

1989

Session Law 89-218

Florida Senate & House of Representatives

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S 194 GENERAL BILL/CS/2ND ENG by Health Care; Casas and others (Similar CS/1ST ENG/H 209, CS/S 462, Compare H 53, CS/1ST ENG/H 60, H 163, CS/H 654, CS/S 160, S 174, CS/S 227)
Adult Congregate Living/Pharmacist; requires the consultant services of pharmacist or dietitian under certain circumstances; requires certain out-of-state pharmacies to register with state Board of Pharmacy; provides appropriate disclosure of certain patient records to State Nursing Home & Long-Term Care Facility Ombudsman Council & district nursing home, etc. Creates 400.442; amends 395.017, 465.0156,.025. Effective Date: 10/01/89.

02/08/89 SENATE Prefiled
02/17/89 SENATE Referred to Health Care
04/04/89 SENATE Introduced, referred to Health Care -SJ 23; On Committee agenda—Health Care, 04/04/89, 2:00 pm, Room-A-(LL-37); Comm. Report: CS by Health Care, placed on Calendar -SJ 97
04/07/89 SENATE CS read first time -SJ 114
05/02/89 SENATE Placed on Special Order Calendar -SJ 242; CS passed as amended; YEAS 35 NAYS 0 -SJ 248
05/09/89 HOUSE In Messages
05/16/89 HOUSE Received, placed on Calendar -HJ 490
05/18/89 HOUSE Taken up in lieu of CS/HB 60 -HJ 524; Read second time; Amendments adopted; Read third time; CS passed as amended; YEAS 112 NAYS 0 -HJ 525; Immediately certified -HJ 525
05/18/89 SENATE In Messages
05/25/89 SENATE Amendments to House amendments adopted; Concurred in House amendments as amended; Requested House to concur; Concurred in amendments totaling 3; CS passed as amended; YEAS 39 NAYS 0 -SJ 472
05/26/89 HOUSE In Messages
05/29/89 HOUSE Concurred; CS passed as amended; YEAS 114 NAYS 0 -HJ 703
05/29/89 Ordered engrossed, then enrolled -SJ 503
06/12/89 Signed by Officers and presented to Governor
06/28/89 Became Law without Governor's Signature; Chapter No. 89-218

NOTES: Above bill history from Division of Legislative Information's *FINAL LEGISLATIVE BILL INFORMATION, 1989 SESSIONS*. Staff Analyses for bills amended beyond final committee action may not be in accordance with the enacted law. Journal page numbers (HJ & SJ) refer to daily Journals and may not be the same as final bound Journals.

REVISED: _____

BILL NO. CS/SB 194DATE: April 5, 1989Page 1

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

<u>ANALYST</u>	<u>STAFF DIRECTOR</u>	<u>REFERENCE</u>	<u>ACTION</u>
1. <u>Howell</u>	<u>Wilson</u>	1. <u>HC</u>	<u>Fav/CS</u>
2. _____	_____	2. _____	_____
3. _____	_____	3. _____	_____
4. _____	_____	4. _____	_____

SUBJECT: Adult Congregate Living/Pharmacists BILL NO. AND SPONSOR: CS for SB 194 by
Committee on Health Care and
Senators Casas and Forman

I. SUMMARY:

A. Present Situation:

An adult congregate living facility (ACLF), by statutory definition, is any building or buildings, section of a building, or distinct part of a building, residence, private home, boarding home, home for the aged, or other place, whether operated for profit or not, which undertakes through its ownership or management to provide, for a period exceeding 24 hours, housing, food service, and one or more personal services for four or more adults, not related to the owner or administrator by blood or marriage. (s. 400.402(2), Florida Statutes)

There are approximately 1,400 ACLFs licensed by the Department of Health and Rehabilitative Services (HRS or department). These facilities account for approximately 57,000 beds statewide. According to HRS, which conducts annual inspections, the number of ACLFs is increasing at an annual rate of 10-12%. By 1995, it is estimated there will be 2,730 licensed ACLFs in Florida, serving 98,700 residents.

Among the "personal services" which an ACLF may provide to its residents, the statute permits trained staff of the facility to supervise "self-administered medication." (s. 400.402(8), Florida Statutes) The "supervision of self-administered medication," as defined by statute and administrative rule, includes such acts as: (1) reminding residents to take medication, (2) preparing necessary items such as juice or water, (3) opening bottle caps for residents, (4) reading the medication label to the resident, (5) checking the dosage against the label on the container, (6) keeping daily records of when residents receive medication and (7) reporting changes in the resident's condition to the physician. [10A-5.0182(3)(b), Florida Administrative Code (F.A.C.)]

In addition, the department has, pursuant to its statutory authority, promulgated administrative rules governing the storage and administration of medication for those living in ACLFs which provide limited nursing services. The rules provide that: "There shall be a staff person available at all times who has access to, is responsible for and is trained in the supervision of self-administered medications." (10A-5.0182(3)(b)1, F.A.C.)

The Office of the Deputy Secretary for Operations, within HRS, through its district offices is charged with the responsibility of implementing core training for ACLF administrators and staff. In addition to information on such topics as nutrition, the mandated staff training program includes a core unit on the supervision of self-administered medications. This program involves presentation of video tapes to ACLF staff on care for

residents, including supervised medication training. The program also presents hypothetical problem situations for each trainee to discuss and analyze, such as what to do when medication is mislabeled.

Presently, the department requires that every licensed ACLF have its nutritional plans or menus reviewed by a registered dietitian or dietitian technician on a periodic basis. Reviews are conducted in accordance with "recommended Dietary Allowances established by the Food and Nutrition Board, National Research Council, adjusted for age, sex, and activity." (10A-5.020(1)(c), F.A.C.)

In addition, facilities with a licensed capacity of 17 or more residents are required to have written policies and procedures regarding food service standards. The department makes available to all ACLF facilities a daily food guide containing recommended dietary allowances. Pursuant to the staff training requirements for ACLF employees which are mandated under s. 400.452, Florida Statutes, the department provides ACLFs with training and materials on proper dietary standards.

Through annual inspections of all ACLFs and investigations conducted in response to complaints, the department documents dietary deficiencies in each facility. Where a deficiency is found and documented, the facility is given a "corrective action date" by which to bring nutritional standards into compliance. If a facility fails to comply with the requirements of the law, the department then issues appropriate sanctions.

B. Effect of Proposed Changes:

Committee Substitute for Senate Bill 194, creates s. 400.442, Florida Statutes, which provides that the department "may" require an ACLF to employ the consultant services of a licensed pharmacist or a registered dietitian upon a documented finding of a class I violation, a class II violation, or multiple related class III violations which have not been corrected within the time frame established by the department.

Where a documented violation is discovered within an ACLF as the result of the annual survey by the department, a monitoring visit, or an investigation in response to a complaint, notice of the deficiency would be given to the facility by the department. The department would then have authority to order, in its discretion, that consultant services be retained by an ACLF on a monthly basis until such violations are corrected.

The facility would have a reasonable time, not to exceed 6 months from the date of notice of the deficiency, to comply with the standards of the department for pharmacy and dietary services. The department would be required to determine, by no later than the next annual inspection of the facility, if consultant services should be continued.

This bill, if enacted into law, would become effective October 1, 1989.

II. ECONOMIC IMPACT AND FISCAL NOTE:

A. Public:

Because CS for SB 194 contains no definite time frame or number of work hours for which a consultant pharmacist or dietitian must be retained, it would be speculative to estimate what the cost would be to the typical ACLF. It is reasonable to assume that any increased cost will be passed on to the residents.

According to a study conducted by HRS, the average cost to residents for services rendered in an ACLF was \$595 per month.

Some ACLFs charge monthly fees ranging from \$900 to \$1,600 per resident. Many residents of ACLFs receive Optional State Supplementation (OSS) benefits which average approximately \$190 per month, and are capped at \$508 per month. Since residents receiving OSS benefits have limited income, the bulk of the increased cost which the bill creates would probably be passed on to private-pay residents.

B. Government:

None.

III. COMMENTS:

There appears to be no demonstrated need in adult congregate living facilities for consultant pharmacy services. Dietary and nutritional problems, however, have been observed in ACLFs with greater frequency. In the 1988 Long-Term Care Ombudsman Council Annual Report, complaints by ACLF residents involving medication amounted to only 4% of all complaints to the ombudsman. This compares to other types of complaints such as "administrative" which comprised 25% of all complaints and "dietary" complaints which were brought to the attention of the ombudsman 19% of the time.

ACLFs by nature and statutory design are not health care facilities. A 1985 study by the department found that 53% of licensed ACLFs were former single family homes. ACLFs provide food, room, and board to individuals who may need some assistance with activities essential to daily living such as bathing, grooming, eating, or ambulating.

To the extent that medication is prescribed by a resident's private physician and purchased through a private pharmacist, employee-staff of an ACLF play a limited role in the storage and distribution of medicine. A report by the Office of Evaluation and Management Review for HRS, concluded that only 12% of the residents in ACLFs were unable to take medication without assistance. The same report noted that 30% of the residents required "some help" and 58% required "no help" whatsoever.

Currently, HRS rules governing the storage, distribution, and administration of medication in ACLFs appear to adequately protect the residents of these facilities. Pursuant to s. 400.452, Florida Statutes, the department includes among its core training requirements education on supervision of self-administered medication. Pharmacist consultants presently volunteer their services to the department's adult protection investigation teams. In addition, the Office of Licensure and Certification employs pharmacists who are available to assist in the investigation of ACLFs.

Though department rules appear to provide adequate protection to residents in the area of dietary service standards, strengthening the existing ACLF staff training program requirements may reduce the number of documented deficiencies without increasing costs.

IV. AMENDMENTS:

None.

STORAGE NAME: h209s-f.rr
DATE: July 7, 1989

HOUSE OF REPRESENTATIVES
COMMITTEE ON REGULATORY REFORM
as revised by the Committee on
APPROPRIATIONS
FINAL STAFF ANALYSIS & ECONOMIC IMPACT STATEMENT

BILL #: CS/HB 209 (similar provisions passed as CS/SB 194)

RELATING TO: Pharmacy

SPONSOR(S): Representative Kelly

EFFECTIVE DATE: October 1, 1989

COMPANION BILL(S): CS/SB 462, CS/SB 194

OTHER COMMITTEES OF REFERENCE: (1) Appropriations
(2)

I. SUMMARY:

CS/HB 209 would require pharmacies located outside of Florida, which ship, mail, or deliver dispensed medicinal drugs into Florida to be registered with the Florida Board of Pharmacy; would provide for certain fees; would allow the board to deny, revoke, suspend, fine, or reprimand a nonresident pharmacy; would provide for certain advertising by and for nonresident pharmacies; and would require that nonresident pharmacies adhere to Florida's statutory provisions for drug substitutions.

A. PRESENT SITUATION:

Chapter 465, Florida Statutes, known as the Florida Pharmacy Act, mandates the Board of Pharmacy, within the Department of Professional Regulation to regulate pharmacists and pharmacies. The chapter also authorizes the department to inspect pharmacies and issue permits to persons or institutions that operate pharmacies. The law also provides for the revocation or suspension of registration for a practitioner or pharmacy who violates the provisions of the law.

The Legislature first addressed nonresident pharmacies with the passage of chapter 86-256, Laws of Florida, which is now codified at section 465.0156, Florida Statutes. Although Florida does not currently regulate nonresident pharmacies, it does require every nonresident pharmacy which ships, mails, or delivers a dispensed medicinal drug into Florida to meet certain conditions. Also, each nonresident pharmacy is required to disclose certain information to the board; a nonresident pharmacy which complies with the required disclosures is not required to obtain a permit.

The Board of Pharmacy is funded through licensure and other fees paid by pharmacists and pharmacies. These fees cover many costs (i.e., board administrative office expenses, departmental 000147

support, issuing licenses, exams, etc.).

In accordance with the provisions of chapter 120, Florida Statutes, the Board of Pharmacy establishes rules relating to examinations, discipline, fees, and licensure. The board may deny, revoke, suspend registration, fine, or reprimand any pharmacy or practitioner who is in violation of chapter 465. Additionally, the rules allow for the advertisement of medicinal drugs (with the exception of controlled substances listed in chapter 893, Florida Statutes,) as long as the advertising is not false, misleading or deceptive.

The Florida Pharmacy Act of 1979 also addresses the issue of drug substitution. The Act requires the Board of Pharmacy and the Board of Medical Examiners to establish a "negative" drug formulary of generic drug type and brand name drug products which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication. The Board of Pharmacy is required to mail a copy of the negative formulary to each licensed community pharmacy and board which regulates practitioners licensed to prescribe drugs.

B. EFFECT OF PROPOSED CHANGES:

CS/HB 209 would require any nonresident pharmacy to be registered with the Board of Pharmacy, provide a high level of protection and competence, and provide the board with the following information:

- That it at all times maintains a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with laws of the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed.
- The location, names, and titles of all principal corporate officers and all pharmacists who are dispensing medicinal drugs to residents of Florida. This information is to be disclosed to the board annually, and within 30 days after any change of office location, corporate officer, or pharmacist.
- That it complies with all the laws and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the board as provided in this bill.
- That it maintains its records of medicinal drugs dispensed to patients in this state so that the records are readily available and separate from other pharmacy business records.

CS/HB 209 also would require nonresident pharmacies to apply for registration on a form provided by the Board of Pharmacy.

In addition, the bill would require nonresident pharmacies to pay a registration and biennial renewal fee.

The Board of Pharmacy would also be given the authority to deny, revoke, or suspend the nonresident pharmacy registration, and fine or reprimand a nonresident pharmacy for failure to comply with the provision of the Florida Pharmacy Act. Likewise, the board would be allowed to deny, revoke, suspend registration, fine, or reprimand a nonresident pharmacy:

- If the nonresident pharmacy does anything to cause serious bodily or serious psychological injury to a Florida resident.
- If the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located; and
- If the regulatory or licensing agency fails to investigate within 180 days of the referral.

CS/HB 209 also would make it illegal for a nonresident pharmacy, not registered in Florida, to advertise its services in Florida, and for any person who is a resident of this state to advertise the pharmacy services of a nonresident pharmacy which has not registered with the board, if the person knows that the advertisement will or is likely to influence Florida residents into using the nonresident pharmacy.

Finally, the bill would require the Board of Pharmacy to mail the negative drug formulary to every nonresident pharmacy who is registered in Florida, requiring all registered nonresident pharmacies to adhere to Florida's statutory provisions for drug substitution.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT: FY 89-90 FY 90-91

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring or First Year Start-Up Effects:

None

2. Recurring or Annualized Continuation Effects:

EXPENDITURES:

Department of Professional
Regulation
Expenses

\$ 8,750 \$ 8,750

REVENUES:

Department of Professional
Regulation
Permit Fees

\$ 8,750 \$ 8,750

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3. Long Run Effects Other Than Normal Growth:

None

4. Appropriations Consequences:

EXPENDITURES:

Professional Regulation Trust Fund	\$ 8,750	\$ 8,750
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REVENUE:

Professional Regulation Trust Fund	\$ 8,750	\$ 8,750
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B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring or First Year Start-Up Effects:

None

2. Recurring or Annualized Continuation Effects:

None

3. Long Run Effects Other Than Normal Growth:

None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

None

2. Direct Private Sector Benefits:

None

3. Effects on Competition, Private Enterprise, and Employment Markets:

None

D. FISCAL COMMENTS:

The Department of Professional Regulation reports that no data is available as to the estimated number of delinquencies, changes of locations, or new registrations each year.

The department also reports CS/HB 209 would generate revenue sufficient to cover the agency costs of implementing such registration and any other related administrative costs.

III. LONG RANGE CONSEQUENCES:

CS/HB 209 is consistent with section 187.201(21), Florida Statutes, the State Comprehensive Plan for government to economically and efficiently provide the amount and quality of services required by the public.

IV. COMMENTS:

CS/HB 209 is also consistent with the House of Representatives mission statements set forth for the Regulatory Reform Committee to "Ensure that the statutes foster only necessary and effective regulations of Florida's business sector to protect the public interest" and to "Review and change regulatory laws dealing with professions, occupations and businesses so that they protect the public health, safety, and welfare, without having costs greater than the benefits conferred."

Requiring nonresident pharmacies, which are providing pharmaceutical services to Florida's citizens, to adhere to Florida's pharmacy laws will provide long-term protection to consumers who are in need of medicinal drugs, and are inclined to purchase these drugs from nonresident pharmacies.

The Board of Pharmacy is comprised of seven members (five licensed pharmacists and two consumer members). The board currently regulates approximately 8,000 licensed pharmacists, and approximately 3,000 state pharmacies.

V. FINAL ACTION:

CS/HB 209 passed the House and died in the Senate Committee on Economic, Professional and Utility Regulation. Similar provisions were passed by the Legislature in CS/SB 194 which became law without the Governor's signature on June 28, 1989, chapter 89-218, Laws of Florida.

VI. SIGNATURES:

SUBSTANTIVE COMMITTEE:

Prepared by:



Marcia A. Mathis

Staff Director:



Patrick L. "Booter" Imhof

STORAGE NAME: h209s-f.rr

DATE: July 7, 1989

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SECOND COMMITTEE OF REFERENCE:

Prepared by:

Staff Director:

APPROPRIATIONS:

Prepared by:

Leo Lachat

Staff Director:

Dr. James A. Zingale

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***AS PASSED BY THE 1989 LEGISLATURE**

STORAGE NAME: h60f.hrs/cn/sg
DATE: June 6, 1989

HOUSE OF REPRESENTATIVES
COMMITTEE ON HEALTH & REHABILITATIVE SERVICES
FINAL STAFF ANALYSIS & ECONOMIC IMPACT STATEMENT

BILL #: CS/HBs 60 and 163 (Passed as CS/SB 194)

RELATING TO: Adult Congregate Living Facilities

SPONSOR(S): Committee on Health and Rehabilitative Services and
Representatives Deutsch and Lippman

EFFECTIVE DATE: October 1, 1989

DATE BECAME LAW: June 28, 1989

CHAPTER #: 89-218, Laws of Florida

COMPANION BILL(S): Similar to CS/SB 194 and SB 174

OTHER COMMITTEES OF REFERENCE: (1) Appropriations
(2)

I. SUMMARY:

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Committee Substitute for House Bills 60 and 163 creates a new section in Florida Statutes to require consultant pharmacist or dietitian services in an adult congregate living facility where there are documented deficiencies regarding medicinal drugs or over-the-counter preparations or dietary services. The consultant services are to be provided onsite and continue at least quarterly until the Department of HRS inspection teams determine they are no longer required. The Department must employ at least two pharmacists on its staff that inspects adult congregate living facilities.

The State Nursing Home and Long Term Care Facility Ombudsman Council and District Nursing Home and Long Term Care Facility Ombudsman Councils are given access to patient records under certain conditions.

Non-resident pharmacies are required to register with the Board of Pharmacy, to pay a registration fee, to comply with state laws, and are subject to sanctions for violations of state law.

A. PRESENT SITUATION:

An adult congregate living facility provides housing, food service and one or more personal services to four or more adults. They are licensed under the authority of Chapter 400, Part II, F.S., by the Department of Health and Rehabilitative Services. There are approximately 1,500 facilities licensed in Florida with a bed capacity of approximately 57,000. The state, through the

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DATE: June 6, 1989

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optional state supplementation program, assists approximately 5,000 persons with placement in ACLFs.

The personal services that ACLFs may provide include individual assistance with or supervision of activities of daily living, such as eating, bathing, grooming, dressing, ambulating, and supervision of self-administered medication. Medical, nursing, dental, or mental health services may not be provided; however, a facility may provide limited nursing services if specifically licensed to do so.

The department has promulgated administrative rules governing the storage and administration of medication. Rule 10A-5.0182(3)(b)(1), Fla. Admin. Code, provides that "There shall be a staff person available at all times who has access to, is responsible for and is trained in the supervision of self-administered medication".

The rules also require that every licensed ACLF have its nutritional plans or menus reviewed by a registered dietitian or dietitian technician on a periodic basis. Reviews are conducted in accordance with recommended dietary allowances established by the Food and Nutrition Board, National Research Council, and adjusted for age, sex, and activity. Rule 10A-5.020(1)(c), Fla. Admin. Code.

The Department of HRS currently has pharmacists in the Office of Licensure and Certification who assist in the monitoring of adult congregate living facilities.

The State Nursing Home and Long Term Care Facility Ombudsman Council is established in s. 400.304, F.S. The State and district ombudsman councils investigate complaints in nursing homes and other long term care facilities. The State and district ombudsman councils do not have specific statutory authority to review a patient's medical record, however, the practice is to allow the ombudsman council members to have such access. When a patient is transferred from a long term care facility to a hospital, the ombudsman councils do not have access to the hospital records.

Chapter 465, Florida Statutes, known as the Florida Pharmacy Act, mandates the Board of Pharmacy, within the Department of Professional Regulation to regulate pharmacists and pharmacies. The chapter also authorizes the department to inspect pharmacies and issue permits to persons or institutions that operate pharmacies. The law also provides for the revocation or suspension of registration for a practitioner or pharmacy who violates the provisions of the law.

The Legislature first addressed non-resident pharmacies with the passage of chapter 86-256, Laws of Florida, which is now codified at section 465.0156, Florida Statutes. Although Florida does not currently regulate non-resident pharmacies, it does require every non-resident pharmacy which ships, mails, or delivers a dispensed medicinal drug into Florida to meet certain conditions. Also,

each non-resident pharmacy is required to disclose certain information to the board; a non-resident pharmacy which complies with the required disclosures is not required to obtain a permit.

The Board of Pharmacy is funded through licensure and other fees paid by pharmacists and pharmacies. These fees cover many costs (i.e., board administrative office expenses, departmental support, issuing licenses, exams, etc.).

In accordance with the provisions of chapter 120, Florida Statutes, the Board of Pharmacy establishes rules relating to examinations, discipline, fees, and licensure. The board may deny, revoke, suspend registration, fine, or reprimand any pharmacy or practitioner who is in violation of chapter 465. Additionally, the rules allow for the advertisement of medicinal drugs (with the exception of controlled substances listed in chapter 893, Florida Statutes,) as long as the advertising is not false, misleading or deceptive.

The Florida Pharmacy Act of 1979 also addresses the issue of drug substitution. The Act requires the Board of Pharmacy and the Board of Medical Examiners to establish a "negative" drug formulary of generic drug type and brand name drug products which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication. The Board of Pharmacy is required to mail a copy of the negative formulary to each licensed community pharmacy and board which regulates practitioners licensed to prescribe drugs.

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B. EFFECT OF PROPOSED CHANGES:

Committee Substitute for House Bills 60 and 163 requires facilities that have documented deficiencies regarding medicinal drugs or over-the-counter preparations or dietary services to employ the consultant services of a licensed pharmacist or a registered or licensed dietitian or both, as applicable. The facility would be required to continue such services onsite, at least quarterly, until the inspection team from the Department of HRS determined that the standards were being met so that such services were no longer required. The Department of HRS is required to employ at least two pharmacists among its personnel that inspect adult congregate living facilities.

The State Nursing Home and Long Term Care Facility Ombudsman Council and District Nursing Home and Long Term Care Facility Ombudsman Councils are provided access to hospital patient records under certain circumstances.

Non-resident pharmacies are required to register with the Board of Pharmacy, to pay a registration fee, to comply with state laws including the formulary on generic drugs and are subject to sanctions for violation of state law.

C. SECTION-BY-SECTION ANALYSIS:

Section 1. Section 400.442, F.S., is created to provide that ACLFs which have documented deficiencies regarding medicinal drugs or over-the-counter preparations or dietary services through class I or class II violations or uncorrected class III violations must employ the consultant services of a licensed pharmacist or a registered or licensed dietitian as applicable. The facility must continue with the consultant services on site, at least quarterly, until the inspection team from the department determines that the standards are being met so that such services are no longer required. The Department of HRS is required to employ at least two pharmacists among its personnel who inspect adult congregate living facilities.

Section 2. Section 395.017, Florida Statutes, 1988 Supplement, is amended to provide that the State Nursing Home and Long Term Care Facility Ombudsman Council and the District Nursing Home and Long Term Care Facility Ombudsman Councils can have access to patient records when

1. The patient has transferred from a long term care facility to a hospital,
2. The Council is conducting an authorized investigation,
3. The Council member presents identification, and
4. The patient or his representative has been notified and does not object to disclosure.

Section 3. Section 465.0156, Florida Statutes on non-resident pharmacies is amended. Subsection (1) provides that non-resident pharmacies must register with the Board of Pharmacy, provide a high level of protection and competence, and disclose to the Board, the following information.

- That it at all times maintains a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with laws of the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed.
- The location, names, and titles of all principal corporate officers and all pharmacists who are dispensing medicinal drugs to residents of Florida. This information is to be disclosed to the board annually, and within 30 days after any change of office location, corporate officer, or pharmacist.
- That it complies with all the laws and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the board as provided in this bill.
- That it maintains its records of medicinal drugs dispensed to patients in this state so that the records are readily

available and separate from other pharmacy business records.

- That it maintains a toll free telephone number at least 40 hours a week.

Subsection (2) authorizes the Board of Pharmacy to develop the application form for non-resident pharmacies and authorizes the Board to exempt non-resident pharmacies who are only involved in isolated transactions in Florida. Isolated transactions are to be defined by rule by the Board.

Subsection (3) authorizes a registration fee for non-resident pharmacies.

Subsection (4) authorizes the Board to deny, revoke or suspend a registration of a non-resident pharmacy or to fine or reprimand a non-resident pharmacy if the non-resident pharmacy fails to comply with the formulary on generic drugs or fails to comply with the section requiring registration.

Subsection (5) authorizes the Board to deny, revoke or suspend a registration of a non-resident pharmacy or to fine or reprimand a non-resident pharmacy if the non-resident pharmacy engages in conduct which causes serious bodily or psychological injury to a Florida resident and the licensing agency in the state in which the pharmacy is located fails to investigate within 180 days.

Subsection (6) makes it unlawful for a non-resident pharmacy to advertise in this state unless it is registered. It is also unlawful for residents of this state to advertise the services of a non-resident pharmacy which is not registered in Florida.

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Section 4. Section 465.025, Florida Statutes is amended to require the Board of Pharmacy to mail a copy of the formulary on generic drugs to each non-resident pharmacy registered in Florida.

Section 5. Provides an effective date of October 1, 1989.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring or First Year Start-Up Effects:

None

2. Recurring or Annualized Continuation Effects:

Since the Department of HRS already has at least pharmacists among its personnel who inspect adult congregate living facilities there would be no additional cost for this provision.

There would be no additional cost to allow the Ombudsman

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Councils access to hospital records.

The Department of Professional Regulation reports that the provisions on registering non-resident pharmacies would result in minimal costs to the Department and could be absorbed within existing resources. The Department also reports that these provisions would generate the following revenue:

	Amount Year 1 (FY 89-90)	Amount Year 2 (FY 90-91)
Initial Permit (50 @ \$175)	\$ 8,750	\$ 0
Renewal (50 @ \$175)	0	8,750
Delinquent Fee (\$100)	0	0
Change of Location (\$100)	0	0
	-----	-----
TOTAL REVENUE	\$ 8,750	\$ 8,750
	=====	=====

3. Long Run Effects Other Than Normal Growth:

None

4. Appropriations Consequences:

None

B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring or First Year Start-Up Effects:

None

2. Recurring or Annualized Continuation Effects:

None

3. Long Run Effects Other Than Normal Growth:

None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

It is difficult to estimate the costs to the ACLF industry. There would be some additional costs in those facilities to provide consultant services with class I, class II or uncorrected class III deficiencies. Increased costs to the facilities will likely be passed on to the private residents.

It is possible that some hospitals would be asked to copy records for ombudsman council members and incur the costs

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associated with that function. However, the hospitals should be able to charge a fee pursuant to s. 395.017, F.S.

Non-resident pharmacies would be required to pay a registration fee and conform to certain provisions in Florida law that may be different than their normal procedure in another state.

2. Direct Private Sector Benefits:

Cannot be determined.

3. Effects on Competition, Private Enterprise, and Employment Markets:

None

D. FISCAL COMMENTS:

III. LONG RANGE CONSEQUENCES:

The provisions on consultant services in adult congregate living facilities are neither consistent nor inconsistent with the State Comprehensive Plan, s. 187.201, F.S.

The provisions on access to hospital records by the ombudsman councils are generally consistent with the State Comprehensive Plan, s. 187.201(6)(b)(11)w, F.S., by helping reduce the incidence of elderly abuse and neglect.

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The provisions on registration of non-resident pharmacies are consistent with the State Comprehensive Plan, s. 187.201(21), F.S., by having government economically and efficiently provide the amount and quality of services required by the public.

IV. COMMENTS:

In the 1988 Long-Term Care Ombudsman Council Annual Report, complaints by ACLF residents involving medication amounted to only 4% of all complaints to the council.

To the extent that medication is prescribed by a resident's private physician and purchased through a private pharmacist, staff in an ACLF play a limited role in the storage and distribution of medicine. Currently, HRS rules governing the storage, distribution, and administration of medication in ACLFs appear to adequately protect the residents of these facilities. Pursuant to s. 400.452, F.S., the department includes training on supervision of self-administered medication. The office of licensure and certification employs pharmacists who are available to assist in the investigation of ACLFs. Further, the existing department rules appear to adequately address dietary service standards. This bill requires only facilities with class I, class II or uncorrected class III violations to retain the consultant services and gives the Department of HRS a

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specific mechanism to address problems in a facility.

This bill is consistent with the Mission Statement for the HRS Committee and is generally consistent with the Policy Statement, Human Resource Development, III. C. 3, by trying to ensure the safety of residents in long term care facilities. By requiring non-resident pharmacies which do business in Florida to adhere to certain pharmacy laws in Florida, the state is providing long term protection to consumers who use out of state pharmacies.

V. SIGNATURES:

SUBSTANTIVE COMMITTEE:

Prepared by:

Elaine New/sg/

Staff Director:

Judy C. Justice



SECOND COMMITTEE OF REFERENCE:

Prepared by:

Staff Director:

APPROPRIATIONS:

Prepared by:

Staff Director: