The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health and Human Services Appropriations Committee

BILL:	CS/SB 574
INTRODUCER:	Health Regulation Committee and Senator Gaetz
SUBJECT:	Prescription Drugs/Purchase
DATE:	March 24, 2009 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	**Fav/CS**
2.	Peters	Peters	HA	**Favorable**
3.			RC	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The committee substitute authorizes a business entity to purchase and possess prescription drugs for an establishment that operates as a medical clinic or veterinary clinic pursuant to the oversight and responsibility of a qualifying practitioner at that establishment. The committee substitute establishes certain conditions for the purchase and possession of prescription drugs by clinics in order to protect the public health. The committee substitute repeals the health care clinic establishment permit authorized under the Florida Drug and Cosmetic Act in ch. 499, F.S., (the Act). In addition, the committee substitute authorizes the Department of Health (Department) to assess a non-refundable fee of $150 or 50 percent of the permit or certification fee, whichever is less, when an application for a permit or certification as a designated representative is withdrawn or becomes void.

The Department of Health will be required to refund an estimated $379,695 in revenues received from the Health Care Clinic Establish (HCCE) permit collected in FY 2008-09. It is estimated that revenues received from the Qualifying Practitioner registration fee and non-refundable application fee are estimated to be $362,525. The net impact in revenue is a reduction of $17,170 in year one. There is currently an estimated ending cash balance of $2.8 million in the Drugs, Devices and Cosmetics Trust Fund.

This committee substitute substantially amends the following sections of the Florida Statutes: 499.003; 499.01; 499.01211; 499.03; 499.041; 499.05; 400.9935; 409.9201; and 465.0265.

This committee substitute creates s. 499.031, Florida Statutes.

II. Present Situation:

Overview of The Florida Drug and Cosmetic Act

The Florida Drug and Cosmetic Act (Act) is found in part I of ch. 499, F.S. Its purpose is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.[1] The Department is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.[2]

The Department issues permits to persons (defined to also include business entities) who qualify to engage in activity regulated under the Act. Generally, each establishment (location) must be permitted. Prior to operating, a permit is required for each person and establishment that intends to operate as:

- A prescription drug manufacturer;
- A prescription drug repackager;
- A nonresident prescription drug manufacturer;
- A prescription drug wholesale distributor;
- An out-of-state prescription drug wholesale distributor;
- A retail pharmacy drug wholesale distributor;
- A restricted prescription drug distributor;
- A complimentary drug distributor;
- A freight forwarder;
- A veterinary prescription drug retail establishment;
- A veterinary prescription drug wholesale distributor;
- A limited prescription drug veterinary wholesale distributor;
- A medical oxygen retail establishment;
- A compressed medical gas wholesale distributor;
- A compressed medical gas manufacturer;
- An over-the-counter drug manufacturer;
- A device manufacturer;
- A cosmetic manufacturer;
- A third party logistics provider; or
- A health care clinic establishment.

[1] The Federal Food, Drug and Cosmetic Act, 21 United States Code, beginning at section 301, forms the basis for the Act and also protects Floridians from dangerous drugs, devices, and cosmetics.
[2] Section 449.004, Florida Statutes.

The Act identifies authorized and proscribed activities for each permitted activity as well as particular storage, handling, and recordkeeping requirements for each. A designated representative is required for each permitted prescription drug wholesale distributor and out-of-state prescription drug wholesale distributor.[3] The designated representative must be knowledgeable in the laws and rules governing the wholesale distribution of prescription drugs, as demonstrated by passing an examination, and must be actively involved in and aware of the actual daily operation of the wholesale distributor. Administrative and criminal penalties may result for the failure to comply with requirements in the Act and administrative rules.[4] The Act also establishes the Cancer Drug Donation Program.

The presence of adulterated, diverted, and counterfeit drugs in the United States has been a concern for years. Some life saving or life sustaining drugs are very expensive. Most drugs are subject to compromised integrity due to improper manufacturing, packaging, storage, or use beyond the expiration date. Generally a compromised drug is undetectable to a medical practitioner and the consuming patient, which can lead to ineffective treatment or potentially fatal results. As a result, the laws addressing the manufacture, distribution, consumption, and disposal of drugs, especially prescription drugs, are very strict in this country. A prescription drug is one that is not safe for use except under the supervision of a practitioner licensed by law to administer the drug and can only be dispensed pursuant to a prescription.[5]

The regulatory structure in Florida requires that a licensed or permitted person possess a prescription drug from cradle to grave, unless a patient possesses a dispensed prescription drug pursuant to a valid prescription. [6] A permit or license authorizes the possession of prescription drugs either explicitly or by virtue of the responsibilities authorized under that permit or license.

Health Care Clinic Establishment Permit

The Act was substantially reorganized during the 2008 Legislative Session. Several new provisions were added, including the creation of a Health Care Clinic Establishment (HCCE) permit that took effect on January 1, 2009. The HCCE permit is required for the purchase of prescription drugs by a place of business at one general location owned and operated by a:

- Professional corporation described in ch. 621, F.S., with a qualifying practitioner,
- Professional limited liability company described in ch. 621, F.S., with a qualifying practitioner, or
- Corporation that employs a veterinarian as a qualifying practitioner.

A qualifying practitioner is a licensed health care practitioner defined in s. 456.001, F.S., or a veterinarian licensed under chapter 474, F.S. The health care practitioners defined in s. 456.001, F.S., that are authorized to prescribe prescription drugs include a: medical physician, osteopathic physician, physician assistant, advanced registered nurse practitioner, optometrist, podiatric physician, dentist, or chiropractic physician. Both the qualifying practitioner and the HCCE must notify the Department within ten days of a change in the qualifying practitioner.

[3] s. 499.012(16)(a), F.S.
[4] Chapter 64F-12, Florida Administrative Code, contains the rules adopted under the Act's authority.
[5] See Section 503(b) of the Federal Food, Drug and Cosmetic Act.
[6] s. 499.03, F.S.

The biennial fee for the HCCE permit is $255 and the permit is valid for two years, unless suspended or revoked.

The HCCE permit is an optional permit that a health care clinic (group practice) may obtain in order to purchase and own prescription drugs in the business entity's name. The HCCE permit is not required if a practitioner in the clinic or practice wants to purchase and own prescription drugs in his or her own name using his or her professional license that authorizes that practitioner to prescribe prescription drugs.

The HCCE permit provisions in the Act do not adequately address the needs of the medical community because, among other reasons, many medical practices are not organized as a professional service corporation or professional limited liability company under ch. 621, F.S. Chapter 621, F.S., is available for business entities that provide professional services. It requires as a condition precedent to the rendering of the service, the obtaining of a license or other legal authorization; however, there is no requirement that a medical clinic must be organized under that chapter. Medical practices, health care clinics, and the like, may be organized, for example, as a: corporation under ch. 607, F.S., or ch. 617, F.S.; limited liability company under ch. 608, F.S.; or partnership under ch. 620, F.S.

Health Care Clinics Licensed Under Chapter 400, F.S.

Certain health care clinics are licensed by the Agency for Health Care Administration (Agency) under part X of ch. 400, F.S. A clinic is defined as an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider.[7] However, the term does not include and licensure is not required for:

- Entities that are licensed or registered under ch. 395, F.S., (hospitals, ambulatory surgical centers, and mobile surgical facilities); entities licensed or registered and providing only health care services within the scope of services authorized under their respective licenses for:
  - Birth centers under s. 383.30-383.335, F.S.,
  - Abortion clinics under ch. 390, F.S.,
  - Mental health facilities under ch. 394, F.S.,
  - Substance abuse treatment and services under ch. 397, F.S.,
  - Nursing homes and related facilities under ch. 400, F.S., (except part X related to the licensure of health care clinics),
  - Assisted care communities under ch. 429, F.S.,
  - Optometry under ch. 463, F.S.,
  - Pharmacy under ch. 465, F.S.,
  - Dentistry under ch. 466, F.S.,
  - Electrolysis under ch. 478, F.S.,
  - Clinical laboratories under part I of ch. 483, F.S.,
  - The dispensing of optical devices and hearing aids under ch. 484, F.S., or
  - Continuing care facilities under ch. 651, F.S.;

[7] s. 400.9905(4), F.S.

end-stage renal disease providers; providers of comprehensive outpatient rehabilitation services certified under 42 C.F.R. part 485, subpart B; outpatient physical therapy and speech-language pathology certified under 42 C.F.R. part 485, subpart H; or any entity that provides neonatal or pediatric hospital-based health care services or other health care services by licensed practitioner solely within a hospital licensed under ch. 395, F.S.;

- Entities that own, directly or indirectly, an entity identified above;
- Entities that are owned, directly or indirectly by an entity identified above in the first bullet;
- Entities that are under common ownership, directly or indirectly, with an entity identified above in the first bullet;
- Certain entities that are exempt from federal taxation;
- Certain entities that are an employee stock ownership plan;
- Any community college or university clinic;
- Entities owned or operated by the federal or state government, including their agencies, subdivisions, or municipalities;
- A sole proprietorship, group practice, partnership, or corporation that provides health care services by physicians covered by s. 627.419, F.S., related to health insurance policies, health care services plans, or other contract, that is directly supervised by one or more of such physicians, and that is wholly owned by one or more of those physicians or by a physician and that physician's spouse, parent, child, or sibling;
- A sole proprietorship, group practice, partnership, or corporation that provides health care services by licensed health care practitioners licensed under ch. 457, F.S., related to acupuncture; ch. 458, F.S., related to medical practice; ch. 459, F.S., related to osteopathic medicine; ch. 460, F.S., related to podiatric medicine; ch. 461, F.S., related to podiatric medicine; ch. 462, F.S., related to naturopathy; ch. 463, F.S., related to optometry; ch. 466, F.S., related to dentistry; ch. 467, F.S., related to midwifery; ch. 480, F.S., related to massage practice; ch. 484, F.S., related to dispensing of optical devices and hearing aids; ch. 486, F.S., related to physical therapy practice; ch. 490, F.S., related to psychological services; ch. 491, F.S., related to clinical, counseling, and psychotherapy services; or part I, part III, part X, part XIII, or part XIV of ch. 468, F.S., related to speech-language pathology and audiology, occupational therapy, dietetics and nutrition practice, athletic trainers, and orthotics, prosthetics, and pedorthics; or s. 464.012, F.S., related to advanced registered nurse practitioners and which are wholly owned by one or more licensed health care practitioners, or a health care practitioner and that practitioner's spouse, parent, child, or sibling, provided the practitioner supervises the business activities and is legally responsible for the entity's compliance with all federal and state laws;
- Clinical facilities affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- Certain entities that provide oncology or radiation therapy services by allopathic or osteopathic physicians;
- Certain clinical facilities affiliated with a college of chiropractic at which training is provided for chiropractic students;
- Certain entities that provide licensed practitioners to staff emergency departments or to deliver anesthesia services in hospitals, ambulatory service centers, or mobile surgical facilities; and
- Orthotic or prosthetic clinical facilities that are a publicly traded corporation or owned by a publicly traded corporation.

As of February 4, 2009, there were 2,189 health care clinics in Florida licensed by the Agency.

III. Effect of Proposed Changes:

Section 1. Amends s. 499.003, F.S., to define a qualifying practitioner. A qualifying practitioner includes a person who is licensed and authorized under the appropriate practice act to prescribe and administer a prescription drug. The list of licensed health care practitioners in s. 456.001, F.S., which is referred to in the definition, includes numerous practitioners who are not authorized under their practice act to prescribe and administer a prescription drug. The definition in this committee substitute includes a: medical physician, osteopathic physician, physician assistant, advanced registered nurse practitioner, optometrist, podiatric physician, dentist, or chiropractic physician. A veterinarian is also a qualifying practitioner.

Section 2. Amends s. 499.01, F.S., to repeal the HCCE permit and conform a cross reference.

Section 3. Amends s. 499.01211, F.S., related to the Drug Wholesale Distributor Advisory Council to conform a cross reference.

Section 4. Amends s. 499.03, F.S., to authorize the possession of prescription drugs by an establishment of a legal business entity:

- At which qualifying practitioners practice their profession and
- That complies with the provisions of s. 499.031, F.S., where the conditions for the establishment and business entity are set forth.

Section 5. Creates s. 499.031, F.S., to authorize a medical clinic or veterinary clinic to lawfully purchase and possess prescription drugs in accordance with certain conditions intended to protect the public health. These conditions include:

- A description of a medical clinic that is eligible to purchase and possess prescription drugs under this section. In summary, a business entity may purchase prescription drugs for an establishment with a qualifying practitioner. More specifically:
  - The legal business entity must have a federal tax identification number,
  - Qualifying practitioners must practice their profession under state law at the establishment, and
  - The establishment must have a qualifying practitioner who is:
    - An owner or member of the entity or an employee of the entity at that establishment and who has registered with the Department as the qualifying practitioner for that entity and establishment, or
    - The medical director for a health care clinic that is licensed under part X of ch. 400, F.S., and who has executed a written agreement with the health care clinic that assigns the responsibility to him or her to serve as the qualifying practitioner for the clinic;
- Ensuring that an establishment does not purchase or possess prescription drugs without a qualifying practitioner for longer than 10 days as follows:
  - If the licensed health care clinic does not have a medical director serving as the qualifying practitioner for more than 10 days, the health care clinic must ensure that it has

a qualifying practitioner registered with the Department in order to purchase and possess prescription drugs, and
    - If a qualifying practitioner that is registered for an establishment ceases serving as the qualifying practitioner, both the qualifying practitioner and the business entity must notify the department and the business entity's sources of prescription drugs, within 10 days that the qualifying practitioner is no longer serving in that capacity. In addition, the establishment must ensure that is has a new qualifying practitioner registered with the department within 10 days after the previous one ceases serving as the qualifying practitioner;
- Controlling the purchase and possession of prescription drugs by the entity at the establishment through the oversight and responsibility of the qualifying practitioner by:
    - Limiting the prescription drugs that may be purchased to those that the qualifying practitioner of the establishment is authorized to prescribe,
    - Clarifying that the business entity is not authorized by this section to purchase controlled substances and that the business entity and establishment must comply with applicable state and federal laws related to controlled substances,
    - Specifying that the qualifying practitioner is responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs, including ensuring that there are policies and procedures for handling the prescription drugs at the establishment upon the termination of the qualifying practitioner from serving in that capacity at the establishment, and
    - Providing that the qualifying practitioner may be subject to discipline under his or her regulatory board for a violation of part I of the Act;
- Providing for the registration of one qualifying practitioner who is serving in that capacity to enable a medical or veterinary clinic to purchase prescription drugs and who is not a medical director of a licensed health care clinic serving in that capacity in accordance with the medical director's written agreement with a licensed health care clinic, through the submission of documentation until the department establishes an on-line registration system. As a part of registration, the qualifying practitioner must certify his or her acceptance of the responsibilities of a qualifying practitioner and pay a $25 registration fee for each establishment in which he or she is serving as the qualifying practitioner to enable the business entity to purchase prescription drugs. Registration of a qualifying practitioner for an establishment expires upon the license renewal date of the qualifying practitioner's professional license, unless the qualifying practitioner has previously notified the department that he or she has discontinued serving in that capacity or the registration has been previously revoked. The department is to provide for renewal of the registration as a part of the renewal of the practitioner's professional license; and
- Requiring the registered qualifying practitioner's registration number for that business entity and establishment, or the health care clinic's license number to be included on the documentation for the distribution of prescription drugs to or returns by the business entity.

The committee substitute further provides that this section does not prohibit a licensed practitioner whose professional license authorizes the practitioner to prescribe prescription drugs from purchasing prescription drugs under that professional license. Accordingly, practitioners and veterinarians may continue to practice their profession and purchase prescription drugs under their own license without registering as a qualifying practitioner under this section.

Section 6. Amends s. 499.041, F.S., to eliminate the fee associated with the health care clinic establishment permit and provide for a $25 fee for a person registering as a qualifying practitioner for a medical or veterinary clinic. If a qualifying practitioner is serving in that capacity for more than one establishment a separate fee is required for each registration. In addition, the Department is authorized to assess a non-refundable fee of $150 or 50 percent of the permit or certification fee, whichever is less, when an application for a permit or certification as a designated representative is withdrawn or becomes void.

Section 7. Amends s. 499.05, F.S., related to the Department's rulemaking authority to conform cross references.

Section 8. Amends s. 400.9935, F.S., to require the written agreement that a medical director executes with a licensed health care clinic to include the responsibilities of a qualifying practitioner as set forth under s. 499.031, F.S., if the medical director is to serve as the qualifying practitioner in order for the clinic to purchase and possess prescription drugs in its own name.

Section 9. Amends s. 409.9201, F.S., related to Medicaid fraud to conform a cross reference in the definition of prescription drug.

Section 10. Amends s. 465.0265, F.S., related to centralized prescription filling under the Florida Pharmacy Act, to conform a cross reference.

Section 11. Establishes an effective date of July 1, 2009.

Other Potential Implications: This committee substitute creates an exception to the regulatory scheme that requires every person who purchases or possesses a prescription drug (other than pursuant to a dispensed prescription) to maintain a valid license or permit by allowing an unlicensed or unpermitted business entity to purchase and possess prescription drugs.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The committee substitute provides for a $25 fee when a qualifying practitioner registers with the Department and repeals the HCCE permit and the associated $255 biennial fee.

B. Private Sector Impact:

The committee substitute enables more medical practices to be able to purchase and possess prescription drugs as a group practice instead of individual practitioners purchasing the prescription drugs under their professional license.

C. Government Sector Impact:

Although the number of qualifying practitioners is unknown, estimates are based on the number of veterinary establishments and the application of the ratio of veterinarians to veterinary establishments. This will allow for an estimate of the number of establishments that will require the use; thus registration of, at least one qualifying practitioner.

According to the Board of Veterinary Medicine, currently there are 6,369 veterinarians and 1,869 veterinary establishments; therefore, the number of veterinary establishments is 29% of the number of veterinarians. As of June 30, 2008, there are 40,936 licensed, active, in-state medical doctors; therefore, for the purposes of this analysis, it is projected there are 13,740 (40,936 X 0.29 estimated healthcare establishments + 1,869 veterinary establishments) qualifying practitioners (one for each establishment).

Further, the number of medical doctors increased from June 30, 2007, to June 30, 2008, by 2%; therefore, it is assumed that the number of qualifying practitioners will also increase by 2% annually. As this bill becomes effective July 1, 2009, the number of new registrations in year 1 is estimated as 14,015 (13,740 X 1.02). The number of new registrations in year 2 is estimated as 281 (14,015 X 1.02 – 14,015). The number of new registrations in year 3 is estimated as 286 (14,295 X 1.02 – 14,295). The number of new registrations issued in year 4 is estimated as 292 (14,581 X 1.02 – 14,581). Registrations will be renewed with the practitioner's license (every two years).

Estimated Expenditures:

DOH will be required to refund all revenues received since inception of the HCCE permit, January 1, 2009, through the effective date of this bill, July 1, 2009. As of February 28, 2009, DOH has received 1,489 applications for this permit. The permit fee is $255. It is estimated that the minimum amount DOH will refund in fees in year 1 is $379,695 (1,489 X $255). Although these revenues will be refunded in year 1; thus, included as expenditures in this analysis, these expenditures will be offset by the revenues initially collected in the current fiscal year (FY08-09).

Existing DOH staff and operating budget will be used to manage the qualified practitioner registrant pool, make necessary programming changes to the COMPAS licensure system, develop and implement a method of online registration, and provide a method of enforcement.

Estimated Revenues:
Revenues associated with the new qualifying practitioner registration are estimated based on year 1 registration applications of 14,015, year 2 applications of 281, year 3 applications of 286 and year 4 applications of 292. Although registrations expire with the practitioner's license, and DOH is required to provide a method of renewal, the assessment of a renewal fee for this registration is not specifically authorized.

Revenues associated with the non-refundable application fee are based on the count of refund transactions from July 1, 2007 to June 30, 2008. A count of 81 refund transactions were made during this time period. It is assumed all refund transactions were made as a result of a withdrawn application; therefore, assuming an application fee of $150 for all permit and certification types, DOH is projected to increase revenues by $12,150 annually ($150 X 81).

Surplus/Deficit is the annual difference between annual expenditures and revenues. The year 1 surplus/deficit includes the impact of the refund of HCCE permit fees; although the expenditures reported in this analysis related to this refund will be offset by revenues collected in the current fiscal year (FY08-09).

Cash Balance is the sum of annual surplus/deficits. The cash balance includes the impact of the refund of HCCE permit fees; although the expenditures reported in this analysis related to this refund will be offset by revenues collected in the current fiscal year (FY08-09).

These revenues are deposited into the Drugs Devices and Cosmetics Trust Fund. The estimated balance in the trust fund is $2.8 million.

Estimated Expenditures	**1st Year**	**2nd Year**	**3rd Year**	**4th Year**
Refund of Revenues				
Healthcare Clinic fee refund	$ 379,695	$ -	$ -	$ -
Total Estimated Expenditures	$ 379,695	$ -	$ -	$ -

Estimated Revenue	**1st Year**	**2nd Year**	**3rd Year**	**4th Year**
Registration Fee - Qualified Practitioner	$ 350,375	$ 7,025	$ 7,150	$ 7,300
Non-refundable Application Fee	$ 12,150	$ 12,150	$ 12,150	$ 12,150

Total Estimated Revenues	$ 362,525	$ 19,175	$ 19,300	$ 19,450
Surplus/Deficit	$ (17,170)	$ 19,175	$ 19,300	$ 19,450
Cash Balance	$ (17,170)	$ 2,005	$ 21,305	$ 40,755

VI. Technical Deficiencies:

None.

VII. Related Issues:

Under the committee substitute, a medical director that is to serve as the qualifying practitioner of a health care clinic licensed under ch. 400, F.S., is not required to register with the department. Prescription drug wholesale distributors and other permittees that are authorized to distribute prescription drugs to licensed health care clinics must ascertain that any purchaser and recipient is in fact authorized to purchase and possess prescription drugs. Since the health care clinic and qualifying practitioner will not be listed on the department's website, the distributor will need to verify that the health care clinic is licensed by the Agency, the medical director at the clinic has executed an agreement that assigns the responsibilities of a qualifying practitioner to that medical director, and determine the type of professional license that the medical director has. In addition, there is no requirement for a health care clinic to notify its prescription drug distributor(s) of a change in medical director or other change that would affect the lawful purchase of prescription drugs by the clinic and the corresponding sale by the distributor.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation on March 4, 2009:
The committee substitute:

- Repeals the health care clinic establishment permit;
- Authorizes a business entity to purchase and possess prescription drugs based on the oversight and responsibilities assigned to a qualifying practitioner;
- Provides for certain regulatory controls when business entities choose to purchase prescription drugs, including: notification when there is a change in qualifying practitioner and replacing the qualifying practitioner, limitations on the prescription drugs that the clinic is able to purchase, and recordkeeping requirements; and
- Authorizes the department to assess a non-refundable fee when applications are withdrawn or become void.

B. Amendments:

None.