SENATE . . . . . No. 2486

Senate, May 24, 2016 – Text of amendment (522) (offered by Senator L'Italien) to the Ways and Means amendment (Senate, No. 4) to the House Bill making appropriations for the fiscal year 2017 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 Eighty-Ninth General Court
(2015-2016)

by inserting the following new sections:-

SECTION X. Chapter 175 of the General Laws is hereby amended by inserting after section 47BB the following 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.

"Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by an insurer or health plan 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 are to be prescribed and paid for by a health plan.

"Step Therapy Override 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:

(A) Independently developed by a professional medical society with expertise in the medical condition, or conditions, for which coverage decisions said criteria will be applied; and

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

(2) Exceptions Process. When coverage of medications for the treatment of any medical condition are restricted for use by an insurer, health plan, or utilization review organization via a

step therapy protocol, the patient and prescribing practitioner shall have access to a clear and convenient process to request a Step Therapy Exception Determination. An insurer, health plan, 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 insurer's or health plan's website.

(3) Exceptions. An exception request shall be expeditiously granted if:

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

(B) 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;

(C) 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;

(D) The patient is stable on a drug recommended by their health care provider for the medical condition under consideration, based on, but not limited to, a trial with medication samples or a prescription filled at a pharmacy;

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

(4) Effect of Exception. Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize dispensation of and coverage

for the drug prescribed by the enrollee's treating health care provider, provided such drug is a covered drug under such policy or contract.

(5) Limitations. This section shall not be construed to prevent:

(A) An insurer, health plan, or utilization review organization from requiring an enrollee try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

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

SECTION XX. Chapter 176A of the General Laws is hereby amended by inserting after section 8EE the following 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.

"Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by an insurer or health plan 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 are to be prescribed and paid for by a health plan.

"Step Therapy Override 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:

(A) Independently developed by a professional medical society with expertise in the medical condition, or conditions, for which coverage decisions said criteria will be applied; and

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

(2) Exceptions Process. When coverage of medications for the treatment of any medical condition are restricted for use by an insurer, health plan, or utilization review organization via a step therapy protocol, the patient and prescribing practitioner shall have access to a clear and convenient process to request a Step Therapy Exception Determination. An insurer, health plan,

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 insurer's or health plan's website.

(3) Exceptions. An exception request shall be expeditiously granted if:

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

(B) 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;

(C) 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;

(D) The patient is stable on a drug recommended by their health care provider for the medical condition under consideration, based on, but not limited to, a trial with medication samples or a prescription filled at a pharmacy;

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

(4) Effect of Exception. Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize dispensation of and coverage for the drug prescribed by the enrollee's treating health care provider, provided such drug is a covered drug under such policy or contract.

(5) Limitations. This section shall not be construed to prevent:

(A) An insurer, health plan, or utilization review organization from requiring an enrollee try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

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

SECTION XX. Chapter 176B of the General Laws is hereby amended by inserting after section 4EE the following 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.

"Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by an insurer or health plan 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 are to be prescribed and paid for by a health plan.

"Step Therapy Override 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:

(A) Independently developed by a professional medical society with expertise in the medical condition, or conditions, for which coverage decisions said criteria will be applied; and

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

(2) Exceptions Process. When coverage of medications for the treatment of any medical condition are restricted for use by an insurer, health plan, or utilization review organization via a step therapy protocol, the patient and prescribing practitioner shall have access to a clear and convenient process to request a Step Therapy Exception Determination. An insurer, health plan, 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 insurer's or health plan's website.

(3) Exceptions. An exception request shall be expeditiously granted if:

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

(B) 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;

(C) 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;

(D) The patient is stable on a drug recommended by their health care provider for the medical condition under consideration, based on, but not limited to, a trial with medication samples or a prescription filled at a pharmacy;

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

(4) Effect of Exception. Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize dispensation of and coverage for the drug prescribed by the enrollee’s treating health care provider, provided such drug is a covered drug under such policy or contract.

(5) Limitations. This section shall not be construed to prevent:

(A) An insurer, health plan, or utilization review organization from requiring an enrollee try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

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

SECTION XX. Chapter 176G of the General Laws is hereby amended by inserting after section 4W the following 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.

"Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice guidelines used by an insurer or health plan 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 are to be prescribed and paid for by a health plan.

"Step Therapy Override 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:

(A) Independently developed by a professional medical society with expertise in the medical condition, or conditions, for which coverage decisions said criteria will be applied; and

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

(2) Exceptions Process. When coverage of medications for the treatment of any medical condition are restricted for use by an insurer, health plan, or utilization review organization via a step therapy protocol, the patient and prescribing practitioner shall have access to a clear and convenient process to request a Step Therapy Exception Determination. An insurer, health plan, 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 insurer's or health plan's website.

(3) Exceptions. An exception request shall be expeditiously granted if:

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

(B) 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;

(C) 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;

(D) The patient is stable on a drug recommended by their health care provider for the medical condition under consideration, based on, but not limited to, a trial with medication samples or a prescription filled at a pharmacy;

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

(4) Effect of Exception. Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize dispensation of and coverage for the drug prescribed by the enrollee’s treating health care provider, provided such drug is a covered drug under such policy or contract.

(5) Limitations. This section shall not be construed to prevent:

(A) An insurer, health plan, or utilization review organization from requiring an enrollee try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded drug;

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

SECTION XX. 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, 2016.