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IN ASSEMBLY

March 25, 2010

Introduced by M. of A. BING, BENEDETTO, ESPAILLAT, TITONE, DINOWITZ, MILLMAN, PHEFFER, COOK, GIBSON, JACOBS, SPANO, MARKEY, N. RIVERA, MAISEL, CHRISTENSEN, JAFFEE, HOOPER -- Multi-Sponsored by -- M. of A. BOYLAND, GLICK, McENENY -- read once and referred to the Committee on Insurance

AN ACT to amend the insurance law, in relation to the prohibition on first fail policies

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

Section 1. The insurance law is amended by adding a new article 33 to 2 read as follows: 3

ARTICLE 33

PROHIBITION ON FIRST FAIL POLICIES

SECTION 3301. DEFINITIONS.

- 3302. PHARMACY BENEFITS MANAGER DUTIES.
- 3303. PRESCRIPTION DRUG DENIALS.
- 3304. SWITCH COMMUNICATIONS.
- 9 3305. PENALTIES.

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- 3306. PRESCRIPTION DRUG RESTRICTION OVERRIDES.
- 11 S 3301. DEFINITIONS. AS USED IN THIS ARTICLE:
- (A) "INSURER" SHALL MEAN ANY PERSON OR ENTITY WHO OFFERS A POLICY OF 12 13 ACCIDENT AND/OR HEALTH INSURANCE PURSUANT TO SECTION THREE THOUSAND TWO HUNDRED SIXTEEN, THREE THOUSAND TWO HUNDRED TWENTY-ONE, OR FOUR THOUSAND 14 THREE HUNDRED THREE OF THIS CHAPTER OR ARTICLE FORTY-FOUR OF THE PUBLIC 15 16 HEALTH LAW; EXCEPT WHEN SUCH HEALTH CARE SERVICES ARE PROVIDED, DELIV-17 ERED, ARRANGED FOR, PAID FOR, OR REIMBURSED BY ANY STATE, DEPARTMENT OR 18 AGENCY;
- 19 (B) "PHARMACY BENEFITS MANAGER" OR "PBM", MEANS A PERSON OR ENTITY OTHER THAN A PHARMACY OR PHARMACIST ACTING AS AN ADMINISTRATOR IN 20 21 CONNECTION WITH PHARMACY BENEFITS;
- 22 (C) "SWITCH COMMUNICATION", MEANS A COMMUNICATION FROM ANY INSURER OR 23 PBM TO A PATIENT OR THE PATIENT'S PHYSICIAN THAT RECOMMENDS A PATIENT'S 24 MEDICATION BE SWITCHED BY THE ORIGINAL PRESCRIBING HEALTH CARE PROFES-

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

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SIONAL TO A DIFFERENT MEDICATION THAN THE MEDICATION ORIGINALLY PRESCRIBED BY THE PRESCRIBING HEALTH CARE PROFESSIONAL.

- S 3302. PHARMACY BENEFITS MANAGER DUTIES. (A) A PHARMACY BENEFITS MANAGER SHALL:
- (1) REMIT TO THE COVERED ENTITY EACH INDIVIDUAL CLAIM, THE PRESCRIPTION NUMBER, THE ELEVEN-DIGIT NATIONAL DRUG CODE (NDC) NUMBER, THE QUANTITY AND THE AMOUNT THE PHARMACY BENEFITS MANAGER ACTUALLY PAID EACH PHARMACY OR PHARMACIST, AND THE AMOUNT CHARGED TO THE PERSON, BUSINESS, OR OTHER ENTITY THAT IS PURCHASING PHARMACIST'S SERVICES THROUGH THE PHARMACY BENEFITS MANAGER; AND
- (2) ITEMIZE BY INDIVIDUAL CLAIM THE AMOUNTS THE PHARMACY BENEFITS MANAGER ACTUALLY PAID EACH PHARMACY OR PHARMACIST FOR PHARMACIST'S SERVICES ON ANY INVOICE, STATEMENT, OR REMITTANCE.
 - (B) A PHARMACY BENEFITS MANAGER SHALL NOT:
- (1) AUTOMATICALLY ENROLL OR PASSIVELY ENROLL THE PHARMACY IN A CONTRACT, OR MODIFY AN EXISTING CONTRACT WITHOUT AFFIRMATION FROM THE PHARMACY OR PHARMACIST. THE PHARMACY SHALL SIGN A CONTRACT BEFORE ASSUMING RESPONSIBILITY TO FILL PRESCRIPTIONS;
- (2) REQUIRE THAT A PHARMACY OR PHARMACIST PARTICIPATE IN ONE PHARMACY BENEFITS MANAGER CONTRACT IN ORDER TO PARTICIPATE IN ANOTHER CONTRACT; OR
- (3) DISCRIMINATE BETWEEN PHARMACIES OR PHARMACISTS ON THE BASIS OF COPAYMENTS OR DAYS OF SUPPLY.
- (C) WHEN A PHARMACY BENEFITS MANAGER CALCULATES THE CHARGE FOR A PRESCRIPTION TO THE RECIPIENT OF THE DRUG AND THE COVERED ENTITY, THE PHARMACY BENEFITS MANAGER SHALL USE THE SAME NDC PRICE USED WHEN CALCULATING THE REIMBURSEMENT TO THE DISPENSING PHARMACY.
- (D) WHEN AN INSURED PRESENTS A PRESCRIPTION TO A PHARMACY IN THE PHARMACY BENEFITS MANAGER'S NETWORK, THE PHARMACY BENEFITS MANAGER SHALL NOT REASSIGN SUCH PRESCRIPTION TO BE FILLED BY ANY OTHER PHARMACY. WHEN THE PHARMACY BENEFITS MANAGER CONTACTS THE PRESCRIBING HEALTH CARE PRACTITIONER TO AFFIRM OR MODIFY THE ORIGINAL PRESCRIPTION WHICH HAS BEEN DELIVERED TO A PARTICIPATING PHARMACY, THE AFFIRMED OR MODIFIED PRESCRIPTION SHALL BE FILLED AT THE PHARMACY TO WHICH THE INSURED PRESENTED THE ORIGINAL PRESCRIPTION.
- S 3303. PRESCRIPTION DRUG DENIALS. (A) A POLICY OF ACCIDENT AND/OR HEALTH INSURANCE THAT COVERS PRESCRIPTION DRUGS SHALL NOT LIMIT, REDUCE, OR DENY COVERAGE FOR ANY DRUG IF, PRIOR TO THE LIMITATION, REDUCTION, OR DENIAL OF COVERAGE:
 - (1) ANY INSURED WAS USING THE DRUG;
 - (2) SUCH INSURED OR INSUREDS WERE COVERED UNDER THE POLICY; AND
- (3) THE DRUG WAS COVERED UNDER THE POLICY FOR SUCH INSURED INDIVIDUAL OR INDIVIDUALS.
- (B) A LIMITATION, REDUCTION, OR DENIAL OF COVERAGE INCLUDES REMOVING A DRUG FROM THE FORMULARY OR OTHER DRUG LIST, IMPOSING NEW PRIOR AUTHORIZATION OR OTHER UTILIZATION MANAGEMENT TOOLS, OR PLACING THE DRUG ON A FORMULARY TIER THAT INCREASES THE PATIENT'S COST-SHARING OBLIGATIONS OR OTHERWISE INCREASES THE PATIENT'S COST-SHARING OBLIGATIONS.
- (C) NOTHING IN THIS SECTION SHALL PROHIBIT AN INSURER FROM MAKING UNIFORM CHANGES IN ITS BENEFIT DESIGN THAT APPLY TO ALL COVERED DRUGS, UNIFORMLY REMOVING A DRUG FROM THE FORMULARY LIST FOR ALL INSUREDS, OR INCREASING COST-SHARING OBLIGATIONS MERELY DUE TO A PERCENTAGE COINSURANCE PAYMENT THAT NECESSARILY INCREASES WITH AN INCREASE IN THE UNDERLYING DRUG PRICES.
- 55 S 3304. SWITCH COMMUNICATIONS. (A) ANY TIME A PATIENT'S PRESCRIBED 56 MEDICATION IS RECOMMENDED TO BE SWITCHED TO A MEDICATION OTHER THAN THAT

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ORIGINALLY PRESCRIBED BY THE PRESCRIBING PRACTITIONER, A SWITCH COMMUNI-CATION SHALL BE SENT TO:

- (1) THE PATIENT AND SHALL PROVIDE INFORMATION ABOUT WHY THE SWITCH IS PROPOSED AND THE PATIENT'S RIGHTS FOR REFUSING THE RECOMMENDED CHANGE IN TREATMENT; AND
- (2) THE POLICY SPONSOR AND SHALL INFORM SUCH SPONSOR OF THE COST, SHOWN IN CURRENCY FORM, OF THE RECOMMENDED MEDICATION AND THE COST, SHOWN IN CURRENCY FORM, OF THE ORIGINALLY PRESCRIBED MEDICATION.
 - (B) SUCH SWITCH COMMUNICATION SHALL:
- (1) CLEARLY IDENTIFY THE ORIGINALLY PRESCRIBED MEDICATION AND THE MEDICATION TO WHICH IT HAS BEEN PROPOSED THAT THE PATIENT SHOULD BE SWITCHED;
- (2) EXPLAIN ANY FINANCIAL INCENTIVES THAT MAY BE PROVIDED TO, OR HAVE BEEN OFFERED TO, THE PRESCRIBING HEALTH CARE PROFESSIONAL BY THE INSURER OR PBM THAT COULD RESULT IN THE SWITCH TO THE DIFFERENT DRUG. IN PARTICULAR, CASH OR IN-KIND COMPENSATION PAYABLE TO PRESCRIBERS OR THEIR PROFESSIONAL PRACTICES FOR SWITCHING PATIENTS FROM THEIR CURRENTLY PRESCRIBED MEDICATION TO A DIFFERENT MEDICATION SHALL BE DISCLOSED TO THE PATIENT AS WELL AS INCENTIVES THAT MAY BE PROVIDED THROUGH GENERAL HEALTH CARE PROFESSIONAL COMPENSATION PROGRAMS USED BY THE INSURER OR PBM;
- (3) EXPLAIN ANY FINANCIAL INCENTIVE THAT AN INSURER OR PBM MAY HAVE TO ENCOURAGE THE SWITCH TO A DIFFERENT DRUG;
- (4) ADVISE THE PATIENT OF HIS OR HER RIGHTS TO DISCUSS THE PROPOSED CHANGE IN TREATMENT BEFORE SUCH A SWITCH TAKES PLACE, INCLUDING A DISCUSSION WITH THE PATIENT'S PRESCRIBING PRACTITIONER, THE FILING OF A GRIEVANCE WITH THE INSURER TO PREVENT THE SWITCH IF SUCH A SWITCH IS BASED ON A FINANCIAL INCENTIVE AND THE FILING OF A GRIEVANCE WITH THE DEPARTMENT; AND
- (5) EXPLAIN ANY COST-SHARING CHANGES FOR WHICH THE PATIENT IS RESPONSIBLE.
- (C) SWITCH COMMUNICATIONS TO HEALTH CARE PROVIDERS SHALL DISCLOSE FINANCIAL INCENTIVES OR BENEFITS THAT MAY BE RECEIVED BY THE INSURER OR PBM.
- (D) SWITCH COMMUNICATIONS TO HEALTH CARE PROVIDERS SHALL DIRECT THE PRESCRIBER TO ADVISE THE PATIENT THAT IS SUBJECTED TO A SWITCH BY THE PRESCRIBER OF ANY FINANCIAL INCENTIVES RECEIVED BY THE PRESCRIBER OR OTHER INDUCEMENTS FROM THE INSURER OR PBM THAT MAY INFLUENCE THE DECISION TO SWITCH.
- (E) A COPY OF ANY SWITCH COMMUNICATION SENT TO A PATIENT SHALL ALSO BE SENT TO THE PRESCRIBING PRACTITIONER.
- (F) HEALTH INSURANCE PAYERS, INCLUDING EMPLOYERS, SHALL BE NOTIFIED OF MEDICATION SWITCHES AMONG POLICY PARTICIPANTS. SUCH NOTIFICATION SHALL INCLUDE ANY FINANCIAL INCENTIVE THE INSURER OR PBM MAY BE UTILIZING TO ENCOURAGE OR INDUCE THE SWITCH. INFORMATION CONTAINED IN THE NOTIFICATION SHALL BE IN THE AGGREGATE AND MUST NOT CONTAIN ANY PERSONALLY IDENTIFIABLE INFORMATION.
- (G) THE DEPARTMENT SHALL CREATE ONE FORM FOR INSURERS AND PHARMACY BENEFIT MANAGERS TO USE IN SWITCH COMMUNICATIONS TO PATIENTS, PRESCRIBING PRACTITIONERS, AND HEALTH INSURANCE PAYERS INCLUDING EMPLOYERS.
- (H) THE DEPARTMENT SHALL PROMULGATE RULES GOVERNING SWITCH COMMUNI-CATIONS. SUCH RULES SHALL INCLUDE, BUT NOT BE LIMITED TO THE FOLLOWING:
- (1) PROCEDURES FOR VERIFYING THE ACCURACY OF ANY SWITCH COMMUNICATIONS FROM POLICIES OF ACCIDENT AND/OR HEALTH INSURANCE AND PHARMACY BENEFIT MANAGERS TO ENSURE THAT SUCH SWITCH COMMUNICATIONS ARE TRUTHFUL, ACCURATE, AND NOT MISLEADING BASED ON COST TO THE PATIENT AND POLICY SPON-

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SOR, THE PRODUCT PACKAGE LABELING, MEDICAL COMPENDIA RECOGNIZED BY THE DRUG UTILIZATION REVIEW BOARD, AND PEER-REVIEWED MEDICAL LITERATURE, WITH APPROPRIATE REFERENCES PROVIDED;

- (2) EXCEPT FOR A SUBSTITUTION DUE TO THE FOOD AND DRUG ADMINISTRATION'S WITHDRAWAL OF A DRUG FOR PRESCRIPTION, A REQUIREMENT THAT ALL SWITCH COMMUNICATIONS BEAR A PROMINENT LEGEND ON THE FIRST PAGE THAT STATES: "THIS IS NOT A PRODUCT SAFETY NOTICE. THIS IS A PROMOTIONAL ANNOUNCEMENT FROM YOUR HEALTH CARE INSURER OR PHARMACY BENEFITS MANAGER ABOUT ONE OF YOUR CURRENT PRESCRIBED MEDICATIONS.";
- (3) A REQUIREMENT THAT, IF THE SWITCH COMMUNICATION CONTAINS INFORMATION REGARDING A POTENTIAL THERAPEUTIC SUBSTITUTION, SUCH COMMUNICATION SHALL EXPLAIN THAT MEDICATIONS IN THE SAME THERAPEUTIC CLASS ARE ASSOCIATED WITH DIFFERENT RISKS AND BENEFITS AND MAY WORK DIFFERENTLY IN DIFFERENT PATIENTS.
- S 3305. PENALTIES. (A) ISSUING OR DELIVERING OR CAUSING TO BE ISSUED OR DELIVERED A SWITCH COMMUNICATION THAT HAS NOT BEEN APPROVED AND IS NOT IN COMPLIANCE WITH THE REQUIREMENTS OF SECTION THREE THOUSAND THREE HUNDRED FOUR OF THIS ARTICLE IS PUNISHABLE BY A FINE NOT TO EXCEED TWENTY-FIVE THOUSAND DOLLARS.
- (B) PROVIDING A MISREPRESENTATION OR FALSE STATEMENT IN A SWITCH COMMUNICATION UNDER SECTION THREE THOUSAND THREE HUNDRED FOUR OF THIS ARTICLE IS PUNISHABLE BY A FINE NOT TO EXCEED TWENTY-FIVE THOUSAND DOLLARS.
- (C) ANY OTHER MATERIAL VIOLATION OF SECTION THREE THOUSAND THREE HUNDRED FOUR OF THIS ARTICLE IS PUNISHABLE BY A FINE NOT TO EXCEED TWEN-TY-FIVE THOUSAND DOLLARS.
- S 3306. PRESCRIPTION DRUG RESTRICTION OVERRIDES. (A) WHEN MEDICATIONS FOR THE TREATMENT OF ANY MEDICAL CONDITION ARE RESTRICTED FOR USE BY AN INSURER OR PBM BY A STEP THERAPY OR FAIL FIRST PROTOCOL, A PRESCRIBER MAY OVERRIDE SUCH RESTRICTION IF:
- (1) THE PREFERRED TREATMENT BY THE INSURER OR THE PBM HAS BEEN INEFFECTIVE IN THE TREATMENT OF THE COVERED PERSON'S DISEASE OR MEDICAL CONDITION; OR
- (2) BASED ON SOUND CLINICAL EVIDENCE AND MEDICAL AND SCIENTIFIC EVIDENCE:
- (A) THE PREFERRED TREATMENT IS EXPECTED TO BE INEFFECTIVE BASED ON THE KNOWN RELEVANT PHYSICAL OR MENTAL CHARACTERISTICS OF THE COVERED PERSON AND KNOWN CHARACTERISTICS OF THE DRUG REGIMEN, AND IS LIKELY TO BE INEFFECTIVE OR ADVERSELY AFFECT THE DRUG'S EFFECTIVENESS OR PATIENT COMPLIANCE; OR
- (B) THE PREFERRED TREATMENT HAS CAUSED OR IS LIKELY TO CAUSE AN ADVERSE REACTION OR OTHER HARM TO THE COVERED PERSON.
- (B) THE DURATION OF ANY STEP THERAPY OR FAIL FIRST PROTOCOL SHALL NOT BE LONGER THAN A PERIOD OF FOURTEEN DAYS WHEN SUCH TREATMENT IS DEEMED CLINICALLY INEFFECTIVE BY THE PRESCRIBING PHYSICIAN.
- (C) FOR MEDICATIONS WITH NO GENERIC EQUIVALENT AND FOR WHICH THE PRESCRIBING PHYSICIAN IN THEIR CLINICAL JUDGMENT FEELS THAT NO APPROPRIATE THERAPEUTIC ALTERNATIVE IS AVAILABLE AN INSURER OR PBM SHALL PROVIDE ACCESS TO UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) LABELED MEDICATIONS WITHOUT RESTRICTION TO TREAT SUCH MEDICAL CONDITIONS FOR WHICH AN FDA LABELED MEDICATION IS AVAILABLE.
- 52 (D) NOTHING IN THIS SECTION SHALL REQUIRE COVERAGE FOR A CONDITION 53 SPECIFICALLY EXCLUDED BY THE POLICY WHICH IS NOT OTHERWISE COVERED BY LAW.
 - S 2. This act shall take effect immediately.