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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 Health, the Insurance Department and the Department of Human Services; and imposing penalties.

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

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

CHAPTER 35

ARTIFICIAL INTELLIGENCE IN FACILITIES

Sec.

3506. Retention of records.
3507. Oversight.
3508. Third-party vendor.
3509. Exemption.
3510. Enforcement and penalties.
3511. Plan of correction.
3512. Administrative procedures.
3513. Regulations and guidance.

§ 3501. Definitions.

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

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

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

"Clinical decision making." A patient-centered problem-solving process focused on a health care provider's direct

patient care involving gathering information, diagnosing and planning treatments.

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

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

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

(2) An ambulatory surgical facility.

(3) A cancer treatment center.

(4) A birth center.

(5) An inpatient, outpatient or residential drug and alcohol treatment facility.

(6) A facility licensed by the Department of Human Services' Office of Mental Health and Substance Abuse Services.

(7) A laboratory, imaging, diagnostic or other outpatient medical service or testing facility.

(8) A health care provider office or clinic that is owned by or employs a Commonwealth-licensed physician, physician assistant or nurse practitioner.

"Health care provider." As follows:

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

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

§ 3502. Disclosure.

(a) Duty to disclose.--A facility shall disclose to patients

of the facility if artificial intelligence-based algorithms are or will be used for clinical decision making or other similar tasks. The disclosure shall be:

(1) Provided in all related written communications.

(2) Posted on the publicly accessible Internet website of the facility.

(b) Communications.--

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

(i) A clear and conspicuous disclaimer that indicates that the communication was generated by artificial intelligence.

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

(2) The requirements under paragraph (1) shall not apply to communications that:

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

(ii) have been individually read and reviewed by a human health care provider.

(c) Nature and frequency.--The department shall determine the nature and frequency of disclosure requirements to the patient. The department may request input from facilities and health care providers or their representatives in making the determination.

§ 3503. Responsible use.

(a) Compliance generally.--The criteria for the artificial

intelligence-based algorithms must comply with this chapter and applicable Federal and State law.

(b) Requirements for artificial intelligence-based algorithms.--For each instance in which a facility uses artificial intelligence-based algorithms for clinical decision making, the facility shall comply with the following:

(1) The artificial intelligence-based algorithms must not supersede health care provider clinical decision making.

(2) The artificial intelligence-based algorithms and training data sets must not directly or indirectly discriminate against patients in violation of Federal or State law.

(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 United States Department of Health and Human Services.

(4) The use of the artificial intelligence-based algorithms must be disclosed in accordance with section 3502 (relating to disclosure).

(5) The performance, use and outcomes of the artificial intelligence-based algorithms must be periodically reviewed and revised to maximize accuracy and reliability.

(6) Patient data must not be used beyond the intended and stated purpose of the artificial intelligence-based algorithms, consistent with the laws of this Commonwealth and 42 U.S.C. Ch. 7 Subch. XI Part C (relating to administrative simplification), as applicable.

(7) The artificial intelligence-based algorithms must not create foreseeable, material risks of harm to the patient.

§ 3504. Artificial intelligence compliance statements.

(a) Compliance statement required.--A facility using artificial intelligence-based algorithms for clinical decision making shall annually file with the department in the form and manner prescribed by the department an artificial intelligence compliance statement.

(b) Contents.--Each compliance statement must:

(1) Summarize the function and scope of artificial intelligence-based algorithms used for clinical decision making.

(2) Provide a logic or decision tree of artificial intelligence-based algorithms used for clinical decision making.

(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.

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

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

§ 3505. Reports.

(a) Annual report required.--No later than one year after the effective date of this chapter and each year thereafter, the department shall compile the information from the most recent annual compliance statements under section 3504 (relating to artificial intelligence compliance statements) and issue a

report containing the compiled information, along with any other applicable findings and recommendations. The information in the report shall be aggregated and deidentified.

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

§ 3506. Retention of records.

The department shall establish a record retention policy and determine the amount of time a facility shall retain records related to artificial-intelligence algorithms. The department may request input from facilities and health care providers or their representatives in making the determination under this section.

§ 3507. Oversight.

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

§ 3508. Third-party vendor.

A contractor, subcontractor or other third-party vendor that sells, leases, subscribes or otherwise supplies artificial intelligence-based algorithms or services based on artificial intelligence-based algorithms to the facility shall be subject to this chapter. The department shall develop regulations or guidance regarding the responsibility of a contractor, subcontractor or other third-party vendor that sells, leases, subscribes or otherwise supplies artificial intelligence-based algorithms or services based on artificial intelligence-based

algorithms to the facility. The department may request input from facilities, third-party vendors and health care providers or their representatives in making this determination.

§ 3509. Exemption.

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

§ 3510. Enforcement and penalties.

(a) Civil penalties.--

(1) Subject to paragraph (2), the department may impose a civil penalty not exceeding $5,000 for a violation of this chapter. For purposes of this paragraph, each instance of nondisclosure shall constitute a separate violation of this chapter.

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

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

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

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

(c) Nonexclusive remedies.--The enforcement remedies and penalties imposed under this chapter are in addition to any other remedies or penalties that may be imposed under any other applicable law of this Commonwealth, including the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities

Act.

§ 3511. Plan of correction.

(a) Authorization.--The department may require a facility to develop and adhere to a plan of correction approved by the department. The department may impose a plan of correction in lieu of fines.

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

(c) Availability.--The plan of correction shall, upon request, be made available to patients of the facility.

§ 3512. Administrative procedures.

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

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

§ 3513. Regulations and guidance.

The department shall promulgate regulations or guidance necessary to implement, administer and enforce this chapter. The department shall review regulations or guidance every three years to ensure compliance with Federal law or Federal agency guidance.

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

CHAPTER 52

ARTIFICIAL INTELLIGENCE USE BY INSURERS

Sec.

5201. Definitions.

5202. Disclosure.

§ 5201. Definitions.

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

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

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

"Covered person." A policyholder, subscriber or other individual who is entitled to receive health care services under a health insurance policy.

"Department." The Insurance Department of the Commonwealth.

"Health care provider." As follows:

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

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

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

"Health insurance policy." As follows:

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

(2) The term does not include:

(i) An accident only policy.

(ii) A credit only policy.

(iii) A long-term care or disability income policy.

(iv) A specified disease policy.

(v) A Medicare supplement policy.

(vi) A TRICARE policy, including a Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) supplement policy.

(vii) A fixed indemnity policy.

(viii) A hospital indemnity policy.

(ix) A workers' compensation policy.

(x) An automobile medical payment policy under 75 Pa.C.S. (relating to vehicles).

(xi) A homeowner's insurance policy.

"Insurer." As follows:

(1) An entity licensed by the department that offers, issues or renews an individual or group health insurance policy that is offered or governed under any of the following:

(i) Chapter 61 (relating to hospital plan corporations) or 63 (relating to professional health services plan corporations).

(ii) The act of May 17, 1921 (P.L.682, No.284), known as The Insurance Company Law of 1921, including section 630 and Article XXIV thereof.

(iii) The act of December 29, 1972 (P.L.1701, No.364), known as the Health Maintenance Organization Act.

(2) The term does not include an entity operating as an MA or CHIP managed care plan.

"Participating network provider." A health care provider that has entered into a contractual or operating relationship with an insurer to participate in one or more designated networks of the insurer and to provide health care services to

covered persons under the terms of the insurer's administrative policy.

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

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

§ 5202. Disclosure.

(a) Duty to disclose.--An insurer shall disclose to a participating network provider and all covered persons if artificial intelligence-based algorithms are or will be used in the utilization review process of the insurer.

(b) Posting.--An insurer shall post the information about the use of artificial intelligence-based algorithms in the utilization review process of the insurer on the publicly accessible Internet website of the insurer.

(c) Nature and frequency.--The department shall determine the nature and frequency of disclosure requirements to covered persons. The department may request input from insurers or their representatives in making this determination.

§ 5203. Responsible use.

(a) Compliance generally.--The criteria for the artificial intelligence-based algorithms must comply with this chapter and applicable Federal and State law.

(b) Requirements for artificial intelligence-based algorithms.--For each instance in which an insurer uses artificial intelligence-based algorithms in the utilization review process regarding a covered person, the insurer shall comply with the following:

(1) The artificial intelligence-based algorithms must base a determination on all of the following:

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

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

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

(2) The artificial intelligence-based algorithms must not base a determination solely on a group data set.

(3) The artificial intelligence-based algorithms must not supersede decision making of the health care provider conducting the utilization review.

(4) The artificial intelligence-based algorithms and training data sets must not directly or indirectly discriminate against covered persons in violation of Federal or State law.

(5) The artificial intelligence-based algorithms must be fairly and equitably applied, including in accordance with any applicable regulations or guidance issued by the United States Department of Health and Human Services.

(6) The use of the artificial intelligence-based algorithms must be disclosed in accordance with section 5202 (relating to disclosure).

(7) The performance, use and outcomes of the artificial intelligence-based algorithms must be periodically reviewed and revised to maximize accuracy and reliability.

(8) The data of the covered person must not be used beyond the intended and stated purpose of the artificial intelligence-based algorithms, consistent with Commonwealth

law and 42 U.S.C. Ch. 7, Subch. XI Part C (relating to administrative simplification), as applicable.

(9) The artificial intelligence-based algorithms must not create foreseeable, material risks of harm to the covered person.

§ 5204. Artificial intelligence compliance statements.

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

(b) Contents.--Each compliance statement must:

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

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

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

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

(5) Describe the process of the insurer for overseeing and validating the performance and compliance of the artificial intelligence-based algorithms in accordance with section 5203.

§ 5205. Health care provider requirements.

Prior to issuing or upholding a decision to deny, reduce or terminate benefits for a health care service, including a

decision to deny a prior authorization request, a health care provider who participates in utilization review on behalf of an insurer shall:

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

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

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

§ 5206. Reports.

(a) Annual report required.--No later than one year after the effective date of this chapter, and annually thereafter, the department shall compile the information from the most recent annual compliance statements under section 5204 (relating to artificial intelligence compliance statements) and issue a report to the General Assembly containing the compiled information, along with any other applicable findings and recommendations. The information in the report shall be aggregated and deidentified.

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

§ 5207. Retention of records.

The department shall establish a record retention policy and determine the amount of time an insurer shall retain records. The department may request input from insurers or their representatives in making this determination.

§ 5208. Oversight.

The department may request additional information and evidence from an insurer regarding the items provided under

sections 5202 (relating to disclosure), 5203 (relating to responsible use) and 5204 (relating to artificial intelligence compliance statements) that are necessary to ensure compliance with this chapter.

§ 5209. Third-party vendor.

A contractor, subcontractor or other third-party vendor that sells, leases, subscribes or otherwise supplies artificial intelligence-based algorithms or services based on artificial intelligence-based algorithms to the insurer services shall be subject to this chapter. The department shall develop regulations or guidelines regarding the responsibility of a contractor, subcontractor or other third-party vendor that sells, leases, subscribes or otherwise supplies artificial intelligence-based algorithms or services based on artificial intelligence-based algorithms to the insurer. The department may request input from insurers, third-party vendors and health care providers or their representatives in making this determination.

§ 5210. Exemption.

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

§ 5211. Enforcement and penalties.

(a) Civil penalties.--

(1) Subject to paragraph (2), the department may impose a civil penalty not exceeding $5,000 for a violation of this chapter. For purposes of this paragraph, each instance of nondisclosure shall constitute a separate violation of this chapter.

(2) The following apply to limitations on civil

penalties under this subsection:

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

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

(b) Unfair Insurance Practices Act.--

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

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

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

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

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

(1) The Unfair Insurance Practices Act.

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

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

§ 5212. Plan of correction.

(a) Authorization.--The department may require an insurer to develop and adhere to a plan of correction approved by the department. The department may impose a plan of correction in lieu of fines.

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

(c) Availability.--The plan of correction shall, upon request, be made available to covered persons of the insurer.

§ 5213. Administrative procedures.

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

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

§ 5214. Regulations and guidance.

The department shall promulgate regulations or guidance necessary to implement, administer and enforce this chapter. The department shall review regulations or guidance every three years to ensure compliance with Federal law or Federal agency guidance.

CHAPTER 53

ARTIFICIAL INTELLIGENCE USE BY MA OR CHIP MANAGED CARE PLANS

Sec.

5305. Health care provider requirements.
5306. Reports.
5307. Retention of records.
5308. Oversight.
5309. Third-party vendor.
5310. Exemption.
5311. Enforcement and penalties.
5312. Plan of correction.
5313. Administrative procedures.
5314. Regulations and guidance.

§ 5301. Definitions.

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

"Agreement with the department." As follows:

(1) An agreement between an MA or CHIP managed care plan and the department to manage the purchase and provision of services.

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

"Artificial intelligence" or "AI." A machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments that use machine-based and human-based inputs to perceive real and virtual environments, abstract the perceptions into models through analysis in an automated manner and use model inference to formulate options for information or action. The term includes generative artificial intelligence which is the class of models that emulate the structure and characteristics of input data in order to generate derived

synthetic content which includes information such as images, videos, audio clips and text that has been significantly modified or generated by algorithms, including by artificial intelligence.

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

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

"Enrollee." An individual who is entitled to receive health care services under an agreement with the department.

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

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

(2) An ambulatory surgical facility.

(3) A cancer treatment center.

(4) A birth center.

(5) An inpatient, outpatient or residential drug and alcohol treatment facility.

(6) A facility licensed by the department's Office of Mental Health and Substance Abuse Services.

(7) A laboratory, imaging, diagnostic or other outpatient medical service or testing facility.

(8) A health care provider office or clinic that is owned by or employs a Commonwealth-licensed physician, physician assistant or nurse practitioner.

"Health care provider." As follows:

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

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

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

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

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

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

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

§ 5302. Disclosure.

(a) Duty to disclose.--An MA or CHIP managed care plan shall disclose to a participating network provider and all enrollees if artificial intelligence-based algorithms are or will be used in the utilization review process of the MA or CHIP managed care

plan.

(b) Posting.--An MA or CHIP managed care plan shall post the information about the use of artificial intelligence-based algorithms in the utilization review process of the MA or CHIP managed care plan on the publicly accessible Internet website of the MA or CHIP managed care plan.

(c) Nature and frequency.--The department shall determine the nature and frequency of disclosure requirements to enrollees. The department may request input from MA or CHIP managed care plans or their representatives in making this determination.

§ 5303. Responsible use.

(a) Compliance generally.--The criteria for the artificial intelligence-based algorithms must comply with this chapter and applicable Federal and State law.

(b) Requirements for artificial intelligence-based algorithms.--For each instance in which a MA or CHIP managed care plan uses artificial intelligence-based algorithms in the utilization review process regarding an enrollee, the MA or CHIP managed care plan shall comply with the following:

(1) The artificial intelligence-based algorithms must base a determination on all of the following:

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

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

(iii) Other relevant clinical or nonclinical information contained in the medical or other clinical record of the enrollee.

(2) The artificial intelligence-based algorithms must not base a determination solely on a group data set.

(3) The artificial intelligence-based algorithms must not supersede decision making of the health care provider conducting the utilization review.

(4) The artificial intelligence-based algorithms and training data sets must not directly or indirectly discriminate against the enrollees in violation of Federal or State law.

(5) The artificial intelligence-based algorithms must be fairly and equitably applied, including in accordance with any applicable regulations and guidance issued by the United States Department of Health and Human Services.

(6) The use of the artificial intelligence-based algorithms must be disclosed in accordance with section 5302 (relating to disclosure).

(7) The performance, use and outcomes of the artificial intelligence-based algorithms must be periodically reviewed and revised to maximize accuracy and reliability.

(8) The data of the covered person or enrollees must not be used beyond the intended and stated purpose of the artificial intelligence-based algorithms, consistent with the laws of this Commonwealth and the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191, 110 Stat. 1936), as applicable.

(9) The artificial intelligence-based algorithms must not create foreseeable, material risks of harm to the enrollee.

§ 5304. Artificial intelligence compliance statements.

(a) Compliance statement required.--An MA or CHIP managed

care plan using artificial intelligence-based algorithms in the utilization review process shall annually file with the department, in the form and manner prescribed by the department, an artificial intelligence compliance statement.

(b) Contents.--Each compliance statement must:

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

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

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

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

(5) Describe the process of the MA or CHIP managed care plan for overseeing and validating the performance and compliance of the artificial intelligence-based algorithms in accordance with section 5303.

§ 5305. Health care provider requirements.

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

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

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

(3) Based on the review under paragraph (1), exercise

judgment independent of any recommendations by the artificial intelligence-based algorithms.

§ 5306. Reports.

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

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

§ 5307. Retention of records.

The department shall establish a record retention policy and determine the amount of time an MA or CHIP managed care plan shall retain records. The department may request input from an MA or CHIP managed care plan or their representative to make this determination.

§ 5308. Oversight.

The department may request additional information and evidence from an MA or CHIP managed care plan regarding the items provided under section 5302 (relating to disclosure), 5303 (relating to responsible use) and 5304 (relating to artificial intelligence compliance statements) that are necessary to ensure compliance with this chapter.

§ 5309. Third-party vendor.

A contractor, subcontractor or other third-party vendor that

sells, leases, subscribes or otherwise supplies artificial intelligence-based algorithms or services based on artificial intelligence-based algorithms to the MA or CHIP managed care plan shall be subject to this chapter. The department shall develop regulations or guidelines regarding the responsibility of a contractor, subcontractor or other third-party vendor that sells, leases, subscribes or otherwise supplies artificial intelligence-based algorithms or services based on artificial intelligence-based algorithms to the insurer or MA or CHIP managed care plan. The department may request input from insurers, third-party vendors and health care providers or their representatives in making this determination.

§ 5310. Exemption.

This chapter shall not apply to artificial intelligence-based algorithms used for administrative, scheduling or other purposes not pertaining to the decision to deny, reduce or terminate benefits.

§ 5311. Enforcement and penalties.

(a) Civil penalties.--

(1) Subject to paragraph (2), the department may impose a civil penalty not exceeding $5,000 for a violation of this chapter. For purposes of this paragraph, each instance of nondisclosure shall constitute a separate violation of this chapter.

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

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

(ii) A civil penalty imposed against any other

person may not exceed $100,000 in the aggregate during a single calendar year.

(b) Unfair Insurance Practices Act.--

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

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

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

(d) Effect on enrollment.--The department may issue an order temporarily prohibiting an MA or CHIP managed care plan that violates this chapter from enrolling new enrollees.

§ 5312. Plan of correction.

(a) Authorization.--The department may require an MA or CHIP managed care plan to develop and adhere to a plan of correction approved by the department. The department may impose a plan of correction in lieu of fines.

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

(c) Availability.--The plan of correction shall, upon request, be made available to enrollees of the insurer or MA or CHIP managed care plan.

§ 5313. Administrative procedures.

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

(b) Appeal.--A party against whom penalties are assessed in

an administrative action may appeal to Commonwealth Court as provided in 2 Pa.C.S. Ch. 7 Subch. A (relating to judicial review of Commonwealth agency action).

§ 5314. Regulations and guidance.

The department shall promulgate regulations or guidance necessary to implement, administer and enforce this chapter. The department shall review regulations or guidance every three years to ensure compliance with Federal law or Federal agency guidance.

Section 3. This act shall take effect in one year.