

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1241 Ordering of Medication

SPONSOR(S): Plasencia

TIED BILLS: **IDEN./SIM. BILLS:** SB 152

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	13 Y, 0 N	Siples	Poche
2) Health & Human Services Committee	15 Y, 0 N	Siples	Calamas

SUMMARY ANALYSIS

Florida law authorizes a supervising physician to delegate to a physician assistant (PA), the authority to order medicinal drugs for the physician's patient who is in a hospital, ambulatory surgical center, or mobile surgical facility. However, there is no authority under Florida law for a physician to delegate an equivalent authority to an advanced registered nurse practitioner (ARNP).

The bill expressly authorizes an ARNP to order any medication for administration to a patient in a hospital, ambulatory surgical center, mobile surgical center, or nursing home, within the framework of an established protocol. The bill expands the current ability of a physician to delegate authority to a PA to order medicinal drugs, to allow a PA to order medicinal drugs for a patient in a nursing home.

The bill amends the Florida Comprehensive Drug Abuse Prevention and Control Act to expressly provide that a licensed practitioner may authorize a licensed PA or ARNP, who he or she supervises, to order controlled substances for administration to a patient in a hospital, ambulatory surgical center, mobile surgical facility, or nursing home.

The bill amends the definition of "prescription" to clarify that an order for the administration of a drug is not included in its definition.

The bill may have an indeterminate, negative fiscal impact on the Department of Health and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Physician Assistants

Licensure and Regulation

Physician assistant (PA) licensure in Florida is governed by ss. 458.347(7) and 459.022(7), F.S. The Department of Health (DOH) licenses PAs and the Florida Council on Physician Assistants (Council) regulates them.¹ PAs are also regulated by either the Florida Board of Medicine for PAs licensed under ch. 458, F.S., or the Florida Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S. The duty of a board and its members is to make disciplinary decisions concerning whether a doctor or PA has violated the provisions of his or her practice act.² There are 7,987 PAs who hold active licenses in Florida.³

To be licensed as a PA in Florida, an applicant must demonstrate to the Council:

- Satisfactory passage of National Commission on Certification of Physician Assistants exam;
- Completion of an application and remittance of the applicable fees;⁴
- Completion of an approved PA training program;
- A sworn statement of any prior felony convictions;
- A sworn statement of any previous revocation or denial of licensure in any state;
- Two letters of recommendation; and
- If the applicant is seeking prescribing authority, a copy of course transcripts and the course description from a PA training program describing the course content in pharmacotherapy.⁵

Licenses are renewed biennially.⁶ At the time of renewal, a PA must demonstrate that he or she has met the continuing medical education requirements and must submit a sworn statement that he or she has not been convicted of any felony in the previous two years.⁷ If a PA is licensed as a prescribing PA, an additional 10 hours of continuing medical education in the specialty areas of his or her supervising physician must be completed.⁸

Supervision of PAs

A PA may only practice under the direct or indirect supervision of a medical doctor or doctor of osteopathic medicine with whom they have a clinical relationship.⁹ A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.¹⁰

¹ The Council consists of three physicians who are members of the Board of Medicine; one member who is a member of the Board of Osteopathic Medicine, and a physician assistant appointed by the State Surgeon General. (Sections 458.347(9) and 459.022(8), F.S.)

² Sections 458.347(12) and 459.022(12), F.S.

³ Email correspondence with the Department of Health, Medical Quality Assurance staff on November 9, 2015. The number of active licensed PAs include both in-state and out-of-state licensees, as of November 9, 2015.

⁴ The application fee is \$100 and the initial license fee is \$200. Applicants must also pay an unlicensed activity fee of \$5. See Rules 64B8-30.019 and 64B15-6.013, F.A.C.

⁵ Sections 458.347(7) and 459.022(7), F.S.

⁶ For timely renewed licenses, the renewal fee is \$275 and the prescribing registration fee is \$150. Additionally, at the time of renewal, the PA must pay an unlicensed activity fee of \$5. See Rules 64B8-30.019 and 64B15-6.013, F.A.C.

⁷ Sections 458.347(7)(c)-(d) and 459.022(7)(c)-(d), F.S.

⁸ Rules 64B8-30.005(6) and 64B15-6.0035(6), F.A.C.

⁹ Sections 458.347(2)(f) and 459.022(2)(f), F.S., define supervision as responsible supervision and control which requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.

¹⁰ Rules 64B8-30.012 and 64B15-6.010, F.A.C.

The supervising physician is responsible and liable for any and all acts of the PA and may not supervise more than four PAs at any time.¹¹

The Board of Medicine and the Osteopathic Board have prescribed by rule what constitutes adequate responsible supervision. Responsible supervision is the ability of a supervising physician to reasonably exercise control and provide direction over the services or tasks performed by the PA.¹² Whether the supervision of the PA is adequate is dependent on the:

- Complexity of the task;
- Risk to the patient;
- Background, training, and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.¹³

The decision to permit a PA to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.¹⁴ Direct supervision refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed.¹⁵ Indirect supervision refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication.¹⁶

Delegable Tasks

Rules of both the Board of Medicine and the Osteopathic Board place limitations on a supervising physician's ability to delegate certain tasks. Prescribing, dispensing, or compounding medicinal drugs and making a final diagnosis are not permitted to be delegated to a PA, except when specifically authorized by statute.¹⁷

A supervising physician may delegate to a PA the authority to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice, except controlled substances, general anesthetics, and radiographic contrast materials;¹⁸
- Order medicinal drugs for a hospitalized patient of the supervising physician;¹⁹ and
- Administer a medicinal drug under the direction and supervision of the physician.

Advanced Registered Nurse Practitioners

Licensure and Regulation

Part I of ch. 464, F.S., governs the licensure and regulation of advanced registered nurse practitioners (ARNPs) in Florida. Nurses are licensed by the DOH and are regulated by the Board of Nursing.²⁰ There are 22,003 actively licensed ARNPs in Florida.²¹

¹¹ Sections 458.347(3) and 459.022(3), F.S.

¹² Rules 64B8-30.001(3) and 64B15-6.001(3), F.A.C.

¹³ Id.

¹⁴ Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.

¹⁵ Rules 64B8-30.001(4) and 64B15-6.001(4), F.A.C.

¹⁶ Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.

¹⁷ *Supra* note 12.

¹⁸ Sections 458.347(4)(f)1., F.S., and 459.022(4)(e), F.S., direct the Council to establish a formulary listing of the medicinal drugs that a PA may not prescribe. The formulary in Rules 64B8-30.008 and 64B15-6.0038, F.A.C., prohibits PAs from prescribing controlled substances, as defined in Chapter 893, F.S., general, spinal, or epidural anesthetics, and radiographic contrast materials.

¹⁹ Sections 458.347(4)(g), and 459.022(4)(f), F.S., provides that an order is not a prescription.

²⁰ Pursuant to s. 464.004, F.S., the Board of Nursing is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve 4-year terms. The Board is comprised of three licensed practical nurses who have practiced for at least four years;

In Florida, an ARNP is a licensed nurse who is certified in advanced or specialized nursing practice and may practice as a certified registered nurse anesthetist, a certified nurse midwife, or a nurse practitioner.²² Section 464.003(2), F.S., defines “advanced or specialized nursing practice” to include the performance of advanced-level nursing acts approved by the Board of Nursing, which by virtue of postbasic specialized education, training, and experience are appropriately performed by an ARNP.²³

Florida recognizes three types of ARNPs: nurse anesthetist, certified nurse midwife, and nurse practitioner. The Board of Nursing, created by s. 464.004, F.S., establishes the eligibility criteria for an applicant to be certified as an ARNP and the applicable regulatory standards for ARNP nursing practices.²⁴ To be certified as an ARNP, the applicant must:

- Have a registered nurse license;
- Have earned, at least, a master’s degree; and
- Submit proof to the Board of Nursing of holding a current national advanced practice certification obtained from a board-approved nursing specialty board.²⁵

All ARNPs must carry malpractice insurance or demonstrate proof of financial responsibility.²⁶ An applicant for certification is required to submit proof of coverage or financial responsibility within sixty days of certification and with each biennial renewal.²⁷ An ARNP must have professional liability coverage of at least \$100,000 per claim with a minimum annual aggregate of at least \$300,000, or an unexpired irrevocable letter of credit, which is payable to the ARNP as the beneficiary, in the amount of at least \$100,000 per claim with a minimum aggregate availability of at least \$300,000.²⁸

Supervision of ARNPs

Pursuant to s. 464.012(3), F.S., ARNPs may only perform nursing practices delineated in an established protocol filed with the Board of Nursing that is filed within 30 days of entering into a supervisory relationship with a physician and upon biennial license renewal.²⁹ Florida law allows a primary care physician to supervise ARNPs in up to four offices, in addition to the physician’s primary practice location.³⁰ If the physician provides specialty health care services, then only two medical offices, in addition to the physician’s primary practice location, may be supervised.

The supervision limitations do not apply in the following facilities:

- Hospitals;
- Colleges of medicine or nursing;
- Nonprofit family-planning clinics;
- Rural and federally qualified health centers;
- Nursing homes;

three Florida residents who have never been licensed as nurses, are not connected to the practice of nursing, and have no financial interest in any health care facility, agency, or insurer; and seven members who are registered nurses who have practiced at least four years. Among the seven members who are registered nurses, there must be at least one ARNP, one nurse educator of an approved program, and one nurse executive.

²¹ E-mail correspondence with the Department of Health (Nov. 9, 2015) (on file with committee staff). This number includes all active licenses, including out of state practitioners.

²² Section 464.003(3), F.S.

²³ Section 464.003(2), F.S.

²⁴ Section 464.012(2), F.S.

²⁵ Section 464.012(1), F.S., and Rule 64B9-4.002, F.A.C. A nursing specialty board must attest to the competency of nurses in a clinical specialty area, require nurses to take a written examination prior to certification, require nurses to complete a formal program prior to eligibility of examination, maintain program accreditation, and identify standards or scope of practice statements appropriate for each nursing specialty.

²⁶ Section 456.048, F.S.

²⁷ Rule 64B9-4.002(5), F.A.C.

²⁸ Id.

²⁹ Physicians are also required to provide notice of the written protocol and the supervisory relationship to the Board of Medicine or Board of Osteopathic Medicine, respectively. See ss. 458.348 and 459.025, F.S.

³⁰ Sections 458.348(4) and 459.025(3), F.S.

- Assisted living facilities;
- Student health care centers or school health clinics; and
- Other government facilities.³¹

To ensure appropriate medical care, the number of ARNPs a physician may supervise is limited based on consideration of the following factors:

- Risk to the patient;
- Educational preparation, specialty, and experience in relation to the supervising physician's protocol;
- Complexity and risk of the procedures;
- Practice setting; and
- Availability of the supervising physician or dentist.³²

Delegable Tasks

Within the framework of a written physician protocol, an ARNP may:

- Monitor and alter drug therapies;
- Initiate appropriate therapies for certain conditions;
- Order diagnostic tests and physical and occupational therapy;
- Perform certain acts within his or her specialty;
- Perform medical acts authorized by a joint committee; and
- Perform additional functions determined by rule.³³

Florida law does not authorize ARNPs to prescribe, independently administer, or dispense controlled substances.³⁴ Certified registered nurse anesthetists are permitted to order certain controlled substances "to the extent authorized by an established protocol approved by the medical staff of the facility in which the anesthetic service is performed."³⁵

ARNP Petition for Declaratory Statement

On January 22, 2014, a petition for declaratory statement³⁶ was filed with the Board of Nursing that asked, in substance, whether an ARNP can legally order narcotics for patients treated within an institution with written protocols from an attending physician.³⁷ The petition noted that prior to January 2014, ARNPs ordered controlled substances for patients.³⁸ Effective January 2014, the hospital disallowed the practice and required all ARNPs to get an order from a physician. The hospital cited passage of legislation in 2013,³⁹ which clarified the authority of PAs to order controlled substances for patients in institutions, but did not address the authority of ARNPs.⁴⁰ The Board of Nursing dismissed the petition, finding that it failed to comply with the requirements of Chapter 120, F.S., and that it sought an opinion regarding the scope of practice of a category of licensees based on an employer's policies.⁴¹

³¹ Sections 458.348(4)(e), and 459.025(3)(e), F.S.

³² Rule 64B9-4.010, F.A.C.

³³ Section 464.012(3), F.S. Pursuant to s. 464.012(4), F.S., certified registered nurse anesthetists, certified nurse midwives, and certified nurse practitioners are authorized to perform additional acts that are within their specialty and authorized under an established supervisory protocol.

³⁴ Sections 893.02(21) and 893.05(1), F.S. The definition of practitioner does not include ARNPs.

³⁵ Section 464.012(4), F.S.

³⁶ Pursuant to s. 120.565(1), F.S., a declaratory statement is an agency's opinion regarding the applicability of a statutory provision, rule, or agency order to a petitioner's set of circumstances.

³⁷ *In Re: Petition for Declaratory Statement of Carolann Robley, ARNP*, 40 Fla. Admin. Reg. 81 (Apr. 25, 2014).

³⁸ For a copy of the petition for declaratory statement and the final order disposing of the petition, please see http://www.floridahealth.gov/licensing-and-regulation/declaratory_documents/nursing/DOH-14-0732-DS-MQA.pdf#page=1&zoom=auto,-10,795 (last visited January 30, 2016).

³⁹ See ch. 2013-127, Laws of Fla.

⁴⁰ *Supra*, note 37.

⁴¹ *In Re: Petition for Declaratory Statement of Carolann Robley, ARNP*, 40 Fla. Admin. Reg. 103 (May 28, 2014).

Florida Comprehensive Drug Abuse Prevention and Control Act

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act (Act) and classifies controlled substances into five categories, known as schedules.⁴² The distinguishing factors between the different drug schedules are the “potential for abuse” of the substance and whether there is a currently accepted medical use for the substance. Schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances. The Act provides requirements for the prescribing and administering of controlled substances by health care practitioners and proper dispensing by pharmacists and health care practitioners.⁴³

Drug Enforcement Administration

The Drug Enforcement Administration (DEA), housed within the U.S. Department of Justice, enforces the controlled substances laws and regulations of the United States, including preventing and investigating the diversion of controlled pharmaceuticals.⁴⁴

A health care professional wishing to prescribe controlled substances must apply for a registration number from the DEA. Registration numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee.⁴⁵ The DEA will grant registration numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only engage in those activities authorized under state law for the jurisdiction in which their practice is located.⁴⁶

The DEA exempts certain agents and employees from registration with the agency, including an individual practitioner⁴⁷ who is an agent or an employee of a hospital or other institution. Such practitioner may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or institution, provided that:

- Such dispensing, administering, or prescribing is done in the usual course of his or her professional practice;
- Such practitioner is authorized to do so by the jurisdiction in which he or she is practicing;
- The hospital or institution employing the practitioner has verified that the practitioner is authorized to dispense, administer, or prescribe drugs within the jurisdiction;
- Such individual is acting only within the scope of his or her employment in the hospital or institution;
- The hospital or institution authorizes the practitioner to administer, dispense, or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized; and
- The hospital or institution maintains a current list of internal codes and the corresponding individual practitioners that is available at all times to other registrants and law enforcement agencies for the purpose of verifying the prescribing authority of the individual practitioners.⁴⁸

An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner)⁴⁹ registered to dispense controlled substances may, when acting in the normal course of

⁴² See s. 893.03, F.S.

⁴³ Sections 893.04 and 893.05, F.S.

⁴⁴ Drug Enforcement Administration, *About Us*, available at <http://www.deadiversion.usdoj.gov/Inside.html> (last visited January 30, 2016).

⁴⁵ Registration numbers must be renewed every three years. Drug Enforcement Administration, *Practitioners Manual*, 7(2006), available at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf (last visited January 30, 2016).

⁴⁶ Id.

⁴⁷ An individual practitioner is defined as a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States of the jurisdiction in which he or she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner. (21 C.F.R. s. 1300.01(b)).

⁴⁸ 21 C.F.R. s. 1301.22(c).

⁴⁹ Examples of mid-level practitioners include nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants.

business or employment, administer or dispense (other than by issuance of a prescription)⁵⁰ controlled substances if and to the extent authorized by state law, under the registration of the employer or principal practitioner in lieu of being registered himself or herself.⁵¹

Effect of Proposed Changes

Currently, a PA may order any medication for administration to a patient of his or her supervising physician in a hospital, ambulatory surgical center, or mobile surgical facility. The bill adds authority for a PA to order medication for administration in a nursing home.

The bill authorizes an ARNP to order any medication, including a controlled substance, for administration to a patient, within the framework of an established protocol, in a facility licensed under ch. 395, F.S. (a hospital, ambulatory surgical center, or mobile surgical facility), or part II of ch. 400, F.S. (a nursing home).

The bill amends the Florida Comprehensive Drug Abuse Prevention and Control Act to expressly provide that a licensed practitioner may authorize a licensed PA or ARNP, who he or she supervises, to order controlled substances for administration to a patient in a hospital, ambulatory surgical center, mobile surgical facility, or nursing home.

The bill amends the definition of “prescription” to exclude an order for medication that is dispensed for administration by an authorized, licensed practitioner, and makes conforming changes that clarify the difference between a prescription and an order for administration. The bill also amends the definition of “administer” to include the term “administration.”

The bill reenacts several sections of Florida law for the purpose of incorporating amendments made by the bill.

The bill provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1. Amends s. 458.347, F.S., relating to physician assistants.

Section 2. Amends s. 459.022, F.S., relating to physician assistants.

Section 3. Amends s. 464.012, F.S., relating to certification of advanced registered nurse practitioners; fees.

Section 4. Amends s. 465.003, F.S., relating to definitions.

Section 5. Amends s. 893.02, F.S., relating to definitions.

Section 6. Amends s. 893.04, F.S., relating to pharmacist and practitioner.

Section 7. Amends s. 893.05, F.S., relating to practitioners and persons administering controlled substances in their absence.

Section 8. Reenacts s. 400.462, F.S., relating to definitions.

Section 9. Reenacts s. 409.906, F.S., relating to optional Medicaid services.

Section 10. Reenacts s. 401.445, F.S., relating to emergency examination and treatment of incapacitated persons.

Section 11. Reenacts s. 766.103, F.S., relating to the Florida Medical Consent Law.

Section 12. Reenacts s. 409.9201, F.S., relating to Medicaid fraud.

Section 13. Reenacts s. 465.014, F.S., relating to pharmacy technician.

Section 14. Reenacts s. 465.1901, F.S., relating to the practice of orthotics and pedorthics.

Section 15. Reenacts s. 499.003, F.S., relating to definitions of terms used in this part.

Section 16. Reenacts s. 831.30, F.S., relating to medicinal drugs; fraud in obtaining.

Section 17. Reenacts s. 458.331, F.S., relating to grounds for disciplinary action; action by the board and department.

⁵⁰ The DEA defines “prescription” as an order for medication which is dispensed to or for an ultimate user, but is not an order for a medication dispensed for immediate administration to the user, such as an order to dispense a drug to a patient in a hospital setting. See 21 C.F.R. s. 1300.01(b).

⁵¹ 21 C.F.R. s. 1301.22(b).

- Section 18.** Reenacts s. 459.015, F.S., relating to grounds for disciplinary action; action by the board and department.
- Section 19.** Reenacts s. 465.015, F.S., relating to violations and penalties.
- Section 20.** Reenacts s. 465.016, F.S., relating to disciplinary actions.
- Section 21.** Reenacts s. 465.022, F.S., relating to pharmacies; general requirements; fees.
- Section 22.** Reenacts s. 465.023, F.S., relating to pharmacy permittee; disciplinary action.
- Section 23.** Reenacts s. 112.0455, F.S., relating to the Drug-Free Workplace Act.
- Section 24.** Reenacts s. 381.986, F.S., relating to the compassionate use of low-THC cannabis.
- Section 25.** Reenacts s. 440.102, F.S., relating to drug-free workplace requirements.
- Section 26.** Reenacts s. 499.0121, F.S., relating to storage and handling of prescription drugs; recordkeeping.
- Section 27.** Reenacts s. 768.36, F.S., relating to alcohol or drug defense.
- Section 28.** Reenacts s. 810.02, F.S., relating to burglary.
- Section 29.** Reenacts s. 812.014, F.S., relating to theft.
- Section 30.** Reenacts s. 856.015, F.S., relating to open house parties.
- Section 31.** Reenacts s. 944.47, F.S., relating to introduction, removal, or possession of certain articles unlawful; penalty.
- Section 32.** Reenacts s. 951.22, F.S., relating to county detention facilities; contraband articles.
- Section 33.** Reenacts s. 985.711, F.S., relating to introduction, removal, or possession of certain articles unlawful; penalty.
- Section 34.** Reenacts s. 1003.57, F.S., relating to exceptional students instruction.
- Section 35.** Reenacts s. 1006.09, F.S., relating to duties of school principal relating to student discipline and school safety.
- Section 36.** Reenacts s. 893.0551, F.S., relating to public records exemption for the prescription drug monitoring program.
- Section 37.** Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill may have an indeterminate, negative fiscal impact on the DOH due to a possible increase in practitioner complaints associated with the ARNPs' and PAs' new authority to order medications for administration in new settings.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Physicians or institutions who use ARNPs or PAs to order the administration of medications for hospitalized patients or those in nursing homes may realize cost savings associated with increased efficiencies of using such practitioners. Additionally, patients may be better served by ARNPs and PAs who can order medications for administration under a supervisory protocol, without the direct involvement of the supervising physician.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The DOH has sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES