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 AND SHUSTERMAN, OCTOBER 6, 2025

REFERRED TO COMMITTEE ON COMMUNICATIONS AND TECHNOLOGY, OCTOBER 6, 2025

AN ACT

Amending Titles 35 (Health and Safety) and 40 (Insurance) of the Pennsylvania Consolidated Statutes, providing for artificial intelligence in facilities, for artificial intelligence use by insurers and for artificial intelligence use by MA or CHIP managed care plans; imposing duties on the Department of 2 3 Health, the Insurance Department and the Department of Human 6 Services; and imposing penalties. 8 The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows: 10 Section 1. Title 35 of the Pennsylvania Consolidated 11 Statutes is amended by adding a chapter to read: 12 CHAPTER 35 13 ARTIFICIAL INTELLIGENCE IN FACILITIES 14 Sec. 15 3501. Definitions. 16 3502. Disclosure. 17 3503. Responsible use.

3504. Artificial intelligence compliance statements.

19 3505. Reports.

18

- 1 <u>3506</u>. Retention of records.
- 2 <u>3507. Oversight.</u>
- 3 3508. Third-party vendor.
- 4 <u>3509</u>. Exemption.
- 5 <u>3510</u>. Enforcement and penalties.
- 6 3511. Plan of correction.
- 7 <u>3512</u>. Administrative procedures.
- 8 <u>3513. Regulations and guidance.</u>
- 9 § 3501. Definitions.
- 10 The following words and phrases when used in this chapter
- 11 shall have the meanings given to them in this section unless the
- 12 context clearly indicates otherwise:
- 13 "Artificial intelligence" or "AI." A machine-based system
- 14 that can, for a given set of human-defined objectives, make
- 15 predictions, recommendations or decisions influencing real or
- 16 virtual environments that use machine-based and human-based
- 17 inputs to perceive real and virtual environments, abstract the
- 18 perceptions into models through analysis in an automated manner
- 19 and use model inference to formulate options for information or
- 20 action. The term includes generative artificial intelligence
- 21 which is the class of models that emulate the structure and
- 22 characteristics of input data in order to generate derived
- 23 synthetic content which includes information such as images,
- 24 videos, audio clips and text that has been significantly
- 25 modified or generated by algorithms, including by artificial
- 26 intelligence.
- 27 "Artificial intelligence-based algorithms." The programming
- 28 and data sets that inform an artificial intelligence system.
- 29 "Clinical decision making." A patient-centered problem-
- 30 solving process focused on a health care provider's direct

- 1 patient care involving gathering information, diagnosing and
- 2 planning treatments.
- 3 "Department." The Department of Health of the Commonwealth.
- 4 <u>"Facility." A health care setting or institution providing</u>
- 5 <u>health care services</u>, including:
- 6 (1) A general, special, psychiatric or rehabilitation
- 7 <u>hospital.</u>
- 8 (2) An ambulatory surgical facility.
- 9 <u>(3) A cancer treatment center.</u>
- 10 (4) A birth center.
- 11 (5) An inpatient, outpatient or residential drug and
- 12 <u>alcohol treatment facility.</u>
- 13 (6) A facility licensed by the Department of Human
- 14 <u>Services' Office of Mental Health and Substance Abuse</u>
- 15 <u>Services.</u>
- 16 (7) A laboratory, imaging, diagnostic or other
- 17 outpatient medical service or testing facility.
- 18 (8) A health care provider office or clinic that is
- owned by or employs a Commonwealth-licensed physician,
- 20 <u>physician assistant or nurse practitioner.</u>
- 21 "Health care provider." As follows:
- 22 (1) A facility or individual who is licensed, certified
- or otherwise regulated to provide health care services under
- the laws of this Commonwealth.
- 25 (2) The term does not include an individual providing
- 26 emergency services under a licensed emergency medical
- 27 <u>services agency as defined in section 8103 (relating to</u>
- definitions).
- 29 <u>§ 3502. Disclosure.</u>
- 30 (a) Duty to disclose. -- A facility shall disclose to patients

- 1 of the facility if artificial intelligence-based algorithms are
- 2 or will be used for clinical decision making or other similar
- 3 tasks. The disclosure shall be:
- 4 (1) Provided in all related written communications.
- 5 (2) Posted on the publicly accessible Internet website
- 6 <u>of the facility.</u>
- 7 (b) Communications.--
- 8 (1) A facility that uses artificial intelligence to
- 9 generate written or verbal patient communications pertaining
- 10 to patient clinical information shall include:
- 11 <u>(i) A clear and conspicuous disclaimer that</u>
- 12 <u>indicates that the communication was generated by</u>
- 13 <u>artificial intelligence.</u>
- 14 (ii) Clear instructions on how the patient may
- contact a human health care provider or relevant employee
- of the facility with questions.
- 17 (2) The requirements under paragraph (1) shall not apply
- 18 to communications that:
- 19 (i) only pertain to administrative matters,
- including appointment scheduling, billing or other
- 21 clerical or business matters; or
- 22 (ii) have been individually read and reviewed by a
- human health care provider.
- 24 (c) Nature and frequency. -- The department shall determine
- 25 the nature and frequency of disclosure requirements to the
- 26 patient. The department may request input from facilities and
- 27 <u>health care providers or their representatives in making the</u>
- 28 determination.
- 29 § 3503. Responsible use.
- 30 (a) Compliance generally. -- The criteria for the artificial

- 1 intelligence-based algorithms must comply with this chapter and
- 2 <u>applicable Federal and State law.</u>
- 3 (b) Requirements for artificial intelligence-based
- 4 <u>algorithms.--For each instance in which a facility uses</u>
- 5 <u>artificial intelligence-based algorithms for clinical decision</u>
- 6 making, the facility shall comply with the following:
- 7 (1) The artificial intelligence-based algorithms must
- 8 <u>not supersede health care provider clinical decision making.</u>
- 9 (2) The artificial intelligence-based algorithms and
- training data sets must not directly or indirectly
- 11 <u>discriminate against patients in violation of Federal or</u>
- 12 <u>State law.</u>
- 13 (3) The artificial intelligence-based algorithms must be
- fairly and equitably applied, including in accordance with
- any applicable regulations and or guidance issued by the
- 16 United States Department of Health and Human Services.
- 17 (4) The use of the artificial intelligence-based
- 18 algorithms must be disclosed in accordance with section 3502
- 19 <u>(relating to disclosure).</u>
- 20 (5) The performance, use and outcomes of the artificial
- 21 <u>intelligence-based algorithms must be periodically reviewed</u>
- 22 and revised to maximize accuracy and reliability.
- 23 (6) Patient data must not be used beyond the intended
- 24 and stated purpose of the artificial intelligence-based
- 25 algorithms, consistent with the laws of this Commonwealth and
- 26 42 U.S.C. Ch. 7 Subch. XI Part C (relating to administrative
- 27 simplification), as applicable.
- 28 (7) The artificial intelligence-based algorithms must
- 29 not create foreseeable, material risks of harm to the
- 30 patient.

- 1 § 3504. Artificial intelligence compliance statements.
- 2 (a) Compliance statement required. -- A facility using
- 3 artificial intelligence-based algorithms for clinical decision
- 4 making shall annually file with the department in the form and
- 5 manner prescribed by the department an artificial intelligence
- 6 <u>compliance statement.</u>
- 7 (b) Contents. -- Each compliance statement must:
- 8 (1) Summarize the function and scope of artificial
- 9 <u>intelligence-based algorithms used for clinical decision</u>
- 10 making.
- 11 (2) Provide a logic or decision tree of artificial
- intelligence-based algorithms used for clinical decision
- 13 <u>making</u>.
- 14 (3) Provide a description of each training data set used
- by artificial intelligence-based algorithms for clinical
- decision making, including the source of the data.
- 17 (4) Attest that the artificial intelligence-based
- 18 algorithms and the training data sets comply with section
- 19 3503 (relating to responsible use) and provide evidence of
- the compliance.
- 21 (5) Describe the process of the facility for overseeing
- 22 and validating the performance and compliance of the
- 23 artificial intelligence-based algorithms in accordance with
- 24 section 3503.
- 25 § 3505. Reports.
- 26 (a) Annual report required. -- No later than one year after
- 27 the effective date of this chapter and each year thereafter, the
- 28 department shall compile the information from the most recent
- 29 <u>annual compliance statements under section 3504 (relating to</u>
- 30 artificial intelligence compliance statements) and issue a

- 1 report containing the compiled information, along with any other
- 2 applicable findings and recommendations. The information in the
- 3 report shall be aggregated and deidentified.
- 4 (b) Posting.--The department shall post each report under
- 5 this section on the publicly accessible Internet website of the
- 6 <u>department</u>.
- 7 § 3506. Retention of records.
- 8 The department shall establish a record retention policy and
- 9 <u>determine the amount of time a facility shall retain records</u>
- 10 related to artificial-intelligence algorithms. The department
- 11 may request input from facilities and health care providers or
- 12 their representatives in making the determination under this
- 13 <u>section</u>.
- 14 <u>§ 3507. Oversight.</u>
- The department may request additional information and
- 16 <u>evidence from a facility regarding the items provided under</u>
- 17 sections 3502 (relating to disclosure), 3503 (relating to
- 18 responsible use) and 3504 (relating to artificial intelligence
- 19 compliance statements) that are necessary to ensure compliance
- 20 with this chapter.
- 21 § 3508. Third-party vendor.
- 22 A contractor, subcontractor or other third-party vendor that
- 23 sells, leases, subscribes or otherwise supplies artificial
- 24 intelligence-based algorithms or services based on artificial
- 25 intelligence-based algorithms to the facility shall be subject
- 26 to this chapter. The department shall develop regulations or
- 27 guidance regarding the responsibility of a contractor,
- 28 subcontractor or other third-party vendor that sells, leases,
- 29 <u>subscribes or otherwise supplies artificial intelligence-based</u>
- 30 algorithms or services based on artificial intelligence-based

- 1 algorithms to the facility. The department may request input
- 2 from facilities, third-party vendors and health care providers
- 3 or their representatives in making this determination.
- 4 <u>§ 3509</u>. Exemption.
- 5 This chapter shall not apply to validated, static decision-
- 6 <u>support tools or tools used for administration, scheduling,</u>
- 7 <u>scribe applications or clinical calculators.</u>
- 8 § 3510. Enforcement and penalties.
- 9 (a) Civil penalties.--
- 10 (1) Subject to paragraph (2), the department may impose
- 11 a civil penalty not exceeding \$5,000 for a violation of this
- chapter. For purposes of this paragraph, each instance of
- 13 <u>nondisclosure shall constitute a separate violation of this</u>
- 14 <u>chapter.</u>
- 15 (2) The following apply to limitations on civil
- 16 penalties under this subsection:
- 17 (i) A civil penalty imposed against a facility may
- not exceed \$500,000 in the aggregate during a single
- 19 calendar year.
- 20 (ii) A civil penalty imposed against any other
- 21 person may not exceed \$100,000 in the aggregate during a
- 22 single calendar year.
- 23 (b) Injunction. -- The department may maintain an action in
- 24 the name of the Commonwealth for an injunction to prohibit any
- 25 activity that violates the provisions of this chapter.
- 26 (c) Nonexclusive remedies. -- The enforcement remedies and
- 27 penalties imposed under this chapter are in addition to any
- 28 other remedies or penalties that may be imposed under any other
- 29 applicable law of this Commonwealth, including the act of July
- 30 19, 1979 (P.L.130, No.48), known as the Health Care Facilities

- 1 Act.
- 2 § 3511. Plan of correction.
- 3 (a) Authorization. -- The department may require a facility to
- 4 <u>develop and adhere to a plan of correction approved by the</u>
- 5 <u>department</u>. The department may impose a plan of correction in
- 6 lieu of fines.
- 7 <u>(b) Compliance.--The department shall monitor compliance</u>
- 8 with the plan of correction under this section.
- 9 (c) Availability. -- The plan of correction shall, upon
- 10 request, be made available to patients of the facility.
- 11 § 3512. Administrative procedures.
- 12 (a) Applicable procedures. -- This chapter shall be subject to
- 13 <u>2 Pa.C.S. Ch. 5 Subch. A (relating to practice and procedure of</u>
- 14 <u>Commonwealth agencies</u>).
- 15 (b) Appeal. -- A party against whom penalties are assessed in
- 16 <u>an administrative action may appeal to Commonwealth Court as</u>
- 17 provided in 2 Pa.C.S. Ch. 7 Subch. A (relating to judicial
- 18 review of Commonwealth agency action).
- 19 § 3513. Regulations and guidance.
- The department shall promulgate regulations or guidance
- 21 necessary to implement, administer and enforce this chapter. The
- 22 department shall review regulations or guidance every three
- 23 years to ensure compliance with Federal law or Federal agency
- 24 <u>quidance</u>.
- 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 <u>5203</u>. Responsible use.
- 2 5204. Artificial intelligence compliance statements.
- 3 5205. Health care provider requirements.
- 4 <u>5206</u>. Reports.
- 5 5207. Retention of records.
- 6 5208. Oversight.
- 7 <u>5209</u>. Third-party vendor.
- 8 <u>5210. Exemption.</u>
- 9 <u>5211. Enforcement and penalties.</u>
- 10 5212. Plan of correction.
- 11 <u>5213. Administrative procedures.</u>
- 12 <u>5214. Regulations and guidance.</u>
- 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 <u>context clearly indicates otherwise:</u>
- 17 "Artificial intelligence" or "AI." A machine-based system
- 18 that can, for a given set of human-defined objectives, make
- 19 predictions, recommendations or decisions influencing real or
- 20 virtual environments that use machine-based and human-based
- 21 inputs to perceive real and virtual environments, abstract the
- 22 perceptions into models through analysis in an automated manner
- 23 and use model inference to formulate options for information or
- 24 action. The term includes generative artificial intelligence
- 25 which is the class of models that emulate the structure and
- 26 characteristics of input data in order to generate derived
- 27 <u>synthetic content which includes information such as images</u>,
- 28 videos, audio clips and text that has been significantly
- 29 modified or generated by algorithms, including by artificial
- 30 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 <u>individual who is entitled to receive health care services under</u>
- 5 <u>a health insurance policy.</u>
- 6 <u>"Department." The Insurance Department of the Commonwealth.</u>
- 7 "Health care provider." As follows:
- 8 (1) A facility or individual who is licensed, certified
- 9 <u>or otherwise regulated to provide health care services under</u>
- the laws of this Commonwealth.
- 11 (2) The term does not include an individual providing
- 12 <u>emergency services under a licensed emergency medical</u>
- 13 <u>services agency as defined in 35 Pa.C.S. § 8103 (relating to</u>
- definitions).
- 15 <u>"Health care service."</u> Any covered treatment, admission,
- 16 procedure or other services, including behavioral health,
- 17 prescribed or otherwise provided or proposed to be provided by a
- 18 health care provider to a covered person for the diagnosis,
- 19 prevention, treatment, cure or relief of a health condition,
- 20 illness, injury or disease under the terms of a health insurance
- 21 policy.
- 22 "Health insurance policy." As follows:
- 23 (1) A policy, subscriber contract, certificate or plan
- issued by an insurer that provides medical or health care
- coverage.
- 26 (2) The term does not include:
- 27 <u>(i) An accident only policy.</u>
- 28 (ii) A credit only policy.
- 29 (iii) A long-term care or disability income policy.
- 30 (iv) A specified disease policy.

1	(v) A Medicare supplement policy.
2	(vi) A TRICARE policy, including a Civilian Health
3	and Medical Program of the Uniformed Services (CHAMPUS)
4	supplement policy.
5	(vii) A fixed indemnity policy.
6	(viii) A hospital indemnity policy.
7	(ix) A workers' compensation policy.
8	(x) An automobile medical payment policy under 75
9	Pa.C.S. (relating to vehicles).
10	(xi) A homeowner's insurance policy.
11	"Insurer." As follows:
12	(1) An entity licensed by the department that offers,
13	issues or renews an individual or group health insurance
14	policy that is offered or governed under any of the
15	<pre>following:</pre>
16	(i) Chapter 61 (relating to hospital plan
17	corporations) or 63 (relating to professional health
18	services plan corporations).
19	(ii) The act of May 17, 1921 (P.L.682, No.284),
20	known as The Insurance Company Law of 1921, including
21	section 630 and Article XXIV thereof.
22	(iii) The act of December 29, 1972 (P.L.1701,
23	No.364), known as the Health Maintenance Organization
24	Act.
25	(2) The term does not include an entity operating as an
26	MA or CHIP managed care plan.
27	"Participating network provider." A health care provider
28	that has entered into a contractual or operating relationship
29	with an insurer to participate in one or more designated
30	networks of the insurer and to provide health care services to

- 1 covered persons under the terms of the insurer's administrative
- 2 policy.
- 3 "Prior authorization request." As defined under section 2102
- 4 of The Insurance Company Law of 1921.
- 5 "Utilization review." As defined under section 2102 of The
- 6 <u>Insurance Company Law of 1921.</u>
- 7 § 5202. Disclosure.
- 8 (a) Duty to disclose. -- An insurer shall disclose to a
- 9 participating network provider and all covered persons if
- 10 artificial intelligence-based algorithms are or will be used in
- 11 the utilization review process of the insurer.
- 12 (b) Posting. -- An insurer shall post the information about
- 13 the use of artificial intelligence-based algorithms in the
- 14 <u>utilization review process of the insurer on the publicly</u>
- 15 <u>accessible Internet website of the insurer.</u>
- 16 <u>(c) Nature and frequency.--The department shall determine</u>
- 17 the nature and frequency of disclosure requirements to covered
- 18 persons. The department may request input from insurers or their
- 19 representatives in making this determination.
- 20 § 5203. Responsible use.
- 21 (a) Compliance generally. -- The criteria for the artificial
- 22 intelligence-based algorithms must comply with this chapter and
- 23 <u>applicable Federal and State law.</u>
- 24 (b) Requirements for artificial intelligence-based
- 25 <u>algorithms.--For each instance in which an insurer uses</u>
- 26 artificial intelligence-based algorithms in the utilization
- 27 <u>review process regarding a covered person, the insurer shall</u>
- 28 comply with the following:
- 29 (1) The artificial intelligence-based algorithms must
- 30 base a determination on all of the following:

1	<u>(i) The medical or other clinical history of the</u>
2	covered person.
3	(ii) Individual clinical or nonclinical
4	circumstances as presented by the requesting health care
5	provider.
6	(iii) Other relevant clinical or nonclinical
7	information contained in the medical or other clinical
8	record of the covered person.
9	(2) The artificial intelligence-based algorithms must
10	not base a determination solely on a group data set.
11	(3) The artificial intelligence-based algorithms must
12	not supersede decision making of the health care provider
13	conducting the utilization review.
14	(4) The artificial intelligence-based algorithms and
15	training data sets must not directly or indirectly
16	discriminate against covered persons in violation of Federal
17	or State law.
18	(5) The artificial intelligence-based algorithms must be
19	fairly and equitably applied, including in accordance with
20	any applicable regulations or guidance issued by the United
21	States Department of Health and Human Services.
22	(6) The use of the artificial intelligence-based
23	algorithms must be disclosed in accordance with section 5202
24	(relating to disclosure).
25	(7) The performance, use and outcomes of the artificial
26	<pre>intelligence-based algorithms must be periodically reviewed</pre>
27	and revised to maximize accuracy and reliability.
28	(8) The data of the covered person must not be used
29	beyond the intended and stated purpose of the artificial
30	intelligence-based algorithms, consistent with Commonwealth

- 1 <u>law and 42 U.S.C. Ch. 7, Subch. XI Part C (relating to</u>
- 2 <u>administrative simplification</u>), as applicable.
- 3 (9) The artificial intelligence-based algorithms must
- 4 <u>not create foreseeable, material risks of harm to the covered</u>
- 5 person.
- 6 § 5204. Artificial intelligence compliance statements.
- 7 (a) Compliance statement required. -- An insurer using
- 8 artificial intelligence-based algorithms in the utilization
- 9 <u>review process shall annually file with the department in the</u>
- 10 form and manner prescribed by the department an artificial
- 11 intelligence compliance statement.
- 12 (b) Contents. -- Each compliance statement must:
- 13 (1) Summarize the function and scope of the artificial
- 14 <u>intelligence-based algorithms used for utilization review.</u>
- 15 (2) Provide a logic or decision tree of artificial
- 16 <u>intelligence-based algorithms used for utilization review.</u>
- 17 (3) Provide a description of each training data set used
- 18 by artificial intelligence-based algorithms for utilization
- 19 review, including the source of the data.
- 20 (4) Attest that the artificial intelligence-based
- 21 algorithms and the training data sets comply with section
- 22 5203 (relating to responsible use) and provide evidence of
- the compliance.
- 24 (5) Describe the process of the insurer for overseeing
- and validating the performance and compliance of the
- artificial intelligence-based algorithms in accordance with
- 27 section 5203.
- 28 § 5205. Health care provider requirements.
- 29 Prior to issuing or upholding a decision to deny, reduce or
- 30 terminate benefits for a health care service, including a

- 1 <u>decision to deny a prior authorization request, a health care</u>
- 2 provider who participates in utilization review on behalf of an
- 3 insurer shall:
- 4 (1) Review individual clinical records and other
- 5 <u>relevant information.</u>
- 6 (2) Document the review under paragraph (1).
- 7 (3) Based on the review under paragraph (1), exercise
- 8 judgment independent of any recommendations by the artificial
- 9 <u>intelligence-based algorithms.</u>
- 10 <u>§ 5206</u>. Reports.
- 11 (a) Annual report required. -- No later than one year after
- 12 the effective date of this chapter, and annually thereafter, the
- 13 <u>department shall compile the information from the most recent</u>
- 14 annual compliance statements under section 5204 (relating to
- 15 artificial intelligence compliance statements) and issue a
- 16 report to the General Assembly containing the compiled
- 17 information, along with any other applicable findings and
- 18 recommendations. The information in the report shall be
- 19 aggregated and deidentified.
- 20 (b) Posting. -- The department shall post each report under
- 21 this section on the publicly accessible Internet website of the
- 22 department.
- 23 § 5207. Retention of records.
- The department shall establish a record retention policy and
- 25 determine the amount of time an insurer shall retain records.
- 26 The department may request input from insurers or their
- 27 representatives in making this determination.
- 28 § 5208. Oversight.
- 29 The department may request additional information and
- 30 evidence from an insurer regarding the items provided under

- 1 <u>sections 5202</u> (relating to disclosure), 5203 (relating to
- 2 <u>responsible use</u>) and 5204 (relating to artificial intelligence
- 3 compliance statements) 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 <u>sells, leases, subscribes or otherwise supplies artificial</u>
- 8 <u>intelligence-based algorithms or services based on artificial</u>
- 9 <u>intelligence-based algorithms to the insurer services shall be</u>
- 10 subject to this chapter. The department shall develop
- 11 regulations or guidelines regarding the responsibility of a
- 12 <u>contractor</u>, <u>subcontractor</u> or <u>other third-party vendor that</u>
- 13 <u>sells, leases, subscribes or otherwise supplies artificial</u>
- 14 <u>intelligence-based algorithms or services based on artificial</u>
- 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 <u>§ 5210</u>. Exemption.
- 19 This chapter shall not apply to artificial intelligence-based
- 20 algorithms used for administrative, scheduling or other purposes
- 21 not pertaining to the insurer's decision to deny, reduce or
- 22 <u>terminate benefits</u>.
- 23 <u>§ 5211. Enforcement and penalties.</u>
- 24 (a) Civil penalties.--
- 25 (1) Subject to paragraph (2), the department may impose
- a civil penalty not exceeding \$5,000 for a violation of this
- 27 <u>chapter. For purposes of this paragraph, each instance of</u>
- 28 nondisclosure shall constitute a separate violation of this
- chapter.
- 30 (2) The following apply to limitations on civil

- 1 <u>penalties under this subsection:</u>
- 2 (i) A civil penalty imposed against an insurer may
- 3 not exceed \$500,000 in the aggregate during a single
- 4 <u>calendar year.</u>
- 5 <u>(ii) A civil penalty imposed against any other</u>
- 6 person may not exceed \$100,000 in the aggregate during a
- 7 <u>single calendar year.</u>
- 8 (b) Unfair Insurance Practices Act.--
- 9 <u>(1) An insurer shall be subject to the act of July 22,</u>
- 10 1974 (P.L.589, No.205), known as the Unfair Insurance
- 11 <u>Practices Act.</u>
- 12 (2) A violation of any provision of this chapter shall
- be deemed to be a violation of the Unfair Insurance Practices
- 14 <u>Act.</u>
- 15 (c) Injunction. -- The department may maintain an action in
- 16 the name of the Commonwealth for an injunction to prohibit any
- 17 activity that violates the provisions of this chapter.
- 18 (d) Effect on enrollment. -- The department may issue an order
- 19 temporarily prohibiting an insurer that violates this chapter
- 20 from enrolling new covered persons.
- 21 (e) Nonexclusive remedies. -- The enforcement remedies and
- 22 penalties imposed under this chapter are in addition to any
- 23 other remedies or penalties that may be imposed under any other
- 24 <u>applicable law of this Commonwealth, including:</u>
- 25 (1) The Unfair Insurance Practices Act.
- 26 (2) The act of December 18, 1996 (P.L.1066, No.159),
- 27 <u>known as the Accident and Health Filing Reform Act.</u>
- 28 (3) The act of June 25, 1997 (P.L.295, No.29), known as
- 29 the Pennsylvania Health Care Insurance Portability Act.
- 30 § 5212. Plan of correction.

- 1 (a) Authorization. -- The department may require an insurer to
- 2 develop and adhere to a plan of correction approved by the
- 3 <u>department</u>. The department may impose a plan of correction in
- 4 lieu of fines.
- 5 (b) Compliance. -- The department shall monitor compliance
- 6 with the plan of correction under this section.
- 7 (c) Availability. -- The plan of correction shall, upon
- 8 request, be made available to covered persons of the insurer.
- 9 § 5213. Administrative procedures.
- 10 (a) Applicable procedures. -- This chapter shall be subject to
- 11 <u>2 Pa.C.S. Ch. 5 Subch. A (relating to practice and procedure of</u>
- 12 <u>Commonwealth agencies</u>).
- 13 (b) Appeal. -- A party against whom penalties are assessed in
- 14 an administrative action may appeal to Commonwealth Court as
- 15 provided in 2 Pa.C.S. Ch. 7 Subch. A (relating to judicial_
- 16 <u>review of Commonwealth agency action</u>).
- 17 § 5214. Regulations and guidance.
- 18 The department shall promulgate regulations or guidance
- 19 necessary to implement, administer and enforce this chapter. The
- 20 <u>department shall review regulations or guidance every three</u>
- 21 years to ensure compliance with Federal law or Federal agency
- 22 <u>quidance</u>.
- CHAPTER 53
- 24 <u>ARTIFICIAL INTELLIGENCE USE BY MA OR CHIP</u>
- 25 MANAGED CARE PLANS
- 26 <u>Sec.</u>
- 27 5301. Definitions.
- 28 <u>5302</u>. <u>Disclosure</u>.
- 29 5303. Responsible use.
- 30 5304. Artificial intelligence compliance statements.

- 1 5305. Health care provider requirements.
- 2 <u>5306</u>. Reports.
- 3 5307. Retention of records.
- 4 <u>5308. Oversight.</u>
- 5 5309. Third-party vendor.
- 6 5310. Exemption.
- 7 <u>5311</u>. <u>Enforcement and penalties</u>.
- 8 5312. Plan of correction.
- 9 <u>5313. Administrative procedures.</u>
- 10 5314. Regulations and guidance.
- 11 § 5301. 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 <u>context clearly indicates otherwise:</u>
- 15 "Agreement with the department." As follows:
- 16 (1) An agreement between an MA or CHIP managed care plan
- and the department to manage the purchase and provision of
- 18 services.
- 19 (2) The term includes a county or multicounty agreement
- 20 with the department for behavioral health services.
- 21 "Artificial intelligence" or "AI." A machine-based system
- 22 that can, for a given set of human-defined objectives, make
- 23 predictions, recommendations or decisions influencing real or
- 24 virtual environments that use machine-based and human-based
- 25 inputs to perceive real and virtual environments, abstract the
- 26 perceptions into models through analysis in an automated manner
- 27 <u>and use model inference to formulate options for information or</u>
- 28 action. The term includes generative artificial intelligence
- 29 which is the class of models that emulate the structure and
- 30 characteristics of input data in order to generate derived

- 1 synthetic content which includes information such as images,
- 2 <u>videos</u>, <u>audio clips and text that has been significantly</u>
- 3 modified or generated by algorithms, including by artificial
- 4 <u>intelligence</u>.
- 5 <u>"Artificial intelligence-based algorithms." The programming</u>
- 6 and data sets that inform an artificial intelligence system.
- 7 <u>"Department." The Department of Human Services of the</u>
- 8 Commonwealth.
- 9 "Enrollee." An individual who is entitled to receive health
- 10 care services under an agreement with the department.
- 11 <u>"Facility." A health care setting or institution providing</u>
- 12 <u>health care services</u>, including:
- 13 (1) A general, special, psychiatric or rehabilitation
- 14 <u>hospital.</u>
- 15 (2) An ambulatory surgical facility.
- 16 (3) A cancer treatment center.
- 17 (4) A birth center.
- 18 (5) An inpatient, outpatient or residential drug and
- 19 alcohol treatment facility.
- 20 (6) A facility licensed by the department's Office of
- 21 Mental Health and Substance Abuse Services.
- 22 (7) A laboratory, imaging, diagnostic or other
- 23 outpatient medical service or testing facility.
- 24 (8) A health care provider office or clinic that is
- owned by or employs a Commonwealth-licensed physician,
- 26 physician assistant or nurse practitioner.
- 27 "Health care provider." As follows:
- 28 (1) A facility or individual who is licensed, certified
- 29 or otherwise regulated to provide health care services under
- 30 the laws of this Commonwealth.

- 1 (2) The term does not include an individual providing
- 2 <u>emergency services under a licensed emergency medical</u>
- 3 <u>services agency as defined in 35 Pa.C.S. § 8103 (relating to</u>
- 4 <u>definitions</u>).
- 5 <u>"Health care service." Any covered treatment, admission,</u>
- 6 procedure or other services, including behavioral health,
- 7 prescribed or otherwise provided or proposed to be provided by a
- 8 <u>health care provider to a covered person for the diagnosis,</u>
- 9 prevention, treatment, cure or relief of a health condition,
- 10 illness, injury or disease under the terms of a health insurance
- 11 policy or agreement with the department.
- 12 <u>"Medical Assistance or Children's Health Insurance Program</u>
- 13 managed care plan" or "MA or CHIP managed care plan." As
- 14 defined under section 2102 of the act of May 17, 1921 (P.L.682,
- 15 No.284), known as The Insurance Company Law of 1921.
- 16 "Participating network provider." A health care provider
- 17 that has entered into a contractual or operating relationship
- 18 with an MA or CHIP managed care plan to participate in one or
- 19 more designated networks of the MA or CHIP managed care plan and
- 20 to provide health care services to enrollees under the terms of
- 21 the or an agreement with the department.
- 22 <u>"Prior authorization request." As defined under section 2102</u>
- 23 of The Insurance Company Law of 1921.
- 24 "Utilization review." As defined under section 2102 of The
- 25 Insurance Company Law of 1921.
- 26 § 5302. Disclosure.
- 27 (a) Duty to disclose. -- An MA or CHIP managed care plan shall
- 28 disclose to a participating network provider and all enrollees
- 29 <u>if artificial intelligence-based algorithms are or will be used</u>
- 30 in the utilization review process of the MA or CHIP managed care

- 1 plan.
- 2 (b) Posting. -- An MA or CHIP managed care plan shall post the
- 3 information about the use of artificial intelligence-based
- 4 <u>algorithms in the utilization review process of the MA or CHIP</u>
- 5 managed care plan on the publicly accessible Internet website of
- 6 the MA or CHIP managed care plan.
- 7 (c) Nature and frequency. -- The department shall determine
- 8 the nature and frequency of disclosure requirements to
- 9 <u>enrollees. The department may request input from MA or CHIP</u>
- 10 managed care plans or their representatives in making this
- 11 determination.
- 12 § 5303. Responsible use.
- 13 (a) Compliance generally. -- The criteria for the artificial
- 14 <u>intelligence-based algorithms must comply with this chapter and</u>
- 15 <u>applicable Federal and State law.</u>
- 16 (b) Requirements for artificial intelligence-based
- 17 algorithms. -- For each instance in which a MA or CHIP managed
- 18 care plan uses artificial intelligence-based algorithms in the
- 19 utilization review process regarding an enrollee, the MA or CHIP
- 20 managed care plan shall comply with the following:
- 21 (1) The artificial intelligence-based algorithms must
- 22 base a determination on all of the following:
- 23 (i) The medical or other clinical history of the
- enrollee.
- 25 (ii) Individual clinical or nonclinical
- 26 circumstances as presented by the requesting health care
- 27 <u>provider.</u>
- 28 (iii) Other relevant clinical or nonclinical
- 29 <u>information contained in the medical or other clinical</u>
- 30 record of the enrollee.

1	(2) The artificial intelligence-based algorithms must
2	not base a determination solely on a group data set.
3	(3) The artificial intelligence-based algorithms must
4	not supersede decision making of the health care provider
5	conducting the utilization review.
6	(4) The artificial intelligence-based algorithms and
7	training data sets must not directly or indirectly
8	discriminate against the enrollees in violation of Federal or
9	State law.
10	(5) The artificial intelligence-based algorithms must be
11	fairly and equitably applied, including in accordance with
12	any applicable regulations and guidance issued by the United
13	States Department of Health and Human Services.
14	(6) The use of the artificial intelligence-based
15	algorithms must be disclosed in accordance with section 5302
16	(relating to disclosure).
17	(7) The performance, use and outcomes of the artificial
18	intelligence-based algorithms must be periodically reviewed
19	and revised to maximize accuracy and reliability.
20	(8) The data of the covered person or enrollees must not
21	be used beyond the intended and stated purpose of the
22	artificial intelligence-based algorithms, consistent with the
23	laws of this Commonwealth and the Health Insurance
24	Portability and Accountability Act of 1996 (Public Law 104-
25	191, 110 Stat. 1936), as applicable.
26	(9) The artificial intelligence-based algorithms must
27	not create foreseeable, material risks of harm to the
28	<pre>enrollee.</pre>
29	§ 5304. Artificial intelligence compliance statements.
30	(a) Compliance statement required An MA or CHIP managed

- 1 care plan using artificial intelligence-based algorithms in the
- 2 utilization review process shall annually file with the
- 3 department, in the form and manner prescribed by the department,
- 4 <u>an artificial intelligence compliance statement.</u>
- 5 (b) Contents. -- Each compliance statement must:
- 6 (1) Summarize the function and scope of the artificial
- 7 <u>intelligence-based algorithms used for utilization review.</u>
- 8 (2) Provide a logic or decision tree of artificial
- 9 <u>intelligence-based algorithms used for utilization review.</u>
- 10 (3) Provide a description of each training data set used
- 11 <u>by artificial intelligence-based algorithms for utilization</u>
- 12 <u>review, including the source of the data.</u>
- 13 <u>(4) Attest that the artificial intelligence-based</u>
- 14 <u>algorithms and the training data sets comply with section</u>
- 15 5303 (relating to responsible use) and provide evidence of
- the compliance.
- 17 (5) Describe the process of the MA or CHIP managed care
- 18 plan for overseeing and validating the performance and
- 19 <u>compliance of the artificial intelligence-based algorithms in</u>
- 20 accordance with section 5303.
- 21 § 5305. Health care provider requirements.
- 22 Prior to issuing or upholding a decision to deny, reduce or
- 23 terminate benefits for a health care service, including a
- 24 decision to deny a prior authorization request, a health care
- 25 provider who participates in utilization review on behalf of an
- 26 MA or CHIP managed care plan shall:
- 27 <u>(1) Review individual clinical records and other</u>
- 28 relevant information.
- 29 (2) Document the review under paragraph (1).
- 30 (3) Based on the review under paragraph (1), exercise

- 1 judgment independent of any recommendations by the artificial
- 2 intelligence-based algorithms.
- 3 § 5306. Reports.
- 4 (a) Annual report required. -- No later than one year after
- 5 the effective date of this chapter, and annually thereafter, the
- 6 <u>department shall compile the information from the most recent</u>
- 7 <u>annual compliance statements under section 5304 (relating to</u>
- 8 <u>artificial intelligence compliance statements</u>) and issue a
- 9 report to the General Assembly containing the compiled
- 10 <u>information</u>, along with any other applicable findings and
- 11 recommendations. The information in the report shall be
- 12 <u>aggregated and deidentified.</u>
- 13 (b) Posting. -- The department shall post each report under
- 14 this section on the publicly accessible Internet website of the
- 15 <u>department</u>.
- 16 § 5307. Retention of records.
- 17 The department shall establish a record retention policy and
- 18 determine the amount of time an MA or CHIP managed care plan
- 19 shall retain records. The department may request input from an
- 20 MA or CHIP managed care plan or their representative to make
- 21 this determination.
- 22 § 5308. Oversight.
- 23 The department may request additional information and
- 24 evidence from an MA or CHIP managed care plan regarding the
- 25 items provided under section 5302 (relating to disclosure), 5303
- 26 (relating to responsible use) and 5304 (relating to artificial
- 27 <u>intelligence compliance statements</u>) that are necessary to ensure
- 28 compliance with this chapter.
- 29 § 5309. Third-party vendor.
- 30 A contractor, subcontractor or other third-party vendor that

- 1 sells, leases, subscribes or otherwise supplies artificial
- 2 intelligence-based algorithms or services based on artificial
- 3 <u>intelligence-based algorithms to the MA or CHIP managed care</u>
- 4 plan shall be subject to this chapter. The department shall
- 5 <u>develop regulations or guidelines regarding the responsibility</u>
- 6 of a contractor, subcontractor or other third-party vendor that
- 7 <u>sells, leases, subscribes or otherwise supplies artificial</u>
- 8 intelligence-based algorithms or services based on artificial
- 9 <u>intelligence-based algorithms to the insurer or MA or CHIP</u>
- 10 managed care plan. The department may request input from
- 11 insurers, third-party vendors and health care providers or their
- 12 <u>representatives in making this determination.</u>
- 13 <u>§ 5310. Exemption.</u>
- 14 This chapter shall not apply to artificial intelligence-based
- 15 algorithms used for administrative, scheduling or other purposes
- 16 <u>not pertaining to the decision to deny, reduce or terminate</u>
- 17 benefits.
- 18 § 5311. Enforcement and penalties.
- 19 (a) Civil penalties.--
- 20 (1) Subject to paragraph (2), the department may impose
- 21 <u>a civil penalty not exceeding \$5,000 for a violation of this</u>
- 22 chapter. For purposes of this paragraph, each instance of
- 23 <u>nondisclosure shall constitute a separate violation of this</u>
- 24 <u>chapter</u>.
- 25 (2) The following apply to limitations on civil
- 26 penalties under this subsection:
- 27 <u>(i) A civil penalty imposed against an insurer may</u>
- 28 not exceed \$500,000 in the aggregate during a single
- 29 <u>calendar year.</u>
- 30 (ii) A civil penalty imposed against any other

- person may not exceed \$100,000 in the aggregate during a
- 2 <u>single calendar year.</u>
- 3 (b) Unfair Insurance Practices Act.--
- 4 (1) An MA or CHIP managed care plan shall be subject to
- 5 <u>the act of July 22, 1974 (P.L.589, No.205), known as the</u>
- 6 <u>Unfair Insurance Practices Act.</u>
- 7 (2) A violation of any provision of this chapter shall
- 8 <u>be deemed to be a violation of the Unfair Insurance Practices</u>
- 9 <u>Act.</u>
- 10 (c) Injunction. -- The department may maintain an action in
- 11 the name of the Commonwealth for an injunction to prohibit any
- 12 <u>activity that violates the provisions of this chapter.</u>
- 13 <u>(d) Effect on enrollment.--The department may issue an order</u>
- 14 temporarily prohibiting an MA or CHIP managed care plan that
- 15 <u>violates this chapter from enrolling new enrollees.</u>
- 16 § 5312. Plan of correction.
- 17 (a) Authorization. -- The department may require an MA or CHIP
- 18 managed care plan to develop and adhere to a plan of correction
- 19 approved by the department. The department may impose a plan of
- 20 correction in lieu of fines.
- 21 (b) Compliance. -- The department shall monitor compliance
- 22 with the plan of correction under this section.
- 23 (c) Availability. -- The plan of correction shall, upon
- 24 request, be made available to enrollees of the insurer or MA or
- 25 CHIP managed care plan.
- 26 § 5313. Administrative procedures.
- 27 (a) Applicable procedures. -- This chapter shall be subject to
- 28 2 Pa.C.S. Ch. 5 Subch. A (relating to practice and procedure of
- 29 Commonwealth agencies).
- 30 (b) Appeal. -- A party against whom penalties are assessed in

- 1 <u>an administrative action may appeal to Commonwealth Court as</u>
- 2 provided in 2 Pa.C.S. Ch. 7 Subch. A (relating to judicial_
- 3 review of Commonwealth agency action).
- 4 § 5314. Regulations and guidance.
- 5 The department shall promulgate regulations or guidance
- 6 necessary to implement, administer and enforce this chapter. The
- 7 <u>department shall review regulations or quidance every three</u>
- 8 years to ensure compliance with Federal law or Federal agency
- 9 <u>guidance.</u>
- 10 Section 3. This act shall take effect in one year.