S T A T E O F N E W Y O R K

2834--B

2015-2016 Regular Sessions

I N A S S E M B L Y

January 20, 2015

Introduced by M. of A. TITONE, GOTTFRIED, RODRIGUEZ, GUNTHER, ZEBROWSKI, QUART, PEOPLES-STOKES, MONTESANO, CUSICK, BRINDISI, TEDISCO, WEPRIN, ROSENTHAL, SKOUFIS, ROZIC, JOHNS, JAFFEE, STIRPE, STECK, OTIS, ABINANTI, CLARK, BARRETT, THIELE, PICHARDO, KEARNS, SANTABARBARA -- Multi-Sponsored by -- M. of A. CERETTO, CRESPO, DUPREY, FAHY, GALEF, HEVESI, KOLB, LUPARDO, McLAUGHLIN, PERRY, RIVERA, SCHIMEL, SEPULVEDA -- read once and referred to the Committee on Insurance -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- recommitted to the Committee on Insurance in accordance with Assembly Rule 3, sec. 2 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the insurance law, in relation to the regulation of step therapy policies

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Legislative findings. The legislature hereby finds and declares that:

(a) Health insurance plans are increasingly making use of step therapy protocols under which patients are required to try one or more prescription drugs before coverage is provided for a drug selected by the patient's health care provider.

(b) The legislature further finds that such step therapy protocols, where they are based on well-developed scientific standards and administered in a flexible manner that takes into account the individual needs of patients, can play an important role in controlling health care costs.

(c) The legislature further finds that, in some cases, requiring a patient to follow a step therapy protocol may have adverse and even dangerous consequences for the patient who may not realize a benefit

EXPLANATION--Matter in ITALICS (underscored) is new; matter in brackets [ ] is old law to be omitted.

LBD03838-05-6

from taking a prescription drug or may suffer harm from taking an inappropriate drug.

(d) The legislature further finds that, without uniform policies in the state for step therapy protocols, patients may not receive the best and most appropriate treatment.

(e) The legislature further finds that it is imperative that step therapy protocols in the state preserve the health care provider's right to make treatment decisions in the best interest of the patient.

(f) Therefore, the legislature declares it a matter of public interest that it require health insurers to base step therapy protocols on appropriate clinical practice guidelines developed by independent experts with knowledge of the condition or conditions under consideration; that patients be exempt from step therapy protocols when inappropriate or otherwise not in the best interest of the patients; and that patients have access to a fair, transparent and independent process for requesting an exception to a step therapy protocol when appropriate.

S 2. The insurance law is amended by adding a new article 33 to read as follows:

ARTICLE 33

REGULATION OF STEP THERAPY POLICIES

SECTION 3301. DEFINITIONS.
3302. CLINICAL REVIEW CRITERIA.
3303. EXCEPTIONS PROCESS TRANSPARENCY.
3304. COST-SHARING.
3305. REGULATIONS.

S 3301. DEFINITIONS. AS USED IN THIS ARTICLE:

(A) "CLINICAL PRACTICE GUIDELINES" SHALL MEAN A SYSTEMATICALLY DEVELOPED STATEMENT TO ASSIST HEALTH CARE PROVIDER AND PATIENT DECISIONS ABOUT APPROPRIATE HEALTHCARE FOR SPECIFIC CLINICAL CIRCUMSTANCES AND CONDITIONS.

(B) "CLINICAL REVIEW CRITERIA" SHALL MEAN 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.

(C) "STEP THERAPY PROTOCOL" SHALL MEAN 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 COVERED BY AN INSURER OR HEALTH PLAN.

(D) "STEP THERAPY OVERRIDE DETERMINATION" SHALL MEAN A DETERMINATION AS TO WHETHER A STEP THERAPY PROTOCOL SHOULD APPLY IN A PARTICULAR SITUATION, OR WHETHER THE STEP THERAPY PROTOCOL SHOULD BE OVERRIDDEN IN FAVOR OF IMMEDIATE COVERAGE OF THE HEALTH CARE PROVIDER'S SELECTED PRESCRIPTION DRUG. THIS DETERMINATION IS BASED ON A REVIEW OF THE PATIENT'S OR PRESCRIBER'S REQUEST FOR AN OVERRIDE, ALONG WITH SUPPORTING RATIONALE AND DOCUMENTATION.

(E) "UTILIZATION REVIEW ORGANIZATION" SHALL MEAN AN ENTITY THAT CONDUCTS UTILIZATION REVIEW, OTHER THAN AN INSURER OR HEALTH PLAN PERFORMING UTILIZATION REVIEW FOR ITS OWN HEALTH BENEFIT PLANS.

S 3302. CLINICAL REVIEW CRITERIA. (A) CLINICAL REVIEW CRITERIA USED TO ESTABLISH A STEP THERAPY PROTOCOL SHALL BE BASED ON CLINICAL PRACTICE GUIDELINES THAT:

(1) RECOMMEND THAT THE PRESCRIPTION DRUGS BE TAKEN IN THE SPECIFIC SEQUENCE REQUIRED BY THE STEP THERAPY PROTOCOL.

(2) ARE DEVELOPED AND ENDORSED BY AN INDEPENDENT, MULTIDISCIPLINARY PANEL OF EXPERTS NOT AFFILIATED WITH AN INSURER, HEALTH PLAN OR UTILIZATION REVIEW ORGANIZATION.
(3) ARE BASED ON HIGH QUALITY STUDIES, RESEARCH, AND MEDICAL PRACTICE.
(4) ARE CREATED BY AN EXPLICIT AND TRANSPARENT PROCESS THAT:
(A) MINIMIZES BIASES AND CONFLICTS OF INTEREST;
(B) EXPLAINS THE RELATIONSHIP BETWEEN TREATMENT OPTIONS AND OUTCOMES;
(C) RATES THE QUALITY OF THE EVIDENCE SUPPORTING RECOMMENDATIONS; AND
(D) CONSIDERS RELEVANT PATIENT SUBGROUPS AND PREFERENCES.
(5) ARE CONTINUALLY UPDATED THROUGH A REVIEW OF NEW EVIDENCE AND RESEARCH.
(B) AN INSURER, HEALTH PLAN, OR UTILIZATION REVIEW ORGANIZATION SHALL CERTIFY ANNUALLY IN RATE FILING DOCUMENTS SUBMITTED TO THE DEPARTMENT OF FINANCIAL SERVICES THAT THE CLINICAL REVIEW CRITERIA USED IN STEP THERAPY PROGRAMS FOR PHARMACEUTICALS MEET THE REQUIREMENTS SET FORTH IN THIS ACT.
(C) PROPOSED CLINICAL REVIEW CRITERIA WILL BE SUBMITTED TO THE DEPARTMENT OF FINANCIAL SERVICES FOR REVIEW AND MUST RECEIVE APPROVAL OR ACCREDITATION PRIOR TO IMPLEMENTATION.
S 3303. EXCEPTIONS PROCESS TRANSPARENCY. (A) WHEN COVERAGE OF A PRESCRIPTION DRUG FOR THE TREATMENT OF ANY MEDICAL CONDITION IS RESTRICTED FOR USE BY AN INSURER, HEALTH PLAN, OR UTILIZATION REVIEW ORGANIZATION THROUGH THE USE OF 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 MADE EASILY ACCESSIBLE ON THE INSURER'S, HEALTH PLAN'S, OR UTILIZATION REVIEW ORGANIZATION'S WEBSITE.
(B) A STEP THERAPY OVERRIDE DETERMINATION REQUEST SHALL BE EXPEDITIOUSLY GRANTED IF:
(1) THE REQUIRED PRESCRIPTION DRUG IS CONTRAINDICATED OR WILL LIKELY CAUSE AN ADVERSE REACTION BY OR PHYSICAL OR MENTAL HARM TO THE PATIENT.
(2) THE REQUIRED PRESCRIPTION DRUG IS EXPECTED TO BE INEFFECTIVE BASED ON THE KNOWN RELEVANT PHYSICAL OR MENTAL CHARACTERISTICS OF THE PATIENT AND THE KNOWN CHARACTERISTICS OF THE PRESCRIPTION DRUG REGIMEN.
(3) THE PATIENT HAS TRIED THE REQUIRED PRESCRIPTION DRUG WHILE UNDER THEIR CURRENT OR A PREVIOUS HEALTH INSURANCE OR HEALTH BENEFIT PLAN, OR ANOTHER PRESCRIPTION DRUG IN THE SAME PHARMACOLOGIC CLASS OR WITH THE SAME MECHANISM OF ACTION AND SUCH PRESCRIPTION DRUG WAS DISCONTINUED DUE TO A LACK OF EFFICACY OR EFFECTIVENESS, DIMINISHED EFFECT, OR AN ADVERSE EVENT.
(4) THE REQUIRED PRESCRIPTION DRUG IS NOT IN THE BEST INTEREST OF THE PATIENT, BASED ON MEDICAL APPROPRIATENESS.
(5) THE PATIENT IS STABLE ON A PRESCRIPTION DRUG SELECTED BY THEIR HEALTH CARE PROVIDER FOR THE MEDICAL CONDITION UNDER CONSIDERATION.
(C) UPON THE GRANTING OF A STEP THERAPY OVERRIDE DETERMINATION, THE INSURER, HEALTH PLAN, OR UTILIZATION REVIEW ORGANIZATION SHALL AUTHORIZE COVERAGE FOR THE PRESCRIPTION DRUG PRESCRIBED BY THE PATIENT'S TREATING HEALTHCARE PROVIDER, PROVIDED SUCH PRESCRIPTION DRUG IS A COVERED PRESCRIPTION DRUG UNDER SUCH POLICY OR CONTRACT.
(D) THIS SECTION SHALL NOT BE CONSTRUED TO PREVENT:
(1) AN INSURER, HEALTH PLAN, OR UTILIZATION REVIEW ORGANIZATION FROM REQUIRING A PATIENT TO TRY AN AB-RATED GENERIC EQUIVALENT PRIOR TO PROVIDING COVERAGE FOR THE EQUIVALENT BRANDED PRESCRIPTION DRUG.

(2) A HEALTH CARE PROVIDER FROM PRESCRIBING A PRESCRIPTION DRUG THAT IS DETERMINED TO BE MEDICALLY APPROPRIATE.

(E) EACH HEALTH INSURER SHALL MAINTAIN WRITTEN OR ELECTRONIC RECORDS AND DATA SUFFICIENT TO DEMONSTRATE COMPLIANCE WITH THE REQUIREMENTS OF THIS SECTION AND ON AN ANNUAL BASIS SUBMIT TO THE SUPERINTENDENT OF FINANCIAL SERVICES THE FOLLOWING INFORMATION WITH RESPECT TO REQUESTS MADE UNDER THIS SECTION:

(1) THE TOTAL NUMBER OF REQUESTS RECEIVED;

(2) THE NUMBER OF REQUESTS APPROVED AND DENIED; AND

(3) ANY OTHER INFORMATION THE SUPERINTENDENT MAY REQUEST.

S 3304. COST-SHARING. (A) NOTWITHSTANDING ANY OTHER PROVISION OF STATE OR FEDERAL LAW, AN ENTITY LICENSED IN THIS STATE TO SELL A HEALTH INSURANCE OR HEALTH BENEFITS PLAN DIRECTLY TO A CONSUMER SHALL ENSURE THAT WHERE STEP THERAPY PROTOCOLS ARE USED TO IMPOSE CLINICAL PREREQUISITES FOR COVERAGE OF PRESCRIPTION DRUGS, SUCH DRUGS SHALL BE AVAILABLE TO THE CONSUMER AT THE PREFERRED COST-SHARING LEVEL FOR THE ITEM ONCE THE CLINICAL PREREQUISITES HAVE BEEN SATISFIED.

(B) THIS SECTION SHALL NOT BE CONSTRUED TO PREVENT INSURERS FROM USING TIERED COPAYMENT STRUCTURES.

S 3305. REGULATIONS. NOTWITHSTANDING ANY LAW TO THE CONTRARY, THE SUPERINTENDENT OF FINANCIAL SERVICES SHALL PROMULGATE ANY REGULATIONS NECESSARY TO IMPLEMENT THIS ACT.

S 3. This act shall take effect on January 1, 2017 and shall apply only to health insurance and health benefit plans delivered, issued for delivery, or renewed after such date; provided, further, that effective immediately the superintendent of financial services is authorized to promulgate such rules and regulations and take any other measures as may be necessary for the timely implementation of this act.