implimentasion nu esti na påtti. 3 CMC Seksion 2824(l). Yan más, i CHCC mafa´tinas yan ma´adåpta i personnel system independent nu i civil na setbision sistema ni inaprueba yan i lai. 3 CMC Seksion 2824(k).

I TEMA YAN SUSTÅNSIAN I PALÅBRA SIHA: I Areklamentu yan Regulasion i Human Resources ha pribeni guidance gi todu aspects nu i rilasion i impli´åo entalu´ i CHCC yan i iyo-ñiha petmanienti, provisional, tempuråriu, yan i kontrak na impli´åo siha.

I SUHETU YAN MANERA SIHA NI MANTINEKKA: Esti na Tinilaika para u na´suha i Travel Policy ginen i Areklamentu yan Regulasion i Human Resources gi CHCC.

I TINILAIKA MANTINATTIYI:

Seksion 7.8 Regulasion Travel Siha: Todu i seksion mana´suha. I numeru para i seksion siha ni mantinattitiyi debi na sumåga ya ti matulaika. Seksion 7.8 debi na annuk na [Mana´suha].

DIREKSION SIHA PARA U MAPO´LU YAN PUPBLIKASION: Esti na Nutisia nu i Manmaproponi na Rvision para Regulasion siha debi na u mapupblika gi hålom i Rehistran Commonwealth gi hålom i seksiona gi maproponi yan nuebu na ma'adåpta na regulasion siha (1 CMC § 9102(a)(1) yan u mapega gi hålom i mangkumbinienti na lugåt gi hålom i Civic Center yan i hålom ufisinan gubietnamentu siha gi kada distritun senadot, parehu English yan i dos na lingguåhi Chamorro yan Refaluwasch. (1 CMC § 9104(a)(1) Managuaha kopia siha yanggin manrikuesta hao ginen as Clarinda Ngirausui, i Direktot Human Resources.

P.O. Box 500409 CK, Saipan, MP 96950
Tilifon: (670) 234-8950 Fax: (670) 236-8930

PARA U MAPRIBENIYI OPIÑON SIHA: Nå´hånao pat intrega i upiñon-mu siha guatu gi as Esther Muna; Attn: *Tinilaika para i Areklementu yan Regulasion i HR gi CHCC*, gi sanhilo´ na address, fax pat email address, yan i subject line "Tinilaikan Travel Policy." Todu upiñon debi na u fanhålom trenta (30) dihas ginen i fetchan pupblikasion esti na nutisia. Put fabot na´hålom iyon-mu data, upiñon, yan kuntestasion siha. (1 CMC § 9104(a) (2))

Esti siha i manmaproponi na tinilaika ma´aprueba ginen i CEO gi diha 23 gi Mayu, 2017.

Nina'hålom as: _____ 05/23/17
ESTHER MUNA, CEO — Fetcha
Commonwealth Healthcare Corp.

Rinisibi as: _____ 5/31/17
SHIRLEY P. CAMACHO-OGUMORO — Fetcha
Espisiåt Na Ayudånti Para I Atministrasion

Pine'lu Yan
Ninota as: _____ 06.19.2017
ESTHER SN. NESBITT — Fetcha
Rehistran Commonwealth

Sigun i 1 CMC § 2153(e) (I Abugådu Henerål ha aprueba i regulasion siha na para u macho´gui kumu fotma) yan 1 CMC § 9104(a)(3) (hentan inaprueban Abugådu Henerål) i manmaproponi na regulasion siha ni mañechettun guini ni manmaribisa yan ma´aprueba kumu para fotma yan sufisienti ligåt ginin i CNMI Abugådu Henerål yan debi na u mapupblika sigun gi , 1 CMC § 2153(f) (pupblikasion areklamentu yan regulasion siha).

Mafetcha gi diha 19 gi Mayu, 2017.

_____
EDWARD E. MANIBUSAN — Fetcha
Abugådu Henerål

P.O. Box 500409 CK, Saipan, MP 96950
Tilifon: (670) 234-8950 Fax: (670) 236-8930

Commonwealth Healthcare Corporation
Commonwealth of the Northern Mariana Islands
1 Lower Navy Hill Road Navy Hill, Saipan, MP 96950

PUBLIC NOTICE OF PROPOSED
REVISION TO CHCC PROCUREMENT REGULATIONS

INTENDED ACTION TO ADOPT THESE PROPOSED REVISIONS TO THE RULES AND REGULATIONS: The Commonwealth Healthcare Corporation (CHCC) intends to adopt as permanent the Proposed Revisions to the CHCC Procurement Rules and Regulations listed below, pursuant to the procedures of the Administrative Procedure Act,1 CMC § 9104(a). The CHCC Procurement Rules and Regulations were promulgated as Emergency Regulations with an Intent to Adopt as Permanent Regulations at 37 Com. Reg. 36882 (Sept. 28, 2015). They were adopted 37 Com. Reg. 37237 (Nov. 28, 2015). The Revision will become effective 10 days after adoption and publication in the Commonwealth Register. (1 CMC § 9105(b))

AUTHORITY: CHCC is authorized to adopt rules and regulations as may be necessary for the implementation of this chapter. 3 CMC Section 2824(l).

THE TERMS AND SUBSTANCE OF THE REVISION are in bold type below:

§ 140-80.1-205(f) Public Notice

(f) Public Notice.
Because of the unique nature and varied needs of all parts of the institution, the CEO and the CHCC Director of P&S shall make a determination as to the best way to publicize the ITB.
(1) Every procurement in excess of $10,000 (except for medical services, equipment, supplies or devices within the range for Small Purchase as detailed in § 140-80.1-220), shall be publicized in one or more of the following ways:
(i) in a newspaper of general circulation;
(ii) in a newspaper of local circulation in the area pertinent to the procurement;
(iii) in industry media;
(iv) through electronic mailing lists,
(v) through the internet, agency web site, or other publicly accessible electronic media,
(vi) through electronic mailing lists, or
(vii) in a government publication designed for giving public notice.

§ 140-80.1-220 Small Purchases

a) Any procurement not exceeding the amounts established herein may be made in accordance with small purchase procedures. However, procurement requirements shall not be artificially divided so as to constitute a small purchase.

P.O. Box 500409 CK, Saipan, MP 96950
Telephone: (670) 234-8950 FAX: (670) 236-8930

(b) Bidding is not required for procurement ~~over $5000~~ valued at $3000 or below.

(c) Bidding is not required but is encouraged for procurement over ~~$5,000~~ $3000 and up to $10,000 ~~under $25,000,~~ or $50,000 if it is medical services, equipment, supplies, or devices. The CEO, the official with expenditure authority, must verify that the appropriate manager or other employee attempting to procure the goods or services has obtained under $25,000, obtain price quotations from at least three vendors and base the selection on competitive price and quality for procurement valued ~~at $5,000 to $25,000~~ **over $3000 up to $10,000, or $50,000 only** or $50,000 for medical services, equipment, supplies, or devices. Any price quotations obtained must be written, documented, and submitted to the CHCC P&S Director for approval.

(d) Purchase orders may be used for small purchases pursuant to subsections (b) and (c).

In addition, there shall be the following word substitutions:

For § 140-80.1-225(b), the word "prepared" shall be deleted and the word "approved" substituted.

(b) For any sole source procurement pursuant to subsection (a)(1), a written justification for sole source procurement shall be ~~prepared~~ approved by the CEO, the official with expenditure authority, and shall contain the specific unique capabilities required; the specific unique capabilities of the contractor; the efforts made to obtain competition; and the specific considerations given to alternative sources and specific reasons why alternative sources were not selected.

For § 140-80.1-230(b), the word "made" shall be deleted and the word "approved" substituted.

(b) A written justification of the basis for the emergency and for the selection of the particular contractor must be ~~made~~ approved by the CEO, the official with expenditure authority.

THE SUBJECTS AND ISSUES INVOLVED: Small Purchases, Sole Source Procurement, Emergency Procurement.

DIRECTIONS FOR FILING AND PUBLICATION: These Notice of Proposed Revision to Regulations shall be published in the Commonwealth Register in the section on proposed and newly adopted regulations (1 CMC § 9102(a)(1)) and posted in convenient places in the civic center and in local government offices in each senatorial district, both in English and in the principal vernacular. (1 CMC § 9104(a)(1)) Copies are available upon request from Janet Guerrero at 236-8202. CHCC, at its option, may choose to furnish documents electronically rather than hard or paper copies.

P.O. Box 500409 CK, Saipan, MP 96950
Telephone: (670) 234-8950 FAX: (670) 236-8930

TO PROVIDE COMMENTS: Send or deliver your comments to Esther Muna, Attn: Procurement Revisions, at the above address, fax or email address, with the subject line "Procurement Revisions". Comments are due within 30 days from the date of publication of this notice. Please submit your data, views or arguments. (1 CMC § 9104(a)(2)).

These proposed regulations were approved by the CEO on 23rd of May, 2017.

Submitted by: _____ 05/23/17
ESTHER MUNA, CEO Date

Received by: _____ 5/31/17
SHIRLEY CAMACHO-OGUMURO Date
Governor's Special Assistant for Administration

Filed and
Recorded by: _____ 06.19.2017
ESTHER SN. NESBITT Date
Commonwealth Register

Pursuant to 1 CMC § 2153(e) (AG approval of regulations to be promulgated as to form) and 1 CMC § 9104(a)(3) (obtain AG approval) the proposed regulations attached hereto have been reviewed and approved as to form and legal sufficiency by the CNMI Attorney General and shall be published, 1 CMC § 2153(f) (publication of rules and regulations).

Dated the 19th day of ~~May~~ JUNE, 2017.

_____
EDWARD E. MANIBUSAN
Attorney General

P.O. Box 500409 CK, Saipan, MP 96950
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Commonwealth Healthcare Corporation
Commonwealth gi Sangkattan na Islas Mariånas
1 Lower Navy Hill Road, Saipan, MP 96950

NUTISIAN PUPBLIKU NI MANMAPROPONI NA TINILAIKA PARA REGULASION PROCUREMENT SIHA GI CHCC

I AKSION NI MA'INTENSIONA PARA U MA'ADÅPTA ESTI I MANMAPROPONI NA AREKLAMENTU YAN REGULASION SIHA: I Commonwealth Healthcare Center (CHCC) ha intensiona para u ma´adåpta komu petmanienti i regulasion siha i mañechetton i Manmaproponi na Tinilaika para i CHCC Regulasion Procurement siha ni malista papa´, sigun gi manera siha gi Åkton Atministrasion Procedure, 1 CMC § 9104(a). I Regulasion Procurement i CHCC manmacho´gui kumu Prisisu na Regulasion siha yan i intensiona para u Adåpta kumu Petmanienti na Regulasion siha gi 37 Com. Reg. 36882 (Septembri. 28, 2015). Manma´adåpta gi 37 Com. Reg. 37237 (Nubembri 28, 2015). I Tinilaika siha para u ifektibu gi hålom dies (10) dihas dispues di adåptasion yan pupblikasion gi hålom i Rehistran Commonwealth. (1 CMC § 9105(b))

ÅTURIDÅT: I CHCC ma´aturisa ni para u adåpta i areklamentu yan regulasion siha komu nisisåriu para i implimentasion nu esti na påtti. 3 CMC Seksion 2824(l).

I TEMA YAN SUSTÅNSIAN I PALÅBRA NA TINILAIKA SIHA manma-bold type gi sanpapa´:

§140-80.1-205(f) Nutisian Pupbliku

Put i unique nature yan difirentis na nisisidåt gi todu i påtti gi institution, i CEO yan i Direktot i CHCC nu i P&S debi na u mafa´tinas ditetminasion komu gi maolik na manera para u pupblika i ITB. (1) Kada procurement ni inipus $10,000 **(fuera para setbision mediku siha, equipment, pribension siha pat devices gi hålom i range para Dikiki´ na Finåhan siha komu detailed gi hålom § 140-80.1-220),** debi na u mapupblika gi hålom unu pat más gi tinattiyi na manera siha:
(i) gi hålom gaseta nu i general circulation;
(ii) gi hålom gaseta nu i local circulation gi hålom i lugåt ni aplikåo para i procurement;
(iii) gi hålom industry media;
(iv) gi listan i electronic mailing siha,
(v) gi internet, i web site i ahensia, pat otru na publicly accessible electronic media, pat
(vi) gi hålom pupblikasion i gubietnamentu ni ma-designed para mannånå´i nustisian pupbliku.

§140-80.1-220 Dikiki´ na Finåhan

P.O. Box 500409 CK, Saipan, MP 96950
Tilifon: (670) 234-8950 Fax: (670) 236-8930

(a) Maseha håfa na procurement ni ti inipus i ma'establisi na amount siha guini hålom siña ha' mafa'tinas sigun i mandikiki' na finåhan na manera siha. Låo, i nisisidåt i procurement siha ti debi na u madibidi artificially para u constitute i dikiki' na finåhan.

(b) I atmoneda ti manisisita para i procurement ni ~~más ki $5,000~~ bålin $3,000 pat påpa'.

(c) I atmoneda ti manisisita låo na'matatnga para i procurement komu más ki ~~$5,000~~ $3,000 yan hulo' para $10,000 ~~påpa' $25,000,~~ pat $50,000 komu para setbision mediku, equipment, pribension siha, pat devices. I ufisiåt CEO, yan i ma'aturisa para u fanggåsta, debi na u aprueba ayu i propiu na må'gas pat otru na imple'åo ni make'ke'chagi para u fañuli' fektus yan setbisiu siha na machuli' påpa' $25,000, u machuli' price quotations ginen tres na vendors pues u ma'atyik i más maolik na presiu yan kuålidåt para procurement gi bålin ~~$5,000 para $25,000~~ **más ki $3,000 hulo' para $10,000, pat $50,000 ha'** pat $50,000 para setbision mediku siha, equipment, ya un nå'hålom gi CHCC P&S para u ma'aprueba ni Direktot.

(d) I purchase orders siña ma'usa para i dikiki' na finåhan siha sigun para subsections (b) yan (c).

Yan lokkui, guihi debi i tinahguin palåbra gi tinattiyi:

Para § 140-80.1-225(b), i palåbra "mapripåra" debi u mafunas ya matahgui ni palåbra "ma'aprueba".

(b) Para maseha håyi na sole source procurement sigun para subsection (a)(1), rason tinigi' para i sole source procurement debi na u ~~mapripåra~~ ma'aprueba ginin i CEO, i ufisiåt yan i ma'aturisa para u fanggåsta, ya debi na u sahguan i specific unique capabilities ni manisisita; i specific unique capabilities nu i contractor; i ånimu ni mafa'tinas para u hentan i kompitision; yan i espisifiku na konsiderasion siha i manmanå'i para alternative sources yan espisifiku na rason siha na håfa i alternative sources ti manma'atyik.

Para § 140-80.1-230(b), i palåbra "fa'tinas" debi u mafunas ya matahgui ni palåbra "ma'aprueba".

(b) I tinigi' na rason siha nu i basis para i prisisu yan para i sileksion nu i pattikulåt i contractor na debi u ~~mafat'tinas~~ ma'aprueba ginin i CEO, i ufisiåt yan i ma'aturisa para u fanggåsta.

I SUHETU YAN MANERA SIHA NI MANTINEKKA: Dikiki' na Finåhan, Sole Source Procurement, Emergency Procurement.

DIREKSION SIHA PARA U MAPO'LU YAN PUPBLIKASION: Esti na Nutisia nu i Manmaproponi na Rvision para Regulasion siha debi na u mapupblika gi hålom i Rehistran Commonwealth gi hålom i seksiona gi maproponi yan nuebu na ma'adåpta na regulasion siha (1 CMC § 9102(a)(1) yan u mapega gi hålom i mangkumbinienti na lugåt gi hålom i Civic Center yan i hålom ufisinan gubietnamentu siha gi kada distritun senadot, parehu English yan i dos na lingguåhi Chamorro yan Refaluwasch. (1 CMC § 9104(a)(1) Managuaha kopia siha yanggin manrikuesta hao ginen as Janet Guerrero gi 236-8202. I CHCC, gi inayek-ña, siña ha atyik para u pribeni dokumentu siha electronically adimås ki ma'imprenta pat kopian påppit.

PARA U MAPRIBENIYI OPIÑON SIHA: Nå'hånao pat intrega i upiñon-mu siha guatu gi as Esther Muna; Attn: Revision i Procurement siha, gi sanhilo' na address, fax pat email address, yan i subject line "Revision i Procurement." Todu upiñon debi na u fanhålom trenta (30) dihas ginen i fetchan pupblikasion esti na nutisia. Pot fabot na'hålom iyon-mu data, upiñon, yan kuntestasion siha. (1 CMC § 9104(a) (2))

Esti siha i manmaproponi na regulasion ma'aprueba ginen i CEO gi diha 23 gi Måyu, 2017.

Nina'hålom as: _____ 05/23/17
ESTHER MUNA, CEO — Fetcha
Commonwealth Healthcare Corp.

Rinisibi as: _____ 5/31/17
SHIRLEY P. CAMACHO-OGUMORO — Fetcha
Espisiåt Na Ayudånti Para I Atministrasion

Pine'lu Yan Ninota as: _____ 06-19-2017
ESTHER SN. NESBITT — Fetcha
Rehistran Commonwealth

Sigun i 1 CMC § 2153(e) (I Abugådu Henerål ha aprueba i regulasion siha na para u macho'gui kumu fotma) yan 1 CMC § 9104(a)(3) (hentan inaprueban Abugådu Henerål) i manmaproponi na

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Tilifon: (670) 234-8950 Fax: (670) 236-8930

regulasion siha ni mañechettun guini ni manmaribisa yan ma´aprueba kumu para fotma yan sufisienti ligåt ginin i CNMI Abugådu Henerål yan debi na u mapupblika sigun gi , 1 CMC § 2153(f) (pupblikasion areklamentu yan regulasion siha).

Mafetcha gi diha 19 gi Mayu, 2017.

EDWARD E. MANIBUSAN
Abugådu Henerål

6/19/17
Fetcha

P.O. Box 500409 CK, Saipan, MP 96950
Tilifon: (670) 234-8950 Fax: (670) 236-8930

Commonwealth of the Northern Mariana Islands
HEALTH CARE PROFESSIONS LICENSING BOARD
P.O. Box 502078, Bldg., 1242 Pohnpei Court
Capitol Hill, Saipan, MP 96950
Tel No: (670) 664-4809 Fax: (670) 664-4814
Email: cnmi@cnmibpl-hcplb.net
Website: cnmibpl-hcplb.net

NOTICE OF PROPOSED AMENDMENTS TO THE HEALTH CARE PROFESSIONS LICENSING BOARD FOR PHARMACIST, PHARMACY INTERN, CERTIFIED PHARMACY TECHNICIAN, AND PHARMACY TECHNICIAN

INTENDED ACTION TO ADOPT THESE PROPOSED REGULATIONS: The Health Care Professions Licensing Board (HCPLB) intends to adopt as permanent regulations the attached Proposed Regulations, pursuant to the procedures of the Administrative Procedure Act, 1 CMC § 9104(a). The regulations would become effective 10 days after compliance with 1 CMC §§ 9102 and 9104(a) or (b) (1 CMC § 9105(b)).

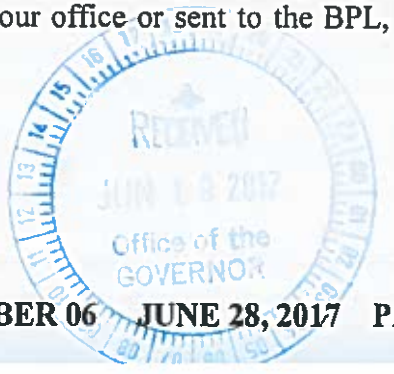
These regulations shall supersede the prior Rules and Regulations Governing the Importation, Storage, Sales and Distribution of Drug and Pharmaceutical Products (as amended) adopted and published at Volume 21, No. 4, page 16711 on April 19, 1999 of the Commonwealth Register.

AUTHORITY: The Health Care Professions Licensing Board has statutory power to promulgate and effect regulations pursuant to P.L. 15-105, Section 3, §2206(b), as amended.

THE TERMS AND SUBSTANCE: The attached proposed amendments is to amend the regulations to make it more consistent with the national association's standards and to establish the rules governing pharmacists, pharmacy interns, certified pharmacy technicians, pharmacy technicians and the pharmacy.

THE SUBJECTS AND ISSUES INVOLVED: The proposed amendments is to amend the regulations to make it more consistent with the national standards governing pharmacists, pharmacy interns, certified pharmacy technicians, pharmacy technicians and the pharmacy.

DIRECTIONS FOR FILING AND PUBLICATION: The Board is soliciting comments regarding these proposed amendments which must be received by the Board within thirty (30) days of first publication of this notice in the Commonwealth Register. Interested persons may request copies of the proposed amendments by contacting us at 664-4809 or by email at cnmi@cnmibpl-hcplb.net or come by our office located at Bldg. 1242, Pohnpei Ct., Capitol Hill, Saipan. Written comments on these amendments should be drop off at our office or sent to the BPL, P.O. Box 502078, Saipan, MP 96950.



Submitted By: _____ 6/7/2017
Theodore R. Parker, R.Ph., MPH — Date
HCPLB Chairman

Received By: _____ 06/19/17
Shirley P. Camacho-Ogumoro — Date
Special Assistant for Administration

Filed and Recorded By: _____ 06.19.2017
Esther SN Nesbitt — Date
Commonwealth Register

Pursuant to 1 CMC § 2153(e) (AG approval of regulations to be promulgated as to form) and 1 CMC § 9104(a) (3) (obtain AG approval) the proposed regulations attached hereto have been reviewed and approved as to form and legal sufficiency by the CNMI Attorney General and shall be published, 1 CMC § 2153(f) (publication of rules and regulations).

_____ 6/28/17
EDWARD MANIBUSAN — Date
Attorney General

Commonwealth gi Sangkattan na Islas Marianas Siha
HEALTH CARE PROFESSIONS LICENSING BOARD
P.O. Box 502078, #1242 Pohnpei Court
Capitol Hill, Saipan, MP 96950
Tel. No.: (670) 664-4809 Fax No. : (670) 664-4814
Email: cnmi@cnmibpl-hcplb.net
Website: cnmibpl-hcplb.net

NUTISIAN I MANMAPROPONI NA AMENDASION PARA I HEALTH CARE PROFESSIONS LICENSING BOARD PARA I PHARMACIST, PHARMACY INTERN, CERTIFIED PHARMACY TECHNICIAN, YAN PHARMACY TECHNICIAN

I AKSION NI MA'INTENSIONA NI PARA U MA'ADÅPTA ESTI I MANMAPROPONI NA REGULASION SIHA: I Health Care Professions Licensing Board (HCPLB) ha intensiona para u adåpta kumu petmanienti na regulasion siha ni mañechettun i Manmaproponi na Regulasion siha, sigun para i manera siha gi Åktun Administrative Procedure, 1 CMC § 9104 (a). I regulasion siha para u ifektibu gi dies(10) dihas dispues di compliance yan i 1 CMC §§ 9102 yan 9104 (a) pat (b) (1 CMC § 9105 (b)).

Esti na regulasion siha debi na u tinilaika i finene'na na Areklamentu yan Regulasion siha ni Gumubietbietna i Importation, Storage, Sales yan Distribution nu i Åmot yan Produktun Pharmaceutical siha (kumu ma´amenda) ma´adåpta yan mapupblika gi Baluma 21, Numiru 4, påhina 16711 gi Abrit 19, 1999 gi Rehistran Commonwealth.

ÅTURIDÅT: I Health Care Professions Licensing Board gai fuetsa ni para u macho'gui yan u huyong i regulasion siha sigun gi Lai Pupbliku 15-105, Seksiona 3, § 2206(b), kumu ma'amenda.

I TEMA YAN SUSTÅNSIAN I PALÅBRA SIHA: I mañechettun na manmaproponi na amendasion siha para u amenda i regulasion ni para mås regulåt yan i national association's standards yan para ma´establisi i areklamentu ni gumibietbietna i pharmacists, pharmacy interns, certified pharmacy technicians, pharmacy technicians yan i pharmacy.

I SUHETU NI MASUMÅRIA YAN ASUNTU NI TINEKKA: I manmaproponi na amendasion para u amenda i regulasion siha ni para mås regulåt yan i national standards ni gumibietbietna i pharmacists, pharmacy interns, certified pharmacy technicians, pharmacy technicians yan i pharmacy.

DIREKSION PARA U MAPO´LU YAN PUPBLIKASION: I Kuetpu manmamamaisin infotmasion sigun gi manmaproponi na amendasion siha ni debi na u marisibi ginin i Kuetpu gi hålum i trenta (30) dihas na tiempu gi primet na pupblikasion esti na nutisia gi hålum i Rehistran Commonwealth. Håyi gai intires na petsona siña manggågåo kopia siha gi manmaproponi na amendasion siha ya å'agang ham gi 664-4809 pat i email gi cnmi@cnmibpl-hcplb.net pat fåttu gi ufisinan-måmi ni gaigi gi Bldg. 1242, Pohnpei Ct., Capitol Hill, Saipan. I tinigin upiñon put esti na amendasion siha debi na u machuli' guatu gi ufisinan- måmi pat na'hånåo para i BPL, P.O. Box 502078, Saipan, MP 96950.

Nina'hålum as: _____ 6/12/2017
Theodore R. Parker, R.PH., MPH — Fetcha
Kabesiyu, HCPLB

Rinisibi as: _____ 06/19/17
Shirley P. Camacho-Ogumoro — Fetcha
Ispisiåt Na Ayudånti Para I Atministrasion

Pine'lu Yan Ninota as: _____ 06-19-2017
Esther SN. Nesbitt — Fetcha
Rehistran Commonwealth

Sigun i 1 CMC § 2153 (e), (Inaprueban Abugådu Heneråt i regulasion siha ni para u macho'gui kumu fotma) yan i 1 CMC § 9104 (a) (3) (inahentan inaprueban Abugådu Heneråt) i manmaproponi na regulasion siha ni mañechettun guini ni manmaribisa yan manma'aprueba kumu fotma yan sufisientI ligåt ginin i CNMI Abugådu Heneråt yan debi na u mapupblika, 1 CMC § 2153 (f) (pupblikasion areklamentu yan regulasion siha).

_____ 6/28/17
Edward E. Manibusan — Fetcha
Abugådu Heneråt

Commonwealth Téél Falúw kka Efáng llól Marianas
HEALTH CARE PROFESSIONS LICENSING BOARD
P. O. Box 502078, Bldg., 1242 Pohnpei Court
Asúngúl, Seipél, MP 96950
Tel No: (670) 664-4809 Fax: (670) 664-4814
Email: cnmi@cnmibpl-hcplb.net
Website: cnmibpl-hcplb.net

ARONGORONG REEL POMMWOL LIIWEL NGÁLI
HEALTH CARE PROFESSIONS LICENSING BOARD REEL
PHARMACIST, PHARMACY INTERN, CERTIFIED PHARMACY TECHNICIAN,
ME PHARMACY TECHNICIAN

MÁNGEMÁNGIL MWÓGHUT REEL REBWE ADÓPTAAI POMMWOL MWÓGHUTUGHUT KKAL: Health Care Professions Licensing Board (HCPLB) re mángemángil rebwe adóptáali bwe ebwe lléghló allégh sángi mwóghutughut ikka e appasch bwe Pommwol Mwóghutughut, sángi mwóghutughutúl Administrative Procedure Act, 1 CMC § 9104(a). E bwe bwunguló mwóghutughut kkal llól seigh ráál mwiril igha re palúweli sángi 1 CMC §§ 9102 me 9104(a) ngare (b) (1 CMC § 9105(b)).

Mwóghutughut kkal nge ebwe liiweli allégh kkewe akkááw ngáli allégh me atiwlighil Governing the Importation, Storage, Sales, me isiiswoowul safeey me Pharmaceutical Products (igha e liiwel) igha re adóptáali me igha re arongowow me reel Volume 21, No. 4, peighil 16711 wóól Abrid 19, 1999 reel Commonwealth Register.

BWÁNGIL: Eyoor bwángil Health Care Professions Licensing Board re bwe arongowow me ghitipwotchuw allégh sángi P.L. 15-105, Tálil 3, §2206(b), igha e liiwel.

KKAPASAL ME WEEWEL: Pommwol liiwel ikka e appasch nge ebwe liiweli mwóghutughutúl bwe ebwe aweewey ngáli national association standards me ebwe aweewey alléghúl governing pharmacists, pharmacy interns, certified pharmacy technicians, pharmacy technicians me pharmacy.

KKAPASAL ME ÓUTOL: Pommwol liiwel kkal nge ebwe aweewey me ebwe ffat ngáli national standards governing pharmacists, pharmacy interns, certified pharmacy technicians, pharmacy technician me pharmacy.

AFAL REEL AMMWELIL ME AKKATÉÉWOWUL: Board re tingór mángemángiir toulap reel pommwol liiwel kka rebwe bwughi llól eliigh (30) ráál ngáre schagh aa akkatééwow arongorong merel Commonwealth Register. Schóó kka re mwuschel pappidil pommwol liiwel kkal emmwel rebwe faingi numuro iye 664-4809 ngáre email reel cnmi@cnmicnmibpl-hcplb.net me ngáre mweteló reel bwulasiyo iye e lo reel Bldg. 1242, Pohnpei Ct., Asúngúl, Seipél. Ischil mángemáng ebwe isiislong llól bwulasiyo me ngare afanga ngáli BPL, P. O. Box 502078, Saipan, MP 96950.

Isáliyalong: _____ 6/12/2017
Theodore R. Parker, R.Ph., MPH
HCPLB Chairman
Ráál

Bwughiyal: _____ 06/19/17
Shirley P. Camacho-Ogumoro
Special Assistant ngáli Administration
Ráál

Ammwelil: _____ 06.19.2017
Esther SN. Nesbitt
Commonwealth Register
Ráál

Sángi 1 CMC § 2153(e) (Allégh kkal aa lléghló sángi AG bwe ebwe ffil reel ffééról) me 1 CMC § 9104(a) (3) (mwiir sángi AG) pommwol atiwligh kka e appaschlong aa takkal amwuri fischiiy me átirow bwe ebwe ffil reel ffééról me legal sufficiency sángi Soulemelemil Allégh Lapalapal CNMI me ebwe akkatééwow, 1 CMC § 2153(f) (arongowowul allégh me atiwligh).

_____ 6/28/17
EDWARD MANIBUSAN
Soulemelemil Allégh Lapalap
Ráál

§ 140-50.3-3500 Part 3500 Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, Pharmacy Technician.

These Regulations shall repeal the prior Pharmacy Regulations published at Volume 21, and No. 04, page 16711 on April 19, 1999 of the Commonwealth Register, and the changes published at Volume 29, No. 5, page 26513. These Regulations shall be codified at Title 140, Chapter 50, Subchapter 50.3, part 3500.

§ 140-50.3-3501 Definitions

(a) "Administer" means the direct application of a Drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

(b) "Adverse Action Report" means a report detailing adverse action, including but not limited to disciplinary action or denial of licensure in any jurisdictions, from the National Practitioner Data Bank, the American Society of Health System Pharmacists, the American Pharmacists Association or the licensing or regulatory entity of any jurisdiction, including foreign countries.

(c) "Automated Pharmacy Systems" include, but are not limited to, mechanical systems that perform operations or activities, other than Compounding or Administration, relative to the storage, packaging, Dispensing, or Distribution of medications, and which collect, control, and maintain all transaction information.

(d) "Beyond-Use Date" means a date placed on a prescription label at the time of Dispensing that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.

(e) "Board" means the Health Care Professions Licensing Board or its successor agency empowered to regulate pharmaceutical practices including granting and disciplining licenses of individuals and companies.

(f) "Cease and Desist" is an order of the Board prohibiting a licensee or other Person or entity from continuing a particular course of conduct that violates the Health Care Professions Licensing Act of 2007, codified at 4 CMC § 2201 et seq., or its rules and regulations.

(g) "Centralized Prescription Filling" means the filling by a Pharmacy of a request from another Pharmacy to fill or refill a Prescription Drug Order.

(h) "Centralized Prescription Processing" means the processing by a Pharmacy of a request from another Pharmacy to fill or refill a Prescription Drug Order or to perform processing functions such as Dispensing, Drug Utilization Review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.

(i) "Certified Pharmacy Technician" means personnel licensed by the Board who have completed a certification program approved by the Board and have successfully passed the National Pharmacy Certification Exam may, under the supervision of a Pharmacist, perform certain activities involved in the Practice of Pharmacy, such as:

(1) receiving new written or electronic Prescription Drug Orders;
(2) prescription transfer;
(3) Compounding;
(4) assisting in the Dispensing process; and
(5) performing all functions allowed to be performed by pharmacy technicians

but excluding:

(1) Drug Utilization Review (DUR);
(2) clinical conflict resolution;
(3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;
(4) Patient Counseling; and
(5) Dispensing process validation.

(j) "Chart Order" means a lawful order entered on the chart or a medical record of an inpatient or resident of an Institutional Facility by a Practitioner or his or her designated agent for a Drug or Device and shall be considered a Prescription Drug Order provided that it contains:

(1) the full name of the patient;
(2) date of issuance;
(3) name, strength, and dosage form of the Drug prescribed;
(4) directions for use; and
(5) if written, the prescribing Practitioner's signature or the signature of the Practitioner's agent (including the name of the prescribing Practitioner); or if electronically submitted, the prescribing Practitioner's electronic or digital signature.

(k) "Collaborative Pharmacy Practice" is that Practice of Pharmacy whereby one or more Pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more Practitioners under protocol and in collaboration with Practitioner(s) to provide patient care services to achieve optimal medication use and desired patient outcomes.

(l) "Collaborative Pharmacy Practice Agreement" is a written and signed agreement between one or more Pharmacists and one or more Practitioners that provides for Collaborative Pharmacy Practice.

(m) "Compounding" means the preparation of Components into a Drug product (1) as the result of a Practitioner's Prescription Drug Order or initiative based on the Practitioner/patient/Pharmacist relationship in the course of professional practice, or (2) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or Dispensing. Compounding includes the preparation of Drugs or Devices in anticipation of receiving Prescription Drug Orders based on routine, regularly observed prescribing patterns.

(n) "Coordinating Pharmacy" is a Pharmacy responsible for the Practice of Telepharmacy performed at Remote Pharmacies and Remote Dispensing Sites.

(o) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under Federal law to bear the label, "Caution: Federal or State law requires Dispensing by or on the order of a physician."

(p) "Digital Signature" means an electronic signature based upon cryptographic methods of originator authentication, and computed by using a set of rules and a set of parameters so that the identity of the signer and the integrity of the data can be verified.

(q) "Dispense" or "Dispensing" means the interpretation, evaluation, and implementation of a Prescription Drug Order, including the preparation and Delivery of a Drug or Device to a patient or patient's agent in a suitable container appropriately labeled for subsequent Administration to, or use by, a patient.

(r) "Drug" means:
(1) articles recognized as Drugs in any official compendium, or supplement thereto, designated from time to time by the Board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(3) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and

(4) articles intended for use as a Component of any articles specified in clause (1), (2), or (3) of this definition.

(s) "Drug Utilization Review (DUR)" includes but is not limited to the following activities:
(1) Evaluation of the Prescription Drug Order(s) and patient record(s) for:
(i) known allergies;
(ii) rational therapy contraindications;
(iii) reasonable dose, duration of use, and route of Administration, considering age, gender, and other patient factors;

(iv) reasonable directions for use;
(v) potential or actual adverse Drug reactions;
(vi) Drug-Drug interactions;
(vii) Drug-food interactions;
(viii) Drug-disease contraindications;
(ix) therapeutic duplication;
(x) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
(xi) abuse/misuse.

(t) "Electronic Signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

(u) "Emergency Prescription Drug Order" means a standing Prescription Drug Order issued by the State Health Officer for Pharmacists to Dispense designated Prescription Drugs during a Public Health Emergency requiring mass Dispensing to expeditiously treat or provide prophylaxis to large numbers of Patients.

(v) "Equivalent Drug Product" means a generic version of a brand name drug approved by the U.S. Food and Drug Administration as therapeutically equivalent on the basis of bio-equivalence, safety, and effectiveness.

(w) "Executive Director" means the Executive Director of the Health Care Professions Licensing Board.

(x) "FDA" means Food and Drug Administration, a federal agency within the United States Department of Health and Human Services, established to set safety and quality standards for Drugs, food, cosmetics, and other consumer products.

(y) "Fill date" means the actual date a new or refilled prescription is dispensed but not necessarily delivered to a patient from a pharmacy.

(z) "Immediate Supervision" means that a pharmacist is physically present in the area or location where the preparation of prescription orders is conducted.

(aa) "Institutional Pharmacy" means any pharmacy that provides pharmaceutical services to a recognized government institution.

(bb) "Institutional Facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a(n):

(1) hospital;
(2) Long-Term Care Facility;
(3) convalescent home;
(4) nursing home;
(5) extended care facility;
(6) mental health facility;
(7) rehabilitation center;
(8) psychiatric center;
(9) developmental disability center;
(10) Drug abuse treatment center;
(11) family planning clinic;
(12) penal institution;
(13) hospice;
(14) public health facility;
(15) athletic facility.

(cc) "Label" means a display of written, printed, or graphic matter upon the immediate container of any Drug or Device.

(dd) "Labeling" means the process of preparing and affixing a label to any Drug container exclusive, however, of the Labeling by a Manufacturer, packer, or Distributor of a Non-Prescription Drug or commercially packaged Legend Drug or Device. Any such label shall include all information required by Federal and State law or rule.

(ee) "Medical Order" means a lawful order of a Practitioner that may or may not include a Prescription Drug Order.

(ff) "Medication Therapy Management" is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication or a medical device. Medication Therapy Management encompasses a broad range of professional activities and responsibilities within the licensed Pharmacist's scope of practice. These services may include, but are not limited to, the following, according to the individual needs of the patient:

(1) performing or obtaining necessary assessments of the patient's health status;

(2) formulating a medication treatment plan;

(3) selecting, initiating, modifying, or administering medication therapy;

(4) monitoring and evaluating the patient's response to therapy, including safety and effectiveness;

(5) performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;

(6) documenting the care delivered and communicating essential information to the patient's other primary care providers;

(7) providing verbal education and training designed to enhance patient understanding and appropriate use of his or her medications;

(8) providing information, support services and resources designed to enhance patient adherence with his or her therapeutic regimens;

(9) coordinating and integrating Medication Therapy Management services within the broader health care management services being provided to the patient; and

(10) such other patient care services as may be allowed by law.

(gg) "Mobile Pharmacy" means a Pharmacy that is self-propelled or movable by another vehicle that is self-propelled.

(hh) "National Association of Boards of Pharmacy" or "NABP" means the independent and impartial national association that assists member boards in developing, implementing, and enforcing standards for protection of public health.

(ii) "Non-Prescription Drug" means a Drug that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws and rules of the Commonwealth and the Federal government.

(jj) "Non-Resident Pharmacy" means a Pharmacy located outside the Commonwealth.

(kk) "Parenteral" means by some other route than through the gastrointestinal tract such as, but not limited to, intravenous, subcutaneous, or intramuscular routes.

(ll) "Patient Counseling" means the oral communication by the Pharmacist of information to the patient or caregiver in order to ensure proper use of Drugs and Devices.

(mm) "Patient-Practitioner Relationship" means the formal or inferred relationship between a physician and a patient, which is established once the physician assumes or undertakes the medical care or treatment of a patient.

(nn) "Pharmacist" means an individual currently licensed by the Commonwealth to engage in the Practice of Pharmacy. A Pharmacist is entitled to engage in the Practice of Pharmacy, as defined in this chapter, within or outside of a licensed Pharmacy, as defined in the Rules of the Board.

(oo) "Pharmacist-in-Charge" means a Pharmacist currently licensed in the Commonwealth who accepts responsibility for the operation of a Pharmacy in conformance with all laws and rules pertinent to the Practice of Pharmacy and the Distribution of Drugs, and who is personally in full and actual charge of such Pharmacy and personnel.

(pp) "Pharmacy" means any place within the Commonwealth where Drugs are Dispensed and Pharmacist Care is provided and any place outside of the Commonwealth where Drugs are Dispensed and Pharmacist Care is provided to residents of the Commonwealth.

(qq) "Pharmacy Intern" means an individual who is:

(1) currently licensed by the Commonwealth to engage in the Practice of Pharmacy while under the supervision of a Pharmacist and is enrolled in a professional degree program of a school or college of pharmacy that has been approved by the Board and is satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist; or

(2) a graduate of an approved professional degree program of a school or college of Pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certificate, who is currently licensed by the Board for the purpose of obtaining practical experience as a requirement for licensure as a Pharmacist; or

(3) a qualified applicant awaiting examination for licensure or meeting Board requirements for re-licensure; or

(4) an individual participating in a residency or fellowship program.

(rr) "Pharmacy Technician" means personnel who may, under the supervision of a pharmacist, assist in the pharmacy and perform such functions as:

(1) assisting in the Dispensing process;
(2) processing of medical coverage claims;
(3) stocking of medications; and
(4) cashiering but excluding:
    (1) Drug Utilization Review (DUR);
    (2) clinical conflict resolution;
    (3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;
    (4) Patient Counseling;
    (5) Dispensing process validation;
    (6) prescription transfer; and
    (7) receipt of new oral Prescription Drug Orders.

(kk) The "Practice of Pharmacy" means the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Tele-pharmacy within and across state lines; the provision of Patient Counseling; the provision of those acts or services necessary to provide Pharmacist Care in all areas of patient care, including Primary Care, Medication Therapy Management, Collaborative Pharmacy Practice, the ordering, conducting, and interpretation of appropriate tests, and the recommendation and administration of immunizations; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, Repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices, and maintenance of required records. The practice of pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training.

(ll) "Practice of Telepharmacy" means the provision of Pharmacist Care by registered Pharmacies and Pharmacists located within the Commonwealth through the use of telecommunications or other technologies to patients or their agents at distances that are located within the Commonwealth.

(mm) "Practitioner" or "Licensed Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and Administer Drugs in the course of professional practice.

(nn) "Preceptor" means an individual who is currently licensed as a Pharmacist by the Board, meets the qualifications as a Preceptor under the Rules of the Board, and participates in the instructional training of Pharmacy Interns.

(oo) "Prescription Drug" or "Legend Drug" means a Drug that is required under Federal law to be labeled with either of the following statements prior to being Dispensed or Delivered: (1) "Rx Only"; (2) "Caution: Federal law restricts this Drug to use by, or on the order of, a licensed veterinarian"; or (3) a Drug that is required by any applicable Federal or State law or rule to be Dispensed pursuant only to a Prescription Drug Order or is restricted to use by Practitioners only.

(pp) "Prescription Drug Order" means a lawful order from a Practitioner for a Drug or Device for a specific patient, including orders derived from Collaborative Pharmacy Practice, where a valid Patient-Practitioner relationship exists, that is communicated to a Pharmacist in a licensed Pharmacy.

(qq) "Public Health Emergency" means an imminent threat or occurrence of an illness or health condition caused by terrorism, bioterrorism, epidemic or pandemic disease, novel and highly fatal infectious agent or biological toxin, or natural or man-made disaster, that poses a substantial risk of significant number of human fatalities or incidents of permanent or long-term disability that is beyond the capacity of local government or nongovernmental organizations to resolve.

(rr) "Remote Dispensing Site" is a site located within an Institutional Facility or a clinic that utilizes an Automated Pharmacy System and that is electronically linked to the Coordinating Pharmacy via a computer system and/or a video/auditory communication system.

(ss) "Remote Pharmacy" is a Pharmacy staffed by a Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician that is electronically linked to the Coordinating Pharmacy via a computer system and/or a video/auditory communication system approved by the Board.

(tt) "Temporary Pharmacy Facility" means a facility established as a result of a Public Health Emergency or State of Emergency to temporarily provide Pharmacy services within or adjacent to Declared Disaster Areas.

(uu) "'use by' date" means the date after which medication should not be used.

(vv) "USP Standards" means standards published in the current official United States Pharmacopeia or National Formulary.

(ww) "Wholesale Distribution" means the Distribution of Prescription Drugs or Devices by Wholesale Distributors to Persons other than consumers or patients, and includes the transfer of Prescription Drugs by a Pharmacy to another Pharmacy if the value of the goods transferred exceeds five percent (5%) of total Prescription Drug sales revenue of either the transferor or transferee Pharmacy during any consecutive twelve (12)-month period. Wholesale Distribution does not include:

(1) the sale, purchase, or trade of a Prescription Drug or Device, an offer to sell, purchase, or trade a Prescription Drug or Device, or the Dispensing of a Prescription Drug or Device pursuant to a Prescription;

(2) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device for Emergency Medical Reasons;

(3) Intracompany Transactions, unless in violation of own use provisions;

(4) the sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device among hospitals, Chain Pharmacy Warehouses, Pharmacies, or other health care entities that are under common control;

(5) the sale, purchase, or trade of a Prescription Drug or Device or the offer to sell, purchase, or trade a Prescription Drug or Device by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(6) the purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Prescription Drug or Device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;

(7) the transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing agreement;

(8) the sale, purchase, or trade of blood and blood components intended for transfusion;

(9) the return of recalled, expired, damaged, or otherwise non-salable Prescription Drugs, when conducted by a hospital, health care entity, Pharmacy, or charitable institution in accordance with the Board's regulations; or

(10) the sale, transfer, merger, or consolidation of all or part of the business of a retail Pharmacy or Pharmacies from or with another retail Pharmacy or Pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the Board's regulations.

(xx) "Wholesale Distributor" means any Person engaged in Wholesale Distribution of Prescription Drugs or Devices in or into the Commonwealth, including but not limited to Manufacturers, Repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including Manufacturers' and Distributors' warehouses, Co-licensees, Exclusive Distributors, Third-Party Logistics Providers, Chain Pharmacy Warehouses, and Wholesale Drug warehouses, independent Wholesale Drug traders, and retail Pharmacies that conduct Wholesale Distributions.

§ 140-50.3-3505 Exemptions from License Requirements.

The following individuals are exempt from obtaining a Commonwealth license to practice as a Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician:

- (a) A Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician in the U.S. Military in the discharge of official duties;

(b) A visiting Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician from another jurisdiction presenting information or demonstrating procedures or new techniques before an organization or group of individuals involved with the practice of pharmacy; or

(c) Licensed Practitioners authorized under the laws of the Commonwealth to prescribe drugs and devices requiring a prescription in the practice of their respective professions shall be allowed to dispense medications and devices, which they themselves have prescribed, as long as the same standards, record keeping requirements, and all other requirements, whether in Health Care Professions Licensing Act of 2007, codified at 4 CMC § 2201 et seq., the Pure Food, Drug and Cosmetic Device Act of 1998, 4 CMC § 2701 et seq., or the regulations of the Health Care Professions Licensing Board, § 140-50.3-101 et seq., for the dispensing of drugs applicable to Pharmacists are followed, and only in instances where a Licensed Pharmacist is not reasonably available to dispense.

§ 140-50.3-3510 Unlawful Practice

(a) Except as otherwise provided in these regulations or the Health Care Professions Licensing Act of 2007, codified at 4 CMC § 2201 et seq., it shall be unlawful for any individual, whether located in or outside the Commonwealth, to engage in the Practice of Pharmacy in the Commonwealth unless currently licensed to practice under any the provisions of these regulations.

(b) The provision of Pharmacist Care services to an individual in the Commonwealth, through the use of telecommunications, the Internet, mail order or other technologies, regardless of the location of the pharmacist, shall constitute the Practice of Pharmacy and shall be subject to regulation.

(1) Licensed Pharmacies located outside the Commonwealth that provide Pharmacist Care services to individuals in the Commonwealth must be licensed within the Commonwealth under NMIAC § 140-50.3-3570(b).

(2) Pharmacists located outside the Commonwealth who are providing Pharmacist Care services outside of a licensed Pharmacy to individuals located in the Commonwealth must register with the Commonwealth to engage in the Practice of Pharmacy.

(c) It shall be unlawful for any individual to perform the activities of a Certified Pharmacy Technician unless currently registered to do so under the provisions of this Act.

(d) This section (§ 140-50.3-3510) shall not apply to any practitioner of a health care profession from a state or foreign country when in limited consultation, including in-person, mail, telephonic, telemedicine, or other electronic consultation, with a Commonwealth-licensed health care professional, if the health care professional from the other jurisdiction is licensed to practice in another jurisdiction.

§ 140-50.3-3515 Licensure by Endorsement.

(a) The Board may grant a license to a person to practice as a Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician without examination if:

(1) The person holds a valid, active license to practice as a Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician in any U.S. state or Province of Canada; and

(2) The person substantially complies with the requirements for licensure in § 140-50.3-003520; and

(3) The requirements in the jurisdiction of licensure are at least as stringent as those under these regulations;

(4) Applicant is not the subject of an adverse action report from the National Practitioner Data Bank, the American Society of Health System Pharmacists, the American Pharmacists Association or the licensing/regulatory entity of any jurisdiction, including foreign countries.

(b) The Board may deny a license by endorsement to a person to practice as a Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician if the person has been the subject of an adverse action in which his/her license was suspended, revoked, placed on probation, conditioned, or renewal denied.

§ 140-50.3 – 3520 Pharmacist Licensure

(a) To obtain a license to engage in the Practice of Pharmacy as a Registered Pharmacist, an applicant for licensure by examination shall:

(1) have submitted a written application in the form prescribed by the Board ;

(2) have attained the age of majority;

(3) be of good moral character;

(4) have graduated and received the first professional degree from a college or school of Pharmacy accredited by the American Council on Pharmaceutical Education or other institution approved by the Board or;

(5) have graduated from a foreign college of Pharmacy, completed a transcript verification program, taken and passed a college of Pharmacy equivalency examination program, and completed a process of communication-ability testing as defined under the National Association of Boards of Pharmacy (NABP) regulations so that it is ensured that the applicant meets standards necessary to protect public health and safety;

(6) have submitted a notarized copy of the Pharmacist's license to practice pharmacy in any state of the United States of America or any province in Canada;

(7) have submitted a signed statement indicating any information regarding any disciplinary proceedings pending or disciplinary actions taken by any state against the license including, but not limited to any conviction or revocation of license related to the practice of pharmacy, drugs, drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(8) have submitted a current report from the National Practitioner Data Bank (NPDB), the American Association of Health Systems Pharmacists, or any other entity having information pertinent to the applicant's performance

(9) have submitted proof of the applicant to be a U.S. Citizen or is lawfully entitled to remain or work in the Commonwealth;

(10) have submitted a 2" X 2" photograph of the applicant for identification purposes;

(11) have submitted any other information the Board may require to investigate the applicant's qualifications for licensure.

(b) 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.

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

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

(e) Applications submitted to the Board shall remain active for period of (6) months from the date it is received. After this time period, incomplete applications will then automatically be denied.

§ 140-50.3-3525 Qualifications for Temporary License.

To obtain a temporary license for Pharmacist, which shall not exceed ninety (90) days or other time period approved by the Board, an applicant shall:

(a) have submitted an application in the form prescribed by the Board;
(b) have attained the age of majority;
(c) have good moral character;
(d) have possessed at the time of initial licensure as a Pharmacist all qualifications listed in § 140-50.3-3520;
(e) submit a notarized copy of a current and valid license to practice pharmacy from any state in the United States or any province in Canada;
(f) have paid the fees specified by the Board.

§ 140-50.3-3530 Pharmacy Intern Licensure.

To obtain a license to Practice as a Pharmacy Intern, an applicant shall:

(a) have submitted a written application in the form prescribed by the Board;
(b) have attained the age of majority;
(c) be of good moral character;
(d) be either

(1) enrolled in a professional degree program of a school or college of pharmacy approved by the National Association of Boards of Pharmacy and satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist; or

(2) a graduate of an approved professional degree program of a school or college of Pharmacy or be graduates who have established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certificate, for the purpose of obtaining practical experience as a requirement for licensure as a Pharmacist;

(e) have submitted a notarized copy of the Pharmacy Intern's license from any state of the United States of America;

(f) have submitted a signed statement indicating any information regarding any disciplinary proceedings pending or disciplinary actions taken by any state against the license including but not limited to any conviction or revocation

of license related to the practice of pharmacy, drugs, drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(g) have submitted a proof of the applicant to be a U.S. Citizen or is lawfully entitled to remain or work in the Commonwealth;

(h) have submitted a photograph of the applicant for identification purposes;

(i) have submitted any other information the Board may require to investigate the applicant's qualifications for licensure.

§ 140-50.3-3535 Pharmacy Intern – Scope of Practice.

Pharmacy Interns will be allowed to participate in a Pharmacy Practice Experience program for the purpose of providing the practice experience necessary for licensure as a Pharmacist under the following conditions:

(a) Every individual shall obtain a Pharmacy Intern license from the Board before beginning their Pharmacy practice experiences in the Commonwealth.

(b) A Pharmacy Intern shall be allowed to engage in the Practice of Pharmacy provided that such activities are under the direct supervision of a Pharmacist. A Pharmacist shall be in contact with, and actually giving instructions to, the Pharmacy Intern during all professional activities throughout the entire Pharmacy practice experience period. The Pharmacist is responsible for supervising all the Practice of Pharmacy activities performed by the Pharmacy Intern, including but not limited to the accurate dispensing of the medication. Under no circumstances will the Pharmacy Intern be allowed to perform the final check in the preparation of a prescription.

(c) The Pharmacy at which a Pharmacy Intern is being trained shall provide an environment that is conducive to the learning of the Practice of Pharmacy by a Pharmacy Intern. Pharmacy practice experience sites shall meet the standards approved by the Board.

(d) The Pharmacy Intern, excluding those who are currently enrolled in a professional degree program of a school or college of pharmacy approved by the NABP and satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist, shall notify the Board within two weeks of beginning practice as a Pharmacy Intern, on a form provided by the Board, of the identity of the Pharmacy practice experience site and of the Preceptor.

(e) A Preceptor may be responsible for the training of more than one Pharmacy Intern. The number of Pharmacy Interns engaged in the Practice of Pharmacy supervised by a single preceptor is limited to 2 (two) at any time.

(f) A Pharmacy Intern, utilizing a Pharmacy Practice Experience program for the fulfillment of the requirements of becoming a Registered Pharmacist will be limited to no more than 1 renewal of their pharmacy intern license or a total of 4 years' practical experience, whichever is less.

(g) The Pharmacy Intern shall be so designated in his or her professional relationships, and shall in no manner falsely assume, directly or by inference, to be a Pharmacist. The Board shall issue to the Pharmacy Intern a license for purposes of identification and verification of his or her role as a Pharmacy Intern, which license shall be surrendered to the Board upon discontinuance of Pharmacy practice experiences for any reason including licensure as a Pharmacist. No individual not properly licensed by the Board as a Pharmacy Intern shall take, use, or exhibit the title of Pharmacy Intern, or any other term of similar like or import.

§ 140-50.3-3540 Registration of Certified Pharmacy Technicians.

(a) In order to be registered as a Certified Pharmacy Technician in the Commonwealth, an applicant shall:

(1) have submitted a written application in the form prescribed by the Board;

(2) have attained the age of 18;

(3) have good moral character;

(4) have graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent;

(5) have:

(i) graduated from a competency-based pharmacy technician education and training program approved by the Board ; or

(ii) been documented by the Pharmacist-in-Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific, competency-based education and training program approved by the Board ;

(6) have successfully passed an examination developed by the Pharmacy Technician Certification Board (PTCB) using nationally recognized and validated psychometric and pharmacy practice standards approved by the Board;

(7) have paid the fees specified by the Board for the examination and any related materials, and have paid for the issuance of the registration.

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as a Certified Pharmacy Technician.

§ 140-50.3-3545 Certified Pharmacy Technician – Scope of Practice

The duties and responsibilities of a Certified Pharmacy Technician who is licensed by the Board may under the supervision of a Pharmacist:

(a) Interpret and prepare prescription drug orders for subsequent checking by the Pharmacist;

(b) Input drug inventory orders for the purposes of ordering prescription medications or annual or bi-annual inventories;

(c) Transfer prescriptions over the phone or via other electronic means to another Certified Pharmacist Technician or Pharmacist;

(d) Request prescription refills or new prescriptions from a Practitioner or Practitioner's authorized representative.

(e) Accept prescription refill authorizations from a physician or a physician's duly authorized representative. New prescriptions or changes in a prescription are not permitted.

(f) No individual not properly licensed by the Board as a Certified Pharmacy Technician shall take, use, or exhibit the title of Certified Pharmacy Technician, or any other term of similar like or import.

§ 140-50.3-3550 Renewal of Licenses and Registrations

(a) Each Pharmacist, Pharmacy Intern, and Certified Pharmacy Technician, shall apply for renewal of his or her license bi-annually. A Pharmacist, Pharmacy Intern or Certified Pharmacy Technician who desires to continue in the Practice of Pharmacy in the Commonwealth shall file with the Board an application in such form and containing such data as the Board may require for renewal of the license. If the Board finds that the applicant has been licensed, and that such license has not been Revoked or placed under Suspension, that the applicant has attested that he or she has no criminal convictions or arrests since the previous licensing period, has paid the renewal fee, has continued his or her Pharmacy education in accordance with the rules of the Board, and is entitled to continue in the Practice of Pharmacy, the Board shall issue a license to the applicant.

(b) If a Pharmacist fails to make application to the Board for renewal of his or her license within a period of three years from the expiration of his or her license, he or she must pass an examination for license renewal; except that a Person who has been licensed under the laws of the Commonwealth and after the expiration of his or her license, has continually practiced Pharmacy in another State of the United States or Province of Canada under a license issued by the authority of such State or Province, may renew his or her license upon payment of the designated fee.

(c) Each Pharmacist or Certified Pharmacy Technician will be required to complete 15 CPE hours per year which are accredited by the American Council on Pharmaceutical Education prior to renewal.

§ 140-50.3-3555 Practice of Pharmacy – Non-Institutional Facilities

(a) To obtain a license for a Pharmacy, an applicant shall:
(1) have submitted a written application in the form prescribed by the Board;
(2) have attained the age of majority;
(3) be of good moral character; and
(4) have paid the fees specified by the Board for the issuance of the license.

(b) The facility shall have undergone an inspection by the Executive Director or his or her designee, and any other inspection of the premises as required by Commonwealth or federal law;

(c) Minimum requirements for a Pharmacy:
(1) Each Pharmacy shall be of sufficient size, as determined by National Association of Boards of Pharmacy, to allow for the safe and proper storage of Prescription Drugs and for the safe and proper Compounding and/or preparation of Prescription Drug Orders.

(2) Each Pharmacy shall maintain an area designated for the provision of Patient Counseling services. This area shall be designed to provide a reasonable expectation of privacy of Protected Health Information.

(3) Each Pharmacy shall maintain on file or electronically at least one current reference in each of the following categories:
(i) State and Federal Drug laws relating to the Practice of Pharmacy and the legal Distribution of Drugs and any rules or regulations adopted pursuant thereto;
(ii) pharmacology;
(iii) dosage and toxicology;
(iv) general.

(4) Each Pharmacy shall maintain patient-oriented reference material for guidance in proper Drug usage.

(5) All areas where Drugs and Devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the Drugs prior to their Dispensing as stipulated by the United States Pharmacopeia–National Formulary (USP-NF) and/or the Manufacturer's or Distributor's Product Labeling unless otherwise indicated by the Board.

(6) Each Pharmacy shall have access to a sink with hot and cold running water that is convenient to the Compounding area for the purpose of hand scrubs prior to Compounding.

(7) Security.
(i) Facility
(A) Each Pharmacist, while on duty, shall be responsible for the security of the Pharmacy, including provisions for effective control against theft or diversion of Drugs and/or Devices.

(B) The Pharmacy shall be secured by a physical barrier with suitable locks, an electronic barrier, and/or security personnel to detect entry at a time when a Pharmacist is not present. In the event of separation of employment of an employee due to any confirmed Drug-related reason, including diversion, or other acts involving dishonesty, suitable action shall be taken to ensure the security of the pharmacy.

(C) Prescription and other patient health care information shall be maintained in a manner that protects the integrity and confidentiality of such information as provided by the rules of the Board.

(D) The Pharmacy shall implement and maintain technologies that will aid in theft prevention and suspect apprehension that may include:

(1) Video equipment positioned to identify individuals who may be involved in diversion or theft, if utilized, shall have adequate recording, storage, and retrieval capabilities; and

(2) monitored alarm system with backup mechanism.

(ii) Internal Theft/Diversion

(A) the Pharmacist-in-Charge and owner/licensee (facility permit holder) shall ensure policies and procedures are in place that address the following:

(1) inspection of shipments;

(2) receipt Verification oversight and checking in shipments;

(3) reconciliation of orders; and

(4) inventory management including:

(A) determination of Medications that need to be monitored and controlled beyond existing systems such as controlled substances and Drugs of concern; and

(B) conducting quarterly reconciliations at a minimum but shall be more frequent up to perpetual, depending on the potential for or incidence of diversion for a particular Drug.

(8) Equipment/Supplies.

The Pharmacy shall carry and utilize the equipment and supplies necessary to conduct a Pharmacy in a manner that is in the best interest of the patients served and to comply with all Commonwealth and Federal laws.

(9) The Pharmacy shall provide a means for patients to prevent disclosure of Confidential Information or personally identifiable information that was obtained or collected by the Pharmacist or Pharmacy incidental to the Delivery of Pharmacist Care other than as authorized by law or rules of the Board.

§ 140-50.3-3560 Practice of Pharmacy –Institutional Facilities

(a) Absence of Pharmacist.

(1) During such times as an Institutional Pharmacy may be unattended by a Pharmacist, arrangements shall be made in advance by the Pharmacist-in-Charge for provision of Drugs to the medical staff and other authorized personnel of the Institutional Facility by use of night cabinets and, in emergency circumstances, by access to the Pharmacy. A Pharmacist must be "on call" during all absences.

(2) In the absence of a Pharmacist, Drugs shall be stored in a locked cabinet or other enclosure constructed and located outside of the Pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Pharmacist-in-Charge shall, in conjunction with the appropriate committee of the Institutional Facility, develop inventory listings of those Drugs to be included in such cabinet(s) and determine who may have access, and shall ensure that:

(i) Drugs are properly Labeled;
(ii) only prepackaged Drugs are available, in amounts sufficient for immediate therapeutic requirements;
(iii) whenever access to the pharmacy occurs, written Practitioner's orders and proofs-of-use are provided;
(iv) all Drugs in such cabinets are inventoried no less than once per month;
(v) a complete audit of all activity concerning such cabinet is conducted no less than once per year; and
(vi) written policies and procedures are established to implement the requirements of NMIAC § 140-50.3–3560.

(3) Whenever any Drug is not available from floor supplies or night cabinets, and such Drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such Drug may be obtained from the Pharmacy in accordance with the requirements of NMIAC § 140-50.3-3560. One supervisory nurse or designated Pharmacy Technician in any given eight-hour shift is responsible for obtaining Drugs from the Pharmacy. The responsible nurse or Pharmacy Technician shall be designated in writing by the appropriate committee of the Institutional Facility. Removal of any Drug from the Pharmacy by an

authorized nurse or Pharmacy Technician must be recorded on a suitable form showing the patient name, room number, name of Drug, strength, amount, date, time, and signature of nurse. The form shall be left with the container from which the Drug was removed.

(4) Emergency kit Drugs may be provided for use by authorized personnel of the Institutional Facility provided, however, such kits meet the following requirements:

(i) Emergency kit Drugs are those Drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such Drugs from such other sources.

(ii) All emergency kit Drugs shall be provided and sealed by a Pharmacist (the "Supplying Pharmacist").

(iii) The supplying Pharmacist and the medical staff of the Institutional Facility shall jointly determine the Drugs, by identity and quantity, to be included in emergency kits.

(iv) Emergency kits shall be stored in secured areas to prevent unauthorized access, and to ensure a proper environment for preservation of the Drugs within them.

(v) The exterior of each emergency kit shall be labeled so as to clearly indicate that it is an emergency Drug kit and that it is for use in emergencies only. The label shall contain a listing of the Drugs contained in the kit, including name, strength, quantity, and expiration date of the contents, and the name, address(es), and telephone number(s) of the supplying Pharmacist.

(vi) Drugs shall be removed from emergency kits only pursuant to a valid Chart Order.

(vii) Whenever an emergency kit is opened, the supplying Pharmacist shall be notified and the Pharmacist shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.

(viii) The expiration date of an emergency kit shall be the earliest date of expiration of any Drug supplied in the kit. Upon the occurrence of the expiration date, the supplying Pharmacist shall replace the expired Drug.

(b) Centralized Prescription Processing or Filling for Immediate Need.

(1) In accordance with the Model Rules for the Practice of Pharmacy and Centralized Prescription Processing and Filling, an Institutional Pharmacy may outsource services to another Pharmacy for the limited purpose of ensuring that Drugs or Devices are attainable to meet the immediate needs of patients and residents of the Institutional Facility or when the Institutional Pharmacy cannot provide services on an ongoing basis, provided that the Institutional Pharmacy:

(i) has obtained approval from the Institutional Facility to outsource Centralized Prescription Processing or Filling services for its inpatients and residents; and

(ii) provides a valid Chart Order to the Pharmacy it has contracted with for the Centralized Prescription Processing or Filling services.

§ 140-50.3-003565 Pharmacist in Charge

Each Pharmacy, regardless of its physical location shall be directed by a Pharmacist, referred to as the "Pharmacist-in-Charge," who is licensed to engage in the Practice of Pharmacy in the Commonwealth.

(a) Duties and Responsibilities of the Pharmacist-in-Charge

(1) No Person shall operate a Pharmacy without a Pharmacist-in-Charge. The Pharmacist-in-Charge of a Pharmacy shall be designated in the application of the Pharmacy for license, and in each renewal thereof. A Pharmacist may not serve as Pharmacist-in-Charge unless he or she is physically present in the Pharmacy a sufficient amount of time to provide supervision and control. A Pharmacist may not serve as Pharmacist-in-Charge for more than one Pharmacy at any one time except upon obtaining written permission from the Board.

(2) The Pharmacist-in-Charge has the following responsibilities:

(i) Developing or adopting, implementing, and maintaining:

(A) quality assurance programs for Pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;

(B) policies and procedures for the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and drugs of concern. Quality assurance programs shall be designed to prevent and detect Drug diversion;

(C) policies and procedures for the provision of Pharmacy services;

(D) an ongoing quality assurance program that monitors performance of the Automated Pharmacy System, which is evidenced by written policies and procedures developed by the Pharmacy;

(E) policies and procedures for preventing the illegal use or disclosure of Protected Health Information, or verifying the existence thereof and ensuring that all employees of the Pharmacy read, sign, and comply with the established policies and procedures;

(ii) Ensuring that:

(A) the Automated Pharmacy System is in good working order and accurately Dispenses the correct strength, dosage form, and quantity of the Drug prescribed while maintaining appropriate record keeping and security safeguards; and

(B) all Pharmacists and Pharmacy Interns employed at the Pharmacy are currently licensed and that all Certified Pharmacy Technicians and employed at the Pharmacy are currently licensed with the Board.

(iii) Notifying the Board immediately of any of the following changes:

(A) change of employment or responsibility as the Pharmacist-in-Charge;

(B) the separation of employment of any Pharmacist, Pharmacy Intern, Pharmacy Technician, or Certified Pharmacy Technician for any confirmed Drug-related reason, including but not limited to, Adulteration, abuse, theft, or diversion, and shall include in the notice the reason for the termination. If the employment of the Pharmacist-in-Charge that is terminated, the owner and/or pharmacy permit holder shall be responsible for notifying the Board of the termination and the reason for the termination;

(C) change of ownership of the Pharmacy;

(D) change of address of the Pharmacy; or

(E) permanent closing of the Pharmacy.

(iv) Making or filing any reports required by Commonwealth or Federal laws and rules.

(v) Reporting any theft, suspected theft, diversion, or other Significant Loss of any Prescription Drug within one business day of discovery to the Board and as required by Drug Enforcement Administration (DEA) or other State or federal agencies for Prescription Drugs and controlled substances.

(vi) Responding to the Board regarding any minor violations brought to his or her attention.

(vii) Establishing policies and procedures for preventing the illegal use or disclosure of Protected Health Information, or verifying the existence thereof and ensuring that all employees of the Pharmacy read, sign, and comply with the established policies and procedures.

(viii)Providing the Board with prior written notice of the installation or removal of Automated Pharmacy Systems. Such notice must include, but is not limited to:

(A) the name and address of the Pharmacy;
(B) the location of the automated equipment; and
(C) the identification of the responsible Pharmacist.

(3) The Pharmacist-in-Charge shall be assisted by a sufficient number of Pharmacists, and Certified Pharmacy Technicians, as may be required to competently and safely provide Pharmacy services.

(i) The Pharmacist-in-Charge shall maintain and file with the Board, on a form provided by the Board, a current list of all Certified Pharmacy Technicians and Pharmacy Technicians assisting in the provision of Pharmacy services.

(ii) The Pharmacist-in-Charge shall develop and implement written policies and procedures to specify the duties to be performed by Certified Pharmacy Technicians and Pharmacy Technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience and shall address the method and level of necessary supervision specific to the practice site. These policies and procedures shall, at a minimum, specify that Certified Pharmacy Technicians and Pharmacy Technicians are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Pharmacy Technicians shall not be assigned duties that may be performed only by Certified Pharmacy Technicians.

(4) The Pharmacist-in-Charge shall develop and implement a procedure for proper management of Drug recalls which may include, where appropriate, contacting patients to whom the recalled Drug product(s) have been Dispensed.

(b) If any action of the Pharmacy is deemed to contribute to or cause a violation of any provision of this section, the Board may hold the owner and/or Pharmacy permit holder responsible and/or absolve the Pharmacist-in-Charge from the responsibility of that action.

§ 140-50.3-3570. Pharmacy Practice

(a) Prescriptions

(1) Prescription Drug Order. A Prescription Drug Order shall contain the following information at a minimum:

(i) full name, date of birth, and street address or P.O. Box of the patient;

(ii) name, prescribing Practitioner's license designation, address, and, if required by law or rules of the Board, DEA registration number of the prescribing Practitioner;

(iii) date of issuance;

(iv) name, strength, dosage form, and quantity of Drug prescribed;

(A) For prescriptions in Schedule II, the quantity of drug must be clearly written either in words or numerals or both;

(B) For prescriptions in Schedule II, the strength of the medication must be clearly written whether for single entities or combination entities

(v) directions for use; "use as directed" will not be valid as directions for use;

(vi) refills authorized, if any;

(vii) if a written Prescription Drug Order, prescribing Practitioner's signature;

(viii) if an electronically transmitted Prescription Drug Order, prescribing Practitioner's electronic or digital signature;

(ix) if a hard copy Prescription Drug Order generated from electronic media, prescribing Practitioner's electronic or manual signature. For those with electronic signatures, such Prescription Drug Orders shall be applied to paper that utilizes security features that will ensure the Prescription Drug Order is not subject to any form of copying and/or alteration.

(2) Manner of Issuance of a Prescription Drug Order. A Prescription Drug Order, to be valid, must be issued for a legitimate medical purpose by a Practitioner acting within the course of legitimate professional practice.

(i) A Prescription Drug Order must be communicated to a Pharmacist, or when recorded in such a way that the Pharmacist may review the Prescription Drug Order as transmitted, to a Pharmacy Intern or a Certified Pharmacy Technician, in a licensed Pharmacy. This may be accomplished in one of the following ways:

(A) A Prescription Drug Order, including that for a controlled substance listed in Schedules II through V, may be communicated in written form.

(B) A Prescription Drug Order, including that for a controlled substance listed in Schedules III through V, and, in situations listed in 140-50.3-3570(a)(2)(iv), that for a controlled substance listed in Schedule II, may be communicated orally (including telephone voice communication) or issued electronically.

(ii) The Pharmacist shall not dispense a Prescription Drug if the Pharmacist knows or reasonably should know that the Prescription Drug Order was issued solely on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid Patient-Practitioner relationship.

(iii) If communicated orally, the Prescription Drug Order shall be immediately reduced to a form by the Pharmacist, the Pharmacy Intern, or Certified Pharmacy Technician that may be maintained for the time required by laws or rules.

(iv) A Prescription Drug Order for a Schedule II controlled substance may be communicated orally only in the following situations and/or with the following restrictions. Otherwise, a Prescription Drug Order for a Schedule II controlled substance must be communicated in written form or issued electronically.

(A) A Prescription Drug Order for a Schedule II controlled substance may be communicated by the Practitioner or the Practitioner's agent by way of Electronic Transmission, provided the original written, signed Prescription Drug Order is presented to the Pharmacist for review prior to the actual Dispensing of the controlled substance, except as noted in paragraph § 140-50.3-3570(a)(iv)(B) or (C). The original, written Prescription Drug Order shall be maintained in accordance with Section § 140-50.3-3570(a)(7) (Patient Records).

(B) In the case of an Emergency Situation, a Prescription Drug Order for a Schedule II controlled substance may be communicated by the Practitioner orally, provided that:

(1) the quantity prescribed and Dispensed is limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period must be pursuant to a Prescription Drug Order either written and signed or electronically issued by the prescribing Practitioner;

(2) the orally communicated Prescription Drug Order shall be immediately reduced to writing by the Pharmacist or Certified Pharmacy Technician, or, if necessary, and shall contain the information required by § 140-50.3-3570(a)(1) (Prescription Drug Order);

(3) if the prescribing Practitioner is not known to the Pharmacist or Certified Pharmacy Technician, he or she must make a reasonable effort to determine that the oral authorization came from a registered Practitioner, which may include a callback to the Practitioner using the

Practitioner's phone number as listed in the telephone directory and/or other good faith efforts to ensure his or her identity; and

(4) within 72 hours after authorizing an emergency oral Prescription Drug Order, the Practitioner shall cause a written Prescription Drug Order for the emergency quantity prescribed to be delivered to the Dispensing Pharmacist. In addition to conforming to the requirements of § 140-50.3-3570(a)(1), the Prescription Drug order shall have written on its face "Authorization for Emergency Dispensing," and the date of the orally transmitted Prescription Drug Order. The written Prescription Drug Order may be delivered to the Pharmacist in Person or by mail, but if delivered by mail, it must be postmarked within the seven (7)-day period. Upon receipt, the Dispensing Pharmacist shall attach this written Prescription Drug Order to the emergency oral Prescription Drug Order, which had earlier been reduced to writing. The Pharmacist shall notify the nearest office of the DEA if the prescribing Practitioner fails to deliver a written Prescription Drug Order.

(C) The prescribing Practitioner may authorize his or her agent to communicate a Prescription Drug Order orally or by way of Electronic Transmission via facsimile to a Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician in a licensed Pharmacy, provided that the identity of the transmitting agent is included in the order. In an Institutional Facility, the prescribing Practitioner's agent must be authorized by and in accordance with written policies and procedures of the Facility and applicable Commonwealth and federal laws.

(v) All Prescription Drug Orders for a Schedule III – V controlled substance communicated by way of Electronic Transmission via facsimile shall:

(A) be transmitted to a Pharmacist, Pharmacy Intern, or Certified Pharmacy Technician in a licensed Pharmacy of the patient's choice;

(B) identify the transmitter's phone number or any other suitable means to contact the transmitter for verbal and/or written confirmation, the time and date of transmission, and the identity of the Pharmacy intended to receive the transmission, as well as any other information required by federal or Commonwealth law;

(C) be transmitted by an authorized Practitioner or his or her designated agent; and

(D) be deemed the original Prescription Drug Order, provided it meets the requirements of this subsection.

(vi) All Prescription Drug Orders for a Schedule II – V controlled substance issued and processed electronically shall be in compliance with existing federal or Commonwealth laws and rules.

(vii) The Pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the Prescription Drug Order issued electronically or by facsimile to ensure it is consistent with existing federal or Commonwealth laws and rules.

(viii) All electronic equipment for receipt of Prescription Drug Orders issued electronically or by facsimile shall be maintained so as to ensure against unauthorized access.

(ix) Prescription Drug Orders for a Schedule III – V controlled substance may be filled only if prescribed by a practitioner licensed to prescribe Schedule III – V controlled substances in the Commonwealth, which includes having their residence address on their DEA registration located within the Commonwealth or a duly licensed practitioner practicing on the Territory of Guam, which includes having their residence address on their DEA registration located on Guam, and only for patients treated on Guam and who reside in the Commonwealth.

(x) Prescription Drug Orders for a Schedule II controlled substance may only be dispensed if:

(A) written by a practitioner duly licensed to prescribe Schedule II controlled substances in the Commonwealth, which includes having their residence address on their DEA registration located within the Commonwealth; or

(B) written by a visiting or specialty practitioner duly licensed in the Commonwealth to prescribe medications and has a valid DEA registration to prescribe medications in Schedule II in their primary state or territory of licensure; the patient must be treated at an established facility physically located within the Commonwealth and only within the scope of practice of the practitioner.

(C) the prescription is dispensed within 93 (ninety-three) days in which the prescription was originally written.

(3) Transfer of a Prescription Drug Order. Pharmacies utilizing automated data-processing systems shall satisfy all information requirements of a manual mode for Prescription Drug Order transferal, except as noted in subsection § 140-50.3-3570(a)(3)(iv) below. The transfer of original Prescription Drug Order information for the purpose of refill Dispensing is permissible between Pharmacies subject to the following requirements:

(i) The information is communicated directly between Pharmacists or Certified Pharmacy Technicians and the transferring Pharmacist or Certified Pharmacy Technician records the following information:

(A) write the word "VOID" on the face of the invalidated Prescription Drug Order; or deactivates the active drug order if the order is electronic;

(B) record on the reverse side of the invalidated Prescription Drug Order or electronic drug order, the name and address of the Pharmacy to which it was transferred and the name of the Pharmacist or Certified Pharmacy Technician receiving the Prescription Drug Order;

(C) record the date of the transfer and the name of the Pharmacist or Certified Pharmacy Technician transferring the information; and

(D) the computer record shall reflect the fact that the original Prescription Drug Order has been voided and shall contain all the other information required above.

(ii) The Pharmacist or Certified Pharmacy Technician receiving the transferred Prescription Drug Order information shall reduce to writing the following:

(A) Write the word "TRANSFER" on the face of the transferred Prescription Drug Order or have the word "TRANSFER" on a preprinted form or;

(B) Provide all information required to be on a Prescription Drug Order pursuant to state and federal laws and rules, and include:

(1) date of issuance of original Prescription Drug Order;
(2) original number of refills authorized on original Prescription Drug Order;
(3) date of original Dispensing;
(4) number of valid refills remaining and date of last refill;
(5) Pharmacy's name, address, and original prescription number from which the Prescription Drug Order information was transferred; and
(6) name of transferring Pharmacist or Certified Pharmacy Technician.

(C) Systems providing for the electronic transfer of information shall not infringe on a patient's freedom of choice as to the provider of Pharmacist Care.

(iii) Both the original and transferred Prescription Drug Order shall be maintained for a period of five years from the date of last refill.

(iv) Pharmacies accessing a common electronic file or database used to maintain required Dispensing information are not required to transfer Prescription Drug Orders or information for Dispensing purposes between or among Pharmacies participating in the same common prescription file. Provided, however, that any such common file shall contain complete records of each Prescription Drug Order and refill Dispensed.

Further, a hard copy record of each Prescription Drug Order transferred or accessed for purposes of refilling shall be generated and maintained at the Pharmacy refilling the Prescription Drug Order, or the Pharmacy to which the Prescription Drug Order is transferred. Pharmacies shall protect against the illegal use or disclosure of Protected Health Information.

(v) In an emergency, a Pharmacy may transfer original Prescription Drug Order information for a non-controlled substance to a second Pharmacy for the purpose of Dispensing up to a 72-hour supply without voiding the original Prescription Drug Order.

(4) Drug Product Selection by the Pharmacist

(i) A Pharmacist Dispensing a Prescription Drug Order for a Drug product prescribed by its brand name may select any Equivalent Drug Product provided that the Manufacturer or Distributor holds, if applicable, either an approved New Drug Application (NDA) or an approved Abbreviated New Drug Application (ANDA), unless other approval by law or from the Federal Food and Drug Administration is required.

(ii) The Pharmacist shall not select an Equivalent Drug Product if the Practitioner instructs otherwise, either orally or in writing, on the Prescription Drug Order.

(iii) The Pharmacist shall notify the patient or patient's agent if a Drug other than the brand name Drug prescribed is Dispensed.

(iv) Whenever Drug product selection is performed by a Pharmacist, the Pharmacist shall Dispense the Equivalent Drug Product in a container Labeled in accordance with § 140-50.3-3570(a)(5)(Labeling).

(5) Labeling

(i) All Drugs Dispensed for use by inpatients of a hospital or other health care facility, whereby the Drug is not in the possession of the ultimate user prior to Administration, shall meet the following requirements:

(A) The label of a single-unit package of an individual-dose or unit-dose system of packaging of Drugs shall include:

(1) the nonproprietary or proprietary name of the Drug;
(2) the route of Administration, if other than oral;
(3) the strength and volume, where appropriate, expressed in the metric system whenever possible;
(4) the control number and expiration date;
(5) identification of the repackager by name or by license number shall be clearly distinguishable from the rest of the label; and
(6) special storage conditions, if required.

(B) When a multiple-dose Drug Distribution system is utilized, including Dispensing of single unit packages, the Drugs shall be Dispensed in a container to which is affixed a label containing the following information:

(1) identification of the Dispensing Pharmacy;
(2) the patient's name;
(3) the date of Dispensing;
(4) the nonproprietary and/or proprietary name of the Drug Dispensed; and
(5) the strength, expressed in the metric system whenever possible.

(ii) All Drugs Dispensed to inpatients for self-administration shall be Labeled in accordance with NMIAC § 140-50.3-3570(a)(5)(iv).

(iii) Whenever any Drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:

(A) name of solution, lot number, and volume of solution;
(B) patient's name;
(C) infusion rate;
(D) bottle sequence number or other system control number;

(E) name and quantity of each additive;
(F) date of preparation;
(G) Beyond-Use Date and time of parenteral admixture; and
(H) ancillary precaution labels.

(iv) All Drugs Dispensed to ambulatory or outpatients shall contain a label affixed to the container in which such Drug is Dispensed including:

(A) Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif typeface (such as "Arial"), minimum 12-point size, and in "sentence case." Field size and font size may be increased in the best interest of patient care. Critical information text should never be truncated and shall include:

(1) patient name
(a) legal name of the patient; or
(b) if patient is an animal, include the last name of the owner, name of the animal, and animal species.

(2) directions for use
(a) directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order; and
(b) language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.

(3) drug name
(a) if written for a brand name and a generic drug is dispensed, include phrase "Generic for [brand name];"and
(b) include drug name suffixes, such as CD, SR, XL, XR, etc.

(4) drug strength

(5) "use by" date
(a) date after which medication should be used; not the expiration date of medication or expiration date of prescription; and
(b) format as – "Use by: MM/DD/YY."

(B) Important information for patients – Must appear on the label but should not supersede critical information for patients and shall include:

(1) pharmacy name;

(2) pharmacy telephone number;

(3) prescriber name;
(a) format as – "Prescriber: [prescriber name]."

(4) "fill date;"
(a) format as – "Date filled: MM/DD/YY."

(5) prescription number;

(6) drug quantity;
(a) format as – "Qty: [number]."

(7) number of remaining refills;
(a) format as – "Refills: [number remaining]" or "No refills," using whole numbers only and managing partial fills through the pharmacy record keeping system;

(8) written or graphic product description;

(9) auxiliary information;

(10) any cautions and other provisions which may be required by federal or state law.

(C) The following additional information for Patients – may appear on the label:
(1) bar codes;
(2) pharmacy address; and
(3) store number.

(6) Prepackaging

(i) A Pharmacy may prepackage drugs under the following circumstances:

(A) written policies and procedures have been developed that address the processes of Prepackaging within the Pharmacy;

(B) the Prepackaging processes are conducted under conditions that ensure the integrity of the Drug and under the direct supervision of a Pharmacist;

(C) the Prepackaged Drugs are labeled with the following components:
(1) Drug Name;
(2) Drug Strength;
(3) Pharmacy Control and Manufacturer lot number;
(4) Name of the Manufacturer or Distributor of the Drug; and
(5) Beyond-Use Date.

(D) Records of all Prepackaging operations are maintained and include the following:
(1) the name (nonproprietary and proprietary name), strength, dosage form, quantity per container, and quantity of containers of the Drug being Prepackaged;
(2) the name of the Manufacturer or Distributor of the Drug;
(3) Pharmacy Control and Manufacturer lot number;
(4) expiration date of the Drug according to the original Manufacturer or Distributor container and the Beyond-Use Date;
(5) the name or initials of the Certified Pharmacy Technician or Pharmacy Technician that Prepackaged the Drug and the name or initials of the Pharmacist that verified the appropriateness of the Prepackaged Drug; and
(6) the date the Drug is Prepackaged.

(E) All Drugs Prepackaged are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the Labeling of such Drugs, or with requirements in the current edition of an official compendium.

(7) Patient Records

(i) A patient record system shall be maintained by all Pharmacies for patients for whom Prescription Drug Orders are Dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the Dispensing Pharmacist to identify previously Dispensed Drugs at the time a Prescription Drug Order is presented for Dispensing, and be created and stored in a manner to protect against illegal use or disclosure of Protected Health Information. The Pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

(A) full name of the patient for whom the Drug is intended;
(B) street address and telephone number of the patient;
(C) patient's age or date of birth;
(D) patient's gender;

(E) a list of all Prescription Drug Orders obtained by the patient at the Pharmacy maintaining the patient record during the 5 years immediately preceding the most recent entry showing the name of the Drug, prescription number, name and strength of the Drug, the quantity and date received, and the name of the Practitioner; and

(F) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

(ii) The Pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, Drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other Drugs, including over-the-counter Drugs or Devices currently being used by the patient which may relate to Prospective Drug Review.

(iii) A patient record shall be maintained for a period of not less than five years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(iv) Protected Health Information may be used or disclosed as allowed under Section 4 of this regulation.

(7) Prospective Drug Utilization Review (DUR). A Pharmacist shall review the patient record and each Prescription Drug Order for:

(i) known allergies;
(ii) rational therapy contraindications;
(iii) reasonable dose, duration of use, and route of Administration, considering age, gender, and other patient factors;
(iv) reasonable directions for use;
(v) potential or actual adverse Drug reactions;
(vi) Drug-Drug interactions;
(vii) Drug-food interactions;
(viii) Drug-disease contraindications;
(ix) therapeutic duplication;
(x) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
(xi) abuse/misuse.

Upon recognizing any of the above, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

(8) Patient Counseling

(i) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall personally initiate discussion of matters which will enhance or optimize Drug therapy with each patient or caregiver of such patient. Such discussion shall be in Person, whenever practicable, or by telephone and shall include appropriate elements of Patient Counseling. Such elements may include the following:

(A) the name and description of the Drug;

(B) the dosage form, dose, route of Administration, and duration of Drug therapy;

(C) intended use of the Drug and expected action;

(D) special directions and precautions for preparation, Administration, and use by the patient;

(E) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(F) techniques for self-monitoring Drug therapy;

(G) proper storage and appropriate disposal method(s) of unwanted or unused medication;

(H) prescription refill information;

(I) action to be taken in the event of a missed dose; and

(J) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

(ii) Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(iii) A Pharmacist providing Telepharmacy services across state lines shall:
(A) identify himself or herself to patients as a "licensed Pharmacist"; and

(B) notify patients of the State in which he or she is currently licensed to Practice Pharmacy and registered to Practice Telepharmacy across state lines.

(iv) Patient Counseling, as described above and defined in this Act, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to Administer the Drug(s).

(v) A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

(9) Collaborative Pharmacy Practice
(i) Collaborative Pharmacy Practice Agreement. A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be approved by the Board prior to initiation. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct activities approved by the Practitioner, and as defined by law and by the Rules of the Board. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.

(ii) Contents The Collaborative Pharmacy Practice Agreement shall include:
(A) identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;

(B) the types of decisions that the Pharmacist is allowed to make may include:
(A) a detailed description of the types of diseases, Drugs, or Drug categories involved, and the activities allowed in each case;
(B) a detailed description of the methods, procedures, decision Criteria, and plan the Pharmacist is to follow when conducting allowed activities; and
(C) a detailed description of the activities the Pharmacist is to follow, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made. In addition to the Agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system.

(C) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;

(D) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;

(E) a provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;

(F) a provision that allows either party to cancel the Agreement by written notification;

(G) proof of Professional Liability insurance for both parties where the address listed on the Declarations page is located within the Commonwealth for those names which are attached to the agreement and/or a memorandum of understanding between the parties for the provision of damages and/or rewards to a patient should damages be warranted or awarded by a Court of Law located within or outside the Commonwealth, or agreed to as part of a settlement agreement for a patient where damages are acknowledged;

(H) an effective date; and

(I) signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing. Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, dated and submitted to the Board for approval.

(iii) Initiation of the Collaborative Pharmacy Practice Agreement. The Collaborative Pharmacy Practice Agreement must be coupled with a medical order from the Practitioner to initiate allowed activities for any particular patient.

(iv) Documentation of Pharmacist activities. Documentation of allowed activities must be kept as part of the patient's permanent record and be readily available to other health care professionals providing care to that patient and who are authorized to received it. Documentation of allowed activities shall be considered Protected Health Information.

(v) Review. At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year.

(10) Adverse Drug Reactions. Significant Adverse Drug Reactions shall be reported to the Practitioner and, in writing, to the Board immediately upon discovery. Appropriate entry on the patient's record shall also be made.

(11) Records of Dispensing/Delivery

(i) Records of receipt, Dispensing, Delivery, Distribution, or other disposition of all Drugs or Devices are to be made and kept by Pharmacies for five years and shall include, but not be limited to:

(A) quantity Dispensed for original and refills, if different from original;
(B) date of receipt, Dispensing, Delivery, Distribution, or other disposition;
(C) serial number (or equivalent if an institution);
(D) the identification of the Pharmacist responsible for Dispensing;
(E) name and Manufacturer of Drug Dispensed if Drug product selection occurs; and
(F) records of refills to date.

(ii) Pharmacies that ship medications by mail, common carrier, or other type of Delivery service shall implement a mechanism to verify that a patient or caregiver has actually received the Delivered medication.

(12) Computer Records

(i) Systems Manuals: An up-to-date policy and procedure manual shall be developed by the Pharmacist-in-Charge that explains the operational aspects of the automated system and shall:

(A) include examples of all required output documentation provided by the automated system;

(B) outline steps to be followed when the automated system is not operational due to scheduled or unscheduled system interruption;

(C) outline regular and routine backup file procedure and file maintenance;

(D) outline audit procedures, personnel code assignments, and personnel responsibilities; and

(E) provide a quality assurance mechanism for data entry validation.

(ii) Automated Data Processing System

(A) Data storage and retrieval. The system shall have the capability of producing sight-readable information on all original and refill Prescription Drug Orders. The term "sight-readable" means that an authorized individual shall be able to examine the record and read the information from the cathode ray tube (CRT), microfiche, microfilm, printout, or other method acceptable to the Board.

(B) The system shall provide online retrieval (via CRT display or hard copy printout) of original Prescription Drug Order information. Such information shall include, but not be limited to, the Prescription Drug Order requirements and records of Dispensing as indicated in Section 3 of this Rule.

(C) The computerized system shall have the capability of producing a printout of any Prescription Drug Order data. The system shall provide a refill-by-refill audit trail for any specified strength and dosage form of any Drug. Such an audit trail shall be by printout, and include the name of the prescribing Practitioner, name and location of the patient, quantity Dispensed on each refill, date of Dispensing of each refill, name or identification code of the Dispensing Pharmacist, and unique identifier of the Prescription Drug Order.

(D) Any facility maintaining centralized prescription records shall be capable of sending a requested printout to the Pharmacy within 72 hours.

(iii) Security: To maintain the confidentiality of patient records, the system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the Drug has been Dispensed, any alterations in Prescription Drug Order data shall be documented, including the identification of the Pharmacist responsible for the alteration.

(iv) System Backup (Auxiliary Records Maintenance)

(A) In the event of an unscheduled system interruption, sufficient patient data and Prescription Drug Order data should be available to permit reconstruction of such data within a two-hour time period for the Pharmacist to Dispense Drugs with sound professional judgment.

(B) An auxiliary system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason and to ensure that all refills are authorized by the original Prescription Drug Order and that the maximum number of refills is not exceeded.

(C) The auxiliary system shall be in place to provide for the maintenance of all necessary patient Drug information (as outlined in this rule) until the automated system becomes operational. However, nothing in this Subsection (§ 140-50.3-3570 (a)(12)(iv)(C)) shall preclude the Pharmacist from using professional judgment for the benefit of a patient's health and safety.

(D) When the automated system is restored to operation, the information regarding Prescription Drug Orders Dispensed and refilled during the inoperative period shall be entered into the automated system within 96 hours.

(E) Routine backup systems and procedures (hard copy, copy, disk, etc) shall be in place and operational to ensure against loss of patient data.

(F) In the event that permanent Dispensing information is lost due to unscheduled system interruption, the Board shall be notified within 24 hours.

(13) Remote Pharmacy Services

(i) General Requirements

(A) The Pharmacist-in-Charge of the Coordinating Pharmacy shall apply to the Board for a permit prior to engaging in the Practice of Telepharmacy via the Remote Pharmacies and Remote Dispensing Sites.

(B) A Coordinating Pharmacy shall demonstrate to the Board that there is limited access to pharmacy services in the community prior to engaging in the Practice of Telepharmacy via the Remote Pharmacies and Remote Dispensing Sites.

(C) One Pharmacist shall not operate more than three simultaneously open Remote Pharmacies or Remote Dispensing Sites. An exception to this limit may be granted by the Board in situations where the Coordinating Pharmacy has documented a need to supervise additional Remote Pharmacies or Remote Dispensing Sites and has demonstrated that appropriate safeguards are in place to ensure proper supervision of each.

(D) Remote Pharmacies that are principally staffed by Certified Pharmacy Technicians or Pharmacy Interns shall be under the continuous supervision of a Pharmacist at the Coordinating Pharmacy at all times that it is open to provide pharmacy services. To qualify as continuous supervision, the Pharmacist is not required to be physically present at the Remote Pharmacy, but shall supervise operations electronically through the use of a video/auditory communication system.

(E) A Coordinating Pharmacy shall comply with appropriate federal and state controlled substance registrations for each Remote Pharmacy or Remote Dispensing Site if controlled substances are maintained.

(F) A Coordinating Pharmacy shall notify the Board in writing within 10 days of a change of location, discontinuance of service or closure of a Remote Pharmacy or Remote Dispensing Site operated by the Coordinating Pharmacy.

(iv) Remote Pharmacy: A Remote Pharmacy may have a limited Drug inventory consisting of suitable unit-of-use containers Prepackaged by the Coordinating Pharmacy or a registered Repackager or as provided in the original Manufacturer's container. A Remote Pharmacy may utilize an Automated Pharmacy System.

(iii) Remote Dispensing Site

A Remote Dispensing Site shall utilize an Automated Pharmacy System located in an area accessible only to authorized personnel or shall be staffed by authorized personnel under the direct supervision, via skype or other telemetric means for the supervising Pharmacist.

(iv) Personnel

(A) The Pharmacist-in-Charge of the Coordinating Pharmacy:

(1) is responsible for the Practice of Telepharmacy performed at Remote Pharmacies and Remote Dispensing Sites, including the supervision of any Automated Pharmacy System and compliance with these Rules;

(2) is responsible for ensuring that the Coordinating Pharmacy and the Remote Pharmacy and Remote Dispensing Site have entered into a written agreement that outlines the services to be provided and the responsibilities and accountability of each party in fulfilling the terms of the agreement in compliance with federal and state laws and regulations. Such contract or agreement is not required if the Remote Pharmacy or Remote Dispensing Site are under common control or ownership of the Coordinating Pharmacy;

(3) shall ensure the Coordinating Pharmacy has sufficient Pharmacists on duty for the safe operation and supervision of all Remote Pharmacies and Remote Dispensing Sites; and

(4) shall ensure that the Automated Pharmacy System is in good working order and accurately Dispenses the correct strength, dosage form, and quantity of the Drug prescribed while maintaining appropriate record keeping and security safeguards.

(B) Pharmacists, Pharmacy Interns, and Certified Pharmacy Technicians at Remote Pharmacies shall be registered with the Board and be trained in the operation of the video/auditory communication system used for Dispensing and Patient Counseling.

(v) Operations

(A) Remote Pharmacies:

(1) that are principally staffed by Certified Pharmacy Technicians or Pharmacy Interns shall be under the continuous supervision of a Pharmacist;

(2) may receive Prescription Drug Orders or refill requests by the patient or the patient's agent in accordance with the policies and procedures designated by the Pharmacist-in-Charge. The Certified Pharmacy Technician or Pharmacy Intern shall either transmit the Prescription Drug Order or refill request to the Coordinating Pharmacy or process the Prescription Drug Order or refill request so that the Pharmacist at the Coordinating Pharmacy may perform a Prospective Drug Utilization Review prior to Dispensing;

(3) shall contain an appropriate area for Patient Counseling by the Pharmacist, if required;

(4) may employ Certified Pharmacy Technicians or Pharmacy Interns, who shall be under the continuous supervision of a Pharmacist at the Coordinating Pharmacy, to assist in the Dispensing process and maintain appropriate video/auditory communication with the Coordinating Pharmacy; and

(5) may contain an Automated Pharmacy System or a limited Drug inventory for the purposes of preparing medications for Dispensing. The Pharmacist at the Coordinating Pharmacy shall have access to the Remote Pharmacy's automated data processing system to perform a Prospective Drug Utilization Review (DUR) prior to Dispensing. The Pharmacist shall ensure, through the use of the video/auditory communication system, that the Certified Pharmacy Technician or Pharmacy Intern has accurately and correctly prepared the Drug for Dispensing according to the Prescription Drug Order.

(B) Remote Dispensing Sites:

(1) that are located within an Institutional Facility shall utilize an Automated Pharmacy System or direct visual inspection via skype or other means for the purposes of Dispensing. The Pharmacist at the Coordinating Pharmacy shall have the necessary patient information to perform a Prospective Drug Utilization Review (DUR) prior to Dispensing; and

(2) that are located in clinics shall utilize an Automated Pharmacy System or direct visual inspection via skype or telemetric means. Such remote dispensing sites shall be located in an area that will provide for Patient Counseling and must be installed within the same area utilized by the dispenser. The coordinating pharmacy must have available direct contact, either through skype or other electronic means, access to the Pharmacist for consultation purposes.

(vi) Security

(A) Drugs shall be stored in compliance with Commonwealth and federal laws and in accordance with these Rules, including those addressing temperature, proper containers, and the handling of outdated drugs.

(B) Drugs stored at Remote Dispensing Sites shall be stored in an area that is:

(1) separate from any other Drugs used by the health care facility; and

(2) locked by key or combination, so as to prevent access by unauthorized personnel.

(C) Access to the area where Drugs are stored at the Remote Pharmacy or Remote Dispensing Site must be limited to:

(1) Pharmacists, Certified Pharmacy Technicians, or Pharmacy Interns who are employed by the Coordinating Pharmacy; or

(2) Personnel employed at the Institutional Facility or clinic where the Remote Dispensing Site is located who:

(a) are licensed health care providers;
(b) are designated in writing by the Pharmacist-in-Charge or the Person responsible for the supervision and on-site operation of the facility where the remote dispensing site is located; and
(c) have completed documented training concerning their duties associated with the remote site.

(D) Remote Pharmacies and Remote Dispensing Sites shall have adequate security to:
(1) comply with federal and Commonwealth laws and regulations; and

(2) maintain patient confidentiality.

(E) The Coordinating Pharmacy shall have procedures that specify that Drugs may only be Delivered to the Remote Pharmacy or Remote Dispensing Site in accordance with the policies and procedures of the Coordinating Pharmacy.

(vii) Policies and Procedures

(A) The Coordinating Pharmacy, Remote Pharmacy, and Remote Dispensing Site shall operate in compliance with written policies and procedures that are established by the Coordinating Pharmacy. The policy and procedure manual shall include, but not be limited to, the following:

(1) a current list containing the name and business address of the Pharmacist-in-Charge and personnel designated by the Pharmacist-in-Charge to have access to the area where Drugs are stored at the Remote Pharmacy or Remote Dispensing Site;

(2) duties that may only be performed by a Pharmacist;

(3) a copy of the written agreement between the Coordinating Pharmacy and the Remote Pharmacy or between the Coordinating Pharmacy and the Institutional Facility or clinic where the Remote Dispensing Site is located. Such contract or agreement is not required if the Remote Pharmacy or Remote Dispensing Site are under common control or ownership of the Coordinating Pharmacy;

(4) date of last review and revision of policy and procedure manual; and

(5) policies and procedures for:
(a) operation of the video/auditory communication system;
(b) security;
(c) sanitation;
(d) storage of Drugs;
(e) Dispensing;
(f) supervision;
(g) Drug procurement, receipt of Drugs, and Delivery of Drugs.

(i) Drugs may only be Delivered to the Remote Pharmacy or Remote Dispensing Site in a sealed container with a list of Drugs Delivered.

(ii) Drugs Delivered to the Remote Pharmacy or Remote Dispensing Site must be checked by personnel designated by the Pharmacist-in-Charge to verify that the Drugs sent were actually received. The designated Person who checks the order shall document the verification by signing and dating the list of Drugs Delivered.

(h) Record keeping.

(B) A Coordinating Pharmacy providing pharmacy services at a Remote Pharmacy or Remote Dispensing Site shall, at least annually, review and revise as necessary its written policies and procedures, and document such review.

(C) A Coordinating Pharmacy providing pharmacy services at a Remote Pharmacy or Remote Dispensing Site shall maintain a written plan for recovery from an event that interrupts the ability of a Pharmacist to electronically supervise the Dispensing of Drugs at the Remote Pharmacy or Remote Dispensing Site. The written plan for recovery shall include:

(1) a statement that Drugs shall not be Dispensed at the Remote Pharmacy or Remote Dispensing Site if a Pharmacist is not able to electronically supervise such Dispensing;

(2) procedures for response when the video/auditory communication system is experiencing downtime; and

(3) procedures for the maintenance and testing of the written plan for recovery.

(D) All policies and procedures must be maintained and made available for inspection by the Board in the Coordinating Pharmacy responsible for the Automated Pharmacy System and at the Remote Pharmacy or Remote Dispensing Site where the Automated Pharmacy System is being used.

(viii) Quality Assurance

(A) A Coordinating Pharmacy that provides pharmacy services via a Remote Pharmacy or Remote Dispensing Site shall operate according to a written program for quality assurance that:

(1) requires continuous supervision of the Remote Pharmacy at all times the site is open to provide pharmacy services;

(2) requires a Pharmacist of the Coordinating Pharmacy to be accessible to respond to inquiries or requests pertaining to Drugs Dispensed from the Remote Pharmacy or from the Automated Pharmacy System located at the Remote Dispensing Site; and

(3) establishes procedures to test the operation of all Automated Pharmacy Systems and all video/auditory communication systems at a minimum of every six months and whenever any upgrade or change is made to the system and document the testing of each such system.

(ix) Record Keeping

(A) Required Records

(1) A Coordinating Pharmacy shall keep a record of all Drugs received, Dispensed, and Distributed from the Coordinating Pharmacy.

(2) A Coordinating Pharmacy shall keep a record of all Drugs received, Dispensed, and Distributed from each Remote Pharmacy or Remote Dispensing Site.

(3) All records of receipt, Dispensing, and Distribution shall be kept at the Coordinating Pharmacy. Coordinating Pharmacy, Remote Pharmacy, and Remote Dispensing Site records must be kept separate from each other.

(B) Inventory

(1) A Coordinating Pharmacy shall keep a perpetual inventory of controlled substances, and other Drugs required to be inventoried according to Commonwealth and federal law, that are held in the Coordinating Pharmacy, each Remote Pharmacy, and each Remote Dispensing Site.

(2) A Coordinating Pharmacy shall conduct an annual non-controlled substance Drug inventory at the Coordinating Pharmacy and at each Remote Pharmacy or Remote Dispensing Site.

(C) All inventory records shall be kept at the Coordinating Pharmacy. The Coordinating Pharmacy, Remote Pharmacy, and Remote Dispensing Site inventory records must be kept separate from each other.

(b) Licensing.

(i) The following Persons located within the Commonwealth, and the following Persons located outside the Commonwealth that provide services to patients within the Commonwealth, shall be licensed by the Board and shall Bi-annually renew their license with the Board:

(A) persons engaged in the Practice of Pharmacy;

(B) persons engaged in the Manufacture, production, sale, or Distribution or Wholesale Distribution of Drugs or Devices;

(C) pharmacies where Drugs or Devices are Dispensed, or Pharmacist Care is provided; and

(D) pharmacies that provide medications through the mail or other courier.

(ii) Where operations are conducted at more than one location, each such location shall be licensed by the Board.

(iii) Each Pharmacy shall have a Pharmacist-in-Charge. Whenever an applicable rule requires or prohibits action by a Pharmacy, responsibility shall be that of the owner and/or pharmacy permit holder and the Pharmacist-in-Charge of the Pharmacy, whether the owner and/or pharmacy permit holder is a sole proprietor, partnership, association, corporation, or otherwise.

(iv) Each licensed Person located outside of the Commonwealth who ships, mails, Distributes, Wholesale Distributes, or Delivers Drugs or Devices in the Commonwealth, or Pharmacy located outside of the Commonwealth who ships, mails, Distributes, or Delivers Drugs or Devices in the Commonwealth, shall designate a registered agent in the Commonwealth for service of process. Any such licensed Person or Pharmacy who does not so designate a registered agent shall be deemed to have violated these rules and will be issued a cease and desist order until a registered agent has been designated.

(v) The Board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the licensure and inspection of entities located in this jurisdiction and those located outside the Commonwealth.

(vi) The Board may deny or refuse to renew a license if it determines that the granting or renewing of such license would not be in the public interest.

(vii) The Board shall establish the standards that a Person must meet for initial and continued licensure under Article V and shall require initial inspections and periodic inspections thereafter for purposes of licensure or licensure renewal.

(viii) The Board may enter into an agreement with a third party to undertake inspections of facilities of a Person seeking initial or continued licensure where such third party maintains a program which has standards acceptable to the Board that must be met for any such Person to be accredited or certified by such third party.

The Board may rely on such accreditation or certification in determining eligibility for initial licensure or licensure renewal.

(c) Notifications.

(i) All licensed Persons shall report to the Board the occurrence of any of the following:

(A) permanent closing;
(B) change of ownership, management, location, or Pharmacist-in-Charge of a Pharmacy;
(C) any theft or loss of Drugs or Devices;
(D) any conviction of any employee of any State or Federal Drug laws;
(E) any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel;
(F) disasters, accidents, or any theft, destruction, or loss of records required to be maintained by the Commonwealth or Federal law;
(G) occurrences of Significant Adverse Drug Reactions as defined by Rules of the Board;
(H) illegal use or disclosure of Protected Health Information; or
(I) any and all other matters and occurrences as the Board may require by rule.

(d) Grounds, Penalties, and Reinstatement. The Board may refuse to issue or renew, or may Revoke, Summarily Suspend, Suspend, place on Probation, Censure, Reprimand, issue a Warning against, or issue a Cease and Desist order against, the licenses or the registration of, or assess a Fine/Civil Penalty or Costs/Administrative Costs against any Person pursuant to the procedures set forth in NMIAC §§ 140-50.3-901 to 140-50.3-1215, upon one or more of the following grounds:

(i) engaging in conduct that is cause for discipline under 4 CMC § 2224;

(ii) incapacity that prevents a licensee from engaging in the Practice of Pharmacy or a registrant from assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public;

(iii) being guilty of one (1) or more of the following:

(A) a felony;
(B) any act involving moral turpitude or gross immorality; or
(C) violations of the pharmacy or drug laws of the Commonwealth or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other State or territory; or of the Federal government;

(iv) disciplinary action taken by another state or jurisdiction against a license or other authorization to Practice Pharmacy based upon conduct by the licensee similar to conduct that would constitute grounds for actions as defined in this section;

(v) failure to report to the Board any adverse action taken by another licensing jurisdiction (United States or foreign), government agency, law enforcement agency, or court for conduct that would constitute grounds for action as defined in this section;

(vi) failure to report to the Board one's surrender of a license or authorization to Practice Pharmacy in another state or jurisdiction while under disciplinary investigation by any of those authorities or bodies for conduct that would constitute grounds for action as defined in this section;

(vii) failure to report to the Board any adverse judgment, settlement, or award arising from a malpractice claim arising related to conduct that would constitute grounds for action as defined in this section;

(viii) knowing or suspecting that a Pharmacist or Pharmacy Intern is incapable of engaging in the Practice of Pharmacy or that a Pharmacy Technician is incapable of assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public, and failing to report any relevant information to the Board;

(ix) misrepresentation of a material fact by a licensee in securing the issuance or renewal of a license or registration;

(x) fraud by a licensee in connection with the Practice of Pharmacy;

(xi) engaging, or aiding and abetting an individual to engage in the Practice of Pharmacy without a license; assisting in the Practice of Pharmacy or aiding and abetting an individual to assist in the Practice of Pharmacy without having registered with the Board; or falsely using the title of Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Pharmacy Technician;

(xii) making false or misleading statements against another licensee or health care provider for the purpose of self-enrichment, patient coercion, or intentional defamation;

(xiii) engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of any licensing examination;

(xiv) being found by the Board to be in violation of any of the provisions of the Health Care Professions Licensing Act of 2007, codified at 4 CMC § 2201 et seq., or the rules adopted pursuant to the Act;

(xv) illegal use or disclosure of Protected Health Information; or

(xvi) failure to furnish to the Board, its investigators, or representatives any information legally requested by the Board.

§ 140-50.3-3575: Unprofessional Conduct

Unprofessional conduct shall include, but is not limited to, the following acts of a Pharmacist or Pharmacy:

(a) the publication or circulation of false, misleading, or otherwise deceptive statements concerning the Practice of Pharmacy;
(b) unreasonably refusing to Compound or Dispense Prescription Drug Orders that may be expected to be Compounded or Dispensed in Pharmacies by Pharmacists;
(c) attempting to circumvent the Patient Counseling requirements, or discouraging the patient from receiving Patient Counseling concerning their Prescription Drug Orders;
(d) the illegal use or disclosure of Protected Health Information;
(e) failure to maintain adequate records, systems, and security to protect against the illegal use or disclosure of Protected Health Information;
(f) failure to maintain adequate records to account for disclosures of Protected Health Information;
(g) selling, giving away, or otherwise disposing of accessories, chemicals, or Drugs or Devices found in illegal Drug traffic when the Pharmacist knows or should have known of their intended use in illegal activities;
(h) engaging in conduct likely to deceive, defraud, or harm the public, or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from the standards of care ordinarily exercised by a Pharmacist, with proof of actual injury not having to be established;
(i) selling a Drug for which a Prescription Drug Order from a Practitioner is required, without having received a Prescription Drug Order for the Drug;
(j) willfully and knowingly failing to maintain complete and accurate records of all Drugs received, Dispensed, or disposed of in compliance with the Federal laws and regulations and State laws and rules;
(k) obtaining any remuneration by fraud, misrepresentation, or deception, including, but not limited to, receiving remuneration for amending or modifying, or attempting to amend or modify, a patient's Pharmacist Care Services, absent a clear benefit to the patient, solely in response to promotion or marketing activities.

PART 3600: Pharmacy

§ 140-50.3-3600. Licensing.

(a) The following Persons located within the Commonwealth, and the following Persons located outside the Commonwealth that provide services to patients within the Commonwealth, shall be licensed by the Board and shall bi-annually renew their license with the Board:
  (1) persons engaged in the Practice of Pharmacy;

(2) persons engaged in the Manufacture, production, sale, or Distribution or Wholesale Distribution of Drugs or Devices;

(3) pharmacies where Drugs or Devices are Dispensed, or Pharmacist Care is provided; and

(4) pharmacy Benefits Managers.

Where operations are conducted at more than one location, each such location shall be licensed by the Board.

(b) Each Pharmacy shall have a Pharmacist-in-Charge. Whenever an applicable rule requires or prohibits action by a Pharmacy, responsibility shall be that of the owner and/or pharmacy permit holder and the Pharmacist-in-Charge of the Pharmacy, whether the owner and/or pharmacy permit holder is a sole proprietor, partnership, association, corporation, or otherwise.

(c) Each Pharmacy located outside of the Commonwealth that ships, mails, Distributes, or Delivers Drugs or Devices in the Commonwealth, shall designate a registered agent in the Commonwealth for service of process. A copy of any such service of process shall be mailed to such Agent by the Board by certified mail, return receipt requested, postage prepaid, at the address such Agent has been designated on its application for licensure in the Commonwealth.

(d) The Board may enter into agreements with other states, territories, or with third parties for the purpose of exchanging information concerning the licensure and inspection of entities located in this jurisdiction and those located outside of the Commonwealth.

(e) The Board may deny or refuse to renew a license if it determines that the granting or renewing of such license would not be in the public interest.

(f) The Board shall establish the standards that a Person or Entity must meet for initial and continued licensure under this act and may require periodic inspections for purposes of licensure or licensure renewal of the Pharmacy.

(g) The Board may enter into an agreement with a third party to undertake inspections of facilities of a Person seeking initial or continued licensure where such third party maintains a program which has standards acceptable to the Board that must be met for any such Person to be accredited or certified by such third party. The Board may rely on such accreditation or certification in determining eligibility for initial licensure or licensure renewal.

§ 140-50.3-3605 Application

(a) The Board shall specify by rule the licensure procedures to be followed, including but not limited to, specification of forms for use in applying for such licensure and times, places, and applicable fees. Should be Applicant shall fill out form provided by the Board.

(b) Applicants for licensure to Distribute, Wholesale Distribute, Manufacture, sell, purchase, and/or produce Drugs or Devices, and applicants for licensure as a Pharmacy Benefits Manager, shall file with the Board of Pharmacy a verified application containing such information as the Board requires of the applicant relative to the qualifications for a license.

(c) Licenses issued by the Board pursuant to this Part shall not be transferable or assignable.

(d) Licensed practitioners allowed to prescribe medications are not allowed to be an owner, officer, director or shareholder of a corporation may not be considered as an applicant;

(e) The Board shall specify by rule minimum standards for responsibility of any Person, Pharmacy, or Pharmacy Benefits Manager that has employees or personnel engaged in the Practice of Pharmacy, or Manufacture, Distribution, Wholesale Distribution, production, sale, or use of Drugs or Devices in the conduct of their business. If the licensed Person is a Pharmacy located in the Commonwealth, that portion of the facility to which

such license applies shall be operated only under the direct supervision of a Pharmacist licensed to practice in the Commonwealth.

(e) Applicants must provide and certify the following:
(1) The name, address and contact information of the individual requesting the license;
(2) The name(s) under which the applicant does business;
(3) The name of the Pharmacist-in-Charge of the facility to be licensed;
(4) A copy of the Commonwealth license for the applicants Pharmacist in Charge;
(5) The names and contact information of all of the individual owners and/or corporate officers;
(6) If the applicant is a corporation, a copy of the corporation's articles of incorporation and a letter of good standing from the jurisdiction of incorporation;
(7) A copy of the applicants Commonwealth business license;
(8) A statement by all of the owners, corporate officers, pharmacists, technical staff and any other individual with decision making responsibilities, stating whether:
a. they have been arrested or involved in litigation and/or arbitration;

b. have ever had their professional license disciplined for any reason;

c. ever had a denial of a personal license, permit, certificate, or registration for a privileged, occupational, or professional activity

d. denials of a business or industry license or related finding of suitability, or participation in a group that has been denied a business or industry license or related finding of suitability;
e. Administrative actions or proceedings related to the pharmaceutical industry or participation in a group that has been the subject of such administrative actions or proceedings;

f. guilty findings or pleadings or pleas of nolo contendere to any offense, federal or state, related to prescription Drugs and/or controlled substances or participation in a group that has been found or pled guilty or that has pled nolo contendere to any such offense;

g. surrender, voluntary or otherwise, of licensure, permit, or certificate of registration relating to the pharmaceutical industry, or participation in a group that has surrendered, voluntary or otherwise, any such licensure, permit, or certificate of registration.

(9) A map showing the physical location of the pharmacy;

(10) A floor plan of the pharmacy showing the essential areas for appropriately securing pharmaceutical products, securing controlled substances, compounding area, private patient counseling area, and prescription preparation area;

§ 140-50.3-3610 Notifications

(a) All licensed Persons shall report to the Board the occurrence of any of the following:
(1) permanent closing;
(2) change of ownership, management, location, or Pharmacist-in-Charge of a Pharmacy;
(3) any theft or loss of Drugs or Devices;
(4) any conviction of any employee of any State or Federal Drug laws;
(5) any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel;
(6) disasters, accidents, or any theft, destruction, or loss of records required to be maintained by State or Federal law;
(7) occurrences of Significant Adverse Drug Reactions as defined by Rules of the Board;
(8) illegal use or disclosure of Protected Health Information; or
(9) any and all other matters and occurrences as the Board may require by rule.