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

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2011-2012 Regular Sessions

I N A S S E M B L Y

June 8, 2011

Introduced by M. of A. P. RIVERA, CASTRO, CYMBROWITZ, CRESPO, SCARBOROUGH, N. RIVERA, JAFFEE, GIBSON, MOYA, HIKIND, ARROYO, J. RIVERA, RODRIGUEZ, LINARES, STEVENSON, RAMOS, ROSENTHAL, ABINANTI, PERRY, MILLMAN, GUNTHER, BURLING, HOOPER, WEISENBERG, SCHIMEL -- Multi-Sponsored by -- M. of A. COOK, GLICK, HEASTIE, V. LOPEZ, McDONOUGH, SWEENEY, TITONE -- read once and referred to the Committee on Health -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- again reported from said committee with amendments, ordered reprinted as amended and recommitted to said committee -- recommitted to the Committee on Health 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 social services law, in relation to requiring managed care providers to provide coverage of medically necessary prescription drugs and medical supplies

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

Section 1. Subdivision 1 of section 364-j of the social services law is amended by adding a new paragraph (z) to read as follows:

(Z) "PHARMACY AND THERAPEUTICS COMMITTEE". AN INDEPENDENT COMMITTEE USED BY A MANAGED CARE PROVIDER TO DEVELOP AND MANAGE A FORMULARY OR PREFERRED DRUG LIST THAT OPERATES PURSUANT TO THE REQUIREMENTS OF SUBDIVISION TWENTY-SIX OF THIS SECTION.

S 2. Section 364-j of the social services law is amended by adding two new subdivisions 26 and 27 to read as follows:

26. NOTWITHSTANDING ANY OTHER PROVISION OF LAW TO THE CONTRARY, MANAGED CARE PROVIDERS SHALL COVER MEDICALLY NECESSARY PRESCRIPTION DRUGS AND MEDICAL SUPPLIES IN ACCORDANCE WITH THE FOLLOWING REQUIREMENTS:

(A) A MANAGED CARE PROVIDER MAY UTILIZE A FORMULARY OR PREFERRED DRUG LIST IN THE ADMINISTRATION OF THIS BENEFIT PROVIDED THAT SUCH FORMULARY

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

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SHALL HAVE BEEN REVIEWED AND APPROVED BY AN INDEPENDENT PHARMACY AND THERAPEUTICS COMMITTEE COMPRISED OF MEMBERS FROM VARIOUS CLINICAL SPECIALTIES THAT ADEQUATELY REPRESENT THE NEEDS OF ENROLLEES INCLUDING, AT A MINIMUM, THE FOLLOWING CATEGORIES OF MEMBERS:

(I) NEW YORK STATE LICENSED, BOARD CERTIFIED PHYSICIAN PRACTICING IN THE COMMUNITY AND SERVING THE MEDICAID POPULATION;

(II) NEW YORK STATE LICENSED, BOARD CERTIFIED SPECIALTY PHYSICIANS, INCLUDING, AT A MINIMUM:

(A) PHYSICIAN WHO IS BOARD CERTIFIED IN CARDIOLOGY, AND

(B) PHYSICIAN WHO IS BOARD CERTIFIED IN PSYCHIATRY;

(III) NEW YORK STATE LICENSED PHARMACIST PRACTICING IN THE COMMUNITY; AND

(IV) AT LEAST ON A CONSULTING BASIS, AN ADEQUATE NUMBER OF HIGH VOLUME SPECIALISTS, INCLUDING, BUT NOT LIMITED TO, AN HIV SPECIALIST, DEFINED AS A PHYSICIAN THAT HAS MET THE CRITERIA OF:

(A) THE HIV MEDICINE ASSOCIATION (HIVMA) DEFINITION OF AN HIV-EXPERIENCED PROVIDER, OR

(B) HIV SPECIALIST STATUS ACCORDED BY THE AMERICAN ACADEMY OF HIV MEDICINE (AAHIVM).

(B) THE DEPARTMENT OF HEALTH SHALL DEVELOP STANDARDS TO ENSURE THAT EACH MANAGED CARE PROVIDER'S PHARMACY AND THERAPEUTICS COMMITTEE MEMBERS COME FROM VARIOUS CLINICAL SPECIALTIES AND ADEQUATELY REPRESENT THE NEEDS OF PLAN BENEFICIARIES. A MAJORITY OF MEMBERS SHALL BE PRACTICING PHYSICIANS OR PRACTICING PHARMACISTS LICENSED PURSUANT TO TITLE EIGHT OF THE EDUCATION LAW. SUCH DEPARTMENT SHALL ALSO DEVELOP STANDARDS TO ENSURE A TRANSPARENT PROCESS FOR FORMULARY DEVELOPMENT WHICH SHALL INCLUDE THE OPPORTUNITY FOR PUBLIC COMMENT PRIOR TO ANY CHANGES TO THE FORMULARY. EACH MANAGED CARE PROVIDER'S COMMITTEE SHALL MEET NO LESS FREQUENTLY THAN ON A QUARTERLY BASIS AND SHALL MEET THE FOLLOWING REQUIREMENTS:

(I) MINUTES OF THE MEETINGS SHALL BE MADE AVAILABLE TO THE PUBLIC AND ON THE APPROPRIATE STATE INTERNET WEBSITE WITHIN TEN BUSINESS DAYS AFTER SUCH MINUTES ARE APPROVED;

(II) NOT LESS THAN THIRTY DAYS PRIOR TO A MEETING THE PHARMACY AND THERAPEUTICS COMMITTEE SHALL POST TO THE APPROPRIATE STATE INTERNET WEBSITE (A) THE MEETING AGENDA, (B) A LIST OF THE DRUG CLASSES TO BE CONSIDERED AT THE MEETING, AND (C) BACKGROUND MATERIALS AND SUPPORTING DOCUMENTATION PROVIDED TO THE MEMBERS OF SUCH COMMITTEE WITH RESPECT TO DRUGS AND DRUG CLASSES THAT ARE BEFORE THE COMMITTEE FOR REVIEW; AND

(III) THE PHARMACY AND THERAPEUTICS COMMITTEE SHALL PROVIDE APPROPRIATE OPPORTUNITY FOR PUBLIC TESTIMONY AT EACH REGULARLY SCHEDULED COMMITTEE MEETING. PRIOR TO DELIBERATING ON ANY RECOMMENDATIONS REGARDING A DRUG OR A CLASS OF DRUGS, THE COMMITTEE SHALL ACCEPT TESTIMONY, IN WRITING OR IN PERSON, THAT IS OFFERED BY A MANUFACTURER OF SUCH DRUGS OR ANOTHER INTERESTED PARTY.

(C) A MANAGED CARE PROVIDER THAT ADOPTS A FORMULARY SHALL COVER PRESCRIPTION DRUGS IN ALL CATEGORIES AND CLASSES FOR ALL DISEASE STATES AND PROVIDE A BROAD RANGE OF THERAPEUTIC OPTIONS FOR ALL USP MODEL GUIDELINES FOR FORMULARY KEY DRUG TYPES AND DESIGNATED DRUG CLASSES, INCLUDING ALL OR SUBSTANTIALLY ALL DRUGS IN THE ANTIDEPRESSANT, ATYPICAL ANTIPSYCHOTIC, ANTINEOPLASTIC, ANTICONVULSANT, IMMUNOSUPPRESSANT AND ANTI-RETROVIRAL CLASSES. A MANAGED CARE PROVIDER SHALL ALSO COVER A PRESCRIPTION DRUG WHEN THE PHARMACY AND THERAPEUTICS COMMITTEE DETERMINES A DRUG IS SIGNIFICANTLY MORE CLINICALLY EFFECTIVE OR SAFE THAN OTHER DRUGS IN THE CLASS.

(D) A MANAGED CARE PROVIDER SHALL PROVIDE COVERAGE FOR NON-PREFERRED/NON-FORMULARY PRESCRIPTION DRUGS THAT WERE PRESCRIBED TO THE PARTICIPANT TO TREAT A CONDITION THAT IS TREATED ON AN ONGOING BASIS, EITHER WITH CONTINUOUS MEDICATION OR A MEDICATION TAKEN AS NEEDED PRIOR TO PRESCRIPTION DRUGS BEING ADDED TO THE MANAGED CARE PROGRAM OR BEING REMOVED FROM THE FORMULARY.

(E) THE PRIOR AUTHORIZATION SHALL BE PROCESSED, AND A RESPONSE SENT TO THE REQUESTING PHARMACIST WITHIN TWO BUSINESS DAYS OF SUBMISSION. PRIOR TO THE COMPLETION OF THE PRIOR AUTHORIZATION PROCESS, A PLAN SHALL COVER A MINIMUM SEVENTY-TWO HOUR SUPPLY OF THE PRESCRIBED DRUG AND THE PHARMACIST SHALL BE REIMBURSED FOR DISPENSING A SEVENTY-TWO HOUR SUPPLY TO AN ENROLLEE.

(F) A MANAGED CARE PROVIDER SHALL ONLY IMPLEMENT REASONABLE AND GENERALLY ACCEPTABLE FORMULARY AND UTILIZATION MANAGEMENT INCLUDING, BUT NOT LIMITED TO, PRIOR AUTHORIZATION, STEP THERAPY AND GENERIC SUBSTITUTIONS; PROVIDED SUCH TOOLS ARE REVIEWED AND APPROVED BY THE PHARMACY AND THERAPEUTICS COMMITTEE BASED ON THE STRENGTH OF SCIENTIFIC EVIDENCE, STANDARDS OF PRACTICE AND NATIONALLY ACCEPTED TREATMENT GUIDELINES.

(G) PRIOR TO REMOVING A COVERED DRUG FROM ITS FORMULARY, A MANAGED CARE PROVIDER MUST PROVIDE AT LEAST SIXTY DAYS NOTICE TO ENROLLEES, AUTHORIZED PRESCRIBERS, NETWORK PHARMACIES AND PHARMACISTS PRIOR TO THE DATE SUCH CHANGE BECOMES EFFECTIVE.

(H) A MANAGED CARE PROVIDER SHALL REVIEW, THROUGH THE PHARMACY AND THERAPEUTICS COMMITTEE, ALL DRUGS THAT RECEIVE APPROVAL FROM THE FEDERAL FOOD AND DRUG ADMINISTRATION WITHIN NINETY DAYS OF THEIR RELEASE IN THE MARKET, AND DECISIONS REGARDING INCLUSION IN ANY FORMULARY OR PREFERRED DRUG LIST SHALL BE MADE WITHIN ONE HUNDRED EIGHTY DAYS OF THEIR RELEASE IN THE MARKET. PROVIDED, HOWEVER, THAT IN THE CASE OF THOSE DRUGS WHICH HAVE RECEIVED PRIORITY EXPEDITED REVIEW AND APPROVAL OF THE FOOD AND DRUG ADMINISTRATION, A DECISION FOR INCLUSION IN THE FORMULARY OR PREFERRED DRUG LIST SHALL BE MADE WITHIN NINETY DAYS OF SUCH APPROVAL BY THE FOOD AND DRUG ADMINISTRATION.

(I) A MANAGED CARE PROVIDER SHALL BE SUBJECT TO AND SHALL USE THE GRIEVANCE AND APPEALS PROCESS, INCLUDING THE RIGHT TO EXTERNAL REVIEW, MANDATED BY ARTICLE FORTY-NINE OF THE PUBLIC HEALTH LAW AND TITLE 42 OF THE CODE OF FEDERAL REGULATIONS, PART 438, UPON RECEIPT OF AN APPEAL OF A DENIAL OF A REQUESTED PRESCRIPTION DRUG, INCLUDING A DENIAL BASED ON STEP THERAPY OR FAIL FIRST PROTOCOLS.

(J) ON OR BEFORE APRIL FIRST, TWO THOUSAND THIRTEEN, THE DEPARTMENT OF HEALTH SHALL DEVELOP STANDARDIZED DRUG PRIOR AUTHORIZATION REQUEST FORMS TO BE UTILIZED BY HEALTHCARE PROVIDERS, AND ACCEPTED BY MANAGED CARE ORGANIZATIONS CONTRACTED BY THE STATE. TO THE EXTENT ELECTRONIC PRESCRIBING SYSTEMS ARE USED, ELECTRONIC PRIOR AUTHORIZATION CAPABILITIES SHALL BE INCORPORATED INTO THE PROGRAM.

27. THE DEPARTMENT OF HEALTH SHALL PREPARE A REPORT NO LATER THAN EIGHTEEN MONTHS AFTER THE IMPLEMENTATION OF ANY EXPANSION OF MANAGED CARE TO A NEW POPULATION AND/OR FOR NEW BENEFITS OR SERVICES. THE DEPARTMENT SHALL POST A DRAFT REPORT ON ITS WEBSITE AND PROVIDE AN OPPORTUNITY FOR PUBLIC COMMENT. THE FINAL REPORT SHALL BE SUBMITTED TO THE GOVERNOR AND THE LEGISLATURE, ALONG WITH A DESCRIPTION OF THE PROCESS PROVIDED FOR PUBLIC INPUT. THE REPORT SHALL INCLUDE AN ASSESSMENT OF THE FOLLOWING:

(A) THE IMPACT OF MANAGED CARE ON PATIENT ACCESS TO CARE, INCLUDING AN EVALUATION OF ANY BARRIERS TO USE OF SERVICES, INCLUDING PRESCRIPTION DRUGS, CREATED BY THE USE OF MEDICAL MANAGEMENT OR COST CONTAINMENT TOOLS;

(B) THE IMPACT OF THE MANAGED CARE EXPANSION ON UTILIZATION OF SERVICES, QUALITY OF CARE AND PATIENT OUTCOMES; AND

(C) THE USE OF PRIOR AUTHORIZATION AND OTHER UTILIZATION MANAGEMENT TOOLS, INCLUDING AN ASSESSMENT OF WHETHER THESE TOOLS POSE AN UNDUE ADMINISTRATIVE BURDEN FOR PHYSICIANS AND/OR CREATE BARRIERS TO NEEDED CARE.

S 3. This act shall take effect immediately; provided, however, that the amendments to section 364-j of the social services law made by sections one and two of this act shall not affect the repeal of such section and shall be deemed repealed therewith.