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

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I N A S S E M B L Y

March 3, 2016

Introduced by M. of A. LAVINE, DUPREY -- read once and referred to the Committee on Health -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the public health law, in relation to audits of pharmacies

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

Section 1. The public health law is amended by adding a new section 280-b to read as follows:

S 280-B. PHARMACY AUDITS. 1. DEFINITIONS. AS USED IN THIS SECTION, THE FOLLOWING TERMS SHALL HAVE THE FOLLOWING MEANINGS:

(A) "AUDIT" MEANS A REVIEW OF THE RECORDS OF A PHARMACY BY OR ON BEHALF OF AN ENTITY THAT PAYS FOR OR REIMBURSES THE COST OF PHARMACEUTICAL PRODUCTS AND HEALTH CARE SERVICES THAT IS CONDUCTED AT A PHARMACY OR FROM A REMOTE LOCATION OTHER THAN A PHARMACY.

(B) "ENTITY" MEANS:

(I) A PHARMACY BENEFITS MANAGER;

(II) A HEALTH PLAN;

(III) A STATE AGENCY, EXCEPT THE OFFICE OF THE MEDICAID INSPECTOR GENERAL;

(IV) AN INSURER;

(V) A THIRD PARTY ADMINISTRATOR;

(VI) A MANAGED CARE ORGANIZATION; OR

(VII) A COMPANY, GROUP OR AGENT THAT REPRESENTS OR IS ENGAGED BY ANY OF THESE.

(C) "PHARMACY BENEFITS MANAGER" MEANS AN ENTITY THAT CONTRACTS WITH PHARMACIES OR PHARMACY CONTRACTING AGENTS ON BEHALF OF A HEALTH PLAN, STATE AGENCY, INSURER, MANAGED CARE ORGANIZATION, OR OTHER THIRD PARTY PAYER TO PROVIDE PHARMACY BENEFIT SERVICES OR ADMINISTRATION.

(D) "PHARMACY" HAS THE SAME MEANING AS SET FORTH IN SECTION SIX THOUSAND EIGHT HUNDRED TWO OF THE EDUCATION LAW.

(E) "FRAUD" MEANS AN INTENTIONAL DECEPTION OR MISREPRESENTATION MADE BY A PERSON WITH THE KNOWLEDGE THAT THE DECEPTION COULD RESULT IN SOME

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

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UNAUTHORIZED BENEFIT TO HIMSELF OR SOME OTHER PERSON. IT INCLUDES ANY ACT THAT CONSTITUTES FRAUD UNDER APPLICABLE FEDERAL OR STATE LAW.

(F) "AUDIT PERIOD" MEANS THE TIME PERIOD THAT BEGINS ON THE DAY ON WHICH THE AUDITOR ARRIVES AT THE PHARMACY FOR THE ON-SITE AUDIT OR IN THE CASE OF A REMOTE AUDIT, THE DAY ON WHICH THE PHARMACY SUBMITS THE CLAIMS REQUESTED IN THE AUDIT. THE AUDIT PERIOD ENDS ON THE DAY ON WHICH THE FINAL AUDIT REPORT IS RECEIVED BY THE SUPERVISING PHARMACIST, THE PHARMACY CORPORATE OFFICE OR THE PHARMACY ACCEPTS THE SETTLEMENT OF THE AUDIT, WHICHEVER IS LATER.

2. A CONTRACT BETWEEN A PHARMACY BENEFIT MANAGER OR ALTERNATIVELY THE AGENT OF A PHARMACY AND A PHARMACY BENEFIT MANAGER SHALL INCLUDE A PROCESS BY WHICH A PHARMACY MAY APPEAL A FINDING IN A PRELIMINARY AUDIT REPORT OR A FINAL AUDIT REPORT. THE AUDIT APPEAL PROCESS SHALL BE PRESENTED TO THE PHARMACY IN WRITING OR ELECTRONICALLY PRIOR TO THE ISSUING OF ANY AUDIT NOTIFICATION AND SHALL PROVIDE THE NAME AND ELECTRONIC ADDRESS OF THE INDIVIDUAL RESPONSIBLE FOR PROCESSING APPEALS, A REASONABLE TIMEFRAME FOR FILING AN APPEAL AND FOR NOTICE OF THE RESULT OF ANY APPEAL. THE APPEAL PROCESS SHALL BE INCLUDED WITH A NOTICE OF AUDIT. IF THE RESULT OF THE INTERNAL APPEAL PROCESS IS NOT SATISFACTORY TO EITHER PARTY, THAT PARTY MAY SEEK MEDIATION FROM AN OUTSIDE ENTITY ACCEPTABLE TO BOTH PARTIES. THE ENTITY CONDUCTING AN AUDIT OF A PHARMACY OR ITS AGENT MAY NOT RECEIVE PAYMENT BASED ON A PERCENTAGE OF THE AMOUNT RECOVERED.

3. AN ENTITY CONDUCTING AN ON-SITE AUDIT OF A PHARMACY SHALL:

(A) PROVIDE AT LEAST FIFTEEN DAYS ADVANCE WRITTEN NOTICE OF AN AUDIT BY MAIL OR COMMON CARRIER, RETURN RECEIPT REQUESTED, OR ELECTRONICALLY WITH ELECTRONIC RECEIPT CONFIRMATION, ADDRESSED TO THE SUPERVISING PHARMACIST OF RECORD AND THE PHARMACY CORPORATE OFFICE WHERE APPLICABLE.

(B) ALLOW A PHARMACY SEVEN DAYS AFTER RECEIVING NOTICE OF AN ON-SITE AUDIT IN WHICH TO REQUEST A CHANGE OF THE AUDIT DATE. THE ENTITY CONDUCTING THE AUDIT SHALL GRANT REASONABLE REQUESTS.

(C) INCLUDE IN THE WRITTEN ADVANCE NOTICE OF AN ON-SITE AUDIT THE LIST OF SPECIFIC AND COMPLETE PRESCRIPTION NUMBERS TO BE INCLUDED IN THE AUDIT.

(D) EXCEPT IN CASES OF FRAUD, LIMIT AUDITS TO NO MORE THAN ONE AUDIT BY THE SAME ENTITY IN A TWELVE-MONTH PERIOD.

(E) LIMIT THE TOTAL NUMBER OF PRESCRIPTIONS AUDITED TO NO MORE THAN ONE HUNDRED RANDOMLY SELECTED IN A TWELVE-MONTH PERIOD, EXCEPT IN CASES OF ALLEGED FRAUD.

(F) LIMIT AUDITS TO CLAIMS ADJUDICATED WITHIN THE PREVIOUS TWENTY-FOUR MONTHS.

(G) REFRAIN FROM ON-SITE AUDITS DURING THE FIRST FIVE CALENDAR DAYS OF ANY MONTH OR THE DAY BEFORE OR AFTER A FEDERAL HOLIDAY DUE TO HIGH ANTICIPATED PRESCRIPTION VOLUME, EXCEPT WITH CONSENT FROM THE SUPERVISING PHARMACIST.

4. AN ENTITY CONDUCTING A REMOTE OR DESK AUDIT SHALL:

(A) PROVIDE AT LEAST FIVE BUSINESS DAYS ADVANCE WRITTEN NOTICE OF AN AUDIT BY MAIL OR COMMON CARRIER, RETURN RECEIPT REQUESTED, OR ELECTRONICALLY WITH ELECTRONIC RECEIPT CONFIRMATION, ADDRESSED TO THE SUPERVISING PHARMACIST OF RECORD AND THE PHARMACY CORPORATE OFFICE WHERE APPLICABLE.

(B) IN THE CASE OF AN ELECTRONIC NOTIFICATION, CONFIRM THAT THE SUPERVISING PHARMACIST OF RECORD OR THE PHARMACY CORPORATE OFFICE HAS ACKNOWLEDGED RECEIPT BEFORE PROCEEDING WITH THE AUDIT.

(C) ALLOW A MINIMUM OF TEN BUSINESS DAYS FOR A PHARMACY TO COMPLY WITH AN AUDIT REQUEST SENT ELECTRONICALLY, BEGINNING ON THE DAY ON WHICH THE

SUPERVISING PHARMACIST OF RECORD OR THE PHARMACY CORPORATE OFFICE ACKNOWLEDGED RECEIPT OF THE AUDIT NOTIFICATION.

(D) LIMIT THE NUMBER OF CLAIMS TO NO MORE THAN TWENTY-FIVE RANDOMLY SELECTED CLAIMS.

(E) IF A REMOTE OR DESK AUDIT REVEALS THE NECESSITY FOR A REVIEW OF ADDITIONAL CLAIMS, THE FOLLOW-UP AUDIT SHALL BE CONDUCTED ON-SITE.

5. AN ENTITY CONDUCTING EITHER AN ON-SITE AUDIT OR A DESK AUDIT SHALL:

(A) AUDIT A PHARMACY USING THE SAME STANDARDS AND PARAMETERS USED IN AUDITING SIMILARLY SITUATED PHARMACIES ON BEHALF OF THE SAME AUDIT CLIENT. ANY DOCUMENTATION AND RECORDS REQUIRED BY AN AUDITOR DURING AN AUDIT SHALL BE OF THE SAME TYPE AS DOCUMENTATION AND RECORDS REQUIRED FOR OTHER SIMILARLY SITUATED PHARMACIES.

(B) ACCEPT THAT THE FINAL ADJUDICATION OF A CLAIM MEANS THAT THE DRUG, PRESCRIBER AND PATIENT ELIGIBILITY HAS BEEN APPROVED.

(C) ACCEPT INFORMATION PERTAINING TO THE RECORDS OF A HOSPITAL, PHYSICIAN OR OTHER AUTHORIZED HEALTHCARE PROVIDER WRITTEN OR TRANSMITTED BY ANY MEANS OF COMMUNICATION AS VALIDATION OF THE PHARMACY RECORD WITH RESPECT TO ORDERS OR REFILLS OF ANY LEGEND OR NARCOTIC DRUG.

(D) ACCEPT AS VALIDATION THE ELECTRONIC OR PHYSICAL COPY OF A PRESCRIPTION THAT COMPLIES WITH STATE LAW.

(E) ACCEPT AS VALIDATION ANY REASONABLY CLEAR AND ACCURATE ELECTRONIC DOCUMENTATION SUCH AS A SIGNATURE LOG OR SCANNED PATIENT RECORDS INDICATING THAT THE PRESCRIPTION WAS PICKED UP, DELIVERED BY THE PHARMACY OR SENT TO THE PATIENT BY COMMON CARRIER. IF SUCH RECORDS ARE NOT AVAILABLE, ACCEPT WRITTEN VERIFICATION FROM THE PATIENT THAT THE PRESCRIPTION WAS RECEIVED.

(F) VALIDATION OF APPROPRIATE DAYS' SUPPLY AND DRUG DOSING MUST BE BASED ON MANUFACTURER GUIDELINES AND DEFINITIONS, OR IN THE CASE OF TOPICAL PRODUCTS OR TITRATED PRODUCTS, THE PROFESSIONAL JUDGMENT OF THE PHARMACIST BASED ON COMMUNICATION WITH THE PATIENT OR PRESCRIBER.

(G) AN AUDIT THAT INVOLVES CLINICAL OR PROFESSIONAL JUDGMENT MUST BE CONDUCTED BY OR IN CONSULTATION WITH A PHARMACIST WITH A VALID NEW YORK STATE LICENSE.

(H) IN THE CASE OF INVOICE AUDITS, AN ENTITY SHALL:

(I) ACCEPT AS VALIDATION INVOICES FROM ANY WHOLESALER REGISTERED WITH THE DEPARTMENT OF EDUCATION FROM WHICH THE PHARMACY HAS PURCHASED PRESCRIPTION DRUGS;

(II) ACCEPT AS VALIDATION A RECEIPT FROM ANOTHER PHARMACY FOR TRANSACTIONS AUTHORIZED UNDER STATE LAW;

(III) ACCEPT INVOICES THAT SUPPORT INVENTORY ON HAND; AND

(IV) REQUEST DOCUMENTATION PERTAINING ONLY TO THE CLAIMS UNDER AUDIT.

6. AN ENTITY CONDUCTING AN AUDIT OF A PHARMACY SHALL PROVIDE THE PHARMACY AND THE PHARMACY CORPORATE OFFICE WHERE APPLICABLE WITH A PRELIMINARY AUDIT REPORT NO LATER THAN FORTY-FIVE DAYS AFTER THE DATE ON WHICH THE AUDIT WAS COMPLETED AND SHALL CONTAIN CLAIM LEVEL INFORMATION FOR ANY DISCREPANCY FOUND. THE PRELIMINARY AUDIT REPORT SHALL BE SENT BY MAIL OR COMMON CARRIER WITH RETURN RECEIPT REQUESTED OR ELECTRONICALLY WITH ELECTRONIC RECEIPT CONFIRMATION.

7. THE PHARMACY RECEIVING THE PRELIMINARY AUDIT REPORT SHALL HAVE NO FEWER THAT FORTY-FIVE DAYS IN WHICH TO PRODUCE DOCUMENTATION TO ADDRESS ANY FINDINGS OR CONTEST ANY FINDINGS IN THE REPORT IN ACCORDANCE WITH THE AUDIT PROCEDURE. THE ENTITY SHALL CONSIDER A REASONABLE REQUEST FROM THE PHARMACY FOR AN EXTENSION OF TIME TO SUBMIT DOCUMENTATION TO ADDRESS OR CORRECT ANY FINDINGS IN THE REPORT.

8. IF THE AUDIT RESULTS IN A DISPUTE OR DENIAL OF A CLAIM, THE ENTITY CONDUCTING THE AUDIT SHALL ALLOW THE PHARMACY TO RESUBMIT A CORRECTED

CLAIM USING ANY COMMERCIALLY REASONABLE METHOD INCLUDING FACSIMILE, MAIL OR ELECTRONIC MAIL.

9. AN ENTITY CONDUCTING AN AUDIT MUST PROVIDE THE PHARMACY THAT IT THE SUBJECT OF AN AUDIT AND THE PHARMACY CORPORATE OFFICE WHERE APPLICABLE WITH A FINAL AUDIT REPORT CONTAINING CLAIM LEVEL INFORMATION FOR ANY DISCREPANCY FOUND NO LATER THAN SIXTY DAYS AFTER THE PRELIMINARY AUDIT REPORT WAS RECEIVED BY THE PHARMACY OR SIXTY DAYS FOLLOWING THE DAY ON WHICH THE PHARMACY CONTESTED THE PRELIMINARY REPORT, WHICHEVER IS LATER.

10. WITH REGARD TO FINANCIAL RECOUPMENTS OR RECOVERIES:

(A) AN ENTITY CONDUCTING AN AUDIT OF A PHARMACY MAY NOT ASSESS A RECOUPMENT ASSOCIATED WITH A TYPOGRAPHICAL, SCRIVNER'S OR CLERICAL ERROR. A CLERICAL ERROR IS AN ERROR THAT DOES NOT RESULT IN ACTUAL FINANCIAL HARM TO THE COVERED ENTITY OR CONSUMER AND DOES NOT INCLUDE THE DISPENSING OF AN INCORRECT DOSE, AMOUNT OR TYPE OF MEDICATION OR DISPENSING A PRESCRIPTION DRUG TO THE WRONG PERSON.

(B) EXCEPT IN CASES IN WHICH FRAUD IS EVIDENCED, AN ENTITY'S FINDING THAT A CLAIM WAS INCORRECTLY PRESENTED OR PAID MUST BE BASED ON IDENTIFIED TRANSACTIONS AND NOT BASED ON PROBABILITY SAMPLING, EXTRAPOLATION OR OTHER MEANS THAT PROJECT AN ERROR USING THE NUMBER OF PATENTS SERVED WHO HAVE A SIMILAR DIAGNOSIS OR THE NUMBER OF SIMILAR PRESCRIPTIONS OR REFILLS FOR SIMILAR DRUGS.

(C) AN ENTITY MAY NOT CHARGE INTEREST DURING THE AUDIT PERIOD.

(D) EXCEPT FOR ADDITIONAL SAFETY REQUIREMENTS FOR AN INDIVIDUAL DRUG REQUIRED BY THE MANUFACTURER OR BY THE FEDERAL FOOD AND DRUG ADMINISTRATION, A RECOUPMENT MAY NOT BE BASED ON DOCUMENTATION REQUIREMENTS THAT EXCEED REQUIREMENTS OF THE NEW YORK STATE BOARD OF PHARMACY OR THE PERFORMANCE OF A PROFESSIONAL DUTY THAT EXCEEDS REQUIREMENTS OF THE NEW YORK STATE BOARD OF PHARMACY.

(E) AMOUNTS RECOVERED PURSUANT TO AUDIT RESULTS SHALL BE IDENTIFIED IN REMITTANCE STATEMENTS AND REFLECTED IN THE 835 EDI REMITTANCE BY CLAIM OR PRESCRIPTION NUMBERS LEVEL AND SHALL NOT APPEAR AS A LUMP SUM ADJUSTMENT.

(F) RECOUPMENTS OF ANY DISPUTED FUNDS SHALL OCCUR AFTER THE FINAL INTERNAL DISPOSITION OF THE AUDIT, INCLUDING THE APPEALS PROCESS SET FORTH IN THIS SECTION.

(G) AN ENTITY MAY RECOUP THE DISPENSING FEE ONLY IF:

(I) THE PRESCRIPTION WAS NOT ACTUALLY DISPENSED;

(II) THE PRESCRIBER DENIED AUTHORIZATION;

(III) THE PRESCRIPTION WAS A DISPENSING ERROR BY THE PHARMACY;

(IV) THE AMOUNT OF THE DISPENSING FEE PAID WAS INCORRECT; OR

(V) THE IDENTIFIED ERROR IS BASED SOLELY ON AN EXTRA PAID DISPENSING FEE.

(H) IN THE CASE OF ERRORS THAT HAVE NO FINANCIAL HARM TO THE PATIENT OR TO THE PLAN, THE AUDITING ENTITY MAY NOT ASSESS ANY CHARGEBACKS.

S 2. This act shall take effect on the ninetieth day after it shall have become law.