The meeting was called to order at 2:30 p.m. in Room 213 Senator Thomas R. C. Wilson was in the chair.

PRESENT: Senator Thomas R. C. Wilson, Chairman
Senator Richard E. Blakemore, Vice Chairman
Senator Don Ashworth
Senator Clifford E. McCorkle
Senator Melvin D. Close
Senator C. Clifton Young
Senator William H. Hernstadt

ABSENT: None

OTHERS PRESENT: Senator Jean Ford
Assemblyman Dean Rhoads
Pat Gothberg, Nevada Nurses' Association
Ellen Pope, Nevada Licensed Practical Nurses Association
Dawn Magnuson, Division of Mental Hygiene & Mental Retardation
Steven P. Bradford, Welfare Division
Neil Swissman, M.D., Nevada State Medical Association
Jo Anne Fuller, Nevada State Labor Commission
Ed Gasson, GIBA, Geigy Pharmaceuticals Division
George Bennett, Secretary, Nevada State Board of Pharmacy
Frank L. Titus, Member, Nevada State Board of Pharmacy
G. R. "Bob" Tucker, Member, Nevada State Board of Pharmacy
Harvey Riceberg, Pharmacist
S. L. Sparks, President, State Nursing Home Facilities
Norma J. Beales, Administrator, Reno Convalescent Center
Linda G. Quilici, Registered Nurse, Reno Convalescent Center
Richard D. Grundy, M.D., Nevada State Board of Medical Examiners
Ed Vogel, Las Vegas Review-Journal
Claude Evans, Secretary, AFL-CIO
C. B. Knaus, Nevada Insurance Division
Jean Peavy, Board of Nursing
Charles Perry, Administrator, Vegas Valley Convalescent Hospital
Jeff Monahan, Pharmacist

SB 91 Reduces bonds for certain money order issuers.

For previous testimony, discussion and action on AB 91 see minutes of meetings dated January 29, 28, March 5 and 12, 1979.

Assemblyman Dean Rhoads stated that SB 91 is a result of a study made during the interim from last session. Mr. Rhoads explained that due to an Assembly Bill passed last session he had received complaints from constituents that they were not able to write money orders without posting large bonds. However, he continued, the way SB 91 is written nothing is solved, because $300 has to be posted. Mr. Rhoads explained that his constituents and the Legislative Counsel Bureau are working on the problem and asked if he

could report back at a later date.

Chairman Wilson agreed to Mr. Rhoads suggestion.

SB 331 Allows skilled nursing facilities under certain circumstances to retain possession of certain drugs past period prescribed.

Senator Jean Ford explained that SB 331 amends NRS 639. Senator Ford stated that it is costly and wasteful to dispose of good quality drugs. The present statute reads as follows: "it is unlawful for any person to have in his possession or under his control, for the purpose of resale, or to sell or offer to sell or dispense or give away any pharmaceutical preparation, drug or chemical which: (a) Has been dispensed pursuant to a prescription or chart order and has left the control of a registered pharmacist". She added, however, that in its present form SB 331 does not answer the problem properly because it would tend to give new powers to nursing facilities in the dispensing of drugs and that was not the intent of the proponents of the bill. She continued that the powers of controlling the supervision of the drugs once the prescription has been written by the licensed physician must remain with the pharmacist; the board of pharmacy could develop regulations to handle precautions needed. Senator Ford explained that there are drugs that cost as much as $8 per unit which have to be destroyed.

Harvey Riceberg, Consulting Pharmacist, presented suggested amendments to SB 331 (see Exhibit A), that would rewrite the bill, and an explanation of Unit Dose Dispensing (see Exhibit B). Mr. Riceberg defined skilled nursing facilities and immediate care facilities as levels of care that take place in facilities and the number of hours of licensed personnel on shift, with medication rooms, total control and storage of medications. Mr. Riceberg explained that the present statutes do not address "unit dose" and he presented different examples of unit doses such as injectable and individual packaging. He continued that 90 percent of all acute hospitals use unit dose and unit dose cannot be contaminated if properly stored and ventilated because each dose is labeled, has an expiration date and is sealed. Mr. Riceberg also explained that a year and a half ago a survey was made of three facilities with 400 beds over a three-month period and projected it to the 2,000 beds in Nevada; this would have meant possibly $50,000 to $60,000 worth of drugs being destroyed. He explained that a multiple-dose sealed vial would be considered a unit dose. He defined unit dose as follows: the quantity of drugs which conforms to the packaging and storage requirements for unit dose medication as contained in the most current provision of the U. S. Pharmacopia. Injectable medication also falls into this category. Labeling shall include at least the name and strength of the medication, the control number and the expiration date.

Mr. Riceberg explained the procedure for prescribing medication. He stated that the physician gives the order to the pharmacy and the pharmacy delivers the medication. Medication can be discontinued when the patient deceases, or doesn't respond to the medication or has an allergic reaction. He added that the pharmacy delivers medication on a daily basis but the prescriptions are generally filled for a month's supply. He stated that 85 to 90 percent of all patients in convalescent facilities are welfare patients so that percentage of his reimbursement comes from the state, and the state only reimburses once for a prescription. He explained that the state pays $3.40 per prescription plus cost. Mr. Riceberg stated that if a credit system for unused medication were set up, the medication would first be sealed and counted at the facility, returned to the pharmacy, recounted and entered in the patient's profile on the patient's chart. He explained that he had attempted to arrive at some estimated figures of losses because of unused medication: 71 medications that could have been returned for credit totaled $345 and were about two-thirds of destroyed medication for the month, so about $500 for the month was destroyed. He said if that were projected for the 2,000 beds in Nevada times 12 months, the total would be $120,000. He stated that some figures had been supplied to him from the Sierra Health Care Center, which has 150 beds, that show $2,740 worth of medication was returned; reduced to 100 beds the total would be $1,827 and reduced to one month the total would be $304. Mr. Riceberg explained that the amount of return depends on the type of patient; the turnover is greater in acute facilities where there is a greater turnover than in intermediate care facilities where patients are mentally more alert and stable.

Mr. Riceberg explained to Senator Young that it would be worthwhile to return drugs if the cost of keeping records were $.25 per prescription. He stated that when medication is needed on an "if needed" basis, a 30-day supply is not sent out.

Senator Blakemore stated concern where there is an excess of narcotic drugs and possible abuse. Mr. Riceberg explained that all medication is under tight control and the only people with access are the pharmacists or the registered licensed personnel. Senator Blakemore suggested that a person could take a capsule apart and exchange the contents. Mr. Riceberg explained that the capsule would have been sealed, either individually or in a bottle, and would not be acceptable for return. He explained that each medication that comes out in package form will, by its nature and its packaging, have an expiration date. He continued that Schedule 2 drugs, narcotics, would not be returnable because of severe bookkeeping problems. Mr. Riceberg explained that the amount of medication dispensed is determined by the physician, but if the physician does not specify amount, he, the pharmacist, will normally send a 30-day supply.

Charles Perry, Administrator, Vegas Valley Convalescent Hospital, stated that in 1976 and 1977 Nevada's welfare program began to run short of funds and began to cut down on the amount of doses it would pay for for patients in long-term care facilities. Mr. Perry stated that there is something wrong with destroying medication on one hand and cutting down the amount allowed a patient. Mr. Perry stated that he supports SB 331. He continued that Texas is using the unit dose system and intends to allow for the return of unused unit dose medication in the future.

Mr. Riceberg explained that presently there are eight states that have legislation allowing unit dose and several allowing return.

Jeff Monahan, Pharmaceutical Consultant, Nevada State Welfare Division, stated that he has been in every nursing home in Nevada this year. Mr. Monahan explained that in January, 1978 an advisory committee met to review the problem of the destruction of so much medication, and at that time a deputy attorney general advised that to correct the problem there would have to be a statute change. He stated that a survey was made over a three-month period and revealed that approximately $50,000 worth of medication is being destroyed annually; however, that would not all be returnable. Mr. Monahan explained to Chairman Wilson that 60 percent of nursing home beds are on a unit dose system and that percentage is increasing. He clarified that packaging unit doses cost about 30 cents extra per prescription per month. He estimated that about 40 hours nursing time per month is spent destroying medication and nurses make about $350 per week. Mr. Monahan presented a copy of a Record of Disposal of Outdated and Discontinued Drugs for the record (see Exhibit C).

Dawn Magnuson, Social Service Specialist, Division of Mental Hygiene and Mental Retardation, presented prepared testimony in support of SB 331 (see Exhibit D) which includes an amendment that would include intermediate care facilities for the mentally retarded.

Senator Young suggested that all facilities be required to use unit dose and be allowed to return for credit.

Linda G. Quilici, R.N., Reno Convalescent Center, concurred with the previous testimony and stated that the Center uses the unit dose system and it is very satisfactory; that it is her duty to dispose of unused medication and this is very costly in terms of time and money.

George Bennett, Secretary, Nevada State Board of Pharmacy, stated that he is opposed to SB 331 for the following reasons: one, it would be illegal to return Schedule 2 drugs; two, nitroglycerin cannot be repackaged; three, there are many types of unit dose systems, but all are not efficient because there is a limited expiration date. Mr. Bennett explained to Senator Ashworth that when medication is transferred from its original packaging into dose packaging, it can lose strength and longevity of effectiveness.

Mr. Bennett continued that, as Senator Blakemore had suggested, it would be possible to take a capsule apart, substitute a placebo, reassemble the capsule and then reseal the packaging with glue. He stated that another reason for not allowing return of drugs is that all drugs have expiration dates and lot numbers and the FDA requires that lot numbers cannot be mixed. Mr. Bennett continued that refrigerated drugs would be jeopardized in transport, the system would be almost impossible to audit, and the record-keeping requirements would cut the net savings substantially. Mr. Bennett explained that with State Aid for the Medically Indigent (SAMI) prescriptions, the pharmacy would credit SAMI, but with Medicare the pharmacy would have to credit the nursing home and then the nursing home would credit Medicare; with the private patient the pharmacy would credit the facility and the facility would credit the patient. Mr. Bennett suggested that a better system for saving on unused drugs would be to give fewer amounts in prescriptions.

Mr. Bennett stated that there are no drugs that are indestructible, all can be destroyed by heat, and that the only drug that could be returned would be a sealed ampule that air or moisture cannot reach, that does not need refrigeration and is not sensitive to light. Mr. Bennett concluded that large amounts of drugs can be destroyed by arranging with the city dump for supervised destruction.

Senator Ford concluded that all of the control problems discussed during the hearing are present every day and are being handled adequately and unless a system is tried, such as returning unused drugs, its success cannot be known.

Mr. Bennett explained to Senator Young that NRS 639.282 states that it is unlawful for any person to have in his possession or under his control, for the purpose of resale, or to sell or offer to sell, anything that has been dispensed pursuant to a prescription or chart order and has left the control of a registered pharmacist; and in hospitals where the pharmacy is within the facility, the control is still resting in the pharmacy. He continued that most large hospitals have gone to the unit dose system; Washoe Medical Center, for example, gives a one-day supply, St. Mary's gives three days, so there is no lot problem. He stated that on prescriptions, lot numbers may be mixed.

Chairman Wilson closed the public hearing on SB 331.

SB 348 Authorizes board of medical examiners to require continuing education as prerequisite of renewal of physicians licenses.

Richard D. Grundy, M.D., President, Nevada State Board of Medical Examiners, stated that the Board supports SB 348, which will give

the Board the power to require continuing education for licensing physicians. Dr. Grundy explained that an interim legislative committee, after a study of malpractice, has recommended continuing education. He continued that over 20 states have some form of requirement for continuing education. Mr. Grundy stated that most doctors do continue education but that from 5 to 10 percent of doctors in Nevada do not, that's about 50 to 100 doctors. He stated that enough courses are offered in Nevada to satisfy the requirement of 20 hours per year.

Dr. Grundy explained to Senator Ashworth that the rural areas might have to do without their doctor for a week, but it would be worth his absence because he would be bettering his abilities. He added that the Medical Association has a committee encouraging doctors in the urban areas to go out into the rural areas for a week or two to allow the local doctor to obtain continuing education. He stated that the Board will promulgate rules and regulations that would waive the requirement if hardship could be proved.

Dr. Grundy answered Senator Hernstadt's question by stating that he doesn't know if continuing education would lower malpractice insurance, but that he is more concerned with the quality of doctors than insurance premiums. He stated that a few years ago a doctor had come before the Board who had not taken a postgraduate course since obtaining his license in 1942; the Board required him to take 200 hours of postgraduate work within the next year and then appear back before the Board for an examination. Dr. Grundy concluded that the doctor completed the 200 hours, reported back to the Board and is now a much improved physician.

Neil Swissman, M.D., President, Nevada State Medical Association, presented prepared testimony in opposition of SB 348 (see Exhibit E). Dr. Swissman maintained that aging people do not retain material presented in "cram" courses so they are of no benefit.

Chairman Wilson stated that George Smith, formerly Dean of a Medical School, had claimed that the field of medicine is so dynamic and changing so fast and advancing so rapidly that graduates are obsolete and asked Dr. Swissman how this problem could be solved without continuing education.

Dr. Swissman stated that he feels that doctors are doing postgraduate work voluntarily and it should not be mandated. He stated that upon notice of this proposed legislation he had done a survey of the members of the Medical Association revealing that 90 percent who responded, which is over 50% of the members, are taking courses in excess of what the Board of Medical Examiners is proposing. He added that requiring continuing education does not guarantee its quality.

In reply to Senator Hernstadt's question, Dr. Swissman stated that he does not think that mandatory continuing education will do anything to lower the malpractice insurance premiums, but he agreed that inadequate doctors who are sued for malpractice raise premiums.

Senator Blakemore stated that the interim committee had decided that a good way to upgrade the medical profession would be to require continuing education.

Dr. Swissman stated that the Board of Medical Examiners has information available regarding malpractice suits and is able to investigate, but that requiring mandatory continuing education will not "weed out" bad doctors.

In response to Chairman Wilson's question, Dr. Swissman explained that the Nevada State Medical Association has gone a long way in reaching the 10 percent of doctors who do not continue their education and that the percentage is diminishing continually. He stated that the 10 percent consists mostly of rural doctors, and the Medical Association now has 60 physicians who are volunteering time to cover for rural doctors who want postgraduate courses. He explained that about 88 percent of all doctors in Nevada belong to the Nevada State Medical Association and all county medical associations must belong to the State Association. Dr. Swissman concluded that SB 348 is written poorly, would be costly and just create more bureaucracy.

Chairman Wilson closed the public hearing on SB 348.

SB 145 Permits registered nurses to perform additional functions under certain circumstances.

For previous testimony and discussion on SB 145 see minutes of meeting dated February 12, 1979.

Richard D. Grundy, M.D., Nevada State Board of Medical Examiners, stated that the Board has recommended that the number of nurse practitioners that can be supervised by one physician be two, and that the nurses feel that there should be an exception made for nurse practitioners working for the state health department. Dr. Grundy stated that this is a reasonable suggestion. He continued that the physician must visit the place of the nurse practitioner's practice at least once a week and must be in contact with the nurse practitioner daily, but that the Nursing Board does not agree; the Nursing Board feels that the physician's visit is not necessary more than once a month and that there need be no daily communication. Dr. Grundy agreed that the remainder of the differences will be easily worked out. He also agreed that continuing education for anyone is the best way to insure quality of professionalism.

Chairman Wilson closed the public hearing on SB 145.

SB 348 Authorizes board of medical examiners to require continuing education as prerequisite of renewal of physicians licenses.

Discussion followed regarding SB 348 and whether the state board of medical examiners should have jurisdiction to require continuing education, and whether the discretionary language "shall" should remain.

Senator Ashworth moved that SB 348 be passed out of Committee with a "Do Pass" recommendation.

Seconded by Senator Young.

Motion carried.

Senator McCorkle absent.

SB 331 Allows skilled nursing facilities under certain circumstances to retain possession of certain drugs past period prescribed.

Discussion followed regarding SB 331. It was agreed that the concept is good but if the bill is to be processed, it should be rewritten. It was decided to defer action on SB 331 to a later date.

SB 302 Prohibits certain persons from offering specified inducements to enter into a real estate transaction.

For previous testimony, discussion and action on SB 302 see minutes of meetings dated March 12 and 14, 1979.

Senator Ashworth moved that SB 302 be indefinitely postponed.

Seconded by Senator Hernstadt.

Motion carried.

Senator McCorkle absent.

SB 308 Prohibits public utilities from basing any rate upon property not being used to provide service for customers.

For previous testimony and discussion on SB 308 see minutes of meeting March 26, 1979.

Senator Blakemore moved that SB 308 be indefinitely postponed.

Seconded by Senator Young.

Motion Carried.

Senator McCorkle absent.

SB 173 Establishes the manufactured housing division.

For previous testimony, discussion, and action on SB 173 see minutes of meetings February 14 and 21, 1979.

Senator Ashworth moved that SB 173 be passed out of Committee with a "Do Pass as Amended" recommendation.

Seconded by Senator Close.

Motion carried.

Senator McCorkle absent.

SB 312 Authorizes registered nurses to perform certain obstetrical acts under certain circumstances.

For previous testimony, discussion and action on SB 312 see minutes of meeting March 21, 1979.

Discussion followed regarding the language of the bill.

Senator Blakemore moved that SB 312 be amended and re-referred to Committee.

Seconded by Senator Ashworth.

Motion carried.

Senator McCorkle absent.

AB 51 Sets certain requirements for continuing education of nurses.

For previous testimony and discussion on AB 51 see minutes of meeting March 21, 1979.

Discussion followed regarding the number of hours that should be required for continuing education.

Senator Ashworth stated that there isn't much difference between 15 and 30 hours. There had been much reaction from nurses in Nevada for and against continuing education. It was decided that the 15-hour requirement would be satisfactory.

Senator Young moved that AB 51 be passed out of Committee with an "Amend and Do Pass as Amended" recommendation.

Seconded by Senator Hernstadt.

Senator Close dissented.

Motion carried.

Senator McCorkle absent.

AB 49 Increases standards for licensing of nurses and limits reciprocity of admission of foreign nurses.

For previous testimony and discussion on AB 49 see minutes of meeting March 21, 1979.

Discussion followed regarding reciprocity and language with reference to examinations for foreign nurses and nurses out of Nevada. Chairman Wilson suggested that reciprocity be granted when the licensure requirements are substantially equal or better than Nevada's.

Pat Gothberg, Nevada Nurses' Association, stated that the language of the bill had been quite a problem.

Senator Blakemore stated that in Tonapah there are Filipino nurses who can't pass the exam because of a language barrier.

Chairman Wilson stated that in other states an examination must be passed for reciprocity but that Nevada does not have such an examination.

Sadie Thelen, R.N., stated that Nevada has been deluged with applications from Filipino nurses because Nevada has no such examination requirement.

Senator Close stated that Nevada is a health-care-poor state and it would not be a good idea to make reciprocity too strict.

Chairman Wilson asked Sadie Thelen to consult with Sam McMullen, Deputy Attorney General, and report to the Committee with satisfactory language.

Action on AB 49 was deferred to a later date.

There being no further business, the meeting adjourned at 5:50 p.m.

Respectfully submitted,

Betty Kalicki, Secretary

APPROVED:

Thomas R. C. Wilson, Chairman

There being no further business, the meeting adjourned at 5:50 p.m.

Respectfully submitted,

Betty Kalicki, Secretary

APPROVED:

Thomas R. C. Wilson, Chairman

SENATE Commerce and Labor COMMITTEE

GUEST LIST

DATE: Wednesday, March 28, 1979

NAME	AGENCY OR ORGANIZATION
[illegible]	Nevada Nurses' Assn.
Mabel M. [illegible]	Consumer
Ellen Pope	Nevada LPN Assn.
[illegible] Magnuson	Division of Mental Hygiene and Mental Retardation
[illegible]	Health Div.
[illegible]	Welfare Div.
Neil [illegible] MD	Nev. State Med. Assn.
Johnny Fuller	Nevada State Labor Commission
Ed [illegible]	CIBA-GEIGY PHARMACEUTICALS DIV.
George Bennett	Nev. State Bd. of Pharmacy
Frank R. Titus	Member Nevada State Bd of Pharmacy
Bob Tucker	Member Nevada State Bd. of Pharmacy
Harvey [illegible]	Consultant Pharmacist
[illegible]	Pres. State Nursing Home Facilities
Norma [illegible]	Admin - Reno Convalescent Center
[illegible] Jr.	Admin. Vegas Valley Conv. Hospital
Linda A. Quilici, RN	Reno Convalescent Center
Richard D. Grundy, M.D.	Nev. State Board of Medical Examiners
Ed Vogel	Las Vegas Rev-Jour
CLAUDE EVANS	AFL-CIO
Knaus	Nevada Ins Div
Jean I. Peavy	Bd. of Nursing

SUGGESTED AMENDMENTS FOR SB 331

Exhibit A

EXHIBIT A

Section 1. Chapter 639 of NRS is hereby amended by adding thereto a new section which will read as follows:

1. As used in this section, "unit dose" means that quantity of drug which conforms to the packaging, storage, and labeling requirements for unit dose medication as contained in the most current revision of the United States Pharmacopia. Injectable medication also falls into this category. labeling must include at least the name, strength of medication, control # expiration date

2. A pharmacy who provides unit dose medication to patients in a SNF (skilled nursing or intermediate care facility (to include facilities for the mentally retarded), as defined in NRS 449.018 and 449.014, may return the unused portion of the prescription to the pharmacy for the purpose of redispensing. & financial reimbursement to the patient's responsible party,

& SNF defined as long term convalescent facility & licensed nursing personnel & controlled drug environment.

3. The State Board of Pharmacy will define by regulation those forms of unit dose medication which may qualify for ~~redispensing~~ return. (reason being the several forms of unit dose packaging on the market for stability & need).

Section 2. ~~NRS 639.282~~ USP as amended is hereby amended to read as follows:

- Refrigerated items would be excluded
- Sch II items would be excluded

639.282 1. [It] Except as provided in section 1 of this act,

.....

Exhibit B

SB 331

EXHIBIT B

Unit Dose Dispensing

Unit dose dispensing systems are designed to reduce the incidence of medication handling errors, decrease the quantity of destroyed medications, and shorten the time spent by facility personnel in dispensing and administering the medications. Several types of unit dose systems are being used today. An acceptable unit dose system is one in which:

All medication orders are filled from an original or direct copy of physician's orders.

Pharmacists maintain medication profiles on each patient and refer to these profiles each time a medication order is filled.

Each patient's prescription requirements are individually packaged and labeled. Before a system can be considered a true unit dose system, all doses of all medications must be dispensed in unit-of-use packaging. The physical appearance of the unit dose package will vary according to the system, but always includes a clear product identification, clear patient identification and instructions for administration of the medication.

Doses of medications for individual patients are placed into an individual patient container, bin, compartment, or drawer and, whenever possible, are subdivided by dose and administration time.

EXHIBIT B

AMERICAN SOCIETY OF CONSULTANT PHARMACISTS
...progress in patient oriented pharmacy service.
B-328

MEMORANDUM

TO: ASCP Board of Directors

FROM: R. Tim Webster RTW

DATE: October 25, 1978

SUBJECT: FDA Unit Dose Repackaging Statement

Attached is recent correspondence from the Food and Drug Administration regarding their position on extemporaneous (in-pharmacy) unit dose repackaging.

Basically, FDA has changed its position such that 6 month expiration dates can be placed on items packaged in Class A or B packages (as defined by USP; see memo B-285) while 60 days continues as the expiration date limit for Class C and D packages.

2300 Ninth Street South, Arlington, Virginia 22204 (703) 920-8492

EXHIBIT B

Attachment

LABELING GUIDELINES

The label of the actual unit package must bear the following:

I. Prescription Drugs: (Solid Oral Dosage Forms, e.g., Capsule, Tablet)

1. The proprietary name of the drug, if any.

2. The established name of the drug, if there is one, and its strength; if a combination drug, the label must bear the established name and quantity of each of the active ingredients.

3. The lot or control number.

4. The expiration date providing the other conditions of this letter are met as described above.

5. Name of the manufacturer, distributor, or repacker, as provided for in 21 CFR 201.1(a).

6. For official drugs, any pertinent statement required by the compendia (e.g., refrigerate).

7. If more than one dosage unit is contained in the unit dose packet, the number of contained units should be specified regardless of whether the multiple number contained in the packet constitutes one dose.

8. Special characteristics of the contained dosage form, e.g., sustained release, enteric coated, sublingual, chewable, etc.

9. The statement "Warning" May be habit forming" where applicable, and the controlled drug substances symbol, if possible.

In cases where the unit dose container is too small to accommodate a label with sufficient space to bear the following information, such information must appear in addition to the above, on the outer enclosing container from which the unit dose is to be dispensed:

1. The prescription legend.

2. The recommended or usual dose.

3. The name and address of the manufacturer, packer, or distributor. If either a repacker or distributor, the name should be qualified by "repacked by" or "distributed by" as provided for in 21 CFR 201.1(a).

4. The number of unit dose packets contained in the container. If more than one dosage unit is contained in the unit package, then the number of contained units per packet should also be stated, regardless of whether the multiple number contained in each packet constitutes one dose, e.g., "100 packets of 2 tablets each" or "100 packets' each packet contains 2 tablets."

5. Recommended, although not mandatory, the National Drug Code designation.

6. The enclosing container must bear adequate full disclosure information, as detailed in 21 CFR 201.100. In those cases where unit dose repacking is performed by a single facility for a closed membership or group, a current package insert on the premises of the member to whom the repacked goods are shipped is sufficient to satisfy this requirement.

II. Non- Prescription Drugs: (Solid Oral Dosage Forms, e.g., CApsule, Tablet)

The label of the actual unit package must bear the following:

1. The proprietary name, if any.

2. The established name of each active ingredient and the quantities of those ingredients (whether active or not) specifically named in Section 502(e); and the quantity of any drug recognized in an official compendia (e.g., aspirin, acetaminophen). If a combination product, the label must bear this information for all appropriate ingredients.

3. The name of the manufacturer, packer, or distributor,

4. The statement "Warning: May be habit forming" where applicable, and the controlled drug substances symbol, if possible.

5. The lot or control number.

6. The expiration [illegible] meeting the other conditions of this letter are met as described above.

7. For official [illegible] specified by the compendia.

8. If more than one dosage unit is contained in the unit dose packet, the number of contained units should be specified regardless of whether the multiple number contained in the packet constitutes one dose (e.g., 2 tablets).

9. Special characteristics of the contained dosage form, e.g., sustained release, enteric coated, chewable, etc.

In addition to the above, the following information must appear on the outer carton from which the unit dose is to be dispensed:

1. The address of the manufacturer, packer, or distributor, in addition to the name. If either a repacker or distributor, the name should be qualified by "manufactured for, " or "distributed by," etc.

2. The number of unit dose packets contained in the carton. If more than one dosage unit is contained in the unit dose packet, then the number of contained units per packet should also be stated, regardless of whether the multiple number contained in each packet constitutes one dose, e.g., "100 packets of 2 tablets each," or "100 packets, each packet contains 2 tablets".

3. Recommended, although not mandatory, the National Code Designation.

4. The enclosing carton must bear adequate directions for use (per regulation 201.5) and should include:

   A. Statements of all conditions, purposes, or uses for which the drug is intended.

   B. Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and conditions.

   C. Frequency of administration.

   D. Duration of administration.

In those cases where unit dose repacking is performed by a single facility for a current package insert on the premises of each receiver to which the shipment is made bearing adequate directions for use is regarded as satisfying this requirement. The absence of such current package insert on the premises of a institution to which a drug is shipped will cause that drug to be misbranded.

EXHIBIT B

DEPARTMENT OF HEALTH EDUCATION AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND

October 3, 1978

Mr. R. Tim Webster
Executive Director
American Society of Consultant Pharmacists
2300 9th. Street, So.
Suite 515
Arlington, Virginia 22204

Dear Mr. Webster:

We are enclosing a text of a letter which represents a revision in our earlier interim policy on unit dose repackaging. This is a step which was made possible by the proposed USP standards for unit dose packaging. We believe that the new specifications represent a significant quality gain in small scale unit dose repackaging at the user level. We also look forward to the utilization of these standards for stability studies by hospitals, pharmacies and other users of unit dose packaging. We believe good studies, when published, can be shared and relied on by other repackers to support periods in excess of 6 months. The "60 days" can continue to be used for "C" or "D."

Sincerely yours,

J. Joseph Belson
Director
Division of Drug Product Quality
Bureau of Drugs

Enclosure

RECEIVED OCT 5 19

719

In April 1977, the Food and Drug Administration took an interim position with regard to Shared Services repackers of human drugs that (among other things) said: "If a 60 day expiry period or less is used on the unit dose package, the FDA will not require that stability studies be done on the drug product at this time." At the same time, in a letter to the American Society of Hospital Pharmacists, we stated that we proposed to make certain exemptions from the Current Good Manufacturing Practice Regulations (CGMP) and to recognize (among others) the following practices as adequate to allow Shared Service and Hospital Pharmacy repackers to comply with CGMP. "If a 30 to 60 day expiry date is used on the unit dose package, the Food and Drug Administration would not ordinarily deem it necessary for health protection, nor for assurance of stability of the drug, to require that stability studies be done on the drug in the unit dose package." We have advised you that the interim (pending revisions in the regulations themselves) policy for expiration dates would also apply to the unit dose repackers, including your firm.

We have reevaluated our interim position, in the light of the Pharmacopeial proposals for unit dose container classifications published in "Pharmacopeial Forum" (March-April 1978 edition, Pages 201-205).

Pending revision of the regulations, no action will be initiated against any unit dose repackaging firm or repackaged unit dose product, meeting all other conditions of FDA's repackaging requirements, solely on the basis of the failure of the repackaging firm to have stability studies supporting the expiration dates used, provided:

1. The unit dose packaged drug complies with the Class A or Class B standard described in the March-April "Pharmacopeial Forum;" and

2. The expiration date does not exceed 6 months; and

3. The 6 month expiration period does not exceed 25% of the remaining time between the date of repackaging and the expiration date shown on the original manufacturer's bulk container of the drug being repackaged; and

4. Drugs with well known stability problems (e.g., nitroglycerin) may not be repackaged at all.

EXHIBIT B

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

December 21, 1978

Thomas W. Chamberlain, Sr.
Vice President & Secretary
C & T Health Care Systems, Inc.
28 New Plant Court
Owings Mills, MD 21117

Dear Mr. Chamberlain:

This letter is being sent to C & T Health Care Systems, Inc. (C & T) to give the Food and Drug Administrations' position on "Shared Services". Your operation, which repackages drugs received from hospitals into unit dose packages is one which falls within the guidelines we have set up for "Shared Services".

Shared Services, as used here, means a drug repackaging operation serving more than one hospital and/or related institutions, not necessarily adjaeent to each other, having separate pharmacy services. A Shared Services repackaging operation is necessarily one segment of a closed distribution system; that is, the Shared Services operation is responsible to users of its services, although not necessarily directly responsible to the management of the pharmacy services at each institution. Such a Shared Services supplies medications with the understanding that the receiving institutions individually bear the responsibilities of adequate controls for handling, storage, and limiting distribution of the drugs received from the Shared Services to the institution.

Shared Services operations are also expected to meet all applicable requirements of the Good Manufacturing Practices Regulations under the Food, Drug and Cosmetic Act, insofar as they pertain to repackaging.

We will propose the following interpretations of CGMP's and recognize on an interim basis the practices which follow as adequate to allow Shared Services repackers to comply with Good Manufacturing Practices, so long as all are met completely:

1. It will not be necessary to perform chemical or other analysis on oral solid drug products in finished dosage form, (hereinafter called only drug products) which are to be repackaged, provided the following conditions are met: (a) before opening, each container of drug product is individually examined, and assurance obtained that it has not been tampered with, and it is an undamaged, intact package; (b) organoleptic evaluation (e.g. physical appearance, markings, color, odor & taste) procedures are used to identify the drug products, comparing it with a standard drug product

unit which is maintained on file as a control; (c) control records are maintained, identifying the lot received, the controls maintained, and the labeling applied; (d) a physical sample of one completed unit of the finished repacked drug product is attached to the control record.

2. If a 60 day expiry date or less is used on the unit dose package, the Food and Drug Administration will not require that stability studies be done on the drug product or on the packaging at this time. A six month expiration date may be used if:

   A. The unit dose packaged drug complies with the Class A or Class B Standard described in the March-April "Pharmacopeial Forum"; and

   B. The drug to be repackaged is in an original sealed manufacturer's package which has not been opened prior to repackaging; and

   C. The 6 month expiration period does not exceed 25% of the remaining time between the date of repackaging and the expiration date shown on the original manufacturer's bulk container of the drug being repackaged; and

   D. Drugs with well known stability problems (e.g., nitroglycerin) may not be repackaged at all.

3. Only one drug product is brought into the repackaging area at a time; no other drugs or medications are to be in the repackaging area at the time this drug product is being repackaged; up completion of the repackaging operation, all remaining unused stocks and finished repacked stocks are removed from the area; the machinery is completely emptied, cleaned, and inspected before any preparation for repacking the next product.

4. All excess or unused labels are to be removed from the repackaging area and an accountability procedure used to assure the accuracy of the count, reconcile differences, and assure that none remain in the repackaging system.

5. All unit dose repacked drug products will be placed into a larger container, and that larger container will be fully labeled before removal from the premises.

6. Upon completion of steps 1 through 5 an inspection will be made by a separate responsible person who has not been involved in steps 1 to 5, to verify that all repackaged drug products and labels are removed from the repackaging area; completion of the inspection shall be recorded on the control records.

All of these steps must be fully completed before another drug is moved into the area. It is understood that not more than one such repackaging operation can be in operation at one time, in one closed area. Product labeling shall comply with the guidelines attached.

7. Antibiotics may not be repacked unless the procedures necessary for recertification are carried out as provided for in Section 507 of the Federal Food, Drug, and Cosmetic Act. An antibiotic drug manufactured compounded, or processed in violation of this requirement is regarded to be misbranded under Section 502(l) in that no certificate or release is in effect for such drug.

8. Drugs with known stability problems (such as drugs which leach, hygroscopic drugs, and drugs which interact with packaging materials) may not be repacked in the absence of specific data demonstrating the stability of the repacked dosage unit, e.g. Nitroglycerin Tablets, Ethambutol HCl Tablets).

9. In order to be considered as a true "Shared Service" operation, a firm can only service institutions which may legally provide you with products to be repackaged into unit dose form (e.g., hospitals, nursing homes). You may not purchase bulk drugs yourself and unit dose package them for C & T, nor distribute such repacked drugs to other "shared service" firms or any other outlet which will market the products.

If C & T complies with CGMP's modified by the added interpretations listed above, together with compliance with Registration, Product Listing and all other general requirements, the Food and Drug Administration will regard C & T as being in compliance. C & T is expected to continue to meet the same requirements as other Shared Services repackaging operations, and in the same manner, keeping current with requirements for Shared Services repackaging operations.

Sincerely yours,

T. E. Byers
Associate Director for Compliance

Attachment

NEVADA STATE WELFARE DIVISION
MEDICAL CARE SECTION (TITLE XIX)

RECORD OF DISPOSAL OF OUTDATED AND DISCONTINUED DRUGS

PHARMACY NAME	Rx NUMBER	DRUG NAME AND STRENGTH	QUANTITY	DATE	WITNESS' INITIAL	DIRECTOR OF NURSES' INITIAL

EXHIBIT C - 1

3231 - SM (3/79)

EXHIBIT C

Drug Waste and Prescribing Patterns in Two Nursing Homes

1200 pts x 42.60/yr = 51,120

Roland A. Patry*

Assistant Professor of Clinical Pharmacy, University of Houston, Houston, TX 77004

Ruth Kroeger

Associate Professor and Chairman of Clinical Pharmacy Department, University of Houston, Houston, TX 77004

Abstract. A study of physicians' prescribing patterns in two nursing homes was conducted via retrospective chart review of 311 institutionalized geriatric patients. Drug waste resulting from the use of a traditional drug distribution system was measured by conducting an inventory of the discarded legend medication stored in the study nursing homes. Cerebrovascular or coronary disease was the most prevalent problem in those patients receiving Medicaid and/or requiring skilled nursing care. Controlled substances and drugs acting on the CNS that were prescribed on a pro re nata (PRN) basis were major contributors to the drug waste problem. Patient utilization of 5 doses or less for the 3-month study period was recorded in 70% of all PRN orders. A process of drug utilization review may reduce the numbers of PRN orders prescribed to institutionalized geriatric patients and ultimately reduce patient care costs.

In 1971 a medication study of 40 patients estimated that $3.55 per patient per month was wasted under a traditional (e.g., individual prescription) drug distribution system as a result of medications having to be discarded (1). Discarded medication occurs as a result of a patient's demise or discontinued medication orders. Although the study was basically an evaluation of unit-dose drug distribution in nursing homes, the data raise the question whether a consultant or community pharmacist could reduce the amount of drug waste without having to incur the financial risk of converting to unit-dose drug distribution.

In Texas a traditional drug distribution system may not be the only contributing factor to the drug waste problem. For Medicaid recipients, state reimbursement to the providers of pharmaceutical service is limited to three legend prescriptions (including refills) per month per recipient. Required medications prescribed in excess of the reimbursement limitation are received by the patient provided the patient or guardian is financially able to purchase them at a local pharmacy[1].

Although the physician, by regulation, is under no patient visit limitation, most physicians probably do not visit their institutionalized Medicaid patients more than once per month except in an emergency. Hypothetically, it would appear that to treat the wide range of minor maladies that develop in the elderly, without imposing an unnecessary financial burden upon the patient, the physician is forced to circumvent the monthly three-prescription limit by prescribing pro re nata (PRN) medication in quantities such that frequent reordering is not required. Refills can be staggered so that a minimal financial burden is imposed upon patients who require chronic medication.

The long-range effects of ordering larger quantities of medication, particularly medication used infrequently, are that the pharmacists receive fewer dispensing fees and that whenever a patient dies, large quantities of medication have to be destroyed. Current state regulations require that discontinued medications be stored until a designated state official can conduct an inventory of the medications to be destroyed[2]. The infrequency of these destruction periods may result in a considerable stockpile of medication in each nursing home. Although these medications are stored in a secure location, the possibilities of "borrowing" and pilferage do exist.

Methodology

This study was conducted to gain more specific knowledge of the drug waste problem and to determine whether any particular drug prescribing or drug use patterns were contributing factors. A detailed 3-month study in two community nursing homes (Home A and Home B) was conducted via retrospective chart review on 311 residents. The medical records review was conducted on all patients who resided in the study nursing homes during the investigation. Pertinent demographic, medical, and drug use data were collected, coded, and analyzed by computer with the use of the Statistical Package for the Social Sciences[3].

All discarded medication stored in the administrators' offices at the nursing homes was inventoried, and the following data were abstracted for each discarded prescription: patient's name, drug name (as labeled), directions for use, quantity prescribed, and quantity remaining. Only unopened, nonexpired injectables or solid dosage forms (e.g., tablets and capsules) exhibiting no visible decomposition were included in the inventory.

In selecting the study nursing homes the following criteria were used:

- Each nursing home was a licensed facility;
- No unusual services were provided in the nursing homes which might bias the data collected;
- Each nursing home possessed variations in the category of patient care (e.g. skilled or intermediate). (Category of patient care was determined by the nursing staff in each nursing home.);
- Each nursing home had a majority resident population consisting of Medicaid recipients.

Results

Of the patients studied, 77% were qualified to receive assistance under the Medicaid program. Interestingly (although no statistical relationship could be established), the nursing home with the larger male population (Home B) had

* To whom inquiries should be directed.

Over-the-counter products for Medicaid recipients are provided by the nursing home as part of the services covered by the per diem received from the state of Texas.

[2] Recent changes to the regulation now permit the consultant pharmacist to inventory and destroy these medications.

[3] Chi Corporation, Cleveland, Ohio.

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staff pharmacists. Many traditional prescription-filling activities provide limited opportunities for motivation. To expand the range of activities and opportunities for intellectual challenge, clinical pharmacy concepts must be emphasized: patient counseling, profile monitoring for adverse effects such as drug interactions, developing drug case histories, and educating other health professionals and patients about drugs are areas that pharmacists may explore. Any or all of these and other concepts of clinical pharmacy along with administrative and managerial responsibilities should be implemented to the extent possible in any pharmacy environment.

To facilitate clinical involvement, effective drug distribution systems must be developed that require minimal pharmacist supervision. These systems may be used by pharmacists as a springboard into the more clinical areas. An effective drug distribution system gives pharmacists needed access to sources of information and to patients and other health professionals.

The distribution system should not be the end goal of the pharmacy; instead it should open even greater and ever widening intellectual challenges for pharmacists. Many current continuing education programs emphasize the methods and the knowledge required for pharmacists to function as professionals and as people. Supervisors and pharmacists who aspire to become supervisors should consult references and attend conferences that will assist them in developing an appropriate environment in which pharmacists may exercise their skills fully.

References

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Table 1. Frequency of Primary Diagnoses in the 311 Study Patients

Primary Diagnosis[a]	Frequency of Patients	
	Home A	Home B
Cerebrovascular accident	8	20
Organic brain syndrome	5	17
Arteriosclerosis	29	16
Osteoarthritis	10	13
Cancer	5	11
Hypertension	8	11
Diabetes	7	11

[a] Diagnosis listed only if total frequency of patients greater than 10.

greater variability in patient age (73.3 ± 13.1 years compared to 80.4 ± 7.8 years) and required more daily skilled nursing care (51% compared to 14% of the patients).

Both nursing homes used some variation of the Problem-Oriented Medical Record format. Table 1 illustrates primary diagnoses as recorded for the study patients. Those nursing home residents qualifying for Medicaid and/or requiring skilled nursing care usually presented a history of cerebrovascular or coronary disease. Those Medicaid recipients not requiring skilled nursing care as well as the private pay patients generally presented a history of either arteriosclerosis, arthritis, fractures, or a combination of less acute problems.

Table 2 lists the most frequently prescribed legend medications. Data analysis showed that a majority of the patients, and in particular those requiring skilled nursing care, were prescribed at least one hypnotic–sedative, one analgesic, or one neuroleptic/anxiolytic on a PRN basis. Darvon Compound (a combination product containing propoxyphene, aspirin, phenacetin, and caffeine) was more frequently prescribed as a PRN medication and also had the greatest consumption rate of any drug prescribed on a PRN basis. Of the patients for whom Darvon Compound was prescribed, 18 (36.7%) did not consume any of the medication during the 3-month study period. All but one of the drug nonutilizers were residents of Home A.

The data also showed that 213 doses of Lomotil (a combination product containing diphenoxylate hydrochloride and atropine sulfate) were consumed during the study period but that one patient accounted for 80% of the consumption rate. Overall, 41% of all PRN orders recorded no patient utilization, and 70% recorded five or fewer doses consumed during the investigation. Since most PRN orders were for 15-, 30-, or 60-day quantities or, in the case of injectable items, for standard package sizes (e.g., five ampules or syringes), significant amounts of these drugs were available for patient use.

The data also showed that the nursing home (Home A) whose patient population required less skilled nursing care had more PRN drugs prescribed. The consumption data must be viewed with some caution, however, since this was a retrospective study utilizing information obtained from nursing medication administration records. For the purposes of this study the assumption was made that the incidences of non-

Table 2. Ten Most Frequently Prescribed Legend Medications During 3-Month Study Period for 311 Patients

Home A			Home B		
Rank	Drug	Frequency	Rank	Drug	Frequency
1	digoxin	40	1	Valium	53
2	Thorazine (chlorpromazine)	30	2	Pavabid	35
3	Lomotil	28	3	Thorazine	33
4	Pavabid (papaverine hydrochloride)	27[a]	4	Darvon Compound	32
	Mellaril (thioridazine)	27[a]			
5	Dalmane (flurazepam hydrochloride)	23	5	digoxin	30
6	Valium (diazepam)	22	6	Lasix	29
7	Darvocet-N (a combination product containing propoxyphene napsylate and acetaminophen)	21	7	Mellaril	25
8	Lasix (furosemide)	20[a]	8	Lomotil	22
	Darvon Compound	20[a]			
9	Tigan (trimethobenzamide hydrochloride)	15[a]	9	Dilantin (phenytoin)	17
	Hiprex (methenamine hippurate)	15[a]			
10	Aldomet (methyldopa)	14[a]	10	Donnatal (a combination product containing hyoscyamine sulfate, atropine sulfate, hyoscine hydrobromide, and phenobarbital)	14[a]
	cyanocobalamin	14[a]			
	Hydergine (a combination product containing dihydroergocornine mesylate, dihydroergocristine mesylate, and dihydroergokryptine mesylate)	14[a]		phenobarbital	14[a]
				Benadryl (diphenhydramine hydrochloride)	14[a]
	chloral hydrate	14[a]			
	Placidyl (ethchlorvynol)	14[a]			

[a] Indicates an equal number of medication orders.

EXHIBIT C

Table 3. Inventory of PRN Discarded Legend Drugs in Home A ($N = 180$)

Classification	Quantity Originally Prescribed	Quantity Discarded	Cost of Discarded Medication[a]
Controlled substances			
Oral (tablet, capsule)	3786	2235	$156.99
Injection (ampule, vial)	250	218	$61.60
CNS drugs[b]			
Oral	4245	2579	$272.92
Injection	189	127	$83.78
Oral electrolytic, caloric, and water balance[b]	618	309	$25.42

N is the number of days since last inventory and destruction.
[a] Actual cost based on Average Wholesale Price.
[b] Classification used in *American Hospital Formulary Service* published by the American Society of Hospital Pharmacists.

Table 4. Inventory of PRN Discarded Legend Drugs in Home B ($N = 58$)

Classification	Quantity Originally Prescribed	Quantity Discarded	Cost of Discarded Medication[a]
Controlled substances			
Oral (tablet, capsule)	2577	1581	$125.46
Injection (ampule, vial)	24	14	$6.89
CNS drugs[b]			
Oral	4853	3144	$385.82
Injection	51	49	$38.40
Oral electrolytic, caloric, and water balance[b]	636	423	$47.73

N is the number of days since last inventory and destruction.
[a] Actual cost based on Average Wholesale Price.
[b] Classification used in *American Hospital Formulary Service* published by the American Society of Hospital Pharmacists.

charted doses would not affect significantly the consumption data presented here.

Tables 3 and 4 summarize the results of the drug waste inventories conducted at the two study nursing homes. Any comparison of the data must be done with caution, since the accumulation periods prior to the drug inventory were unequal. The tables, however, dramatically present the amount of waste in terms of both drug quantities and money. An analysis of the labeled directions for use revealed that the majority of controlled substances and, to a lesser extent, drugs acting on the central nervous system (CNS) were prescribed on a PRN basis. The data also suggest that large numbers of CNS drugs are prescribed to the elderly. The discarding of 3144 tablets and capsules of CNS acting medication at Home B is clearly a problem that requires some modification in physicians' prescribing habits.

Equally disturbing was the amount of controlled substances discarded in both study nursing homes. The dispensing and control of these agents require additional administrative time for the provider and consultant pharmacists as well as the nursing personnel at the facility. This time could be spent better in caring for patient needs than in controlling drugs that eventually are destroyed.

Conclusions

There is probably no one solution to the problem of drug waste in nursing homes. Admittedly, converting from a traditional drug distribution system to unit-dose drug distribution would reduce greatly the amount of drug waste provided the state regulatory agencies would allow redistribution of medication. In addition, the cost of converting a nursing home to unit-dose drug distribution is an expense that many community pharmacists are not willing to undertake given the present economic situation.

An alternative solution to the drug waste problem might be using capitation as a method of reimbursement for the providers of medications to Medicaid recipients. Capitation would benefit both the institutionalized Medicaid recipient and the state Medicaid program by allowing unbiased medication reviews that could reduce the numbers of duplicate and irrational combinations of medication. Further studies will have to be conducted on the economic feasibility of capitation as an adequate means of reimbursing pharmacists for their services to Medicaid recipients.

The data from this study show that drugs prescribed on a PRN basis are major contributors to the drug waste problem. It would appear that any improvements in the patient record review process would reduce the number of PRN orders or at least reduce the quantities of PRN drugs prescribed. At the present time, both pharmaceutical providers to institutionalized Medicaid recipients and pharmacy consultants to nursing home facilities are expected to provide professional services and at the same time must defend the amount of reimbursement received for those services. Controlling drug utilization in the Medicaid population must begin with the prescriber, not the provider. Pharmacists are trained to provide assistance in the development of cost containment models, but successful implementation of these programs will still require the cooperation of the prescribing physicians.

Acknowledgment

The authors wish to acknowledge the data analysis assistance of Ralph M. Palmer.

Reference

(1) D. R. Mathieson and J. L. Rawlings, Evaluation of a unit dose system in nursing homes as implemented by a community pharmacy, *Am. J. Hosp. Pharm.*, 28, 254 (1971).

Exhibit D

STATE OF NEVADA
DIVISION OF MENTAL HYGIENE
AND MENTAL RETARDATION
4600 KIETZKE LANE, SUITE 108
RENO, NEVADA 89502
(702) 784-4071

ROBERT LIST
Governor

Administrator

Associate Administrator for
Mental Health

JACK MIDDLETON
Associate Administrator for
Mental Retardation

March 27, 1979

I am Dawn Magnuson, Social Services Specialist, Division of Mental Hygiene and Mental Retardation. The Division is very much in support of SB 331 and would ask the Committee to consider an amendment to include intermediate care facilities for the mentally retarded.

We would suggest the amendment appear in line 6 to read as follows:

5. A pharmacist who provides a patient at a skilled nursing facility,
6. as defined in NRS 449.018, or an intermediate care facility, as defined in NRS 449.014 (including an intermediate care facility for the mentally retarded) with a regimen of a drug in unit doses may...

The Division currently has two facilities licensed and certified as intermediate care facilities for the mentally retarded. They are the Sierra Developmental Center and the Desert Developmental Center. Although neither of these facilities currently utilize a unit does method of drug packaging, Sierra Developmental Center is currently working toward changing over to this sytem.

The Division would ask that intermediate care facilities for the mentally retarded be included as an amendment. Such would allow the State to take advantage of the cost savings afforded through return to the pharmacy and redispensing of the medication as well as eliminate the waste resulting from the distruction of unused drugs required when the traditional or vial method of packaging medication is utilized.

Dawn Magnuson
Social Service Specialist
Division of Mental Hygiene
and Mental Retardation

DM:ja

cc: Committee Members

EXHIBIT E

NEVADA STATE MEDICAL ASSOCIATION

3660 Baker Lane • Reno, Nevada 89509 • (702) 825-6788

March 28, 1979

TO: Senate Commerce Committee
Senator Thomas Wilson, Chairman

FROM: Neil Swissman, President

SUBJ: Testimony on S.B. 348

Senator Wilson and Members of the Senate Commerce Committee:

I appreciate this opportunity to appear before you again. It is essential to continue to stress physician competence and skill if patient care is to continue to improve. Since strong and well motivated desires to see things improve quickly can pressure state legislators to mandate educational activities that are ahead of the state of the art, it is essential to test methodologies and approaches before legislation is enacted.

Long before any mandatory continuing medical education requirements were imposed by medical organizations or licensing boards, physicians were voluntarily participating in continuing medical education programs with an intent to improve their knowledge and skills.

Mandatory continuing medicatl education in Nevada has many drawbacks.

1. It would require an additional bureaucratic function to police these requirements and ascertain that each one submitted is authorized. This is counterproductive to our current feelings of trimming agency expenditures.

2. As of July, 1978, 1.9 billion dollars (or approximately 1% of the total health care dollar expenditure) is spent annually for continuing medical education. Mandatory requirements would only increase those expenditures. Obviously, those increased costs would be passed on to patients.

3. Mandatory continuing medical education does not guarantee what the public expects and is in no way a measure of physician competence.

4. In excess of 90% of Nevada physicians now participate in similar programs. Therefore, there is no need for this mandatory regulation. I have submitted to you a copy of a recent survey of our membership which substantiates these figures.

I urge this committee to reject the concepts of S.B. 348 and reject this bill.

EXHIBIT E

MANDATORY CONTINUING MEDICAL EDUCATION QUESTIONNAIRE

1. Continuing medical education should be mandatory for physicians.

YES	NO	TOTAL
136	248	384

2. I voluntarily participated in CME programs this last year.

YES	NO RESPONSE	YES	NO	NO RESPONSE	TOTAL (YES)
114	22	203	15	30	317
(avg.credits) 30–60 yr.		(avg.credits) 30–60 yr.			

3. I am a member of my specialty society.

YES	YES	TOTAL
114	204	318

4. My specialty society has mandatory CME requirements.

YES	YES	TOTAL
53	50	103
(Avg.credits) 30 yr.	(Avg. credits) 30 yr.	

SUMMARY:

384 doctors responded to the questionnaire. Two to one are opposed to the concept of mandatory continuing medical education. Ten to one voluntarily participated in CME programs last year.

318 of the responding doctors are members of their specialty societies, 103 of which require an average of 30 CME credits per year.

SENATE BILL NO. 331—SENATORS FORD, WILSON, BLAKEMORE, DON ASHWORTH, CLOSE, HERNSTADT AND McCORKLE

MARCH 13, 1979

Referred to Committee on Commerce and Labor

SUMMARY—Allows skilled nursing facilities under certain circumstances to retain possession of certain drugs past period for which they were prescribed. (BDR 54-1317)

FISCAL NOTE: Effect on Local Government: No.
Effect on the State or on Industrial Insurance: No.

EXPLANATION—Matter in *italics* is new; matter in brackets [ ] is material to be omitted.

AN ACT relating to pharmacists and pharmacy; allowing skilled nursing facilities under certain circumstances to retain possession of certain drugs past the period for which they were prescribed; and providing other matters properly relating thereto.

The People of the State of Nevada, represented in Senate and Assembly, do enact as follows:

SECTION 1. Chapter 639 of NRS is hereby amended by adding thereto a new section which shall read as follows:

1. As used in this section, "unit dose" means that quantity of a drug which is packaged as a single dose.

2. A pharmacist who provides a patient at a skilled nursing facility, as defined in NRS 449.018, with a regimen of a drug in unit doses may credit the facility for any drugs remaining at the end of the period for which the regimen was provided. The facility may then retain possession of the drug to dispense it to other patients for whom the drug is prescribed. The amount of drugs remaining must be deducted from the amount supplied in any succeeding regimen of the same drug which the pharmacist provides for a patient at the same facility.

SEC. 2. NRS 639.282 is hereby amended to read as follows:

639.282 1. [It] *Except as provided in section 1 of this act, it* is unlawful for any person to have in his possession, or under his control, for the purpose of resale, or to sell or offer to sell or dispense or give away, any pharmaceutical preparation, drug or chemical which:

(a) Has been dispensed pursuant to a prescription or chart order and has left the control of a registered pharmacist;

(b) Has been damaged or subjected to damage by heat, smoke, fire

SENATE BILL NO. 348—SENATOR JACOBSEN

MARCH 21, 1979

Referred to Committee in Commerce and Labor

SUMMARY—Authorizes board of medical examiners to require continuing education as prerequisite of renewal of physicians' licenses. (BDR 54-1469)

FISCAL NOTE: Effect on Local Government: No.
Effect on the State or on Industrial Insurance: No.

EXPLANATION—Matter in *italics* is new; matter in brackets [ ] is material to be omitted.

AN ACT relating to physicians; authorizing the board of medical examiners to require compliance with certain continuing education requirements as a prerequisite to the renewal of a license to practice medicine; and providing other matters properly relating thereto.

The People of the State of Nevada, represented in Senate and Assembly, do enact as follows:

SECTION 1. Chapter 630 of NRS is hereby amended by adding thereto a new section which shall read as follows:

The board may require physicians who are licensed under this chapter to comply with continuing education requirements adopted by the board as a prerequisite to the renewal of their licenses.