

1999 SENATE POLITICAL SUBDIVISIONS

SB 2176


1999 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB2176

Senate Political Subdivisions Committee

Conference Committee

Hearing Date January 13, 1999

| Tape Number | Side A | Side B | Meter # |
|---|--------|--------|-------------|
| 1 | | x | 2536 to end |
| | | | |
| Committee Clerk Signature  | | | |

Minutes:

SENATOR MUTCH: introduce SB2176

HOWARD ANDERSON: DIRECTOR OF THE BOARD OF PHARMACY

SEE TESTIMONY, change the wording for practitioner on the bill.

SENATOR KLEIN: what is the schedule 4

HOWARD ANDERSON: abuse potential of drugs, schedules two, three, four and five and the activity of each schedule.

SENATOR MUTCH: any other questions

HOWARD ANDERSON: implementing of schedules on the drugs that are used.

GALEN JORDREY: support SB2176

SENATOR MUTCH: any further questions

SENATOR SAND: motion for DO PASS

Page 2

Senate Political Subdivisions Committee

Bill/Resolution Number SB2176 IBL

Hearing Date January 13, 1999

SENATOR KLEIN: SECOND DO PASS

SENATOR MUTCH: any further questions

ROLL CALL: 7 YEAS, 0 NEAS

SENATOR KLEIN: TO CARRY THE BILL

DISCUSSION

Date: 1/13
Roll Call Vote #: 2176

**1999 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO.**

Senate INDUSTRY, BUSINESS AND LABOR COMMITTEE Committee

Subcommittee on _____
or
 Conference Committee

Legislative Council Amendment Number _____

Action Taken DO PASS

Motion Made By _____ Seconded By _____

| Senators | Yes | No | Senators | Yes | No |
|-------------------|-----|----|----------|-----|----|
| Senator Mutch | X | | | | |
| Senator Sand | X | | | | |
| Senator Klein | X | | | | |
| Senator Krebsbach | X | | | | |
| Senator Heitkamp | X | | | | |
| Senator Mathern | X | | | | |
| Senator Thompson | X | | | | |
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Total (Yes) 7 No 0

Absent 0

Floor Assignment KLEIN

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE (410)
January 13, 1999 11:54 a.m.

Module No: SR-07-0544
Carrier: Klein
Insert LC: . Title: .

REPORT OF STANDING COMMITTEE

SB 2176: Industry, Business and Labor Committee (Sen. Mutch, Chairman) recommends **DO PASS** (7 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2176 was placed on the Eleventh order on the calendar.

1999 HOUSE HUMAN SERVICES

SB 2176

1999 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 2176

House Human Services Committee

Conference Committee

Hearing Date February 10, 1999

| Tape Number | Side A | Side B | Meter # |
|---|--------|--------|------------|
| 1 | X | | 0.0 - 11.7 |
| | | | |
| | | | |
| Committee Clerk Signature <i>Susann Lindsteigen</i> | | | |

Minutes:

Chairman Rep. CLARA SUE PRICE called the committee to order. Present were Reps. Clara Sue Price, Robin Weisz, William Devlin, Pat Galvin, Dale Henegar, Roxanne Jensen, Amy Kliniske, Chet Pollert, Todd Porter, Blair Thoreson, Bruce Eckre, Ralph Metcalf, Carol Niemeier, Wanda Rose, and Sally Sandvig.

HOWARD ANDERSON, JR., Executive Director, ND State Board of Pharmacy, testified (Testimony attached).

Rep. BRUCE ECKRE stated on Section 3 are you going from three days to seven days for deliveries and asked how did you choose the seven days? HOWARD ANDERSON stated when a physician or a practitioner writes a controlled substances prescription, I'm required by North Dakota law to get that physician's signature on the prescription. I have seven days to get it back

and have it on file. The seven days was made because DEA allowed seven days, the federal control substances regulation. They expanded theirs to seven days.

Rep. CAROL NIEMEIER asked what are the other duties assigned to a pharmacist's technician?

HOWARD ANDERSON stated pharmacy technicians can do everything in the pharmacy except things that require decision making. When they get a prescription in, they can read it, enter it into the computer, get the medication ready for the pharmacist's final check, count the pills, put them in the bottle, affix the label to the prescription, and so forth. Then the pharmacist does the final check. In North Dakota, our board has always maintained that the pharmacist is the final control. We'll never let the pharmacist say "the technician did that, its not our fault." The technician may have done it, but its still the pharmacist's fault.

GALEN JORDRE, ND Pharmaceutical Association, testified we favor this bill.

DAVID PESKE, ND Medical Association, testified in the Senate we stood up and supported this bill and wish to indicate our support for it at this time as well.

OPPOSITION

None

Hearing Closed.

1999 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2176

House Human Services Committee

Conference Committee

Hearing Date February 15, 1999

| Tape Number | Side A | Side B | Meter # |
|-------------|--------|--------|-----------|
| 1 | | X | 0.0 - 1.6 |
| | | | |
| | | | |

Committee Clerk Signature *Susann Lindteigen*

Minutes:

Committee Discussion.

Rep. TODD PORTER moved DO PASS.

Rep. AMY KLINISKE second the motion

ROLL CALL VOTE #3: 10 yeas, 3 nays, 2 absent

CARRIER: Rep. TODD PORTER

Date: 2-15-99
 Roll Call Vote #: 3

1999 HOUSE STANDING COMMITTEE ROLL CALL VOTES
 BILL/RESOLUTION NO. 2176

House Human Services Committee

Subcommittee on _____
 or

Conference Committee

Legislative Council Amendment Number _____

Action Taken No Pass

Motion Made By Todd Porter Seconded By Amy Kliniske

| Representatives | Yes | No | Representatives | Yes | No |
|------------------------------|-----|----|-------------------|-----|----|
| Clara Sue Price - Chairwoman | X | | Bruce A. Eckre | | X |
| Robin Weisz - Vice Chairman | X | | Ralph Metcalf | | X |
| William R. Devlin | X | | Carol A. Niemeier | | X |
| Pat Galvin | X | | Wanda Rose | X | |
| Dale L. Henegar | | | Sally M. Sandvig | X | |
| Roxanne Jensen | X | | | | |
| Amy N. Kliniske | X | | | | |
| Chet Pollert | X | | | | |
| Todd Porter | X | | | | |
| Blair Thoreson | | | | | |
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Total Yes 10 No 3
 Absent 2

Floor Assignment Todd Porter

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE (410)
February 15, 1999 3:31 p.m.

Module No: HR-30-3017
Carrier: Porter
Insert LC: . Title: .

REPORT OF STANDING COMMITTEE

SB 2176: Human Services Committee (Rep. Price, Chairman) recommends **DO PASS**
(10 YEAS, 3 NAYS, 2 ABSENT AND NOT VOTING). SB 2176 was placed on the
Fourteenth order on the calendar.

1999 TESTIMONY

SB 2176



DEA's Revised Regulations

By James R. Phelps and F. Gail Bormel
Hyman, Phelps & McNamara, P.C.



On March 24, 1997, the Drug Enforcement Administration (DEA) published a final rule revising its regulations which appear at 21 C.F.R. Parts 1300-1316.^{1/} These revised regulations, which took effect on March 28, 1997, implement federal law, specifically the Controlled Substances Act, the Narcotic Addict Treatment Act, the Controlled Substances Import/Export Act, the Chemical Diversion and Trafficking Act, and the Domestic Chemical Diversion Control Act. DEA states that this final rule represents a comprehensive review of its regulations consistent with the President's National Performance Review, Regulatory Reinvention Initiative.^{2/} DEA asserts that the result of this review is the consolidation, elimination, and clarification of the regulations. In addition, DEA has revised several regulations that have been unclear to members of the pharmaceutical, chemical, and health care industries. However, DEA has missed the opportunity to clarify other provisions, such as the one requiring notification of a "significant loss" of controlled substances.

DEA made two structural changes that should assist individuals reading the regulations. First, DEA relocated definitions which previously were found throughout 21 C.F.R. Part 1301 to 1313. These definitions are now found in two sections, 21 C.F.R. §§ 1300.01 and 1300.02. By grouping these definitions in two sections, an individual may readily find those terms which pertain to one's business activity. Controlled substance handlers may refer to § 1300.01 for the relevant definitions while § 1300.02 provides the terms which are applicable to chemical handlers.

Second, DEA included a table summarizing the registration categories. This provides an easy reference to the categories and requirements for registration.

Several of DEA's revisions affect pharmacy practice, including the way in which controlled substances prescriptions are filed in a pharmacy. For example, while both DEA's previous and current regulations require separate files for Schedule I and II controlled substances, DEA has revised the filing requirements for Schedule III through V prescriptions.^{3/} In the past, DEA required that

pharmacies either maintain a separate file for these records or maintain them with the non-controlled substance prescriptions provided the controlled substances records are imprinted with a red "C."^{4/} The revised regulation waives the requirement of the imprinted red "C" provided that the pharmacy has an automatic data processing or other electronic recordkeeping system which allows the identification and retrieval of the appropriate prescription records. Therefore, pharmacies with the above-described processing or recordkeeping systems that choose to file Schedule III through V and non-controlled prescriptions together need not mark the controlled prescriptions with a red "C."

Another practice affected by the revised regulations is the timing of the biennial inventory. The regulations formerly provided some, but not much, flexibility in the biennial inventory date. According to the prior regulations, pharmacies and other registrants had to conduct this inventory every other year on the same date.^{5/} The exceptions to the same date requirement allowed a registrant to conduct the inventory on the registrant's regular general physical inventory date or another fixed date, provided either date fell within six months of the biennial date.^{6/} The regulations also provided for flexibility in the "fixed date" of the inventory allowing the activity to be conducted within four days of the biennial inventory date so long as the registrant notified in advance the Special Agent in Charge of the Administration in the local DEA office.^{7/} The revised regulations provide far more flexibility in the biennial inventory date by eliminating the requirement of a fixed date, and instead, permitting a registrant to conduct a biennial inventory "on any date which is within two years of the previous biennial inventory date."^{8/}

DEA's regulations also extend the time in which a pharmacy must receive a written prescription for an emergency oral prescription for a Schedule II controlled substances. Previously, regulations required that a pharmacy receive the prescription within 72 hours of the telephone call, but DEA reports that pharmacists stated this time period was not sufficient.^{9/} In response, DEA

(Continued on page 6)

DEA's Revised Regulations

Continued from page 5)

has revised the regulations to require receipt of the prescription within seven days.^{10/}

With respect to facsimile prescriptions of Schedule II controlled substances, DEA previously permitted in its regulations that these facsimiles may serve as the original prescription for patients who either are in a long term care facility or receive a parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion from a home infusion pharmacy.^{11/} DEA's revised regulations now permit a facsimile to also serve as the original Schedule II prescription for patients residing in a hospice certified by Medicare under Title XVIII or licensed by the state.^{12/}

Two other revisions affecting pharmacy practice include those concerning partial filling of prescriptions and prescription transfer. With respect to partial filling of Schedule II prescriptions, the new regulations eliminate the requirement that a pharmacist determine, before providing the partial quantity, whether the additional partial filling is necessary.^{13/} Instead, the pharmacist is permitted to dispense a partial quantity subject to the same limitations that previously existed in the regulations. These limitations are that the total quantity dispensed does not exceed the amount prescribed and that the quantity is dispensed within 60 days after the prescription is issued.^{14/} The pharmacist also must make the appropriate notations on the prescription, including the date of the partial dispensing, the quantity dispensed, the remaining amount that may be dispensed and the identification of the dispensing pharmacist.^{15/}

DEA's regulations on prescription transfers have been revised so that pharmacies which share a real-time, on-line electronic database may transfer Schedule III - V prescription information, limited only by the maximum number of refills authorized on the prescription.^{16/} Previously, pharmacies were permitted to transfer a controlled substance prescription only one time, regardless of whether pharmacies shared such databases.^{17/} For pharmacies that do not share a real-time, on-line electronic database, the revised regulations do not apply and these pharmacies are subject to the one-time only transfer rule.

Regarding reports submitted to the ARCOS Unit, the revised regulations have reduced the frequency of such reporting. Previously, the reports by manufacturers,

distributors, labelers and packagers on certain controlled substances as described under 21 C.F.R. §§ 1304.35-1304.38 were required to be submitted on a monthly basis. DEA has eliminated §§ 1304.35-1304.38 and revised § 1304.33 so that ARCOS reports are now submitted quarterly. The reports are now due on the fifteenth day of the month after the end of the quarter.^{18/}

One way in which DEA streamlined its regulations was to remove from the regulations the information that is contained on the back of the DEA Form 222.^{19/} By so doing, DEA has eliminated repetitious requirements. DEA has eliminated the tables on exempted and excluded products which were found previously at 21 C.F.R. §§ 1308.24, 1308.26, 1308.32, and 1308.34. Although these tables no longer appear in the regulations, DEA will continue to publish them for comment in the Federal Register each year.^{20/}

DEA has revised its schedule for administrative inspections for distributors of controlled substance in Schedules II through V and for manufacturers of controlled substances in Schedules III through V. Instead of inspections once every three years as previously provided in the regulations, the inspections will now be based on certain factors which include the registrant's history, the possibility for diversion, and the appearance of controlled substances on the illicit market.^{21/} This system of scheduling inspections will allow DEA to focus resources on registrants who have a history of problems such as diversion, inappropriate recordkeeping or inadequate security.

These revisions do not include a needed clarification of the term "significant loss" found in 21 C.F.R. § 1301.76(b). This section requires a registrant to notify local DEA office "of the theft or significant loss of any controlled substances upon discovery of such loss or theft." The notion of "significant" changes radically depending upon a constellation of variables. An explanation in DEA's regulations of this requirement is necessary so that registrants may analyze loss situations as they arise.

In summary, DEA's revised regulations are designed to address some of the concerns presented by registrants and by members of industry. The changes to these regulations make easier certain recordkeeping requirements and also facilitate the use of the regulations by industry, but do not clarify certain provisions, including

(Continued on page 7)

43-15-33. License to sell emergency medicines. Any person of good moral character over eighteen years of age, who conducts a retail business at a place more than five miles [8.05 kilometers] from a drugstore employing a licensed pharmacist, may procure from the board, upon application and payment to said board of a fee of three dollars annually, a license which shall permit such retailer to keep for sale, and to sell in original packages, the simple household remedies and such other emergency medicines and poisons as from time to time may be approved for such sale by the board. Such license must be for a period of one year commencing on July first and ending on June thirtieth following the date of the application. It must apply to the location for which it is issued and must be posted in a conspicuous place at such location. Upon satisfactory proof to the board of any violation of any law of the state by the licensee in or upon the premises licensed, the board shall revoke the license. The board, from time to time, may add to or eliminate from the approved list of simple household remedies, emergency medicines, and poisons salable under the license. Notice of the alterations must be given by publication in such manner as the board deems proper.

Source: S.L. 1907

**DESIGNATION OF BUTORPHANOL INTO SCHEDULE IV
OF THE UNIFORM CONTROLLED SUBSTANCES ACT PURSUANT TO
Chapter 19-03.1-02 SUBSECTION 4 of the North Dakota Century Code.**

SUMMARY: With the issuance of the final rule by the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) placing the substances Butorphanol, including its salts and optical isomers, into Schedule IV of the Controlled Substances Act (CSA). The North Dakota State Board of Pharmacy places these substances into Schedule IV of the North Dakota Uniform Controlled Substances Act.

The Scheduling of this substances is effective thirty days from the notice published in the Federal Register - October 1st, 1997 - page 51370-51371 (Vol 62, No 190).

**DESIGNATION OF SIBUTRAMINE INTO SCHEDULE IV
OF THE UNIFORM CONTROLLED SUBSTANCES ACT PURSUANT TO
CHAPTER 19-03.1-02 SUBSECTION 6 of the North Dakota Century Code.**

SUMMARY: With the issuance of this final rule, the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance, sibutramine, including its salts and optical isomers, into Schedule IV of the Controlled Substances Act (CSA) As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV will be applicable to the manufacture, distribution, importation and exportation of sibutramine and products containing. The North Dakota State Board of Pharmacy places these substances into Schedule IV of the North Dakota Uniform Controlled Substances Act.

The Scheduling of this substance is effective thirty days from the notice published in the Federal Register - February 11, 1998 pages 6862-6864 (Vol 63, No. 28).



Board of Pharmacy
STATE OF NORTH DAKOTA
EDWARD T. SCHAFER, Governor

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HOWARD C. ANDERSON, Jr., R.Ph.
Turtle Lake, Executive Director

November 12, 1997

Ms. Heidi Heitkamp, J.D.
Attorney General
State of North Dakota
600 E Boulevard Ave
Bismarck ND 58505-0040

Dear Ms. Heitkamp:

The Board of Pharmacy has taken administrative action consistent with the issuance of the final rule by the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) placing the substance Butorphanol, including its salts and optical isomers, into Schedule IV of the Controlled Substances Act (CSA). The scheduling of this substance is effective thirty days from the notice published in the Federal Register - October 1st, 1997 page 51370-51371 (Vol 62, No. 190). The North Dakota State Board of Pharmacy places these substances into Schedule IV of the North Dakota Uniform Controlled Substances Act.

The above scheduling will effect North Dakota Century Code *19-03.1-11 subsection 4 Depressants* of the North Dakota Uniform Controlled Substances Act Schedule IV.

Sincerely,

Howard C. Anderson, Jr., R.Ph.
Executive Director

HCA/eh

CC David A. Lindell, J.D.
Special Assistant Attorney General

[Federal Register: October 1, 1997 (Volume 62, Number 190)]
[Rules and Regulations]
[Page 51370-51371]
From the Federal Register Online via GPO
Access [wais.access.gpo.gov]
[DOCID:fr01oc97-3]

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DEPARTMENT OF JUSTICE
Drug Enforcement Administration
21 CFR Part 1308
[DEA-166F]

SCHEDULES OF CONTROLLED SUBSTANCES
PLACEMENT OF BUTORPHANOL INTO
SCHEDULE IV

AGENCY: Drug Enforcement Administration,
Department of Justice.
ACTION: Final rule.

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SUMMARY: With the issuance of this final rule, the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance butorphanol, including its salts and optical isomers, into Schedule IV of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV will be applicable to the manufacture, distribution, dispensing, importation and exportation of butorphanol and products containing butorphanol.

EFFECTIVE DATE: October 31, 1997.

FOR FURTHER INFORMATION CONTACT:
Frank Sapienza, Chief, Drug and Chemical
Evaluation Section, Drug Enforcement
Administration, Washington, DC 20537,
Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: Butorphanol is classified as an opioid agonist-antagonist analgesic that is marketed as a prescription drug under the trade name Stadol® for the relief of moderate to severe pain in humans. It is also marketed as a veterinary product under the trade names Torbugesic® and Torbutrol® for use in horses and dogs. It was first marketed as an injectable product in 1979. Although there

was limited abuse of the injectable product among certain populations, significant abuse was not observed until after the nasal spray was introduced in 1992.

The Acting Deputy Administrator of the DEA received a letter dated September 30, 1996, from the Assistant Secretary for Health, on behalf of the Secretary of the Department of Health and Human Services (DHHS), recommending that the drug product, Stadol® NS Nasal Spray, be placed into Schedule IV of the CSA. Enclosed with the September 30, 1996, letter from the Assistant Secretary was a scientific and medical evaluation prepared by the Food and Drug Administration (FDA). The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)). Correspondence from the Acting Assistant Secretary for Health dated June 19, 1997, confirmed that the DHHS recommendation included the substance butorphanol and its salts and isomers. The Acting Deputy Administrator of the DEA, in a July 10, 1997, Federal Register notice (62 FR 37004 proposed to place butorphanol into Schedule IV of the CSA. The notice provided an opportunity for all interested persons to submit their comments, objections, or requests for a hearing in writing on the proposed scheduling of butorphanol until August 11, 1997. DEA received nine comments regarding the proposal. Comments in support of the proposal were received from six organizations: National Association of Boards of Pharmacy, Missouri Department of Mental Health, Missouri Department of Health, Missouri Department of Economic Development's State Board of Registration for the Healing Arts, Texas State Board of Pharmacy and Public Citizen. The American Veterinary Medical Association noted that controlled substances are subject to additional recordkeeping and storage requirements, but recognized the abuse potential of butorphanol. It recommended that if butorphanol is to be controlled, it be classified at a level no greater than Schedule IV.

Bristol-Myers Squibb commented that the abuse potential of butorphanol nasal spray is low, as evidenced by the low number of adverse reaction reports received by the company per number of prescriptions. Bristol-Myers Squibb did support the placement of butorphanol in Schedule IV. Fort Dodge Animal Health

butorphanol shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

8. Criminal Liability. Any activity with butorphanol not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful on or after October 31, 1997.

In accordance with the provisions of 21 U.S.C. 811(a) of the CSA, this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, section 3(d)(1). The Acting Deputy Administrator, in accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small-business entities. Butorphanol products are prescription products. Handlers of butorphanol also handle other controlled substances which are already subject to the regulatory requirements of the CSA.

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform act of 1995.

This rule is not a major rule as defined by Sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule will not

have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA [21 U.S.C. 811(a)], and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Acting Deputy Administrator pursuant to 28 CFR 0.104, the Acting Deputy Administrator hereby amends 21 CFR part 1308 as follows.

PART 1308--[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.14 is amended by adding a new paragraph (f)(2) to read as follows:

Sec. 1308.14 Schedule IV.

* * * * *

(f) * * *

(2) Butorphanol (including its optical isomers)-9720

Dated: September 22, 1997.

James S. Milford,

Acting Deputy Administration.

[FR Doc. 97-25969 Filed 9-30-97; 8:45 am]

BILLING CODE 4410-09-M



Board of Pharmacy
 STATE OF NORTH DAKOTA
 EDWARD T. SCHAFER, Governor

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 Turtle Lake, Executive Director

SENATE BILL NO. 2176

SENATE INDUSTRY, BUSINESS AND LABOR COMMITTEE

JANUARY 13, 1999 – 10:00 AM – ROOSEVELT PARK ROOM

Chairman Mutch, members of the Industry, Business and Labor Committee, for the record I am Howard C. Anderson, Jr, R.Ph, Executive Director of the North Dakota State Board of Pharmacy.

This bill comprises the changes the Board of Pharmacy has deemed appropriate to streamline the care of patients and the operation of pharmacies in prescription filling and recordkeeping. It also includes the changes in the Controlled Substances Act, there being two new drugs scheduled during the past two years.

I will address the changes briefly, one at a time. There is additional information in the packets that have been distributed to you, which provide documentation. As always, if you have any questions that I, in my brief explanation or in the documentation do not answer, I will obtain an answer for you.

Lines 10-14 on page 1 of Senate Bill No. 2176 are intended to change the definition of practitioner in the Controlled Substances Act 19-02.1-01 as far as filling prescriptions are concerned. The current language requires the practitioner to be licensed in North Dakota. This means that a patient being referred to the Mayo Clinic or spending the winter in Arizona, bringing their prescriptions back with them in the spring, technically can not get their prescriptions filled in a North Dakota pharmacy unless that physician is licensed here. We believe this is an unnecessary restriction

of the patient's ability to move about and see the physician of their choice. We want to be able to take care of those patients in their hometown pharmacy and believe the patients should be able to fill their prescriptions in North Dakota, even though their physician may be licensed in another state. The board of pharmacy had begun this initiative before the approval of Viagra. As you probably know Viagra is not currently approved in Canada. The language currently in this revision would include Canadian physicians, which would allow patients along our northern border to see the physician of their choice and still fill their prescriptions in their hometown pharmacy. The fact that some patients may seek Viagra in this country because it is not approved in Canada could happen but is an unintended consequence of this legislation. The Board of Medical Examiners Executive, Rolf Sletten tells me that the board of medical examiners treats the training requirements for Canadian physicians the same as we do in North Dakota. It would always be up to the pharmacist to determine if the prescriber is legitimately licensed where they practice before filling the prescription. This should generally not be difficult, when there is a question, an occasional telephone call would have to be made to my office or the state licensing authority of the prescriber.

SECTION 2: Is the scheduling of two additional drugs into the controlled substances act, namely Butorphanol, which is a pain relieving medication, which was until recently only available in an injectable form. But when it became available in a nasal inhaler. It seemed the illicit use of this product expanded and it became necessary for the Drug Enforcement Administration (DEA) to place it in Schedule IV. The second drug is Sibutramine, which is a medication used for the control of appetite in selected patients.

SECTION 3: Changes are to subsections 3 & 4 of 19-03.1-22 concerning Schedule III and IV drugs and Schedule V drugs. The changes expand the time the pharmacists have to obtain and the physician has to deliver a signed prescription, from seventy-two hours to seven days. This is consistent with the changes the DEA has made. Also, we have taken this opportunity to expand the list of those who may take those prescriptions over the phone from the pharmacist and intern; to pharmacist, intern or technician. I will discuss the qualification of the technician a bit further on.

SECTION 4: North Dakota Century Code 43-15 is the section, which applies to the practice of pharmacy. The changes on page 4 lines 11-18 apply to the definition of practitioner, using the same definition as we used in the controlled substances act 19-02.1-01.

SECTION 5: The changes in NDCC 43-15-18 on page 4 lines 21-31 are intended to bring the internship licensure of pharmacy students up to date. Interns since the adoption of the all Pharm.D. Program by the NDSU College of Pharmacy. The change from one year in an approved College of Pharmacy to one year of college, is a change which now reflects a minimum two year prepharmacy program, which can be obtained at any college or university and the four year professional Doctor of Pharmacy Program which follows at a College of Pharmacy. The previous language meshed with the four and five year pharmacy programs that were available in the past. To be registered in a prepharmacy program refers to the fact if they are interested in pharmacy school, they need to contact a College of Pharmacy to make sure they are taking the correct prepharmacy courses. The deletion of the specific fee of five dollars allows the Board more flexibility. It also allows us to charge a low fee for the two or three years that an intern might be licensed prior to entering into the professional program. Upon entry into the professional program, a higher fee will help fund the Externship Rotation Program. The students spend their entire sixth year rotating between professional practice sites while they are actually in school and performing the necessary training under the supervision of their externship preceptors. The Board's intention is to charge \$10.00 for the pre-professional program years and \$100.00 for the four-year professional program years. \$90.00 of that \$100.00 (the Board only keeps \$10.00) goes to the College of Pharmacy for the Dean to enhance the externship programs and the improvement of the practice learning environment for the sixth year students during their rotations.

SECTION 6: Expands who may take a telephone or oral prescription to include the registered pharmacy technician and state that they may take a new or refill prescription. North Dakota has been a leader in the training and registration of pharmacy technicians. This has offered an excellent opportunity for pharmacies, both hospital and retail to utilize these trained individuals in an expanding role. In October of 1993, the Board of Pharmacy repealed NDAC Chapter 61-02-07, the

section referring to clerical personnel and established rules for the qualifications and professional practice by pharmacy technicians. These rules specify the educational preparations necessary for registration. The training and registration requirements include continuing education requirements. NDSU College of Pharmacy in conjunction with North Dakota State College of Science (NDSCS) in Wahpeton developed a pharmacy technician program, which though not the first, is now one of the best in the country. We have not only a one-year program at NDSCS, but also a two-year Associate of Science Degree available. There is also an on-the-job training module program, which is the best in the nation. As the training requirements and the quality of our technician pool have improved, pharmacists are now ready to give these technicians the additional responsibility of taking telephone or oral prescriptions. All of the professional practices of the pharmacy technicians are preformed under the direct supervision of the licensed pharmacist. No pharmacy technician does any particular responsibility without the approval of the supervising pharmacist. If at any time the practitioner or pharmacist wish to speak directly about any prescription they can always do so. The board continues to hold the licensed pharmacist responsible for all the activities, which occur in the pharmacy, including the actions of their pharmacy technicians.

SECTION 7: Is a provision which will substantially reduce some costs for pharmacies in North Dakota as well as updating to current electronic references now available. Historically, North Dakota has been fairly restrictive in requiring that each pharmacy have copies of the United States Pharmacopeia/National Formulary and supplements to it or the United States Pharmacopeia Dispensing Information. Many pharmacies have found in the modern era that other references suit their purposes much better. Pharmacies typically purchase the references of their choice and were additionally required to purchase the United States Pharmacopeia/National Formulary and supplements. If we make this change, a few of the pharmacies will continue to purchase the United States Pharmacopeia/National Formulary and supplements because they are in the research or compounding pharmaceutical business and need the formulary standard. I estimate that out of our 230 pharmacies now required to purchase the \$199.99 USP/NF each year, we will have perhaps 30 continue to purchase it. \$199 multiplied by 200 pharmacies comes to almost \$40,000.00

dollars, which should help reduce cost pressures and is also an incentive for pharmacies to purchase the most useful reference which is acceptable to the board.

SECTION 8: Is the repeal of NDCC 43-15-33, which we feel is an outdated and what we feel is an unnecessary licensure requirement in the Century Code. This section requires licensure of emergency medicine outlets. These emergency medicine outlets could be located more than five miles from a licensed pharmacy and then were allowed to sell over the counter medications. This legislation was passed in 1907 and is now very unfair. As you know every grocery store, convenience store, gas stations and many others sell over the counter medications, which in 1907 were considered to be emergency medicines. But, only those business that are five miles or more from a pharmacy are required to have this license. We still do have a little over 50 of these license renewing. However, the number dwindles each year as the communities expand or the principles expire and businesses close. It is now time to delete this section so we are not unfairly requiring licensure of some and not others. We can call it somewhat of a victory to delete one licensure requirement in North Dakota even though it only effects a few people. The license fee in 1907 was \$3.00 and remains the same today.



Board of Pharmacy
STATE OF NORTH DAKOTA
EDWARD T. SCHAFER, Governor

OFFICE OF THE EXECUTIVE DIRECTOR

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Turtle Lake, Executive Director

March 03, 1998

Mr. Rolf P. Sletten
Executive Secretary/Treasurer
ND Board of Medical Examiners
418 East Broadway Avenue
Bismarck ND 58501

Dear Mr. Sletten:

the Board of Pharmacy has taken administrative action consistent with the issuance of the final rule by Acting Deputy Administrator of the Drug Enforcement Administration (DEA) placing the substance Sibutramine, including it's salts and optical isomers, into Schedule IV of the Controlled Substances Act (CSA). The scheduling of this substance is effective thirty days from the notice published in the Federal Register - February 11, 1998 pages 6862-6864 (Vol 63, No. 28). The North Dakota State Board of Pharmacy places these substances into Schedule IV of the North Dakota Uniform Controlled Substances Act.

The above scheduling will effecting North Dakota Century Code 19-03.1-11 subsection 6 Stimulants of the North Dakota Uniform Controlled Substances Act Schedule IV.

Sincerely,

Howard C. Anderson, Jr., R.Ph.
Executive Director

HCA/eh

CC David A. Lindell, J.D.
Special Assistant Attorney General

312—INVESTIGATIONAL NEW APPLICATION

1. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371; 42 U.S.C. 262.

2. Section 312.33 is amended by revising paragraph (a)(2) to read as follows:

§ 312.33 Annual reports.

* * * * *

(a) * * *

(2) The total number of subjects initially planned for inclusion in the study; the number entered into the study to date, tabulated by age group, gender, and race; the number whose participation in the study was completed as planned; and the number who dropped out of the study for any reason.

* * * * *

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

3. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 379e.

4. Section 314.50 is amended by revising the second sentence and adding two new sentences after the second sentence in paragraph (d)(5)(v), and by adding two new sentences after the first sentence in paragraph (d)(5)(vi)(a) to read as follows:

§ 314.50 Content and format of an application.

* * * * *

(d) * * *

(5) * * *

(v) * * * Evidence is also required to support the dosage and administration section of the labeling, including support for the dosage and dose interval recommended. The effectiveness data shall be presented by gender, age, and racial subgroups and shall identify any modifications of dose or dose interval needed for specific subgroups. Effectiveness data from other subgroups of the population of patients treated, when appropriate, such as patients with renal failure or patients with different levels of severity of the disease, also shall be presented.

(vi) * * *

(a) * * * The safety data shall be presented by gender, age, and racial subgroups. When appropriate, safety data from other subgroups of the population of patients treated also shall be presented, such as for patients with

renal failure or patients with different levels of severity of the disease. * * *

Dated: February 2, 1998.
William B. Schultz,
Deputy Commissioner for Policy.
[FR Doc. 98-3422 Filed 2-10-98; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADA's) filed by Elanco Animal Health, Division of Eli Lilly & Co. The supplemental NADA's provide for transferring the data and information in one NADA into another and withdrawing approval of the vacated NADA. The NADA's provide for use of monensin Type A medicated articles to make a free-choice Type C medicated feed/mineral granules for pastured cattle for increased rate of weight gain.

EFFECTIVE DATE: February 23, 1998.
FOR FURTHER INFORMATION CONTACT: Russell G. Arnold, Center for Veterinary Medicine (HFV-142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1674.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, is the sponsor of NADA's 95-735 and 119-823, both of which provide for use of a monensin Type A medicated article to make a monensin Type C medicated feed/free-choice mineral granules containing 810 milligrams monensin per pound (1,620 grams monensin per ton) to be fed free-choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) for increased rate of weight gain (see 21 CFR 520.1448b and 558.355(f)(3)(x)).

Elanco Animal Health, Division of Eli Lilly & Co. filed supplemental NADA's that provide for combining data and information in NADA 119-823 into NADA 95-735 and withdrawing approval of NADA 119-823. Supplemental NADA 95-735 is

approved as of November 3, 1997, and the regulations are amended in part 520 (21 CFR part 520) by removing § 520.1448b to reflect the approval.

Approval of the supplemental NADA 95-735 or withdrawal of approval of NADA 119-823 does not require a freedom of information summary because the actions concern a change in status of existing applications and do not change the conditions of use of the products. This change does not affect the product's safety or effectiveness.

The agency has determined under 21 CFR 25.33(a)(1) and (g) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.1448b [Removed]

2. Section 520.1448b *Monensin-mineral granules* is removed.

Dated: January 22, 1998.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 98-3355 Filed 2-10-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA No. 173F]

Schedules of Controlled Substances: Placement of Sibutramine Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance,

of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney general by section 201(a) of the CSA [21 U.S.C. 811(a)], and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Acting Deputy Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.14 is amended by redesignating the existing paragraph (e)(10) as (e)(11) and adding a new paragraph (e)(10) to read as follows:

§ 1308.14 Schedule IV.

(e) * * *
(10) Sibutramine1675

Dated: February 5, 1998.
Peter F. Gruden,
Acting Deputy Administrator.
[FR Doc. 98-3439 Filed 2-10-98; 8:45 am]
BILLING CODE 4410-09-M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 397

Removal of Part

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: This document removes obsolete information in Title 32 of the Code of Federal Regulations addressing the organizational establishment of the Defense Printing Service. This part has served the purpose for which it was intended in the CFR and is no longer necessary.

EFFECTIVE DATE: February 11, 1998.

FOR FURTHER INFORMATION CONTACT: L. Bynum or Patricia Toppings, 703-697-4111.

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 397

Organization and functions.

PART 397—[REMOVED]

Accordingly, by the authority of 10 U.S.C. 301, 32 CFR part 397 is removed.

Dated: February 5, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98-3351 Filed 2-10-98; 8:45 am]

BILLING CODE 5000-04-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 412 and 413

[HCFA-1731-F]

RIN 0938-AG00

Medicare Program; Payment for Preadmission Services

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule responds to public comments on the January 12, 1994, interim final rule with comment period that provided that inpatient hospital operating costs include certain preadmission services furnished by the hospital (or by an entity that is wholly owned or operated by the hospital) to the patient up to 3 days before the date of the patient's admission to that hospital. These provisions implement amendments made to section 1886(a)(4) of the Social Security Act by section 4003 of the Omnibus Budget Reconciliation Act of 1990.

EFFECTIVE DATE: These regulations are effective on March 13, 1998.

FOR FURTHER INFORMATION CONTACT: Sandy Hetrick, (410) 786-4542.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1886 of the Social Security Act (the Act) addresses Medicare payment for hospital inpatient operating costs. Before the enactment of section 4003 of Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508), section 1886(a)(4) of the Act defined the operating costs of inpatient hospital services to include "all routine operating costs, ancillary service operating costs, and special care unit operating costs with respect to inpatient hospital services as such costs are determined on an average per admission or per discharge basis * * *." In 1966, the Medicare program established an administrative policy regarding payment for services furnished before

admission to a hospital. Specifically, if a beneficiary with coverage under Medicare Part A was furnished outpatient hospital services and was thereafter admitted as an inpatient of the same hospital before midnight of the next day, our longstanding policy provided that outpatient hospital services furnished to the beneficiary were treated as inpatient services and included in the hospital's Part A payment.

When the prospective payment system for hospitals was implemented in 1983, the costs related to the longstanding policy concerning the payment for preadmission outpatient services as inpatient services were included in the base year costs used to calculate the standardized payment amount and the diagnosis-related group (DRG) weighting factors. (Hospitals excluded from payment under the prospective payment system continue to be paid for inpatient hospital services they furnish, as well as for the preadmission services described above, on the basis of reasonable costs up to the ceiling on the allowable rate of the increase for Medicare hospital inpatient operating costs, as set forth in the Act.) Therefore, these preadmission services could not be billed separately from the covered inpatient admission that follows, since payment for them was included in the payment made under Part A for the inpatient stay (that is, the DRG payment for hospitals under the prospective payment system or, for excluded hospitals, the reasonable cost payment subject to the rate-of-increase limit).

Section 4003(a) of Pub. L. 101-508 amended the statutory definition of "operating costs of inpatient hospital services" at section 1886(a)(4) of the Act to include the costs of certain services furnished prior to admission. These preadmission services are to be included in the Part A payment for the subsequent inpatient stay. As amended, section 1886(a)(4) of the Act defines the operating costs of inpatient hospital services to include certain preadmission services furnished by the hospital (or by an entity that is wholly owned or operated by the hospital) to the patient up to 3 days before the date of the patient's admission to the hospital.

The provisions of section 4003(b) of Public Law 101-508 provided for implementation of the 3-day payment window in the following three phases:

- The first phase, effective from November 5, 1990 (the enactment date of Public Law 101-508) through September 30, 1991, included any services furnished during the day before the date of admission regardless of

PHARMACY TECHNICIAN



NDSCS

North Dakota State College of Science
800 6th Street North • Wahpeton, ND 58076-0002
1-800-342-4325 • www.ndscs.nodak.edu

The Pharmacy Technician is responsible for performing most of the distributive functions in a pharmacy. Well-trained pharmacy technicians allow the pharmacist to concentrate on clinical services such as patient consultation, physician intervention, drug therapy analysis and other clinical topics in community, institutional and other pharmacy practices.

PROGRAM PURPOSES

1. To provide a one-year program leading to a certificate of completion, with an option to obtain an Associate of Science Degree.
2. To prepare students for a career as a Pharmacy Technician where they will assist the pharmacist.
3. Pharmacy Technicians in North Dakota must be registered with the State Board of Pharmacy. This certificate program qualifies the technician for that registration and also makes them eligible for National Certification.

CAREER OPPORTUNITIES

Many pharmacies employ at least one technician and employment opportunities within the field are increasing. The type of practice settings available to registered pharmacy technicians include:

- Community pharmacies
- Hospitals (most hospitals employ more than one pharmacy technician)
- Home Health Care
- Pharmacies Research Institutions
- Manufacturing and other industry

WHAT DO PHARMACY TECHNICIANS DO?

Duties of Pharmacy Technicians vary with the practice setting and type of pharmacy. Pharmacy Technicians are allowed to perform any task in the pharmacy except those which require a pharmacist's professional education or judgement.

ADMISSION REQUIREMENTS FOR THE PHARMACY TECHNICIAN PROGRAM ARE:

1. Completed application to the college.
2. High school graduate or G.E.D.
3. Be 18 years of age before completion of the program.
4. Minimum composite score of 15 on the ACT test.
5. A personal interview may be required.

Note: It is recommended for applicants to have taken algebra and chemistry while in high school. If these were not taken in high school, then algebra should be taken before entering the program. Scholarships are also available for the Pharmacy Technician Program. Applications may be obtained from Admissions upon acceptance into the Program.

A passing grade of "C" or above is required for all Pharmacy Technician courses including:

| | |
|------------|---------------------------------------|
| PHRM 101 | Orientation to Pharmacy Practice |
| PHRM 102 | Pharmaceutical Calculations |
| PHRM 105 | Institutional Pharmacy |
| PHRM 107 | Pharmaceutics |
| PHRM 111 | Pharmacy Record and Inventory Mgmt. |
| PHRM 115 | Community Practice Pharmacy |
| PHRM 116 | I.V. and Aseptic Products |
| PHRM 116L | I.V. and Aseptic Products Lab |
| PHRM 121 | Chemical/Physical Pharmacy |
| PHRM 121 L | Chemical/Physical Pharmacy Lab |
| PHRM 125 | Pharmacology |
| PHRM 131 | Pharmacy Internship - Community Based |
| PHRM 141 | Pharmacy Internship - Hospital Based |
| BOED 171 | Medical Terminology |

Graduates are eligible for registration as a Pharmacy Technician with the State Board of Pharmacy. During the summer semester, students will receive over 300 hours of on-the-job training in community and hospital pharmacy settings.

In order to comply with the American Society of Health-Systems Pharmacists (ASHP) Accreditation Standards, there is a mandatory 90% attendance requirement for all Pharmacy Technician courses.

PHARMACY TECHNICIAN
(CERTIFICATE OR ASSOCIATE OF SCIENCE)

| Program Requirements | Certificate Credits | Associate Credits |
|--|---------------------|-------------------|
| BOED 171 Medical Terminology | 4 | 4 |
| CHEM 115 Introductory Chemistry | 3 | 3 |
| CHEM 115L Introductory Chemistry Lab | 1 | 1 |
| CIS 101 Computer Literacy | 2 | 2 |
| ENGL 105 Communications | 2 | - |
| ENGL 110 Composition I | - | 3 |
| ENGL 120 Composition II | - | 3 |
| HPER 100/101/102/150/250 Activity: | | |
| Intro Level/Intermediate Level/Varsity Athletics | - | 2 |
| PHRM 101 Orientation to Pharmacy Practice | 1 | 1 |
| PHRM 102 Pharmaceutical Calculations | 3 | 3 |
| PHRM 105 Institutional Pharmacy | 3 | 3 |
| PHRM 107 Pharmaceutics | 2 | 2 |
| PHRM 111 Pharmacy Record and Inventory Mgmt | 2 | 2 |
| PHRM 115 Community Practice Pharmacy | 3 | 3 |
| PHRM 116 IV and Aseptic Products | 1 | 1 |
| PHRM 116L IV and Aseptic Products Lab | 1 | 1 |
| PHRM 121 Chemical/Physical Pharmacy | 2 | 2 |
| PHRM 121L Chemical/Physical Pharmacy Lab | 1 | 1 |
| PHRM 125 Pharmacology | 2 | 2 |
| PHRM 131 Pharmacy Internship - Community Based | 3 | 3 |
| PHRM 141 Pharmacy Internship - Hospital Based | 3 | 3 |
| PSYC 100 Human Relations in Organizations | 2 | - |
| PSYC 111 Introduction to Psychology | - | 3 |
| SPCH 110 Fundamentals of Speech | - | 3 |
| Humanities/History | - | 6 |
| <i>From two different prefixes within the categories marked ND:HUM or ND:HIST</i> | | |
| Math, Science and Computer Information Systems | - | 7 |
| <i>From any course marked ND:LABSC, ND:MATH, ND:COMPSC, ND:SCI</i> | | |
| <i>All students must complete one lab science course and one mathematics course.</i> | | |
| <i>No more than four CIS credits apply.</i> | | |
| Social and Behavioral Sciences Electives | - | 5 |
| <i>From two or more prefixes within the category marked ND:SS</i> | | |
| TOTAL REQUIRED CREDITS | 41 | 69 |
| <i>(Six of the credits for both programs are summer experiential hours)</i> | | |

MODEL CURRICULUM FOR PHARMACY TECHNICIANS

GOAL STATEMENTS AND TERMINAL AND ENABLING EDUCATIONAL OBJECTIVES

Goal Statements

Major Areas of Job Responsibility

- Goal 1: Assist the pharmacist in collecting, organizing, and evaluating information for direct patient care, drug use review, and departmental management.
- Goal 2: Receive and screen prescription/medication orders for completeness.
- Goal 3: Prepare medications for distribution.
- Goal 4: Distribute medications.
- Goal 5: Assist the pharmacist in the identification of patients who desire counseling on the use of medications, and equipment, and devices.
- Goal 6: Collect payment and/or initiate billing for pharmacy services and goods.
- Goal 7: Purchase pharmaceuticals, devices, and supplies according to an established purchasing program.
- Goal 8: Control the inventory of medications, equipment, and devices according to an established plan.
- Goal 9: Assist the pharmacist in monitoring the practice site and/or service area for compliance with federal, state, and local laws, regulations, and professional standards.
- Goal 10: Maintain pharmacy equipment and facilities.
- Goal 11: Assist the pharmacist in preparing, storing, and distributing investigational drug products.
- Goal 12: Assist the pharmacist in the monitoring of drug therapy.

Foundation Knowledge and Skills

- Goal 13: Take personal responsibility for assisting the pharmacist in improving the pharmaceutical care of patients.
- Goal 14: Demonstrate ethical conduct in all activities related to the delivery of pharmacy services.
- Goal 15: Maintain an image appropriate for the profession of pharmacy.
- Goal 16: Understand the principles for managing change.
- Goal 17: Appreciate the need to adapt the delivery of pharmacy services for the culturally diverse.
- Goal 18: Appreciate the benefits of active involvement in local, state, and national technician and other pharmacy organizations.
- Goal 19: Appreciate the value of obtaining technician certification.
- Goal 20: Understand the importance of and resources for staying current with changes in

pharmacy practice.

- Goal 21: Communicate clearly orally and in writing.
- Goal 22: Use computers to perform pharmacy functions.
- Goal 23: Efficiently solve problems commonly encountered in one's own work.
- Goal 24: Display compassion for patients and their caregivers.
- Goal 25: Maintain confidentiality of patient information.
- Goal 26: Understand the scope of pharmaceutical care delivery systems.
- Goal 27: Efficiently manage one's work whether performed alone or as part of a team.
- Goal 28: Establish and maintain effective interpersonal working relationships with other members of the health care team.
- Goal 29: Understand the use and side effects of prescription and nonprescription drugs used to treat common disease states.
- Goal 30: Assist the pharmacist in assuring the quality of all pharmaceutical services.