

JAN 21 2026

A BILL FOR AN ACT

RELATING TO THE USE OF ARTIFICIAL INTELLIGENCE IN HEALTH CARE.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Chapter 321, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

"PART . ARTIFICIAL INTELLIGENCE IN HEALTH CARE

§321- Definitions. For the purposes of this part:

"Artificial intelligence" or "artificial intelligence system" means any engineered or machine-based system that varies in its level of autonomy and that can, for explicit or implicit objectives, infer from the input it receives how to generate outputs that can influence physical or virtual environments.

"Authorized representative" means:

(1) An agent, a guardian, or a surrogate of the patient;

or

(2) A person who is given a written individual instruction or power of attorney for health care in the patient's advance health-care directive pursuant to chapter 327E.



1 For the purposes of this definition, "advance health-care
2 directive", "agent", "guardian", "power of attorney for health
3 care", and "surrogate" have the same meanings as defined in
4 section 327E-2.

5 "Consequential decision" means a decision that has a
6 significant effect on the physical or mental health of a patient
7 or a material legal or similarly significant effect on the
8 provision or denial to any patient of, or the cost or terms of,
9 health care services.

10 "Department" means the department of health.

11 "Health care provider" and "health care service" have the
12 same meanings as defined in section 323D-2.

13 "Health information" and "individually identifiable health
14 information" have the same meanings as defined in section
15 323B-2.

16 "Patient" means a person who is under the observation and
17 care of or otherwise receiving health care services from a
18 health care provider.

19 "Personal data" means any information that is linked or
20 could be reasonably linkable to an identified or identifiable



1 natural person. "Personal data" does not include de-identified
2 data or publicly available information.

3 "Profiling" means any form of automated processing
4 performed on personal data to evaluate, analyze, or predict
5 personal aspects related to an identified or identifiable
6 individual's economic situation, health, personal preferences,
7 interests, reliability, behavior, location, or movements.

8 "Remote communication" means communication through means by
9 which a person who is not physically present in the same
10 location as a health care provider may communicate with the
11 health care provider on a substantially simultaneous basis.

12 "Remote communication" includes telecommunication,
13 videoconference, and electronic communication, including
14 internet-based communication and electronic transmission.

15 "Substantial factor" means a factor that:

- 16 (1) Assists in making a consequential decision;
17 (2) Is capable of altering the outcome of a consequential
18 decision; and
19 (3) Is generated by an artificial intelligence system.

20 "Substantial factor" includes any use of an artificial
21 intelligence system to generate any content, decision,



1 prediction, or recommendation concerning a patient that is used
2 as a basis to make a consequential decision concerning the
3 patient.

4 **§321- Health care providers; artificial intelligence;**
5 **patient interaction; disclosure.** (a) Any health care provider
6 that uses or makes available for use an artificial intelligence
7 system intended to interact with patients by means of remote
8 communication shall disclose to the patient or the patient's
9 authorized representative, as applicable, that the person is
10 interacting with artificial intelligence.

11 (b) The disclosure shall be made before or at the time of
12 the interaction; provided that in the case of an emergency, the
13 disclosure shall be made as soon as reasonably possible.

14 (c) The disclosure shall be clear and conspicuous, and
15 include:

16 (1) A disclaimer that:

17 (A) The communication was generated by artificial
18 intelligence; or

19 (B) The communication was generated by artificial
20 intelligence and reviewed by a health care



1 provider who is a natural person or a natural
2 person retained by the health care provider; and

3 (2) Clear instructions on how the patient can directly
4 contact a health care provider who is a natural
5 person, an employee of the health care provider, or
6 other appropriate natural person.

7 **§321- Health care providers; artificial intelligence;**
8 **consequential decisions; notice; statement; opt-out;**
9 **corrections; appeal.** (a) Before using an artificial
10 intelligence system to make, or be a substantial factor in
11 making, a consequential decision, a health care provider shall
12 provide the patient or the patient's authorized representative,
13 as applicable, with a written notice that:

14 (1) Informs the recipient that the health care provider
15 will be using an artificial intelligence system to
16 make, or be a substantial factor in making, the
17 consequential decision;

18 (2) Discloses the purpose of the artificial intelligence
19 system and the nature of the consequential decision;

20 (3) Describes the artificial intelligence system in plain
21 language; and



1 (4) Allows the patient to opt out of the processing of the
2 patient's individually identifiable health information
3 or other personal data for purposes of profiling in
4 furtherance of decisions that have legal or similarly
5 significant effects concerning the patient.

6 (b) Any health care provider that used an artificial
7 intelligence system to make, or be a substantial factor in
8 making, a consequential decision shall provide the patient or
9 the patient's authorized representative, as applicable with:

10 (1) A written statement that describes the consequential
11 decision and the principal reasons for the
12 consequential decision, including:

13 (A) The degree to which, and manner in which, the
14 artificial intelligence system contributed to the
15 consequential decision;

16 (B) The type of data that was processed by the
17 artificial intelligence system in making the
18 consequential decision; and

19 (C) The sources of the data described in
20 paragraph (B);



1 (2) An opportunity to correct any incorrect health
2 information or personal data that the artificial
3 intelligence system processed in making, or as a
4 substantial factor in making, the consequential
5 decision; and

6 (3) An opportunity to appeal the consequential decision,
7 including allowing, to the extent technically
8 feasible, human review of all information relating to
9 the consequential decision; provided that this
10 paragraph shall not apply if providing the opportunity
11 for appeal is not in the best interest of the patient,
12 including in instances in which any delay might pose a
13 risk to the life or safety of the patient.

14 (c) The notice and statement required pursuant to
15 subsections (a) and (b), respectively, shall be provided
16 directly to the patient or the patient's authorized
17 representative, as applicable; provided that if the health care
18 provider is unable to comply with this requirement, the health
19 care provider shall provide the notice or statement in a manner
20 that is reasonably calculated to ensure that the patient or the



1 patient's authorized representative, as applicable, receives the
2 notice or statement.

3 **§321- Health care providers; artificial intelligence;**
4 **consequential decisions; review and validation by qualified**
5 **oversight personnel.** (a) Any health care provider that uses an
6 artificial intelligence system to make, or be a substantial
7 factor in making, a consequential decision shall maintain an
8 artificial intelligence oversight personnel.

9 (b) The artificial intelligence oversight personnel:

10 (1) Shall be a natural person;

11 (2) Shall have the qualifications, experience, and
12 expertise necessary to effectively evaluate outputs,
13 including but not limited to any information, data,
14 assumptions, predictions, scoring, recommendations,
15 decisions, or conclusions, generated by artificial
16 intelligence systems in the field of health care; and

17 (3) May be retained by contracting with a third-party.

18 (c) The artificial intelligence oversight personnel shall:

19 (1) Monitor the artificial intelligence systems used by
20 the health care provider; and



(2) Before the health care provider uses an output generated by an artificial intelligence system to make, or be a substantial factor in making, a consequential decision:

(A) Review and evaluate the output; and

(B) Validate or override the output.

§321- Health care providers; artificial intelligence; consequential decisions; monitoring; performance evaluation; record keeping. Any health care provider that uses an artificial intelligence system to make, or be a substantial factor in making, a consequential decision shall:

(1) Monitor the usage of artificial intelligence systems to make, or be a substantial factor in making, consequential decisions;

(2) Conduct regular performance evaluations of the artificial intelligence systems, including the assessment of:

(A) Potential biases in training data;

(B) Risks to the safety and rights of patients, including the confidentiality of personal data; and



1 (C) Mitigation strategies for any identified risks;

2 (3) Implement procedures to address any deficiencies
3 identified through the monitoring or performance
4 evaluations, including the suspension or recalibration
5 of any artificial intelligence system; and

6 (4) Maintain:

7 (A) An updated inventory of the artificial
8 intelligence systems;

9 (B) Documentation on the system design, intended use,
10 and training data of the artificial intelligence
11 systems;

12 (C) Record of the monitoring, performance
13 evaluations, and oversight activities;

14 (D) Documentation of findings and actions taken to
15 address any deficiencies identified through the
16 monitoring or performance evaluations.

17 **§321- Reports to the department.** Any health care
18 provider who uses an artificial intelligence system pursuant to
19 this part shall submit an annual report to the department
20 relating to the health care provider's compliance with this
21 part.



1 **§321- Rules.** The department of health, in coordination
2 with the department of business, economic development, and
3 tourism, shall adopt rules pursuant to chapter 91 to implement
4 this part. The rules shall include but not be limited to the
5 qualifications, experience, and expertise required for an
6 artificial intelligence oversight personnel and the frequency of
7 regular performance evaluations of artificial intelligence
8 systems required to be performed by certain health care
9 providers."

10 SECTION 2. This Act shall take effect upon its approval.

11
INTRODUCED BY:

A large, stylized handwritten signature in black ink, written over a horizontal line. The signature is cursive and appears to be the name of the person who introduced the bill.

S.B. NO. 2281

Report Title:

DOH; Health Care Providers; Artificial Intelligence; Patient Interaction; Consequential Decisions; Disclosure; Notice; Oversight; Performance Evaluations; Recordkeeping; Reports; Rules

Description:

Requires health care providers using artificial intelligence (AI) in patient interactions to disclose to the patient that the patient is interacting with artificial intelligence. Requires health care providers using AI in making consequential decisions relating to the patient to provide certain notice and statements to the patient; maintain a qualified AI oversight personnel who shall be a natural person that reviews, evaluates, and validates or overrides AI outputs; monitor and conduct regular performance evaluations of their AI systems; implement procedures to address identified deficiencies; and maintain certain records. Requires certain health care providers using AI to submit annual reports to the Department of Health. Requires the Department to adopt rules.

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