SENATE . . . . . No. 2120

Senate, May 24, 2017 -- Text of amendment (519) (offered by Senator L'Italien) to the Ways and Means amendment (Senate, No. 3) to the House Bill making appropriations for the fiscal year 2018 for the maintenance of the departments, boards, commissions, institutions and certain activities of the Commonwealth, for interest, sinking fund and serial bond requirements and for certain permanent improvements

The Commonwealth of Massachusetts

In the One Hundred and Ninetieth General Court
(2017-2018)

SECTION X. Chapter 175 of the General Laws, as appearing in the 2016 Official Edition, is hereby amended by inserting after section 47BB the following new section:-

Section 47CC. (a) As used in this section the following words shall, unless the context clearly requires otherwise, have the following meanings:-

"Clinical practice guidelines" means a systematically developed statement to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances and conditions.

"Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by a carrier or utilization review organization to determine the medical necessity and appropriateness of healthcare services.

"Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition and medically appropriate

for a particular patient and are covered as a pharmacy or medical benefit by a carrier, including self-administered and physician-administered drugs.

"Step Therapy Override Exception Determination" means a determination as to whether step therapy should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug. This determination is based on a review of the patient's and/or prescriber's request for an override, along with supporting rationale and documentation.

"Utilization review organization" means an entity that conducts utilization review, other than a health carrier performing utilization review for its own health benefit plans.

(b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or renewed within the commonwealth that provides coverage for prescription drugs and uses step-therapy protocols shall have the following requirements and restrictions.

(1) Clinical review criteria used to establish step therapy protocols shall be based on clinical practice guidelines that:

(A) That recommend drugs be taken in the specific sequence required by the step therapy protocol.

(B) Are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by:

(i) Requiring members to disclose any potential conflict of interests with entities, including insurers, health plans, and pharmaceutical manufacturers and recluse themselves of voting if they have a conflict of interest.

(ii) Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus.

(iii) Offering opportunities for public review and comments.

(C) Are based on high quality studies, research, and medical practice.

(D) Are created by an explicit and transparent process that:

(i) Minimizes biases and conflicts of interest;

(ii) Explains the relationship between treatment options and outcomes;

(iii) Rates the quality of the evidence supporting recommendations; and

(iv) Considers relevant patient subgroups and preferences.

(E) Are continually updated through a review of new evidence, research and newly developed treatments.

(2) In the absence of clinical guidelines that meet the requirements in section (1), peer reviewed publications may be substituted.

(3) When establishing a step therapy protocol, a utilization review agent shall also take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

(4) This section shall not be construed to require insurers, health plans or the state to set up a new entity to develop clinical review criteria used for step therapy protocols.

(c) When coverage of medications for the treatment of any medical condition are restricted for use by a carrier or utilization review organization via a step therapy protocol, the patient and prescribing practitioner shall have access to a clear readily accessible and convenient process to request a Step Therapy Exception Determination. A carrier or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process shall be disclosed to the patient and health care providers, including documenting and making easily accessible on the carriers' or utilization review organization's website.

(d) A step therapy override exception determination shall be expeditiously granted if:

(1) The required drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient;

(2) The required drug is expected to be ineffective based on the known relevant physical or mental characteristics of the insured and the known characteristics of the drug regimen;

(3) The enrollee has tried the step therapy-required drug while under their current or a previous health plan, or another drug in the same pharmacologic class or with the same mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(4) The patient is stable on a drug recommended by their health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan;

(5) The step therapy-required drug is not in the best interest of the patient, based on medical appropriateness.

(e) Upon the granting of a step therapy override exception determination, the carrier or utilization review organization shall authorize coverage for the drug prescribed by the enrollee's treating health care provider.

(f) The carrier or utilization review organization shall respond to step therapy override exception request or an appeal within seventy two hours of receipt. In cases where exigent circumstances exist a carrier or utilization review organization shall respond within twenty four hours of receipts. Should a response by a carrier or utilization review organization not be received within this time allotted the exception or appeal shall be deemed granted.

(g) This section shall not be construed to prevent:

(1) A carrier or utilization review organization from requiring an enrollee try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

(2) A health care provider from prescribing a drug he or she determines is medically appropriate.

SECTION XX. Chapter 176A of the General Laws, as Appearing in the 2016 Official Edition, is hereby amended by inserting after section 8EE the following new section:-

Section 8FF. (a) As used in this section the following words shall, unless the context clearly requires otherwise, have the following meanings:-

"Clinical practice guidelines" means a systematically developed statement to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances and conditions.

"Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by an insurer, health plan, or utilization review organization to determine the medical necessity and appropriateness of healthcare services.

"Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular patient and are covered as a pharmacy or medical benefit by a carrier, including self-administered and physician-administered drugs, .

"Step Therapy Override Exception Determination" means a determination as to whether step therapy should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug. This determination is based on a review of the patient's and/or prescriber's request for an override, along with supporting rationale and documentation.

"Utilization review organization" means an entity that conducts utilization review, other than a health carrier performing utilization review for its own health benefit plans.

(b) Any contract between a subscriber and the corporation under an individual or group hospital service plan which is delivered, issued or renewed within the commonwealth that provides coverage for prescription drugs and uses step-therapy protocols shall have the following requirements and restrictions.

(1) Clinical review criteria used to establish step therapy protocols shall be based on clinical practice guidelines that:

(A) That recommend drugs be taken in the specific sequence required by the step therapy protocol.

(B) Are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by:

(i) Requiring members to disclose any potential conflict of interests with entities, including insurers, health plans, and pharmaceutical manufacturers and recluse themselves of voting if they have a conflict of interest.

(ii) Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus.

(iii) Offering opportunities for public review and comments.

(C) Are based on high quality studies, research, and medical practice.

(D) Are created by an explicit and transparent process that:

(i) Minimizes biases and conflicts of interest;

(ii) Explains the relationship between treatment options and outcomes;

(iii) Rates the quality of the evidence supporting recommendations; and

(iv) Considers relevant patient subgroups and preferences.

(E) Are continually updated through a review of new evidence, research and newly developed treatments.

(2) In the absence of clinical guidelines that meet the requirements in section (1), peer reviewed publications may be substituted.

(3) When establishing a step therapy protocol, a utilization review agent shall also take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

(4) This section shall not be construed to require insurers, health plans or the state to set up a new entity to develop clinical review criteria used for step therapy protocols.

(c) When coverage of medications for the treatment of any medical condition are restricted for use by a carrier or utilization review organization via a step therapy protocol, the patient and prescribing practitioner shall have access to a clear readily accessible and convenient process to request a Step Therapy Exception Determination. A carrier or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process shall be disclosed to the patient and health care providers, including documenting and making easily accessible on the carriers' or utilization review organization's website.

(d) A step therapy override exception determination shall be expeditiously granted if:

(1) The required drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient;

(2) The required drug is expected to be ineffective based on the known relevant physical or mental characteristics of the insured and the known characteristics of the drug regimen;

(3) The enrollee has tried the step therapy-required drug while under their current or a previous health plan, or another drug in the same pharmacologic class or with the same

mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(4) The patient is stable on a drug recommended by their health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan;

(5) The step therapy-required drug is not in the best interest of the patient, based on medical appropriateness.

(e) Upon the granting of a step therapy override exception determination, the carrier or utilization review organization shall authorize coverage for the drug prescribed by the enrollee's treating health care provider.

(f) The carrier or utilization review organization shall respond to step therapy override exception request or an appeal within seventy two hours of receipt. In cases where exigent circumstances exist a carrier or utilization review organization shall respond within twenty four hours of receipts. Should a response by a carrier or utilization review organization not be received within this time allotted the exception or appeal shall be deemed granted.

(g) This section shall not be construed to prevent:

(1) A carrier or utilization review organization from requiring an enrollee try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

(2) A health care provider from prescribing a drug he or she determines is medically appropriate.

SECTION XXX. Chapter 176B of the General Laws, as appearing in the 2016 Official Edition, is hereby amended by inserting after section 4EE the following new section:-

Section 4FF. (a) As used in this section the following words shall, unless the context clearly requires otherwise, have the following meanings:-

"Clinical practice guidelines" means a systematically developed statement to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances and conditions.

"Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by an insurer, health plan, or utilization review organization to determine the medical necessity and appropriateness of healthcare services.

"Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular patient and are covered under a health benefit plan as a pharmacy or medical benefit by a carrier, including self-administered and physician-administered drugs.

"Step Therapy Override Exception Determination" means a determination as to whether step therapy should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug. This determination is based on a review of the patient's and/or prescriber's request for an override, along with supporting rationale and documentation.

"Utilization review organization" means an entity that conducts utilization review, other than a health carrier performing utilization review for its own health benefit plans.

(b) Any subscription certificate under an individual or group medical service agreement delivered, issued or renewed within the commonwealth that provides coverage for prescription drugs and uses step-therapy protocols shall have the following requirements and restrictions.

(1) Clinical review criteria used to establish step therapy protocols shall be based on clinical practice guidelines that:

(A) That recommend drugs be taken in the specific sequence required by the step therapy protocol.

(B) Are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by:

(i) Requiring members to disclose any potential conflict of interests with entities, including insurers, health plans, and pharmaceutical manufacturers and recluse themselves of voting if they have a conflict of interest.

(ii) Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus.

(iii) Offering opportunities for public review and comments.

(C) Are based on high quality studies, research, and medical practice.

(D) Are created by an explicit and transparent process that:

(i) Minimizes biases and conflicts of interest;

(ii) Explains the relationship between treatment options and outcomes;

(iii) Rates the quality of the evidence supporting recommendations; and

(iv) Considers relevant patient subgroups and preferences.

(E) Are continually updated through a review of new evidence, research and newly developed treatments.

(2) In the absence of clinical guidelines that meet the requirements in section (1), peer reviewed publications may be substituted.

(3) When establishing a step therapy protocol, a utilization review agent shall also take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

(4) This section shall not be construed to require insurers, health plans or the state to set up a new entity to develop clinical review criteria used for step therapy protocols.

(c) When coverage of medications for the treatment of any medical condition are restricted for use by a carrier or utilization review organization via a step therapy protocol, the patient and prescribing practitioner shall have access to a clear readily accessible and convenient process to request a Step Therapy Exception Determination. A carrier or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process shall be disclosed to the patient and health care providers, including documenting and making easily accessible on the carriers' or utilization review organization's website.

(d) A step therapy override exception determination shall be expeditiously granted if:

(1) The required drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient;

(2) The required drug is expected to be ineffective based on the known relevant physical or mental characteristics of the insured and the known characteristics of the drug regimen;

(3) The enrollee has tried the step therapy-required drug while under their current or a previous health plan, or another drug in the same pharmacologic class or with the same mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(4) The patient is stable on a drug recommended by their health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan;

(5) The step therapy-required drug is not in the best interest of the patient, based on medical appropriateness.

(e) Upon the granting of a step therapy override exception determination, the carrier or utilization review organization shall authorize coverage for the drug prescribed by the enrollee's treating health care provider.

(f) The carrier or utilization review organization shall respond to step therapy override exception request or an appeal within seventy two hours of receipt. In cases where exigent circumstances exist a carrier or utilization review organization shall respond within twenty four hours of receipts. Should a response by a carrier or utilization review organization not be received within this time allotted the exception or appeal shall be deemed granted.

(g) This section shall not be construed to prevent:

(1) A carrier or utilization review organization from requiring an enrollee try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

(2) A health care provider from prescribing a drug he or she determines is medically appropriate.

SECTION XXXX. Chapter 176G of the General Laws, as appearing in the 2016 Official Edition, is hereby amended by inserting after section 4W the following new section:-

Section 4X. (a) As used in this section the following words shall, unless the context clearly requires otherwise, have the following meanings:

"Clinical practice guidelines" means a systematically developed statement to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances and conditions.

"Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by an insurer, health plan, or utilization review organization to determine the medical necessity and appropriateness of healthcare services.

"Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular patient and are covered under a health benefit plan as a pharmacy or medical benefit by a carrier, including self-administered and physician-administered drugs, .

"Step Therapy Override Exception Determination" means a determination as to whether step therapy should apply in a particular situation, or whether the step therapy protocol should be

overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug. This determination is based on a review of the patient's and/or prescriber's request for an override, along with supporting rationale and documentation.

"Utilization review organization" means an entity that conducts utilization review, other than a health carrier performing utilization review for its own health benefit plans.

(b) Any individual or group health maintenance that provides coverage for prescription drugs and uses step-therapy protocols shall have the following requirements and restrictions.

(1) Clinical review criteria used to establish step therapy protocols shall be based on clinical practice guidelines that:

(A) That recommend drugs be taken in the specific sequence required by the step therapy protocol.

(B) Are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by:

(i) Requiring members to disclose any potential conflict of interests with entities, including insurers, health plans, and pharmaceutical manufacturers and recluse themselves of voting if they have a conflict of interest.

(ii) Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus.

(iii) Offering opportunities for public review and comments.

(C) Are based on high quality studies, research, and medical practice.

(D) Are created by an explicit and transparent process that:

(i) Minimizes biases and conflicts of interest;

(ii) Explains the relationship between treatment options and outcomes;

(iii) Rates the quality of the evidence supporting recommendations; and

(iv) Considers relevant patient subgroups and preferences.

(E) Are continually updated through a review of new evidence, research and newly developed treatments.

(2) In the absence of clinical guidelines that meet the requirements in section (1), peer reviewed publications may be substituted.

(3) When establishing a step therapy protocol, a utilization review agent shall also take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

(4) This section shall not be construed to require insurers, health plans or the state to set up a new entity to develop clinical review criteria used for step therapy protocols.

(c) When coverage of medications for the treatment of any medical condition are restricted for use by a carrier or utilization review organization via a step therapy protocol, the patient and prescribing practitioner shall have access to a clear readily accessible and convenient process to request a Step Therapy Exception Determination. A carrier or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The

process shall be disclosed to the patient and health care providers, including documenting and making easily accessible on the carriers' or utilization review organization's website.

(d) A step therapy override exception determination shall be expeditiously granted if:

(1) The required drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient;

(2) The required drug is expected to be ineffective based on the known relevant physical or mental characteristics of the insured and the known characteristics of the drug regimen;

(3) The enrollee has tried the step therapy-required drug while under their current or a previous health plan, or another drug in the same pharmacologic class or with the same mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(4) The patient is stable on a drug recommended by their health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan;

(5) The step therapy-required drug is not in the best interest of the patient, based on medical appropriateness.

(e) Upon the granting of a step therapy override exception determination, the carrier or utilization review organization shall authorize coverage for the drug prescribed by the enrollee's treating health care provider.

(f) The carrier or utilization review organization shall respond to step therapy override exception request or an appeal within seventy two hours of receipt. In cases where exigent

circumstances exist a carrier or utilization review organization shall respond within twenty four hours of receipts. Should a response by a carrier or utilization review organization not be received within this time allotted the exception or appeal shall be deemed granted.

(g) This section shall not be construed to prevent:

(1) A carrier or utilization review organization from requiring an enrollee try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

(2) A health care provider from prescribing a drug he or she determines is medically appropriate.

SECTION XXXXX. Sections 1 to 5, inclusive, shall apply to all policies, contracts and certificates of health insurance subject to section 17K of chapter 32A, section 47CC of chapter 175, section 8FF of chapter 176A, section 4FF of chapter 176B and section 4X of chapter 176G of the General Laws which are delivered, issued or renewed on or after January 1, 20XX."