1511

2009-2010 Regular Sessions

IN SENATE

February 2, 2009

Introduced by Sens. DeFRANCISCO, MORAHAN, VOLKER -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law, in relation to audits of Medicaid pharmacy providers

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

- 1 Section 1. The public health law is amended by adding a new section 2 32-a to read as follows:
 - S 32-A. AUDITING STANDARDS. NOTWITHSTANDING ANY OTHER PROVISION OF LAW, AN AUDIT OF THE MEDICAID-RELATED RECORDS OF A PHARMACY PROVIDER SHALL BE CONDUCTED AS FOLLOWS:

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- 1. THE DEPARTMENT, THE OFFICE, OR ANY CONTRACT AUDITOR CONDUCTING AN AUDIT OF A PHARMACY PROVIDER'S MEDICAID OPERATIONS ON BEHALF OF THE DEPARTMENT SHALL PROVIDE APPROPRIATE INDIVIDUALS IN THE CENTRAL OFFICES OF THE PROVIDER'S OPERATIONS WITH NOTICE AT LEAST SEVEN BUSINESS DAYS PRIOR TO AN ON-SITE AUDIT. AN AUDIT MAY NOT BE SCHEDULED DURING THE FIRST FIVE BUSINESS DAYS OF ANY CALENDAR MONTH.
- 2. THE DEPARTMENT, THE OFFICE, OR A CONTRACT AUDITOR SHALL ACCEPT ELECTRONIC RECORDS FOR AUDITING UNDER THE SAME TERMS AND CONDITIONS AND FOR THE SAME PURPOSES AS THE PAPER ANALOGS OF SUCH RECORDS, TO THE EXTENT SUCH RECORDS ARE OTHERWISE ACCEPTABLE AND LEGAL UNDER STATE AND FEDERAL PHARMACY, FOOD AND DRUG, AND MEDICAID LAWS. POINT OF SALE ELECTRONIC REGISTER DATA MAY QUALIFY AS PROOF OF DELIVERY TO THE MEDICAID RECIPIENT, AND ELECTRONIC BENEFICIARY SIGNATURE LOGS, ELECTRONIC TRACKING OF PRESCRIPTIONS, ELECTRONIC PRESCRIBER PRESCRIPTION TRANSMISSIONS, AND IMAGERY OF HARD COPY PRESCRIPTIONS SHALL BE ACCEPTABLE.
- AND IMAGERY OF HARD COPY PRESCRIPTIONS SHALL BE ACCEPTABLE.

 3. IF AN AUDIT IS TO BE CONDUCTED BY A CONTRACT AUDITOR, THE CONTRACT
 AUDITOR'S PAYMENT FOR THE AUDIT MAY NOT BE BASED ON THE NUMBER OF CHALLENGED OR DENIED CLAIMS IDENTIFIED BY THE CONTRACT AUDITOR OR THE AMOUNT
 ALLEGED BY THE AUDITOR TO BE OWED.

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

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 4. EACH MEDICAID PHARMACY AUDIT SHALL BE CONDUCTED BY A FIELD AGENT WHO POSSESSES THE REQUISITE EXPERTISE IN THE RELEVANT PROVIDER PRACTICE. THE AUDITOR SHALL CONDUCT THE AUDIT:

- (A) IN ACCORDANCE WITH GENERALLY ACCEPTED:
- (I) ACCOUNTING PRINCIPLES, STANDARDS, AND PROCEDURES; AND
- (II) AUDITING PRINCIPLES, STANDARDS, AND PROCEDURES; AND
- (B) USING STANDARDS AND PARAMETERS ESTABLISHED BY FINAL REGULATION THAT ARE IDENTICAL FOR ALL AUDITS CONDUCTED.
- 9 5. ANY AUDIT INVOLVING THE REVIEW OF CLINICAL OR PROFESSIONAL JUDGMENT 10 SHALL BE CONDUCTED BY OR IN CONSULTATION WITH THE STATE BOARD OF PHARMA-11 CY.
 - 6. THE PERIOD COVERED BY AN AUDIT MAY NOT EXCEED ONE YEAR FROM THE DATE THE EARLIEST CLAIM WAS SUBMITTED TO THE DEPARTMENT FOR ADJUDICATION.
 - 7. EACH PHARMACY PROVIDER SHALL BE AUDITED ACCORDING TO THE SAME STAN-DARDS, PARAMETERS, AND PROCEDURES AS OTHER SIMILAR AND SIMILARLY SITUATED PHARMACY PROVIDERS AUDITED BY THE DEPARTMENT, THE OFFICE, OR THE CONTRACT AUDITOR.
 - 8. A CLERICAL OR RECORD-KEEPING ERROR SUCH AS A TYPOGRAPHICAL ERROR, A SCRIVENER'S ERROR, OR A COMPUTER ERROR IN A REQUIRED DOCUMENT OR RECORD SUBMITTED IN AN AUDIT MAY NOT BE DEEMED BY THE DEPARTMENT, THE OFFICE, OR THE CONTRACT AUDITOR TO CONSTITUTE A WILLFUL VIOLATION OF THE STATE MEDICAID LAW, AND MAY NOT BE SUBJECT TO CRIMINAL PENALTIES WITHOUT PROOF OF A WILLFUL INTENT TO COMMIT FRAUD.
 - 9. A FINDING OF AN OVERPAYMENT OR UNDERPAYMENT MAY BE DETERMINED USING PROBABILITY SAMPLING OR EXTRAPOLATION BASED ON THE NUMBER OF PATIENTS SERVED HAVING A SIMILAR DIAGNOSIS, OR ON THE NUMBER OF SIMILAR ORDERS OR REFILLS OF SIMILAR DRUGS.
 - 10. THE DEPARTMENT, THE OFFICE, OR A CONTRACT AUDITOR CONDUCTING AN AUDIT OF A MEDICAID PHARMACY MAY NOT USE PROBABILITY SAMPLING OR EXTRAPOLATION TO DETERMINE OVERPAYMENT AMOUNTS DUE TO BE RECOVERED BY RECOUPMENT, OFFSET, OR OTHERWISE FROM THE PHARMACY UNLESS THE DEPARTMENT AND THE AUDITING ENTITY DETERMINE THAT:
 - (A) THERE IS A PATTERN OF A HIGH LEVEL OF PAYMENT ERROR SUSTAINED BY THAT SPECIFIC PHARMACY PROVIDER THROUGHOUT THE AUDITED PERIOD;
 - (B) IF THE OVERPAYMENTS ARE THE RESULT OF CLERICAL OR RECORD-KEEPING ERRORS, THEY ARE WILLFUL;
 - (C) DOCUMENTED EDUCATIONAL INTERVENTION HAS FAILED TO CORRECT THAT SUSTAINED HIGH LEVEL OF PAYMENT ERROR;
 - (D) THE EXTRAPOLATION IS MADE FROM A STATISTICALLY VALID SAMPLE OF CLAIMS;
 - (E) THE LEVEL OF CONFIDENCE FROM EXTRAPOLATION IS PROJECTED BY AN INDEPENDENT STATISTICIAN NOT EMPLOYED BY OR CONNECTED TO THE AUDITING ENTITY TO BE NINETY-FIVE PERCENT OR GREATER; AND
 - (F) THE SAMPLE SIZE OF THE CLAIMS REVIEWED IS AT LEAST TEN PERCENT OF THE TOTAL CLAIMS FOR WHICH OVERPAYMENTS DUE ARE BEING EXTRAPOLATED.
 - 11. AN EXTRAPOLATION MAY NOT BE BASED ON THE PRACTICE PATTERNS OF ANY PHARMACY PROVIDER OTHER THAN THE INDIVIDUAL PROVIDER BEING AUDITED.
 - 12. ANY PROBABILITY SAMPLING AND EXTRAPOLATION PERFORMED BY THE DEPARTMENT, THE OFFICE, OR A CONTRACT AUDITOR IN THE COURSE OF AN AUDIT SHALL BE PERFORMED IN CONFORMITY WITH GENERALLY ACCEPTED STATISTICAL STANDARDS AND PROCEDURES, WHICH SHALL BE MADE AVAILABLE, UPON REQUEST, TO THE AUDITED PHARMACY.
- 13. AN AUDITED PHARMACY SHALL BE ALLOWED AT LEAST TEN BUSINESS DAYS TO PRODUCE DOCUMENTATION TO ADDRESS THE AUDITING ENTITY'S QUESTIONS ABOUT A DOCUMENT OR RECORD PRODUCED IN AN AUDIT.

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14. A PHARMACY MAY USE THE RECORDS OR ORDER OF A PRESCRIBING PHYSI-CIAN, HOSPITAL, OR OTHER AUTHORIZED PRESCRIBER OF DRUGS OR SUPPLIES, WRITTEN OR TRANSMITTED BY ANY LEGAL AND ACCEPTABLE MEANS OF COMMUNI-CATION, TO VALIDATE A PHARMACY RECORD OF A PRESCRIPTION DRUG ORDER OR REFILL OF A LEGEND OR NARCOTIC DRUG.

- 15. THE DEPARTMENT, THE OFFICE, OR THE CONTRACT AUDITOR SHALL DELIVER TO RESPONSIBLE INDIVIDUALS IN THE CENTRAL OFFICES OF THE OPERATIONS OF THE AUDITED PHARMACY:
- (A) A PRELIMINARY AUDIT REPORT, WITHIN NINETY CALENDAR DAYS AFTER THE 9 10 CONCLUSION OF THE AUDIT.
 - (B) A FINAL AUDIT REPORT, WITHIN ONE HUNDRED EIGHTY CALENDAR DAYS LATER OF RECEIPT OF THE AUDIT REPORT BY THE PHARMACY OR THE AFTER THE ISSUANCE OF ANY FINAL DECISION IN AN ADMINISTRATIVE APPEAL OF PRELIMINARY AUDIT REPORT.
 - 16. ABSENT FRAUD OR ABUSE BY THE AUDITED PHARMACY PROVIDER, THE DEPARTMENT OF HEALTH OR THE OFFICE MAY NOT RECOUP ANY PART OF A CLAIM THAT WAS, IN WHOLE OR PART, PREVIOUSLY ADJUDICATED AS FULLY PAYABLE.
 - 17. WHENEVER A FINAL DETERMINATION IS MADE THAT A RECOVERY FROM AN AUDITED PHARMACY PROVIDER IS WARRANTED, THE FUNDS MAY BE RECOVERED ONLY THROUGH THE FOLLOWING METHODS:
 - THE DEPARTMENT OR THE OFFICE MAY RECOVER FUNDS BY CHECK IF THE PHARMACY PROVIDER IS NOTIFIED ON THE WRITTEN NOTIFICATION OF THE FINAL AUDIT DETERMINATION OF:
 - (I) ANY NECESSARY PAYEE INFORMATION;
 - (II) CLAIM DETAILS, INCLUDING THE AMOUNTS OF EACH CONFIRMED OVERPAID OR MISPAID CLAIM; AND
 - (III) TOTAL AMOUNT DUE.
 - (B) THE DEPARTMENT, THE OFFICE, OR A CONTRACT AUDITOR MAY RECOVER FROM A PHARMACY PROVIDER THROUGH ELECTRONIC REMITTANCE IN THE FEDERALLY-AP-PROVED FORMAT THAT IS IN PLACE AT THE TIME OF THE FUNDS RECOVERY, IF CLAIMS ARE DETAILED WITH THE APPROPRIATE NATIONAL COUNCIL PRESCRIPTION DRUG PROGRAMS ADJUSTMENT CODE INDICATING AUDIT. EACH CLAIM LEVEL ELECTRONIC REMITTANCE RECOVERY SHALL INCLUDE THE PROVIDER'S IDEN-TIFICATION NUMBER, THE PRESCRIPTION NUMBER FOR THE RECOVERED CLAIM, THE DATE OF SERVICE OF THE CLAIM TRANSACTION, AND THE RECOVERY AMOUNT FOR SUCH CLAIM.
 - THIS SECTION DOES NOT APPLY TO ANY INVESTIGATIVE AUDIT CONDUCTED BY THE DEPARTMENT, THE OFFICE, OR A CONTRACT AUDITOR WHEN THE DEPARTMENT HAS REASONABLE AND RELIABLE EVIDENCE THAT A CLAIM SUBMITTED TO THE DEPARTMENT FOR PAYMENT WAS SUBMITTED WITH A KNOWING AND WILLFUL INTENT TO DEFRAUD THE DEPARTMENT OR OTHERWISE KNOWINGLY AND WILLFULLY MISREPRE-SENT THE CLAIM.
- 19. THE AUDIT CRITERIA SET FORTH IN THIS SECTION SHALL APPLY ONLY TO 44 AUDITS OF CLAIMS SUBMITTED FOR PAYMENT AFTER THE EFFECTIVE DATE OF THIS SECTION.
 - 20. WITHIN ONE HUNDRED TEN DAYS OF THE EFFECTIVE DATE OF THIS SECTION, THE DEPARTMENT AND THE OFFICE SHALL ESTABLISH BY FINAL REGULATION A PROCESS UNDER WHICH AN AUDITED PHARMACY PROVIDER MAY FILE AN ADMINISTRA-TIVE APPEAL WITH THE DEPARTMENT IF THE PROVIDER IS UNABLE TO RESOLVE A PRELIMINARY AUDIT DETERMINATION SATISFACTORILY. IF AN ADMINISTRATIVE APPEAL IS REOUESTED, THE AUDITED PHARMACY PROVIDER MAY NOT BE REOUIRED TO OBTAIN FORMAL REPRESENTATION BY LEGAL COUNSEL.
- 21. AN ADMINISTRATIVE APPEAL SHALL BE CONDUCTED BY THE DEPARTMENT OR 53 54 BY AN AD HOC PEER-REVIEW PANEL APPOINTED BY THE DEPARTMENT WHICH CONSISTS OF AT LEAST THREE PHARMACY PROVIDERS LICENSED IN THE STATE WHO

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1 ARE ACTIVELY ENGAGED IN THE PRACTICE OF PHARMACY IN THE STATE AND MUTU-2 ALLY AGREEABLE TO THE AUDITED PHARMACY AND THE DEPARTMENT.

- 3 22. IF, FOLLOWING AN ADMINISTRATIVE APPEAL, THE DEPARTMENT OR THE 4 REVIEW PANEL FIND THAT AN UNFAVORABLE AUDIT REPORT IS UNSUBSTANTIATED, 5 THE DEPARTMENT SHALL ISSUE A FINAL DISMISSAL OF THE FINDINGS OF THE 6 AUDIT REPORT WITH PREJUDICE, WITHOUT THE NEED FOR FURTHER PROCEEDINGS OR 7 PENALTY TO THE AUDITED PHARMACY.
- 8 23. THE AUDIT CRITERIA SET FORTH IN THIS SECTION SHALL APPLY ONLY TO 9 AUDITS OF CLAIMS SUBMITTED FOR PAYMENT AFTER THE EFFECTIVE DATE OF THIS 10 SECTION.
- 11 S 2. This act act shall take effect on the one hundred twentieth day 12 after it shall have become a law; provided, however, that effective 13 immediately, the addition, amendment and/or repeal of any rule or regu-14 lation necessary for the implementation of this act on its effective 15 date are authorized and directed to be made and completed on or before 16 such effective date.