HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 433 Prescribed Drug Formularies
SPONSOR(S): Health & Family Services Policy Council, Health Care Regulation Policy Committee, Roberson
TIED BILLS: **IDEN./SIM. BILLS:** SB 1868

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee	7 Y, 0 N, As CS	Holt	Calamas
2)	Health & Family Services Policy Council	16 Y, 7 N, As CS	Lowell	Gormley
3)	Health Care Appropriations Committee	6 Y, 0 N, As CS	Hicks	Pridgeon
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

Class II institutional pharmacies are hospital pharmacies which dispense medicinal drugs to hospital patients, for use on the premises of that hospital. Class I institutional pharmacies are nursing home pharmacies by which all medicinal drugs are administered from individual prescription containers to the individual patient and by which medicinal drugs are not dispensed on the premises but are dispensed by a community pharmacy.

The bill authorizes nursing homes to create a method whereby medical staff may evaluate and select medicinal drugs that are most useful in providing care to patients. This change is accomplished by adding Class I institutional pharmacies to a section of law that authorizes Class II institutional pharmacies to adopt an institutional formulary system in which medicinal drugs may be dispensed by a practicing pharmacist. The bill also amends the definition of "institutional formulary system" to include Class I institutional pharmacies.

The bill requires nursing homes to establish policies and procedures for their institutional formularies addressing prescriber notification, formulary information dissemination, outcome monitoring, and opt out provisions, among other things.

The bill amends the definition of "standard reference compendium" to remove the names of specific organizations and defer to a compendium identified and recognized by the Secretary of the United States Department of Health and Human Services and the Centers for Medicare and Medicaid Services, respectively.

The bill deletes the requirement that written prescriptions for *medicinal drugs* include the quantity prescribed to be both spelled out and numerically indicated; instead the quantity may be either spelled out in text format or written as a number. The bill requires that written prescriptions for *controlled substances* include the quantity in text and numerical format, and the date in a written format. If a prescription for a controlled substance does not contain the quantity or date in both formats and the pharmacist is unable to verify the prescription with the prescriber, a pharmacist may dispense without verification, if the pharmacy has dispensed another prescription for the same person.

This bill does not appear to have a fiscal impact on state or local governments.

The bill takes effect July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background:

Institutional Pharmacy

An "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.[1] All institutional pharmacies are required to be under the *professional supervision of a consultant pharmacist*, and the compounding and dispensing of medicinal drugs may only be done by a licensed pharmacist.[2]

"Dispensing" is the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist must, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction, delivery, and administration of such drug are not considered dispensing.[3]

"Medicinal drugs" or "drugs" are substances or preparations commonly known as "prescription" or "legend" drugs which are required by federal or state law to be dispensed only on a prescription, but *do not* include patents or proprietary preparations.[4] Medicinal drugs may only be dispensed in a Class II or Modified Class II institutional pharmacy (e.g. hospital or short-term, primary care treatment center).

Additionally, medicinal drugs may only be dispensed to outpatients only when the institution has secured a community pharmacy[5] permit from the department.[6] All medicinal drugs dispensed in an

[1] Section 465.003(11)(a)2., F.S.
[2] Section 465.019(5), F.S.
[3] Section 465.019(6), F.S.
[4] Section 465.003(8), F.S
[5] "Community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. (s. 465.003(11)(a)1., F.S.)
[6] Section 465.019(4), F.S.

institutional pharmacy must use a unit dose system that provides a method for the separation and identification of drugs for the individual resident or patient. The unit dose system must indicate clearly the name of the resident or patient, the prescription number or other means utilized for readily retrieving the medication order, the directions for use, and the prescriber's name.[7]

Any institution desiring to operate an institutional pharmacy must apply to the Department of Health ("department"). If the board of pharmacy certifies that the application complies with the laws of the state and the rules of the board, then the department will issue an institutional pharmacy permit.[8]

There are three types of institutional pharmacies:

- "Class I institutional pharmacies" – references nursing homes licensed under part II of chapter 400, F.S., all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are ***not*** dispensed on the premises but are dispensed by an entity permitted as a community pharmacy.[9] *No medicinal drugs may be dispensed in a Class I institutional pharmacy*.[10] Currently, there are 720 Class I Institutional pharmacy permit holders.[11]

- "Class II institutional pharmacies" – references hospitals that employ the services of a registered pharmacist or pharmacists who, in practicing in the institutional pharmacy, provide dispensing and consulting services on the premises to patients, for use on the premises of that hospital.[12] However, a single dose of a medicinal drug may be obtained and administered to a patient on a valid physician's drug order under the supervision of a physician or charge nurse, consistent with good institutional practice procedures. The obtaining and administering of such single dose of a medicinal drug shall be pursuant to drug-handling procedures established by a consultant pharmacist. Medicinal drugs *may* be dispensed in a Class II institutional pharmacy.[13]

- "Modified Class II institutional pharmacies" – refers to institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.[14]

Currently, there are 1,386 Class II and Modified Class II institutional pharmacy permit holders.[15] In a Class II institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs and proprietary preparations that may be dispensed by the pharmacists employed in such institution.

Consultant Pharmacist

A consultant pharmacist is a licensed pharmacist who has successfully passed a twelve hour consultant pharmacy course sponsored by an accredited college of pharmacy; and completed at least 40 hours of training and evaluation under the supervision of a preceptor that includes on-site training at

[7] Rule 64B16-28.108, F.A.C.
[8] Section 465.019(1), F.S.
[9] However, nursing homes may purchase medical oxygen for administration to residents.
[10] Section 465.019(2)(a), F.S.
[11] Email dated March 19, 2009, from the Executive Director of Florida Board of Pharmacy is on file with the Health Care Regulation Policy Committee staff.
[12] However, an institutional pharmacy located in an area or county included in an emergency order or proclamation of a state of emergency declared by the Governor may provide dispensing and consulting services to individuals who are not patients of the institution.
[13] Section 465.019(2)(b), F.S.
[14] Section 465.019(2)(c), F.S.
[15] Email dated March 19, 2009, from the Executive Director of Florida Board of Pharmacy is on file with the Health Care Regulation Policy Committee staff.

an institution that holds a pharmacy permit.[16] Currently, there are 2,277 consultant pharmacists licensed in the state.[17]

After initial licensure a consultant pharmacist's license may be renewed biennially upon completing twenty-four hours of board approved continuing education. The twenty-four hours required for recertification as a consultant pharmacist may not be used toward the thirty hours of continued professional pharmaceutical education credits required for licensure renewal as a licensed pharmacist.[18]

Each facility holding a Class I, a Class II, or a Modified Class II institutional permit must designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Florida Board of Pharmacy must be notified in writing within 10 days of any change in the consultant pharmacist of record. The consultant pharmacist of record for a Class I, or Modified Class II permit shall conduct drug regimen reviews as required by federal or state law, inspect the facility and prepare a written report to be filed at the permitted facility *at least monthly*. In addition, the consultant pharmacist of record must monthly monitor the records of the facility system that administers medication and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review.[19]

The consultant pharmacist is responsible for maintaining all drug records required by law and for establishing drug handling procedures for the safe handling and storage of drugs. The consultant pharmacist may also be responsible for ordering and evaluating any laboratory or clinical testing when, in the judgment of the consultant pharmacist, such activity is necessary for the proper performance of the consultant pharmacist's responsibilities. Such laboratory or clinical testing may be ordered only with regard to patients residing in a nursing home facility, and then only when authorized by the medical director of the nursing home facility. The consultant pharmacist must complete additional training[20] and demonstrate such additional qualifications in the practice of institutional pharmacy in addition to licensure as a registered pharmacist.[21]

Institutional Formulary System

"Institutional formulary system" is a method whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II institutional pharmacy.[22]

A facility with a Class II or Modified Class II institutional permit that operates under the formulary system must establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists for the utilization of a hospital formulary system, which formulary shall be approved by the medical staff.[23]

The Guiding Principles on the Operation of the Hospital Formulary System or "joint standards" provide the following principles:[24]

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[16] Rule 64B16-26.300, F.A.C.
[17] Email dated March 19, 2009, from the Executive Director of Florida Board of Pharmacy is on file with the Health Care Regulation Policy Committee staff.
[18] Rule 64B16-26.300, F.A.C.
[19] Rule 64B16-28.501, F.A.C.
[20] The course must be at least three (3) hours in duration for initial certification and at least one (1) hour for recertification to order and evaluate laboratory tests.
[21] Section 465.0125(1) and (2), F.S., and 64B16-26.320, F.A.C.
[22] Section 465.003(7), F.S.
[23] Section 465.019(6), F.S.
[24] American Hospital Association, Statement of Guiding Principles on the Operation of Hospital Formularies. *American Journal of Hospital Pharmacy*, 1960. 17:609-10.

1. The medical staff should appoint a Pharmacy and Therapeutics Committee ("P & T Committee") composed of physicians and the pharmacist and outline its purposes, organization, function and scope.

2. The formulary system is a creation of the medical staff based upon the recommendations of the P & T Committee. The medical staff should adopt the principles of the formulary system to the needs of the particular hospital.

3. The medical staff should adopt the written policies and procedures as developed by the P & T Committee. Action of the medical staff is subject to the normal process of administrative approval.

4. The medical staff should adopt the policy and formulate the procedure for including drugs in the formulary and dispensing of the drugs by their non-proprietary names, even though the brand name drugs are in common use in the hospital. The writing of prescriptions and medication orders by their non-proprietary names is preferred, but not required as a universal practice.

5. The institution of a hospital formulary system may be accomplished several different ways, but the consent of each person who is authorized to write a prescription or medication order, be obtained in writing so that the hospital may prove consent.

6. A hospital should make certain that its nursing personnel are informed in writing (through its established means of communication) about the existence of the formulary system in the hospital and the procedures governing its operation.

7. In the formulation of policies and procedures, the terms "substitute" and "substitution" should be avoided, since these terms have been used to imply the *unauthorized* dispensing of a brand different from that prescribed or the dispensing of an entirely different drug, neither of which takes place under a properly operated formulary system.

8. Provision should be made to apprise the medical staff of changes in the working of the formulary system or in the content of the hospital formulary.

9. Provision should be made for the appraisal and use by members of the medical staff of drugs not included in the formulary and of investigational drugs.

10. The pharmacist, with guidance from the P & T Committee should be responsible for specifications as to quality, quantity, and source of supply of all drugs, chemicals, biological, and source of supply of all drugs, chemicals, biological, and pharmaceutical preparations used in the diagnosis and treatment of patients and to ensure that quality is not compromised for economic situations. The products must meet the National Formulary, New and Non-official Drugs, Accepted Dental Remedies, or other accepted national standards.

11. The labeling of a medication container with the non-proprietary name of the contents is always proper. The use of a brand name other than describing the actual content is improper if it is used in a manner that can be taken as descriptive of the contents, even though personnel familiar with the formulary system may understand that it is not descriptive. The following format is recommended:

(Non-proprietary Name)
Note for information of staff:
Prescription or order for

(Proprietary Name)
Filled as per formulary policy;
contents are same basic drug as prescribed

but may be of another brand.

12. In the absence of written policies approved by the medical staff relative to the operation of the formulary system, the pharmacist must dispense the brand prescribed, bearing in mind his professional prerogative to confer with the physician should the prescribed brand be unavailable Also, where a formulary system has been adopted, *provision should be made for the exercise of a physician's professional prerogative in those cases where he believes a specific brand of a drug is important to the cure of his patient, and so designates in a manner approved by the medical staff* (other than writing the brand name alone).

American Hospital Association, Statement of Guiding Principles on the Operation of Hospital Formularies (emphasis added).[25] A formulary, based upon these guiding principles, is considered to be essential in the promotion of a rational drug therapy program in hospitals. In the interest of better patient care, its adoption by hospital medical staff is recommended by the American Hospital Association and American Society of Hospital Pharmacists.

Standard Reference Compendium

In a variety of legislative contexts for Medicare and Medicaid, Congress and the Centers for Medicare and Medicaid Services ("CMS") have strongly endorsed the value of recognized medical compendia for ascertaining the medical appropriateness of off-label uses of cancer drugs. "Compendia" are comprehensive listings of FDA-approved drugs and biologicals or comprehensive listings of a specific subset of drugs and biologicals in a specialty compendium, for example a compendium of anti-cancer treatment.[26] A compendium includes a summary of how each drug works in the body, as well as information for health care practitioners about proper dosing and whether the drug is recommended or endorsed for use in treating a specific disease.[27]

The Social Security Act and the Medicare and Medicaid regulations specify that Medicare carriers and state Medicaid programs must provide reimbursement for drugs used for off-label cancer indications when they are recognized as safe and effective by either the FDA, any of the recognized compendia, or in peer-reviewed literature.[28] Medicare local contractors, which process and pay Medicare claims and approve coverage for drugs under Medicare Part B, use compendia as one of several tools to determine whether an anti-cancer drug may be covered under Medicare Part B.[29] CMS also recognizes compendia for determination of covered drugs under Medicare Part D.

The approved compendia change over time. The current CMS approved national compendia are: the American Hospital Formulary Service-Drug Information (AFHS-DI), the NCCN Drugs & Biologics Compendium, Thomson Micromedex DrugDex, and Elsevier Gold Standard's Clinical Pharmacology.[30]

In Florida, the compendia are used to regulate health insurers. Section 627.4239(2), F.S., provides that an insurer may not exclude coverage for the treatment of cancer for any drug prescribed for the treatment of cancer on the ground that the drug is not approved by the U.S. Food and Drug Administration for a particular indication, if that drug is recognized for treatment of that indication in a standard reference compendium or recommended in the medical literature. Section 627.4239 expressly lists those compendia: United States Pharmacopeia Drug Information; American Medical

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[25] American Journal of Hospital Pharmacy, 1960. 17:609-10.
[26] Section 414.930 of the Federal Register, Vol. 72, No. 227. (November 27, 2007).
[27] *Id.*
[28] Centers for Medicare and Medicaid Services. Press Releases: *Medicare adds third recognized source to help determine coverage for anti-cancer chemotherapy drugs*. (July 2, 2008) http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3186&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date (last viewed March 21, 2009).
[29] *Id.*
[30] Centers for Medicare and Medicaid Services. The Social Security Act, Section 1861(t)(2)(B)(ii)(I). (January 2009). http://www.cms.hhs.gov/CoverageGenInfo/02_compendia.asp (last viewed March 20, 2009).

Association Drug Evaluation; and American Hospital Formulary Service Drug Information.[31] However, that section of Florida law has not been updated since CMS updated its compendia list. Of these three compendia, only one is still being published: the American Hospital Formulary Service Drug Information.[32] Similarly, three compendia recognized by CMS are not listed in section 627.4239: the NCCN Drugs & Biologics Compendium, Thomson Micromedex DrugDex, and Elsevier Gold Standard's Clinical Pharmacology.

Written Prescriptions

Section 456.42, F.S., requires that a written prescription for a medicinal drug issued by a licensed health care practitioner must be legibly printed or typed and must contain:

- the name of the prescribing practitioner;
- the name and strength of the drug prescribed;
- the quantity of the drug prescribed in both textual and numerical formats;
- the directions for use of the drug;
- the date with the month written out in textual letters; and
- a signature of the prescribing practitioner on the day when issued.

Section 893.04, F.S., provides that a pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances upon receiving a written or oral prescription from a licensed health care practitioner. If controlled substances listed in Schedule II are being dispensed a pharmacist may only dispense upon receipt of a written prescription by a licensed health care practitioner.[33] In addition a pharmacist may not dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV to any patient or a patient's agent without first determining, in the exercise of her of his professional judgment, that the prescription order is valid.[34]

Effects of the Bill

The bill authorizes nursing homes to create a method whereby medical staff may evaluate and select medicinal drugs that are most useful in providing care to patients. This change is accomplished primarily by adding Class I institutional pharmacies (i.e., nursing homes) to a section of law that authorizes Class II institutional pharmacies to adopt an institutional formulary system in which medicinal drugs may be dispensed by a practicing pharmacist. The bill also amends the definition of "institutional formulary system" to include Class I institutional pharmacies.

The bill requires nursing homes (Class I institutional pharmacies) to establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists for the utilization of a hospital formulary system, which formulary shall be approved by the medical staff. In addition, the bill sets additional criteria for Class I institutional pharmacies. Nursing homes must establish policies and procedures for their institutional formularies, which must:

- Be approved by the medical staff;
- Provide methods and criteria to select and evaluate drugs for the formulary;
- Provide for development, maintenance, approval, and dissemination of the formulary;
- Provide for continuous review of the formulary;
- Provide for regular monitoring of compliance with the policies and procedures, and of clinical outcomes;

[31] Section 627.4239(1)(b), F.S.
[32] Centers for Medicare and Medicaid Services. Press Releases: *Medicare adds third recognized source to help determine coverage for anti-cancer* chemotherapy drugs. (July 2, 2008) http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3186&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date (last viewed March 21, 2009).
[33] Section 893.04(1)(f), F.S.
[34] Section 893.04(2)(a), F.S.

- Provide a mechanism to obtain the prescriber's consent before dispensing and substitution of drugs using a method of communication designated by the prescriber and denoting the communication method in the patient's chart;
- Establish a process for prescribers to opt out of the formulary entirely;
- Establish a process for prescribers to opt out of the formulary for any particular patient;
- Establish a mechanism for informing the patient or guardian of a substitution;
- Provide that practitioners are not penalized for prescribing medically necessary non-formulary drugs; and
- Be consistent with applicable state and federal laws and rules.

The bill amends the definition of "standard reference compendium" to remove the names of specific organizations and defer to a compendium identified and recognized by the Secretary of the United States Department of Health and Human Services and the Centers for Medicare and Medicaid Services, respectively.

The bill deletes the requirement that written prescriptions for *medicinal drugs* include the quantity prescribed to be spelled out and numerically indicated; instead the quantity may be either spelled out in text format or as a number. Additionally, if a pharmacist is not able to verify the prescription they may insist that the person to whom the controlled substance is intended provide a valid photo ID. The bill clarifies that written prescriptions for *controlled substances* require the quantity or date to be in text and numerical format. If a prescription for a controlled substance does not contain the quantity or date in both formats and the pharmacist is unable to verify the prescription with the prescriber, a pharmacist may dispense without verification, if the pharmacy has dispensed another prescription for the same person.

B. SECTION DIRECTORY:

Section 1. Amends 456.42, F.S., relating to written prescriptions for medicinal drugs.

Section 2. Amends s. 465.003, F.S., relating to definitions for pharmacy.

Section 3. Amends s. 465.019, F.S., relating to institutional pharmacy permits.

Section 4. Amends s. 627.4239, F.S., relating to the coverage for use of drugs in treatment of cancer.

Section 5. Amends s. 893.04, F.S., relating to the pharmacist and practitioner.

Section 6. Provides that the bill takes effect July 1, 2009.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None identified.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to: require counties or municipalities to spend funds or take an action requiring the expenditure of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of a state tax sharing with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 18, 2009, the Health Care Regulation Policy Committee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The amendment removes all the language of the original bill house bill and inserts language adding Class I institutional pharmacies to the definition of institutional formulary system and institutional pharmacy permits. In addition, the amendment amended language pertaining to the definition of standard reference compendium.

On March 25, 2009, the Health and Families Policy Council adopted a strike-all amendment and reported the bill favorably as a council substitute. The amendment includes all the language of the prior committee substitute, and creates additional requirements for Class I institutional pharmacies. The amendment requires nursing homes to establish policies and procedures for their institutional formularies to address prescriber notification, formulary information dissemination, outcome monitoring, and opt out provisions, among other things.

On April 13, 2009, the Health Care Appropriations Committee adopted 4 amendments and reported the bill favorably as a committee substitute. The amendments:

- **Amendment 1** - Corrects a statutory conflict related to Class I institutional pharmacies not being able to dispense medicinal drugs and makes the statutory change consistent with the Senate companion.
- **Amendment 2** - Requires that the prescriber be informed prior to any substitution of drugs pursuant to a Class II institutional formulary by using a method of communication designated by the prescriber and noted in the patient's chart. This amendment was superseded by Amendment 4.
- **Amendment 3** -Deletes provision that requires written prescriptions for medicinal drugs include the quantity prescribed to be spelled out and numerically indicated, instead the quantity may be spelled out in text format or as a number. The amendment also clarifies that the quantity and date on prescriptions for controlled substances must be written out textually and numerically**.** Additionally, if a pharmacist is not able to verify the prescription they may insist that the person to whom the controlled substance is intended provide a valid photo ID. Finally, a pharmacist may dispense a controlled substance without verification by the prescriber to a person if a written prescription contains the quantity and date to either

be written out textually or numerically and not both, if the pharmacy has previously dispensed another prescription for the same person.

- **Amendment 4** – Requires a Class II institutional pharmacy to obtain the prescriber's consent prior to any substitution of drugs by using a method of communication designated by the prescriber and noted in the patient's chart. Amendment 4 supersedes Amendment 2.

The analysis is drafted to the committee substitute.