

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1925 Session of 2025

INTRODUCED BY VENKAT, HOGAN, KHAN, KOSIEROWSKI, SCOTT, HILL- EVANS, FREEMAN, RIVERA, HANBIDGE, HADDOCK, SANCHEZ, MAYES, HOWARD, GUZMAN, DONAHUE, GILLEN, GREEN, WAXMAN, PROBST, PIELLI, McNEILL, BOROWSKI, SHUSTERMAN, PARKER, CEPEDA- FREYTIZ, MALAGARI, KOZAK AND DOUGHERTY, OCTOBER 6, 2025

AS REPORTED FROM COMMITTEE ON COMMUNICATIONS AND TECHNOLOGY, HOUSE OF REPRESENTATIVES, AS AMENDED, MAY 5, 2026

AN ACT

1 Amending Titles 35 (Health and Safety) and, 40 (Insurance) AND <--
2 67 (PUBLIC WELFARE) of the Pennsylvania Consolidated
3 Statutes, providing for artificial intelligence in
4 facilities, for artificial intelligence use by insurers and
5 for artificial intelligence use by MA or CHIP managed care
6 plans; imposing duties on the Department of Health, the
7 Insurance Department and the Department of Human Services;
8 and imposing penalties.

9 The General Assembly of the Commonwealth of Pennsylvania
10 hereby enacts as follows:

11 Section 1. Title 35 of the Pennsylvania Consolidated
12 Statutes is amended by adding a chapter to read:

13 CHAPTER 35

14 ARTIFICIAL INTELLIGENCE IN FACILITIES

15 Sec.

16 3501. Definitions.

17 3502. Disclosure.

18 3503. Responsible use.

- 1 3504. Artificial intelligence compliance statements.
- 2 ~~3505. Reports.~~ <--
- 3 ~~3506~~ 3505. Retention of records. <--
- 4 ~~3507~~ 3506. Oversight. <--
- 5 ~~3508~~ 3507. Third-party vendor. <--
- 6 ~~3509~~ 3508. Exemption. <--
- 7 ~~3510~~ 3509. Enforcement and penalties. <--
- 8 ~~3511~~ 3510. Plan of correction. <--
- 9 ~~3512~~ 3511. Administrative procedures. <--
- 10 ~~3513~~ 3512. Regulations and guidance. <--

11 § 3501. Definitions.

12 The following words and phrases when used in this chapter
13 shall have the meanings given to them in this section unless the
14 context clearly indicates otherwise:

15 "Artificial intelligence" or "AI." INTELLIGENCE." A machine- <--
16 based system that can, for a given set of human-defined
17 objectives, make predictions, recommendations or decisions
18 influencing real or virtual environments that use machine-based
19 and human-based inputs to perceive real and virtual
20 environments, abstract the perceptions into models through
21 analysis in an automated manner and use model inference to
22 formulate options for information or action. The term includes
23 generative artificial intelligence which is the class of models
24 that emulate the structure and characteristics of input data in
25 order to generate derived synthetic content which includes
26 information such as images, videos, audio clips and text that
27 has been significantly modified or generated by algorithms,
28 including by artificial intelligence.

29 ~~"Artificial intelligence based algorithms." The programming~~ <--
30 ~~and data sets that inform an artificial intelligence system.~~

1 "Clinical decision making." A patient centered problem
2 solving process focused on a health care provider's direct
3 patient care involving gathering information, diagnosing and
4 planning treatments.

5 "ARTIFICIAL INTELLIGENCE MODEL." A CONCEPTUAL OR <--
6 MATHEMATICAL REPRESENTATION OF ABSTRACTED PHENOMENA CAPTURED AS
7 A SYSTEM OF EVENTS, FEATURES OR PROCESSES.

8 "ARTIFICIAL INTELLIGENCE SYSTEM." A FULLY OPERATIONAL
9 ARTIFICIAL INTELLIGENCE APPLICATION OR SCENARIO IN WHICH
10 ARTIFICIAL INTELLIGENCE IS DEPLOYED, INCLUDING THE MODEL,
11 TECHNICAL INFRASTRUCTURE AND PERSONNEL IN THE WORKFLOW.

12 "CLINICAL DECISION MAKING." THE PROFESSIONAL JUDGMENT OF A
13 HEALTH CARE PROVIDER DIRECTLY PERTAINING TO THE MEDICAL CARE AND
14 TREATMENT OF PATIENTS.

15 "Department." The Department of Health of the Commonwealth.

16 "Facility." A health care setting or institution providing
17 health care services, including:

18 (1) A general, special, psychiatric or rehabilitation
19 hospital.

20 (2) An ambulatory surgical facility.

21 (3) A cancer treatment center.

22 (4) A birth center.

23 (5) A SKILLED NURSING HOME. <--

24 ~~(5)~~ (6) An inpatient, outpatient or residential drug and <--
25 alcohol treatment facility.

26 ~~(6)~~ (7) A facility licensed by the Department of Human <--
27 Services' Office of Mental Health and Substance Abuse
28 Services.

29 ~~(7)~~ (8) A laboratory, imaging, diagnostic or other <--
30 outpatient medical service or testing facility.

1 ~~(8)~~ (9) A health care provider office or clinic that is <--
2 owned by or employs a Commonwealth-licensed physician, <--
3 physician assistant or nurse practitioner HEALTH CARE <--
4 PROVIDER.

5 "Health care provider." As follows:

6 (1) A facility or individual who is licensed, certified
7 or otherwise regulated to provide health care services under
8 the laws of this Commonwealth.

9 (2) The term does not include an individual providing
10 emergency services under a licensed emergency medical
11 services agency as defined in section 8103 (relating to
12 definitions).

13 "THIRD-PARTY VENDOR." A PERSON OR ENTITY THAT MAKES AN <--
14 ARTIFICIAL INTELLIGENCE-BASED ALGORITHM, PRODUCT OR SERVICE
15 COMMERCIALY AVAILABLE, WHETHER BY SALE, LICENSE OR OTHER
16 OFFERING, FOR USE BY A FACILITY.
17 § 3502. Disclosure.

18 (a) Duty to disclose.--A facility shall disclose to patients
19 of the facility if artificial intelligence based algorithms <--
20 INTELLIGENCE MODELS OR SYSTEMS are or will be used for clinical <--
21 decision making or other similar tasks. The disclosure shall be: <--

22 (1) Provided in all related written communications USING <--
23 PLAIN LANGUAGE.

24 (2) Posted on the publicly accessible Internet website
25 of the facility IN PLAIN LANGUAGE. <--

26 (b) Communications.--

27 (1) A facility that uses artificial intelligence to
28 generate written or verbal patient communications pertaining
29 to patient clinical information shall include:

30 (i) A clear and conspicuous disclaimer IN PLAIN <--

1 LANGUAGE that indicates that the communication was
2 generated by artificial intelligence.

3 (ii) Clear instructions on how the patient may
4 contact a human health care provider or relevant employee
5 of the facility with questions.

6 (2) The DISCLOSURE requirements under paragraph (1) <--
7 shall not apply to communications that:

8 (i) only pertain to administrative matters,
9 including appointment scheduling, billing or other
10 clerical or business matters; or

11 (ii) have been individually read and, reviewed AND <--
12 APPROVED by a human health care provider.

13 (c) Nature and frequency.--The department shall determine
14 the nature and frequency of disclosure requirements REQUIRED <--
15 UNDER THIS SECTION to the patient. The department may request
16 input from facilities and health care providers or their
17 representatives in making the determination.

18 § 3503. Responsible use.

19 (a) Compliance generally.--The criteria for the artificial <--
20 intelligence based algorithms USE OF ARTIFICIAL INTELLIGENCE <--
21 MODELS OR SYSTEMS FOR CLINICAL DECISION MAKING must comply with
22 this chapter and applicable Federal and State law.

23 (b) Requirements for artificial intelligence based <--
24 algorithms INTELLIGENCE.--For each instance in which a facility <--
25 uses AN artificial intelligence based algorithms INTELLIGENCE <--
26 MODEL OR SYSTEM for clinical decision making, the facility shall
27 comply with the following:

28 (1) The artificial intelligence based algorithms <--
29 INTELLIGENCE MODEL OR SYSTEM FOR CLINICAL DECISION MAKING <--
30 must not supersede health care provider clinical decision <--

1 making- MADE BY A HUMAN HEALTH CARE PROVIDER. A FACILITY MAY <--
2 NOT PENALIZE A HEALTH CARE PROVIDER SOLELY FOR EXERCISING
3 INDEPENDENT JUDGMENT IN CLINICAL DECISION MAKING THAT DIFFERS
4 FROM A RECOMMENDATION OR OUTPUT GENERATED BY ARTIFICIAL
5 INTELLIGENCE.

6 (2) The artificial intelligence based algorithms <--
7 INTELLIGENCE MODEL OR SYSTEM and training data sets must not <--
8 directly or indirectly discriminate against patients in
9 violation of Federal or State law.

10 (3) The artificial intelligence based algorithms <--
11 INTELLIGENCE MODEL OR SYSTEM must be fairly and equitably <--
12 applied, including in accordance with any applicable
13 regulations and or guidance issued by the United States <--
14 Department of Health and Human Services.

15 (4) The use of the artificial intelligence based <--
16 algorithms INTELLIGENCE MODEL OR SYSTEM must be disclosed in <--
17 accordance with section 3502 (relating to disclosure).

18 (5) The performance, use and outcomes of the artificial
19 intelligence based algorithms INTELLIGENCE MODEL OR SYSTEM <--
20 must be periodically reviewed and revised AT LEAST QUARTERLY <--
21 to maximize accuracy and reliability.

22 (6) Patient data must not be used beyond the intended
23 and stated purpose of the artificial intelligence based <--
24 algorithms INTELLIGENCE MODEL OR SYSTEM, consistent with the <--
25 laws of this Commonwealth and 42 U.S.C. Ch. 7 Subch. XI Part
26 C (relating to administrative simplification), as
27 applicable-, EXCEPT AS PERMITTED BY THE PATIENT THROUGH <--
28 INFORMED CONSENT, AS OTHERWISE AUTHORIZED UNDER APPLICABLE
29 FEDERAL OR STATE LAW OR FOR USE OF DE-IDENTIFIED OR
30 AGGREGATED PATIENT DATA FOR RESEARCH, DEVELOPMENT OR

1 IMPROVEMENT OF ARTIFICIAL INTELLIGENCE-BASED ALGORITHMS.

2 ~~(7) The artificial intelligence based algorithms~~ <--
3 INTELLIGENCE MODELS OR SYSTEMS must not create foreseeable, <--
4 material risks of harm to the patient.

5 (C) INTERNAL GOVERNANCE.--A FACILITY USING ARTIFICIAL <--
6 INTELLIGENCE MODELS OR SYSTEMS FOR CLINICAL DECISION MAKING
7 SHALL ESTABLISH AND MAINTAIN THE FOLLOWING:

8 (1) POLICIES AND PROCEDURES FOR IMPLEMENTING, USING AND
9 MONITORING THE USE OF THE ARTIFICIAL INTELLIGENCE MODELS OR
10 SYSTEMS.

11 (2) A GOVERNANCE STRUCTURE TO MANAGE RESPONSIBLE USE OF
12 THE ARTIFICIAL INTELLIGENCE MODELS OR SYSTEMS WITHIN THE
13 FACILITY.

14 (3) A REASONABLE PROCESS TO VALIDATE AND MONITOR THE
15 FACILITY'S COMPLIANCE WITH THE REQUIREMENTS OF SUBSECTIONS
16 (A) AND (B).

17 § 3504. Artificial intelligence compliance statements.

18 ~~(a) Compliance statement required.--A facility using~~ <--
19 ~~artificial intelligence based algorithms~~ INTELLIGENCE MODELS OR <--
20 SYSTEMS for clinical decision making shall annually file with
21 the department in the form and manner prescribed by the
22 department an artificial intelligence compliance statement.-- <--

23 ATTESTING THAT THE FACILITY'S USE OF ARTIFICIAL INTELLIGENCE <--
24 MODELS OR SYSTEMS IS IN COMPLIANCE WITH SECTION 3503 (RELATING
25 TO RESPONSIBLE USE).

26 ~~(b) Contents. Each compliance statement must:~~ <--

27 ~~(1) Summarize the function and scope of artificial~~
28 ~~intelligence based algorithms used for clinical decision~~
29 ~~making.~~

30 ~~(2) Provide a logic or decision tree of artificial~~

1 ~~intelligence based algorithms used for clinical decision~~
2 ~~making.~~

3 ~~(3) Provide a description of each training data set used~~
4 ~~by artificial intelligence based algorithms for clinical~~
5 ~~decision making, including the source of the data.~~

6 ~~(4) Attest that the artificial intelligence based~~
7 ~~algorithms and the training data sets comply with section~~
8 ~~3503 (relating to responsible use) and provide evidence of~~
9 ~~the compliance.~~

10 ~~(5) Describe the process of the facility for overseeing~~
11 ~~and validating the performance and compliance of the~~
12 ~~artificial intelligence based algorithms in accordance with~~
13 ~~section 3503.~~

14 ~~§ 3505. Reports.~~

15 ~~(a) Annual report required. No later than one year after~~
16 ~~the effective date of this chapter and each year thereafter, the~~
17 ~~department shall compile the information from the most recent~~
18 ~~annual compliance statements under section 3504 (relating to~~
19 ~~artificial intelligence compliance statements) and issue a~~
20 ~~report containing the compiled information, along with any other~~
21 ~~applicable findings and recommendations. The information in the~~
22 ~~report shall be aggregated and deidentified.~~

23 ~~(b) Posting. The department shall post each report under~~
24 ~~this section on the publicly accessible Internet website of the~~
25 ~~department.~~

26 ~~§ 3506. Retention of records.~~

27 ~~§ 3505. RETENTION OF RECORDS.~~

<--

28 ~~The department shall establish a record retention policy and~~
29 ~~determine the amount of time a facility shall retain records~~
30 ~~related to artificial-intelligence algorithms. The department~~

<--

1 may IN ACCORDANCE WITH THE FOLLOWING: <--

2 (1) THE POLICY SHALL NOT BE LESS THAN FIVE YEARS AND AT
3 LEAST AS LONG AS REQUIRED UNDER EXISTING LAW.

4 (2) THE DEPARTMENT MAY request input from facilities and
5 health care providers or their representatives in making the
6 determination under this section.

7 (3) A RECORD RETENTION POLICY SHALL NOT BE IMPLEMENTED <--
8 IN CONFLICT WITH EXISTING LAW.

9 § 3507 3506. Oversight. <--

10 (A) DEPARTMENTAL DUTY.--THE DEPARTMENT SHALL ENSURE <--
11 COMPLIANCE WITH THIS CHAPTER.

12 (B) INFORMATION.--The department may request additional
13 information and evidence from a facility regarding the items
14 provided under sections 3502 (relating to disclosure), 3503
15 (relating to responsible use) and 3504 (relating to artificial
16 intelligence compliance statements) that are necessary to ensure
17 compliance with this chapter.

18 § 3508. Third party vendor. <--

19 A contractor, subcontractor or other third party vendor that
20 sells, leases, subscribes or otherwise supplies artificial
21 intelligence based algorithms or services based on artificial
22 intelligence based algorithms to the facility shall be subject
23 to this chapter. The department shall develop regulations or
24 guidance regarding the responsibility of a contractor,
25 subcontractor or other third party vendor that sells, leases,
26 subscribes or otherwise supplies artificial intelligence based
27 algorithms or services based on artificial intelligence based
28 algorithms to the facility. The department may request input
29 from facilities, third party vendors and health care providers
30 or their representatives in making this determination.

1 (C) CONFIDENTIALITY.--DOCUMENTS SUBMITTED UNDER THIS SECTION <--
2 SHALL REMAIN CONFIDENTIAL AND NOT PUBLICLY ACCESSIBLE UNDER THE
3 ACT OF FEBRUARY 14, 2008 (P.L.6, NO.3), KNOWN AS THE RIGHT-TO-
4 KNOW LAW.

5 § 3507. THIRD-PARTY VENDOR.

6 A FACILITY UTILIZING A THIRD-PARTY VENDOR FOR THE DEVELOPMENT
7 OR DEPLOYMENT OF ARTIFICIAL INTELLIGENCE MODELS OR SYSTEMS FOR
8 CLINICAL DECISION MAKING OR PRODUCTS OR SERVICES FOR CLINICAL
9 DECISION MAKING THAT RELY ON ARTIFICIAL INTELLIGENCE MODELS OR
10 SYSTEMS SHALL ESTABLISH INTERNAL REVIEW AND GOVERNANCE PROCESSES
11 TO ENSURE COMPLIANCE WITH THE REQUIREMENTS UNDER SECTIONS 3502
12 (RELATING TO DISCLOSURE), 3503 (RELATING TO RESPONSIBLE USE) AND
13 3504 (RELATING TO ARTIFICIAL INTELLIGENCE COMPLIANCE
14 STATEMENTS).

15 § ~~3509~~ 3508. Exemption. <--

16 This chapter shall not apply to validated, static decision-
17 support tools or tools used for administration, scheduling,
18 scribe applications or clinical calculators.

19 § ~~3510~~ 3509. Enforcement and penalties. <--

20 (a) Civil penalties.--

21 ~~(1) Subject to paragraph (2), the department may impose <--~~
22 ~~a civil penalty not exceeding \$5,000 for a violation of this~~
23 ~~chapter. For purposes of this paragraph, each instance of~~
24 ~~nondisclosure shall constitute a separate violation of this~~
25 ~~chapter.~~

26 ~~(2) The following apply to limitations on civil~~
27 ~~penalties under this subsection:~~

28 ~~(i) A civil penalty imposed against a facility may~~
29 ~~not exceed \$500,000 in the aggregate during a single~~
30 ~~calendar year.~~

1 ~~(ii) A civil penalty imposed against any other~~
2 ~~person may not exceed \$100,000 in the aggregate during a~~
3 ~~single calendar year.~~

4 (1) SUBJECT TO PARAGRAPHS (2), (3) AND (4), THE
5 DEPARTMENT MAY IMPOSE A CIVIL PENALTY AS FOLLOWS FOR A
6 VIOLATION OF THIS CHAPTER:

<--

7 (I) FOR A KNOWING OR WILLFUL VIOLATION, A CIVIL
8 PENALTY OF NOT MORE THAN \$10,000 PER VIOLATION.

9 (II) EXCEPT AS PROVIDED UNDER SUBPARAGRAPH (III),
10 FOR A NEGLIGENT VIOLATION, A CIVIL PENALTY OF NOT MORE
11 THAN \$5,000 PER VIOLATION.

12 (III) FOR A FIRST-TIME NEGLIGENT VIOLATION BY AN
13 ENTITY THAT THE DEPARTMENT DETERMINES HAS MADE A GOOD-
14 FAITH EFFORT TO COMPLY WITH THIS CHAPTER, A CIVIL PENALTY
15 OF NOT MORE THAN \$1,000 PER VIOLATION OR, AT THE
16 DEPARTMENT'S DISCRETION, A PLAN OF CORRECTION UNDER
17 SECTION 3510 (RELATING TO PLAN OF CORRECTION) IN LIEU OF
18 A PENALTY.

19 (2) FOR THE PURPOSES OF PARAGRAPH (1), EACH INSTANCE OF
20 NONDISCLOSURE SHALL CONSTITUTE A SEPARATE VIOLATION OF THIS
21 CHAPTER.

22 (3) IN DETERMINING THE AMOUNT OF A CIVIL PENALTY, THE
23 DEPARTMENT SHALL CONSIDER:

24 (I) THE NATURE AND SERIOUSNESS OF THE VIOLATION.

25 (II) WHETHER THE VIOLATION HAS RESULTED IN PATIENT
26 HARM.

27 (III) THE VIOLATOR'S HISTORY OF COMPLIANCE.

28 (IV) ANY GOOD-FAITH EFFORTS BY THE VIOLATOR TO
29 COMPLY.

30 (V) THE VIOLATOR'S SIZE AND FINANCIAL RESOURCES.

1 (4) THE AGGREGATE AMOUNT OF CIVIL PENALTIES IMPOSED ON A
2 SINGLE ENTITY UNDER THIS SUBSECTION DURING A SINGLE CALENDAR
3 YEAR SHALL NOT EXCEED \$250,000.

4 (B) ACTIONS.--A VIOLATION OF ANY PROVISION OF THIS CHAPTER
5 SHALL BE DEEMED TO BE AN UNFAIR OR DECEPTIVE ACT OR PRACTICE IN
6 VIOLATION OF THE ACT OF DECEMBER 17, 1968 (P.L.1224, NO.387),
7 KNOWN AS THE UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW.
8 THE OFFICE OF ATTORNEY GENERAL SHALL HAVE EXCLUSIVE AUTHORITY TO
9 BRING AN ACTION UNDER THE UNFAIR TRADE PRACTICES AND CONSUMER
10 PROTECTION LAW FOR A VIOLATION OF ANY PROVISION OF THIS CHAPTER.

11 ~~(b)~~ (C) Injunction.--The department may maintain an action <--
12 in the name of the Commonwealth for an injunction to prohibit
13 any activity that violates the provisions of this chapter.

14 ~~(c)~~ (D) Nonexclusive remedies.--The enforcement remedies and <--
15 penalties imposed under this chapter are in addition to any
16 other remedies or penalties that may be imposed under any other
17 applicable law of this Commonwealth FEDERAL OR STATE LAW, <--
18 including the act of July 19, 1979 (P.L.130, No.48), known as
19 the Health Care Facilities Act-, OR THE HEALTH INSURANCE <--
20 PORTABILITY OR ACCOUNTABILITY ACT OF 1996 (PUBLIC LAW 104-191,
21 110 STAT. 1936) AS AMENDED BY THE HEALTH INFORMATION TECHNOLOGY
22 FOR ECONOMIC AND CLINICAL HEALTH ACT (PUBLIC LAW 111-5, 123
23 STAT. 226-279 AND 467-496).

24 ~~§ 3511~~ 3510. Plan of correction. <--

25 (a) Authorization.--The department may require a facility to
26 develop and adhere to a plan of correction approved by the
27 department. The department may impose a plan of correction in
28 lieu of fines. OR IN ADDITION TO CIVIL PENALTIES IMPOSED UNDER <--
29 SECTION 3509 (RELATING TO ENFORCEMENT AND PENALTIES).

30 (b) Compliance.--The department shall monitor compliance

1 with the plan of correction under this section.

2 (c) Availability.--The plan of correction shall, ~~upon~~ <--
3 ~~request,~~ be made available to patients of the facility UPON <--
4 REQUEST.

5 § ~~3512~~ 3511. Administrative procedures. <--

6 (a) Applicable procedures.--This chapter shall be subject to
7 2 Pa.C.S. Ch. 5 Subch. A (relating to practice and procedure of
8 Commonwealth agencies).

9 (b) Appeal.--A party against whom penalties are assessed in
10 an administrative action may appeal to Commonwealth Court as
11 provided in 2 Pa.C.S. Ch. 7 Subch. A (relating to judicial
12 review of Commonwealth agency action).

13 § ~~3513~~ 3512. Regulations and guidance. <--

14 The department shall promulgate regulations or guidance
15 necessary to implement, administer and enforce this chapter. ~~The~~ <--
16 IN ACCORDANCE WITH THE FOLLOWING: <--

17 (1) THE DEPARTMENT SHALL CONSULT WITH THE INSURANCE
18 DEPARTMENT AND THE DEPARTMENT OF HUMAN SERVICES WHEN
19 DEVELOPING REGULATIONS AND GUIDANCE TO ENSURE CONFORMITY
20 ACROSS REGULATIONS AND GUIDANCE PROMULGATED BY THE THREE
21 DEPARTMENTS.

22 (2) THE department shall review regulations or guidance
23 every three years to ensure compliance with Federal law or
24 Federal agency guidance.

25 Section 2. Title 40 is amended by adding chapters to read:

26 CHAPTER 52
27 ARTIFICIAL INTELLIGENCE USE BY INSURERS

28 Sec.

29 5201. Definitions.

30 5202. Disclosure.

- 1 5203. Responsible use.
- 2 5204. Artificial intelligence compliance statements.
- 3 5205. Health care provider requirements.
- 4 ~~5206. Reports.~~ <--
- 5 ~~5207~~ 5206. Retention of records. <--
- 6 ~~5208~~ 5207. Oversight. <--
- 7 ~~5209~~ 5208. Third-party vendor. <--
- 8 ~~5210~~ 5209. Exemption. <--
- 9 ~~5211~~ 5210. Enforcement and penalties. <--
- 10 ~~5212~~ 5211. Plan of correction. <--
- 11 ~~5213~~ 5212. Administrative procedures. <--
- 12 ~~5214~~ 5213. Regulations and guidance. <--

13 § 5201. Definitions.

14 The following words and phrases when used in this chapter
 15 shall have the meanings given to them in this section unless the
 16 context clearly indicates otherwise:

17 "Artificial intelligence" or "AI." INTELLIGENCE." A machine- <--
 18 based system that can, for a given set of human-defined
 19 objectives, make predictions, recommendations or decisions
 20 influencing real or virtual environments that use machine-based
 21 and human-based inputs to perceive real and virtual
 22 environments, abstract the perceptions into models through
 23 analysis in an automated manner and use model inference to
 24 formulate options for information or action. The term includes
 25 generative artificial intelligence which is the class of models
 26 that emulate the structure and characteristics of input data in
 27 order to generate derived synthetic content which includes
 28 information such as images, videos, audio clips and text that
 29 has been significantly modified or generated by algorithms,
 30 including by artificial intelligence.

1 "Artificial intelligence-based algorithms." The programming
2 and data sets that inform an artificial intelligence system.

3 ~~"Covered person." A policyholder, subscriber or other~~ <--
4 ~~individual who is entitled to receive health care services under~~
5 ~~a health insurance policy.~~

6 "ARTIFICIAL INTELLIGENCE MODEL." A CONCEPTUAL OR <--
7 MATHEMATICAL REPRESENTATION OF ABSTRACTED PHENOMENA CAPTURED AS
8 A SYSTEM OF EVENTS, FEATURES OR PROCESSES.

9 "ARTIFICIAL INTELLIGENCE SYSTEM." A FULLY OPERATIONAL
10 ARTIFICIAL INTELLIGENCE APPLICATION OR SCENARIO IN WHICH
11 ARTIFICIAL INTELLIGENCE IS DEPLOYED, INCLUDING THE MODEL,
12 TECHNICAL INFRASTRUCTURE AND PERSONNEL IN THE WORKFLOW.

13 "COVERED PERSON." AS DEFINED UNDER SECTION 2102 OF THE ACT
14 OF MAY 17, 1921 (P.L.682, NO.284), KNOWN AS THE INSURANCE
15 COMPANY LAW OF 1921.

16 "Department." The Insurance Department of the Commonwealth.

17 "FACILITY." A HEALTH CARE SETTING OR INSTITUTION PROVIDING <--
18 HEALTH CARE SERVICES, INCLUDING:

19 (1) A GENERAL, SPECIAL, PSYCHIATRIC OR REHABILITATION
20 HOSPITAL.

21 (2) AN AMBULATORY SURGICAL FACILITY.

22 (3) A CANCER TREATMENT CENTER.

23 (4) A BIRTH CENTER.

24 (5) A SKILLED NURSING CENTER.

25 (6) AN INPATIENT, OUTPATIENT OR RESIDENTIAL DRUG AND
26 ALCOHOL TREATMENT FACILITY.

27 (7) A FACILITY LICENSED BY THE DEPARTMENT OF HUMAN
28 SERVICES' OFFICE OF MENTAL HEALTH AND SUBSTANCE ABUSES
29 SERVICES.

30 (8) A LABORATORY, IMAGING, DIAGNOSTIC OR OTHER

1 OUTPATIENT MEDICAL SERVICE OR TESTING FACILITY.

2 (9) A HEALTH CARE PROVIDER OFFICE OR CLINIC THAT IS
3 OWNED BY OR EMPLOYS A COMMONWEALTH-LICENSED HEALTH CARE
4 PROVIDER.

5 "Health care provider." As follows:

6 (1) A facility or individual who is licensed, certified
7 or otherwise regulated to provide health care services under
8 the laws of this Commonwealth.

9 (2) The term does not include an individual providing
10 emergency services under a licensed emergency medical
11 services agency as defined in 35 Pa.C.S. § 8103 (relating to
12 definitions).

13 "Health care service." Any covered treatment, admission,
14 procedure or other services, including behavioral health,
15 prescribed or otherwise provided or proposed to be provided by a
16 health care provider to a covered person for the diagnosis,
17 prevention, treatment, cure or relief of a health condition,
18 illness, injury or disease under the terms of a health insurance
19 policy.

20 "Health insurance policy." As follows:

21 (1) A policy, subscriber contract, certificate or plan
22 issued by an insurer that provides medical or health care
23 coverage.

24 (2) THE TERM INCLUDES AN INDIVIDUAL OR GROUP HEALTH <--
25 INSURANCE POLICY, CONTRACT OR PLAN THAT PROVIDES DENTAL OR
26 VISION COVERAGE THROUGH A PROVIDER NETWORK.

27 ~~(2) The~~ (3) EXCEPT AS PROVIDED IN PARAGRAPH (2), THE <--
28 term does not include:

29 (i) An accident only policy.

30 (ii) A credit only policy.

- 1 (iii) A long-term care or disability income policy.
- 2 (iv) A specified disease policy.
- 3 (v) A Medicare supplement policy.
- 4 (vi) A TRICARE policy, including a Civilian Health
- 5 and Medical Program of the Uniformed Services (CHAMPUS)
- 6 supplement policy.
- 7 (vii) A fixed indemnity policy.
- 8 (viii) A hospital indemnity policy.
- 9 (ix) A workers' compensation policy.
- 10 (x) An automobile medical payment policy under 75
- 11 Pa.C.S. (relating to vehicles).
- 12 (xi) A homeowner's insurance policy.

13 ~~"Insurer." As follows:~~

<--

14 ~~(1) An entity licensed by the department that offers,~~

15 ~~issues or renews an individual or group health insurance~~

16 ~~policy that is offered or governed under any of the~~

17 ~~following:~~

18 ~~(i) Chapter 61 (relating to hospital plan~~

19 ~~corporations) or 63 (relating to professional health~~

20 ~~services plan corporations).~~

21 ~~(ii) The act of May 17, 1921 (P.L.682, No.284),~~

22 ~~known as The Insurance Company Law of 1921, including~~

23 ~~section 630 and Article XXIV thereof.~~

24 ~~(iii) The act of December 29, 1972 (P.L.1701,~~

25 ~~No.364), known as the Health Maintenance Organization~~

26 ~~Act.~~

27 ~~(2) The term does not include an entity operating as an~~

28 ~~MA or CHIP managed care plan.~~

29 "INSURER." AS DEFINED UNDER SECTION 635.8 OF THE INSURANCE

30 COMPANY LAW OF 1921.

<--

1 "Participating network provider." A health care provider
2 that has entered into a contractual or operating relationship
3 with an insurer to participate in one or more designated
4 networks of the insurer and to provide health care services to
5 covered persons under the terms of the insurer's administrative
6 policy.

7 "Prior authorization request." As defined under section 2102
8 of The Insurance Company Law of 1921.

9 "THIRD-PARTY VENDOR." A PERSON OR ENTITY THAT MAKES AN <--
10 ARTIFICIAL INTELLIGENCE-BASED ALGORITHM, PRODUCT OR SERVICE
11 COMMERCIALY AVAILABLE, WHETHER BY SALE, LICENSE OR OTHER
12 OFFERING, FOR USE BY AN INSURER.

13 "Utilization review." As defined under section 2102 of The
14 Insurance Company Law of 1921.
15 § 5202. Disclosure.

16 (a) Duty to disclose.--An insurer shall disclose to a
17 participating network provider and all covered persons IN PLAIN <--
18 LANGUAGE if artificial ~~intelligence based algorithms~~ <--
19 INTELLIGENCE MODELS OR SYSTEMS are or will be used in the <--
20 utilization review process of the insurer.

21 (b) Posting.--An insurer shall post the information about
22 the use of artificial ~~intelligence based algorithms~~ INTELLIGENCE <--
23 MODELS OR SYSTEMS in the utilization review process of the <--
24 insurer IN PLAIN LANGUAGE on the publicly accessible Internet <--
25 website of the insurer.

26 (c) Nature and frequency.--The department shall determine
27 the nature and frequency of disclosure ~~requirements~~ REQUIRED <--
28 UNDER THIS SECTION to covered persons. The department may
29 request input from insurers or their representatives in making
30 this determination.

1 § 5203. Responsible use.

2 (a) Compliance generally.--The criteria for the artificial <--
3 intelligence based algorithms USE OF ARTIFICIAL INTELLIGENCE <--
4 MODEL SYSTEMS IN THE UTILIZATION PROCESS must comply with this
5 chapter and applicable Federal and State law.

6 (b) Requirements for artificial intelligence based <--
7 algorithms INTELLIGENCE.--For each instance in which an insurer <--
8 uses AN artificial intelligence based algorithms INTELLIGENCE <--
9 MODEL OR SYSTEM in the utilization review process regarding a
10 covered person, the insurer shall comply with the following:

11 (1) The artificial intelligence based algorithms must <--
12 base a determination on all of the following: INTELLIGENCE <--
13 MODEL OR SYSTEM MUST EVALUATE:

14 (i) The medical or other clinical history of the
15 covered person.

16 (ii) Individual clinical or nonclinical
17 circumstances as presented by the requesting health care
18 provider.

19 (iii) Other relevant clinical or nonclinical
20 information contained in the medical or other clinical
21 record of the covered person.

22 (2) The artificial intelligence based algorithms <--
23 INTELLIGENCE MODEL OR SYSTEM USED IN THE UTILIZATION REVIEW <--
24 PROCESS must not base a determination solely PRODUCE AN <--
25 OUTPUT SOLELY BASED on a group data set.

26 (3) The artificial intelligence based algorithms <--
27 INTELLIGENCE MODEL OR SYSTEM must not supersede decision <--
28 making of the health care provider conducting the utilization
29 review.

30 (4) The artificial intelligence based algorithms and <--

1 ~~training data sets~~ INTELLIGENCE MODEL OR SYSTEM must not <--
2 directly or indirectly discriminate against covered persons
3 in violation of Federal or State law.

4 (5) ~~The artificial intelligence based algorithms~~ <--
5 INTELLIGENCE MODEL OR SYSTEM must be fairly and equitably <--
6 applied, including in accordance with any applicable
7 regulations ~~or guidance~~ issued by the United States <--
8 Department of Health and Human Services.

9 (6) ~~The use of the artificial intelligence based~~ <--
10 ~~algorithms~~ INTELLIGENCE MODEL OR SYSTEM must be disclosed in <--
11 accordance with section 5202 (relating to disclosure).

12 (7) ~~The performance, use and outcomes of the artificial~~
13 ~~intelligence based algorithms~~ INTELLIGENCE MODEL OR SYSTEM <--
14 must be periodically reviewed and revised AT LEAST QUARTERLY <--
15 to maximize accuracy and reliability.

16 (8) ~~The data of the covered person must not be used~~
17 ~~beyond the intended and stated purpose of the artificial~~
18 ~~intelligence based algorithms, INTELLIGENCE MODEL OR SYSTEM, <--~~
19 ~~EXCEPT AS PERMITTED BY THE COVERED PATIENT THROUGH INFORMED~~
20 ~~CONSENT AS OTHERWISE AUTHORIZED UNDER APPLICABLE FEDERAL OR~~
21 ~~STATE LAW, OR FOR THE USE OF DE-IDENTIFIED OR AGGREGATE~~
22 ~~COVERED PERSON DATA FOR RESEARCH, DEVELOPMENT OR IMPROVEMENT~~
23 ~~OF ARTIFICIAL INTELLIGENCE-BASED ALGORITHMS, consistent with~~
24 ~~Commonwealth law and 42 U.S.C. Ch. 7, Subch. XI Part C~~
25 ~~(relating to administrative simplification), as applicable.~~

26 (9) ~~The artificial intelligence based algorithms~~ <--
27 INTELLIGENCE MODEL OR SYSTEM must not create foreseeable, <--
28 material risks of harm to the covered person.

29 (C) INTERNAL GOVERNANCE.--AN INSURER USING ARTIFICIAL <--
30 INTELLIGENCE MODELS OR SYSTEMS IN THE UTILIZATION REVIEW PROCESS

1 SHALL ESTABLISH AND MAINTAIN THE FOLLOWING:

2 (1) POLICIES AND PROCEDURES FOR IMPLEMENTING, USING AND
3 MONITORING THE USE OF THE ARTIFICIAL INTELLIGENCE MODELS OR
4 SYSTEMS.

5 (2) A GOVERNANCE STRUCTURE TO MANAGE RESPONSIBLE USE OF
6 THE ARTIFICIAL INTELLIGENCE MODELS OR SYSTEMS WITHIN THE
7 INSURER.

8 (3) A REASONABLE PROCESS TO VALIDATE AND MONITOR THE
9 INSURER'S COMPLIANCE WITH THE REQUIREMENTS OF SUBSECTIONS (A)
10 AND (B).

11 ~~§ 5204. Artificial intelligence compliance statements.~~ <--

12 ~~(a) Compliance statement required. An insurer using~~
13 ~~artificial intelligence based algorithms in the utilization~~
14 ~~review process shall annually file with the department in the~~
15 ~~form and manner prescribed by the department an artificial~~
16 ~~intelligence compliance statement.~~

17 ~~(b) Contents. Each compliance statement must:~~

18 ~~(1) Summarize the function and scope of the artificial~~
19 ~~intelligence based algorithms used for utilization review.~~

20 ~~(2) Provide a logic or decision tree of artificial~~
21 ~~intelligence based algorithms used for utilization review.~~

22 ~~(3) Provide a description of each training data set used~~
23 ~~by artificial intelligence based algorithms for utilization~~
24 ~~review, including the source of the data.~~

25 ~~(4) Attest that the artificial intelligence based~~
26 ~~algorithms and the training data sets comply with section~~
27 ~~5203 (relating to responsible use) and provide evidence of~~
28 ~~the compliance.~~

29 ~~(5) Describe the process of the insurer for overseeing~~
30 ~~and validating the performance and compliance of the~~

1 ~~artificial intelligence based algorithms in accordance with~~
2 ~~section 5203.~~

3 § 5204. ARTIFICIAL INTELLIGENCE COMPLIANCE STATEMENTS. <--

4 AN INSURER USING ARTIFICIAL INTELLIGENCE MODELS OR SYSTEMS IN
5 THE UTILIZATION REVIEW PROCESS SHALL ANNUALLY FILE WITH THE
6 DEPARTMENT IN THE FORM AND MANNER PRESCRIBED BY THE DEPARTMENT
7 AN ARTIFICIAL INTELLIGENCE COMPLIANCE STATEMENT ATTESTING THAT
8 THE INSURER'S USE OF THE ARTIFICIAL INTELLIGENCE MODELS OR
9 SYSTEMS IS IN COMPLIANCE WITH SECTION 5203 (RELATING TO
10 RESPONSIBLE USE).

11 § 5205. Health care provider requirements.

12 Prior to issuing or upholding a decision to deny, reduce or
13 terminate benefits for a health care service, including a
14 decision to deny a prior authorization request, a health care
15 provider who participates in utilization review on behalf of an
16 insurer shall:

17 (1) Review individual clinical records and other
18 relevant information.

19 (2) Document the review under paragraph (1).

20 (3) Based on the review under paragraph (1), exercise
21 judgment independent of any recommendations by the artificial <--
22 intelligence based algorithms.

23 ~~§ 5206. Reports.~~

24 ~~(a) Annual report required. No later than one year after~~
25 ~~the effective date of this chapter, and annually thereafter, the~~
26 ~~department shall compile the information from the most recent~~
27 ~~annual compliance statements under section 5204 (relating to~~
28 ~~artificial intelligence compliance statements) and issue a~~
29 ~~report to the General Assembly containing the compiled~~
30 ~~information, along with any other applicable findings and~~

1 ~~recommendations. The information in the report shall be~~
2 ~~aggregated and deidentified.~~

3 ~~(b) Posting. The department shall post each report under~~
4 ~~this section on the publicly accessible Internet website of the~~
5 ~~department. ARTIFICIAL INTELLIGENCE. AN INSURER MAY NOT PENALIZE <--~~
6 ~~A HEALTH CARE PROVIDER WHO PARTICIPATES IN UTILIZATION REVIEW ON~~
7 ~~BEHALF OF AN INSURER SOLELY FOR EXERCISING INDEPENDENT JUDGMENT~~
8 ~~IN REFUSING TO ISSUE OR OVERTURNING A DECISION TO DENY, REDUCE~~
9 ~~OR TERMINATE BENEFITS FOR A HEALTH CARE SERVICE GENERATED BY~~
10 ~~ARTIFICIAL INTELLIGENCE.~~

11 ~~§ 5207 5206. Retention of records. <--~~

12 ~~The department shall establish a record retention policy and~~
13 ~~determine the amount of time an insurer shall retain records. <--~~
14 ~~The department may request input from insurers or their~~
15 ~~representatives in making this determination. RELATED TO ITS USE <--~~
16 ~~OF ARTIFICIAL INTELLIGENCE MODELS OR SYSTEMS IN THE UTILIZATION~~
17 ~~REVIEW PROCESS. THE FOLLOWING SHALL APPLY:~~

18 ~~(1) RECORDS SHALL BE RETAINED NOT LESS THAN FIVE YEARS~~
19 ~~AND AT LEAST AS LONG AS REQUIRED UNDER OTHER EXISTING LAW.~~

20 ~~(2) THE DEPARTMENT MAY REQUEST INPUT FROM INSURERS OR~~
21 ~~THEIR REPRESENTATIVES IN MAKING THIS DETERMINATION.~~

22 ~~(3) ANY RECORD RETENTION POLICY SHALL NOT BE IN CONFLICT~~
23 ~~WITH EXISTING LAW.~~

24 ~~§ 5208 5207. Oversight. <--~~

25 ~~(A) COMPLIANCE.--THE DEPARTMENT SHALL ENSURE COMPLIANCE WITH <--~~
26 ~~THIS CHAPTER.~~

27 ~~(B) INVESTIGATION.--The department may INVESTIGATE POTENTIAL <--~~
28 ~~VIOLATIONS OF THIS CHAPTER AND request additional information~~
29 ~~and evidence from an insurer regarding the items provided under~~
30 ~~sections 5202 (relating to disclosure), 5203 (relating to~~

1 responsible use) and, 5204 (relating to artificial intelligence <--
2 compliance statements) AND 5205 (RELATING TO HEALTH CARE <--
3 PROVIDER REQUIREMENTS) that are necessary to ensure compliance
4 with this chapter.

5 ~~§ 5209. Third party vendor.~~ <--

6 ~~A contractor, subcontractor or other third party vendor that~~
7 ~~sells, leases, subscribes or otherwise supplies artificial~~
8 ~~intelligence based algorithms or services based on artificial~~
9 ~~intelligence based algorithms to the insurer services shall be~~
10 ~~subject to this chapter. The department shall develop~~
11 ~~regulations or guidelines regarding the responsibility of a~~
12 ~~contractor, subcontractor or other third party vendor that~~
13 ~~sells, leases, subscribes or otherwise supplies artificial~~
14 ~~intelligence based algorithms or services based on artificial~~
15 ~~intelligence based algorithms to the insurer. The department may~~
16 ~~request input from insurers, third party vendors and health care~~
17 ~~providers or their representatives in making this determination.~~

18 (C) CONFIDENTIALITY.--DOCUMENTS SUBMITTED TO THE DEPARTMENT <--
19 UNDER THIS SUBSECTION SHALL REMAIN CONFIDENTIAL AND SHALL NOT BE
20 ACCESSIBLE FOR INSPECTIONS AND DUPLICATION IN ACCORDANCE WITH
21 THE ACT OF FEBRUARY 14, 2008 (P.L.6, NO.3), KNOWN AS THE RIGHT-
22 TO-KNOW LAW.

23 (D) SELF-INSURED PLANS.--SELF-INSURED HEALTH BENEFIT PLANS
24 SUBJECT TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974
25 (PUBLIC LAW 93-406, 29 U.S.C. § 1001 ET SEQ.) MAY OPT INTO THE
26 REQUIREMENTS OF THIS CHAPTER.

27 § 5208. THIRD-PARTY VENDOR.

28 AN INSURER UTILIZING A THIRD-PARTY VENDOR FOR THE DEVELOPMENT
29 OR DEPLOYMENT OF ARTIFICIAL INTELLIGENCE MODELS OR SYSTEMS FOR
30 USE IN THE UTILIZATION REVIEW PROCESS, OR PRODUCTS OR SERVICES

1 FOR THE UTILIZATION REVIEW PROCESS THAT RELY ON ARTIFICIAL
2 INTELLIGENCE MODELS OR SYSTEMS, SHALL ESTABLISH INTERNAL REVIEW
3 AND GOVERNANCE PROCESSES TO ENSURE COMPLIANCE WITH REQUIREMENTS
4 UNDER SECTIONS 5202 (RELATING TO DISCLOSURE), 5203 (RELATING TO
5 RESPONSIBLE USE), 5204 (RELATING TO ARTIFICIAL INTELLIGENCE
6 COMPLIANCE STATEMENTS) AND 5205 (RELATING TO HEALTH CARE
7 PROVIDER REQUIREMENTS).

8 § ~~5210~~ 5209. Exemption. <--

9 This chapter shall not apply to artificial intelligence-based
10 algorithms used for administrative, scheduling or other purposes
11 not pertaining to the insurer's decision to deny, reduce or
12 terminate benefits.

13 § ~~5211~~ 5210. Enforcement and penalties. <--

14 (a) Civil penalties.--

15 ~~(1) Subject to paragraph (2), the department may impose~~ <--
16 ~~a civil penalty not exceeding \$5,000 for a violation of this~~
17 ~~chapter. For purposes of this paragraph, each instance of~~
18 ~~nondisclosure shall constitute a separate violation of this~~
19 ~~chapter.~~

20 ~~(2) The following apply to limitations on civil~~
21 ~~penalties under this subsection:~~

22 ~~(i) A civil penalty imposed against an insurer may~~
23 ~~not exceed \$500,000 in the aggregate during a single~~
24 ~~calendar year.~~

25 ~~(ii) A civil penalty imposed against any other~~
26 ~~person may not exceed \$100,000 in the aggregate during a~~
27 ~~single calendar year.~~

28 ~~(b) Unfair Insurance Practices Act.--~~

29 ~~(1) An insurer shall be subject to the act of July 22,~~
30 ~~1974 (P.L.589, No.205), known as the Unfair Insurance~~

1 Practices Act.

2 ~~(2) A violation of any provision of this chapter shall~~
3 ~~be deemed to be a violation of the Unfair Insurance Practices~~
4 ~~Act.~~

5 (1) SUBJECT TO PARAGRAPHS (2), (3) AND (4), THE <--
6 DEPARTMENT MAY IMPOSE A CIVIL PENALTY AS FOLLOWS FOR A
7 VIOLATION OF THIS CHAPTER:

8 (I) FOR A KNOWING OR WILLFUL VIOLATION, A CIVIL
9 PENALTY OF NOT MORE THAN \$10,000 PER VIOLATION.

10 (II) EXCEPT AS PROVIDED UNDER SUBPARAGRAPH (III) FOR
11 A NEGLIGENT VIOLATION, A CIVIL PENALTY OF NOT MORE THAN
12 \$5,000 PER VIOLATION.

13 (III) FOR A FIRST-TIME NEGLIGENT VIOLATION BY AN
14 ENTITY THAT THE DEPARTMENT DETERMINES HAS MADE A GOOD-
15 FAITH EFFORT TO COMPLY WITH THIS CHAPTER, A CIVIL PENALTY
16 OF NOT MORE THAN \$1,000 PER VIOLATION OR, AT THE
17 DEPARTMENT'S DISCRETION, A PLAN OF CORRECTION UNDER
18 SECTION 5211 (RELATING TO PLAN OF CORRECTION) IN LIEU OF
19 A PENALTY.

20 (2) FOR THE PURPOSES OF PARAGRAPH (1), EACH INSTANCE OF
21 NONDISCLOSURE SHALL CONSTITUTE A SEPARATE VIOLATION OF THIS
22 CHAPTER.

23 (3) IN DETERMINING THE AMOUNT OF A CIVIL PENALTY, THE
24 DEPARTMENT SHALL CONSIDER:

25 (I) THE NATURE AND SERIOUSNESS OF THE VIOLATION.

26 (II) WHETHER THE VIOLATION HAS RESULTED IN PATIENT
27 HARM.

28 (III) THE VIOLATOR'S HISTORY OF COMPLIANCE.

29 (IV) ANY GOOD-FAITH EFFORTS BY THE VIOLATOR TO
30 COMPLY.

1 (V) THE VIOLATOR'S SIZE AND FINANCIAL RESOURCES.

2 (4) THE AGGREGATE AMOUNT OF CIVIL PENALTIES IMPOSED ON A
3 SINGLE ENTITY UNDER THIS SUBSECTION DURING A SINGLE CALENDAR
4 YEAR SHALL NOT EXCEED \$250,000.

5 (B) ACTIONS.--A VIOLATION OF ANY PROVISION OF THIS CHAPTER
6 SHALL BE DEEMED TO BE AN UNFAIR OR DECEPTIVE ACT OR PRACTICE IN
7 VIOLATION OF THE ACT OF DECEMBER 17, 1968 (P.L.1224, NO.387),
8 KNOWN AS THE UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW.
9 THE OFFICE OF ATTORNEY GENERAL SHALL HAVE EXCLUSIVE AUTHORITY TO
10 BRING AN ACTION UNDER THE UNFAIR TRADE PRACTICES AND CONSUMER
11 PROTECTION LAW FOR A VIOLATION OF ANY PROVISION OF THIS CHAPTER.

12 (c) Injunction.--The department may maintain an action in
13 the name of the Commonwealth for an injunction to prohibit any
14 activity that violates the provisions of this chapter.

15 (d) Effect on enrollment.--The department may issue an order
16 temporarily prohibiting an insurer that violates this chapter
17 from enrolling new covered persons.

18 (e) Nonexclusive remedies.--The enforcement remedies and
19 penalties imposed under this chapter are in addition to any
20 other remedies or penalties that may be imposed under any other
21 applicable FEDERAL OR STATE law of this Commonwealth, including: <--

22 (1) The ACT OF JULY 22, 1974 (P.L.589, NO.205), KNOWN AS <--
23 THE Unfair Insurance Practices Act.

24 (2) The act of December 18, 1996 (P.L.1066, No.159),
25 known as the Accident and Health Filing Reform Act.

26 (3) The act of June 25, 1997 (P.L.295, No.29), known as
27 the Pennsylvania Health Care Insurance Portability Act.

28 (4) THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY <--
29 ACT OF 1996 (PUBLIC LAW 104-191, 110 STAT. 1936), AS AMENDED
30 BY THE HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND

1 CLINICAL HEALTH ACT (PUBLIC LAW 111-5, 123 STAT. 226-279 AND
2 467-496).

3 § 5212 5211. Plan of correction. <--

4 (a) Authorization.--The department may require an insurer to
5 develop and adhere to a plan of correction approved by the
6 department. The department may impose a plan of correction in
7 lieu of ~~finer~~ OR IN ADDITION TO CIVIL PENALTIES IMPOSED UNDER <--
8 SECTION 5210 (RELATING TO ENFORCEMENT AND PENALTIES).

9 (b) Compliance.--The department shall monitor compliance
10 with the plan of correction under this section.

11 (c) Availability.--The plan of correction shall, ~~upon~~ <--
12 ~~request,~~ be made available to covered persons of the insurer, <--
13 UPON REQUEST.

14 § 5213 5212. Administrative procedures. <--

15 (a) Applicable procedures.--This chapter shall be subject to
16 2 Pa.C.S. Ch. 5 Subch. A (relating to practice and procedure of
17 Commonwealth agencies).

18 (b) Appeal.--A party against whom penalties are assessed in
19 an administrative action may appeal to Commonwealth Court as
20 provided in 2 Pa.C.S. Ch. 7 Subch. A (relating to judicial
21 review of Commonwealth agency action).

22 § 5214 5213. Regulations and guidance. <--

23 The department shall promulgate regulations or guidance
24 necessary to implement, administer and enforce this chapter. ~~The~~ <--
25 ~~department shall review regulations or guidance every three~~
26 ~~years to ensure compliance with Federal law or Federal agency~~
27 ~~guidance.~~ IN ACCORDANCE WITH THE FOLLOWING: <--

28 (1) THE DEPARTMENT SHALL CONSULT WITH THE DEPARTMENT OF
29 HEALTH AND THE DEPARTMENT OF HUMAN SERVICES WHEN DEVELOPING
30 REGULATIONS AND GUIDANCE TO ACHIEVE CONFORMITY ACROSS

1 REGULATIONS AND GUIDANCE PROMULGATED BY THE THREE
2 DEPARTMENTS.

3 (2) THE DEPARTMENT SHALL REVIEW REGULATIONS OR GUIDANCE
4 EVERY THREE YEARS TO ENSURE COMPLIANCE WITH FEDERAL LAW OR
5 FEDERAL AGENCY GUIDANCE.

6 SECTION 3. TITLE 67 IS AMENDED BY ADDING A CHAPTER TO READ:

7 CHAPTER 53 41 <--

8 ARTIFICIAL INTELLIGENCE USE BY MA OR CHIP

9 MANAGED CARE PLANS

10 Sec.

11 ~~5301~~ 4101. Definitions. <--

12 ~~5302~~ 4102. Disclosure. <--

13 ~~5303~~ 4103. Responsible use. <--

14 ~~5304~~ 4104. Artificial intelligence compliance statements. <--

15 ~~5305~~ 4105. Health care provider requirements. <--

16 ~~5306.~~ Reports. <--

17 ~~5307~~ 4106. Retention of records. <--

18 ~~5308~~ 4107. Oversight. <--

19 ~~5309~~ 4108. Third-party vendor. <--

20 ~~5310~~ 4109. Exemption. <--

21 ~~5311~~ 4110. Enforcement and penalties. <--

22 ~~5312~~ 4111. Plan of correction. <--

23 ~~5313~~ 4112. Administrative procedures. <--

24 ~~5314~~ 4113. Regulations and guidance. <--

25 § ~~5301~~ 4101. Definitions. <--

26 The following words and phrases when used in this chapter
27 shall have the meanings given to them in this section unless the
28 context clearly indicates otherwise:

29 "Agreement with the department." As follows:

30 (1) An agreement between an MA or CHIP managed care plan

1 and the department to manage the purchase and provision of
2 services.

3 (2) The term includes a county or multicounty agreement
4 with the department for behavioral health services.

5 "Artificial intelligence" or "AI." INTELLIGENCE." A machine- <--
6 based system that can, for a given set of human-defined
7 objectives, make predictions, recommendations or decisions
8 influencing real or virtual environments that use machine-based
9 and human-based inputs to perceive real and virtual
10 environments, abstract the perceptions into models through
11 analysis in an automated manner and use model inference to
12 formulate options for information or action. The term includes
13 generative artificial intelligence which is the class of models
14 that emulate the structure and characteristics of input data in
15 order to generate derived synthetic content which includes
16 information such as images, videos, audio clips and text that
17 has been significantly modified or generated by algorithms,
18 including by artificial intelligence.

19 "Artificial intelligence-based algorithms." The programming
20 and data sets that inform an artificial intelligence system.

21 "ARTIFICIAL INTELLIGENCE MODEL." A CONCEPTUAL OR <--
22 MATHEMATICAL REPRESENTATION OF ABSTRACTED PHENOMENA CAPTURED AS
23 A SYSTEM OF EVENTS, FEATURES OR PROCESSES.

24 "ARTIFICIAL INTELLIGENCE SYSTEM." A FULLY OPERATIONAL
25 ARTIFICIAL INTELLIGENCE APPLICATION OR SCENARIO IN WHICH
26 ARTIFICIAL INTELLIGENCE IS DEPLOYED, INCLUDING THE MODEL,
27 TECHNICAL INFRASTRUCTURE AND PERSONNEL IN THE WORKFLOW.

28 "Department." The Department of Human Services of the
29 Commonwealth.

30 "Enrollee." An individual who is entitled to receive health

1 care services under an agreement with the department.

2 "Facility." A health care setting or institution providing
3 health care services, including:

4 (1) A general, special, psychiatric or rehabilitation
5 hospital.

6 (2) An ambulatory surgical facility.

7 (3) A cancer treatment center.

8 (4) A birth center.

9 (5) A SKILLED NURSING CENTER. <--

10 ~~(5)~~ (6) An inpatient, outpatient or residential drug and <--
11 alcohol treatment facility.

12 ~~(6)~~ (7) A facility licensed by the department's Office <--
13 of Mental Health and Substance Abuse Services.

14 ~~(7)~~ (8) A laboratory, imaging, diagnostic or other <--
15 outpatient medical service or testing facility.

16 ~~(8)~~ (9) A health care provider office or clinic that is <--
17 owned by or employs a Commonwealth-licensed physician, <--

18 ~~physician assistant or nurse practitioner~~ HEALTH CARE <--
19 PROVIDER.

20 "Health care provider." As follows:

21 (1) A facility or individual who is licensed, certified
22 or otherwise regulated to provide health care services under
23 the laws of this Commonwealth.

24 (2) The term does not include an individual providing
25 emergency services under a licensed emergency medical
26 services agency as defined in 35 Pa.C.S. § 8103 (relating to
27 definitions).

28 "Health care service." Any covered treatment, admission,
29 procedure or other services, including behavioral health,
30 prescribed or otherwise provided or proposed to be provided by a

1 health care provider to a covered person for the diagnosis,
2 prevention, treatment, cure or relief of a health condition,
3 illness, injury or disease under the terms of a health insurance
4 policy or agreement with the department.

5 "Medical Assistance or Children's Health Insurance Program
6 managed care plan" or "MA or CHIP managed care plan." As
7 defined under section 2102 of the act of May 17, 1921 (P.L.682,
8 No.284), known as The Insurance Company Law of 1921.

9 "Participating network provider." A health care provider
10 that has entered into a contractual or operating relationship
11 with an MA or CHIP managed care plan to participate in one or
12 more designated networks of the MA or CHIP managed care plan and
13 to provide health care services to enrollees under the terms of
14 the or an agreement with the department.

15 "Prior authorization request." As defined under section 2102
16 of The Insurance Company Law of 1921.

17 "THIRD-PARTY VENDOR." A PERSON OR ENTITY THAT MAKES AN <--
18 ARTIFICIAL INTELLIGENCE-BASED ALGORITHM, PRODUCT OR SERVICE
19 COMMERCIALY AVAILABLE, WHETHER BY SALE, LICENSE OR OTHER
20 OFFERING, FOR USE BY AN MA OR CHIP MANAGED CARE PLAN.

21 "Utilization review." As defined under section 2102 of The
22 Insurance Company Law of 1921.

23 § 5302 4102. Disclosure. <--

24 (a) Duty to disclose.--An MA or CHIP managed care plan shall
25 disclose to a participating network provider and all enrollees
26 IN PLAIN LANGUAGE if artificial intelligence based algorithms <--
27 INTELLIGENCE MODELS OR SYSTEMS are or will be used in the <--
28 utilization review process of the MA or CHIP managed care plan.

29 (b) Posting.--An MA or CHIP managed care plan shall post the
30 information about the use of artificial intelligence based <--

1 ~~algorithms~~ INTELLIGENCE MODELS OR SYSTEMS in the utilization <--
2 review process of the MA or CHIP managed care plan IN PLAIN <--
3 LANGUAGE on the publicly accessible Internet website of the MA
4 or CHIP managed care plan.

5 (c) Nature and frequency.--The department shall determine
6 the nature and frequency of disclosure ~~requirements~~ REQUIRED <--
7 UNDER THIS SECTION to enrollees. The department may request
8 input from MA or CHIP managed care plans or their
9 representatives in making this determination.

10 § 5303 4103. Responsible use. <--

11 (a) Compliance generally.--The ~~criteria for~~ USE OF the <--
12 ~~artificial intelligence based algorithms~~ INTELLIGENCE MODELS OR <--
13 SYSTEMS IN THE UTILIZATION REVIEW PROCESS must comply with this
14 chapter and applicable Federal and State law.

15 (b) Requirements for artificial ~~intelligence based~~ <--
16 ~~algorithms~~ INTELLIGENCE.--For each instance in which a MA or <--
17 CHIP managed care plan uses AN artificial ~~intelligence based~~ <--
18 ~~algorithms~~ INTELLIGENCE MODEL OR SYSTEM in the utilization <--
19 review process regarding an enrollee, the MA or CHIP managed
20 care plan shall comply with the following:

21 (1) The artificial ~~intelligence based algorithms must~~ <--
22 ~~base a determination on all of the following~~ INTELLIGENCE <--
23 MODEL OR SYSTEM USED IN THE UTILIZATION REVIEW PROCESS MUST
24 EVALUATE:

25 (i) The medical or other clinical history of the
26 enrollee.

27 (ii) Individual clinical or nonclinical
28 circumstances as presented by the requesting health care
29 provider.

30 (iii) Other relevant clinical or nonclinical

1 information contained in the medical or other clinical
2 record of the enrollee.

3 (2) The artificial intelligence based algorithms <--
4 INTELLIGENCE MODEL OR SYSTEM USED IN THE UTILIZATION REVIEW <--
5 PROCESS must not base a determination PRODUCE AN OUTPUT <--
6 solely BASED on a group data set. <--

7 (3) The artificial intelligence based algorithms <--
8 INTELLIGENCE MODEL OR SYSTEM must not supersede decision <--
9 making of the health care provider conducting the utilization
10 review.

11 (4) The artificial intelligence based algorithms and <--
12 training data sets INTELLIGENCE MODEL OR SYSTEM must not <--
13 directly or indirectly discriminate against the enrollees in
14 violation of Federal or State law.

15 (5) The artificial intelligence based algorithms <--
16 INTELLIGENCE MODEL OR SYSTEM must be fairly and equitably <--
17 applied, including in accordance with any applicable
18 regulations and guidance issued by the United States <--
19 Department of Health and Human Services.

20 (6) The use of the artificial intelligence based <--
21 algorithms INTELLIGENCE MODEL OR SYSTEM must be disclosed in <--
22 accordance with section 5302 4102 (relating to disclosure). <--

23 (7) The performance, use and outcomes of the artificial
24 intelligence based algorithms INTELLIGENCE MODEL OR SYSTEM <--
25 must be periodically reviewed AT LEAST QUARTERLY and revised <--
26 to maximize accuracy and reliability.

27 (8) The data of the covered person or enrollees must not <--
28 be used beyond the intended and stated purpose of the
29 artificial intelligence based algorithms, INTELLIGENCE MODEL <--
30 OR SYSTEM EXCEPT AS PERMITTED BY THE ENROLLEE THROUGH

1 INFORMED CONSENT, AS OTHERWISE AUTHORIZED UNDER APPLICABLE
2 FEDERAL AND STATE LAW, OR AGGREGATE ENROLLEE DATA FOR USE OF
3 DE-IDENTIFIABLE OR AGGREGATE ENROLLEE DATA FOR RESEARCH,
4 DEVELOPMENT OR IMPROVEMENT OF ARTIFICIAL INTELLIGENCE,
5 consistent with the laws of this Commonwealth and the Health
6 Insurance Portability and Accountability Act of 1996 (Public
7 Law 104-191, 110 Stat. 1936), as applicable.

8 (9) ~~The artificial intelligence based algorithms~~ <--
9 INTELLIGENCE MODEL OR SYSTEM must not create foreseeable, <--
10 material risks of harm to the enrollee.

11 (C) INTERNAL GOVERNANCE.--AN MA OR CHIP MANAGED CARE PLAN <--
12 USING ARTIFICIAL INTELLIGENCE MODELS OR SYSTEMS IN THE
13 UTILIZATION REVIEW PROCESS SHALL ESTABLISH AND MAINTAIN THE
14 FOLLOWING:

15 (1) POLICIES AND PROCEDURES FOR IMPLEMENTING, USING AND
16 MONITORING THE USE OF THE ARTIFICIAL INTELLIGENCE MODELS OR
17 SYSTEMS.

18 (2) A GOVERNANCE STRUCTURE TO MANAGE RESPONSIBLE USE OF
19 THE ARTIFICIAL INTELLIGENCE MODELS OR SYSTEMS WITHIN THE MA
20 OR CHIP MANAGED CARE.

21 (3) REASONABLE PROCESS TO VALIDATE AND MONITOR THE MA OR
22 CHIP MANAGED CARE PLAN COMPLIANCE WITH THE REQUIREMENTS OF
23 SUBSECTIONS (A) AND (B).

24 § ~~5304~~ 4104. Artificial intelligence compliance statements. <--

25 ~~(a) Compliance statement required.--An MA or CHIP managed <--~~
26 care plan using artificial ~~intelligence based algorithms~~ <--
27 INTELLIGENCE MODELS OR SYSTEMS in the utilization review process <--
28 shall annually file with the department, in the form and manner
29 prescribed by the department, an artificial intelligence
30 compliance statement. <--

1 ~~(b) Contents. Each compliance statement must:~~

2 ~~(1) Summarize the function and scope of the artificial~~
3 ~~intelligence based algorithms used for utilization review.~~

4 ~~(2) Provide a logic or decision tree of artificial~~
5 ~~intelligence based algorithms used for utilization review.~~

6 ~~(3) Provide a description of each training data set used~~
7 ~~by artificial intelligence based algorithms for utilization~~
8 ~~review, including the source of the data.~~

9 ~~(4) Attest that the artificial intelligence based~~
10 ~~algorithms and the training data sets comply with section~~
11 ~~5303 (relating to responsible use) and provide evidence of~~
12 ~~the compliance.~~

13 ~~(5) Describe the process of the MA or CHIP managed care~~
14 ~~plan for overseeing and validating the performance and~~
15 ~~compliance of the artificial intelligence based algorithms in~~
16 ~~accordance with section 5303. ATTESTING THAT THE MA OR CHIP <--~~
17 ~~MANGED CARE PLAN IS IN COMPLIANCE WITH SECTION 4103 (RELATING~~
18 ~~TO RESPONSIBLE USE).~~

19 ~~§ 5305 4105. Health care provider requirements. <--~~

20 ~~Prior to issuing or upholding a decision to deny, reduce or~~
21 ~~terminate benefits for a health care service, including a~~
22 ~~decision to deny a prior authorization request, a health care~~
23 ~~provider who participates in utilization review on behalf of an~~
24 ~~MA or CHIP managed care plan shall:~~

25 ~~(1) Review individual clinical records and other~~
26 ~~relevant information.~~

27 ~~(2) Document the review under paragraph (1).~~

28 ~~(3) Based on the review under paragraph (1), exercise~~
29 ~~judgment independent of any recommendations by the artificial <--~~
30 ~~intelligence based algorithms.~~

1 ~~§ 5306. Reports.~~

2 ~~(a) Annual report required. No later than one year after~~
3 ~~the effective date of this chapter, and annually thereafter, the~~
4 ~~department shall compile the information from the most recent~~
5 ~~annual compliance statements under section 5304 (relating to~~
6 ~~artificial intelligence compliance statements) and issue a~~
7 ~~report to the General Assembly containing the compiled~~
8 ~~information, along with any other applicable findings and~~
9 ~~recommendations. The information in the report shall be~~
10 ~~aggregated and deidentified.~~

11 ~~(b) Posting. The department shall post each report under~~
12 ~~this section on the publicly accessible Internet website of the~~
13 ~~department. BY ARTIFICIAL INTELLIGENCE. AN MA OR CHIP MANAGED <--~~
14 ~~CARE PLAN MAY NOT PENALIZE A HEALTH CARE PROVIDER WHO~~
15 ~~PARTICIPATES IN UTILIZATION REVIEW ON BEHALF OF AN MA OR CHIP~~
16 ~~MANAGED CARE PLAN SOLELY FOR EXERCISING INDEPENDENT JUDGING IN~~
17 ~~REFUSING TO ISSUE OR OVERTURNING A DECISION TO DENY, REDUCE OR~~
18 ~~TERMINATE BENEFITS FOR A HEALTH CARE SERVICE GENERATED BY~~
19 ~~ARTIFICIAL INTELLIGENCE.~~

20 ~~§ 5307 4106. Retention of records. <--~~

21 ~~The department shall establish a record retention policy and~~
22 ~~determine the amount of time an MA or CHIP managed care plan~~
23 ~~shall retain records. The department may request input from an <--~~
24 ~~MA or CHIP managed care plan or their representative to make~~
25 ~~this determination. RELATING TO THE USE OF ARTIFICIAL <--~~
26 ~~INTELLIGENCE MODELS OR SYSTEMS IN THE UTILIZATION REVIEW PROCESS~~
27 ~~IN ACCORDANCE WITH THE FOLLOWING:~~

28 ~~(1) RETENTION SHALL BE AT LEAST FIVE YEARS AND AS LONG~~
29 ~~AS REQUIRED UNDER EXISTING LAW.~~

30 ~~(2) THE DEPARTMENT MAY REQUEST INPUT FROM AN MA OR CHIP~~

1 MANAGED CARE PLAN OR THEIR REPRESENTATIVE TO MAKE THIS
2 DETERMINATION.

3 (3) A RECORD RETENTION POLICY SHALL NOT BE IMPLEMENTED
4 IN CONFLICT WITH EXISTING LAW.

5 § 5308 4107. Oversight. <--

6 (A) COMPLIANCE.--THE DEPARTMENT SHALL ENSURE COMPLIANCE WITH <--
7 THIS CHAPTER.

8 (B) INFORMATION.--The department may INVESTIGATE POTENTIAL <--
9 VIOLATIONS OF THIS CHAPTER AND MAY request additional
10 information and evidence from an MA or CHIP managed care plan
11 regarding the items provided under section 5302 4102 (relating <--
12 to disclosure), 5303 4103 (relating to responsible use) and <--
13 5304, 4104 (relating to artificial intelligence compliance <--
14 statements) AND 4105 (RELATING TO HEALTH CARE PROVIDER <--
15 REQUIREMENTS) that are necessary to ensure compliance with this
16 chapter.

17 § 5309. Third party vendor. <--

18 A contractor, subcontractor or other third party vendor that
19 sells, leases, subscribes or otherwise supplies artificial
20 intelligence based algorithms or services based on artificial
21 intelligence based algorithms to the MA or CHIP managed care
22 plan shall be subject to this chapter. The department shall
23 develop regulations or guidelines regarding the responsibility
24 of a contractor, subcontractor or other third party vendor that
25 sells, leases, subscribes or otherwise supplies artificial
26 intelligence based algorithms or services based on artificial
27 intelligence based algorithms to the insurer or MA or CHIP
28 managed care plan. The department may request input from
29 insurers, third party vendors and health care providers or their
30 representatives in making this determination.

1 ~~§ 5310. Exemption.~~

2 ~~(C) CONFIDENTIALITY.--DOCUMENTS SUBMITTED TO THE DEPARTMENT <--~~
3 ~~UNDER THIS SECTION SHALL REMAIN CONFIDENTIAL AND SHALL NOT BE~~
4 ~~ACCESSIBLE UNDER THE ACT OF FEBRUARY 14, 2008 (P.L.6, NO.3),~~
5 ~~KNOWN AS THE RIGHT-TO-KNOW LAW.~~

6 ~~§ 4108. THIRD-PARTY VENDOR.~~

7 ~~AN MA OR CHIP MANAGED CARE PLAN UTILIZING A THIRD-PARTY~~
8 ~~VENDOR FOR THE DEVELOPMENT OR DEPLOYMENT OF ARTIFICIAL~~
9 ~~INTELLIGENCE MODELS OR SYSTEMS FOR USE IN THE UTILIZATION REVIEW~~
10 ~~PROCESS, OR PRODUCTS OR SERVICES FOR THE UTILIZATION REVIEW~~
11 ~~PROCESS THAT RELY ON ARTIFICIAL INTELLIGENCE MODELS OR SYSTEMS,~~
12 ~~SHALL ESTABLISH INTERNAL REVIEW AND GOVERNANCE PROCESSES TO~~
13 ~~ENSURE COMPLIANCE WITH REQUIREMENTS UNDER SECTIONS 4102~~
14 ~~(RELATING TO DISCLOSURE), 4103 (RELATING TO RESPONSIBLE USE),~~
15 ~~4104 (RELATING TO ARTIFICIAL INTELLIGENCE COMPLIANCE STATEMENTS)~~
16 ~~AND 4105 (RELATING TO HEALTH CARE PROVIDER REQUIREMENTS).~~

17 ~~§ 4109. EXEMPTION.~~

18 ~~This chapter shall not apply to artificial intelligence based <--~~
19 ~~algorithms INTELLIGENCE MODELS OR SYSTEMS used for <--~~
20 ~~administrative, scheduling or other purposes not pertaining to~~
21 ~~the decision to deny, reduce or terminate benefits.~~

22 ~~§ 5311 4110. Enforcement and penalties. <--~~

23 ~~(a) Civil penalties.--~~

24 ~~(1) Subject to paragraph (2), the department may impose <--~~
25 ~~a civil penalty not exceeding \$5,000 for a violation of this~~
26 ~~chapter. For purposes of this paragraph, each instance of~~
27 ~~nondisclosure shall constitute a separate violation of this~~
28 ~~chapter.~~

29 ~~(2) The following apply to limitations on civil~~
30 ~~penalties under this subsection:~~

1 ~~(i) A civil penalty imposed against an insurer may~~
2 ~~not exceed \$500,000 in the aggregate during a single~~
3 ~~calendar year.~~

4 ~~(ii) A civil penalty imposed against any other~~
5 ~~person may not exceed \$100,000 in the aggregate during a~~
6 ~~single calendar year.~~

7 ~~(b) Unfair Insurance Practices Act.~~

8 ~~(1) An MA or CHIP managed care plan shall be subject to~~
9 ~~the act of July 22, 1974 (P.L.589, No.205), known as the~~
10 ~~Unfair Insurance Practices Act.~~

11 ~~(2) A violation of any provision of this chapter shall~~
12 ~~be deemed to be a violation of the Unfair Insurance Practices~~
13 ~~Act.~~

14 (1) SUBJECT TO PARAGRAPHS (2), (3) AND (4), THE <--
15 DEPARTMENT MAY IMPOSE A CIVIL PENALTY AS FOLLOWS FOR A
16 VIOLATION OF THIS CHAPTER:

17 (I) FOR A KNOWING OR WILLFUL VIOLATION, A CIVIL
18 PENALTY OF NOT MORE THAN \$10,000 PER VIOLATION.

19 (II) EXCEPT AS PROVIDED UNDER SUBPARAGRAPH (III) FOR
20 A NEGLIGENT VIOLATION, A CIVIL PENALTY OF NOT MORE THAN
21 \$5,000 PER VIOLATION.

22 (III) FOR A FIRST-TIME, NEGLIGENT VIOLATION BY AN
23 ENTITY THAT THE DEPARTMENT DETERMINES HAS MADE A GOOD-
24 FAITH EFFORT TO COMPLY WITH THIS CHAPTER, A CIVIL PENALTY
25 OF NOT MORE THAN \$1,000 PER VIOLATION OR, AT THE
26 DEPARTMENT'S DISCRETION, A PLAN OF CORRECTION UNDER
27 SECTION 4111 (RELATING TO PLAN OF CORRECTION) IN LIEU OF
28 A PENALTY.

29 (2) FOR PURPOSES OF PARAGRAPH (1), EACH INSTANCE OF
30 NONDISCLOSURE SHALL CONSTITUTE A SEPARATE VIOLATION OF THIS

1 CHAPTER.

2 (3) IN DETERMINING THE AMOUNT OF A CIVIL PENALTY, THE
3 DEPARTMENT SHALL CONSIDER:

4 (I) THE NATURE AND SERIOUSNESS OF THE VIOLATION.

5 (II) WHETHER THE VIOLATION HAS RESULTED IN PATIENT
6 HARM.

7 (III) THE VIOLATOR'S HISTORY OF COMPLIANCE.

8 (IV) ANY GOOD-FAITH EFFORTS BY THE VIOLATOR TO
9 COMPLY.

10 (V) THE VIOLATOR'S SIZE AND FINANCIAL RESOURCES.

11 (4) THE AGGREGATE AMOUNT OF CIVIL PENALTIES IMPOSED ON A
12 SINGLE ENTITY UNDER THIS SUBSECTION DURING A SINGLE CALENDAR
13 YEAR SHALL NOT EXCEED \$250,000.

14 (B) DEPARTMENT ENFORCEMENT.--A VIOLATION OF ANY PROVISION OF
15 THIS CHAPTER SHALL BE DEEMED TO BE A VIOLATION OF THE MA OR CHIP
16 MANAGED CARE PLAN'S AGREEMENT WITH THE DEPARTMENT AND SHALL BE
17 SUBJECT TO ENFORCEMENT PROCEEDINGS UNDER REGULATIONS PROMULGATED
18 BY THE DEPARTMENT.

19 (C) ACTIONS.--A VIOLATION OF ANY PROVISION OF THIS CHAPTER
20 SHALL BE DEEMED TO BE AN UNFAIR OR DECEPTIVE ACT OR PRACTICE IN
21 VIOLATION OF THE ACT OF DECEMBER 17, 1968 (P.L.1224, NO.387),
22 KNOWN AS THE UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW.
23 THE OFFICE OF ATTORNEY GENERAL SHALL HAVE EXCLUSIVE AUTHORITY TO
24 BRING AN ACTION UNDER THE UNFAIR TRADE PRACTICES AND CONSUMER
25 PROTECTION LAW FOR A VIOLATION OF ANY PROVISION OF THIS CHAPTER.

26 ~~(e)~~ (D) Injunction.--The department may maintain an action <--
27 in the name of the Commonwealth for an injunction to prohibit
28 any activity that violates the provisions of this chapter.

29 ~~(d)~~ (E) Effect on enrollment.--The department may issue an <--
30 order temporarily prohibiting an MA or CHIP managed care plan

1 that violates this chapter from enrolling new enrollees.

2 (F) NONEXCLUSIVE REMEDIES.--THE ENFORCEMENT REMEDIES AND <--
3 PENALTIES IMPOSED UNDER THIS CHAPTER ARE IN ADDITION TO ANY
4 OTHER REMEDIES OR PENALTIES THAT MAY BE IMPOSED UNDER ANY OTHER
5 APPLICABLE FEDERAL LAW OR LAW OF THIS COMMONWEALTH, INCLUDING
6 THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996
7 (PUBLIC LAW 104-191, 110 STAT. 1936), AS AMENDED BY THE HEALTH
8 INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT
9 (PUBLIC LAW 111-5, 123 STAT. 226-279 AND 467-496).

10 § 5312 4111. Plan of correction. <--

11 (a) Authorization.--The department may require an MA or CHIP
12 managed care plan to develop and adhere to a plan of correction
13 approved by the department. The department may impose a plan of
14 correction in lieu of fines. OR IN ADDITION TO CIVIL PENALTIES <--
15 IMPOSED UNDER SECTION 4110 (RELATING TO ENFORCEMENT AND
16 PENALTIES).

17 (b) Compliance.--The department shall monitor compliance
18 with the plan of correction under this section.

19 (c) Availability.--The plan of correction shall, ~~upon~~ <--
20 ~~request,~~ be made available to enrollees of the insurer or MA or
21 CHIP managed care plan UPON REQUEST. <--

22 § 5313 4112. Administrative procedures. <--

23 (a) Applicable procedures.--This chapter shall be subject to
24 2 Pa.C.S. Ch. 5 Subch. A (relating to practice and procedure of
25 Commonwealth agencies).

26 (b) Appeal.--A party against whom penalties are assessed in
27 an administrative action may appeal to Commonwealth Court as
28 provided in 2 Pa.C.S. Ch. 7 Subch. A (relating to judicial
29 review of Commonwealth agency action).

30 § 5314 4113. Regulations and guidance. <--

