THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL No. 643 Session of 2009

INTRODUCED BY DeLUCA, ARGALL, BAKER, BARBIN, BOYD, CALTAGIRONE, CARROLL, COHEN, CRUZ, DePASQUALE, DONATUCCI, FRANKEL, GALLOWAY, GEORGE, GOODMAN, HALUSKA, HENNESSEY, JOSEPHS, KORTZ, KULA, MANDERINO, MCILVAINE SMITH, MELIO, MILLARD, MUNDY, MURT, M. O'BRIEN, PALLONE, PARKER, PYLE, READSHAW, SIPTROTH, K. SMITH, STURLA, WALKO, YUDICHAK, GIBBONS AND HANNA, FEBRUARY 27, 2009

REFERRED TO COMMITTEE ON INSURANCE, FEBRUARY 27, 2009

AN ACT

Establishing One Pennsylvania, a program to consolidate and 1 2 unify procedures and requirements for the administration of all Commonwealth-funded, Commonwealth-administered and 3 Commonwealth-supported prescription drug programs; and 4 providing for reimbursement for pharmaceutical services. 5 6 The General Assembly of the Commonwealth of Pennsylvania 7 hereby enacts as follows: 8 Section 1. Short title. 9 This act shall be known and may be cited as the One 10 Pennsylvania Act. 11 Section 2. Definitions. 12 The following words and phrases when used in this act shall 13 have the meanings given to them in this section unless the 14 context clearly indicates otherwise: 15 "Adjudication." 16 (1)Except as provided in paragraph (2), an action taken 17 by the Office of Administration, the Secretary of

Administration or a prescription drug plan pursuant to this act that constitutes an adjudication as defined by 2 Pa.C.S. § 101 (relating to definitions), including any of the following:

5 (i) A decision to allow a provider to participate in 6 a prescription drug plan or to suspend, restrict or 7 revoke participation by a provider in a prescription drug 8 plan.

9 (ii) A decision by the Office of Administration to 10 include or exclude a medication from the formulary or 11 preferred drug list.

12 (iii) The establishment of provider reimbursement13 rates and formulas.

14 (iv) A decision to grant or deny prior authorization 15 for the dispensing of prescription drugs or to approve or 16 disapprove the dispensing of drugs not included on the 17 formulary or preferred drug list.

18 (v) An action taken by the program based upon audits
19 of claims submitted for reimbursement by providers.

(2) An action taken by the program with respect to
determining recipient eligibility shall not be deemed an
adjudication by the Office of Administration pursuant to its
authority under this act. Eligibility shall be determined by
the agency or entity under whose authority the prescription
drug plan is authorized.

26 "Alerts." Electronic communications between the Office of 27 Administration or the pharmacy benefits consolidation program 28 and pharmacies providing information pertaining to the 29 implementation of this act, including any of the following: 30 (1) Information regarding the preferred drug lists.

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1 (2) Preferred drug lists.

2 (3) Drug utilization review.

3 (4) Prior authorization.

4 (5) Disease management programs.

5 (6) Claims submission and adjudication procedures.

6 (7) Audits.

7 (8) Pharmacy and patient education.

8 "Best price." As defined under section 1927(c) of the Social
9 Security Act (49 Stat. 620, 42 U.S.C. § 1396r-8(c)).

10 "Medical assistance program." The program established 11 pursuant to Subarticle (f) of Article IV of the act of June 13, 12 1967 (P.L.31, No.21), known as the Public Welfare Code.

13 "Medicare recipient." An individual residing in this 14 Commonwealth who receives benefits under Part A of Subchapter 15 XVIII of Chapter 7 of the Social Security Act (49 Stat. 620, 42 16 U.S.C. § 301 et seq.) or who is enrolled under Part B, C or D of 17 Subchapter XVIII.

18 "Office of Administration." The Office of Administration of 19 the Commonwealth.

20 "Pharmaceutical manufacturer." A manufacturer as defined by 21 section 1927(k)(5) of the Social Security Act (49 Stat. 620, 42 22 U.S.C. § 1396r-8(k)(5)).

23 "Pharmacy." A pharmacy licensed pursuant to the act of 24 September 27, 1961 (P.L.1700, No.699), known as the Pharmacy 25 Act.

26 "Pharmacy Act." The act of September 27, 1961 (P.L.1700, No. 27 699), known as the Pharmacy Act.

28 "Pharmacy services." The provision of health care services 29 defined as the practice of pharmacy by the act of September 27, 30 1961 (P.L.1700, No.699), known as the Pharmacy Act.

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"Preferred drug list." A list of prescription medications
 covered under a prescription drug plan that may be dispensed by
 a prescription drug plan without prior authorization, subject to
 applicable limits and conditions.

5 "Prescription drug." A covered outpatient drug as defined by 6 section 1927(k)(2) of the Social Security Act (49 Stat. 620, 42 7 U.S.C. § 1396r-8(k)(2)).

8 "Prescription drug plan." A Commonwealth operation or funded 9 pharmaceutical program that pays or reimburses for prescription 10 drugs dispensed to individuals enrolled in the program that is 11 supported directly or indirectly, in whole or in part, by 12 Commonwealth public funds, including, but not limited to, all of 13 the following:

14 (1) The medical assistance program, the Special
15 Pharmaceutical Benefit Program in the Department of Public
16 Welfare.

17 (2) The Pharmaceutical Assistance Contract for the
18 Elderly (PACE) and any other pharmacy program administered by
19 the Commonwealth that is recognized by the Centers for
20 Medicare and Medicaid of the United States as a State
21 pharmaceutical assistance program.

(3) Programs or plans paying for prescription drugs
dispensed to employees as a retirement or employee benefit,
including programs established by the Public School
Employees' Retirement System, the State Employees' Retirement
System and the State Employees' Benefit Trust Fund.

(4) A pharmaceutical program that utilizes funds of this
Commonwealth, including the State Lottery Fund, to provide
assistance in obtaining prescription drugs to Medicare
recipients.

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1 (5) Programs where the Commonwealth purchases or 2 reimburses affiliates or designees for a pharmaceutical drug 3 benefit. The programs shall include the Children's Health 4 Insurance Program, Workers' Compensation Program and any 5 program involving the purchase or reimbursement of 6 pharmaceutical drugs for inmates under the Department of 7 Corrections.

8 (6) The End Stage Renal Program in the Department of9 Health.

10 (7) All prescription drug plans that prescribe benefits
11 to members and employees of the General Assembly and the
12 unified judicial system and its retirees.

13 "Program." The One Pennsylvania pharmacy benefits14 consolidation program established pursuant to section 3.

15 "Provider." A pharmacy, a dispensing physician or a 16 certified registered nurse practitioner enrolled as a provider 17 in the One Pennsylvania program.

18 "Public School Employees' Retirement System." The retirement 19 system established by 24 Pa.C.S. Part IV (relating to retirement 20 for school employees).

21 "Public Welfare Code." The act of June 13, 1967 (P.L.31, No.22 21), known as the Public Welfare Code.

23 "Retail pharmacy." A pharmacy licensed to operate pursuant 24 to the act of September 27, 1961 (P.L.1700, No.699), known as 25 the Pharmacy Act, which provides services to the general public, 26 excluding any institutional pharmacy, specialty pharmacy or 27 mail-order pharmacy.

28 "Secretary." The Secretary of Administration of the29 Commonwealth.

30 "Social Security Act." The Social Security Act (49 Stat. 20090HB0643PN0705 - 5 - 620, 42 U.S.C. § 301 et seq.). A reference to the Social
 Security Act shall include regulations implementing the Social
 Security Act adopted by the United States Department of Health
 and Human Services or the Centers for Medicare and Medicaid
 Services.

6 "State agency." Any of the following entities that purchases 7 or provides coverage for prescription medications:

8 (1) An agency under the jurisdiction of the Governor. 9 (2) An independent agency supported by public funds. 10 "State Employees' Benefit Trust Fund." The trust fund 11 established to purchase health insurance coverage, including 12 coverage for prescription medications, for State employees.

13 "State Employees' Retirement System." The retirement system 14 established under 71 Pa.C.S. Part XXV (relating to retirement 15 for State employees and officers).

16 Section 3. One Pennsylvania.

(a) Establishment.--The Office of Administration shall
establish a pharmacy benefits consolidation program to be known
as One Pennsylvania. The program shall administer all publicly
funded Commonwealth prescription drug plans through an
integrated system of plan administration using uniform standards
and requirements for the reimbursement to providers as provided
by this act.

(b) Program requirements.--The Office of Administrationshall do all of the following:

(1) Develop, manage and implement preferred drug lists
for all publicly funded Commonwealth prescription drug plans
to the extent allowed by applicable Federal law. A preferred
drug list shall include all prescription drugs for which a
manufacturer has entered into a rebate agreement pursuant to

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1 section 6 and the requirements and restrictions, except for 2 prior authorization, provided by section 1927(d) of the 3 Social Security Act. A preferred drug list shall comply with the standards established by Part D, section 1860D-4(b)(3) of 4 5 the Social Security Act and any additional regulations as may 6 be adopted by the Office of Administration pursuant to this 7 act. A current list of drugs included in the preferred drug 8 list shall be publicly available, posted electronically on 9 the Internet website of the Office of Administration and 10 communicated to pharmacies through alerts. All preferred drug lists shall be uniform to the extent administratively 11 12 feasible under the statutory authority establishing the 13 individual prescription drug plans. The Office of 14 Administration may, in its discretion, allow exceptions to the uniformity requirements in administrating the individual 15 16 programs due to fiscal and administrative considerations.

17 (2) Adopt regulations relating to the eligibility of 18 participating providers and the adjudication of items and all 19 other provisions necessary to carry out the provisions of 20 this act. Any pharmacy shall be eligible to participate in 21 the program, provided the pharmacy complies with the 22 regulations adopted under the paragraph and other provisions 23 of this act.

(3) The Office of Administration shall promulgate
statements of policy, as necessary, to carry out the
provisions of this act. No statement of this policy adopted
by the Office of Administration shall have the force and
effect of law or regulation or may modify the provisions of
any regulations adopted by the Office of Administration. All
statements of policy adopted by the Office of Administration

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shall, except in emergency circumstances, be published for
 notice and comment prior to adoption and shall be published
 in the Pennsylvania Bulletin.

4 (4) (i) Except as provided in subparagraph (ii), make
5 provisions for generic substitutions in accordance with
6 the act of November 24, 1976 (P.L.1163, No.259), referred
7 to as the Generic Equivalent Drug Law.

8 (ii) Notwithstanding the provisions of the Generic 9 Equivalent Drug Law and the act of August 26, 1971 (P.L. 10 351, No.91), known as the State Lottery Law, generic 11 substitutions shall only be dispensed when it is less 12 expensive for the program.

(5) Provide for a program of prospective drug
utilization review consistent with section 1927(g)(2) of the
Social Security Act.

16 (6) Provide for prior authorization consistent with the 17 requirements of section 1927(g)(5)of the Social Security Act 18 and in accordance with regulations of the Office of 19 Administration.

20 (7) Provide for a program of retrospective drug utilization review and education consistent with section 21 22 1927(q)(2) of the Social Security Act and in accordance with 23 regulations of the Office of Administration to ensure that 24 prescriptions are appropriate, medically necessary and not 25 likely to result in adverse medical results and to educate 26 providers and recipients of pharmacy services through the 27 pharmacy consolidated benefits program and to correct and 28 report misutilization and abuse by licensed prescribers and 29 recipients and provide for fraud and abuse audits, 30 coordinating its activities with the secretary to support

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1 compliance with applicable laws and regulations. Pharmacies 2 shall not be denied payments for medications dispensed based 3 upon the results of retrospective drug utilization review or audits, where the medication was dispensed in good faith by 4 5 the pharmacy without prior knowledge that the prescription of 6 a medication was not appropriate or necessary, was likely to 7 cause adverse medical results or constituted a fraudulent or 8 abusive practice by the prescriber.

9 (8) Establish a program of medication therapy management 10 consistent with section 1860D-4(c)(2) of the Social Security 11 Act.

12 (9) Provide educational materials for program recipients13 of pharmacy services on disease and care management.

14 In accordance with section 1927(a) through (d) of (10)15 the Social Security Act or Chapter 7 of the act of August 26, 16 1971 (P.L.351, No.91), known as the State Lottery Law, bill, 17 recoup and relay to the medical assistance program 18 manufacturers' drug rebates and excessive consumer price 19 inflation discounts and resolve disputes. Upon the 20 establishment of the program, all medical assistance 21 recipients shall be enrolled in prescription drug programs 22 for which rebates and discounts are collected pursuant to 23 section 1927(a) through (d) of the Social Security Act.

(11) Adjudicate claims through an electronic claims
management system consistent with section 1927(h) of the
Social Security Act and which allows for an emergency supply
of prescribed medication in the event of equipment failures.

(12) The Office of Administration shall develop a manual
 setting forth procedures, guidelines and standards to be
 utilized by prescription drug plans in audits of providers

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pertaining to the program.

2 (13) Create a uniform audit and recoupment system
3 subject to the requirements of section 7(c) for all of the
4 following:

5 (i) Pharmacies, pharmacists, dispensing physicians
6 and any other providers under this act.

7 (ii) Pharmaceutical manufacturers, wholesalers and
8 other suppliers of prescription drugs.

9 (14) Provide for the reimbursement of all providers 10 participating in prescription drug programs on a fee-for-11 service basis.

12 (15) Allow providers certified in medication therapy 13 management by a national accrediting body or by any other 14 certification process approved by the State Board of Pharmacy 15 to provide medication therapy management.

16 (c) Considerations.--In preparing and managing the uniform 17 drug list, the Office of Administration shall enter into 18 agreements with drug manufacturers to collect and remit to the 19 program discounts, rebates or other concessions offered by 20 manufacturers.

21 (d) Advisory committee.--

(1) An advisory committee for One Pennsylvania is
 established to assist the program in making informed and
 fiscally responsive decisions in administering and
 consolidating the purchases and reimbursements of
 pharmaceutical drugs and benefits for the Commonwealth.

27 (2) An advisory committee to the Office of
28 Administration shall consist of the following members:

29 (i) Three members appointed by the Governor.
30 (ii) Two members appointed by each of the following:

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1 (A) The President pro tempore of the Senate. 2 (B) The Minority Leader of the Senate. 3 (C) The Speaker of the House of Representatives. The Minority Leader of the House of 4 (D) 5 Representatives. Each legislative appointing authority shall appoint 6 (3) 7 one member pursuant to paragraph (2) (ii) involved in the

8 ownership or operation of independent pharmacies and one 9 member involved in the ownership or operation of chain 10 pharmacies.

11 (4) Members of the committee shall serve without 12 compensation but shall be reimbursed for their reasonable and 13 necessary expenses by the Office of Administration.

14 (5) Members of the committee shall serve for indefinite15 terms at the will of their respective appointing authorities.

16 (6) Action by the committee shall require a vote by at 17 least seven members.

18 (7) Members of the committee shall annually elect a19 chairperson.

20 (8) The advisory committee shall meet twice yearly to 21 provide advice and recommendations to the program in regard 22 to its policies and regulations. The advisory committee shall 23 review the audit manual and rebate agreement yearly and 24 develop recommendations to the Office of Administration as 25 needed.

26 Section 4. Reimbursement.

27 (a) General rule.--Reimbursement to providers shall include28 all of the following:

(1) Payment sufficient to reimburse retail pharmacies
 for the reasonable and necessary costs incurred to purchase

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1 drugs.

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2 Except to the extent otherwise required by Federal (2) 3 law or regulations, payments to retail pharmacies pursuant to paragraph (1) shall be based upon the average retail pharmacy 4 5 acquisition cost for a medication without regard to customary 6 prompt pay discounts in the package size most commonly 7 purchased by retail pharmacies as determined by the Office of 8 Administration pursuant to subsection (d), or a provider's 9 actual acquisition cost for a medication, whichever amount is 10 greater.

(3) Payment for dispensing costs adequate to cover costsassociated with all of the following:

(i) Wages and salaries.

14 (ii) Costs to store and secure inventory.

15 (iii) Patient counseling.

16 (iv) Drug utilization review.

17 (v) Licensing fees.

18 (vi) Taxes.

19 (vii) Insurance.

20 (viii) Other direct and indirect costs of operating21 a pharmacy.

(ix) A reasonable profit to generate a return on theinvestment associated with the costs.

(4) During the first year this section is in effect,
payments pursuant to paragraph (3) shall be not less than \$10
for the dispensing of a single source drug as defined by
section 1927(k)(7)(A)(iv) of the Social Security Act or \$15
for the dispensing of a multiple-source drug as defined by
section 1927(k)(7)(A)(iv) of the Social Security Act.
Beginning on January 1 of each subsequent year, payment

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1 pursuant to paragraph (3) shall be not less than the prior 2 year's minimum payments as adjusted based upon the annual 3 percentage change in Consumer Price Index for medical care professional services as published by the Bureau of Labor 4 5 Statistics of the United States Department of Labor for the month of December of the immediately prior year. 6 7 (5) Additional payment for: 8 (i) Medication therapy management. Concurrent and retrospective utilization 9 (ii) 10 review. 11 Managing prior authorization requirements. (iii) 12 To the extent authorized by section 9.1 of the (iv) 13 Pharmacy Act, implementing drug therapy protocols. 14 Compounding prescriptions. (V) 15 Preparing specialized packaging for the (vi) 16 administration of medications in long-term care 17 facilities. 18 (vii) Preparing medications for intravenous 19 administration. 20 (viii) Other reasonable and necessary pharmacy 21 services. 22 (b) Prompt payment. -- Providers shall be paid within 21 days 23 of the Office of Administration's receipt of appropriate 24 substantiation of the transaction. Providers shall be entitled 25 to interest at the rate provided by section 806 of the act of 26 April 9, 1929 (P.L.343, No.176), known as The Fiscal Code, for any payment not made within the 21-day period. 27 28 (c) Average retail pharmacy acquisition costs. -- The Office 29 of Administration shall determine and publicly make available through its Internet website the average retail pharmacy 30

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1 acquisition cost for covered medications pursuant to regulations 2 approved by the advisory committee in a manner consistent with 3 the methodology used by the Congressional Budget Office in its December 26, 2006, report to the Committee on Energy and 4 Commerce of the United States House of Representatives based 5 upon a survey of retail pharmacy wholesale invoices or through 6 7 the use of commercially available sources of information. 8 Average pharmacy acquisition costs shall be updated weekly.

9 Copayments.--Except for services which are excluded (d) under the Commonwealth's medical assistance program, the Office 10 11 of Administration may require providers to collect a copayment 12 in an amount set by the program. To the extent a provider is 13 required by Federal or State law to dispense prescriptions to 14 persons unable to satisfy copayment obligations, the provider 15 shall be reimbursed for uncollected copayment amounts. The 16 Office of Administration shall neither require copayments from 17 beneficiaries nor deduct copayment amounts from provider 18 reimbursements for any particular classes of drugs or 19 prescription drug plan recipients to the extent there is good 20 cause to conclude that copayment requirements will result in 21 noncompliance with prescription drug treatment protocols and 22 will increase overall health care costs or result in imminent 23 and substantial risk of harm or injury to recipients or other 24 persons. Except to the extent prohibited by Federal law, the 25 Office of Administration may accept compensation for the purpose 26 of reducing or eliminating copayments from drug manufacturers, 27 distributors, health care plans or other persons or 28 organizations for the purpose of encouraging therapeutically 29 desirable compliance with prescription drug treatment protocols. 30 Section 5. Deposit of funds.

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1 A special fund is established in the State Treasury to be 2 known as the Special Pharmaceutical Fund. All moneys 3 appropriated from the State Lottery Fund for PACE operations shall be deposited in the Special Pharmaceutical Fund. All 4 5 Federal moneys received by the Commonwealth per any pharmaceutical program consolidated into One Pennsylvania under 6 this act shall be deposited in the Special Pharmaceutical Fund. 7 8 Any moneys appropriated from the General Fund for pharmaceutical 9 purchasing or reimbursement shall be deposited in this fund. All 10 rebates obtained through prudent pharmaceutical purchasing or through rebate agreements shall be deposited. 11

12 Section 6. Rebate agreement.

13 (a) Required agreements.--Except as provided in subsection 14 (b), the Office of Administration shall not include on the 15 formulary of preferred drug list established pursuant to section 16 3(b)(1) any prescription drug unless the Office of Administration and the pharmaceutical manufacturer have entered 17 18 into a rebate agreement covering that prescription drug on terms 19 comparable to agreements executed pursuant to section 1927(a), 20 (b), (c) and (d) of the Social Security Act. The rebate agreement shall provide that, unless prohibited by Federal law, 21 the rebate shall be based on the best price and that additional 22 23 rebates shall be paid if the pharmaceutical manufacturer 24 increases the price of the drug by an amount greater than the 25 increase in the Consumer Price Index for All Urban Consumers. 26 Nothing in this act shall prevent the Office of Administration from negotiating agreements for the payment of additional 27 28 rebates and discounts for the benefit of the medical assistance 29 program or from entering into rebate and discount agreements for other plans which have been consolidated into the program for 30

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greater rebates and discounts than are required pursuant to
 section 1927(c) of the Social Security Act.

3 (b) Exceptions.--Subsection (a) shall not apply if the 4 availability of the drug is essential to the health of members 5 of the pharmacy consolidated benefits program as determined by 6 the department.

(c) Contracts.--Pharmaceutical manufacturers must enter into 7 8 a rebate agreement with the department to obtain reimbursement 9 for prescription drugs included under this act. The rebate shall 10 be paid by the manufacturer not later than 30 days after the date of receipt of information necessary to calculate the amount 11 of the rebate. The department shall have the authority to levy a 12 13 15% surcharge penalty on any rebate not in dispute that remains 14 unpaid for 90 or more days.

15 Section 7. Adjudications.

16 Adjudications conducted by the Office of Administration shall be subject to 2 Pa.C.S. Chs. 5 Subch. A (relating to practice 17 18 and procedure of Commonwealth agencies) and 7 Subch. A (relating 19 to judicial review of Commonwealth agency action). The Office of 20 Administration shall adopt rules of procedure regarding the conduct of adjudications involving pharmacies consistent with 21 the provisions of 67 Pa.C.S. §§ 1102 (relating to hearings 22 23 before the bureau), 1103 (relating to supersedeas), 1104 24 (relating to subpoenas) and 1105 (relating to determinations, 25 review, appeal and enforcement).

26 Section 8. Applicability.

This act shall apply to the medical assistance program except to the extent the secretary, in consultation with the Secretary of Public Welfare, determines that the application is a violation of Federal law or an existing contractual agreement.

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Nothing in this act shall supersede or impede an existing 1 2 contractual agreement. Contractual agreements in effect on the 3 effective date of this section shall not be renewed or extended to the extent inconsistent with the requirements of this act, 4 5 and the Office of Administration shall promptly enter into negotiations to modify any contractual agreements inconsistent 6 with this act to conform to the requirements of this act. 7 8 Section 9. Prohibited activities.

It shall be unlawful for any individual, partnership or 9 10 corporation to solicit, receive, offer or pay any kickback, 11 bribe or rebate in cash or in kind from or to any person in connection with the furnishing of services under this act to the 12 13 same extent as prohibited with respect to Federal health 14 programs by section 1128(b)(1) and (2) of the Social Security 15 Act, subject to the safe harbors from sanctions provided by 16 sections 1877(a)(1) and 1860D-4(e)(6) of the Social Security Act. Violations of this section shall be subject to the 17 18 sanctions, penalties and remedies under section 1407 of the 19 Public Welfare Code.

20 Section 10. Repeals.

(a) Intent.--The General Assembly declares that the repeal under subsection (b) is necessary to effectuate the purposes of this act.

(b) Provision.--Section 509 of the act of August 26, 1971
(P.L.351, No.91), known as the State Lottery Law, is repealed.
(c) General.--All other acts and parts of acts are repealed
insofar as they are inconsistent with this act.

28 Section 11. Effective date.

29 This act shall take effect as follows:

30 (1) Sections 3(d), 4(a)(4) and 6 shall take effect 20090HB0643PN0705 - 17 - 1 immediately.

2 (2) The remainder of this act shall take effect in one3 year.