
THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 636 Session of
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INTRODUCED BY HOPPER, LINCOLN, SALVATORE, PETERSON, O'PAKE,
REIBMAN, STOUT, SHAFFER, ANDREZESKI AND LYNCH, MARCH 2, 1989

REFERRED TO PUBLIC HEALTH AND WELFARE, MARCH 2, 1989

AN ACT

1 Regulating disclosure of health care information; and
2 prescribing penalties.

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24 The General Assembly of the Commonwealth of Pennsylvania
25 hereby enacts as follows:

26 CHAPTER 1
27 GENERAL PROVISIONS

28 Section 101. Short title.

29 This act shall be known and may be cited as the Uniform
30 Health Care Information Act.

1 Section 102. Legislative findings.

2 The General Assembly finds and declares as follows:

3 (1) Health care information is personal and sensitive
4 information that, if improperly used or released, may do
5 significant harm to patient privacy interests, patient health
6 care interests and other patient interests.

7 (2) Patients need to be able to obtain access to their
8 own health care information as a matter of fairness to enable
9 them to make informed decisions about their health care and
10 to permit them to correct inaccurate or incomplete
11 information about themselves.

12 (3) In order to retain the full trust and confidence of
13 patients, health care providers have an interest in assuring
14 that health care information is not improperly disclosed and
15 in having clear and certain rules for the disclosure of
16 health care information.

17 (4) Nonhealth care providers obtain, use and disclose
18 health record information in many different contexts and for
19 many different purposes. Although this act does not regulate
20 the use and disclosure of health care information by
21 nonhealth care providers, it is the public policy of the
22 Commonwealth that a patient's interest in the proper use and
23 disclosure of that patient's health care information survives
24 even when this information is held by nonhealth care
25 providers.

26 (5) The movement of patients and their health care
27 information across state lines, access to and exchange of
28 health care information from automated data banks and the
29 emergence of multistate health care providers creates a
30 compelling need for uniform law, rules and procedures

1 governing the use and disclosure of health care information.

2 Section 103. Definitions.

3 The following words and phrases when used in this act shall
4 have the meanings given to them in this section unless the
5 context clearly indicates otherwise:

6 "Audit." An assessment, evaluation, determination or
7 investigation of a health care provider by a person not employed
8 by or affiliated with the provider to determine compliance with:

9 (1) statutory, regulatory, fiscal, medical or scientific
10 standards;

11 (2) a private or public program of payments to a health
12 care provider; or

13 (3) requirements for licensing, accreditation or
14 certification.

15 "Directory information." Information disclosing the presence
16 and the general health condition of a particular patient who is
17 an inpatient in a health care facility or who is currently
18 receiving emergency health care in a health care facility.

19 "General health condition." The patient's health status
20 described in terms of "critical," "poor," "fair," "good,"
21 "excellent" or terms denoting similar conditions.

22 "Health care." Any care, service or procedure provided by a
23 health care provider:

24 (1) to diagnose, treat or maintain a patient's physical
25 or mental condition; or

26 (2) that affects the structure or any function of the
27 human body.

28 "Health care facility." A hospital, clinic, nursing home,
29 laboratory, office or similar place where a health care provider
30 provides health care to patients.

1 "Health care information." Any information, whether oral or
2 recorded in any form or medium, that identifies or can readily
3 be associated with the identity of a patient and relates to the
4 patient's health care. The term includes any record of
5 disclosures of health care information.

6 "Health care provider." A person who is licensed, certified
7 or otherwise authorized by the laws of this Commonwealth to
8 provide health care in the ordinary course of business or
9 practice of a profession. The term does not include a person who
10 provides health care solely through the sale or dispensing of
11 drugs or medical devices.

12 "Institutional review board." Any board, committee, or other
13 group formally designated by an institution or authorized under
14 Federal or State law to review, approve the initiation of, or
15 conduct periodic review of research programs to assure the
16 protection of the rights and welfare of human research subjects.

17 "Maintain." As related to health care information, to hold,
18 possess, preserve, retain, store or control that information.

19 "Patient." An individual who receives or has received health
20 care. The term includes a deceased individual who has received
21 health care.

22 "Person." An individual, corporation, business trust,
23 estate, trust, partnership, association, joint venture,
24 government, political subdivision or instrumentality or any
25 other legal or commercial entity.

26 CHAPTER 2

27 DISCLOSURE OF HEALTH CARE INFORMATION

28 Section 201. Disclosures by health care providers.

29 (a) Disclosure.--Except as authorized in section 204, a
30 health care provider, individuals who assist the health care

1 provider in the delivery of health care, and agents and
2 employees of a health care provider may not disclose health care
3 information about a patient to any other person without the
4 patient's written authorization. Disclosure made under the
5 patient's written authorization must conform to the
6 authorization.

7 (b) Receipt recorded.--A health care provider shall
8 maintain, in conjunction with the patient's recorded health care
9 information, a record of all persons who have received or
10 examined, in whole or in part, the recorded health care
11 information during the preceding three years, except for persons
12 who have examined the recorded health care information under
13 section 204(a)(1) or (2). The disclosure record shall include
14 the name, address and institutional affiliation, if any, of each
15 person receiving or examining the recorded health care
16 information; the date of the receipt or examination; and, to the
17 extent practicable, a description of the information disclosed.
18 Section 202. Patient authorization to health care provider for
19 disclosure.

20 (a) Patient authorization.--A patient may authorize a health
21 care provider to disclose the patient's health care information.
22 A health care provider shall honor an authorization and provide
23 a copy of the recorded health care information, if requested,
24 except in those situations in which a health care provider may
25 deny a patient access to health care information under section
26 302. A health care provider may charge a fee, not to exceed the
27 health care provider's actual cost, for providing the health
28 care information and is not required to honor the authorization
29 until the fee is paid.

30 (b) Contents.--To be valid, a disclosure authorization to a

1 health care provider must comply with all of the following:

2 (1) Be in writing, dated and signed by the patient.

3 (2) Identify the nature of the information to be
4 disclosed.

5 (3) Identify the person to whom the information is to be
6 disclosed.

7 (c) Authorization no waiver.--Except as provided by this
8 act, the signing of an authorization by a patient does not
9 constitute a waiver of rights a patient has under other
10 statutes, the rules of evidence or common law.

11 (d) Record retention.--A health care provider shall retain
12 authorizations or revocations in conjunction with the health
13 care information from which disclosures were made.

14 (e) Limitation.--Except for authorizations to provide
15 information to third-party health care payors, no authorization
16 may permit the release of health care information relating to
17 future health care that the patient receives more than six
18 months after the authorization was signed.

19 (f) Validity.--An authorization in effect on the effective
20 date of this act remains valid for a period of 30 months after
21 the effective date of this act unless an earlier date is
22 specified or unless it is revoked under section 204. Health care
23 information disclosed under an authorization is otherwise
24 subject to this act. An authorization written after the
25 effective date of this act becomes invalid after the expiration
26 date contained in the authorization, which (date) may not be
27 more than 30 months after issue. If the authorization does not
28 contain an expiration date, it expires six months after the date
29 it is signed.

30 Section 203. Patient revocation of authorization for

1 disclosure.

2 A patient may revoke a disclosure authorization to a health
3 care provider at any time unless disclosure is required to
4 effectuate payments for health care that has been provided or
5 unless other substantial action has been taken in reliance on
6 the authorization. A patient may not maintain an action against
7 the health care provider for disclosures made in good faith
8 reliance on an authorization if the health care provider has no
9 notice of the revocation of the authorization.

10 Section 204. Disclosures without patient authorization.

11 (a) Limited disclosure.--A health care provider may disclose
12 health care information about a patient without the patient's
13 authorization to the extent the recipient needs to know the
14 information, if any of the following apply:

15 (1) The disclosure is to persons who are providing
16 health care to the patient.

17 (2) The disclosure is to other persons who require
18 health care information for health care education; to provide
19 planning, quality assurance, peer review, administrative,
20 legal, financial or actuarial services to the health care
21 provider; or for assisting the health care provider in the
22 delivery of health care. This paragraph only applies if the
23 health care provider reasonably believes that these persons:

24 (i) will not use or disclose the health care
25 information for any other purpose; and

26 (ii) will take appropriate steps to assure that the
27 health care information is protected.

28 (3) The disclosure is to other health care providers who
29 have previously provided health care to the patient, to the
30 extent necessary to provide health care to the patient,

1 unless the patient has instructed the health care provider
2 not to make the disclosure.

3 (4) The health care provider reasonably believes that
4 disclosure will avoid or minimize an imminent danger to the
5 health or safety of the patient or any other individual.

6 (5) The disclosure is to immediate family members of the
7 patient, or any other individual with whom the patient is
8 known to have a close personal relationship and is made in
9 accordance with good medical or other professional practice.
10 This paragraph does not apply if the patient has instructed
11 the health care provider not to make the disclosure.

12 (6) The disclosure is to a health care provider who is
13 the successor in interest to the health care provider
14 maintaining the health care information.

15 (7) The disclosure is for use in a research project that
16 an institutional review board has determined:

17 (i) is of sufficient importance to outweigh the
18 intrusion into the privacy of the patient that would
19 result from the disclosure;

20 (ii) is impracticable without the use or disclosure
21 of the health care information in individually
22 identifiable form;

23 (iii) contains reasonable safeguards to protect the
24 information from redisclosure;

25 (iv) contains reasonable safeguards to protect
26 against identifying, directly or indirectly, a patient in
27 a report of the research project; and

28 (v) contains procedures to remove or destroy, at the
29 earliest opportunity, consistent with the purposes of the
30 project, information that would enable the patient to be

1 identified, unless an institutional review board
2 authorizes retention of identifying information for
3 purposes of another research project.

4 (8) The disclosure is to a person who obtains
5 information for purposes of an audit. This paragraph only
6 applies if the person agrees in writing:

7 (i) to remove or destroy, at the earliest
8 opportunity, consistent with the purpose of the audit,
9 information that would enable the patient to be
10 identified; and

11 (ii) not to further disclose the information, except
12 to accomplish the audit or to report unlawful or improper
13 conduct involving health care payment fraud by a health
14 care provider or patient or to report other unlawful
15 conduct by the health care provider.

16 (9) The disclosure is to officials of penal or other
17 custodial institutions while the patient is detained.

18 (b) Allowable disclosure.--A health care provider may
19 disclose health care information about a patient without the
20 patient's authorization if the disclosure is any of the
21 following:

22 (1) Directory information. This paragraph does not apply
23 if the patient has instructed the health care provider not to
24 make the disclosure.

25 (2) To Federal, State or local public health
26 authorities, to the extent that the health care provider is
27 required by law to report health care information or that the
28 disclosure is needed to protect the public health.

29 (3) To Federal, State or local law enforcement
30 authorities to the extent required by law.

(4) Pursuant to compulsory process in accordance with section 205.

Section 205. Compulsory process.

(a) Official proceedings.--Health care information shall not be disclosed by a health care provider pursuant to compulsory legal process or discovery in any judicial, legislative or administrative proceeding unless any of the following apply:

(1) The patient has consented in writing to the release of the health care information in response to compulsory process or a discovery request.

(2) The patient has waived the right to claim confidentiality for the health care information sought.

(3) The patient is a party to the proceeding and has placed the patient's physical or mental condition at issue.

(4) The patient's physical or mental condition is relevant to the execution or witnessing of a will.

(5) The physical or mental condition of a deceased patient is placed in issue by a person claiming or defending through or as a beneficiary of the patient.

(6) A patient's health care information is to be used in the patient's commitment proceeding.

(7) The health care information is for use in a law enforcement proceeding or investigation in which a health care provider is the subject or is a party. Health care information obtained under this paragraph may not be used in a proceeding against the patient unless the matter relates to payment for the patient's health care.

(8) The health care information is relevant to a proceeding brought under Chapter 8.

(9) A court has determined that particular health care

1 information should be subject to compulsory legal process or
2 discovery because the party seeking the information has
3 demonstrated that the interest in access outweighs the
4 patient's privacy interest.

5 (b) Notice.--If health care information is sought under
6 subsection (a)(2), (4) or (5) or in a civil proceeding or
7 investigation under subsection (a)(9), the person seeking
8 discovery or compulsory process shall mail a notice, by first-
9 class mail to the patient or the patient's attorney of record,
10 of the compulsory process or discovery request at least ten days
11 before presenting the certificate required under subsection (c)
12 to the health care provider. The court may, for good cause
13 shown, determine that the notification should be waived or
14 modified.

15 (c) Written certification.--

16 (1) Service of compulsory process or discovery requests
17 upon a health care provider must be accompanied by a written
18 certification, signed by the person seeking to obtain health
19 care information or an authorized representative and
20 identifying at least one paragraph of subsection (a) under
21 which compulsory process or discovery is being sought. The
22 certification must also state, in the case of information
23 sought under subsection (a)(2), (4) or (5) or in a civil
24 proceeding under subsection (a)(9), that the notice
25 provisions of subsection (b) have been complied with. A
26 person shall sign the certification only if the person
27 reasonably believes that the paragraph of subsection (a)
28 identified in the certification provides an appropriate basis
29 for the use of discovery or compulsory process.

30 (2) Unless otherwise ordered by the court, the health

1 care provider shall maintain a copy of the process and the
2 written certification as a permanent part of a patient's
3 health care information.

4 (d) No waiver.--Production of health care information under
5 this section, in and of itself, does not constitute a waiver of
6 a privilege, objection or defense existing under other law.

7 CHAPTER 3

8 EXAMINATION AND COPYING OF RECORDS

9 Section 301. Requirements and procedures for patient
10 examination and copying.

11 (a) Information provided.--Upon receipt of a written request
12 from a patient to examine or copy all or part of the patient's
13 recorded health care information, a health care provider, as
14 promptly as required under the circumstances but no later than
15 ten days after receiving the request, shall do one of the
16 following:

17 (1) Make the information available for examination
18 during regular business hours and provide a copy, if
19 requested, to the patient.

20 (2) If the information does not exist or cannot be
21 found, inform the patient.

22 (3) If the health care provider does not maintain the
23 information, inform the patient and provide the name and
24 address, if known, of the health care provider who maintains
25 the information.

26 (4) If the information is in use or unusual
27 circumstances have delayed handling the request, inform the
28 patient and specify in writing the reasons for the delay and
29 the earliest date, not later than 21 days after receipt of
30 the request, when the information will be available for

1 examination or copying or when the request will be otherwise
2 disposed of.

3 (5) Deny the request, in whole or in part, under section
4 302 and inform the patient.

5 (b) Implementation.--In implementing this section:

6 (1) Upon request, the health care provider shall provide
7 an explanation of any code or abbreviation used in the health
8 care information.

9 (2) If the particular health care information requested
10 is not maintained by the health care provider in the
11 requested form, the health care provider is not required to
12 create a new record or reformulate an existing record to make
13 the health care information available in the requested form.

14 (3) The health care provider may charge a fee, not to
15 exceed the health care provider's actual cost, for providing
16 the health care information and is not required to permit
17 examination or copying until the fee is paid.

18 Section 302. Denial of examination and copying.

19 (a) Access denial.--A health care provider may deny access
20 to health care information by the patient if the health care
21 provider reasonably concludes that any of the following apply:

22 (1) Knowledge of the health care information would be
23 injurious to the health of the patient.

24 (2) Knowledge of the health care information could
25 reasonably be expected to lead to the patient's
26 identification of an individual who provided the information
27 in confidence and under circumstances in which
28 confidentiality was appropriate.

29 (3) Knowledge of the health care information could
30 reasonably be expected to cause danger to the life or safety

1 of an individual.

2 (4) The health care information was compiled and is used
3 solely for litigation, quality assurance, peer review or
4 administrative purposes.

5 (5) Access to the health care information is otherwise
6 prohibited by law.

7 (b) Separate access.--If a health care provider denies an
8 examination and copying request under this section, the
9 provider, to the extent possible, shall segregate health care
10 information for which access has been denied under subsection
11 (a) from information for which access may not be denied and
12 permit the patient to examine or copy the disclosable
13 information.

14 (c) Alternate selection.--If a health care provider denies a
15 patient's request for examination and copying, in whole or in
16 part, under subsection (a)(1) or (3), the provider shall permit
17 examination and copying of the record by another health care
18 provider who is selected by the patient and who is licensed,
19 certified or otherwise authorized under the laws of this
20 Commonwealth to treat the patient for the same condition as the
21 original health care provider. The health care provider
22 maintaining the health care information shall inform the patient
23 of the patient's right to select another health care provider
24 for this purpose.

25 CHAPTER 4

26 CORRECTION AND AMENDMENT OF RECORDS

27 Section 401. Requests for correction or amendment.

28 (a) Correction.--For purposes of accuracy or completeness, a
29 patient may request in writing that a health care provider
30 correct or amend the patient's health care information to which

1 a patient has access under section 301.

2 (b) Amendment.--As promptly as required under the
3 circumstances, but no later than ten days after receiving a
4 request from a patient to correct or amend the patient's health
5 care information, the health care provider shall do one of the
6 following:

7 (1) Make the requested correction or amendment and
8 inform the patient of the action and of the patient's right
9 to have the correction or amendment sent to previous
10 recipients of the health care information in question.

11 (2) If the record no longer exists or cannot be found,
12 inform the patient.

13 (3) If the health care provider does not maintain the
14 record, inform the patient and provide the patient with the
15 name and address, if known, of the person who maintains the
16 record.

17 (4) If the record is in use or unusual circumstances
18 have delayed the handling of the correction or amendment
19 request, inform the patient and specify in writing the
20 earliest date, not later than 21 days after receipt of the
21 request, when the correction or amendment will be made or
22 when the request will otherwise be disposed of.

23 (5) Inform the patient in writing of the provider's
24 refusal to correct or amend the record as requested, the
25 reason for the refusal and the patient's right to add a
26 statement of disagreement and to have that statement sent to
27 previous recipients of the disputed health care information.

28 Section 402. Procedures for adding corrections or amendments or
29 statements of disagreement.

30 (a) Marking.--In making any correction or amendment, the

1 health care provider shall:

2 (1) Add the amending information as a part of the health
3 record.

4 (2) Mark the challenged entries as corrected or amended
5 entries and indicate the place in the record where the
6 corrected or amended information is located, in a manner
7 practicable under the circumstances.

8 (b) Refusal.--If the health care provider maintaining the
9 health care information refuses to make a patient's proposed
10 correction or amendment, the provider shall:

11 (1) Permit the patient to file, as a part of the health
12 care information, a concise statement of the correction or
13 amendment requested and the reasons for it.

14 (2) Mark the challenged entry to indicate that the
15 patient claims the entry is inaccurate or incomplete and
16 indicate the place in the record where the statement of
17 disagreement is located, in a manner practicable under the
18 circumstances.

19 Section 403. Dissemination of corrected or amended information
20 or statements of disagreement.

21 (a) Persons designated.--A health care provider, upon
22 request of the patient, shall take reasonable steps to provide
23 copies of corrected or amended information or of the statement
24 of disagreement to all persons designated by the patient who are
25 identified in the health care information as having examined or
26 received copies of the information sought to be corrected or
27 amended.

28 (b) Fee.--A health care provider may charge the patient for
29 the provider's actual cost in distributing corrected or amended
30 information or the statement of disagreement, unless the

1 provider's error necessitated the correction or amendment.

2 CHAPTER 5

3 NOTICE OF INFORMATION PRACTICES

4 Section 501. Content and dissemination of notice.

5 (a) Notice.--A health care provider who provides health care
6 at a health care facility that the provider operates and who
7 maintains health care information shall create a notice of
8 information practices that contains substantially the following:

9 Notice

10 We keep records of the health care services we provide
11 you. You may ask us to see and copy those records that we
12 maintain. You may also ask us to correct those records.
13 We will not disclose your records to others unless you
14 direct us to do so, or unless the law authorizes or
15 compels us to do so. You may see your records, or get
16 more information about them, at _____.

17 (b) Posted copy.--The health care provider shall post a copy
18 of the provider's notice of information practices in a
19 conspicuous place in the health care facility and, upon request,
20 provide patients or prospective patients with a copy of the
21 notice.

22 CHAPTER 6

23 PERSONS AUTHORIZED TO ACT FOR PATIENTS

24 Section 601. Health care representatives.

25 (a) Agency.--A person authorized to consent to health care
26 for another may exercise the rights of that person under this
27 act to the extent necessary to effectuate the terms or purposes
28 of the grant of authority. A patient who is a minor and who is
29 authorized to consent to health care without parental consent
30 under the laws of this Commonwealth may exclusively exercise the

1 rights of a patient under this act as to information pertaining
2 to health care to which the minor lawfully consented.

3 (b) Good faith.--A person authorized to act for a patient
4 shall act in good faith to represent the best interests of the
5 patient.

6 Section 602. Representatives of deceased patients.

7 A personal representative of a deceased patient may exercise
8 the deceased patient's rights under this act. If there is no
9 personal representative or if the personal representative is
10 discharged, a deceased patient's rights under this act may be
11 exercised by persons who are authorized by law to act for the
12 deceased patient.

13 CHAPTER 7

14 SECURITY SAFEGUARDS AND RECORD RETENTION

15 Section 701. Duty to adopt security safeguards.

16 A health care provider shall implement reasonable security
17 safeguards for health care information it maintains.

18 Section 702. Retention of records.

19 A health care provider shall maintain existing health care
20 information for at least one year following receipt of an
21 authorization to disclose that health care information under
22 section 202 and during the pendency of a request for examination
23 and copying under section 301 or a request for correction or
24 amendment under section 401.

25 CHAPTER 8

26 CIVIL REMEDIES AND CRIMINAL SANCTIONS

27 Section 801. Criminal penalty.

28 (a) Prohibited disclosure.--A person who, with knowledge or
29 reason to know that disclosure is prohibited, intentionally
30 discloses health care information in violation of this act

1 commits a misdemeanor of the third degree and shall, upon
2 conviction, be sentenced to pay a fine of not more than \$10,000
3 or to imprisonment for not more than one year, or both.

4 (b) Misrepresentation.--A person who, by intentionally
5 misrepresenting that person's identity or purpose or entitlement
6 to health care information or by bribery, theft or trespass,
7 examines or obtains health care information maintained by a
8 health care provider to which the person would not otherwise be
9 entitled commits a misdemeanor of the third degree and shall,
10 upon conviction, be sentenced to pay a fine of not more than
11 \$10,000 or to imprisonment for not more than one year, or both.

12 (c) False certification.--A person who, with knowledge that
13 a certification under section 205(c)(1) or a disclosure
14 authorization under section 202 is false, intentionally presents
15 the certification or disclosure authorization to a health care
16 provider commits a misdemeanor of the third degree and shall,
17 upon conviction, be sentenced to pay a fine of not more than
18 \$10,000 or to imprisonment for not more than one year, or both.
19 Section 802. Civil enforcement.

20 The Attorney General or appropriate local law enforcement
21 official may maintain a civil action to enforce this act. The
22 court may order relief authorized by section 803.

23 Section 803. Civil remedies.

24 (a) Action for relief.--A person aggrieved by a violation of
25 this act may maintain an action for relief as provided in this
26 section.

27 (b) Compliance.--The court may order the health care
28 provider or other person to comply with this act and may order
29 other appropriate relief.

30 (c) Good faith reliance.--A health care provider who relies

1 in good faith upon a certification under section 205(c)(1) is
2 not liable for disclosures made in reliance on that
3 certification.

4 (d) Burden of proof.--In an action by a patient alleging
5 that health care information was improperly withheld under
6 Chapter 3, the burden of proof is on the health care provider to
7 establish that the information was properly withheld.

8 (e) Damages.--If the court determines that there is a
9 violation of this act, the aggrieved person is entitled to
10 recover damages for pecuniary losses sustained as a result of
11 the violation; in addition, if the violation results from
12 willful or grossly negligent conduct, the aggrieved person may
13 recover up to \$5,000 as penal damages.

14 (f) Attorney fees.--If a plaintiff prevails, the court may
15 assess reasonable attorney fees and all other expenses
16 reasonably incurred in the litigation.

17 (g) Statute of limitations.--An action under this act is
18 barred unless the action is commenced within two years after the
19 cause of action relief arises.

20 CHAPTER 9

21 MISCELLANEOUS PROVISIONS

22 Section 901. Severability.

23 The provisions of this act are severable. If any provision of
24 this act or its application to any person or circumstance is
25 held invalid, the invalidity shall not affect other provisions
26 or applications of this act which can be given effect without
27 the invalid provision or application.

28 Section 902. Conflicting laws.

29 This act does not restrict a health care provider from
30 complying with obligations imposed by Federal health care

1 payment programs or Federal law. If there is a conflict between
2 a provision of this act and a provision of the act of July 8,
3 1986 (P.L.408, No.89), known as the Health Care Cost Containment
4 Act, the Health Care Cost Containment Act shall prevail.

5 Section 903. Effective date.

6 This act shall take effect in 60 days.