| 118TH CONGRESS | \mathbf{C} | |
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| 2D Session | | |
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To regulate electronic medical device use in secure compartmented information facilities, to require the Director of the National Intelligence oversee transparency reporting and related initiatives, to encourage investment in modernization efforts for sensitive compartmented information facilities, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. Welch (for himself and Mr. Casey) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To regulate electronic medical device use in secure compartmented information facilities, to require the Director of the National Intelligence oversee transparency reporting and related initiatives, to encourage investment in modernization efforts for sensitive compartmented information facilities, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Cleared Locations En-
- 5 abling Access to Relevant Essential Devices Act of 2024"
- 6 or the "CLEARED Act of 2024".

| 1 | SEC. 2. ENHANCING NATIONAL ACCESSIBILITY FOR BET- |
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| 2 | TER LONG-TERM EMPLOYMENT ACT OF 2024. |
| 3 | (a) Definitions.—In this section: |
| 4 | (1) COVERED ENTITY.—The term "covered en- |
| 5 | tity' means any entity that— |
| 6 | (A) is established under or sponsored by |
| 7 | any branch of the United States Government; |
| 8 | and |
| 9 | (B) manages a secure compartmented in- |
| 10 | formation facility. |
| 11 | (2) Electronic medical device.—The term |
| 12 | "electronic medical device" has the meaning given |
| 13 | that term in Intelligence Community Directive 124. |
| 14 | (3) GOVERNANCE BOARD.—The term "Govern- |
| 15 | ance Board" means the Electronic Medical Device |
| 16 | Governance Board described in Intelligence Commu- |
| 17 | nity Directive 124. |
| 18 | (b) DEVICE APPROVAL DISCLOSURE.— |
| 19 | (1) Electronic medical device ledgers.— |
| 20 | Beginning on the date of the enactment of this Act, |
| 21 | the head of any covered entity shall begin developing |
| 22 | and maintaining, for each secure compartmented in- |
| 23 | formation facility managed by such covered entity, a |
| 24 | ledger to track the approval and denial of requests |
| 25 | for electronic medical device use, which shall in- |
| 26 | elude— |

| 1 | (A) a case-by-case annotation of each ap- |
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| 2 | proval or denial of an electronic medical device |
| 3 | (B) a justification for each such approva |
| 4 | or denial; |
| 5 | (C) any relevant details regarding device |
| 6 | restrictions or accommodations; and |
| 7 | (D) statistics summarizing the number of |
| 8 | electronic medical devices approved for unre- |
| 9 | stricted use and limited use and devices that |
| 10 | were denied. |
| 11 | (2) Approved electronic medical device |
| 12 | LIST.— |
| 13 | (A) IN GENERAL.—Beginning not later |
| 14 | than 1 year after the date of the enactment of |
| 15 | this Act, the head of any covered entity shall |
| 16 | develop and maintain, for each secure compart- |
| 17 | mented information facility managed by such |
| 18 | covered entity, develop and maintain a list that |
| 19 | includes the following: |
| 20 | (i) Each electronic medical device that |
| 21 | is approved for unrestricted use in the fa- |
| 22 | cility. |
| 23 | (ii) Each electronic medical device |
| 24 | that is approved for limited use in the fa- |
| 25 | cility, including— |

| 1 | (I) any restrictions or accom- |
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| 2 | modations required with respect to |
| 3 | each such device; |
| 4 | (II) a description of whether such |
| 5 | restrictions or accommodations vary |
| 6 | from restrictions imposed or accom- |
| 7 | modations provided by other covered |
| 8 | entities; and |
| 9 | (III) if applicable, an explanation |
| 10 | of the variability of such restrictions |
| 11 | or accommodations. |
| 12 | (iii) Each electronic medical device |
| 13 | that is denied for use in the facility and |
| 14 | the justification for such denial. |
| 15 | (B) Form.— |
| 16 | (i) Access to unclassified list.— |
| 17 | The relevant list of a covered entity devel- |
| 18 | oped pursuant to subparagraph (A) shall |
| 19 | be— |
| 20 | (I) unclassified to the maximum |
| 21 | extent practicable, but may include a |
| 22 | classified annex; and |
| 23 | (II) provided to any applicant or |
| 24 | employee of the covered entity who |
| 25 | seeks a position that requires access |

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| 1 | to a secure compartmented informa- |
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| 2 | tion facility. |
| 3 | (ii) Access to classified list.— |
| 4 | (I) CLEARED APPLICANTS.—On |
| 5 | the date that an applicant or em- |
| 6 | ployee described in clause (i)(II) re- |
| 7 | ceives the security clearance necessary |
| 8 | for access to the secure compart- |
| 9 | mented information facility, the head |
| 10 | of the relevant covered entity shall |
| 11 | make available to such applicant or |
| 12 | employee the classified portion of the |
| 13 | list described in clause (i). |
| 14 | (II) Existing employees.—Not |
| 15 | later than 1 year after the date of the |
| 16 | enactment of this Act, the head of |
| 17 | each covered entity shall provide to |
| 18 | each employee of the covered entity |
| 19 | who has the security clearance nec- |
| 20 | essary to access a secure compart- |
| 21 | mented information facility, the list |
| 22 | developed by the head of such covered |
| 23 | entity with respect to such facility, |
| 24 | which shall be unclassified to the max- |

| 1 | imum extent practicable, but may in- |
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| 2 | clude a classified annex. |
| 3 | (3) Electronic medical device policy.— |
| 4 | (A) IN GENERAL.—Not later than 180 |
| 5 | days after the date of the enactment of this |
| 6 | Act, the head of each covered entity shall de- |
| 7 | velop a policy for the use of electronic medical |
| 8 | devices in secure compartmented information |
| 9 | facilities, which shall include a list of the types |
| 10 | of electronic medical devices that are approved |
| 11 | for use in each such facility managed by the |
| 12 | covered entity. |
| 13 | (B) ANNUAL REVIEW.—The head of each |
| 14 | covered entity shall annually review any policy |
| 15 | developed pursuant to subparagraph (A). |
| 16 | (4) Submission to director of national |
| 17 | INTELLIGENCE AND GOVERNANCE BOARD.—Not |
| 18 | later than 180 days after the date of the enactment |
| 19 | of this Act, and annually thereafter, the head of |
| 20 | each covered entity shall submit to the Director of |
| 21 | National Intelligence and the Governance Board— |
| 22 | (A) any ledger developed pursuant to para- |
| 23 | graph (1); |
| 24 | (B) any list published pursuant to para- |
| 25 | graph $(2)(A)$; and |

| 1 | (C) any policy developed pursuant to para- |
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| 2 | graph $(3)(A)$. |
| 3 | (e) REVIEW OF ELECTRONIC MEDICAL DEVICE SE- |
| 4 | CURITY.— |
| 5 | (1) IN GENERAL.—The Governance Board shall |
| 6 | review electronic medical device security and equity |
| 7 | concerns for covered agencies. |
| 8 | (2) Duties.—The Governance Board shall— |
| 9 | (A) review the policies of covered agencies |
| 10 | regarding the use of electronic medical devices |
| 11 | in secure compartmented information facilities; |
| 12 | (B) review each ledger or list submitted in |
| 13 | accordance with subsection (b)(4); |
| 14 | (C) identify and resolve discrepancies in |
| 15 | such ledgers and lists, with respect to both vari- |
| 16 | ation in justifications for restrictions and ac- |
| 17 | commodations and denials within each covered |
| 18 | entity and across all covered entities; |
| 19 | (D) facilitate and direct security research |
| 20 | and technical risk assessments on electronic |
| 21 | medical devices and determine threats to na- |
| 22 | tional security posed by such devices; |
| 23 | (E) for electronic medical devices that have |
| 24 | been researched pursuant to subparagraph (D), |

| 1 | evaluate threat mitigation measures available |
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| 2 | and the efficacy ratings of such measures; and |
| 3 | (F) provide recommendations for risk man- |
| 4 | agement of electronic medical devices in secure |
| 5 | compartmented information facilities. |
| 6 | (3) Electronic medical ledger data- |
| 7 | BASE.— |
| 8 | (A) IN GENERAL.—Using each ledger and |
| 9 | list submitted to the Governance Board in ac- |
| 10 | cordance with subsection (b)(4), the Governance |
| 11 | Board shall develop and maintain a publicly ac- |
| 12 | cessible database of electronic medical devices |
| 13 | that have been approved or denied for use at |
| 14 | any secure compartmented information facility, |
| 15 | including, to the extent practicable— |
| 16 | (i) approval rates; |
| 17 | (ii) accommodations or restrictions for |
| 18 | usage; and |
| 19 | (iii) for each covered entity, specific |
| 20 | processes for electronic medical device ap- |
| 21 | proval. |
| 22 | (B) Public availability of informa- |
| 23 | TION.—The Governance Board shall make |
| 24 | available on the website of the Office of the Di- |
| 25 | rector of National Intelligence the following: |

| 1 | (i) General approval and denial rates |
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| 2 | for devices described in subparagraph (A) |
| 3 | of different types. |
| 4 | (ii) Points of contact for teams re- |
| 5 | sponsible for approvals and denials of de- |
| 6 | vices described in subparagraph (A). |
| 7 | (C) Ledger discrepancies.—The Gov- |
| 8 | ernance Board shall include in such database |
| 9 | any discrepancy identified pursuant to para- |
| 10 | graph (2), including, for each such discrep- |
| 11 | ancy— |
| 12 | (i) a detailed description of the dis- |
| 13 | crepancy; and |
| 14 | (ii) proposed remediations. |
| 15 | (D) FORM.—The database shall be unclas- |
| 16 | sified, but may include a classified annex as the |
| 17 | Director of National Intelligence considers ap- |
| 18 | propriate. |
| 19 | (4) Report.— |
| 20 | (A) In general.—Not later than 1 year |
| 21 | after the date of the enactment of this Act, and |
| 22 | annually thereafter, the Governance Board shall |
| 23 | submit to the Director of National Intelligence |
| 24 | a report on the state of electronic medical de- |

| vice usage in secure compartmented information |
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| facilities. |
| (B) Content.—Each report submitted |
| pursuant to subparagraph (A) shall include— |
| (i) a description of the research ef- |
| forts, risk management recommendations, |
| and strategic approaches of the Govern- |
| ance Board to support changes or innova- |
| tions that improve the use of electronic |
| medical devices in secure compartmented |
| information facilities; |
| (ii) a description of any barriers to re- |
| solving discrepancies under paragraph |
| (2)(C); |
| (iii) a summary of statistics describing |
| approval rates gleaned from the database |
| developed pursuant to paragraph (3); and |
| (iv) any other information the Govern- |
| ance Board determines is relevant for the |
| Director of National Intelligence to con- |
| sider regarding the use of electronic med- |
| ical devices in secure compartmented infor- |
| mation facilities. |
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| 1 | (5) Annual evaluations.—Not later than |
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| 2 | 180 days after receiving a report under paragraph |
| 3 | (4), the Director of National Intelligence shall— |
| 4 | (A) evaluate the findings and recommenda- |
| 5 | tions of the Governance Board in such report; |
| 6 | and |
| 7 | (B) submit to Congress a report that in- |
| 8 | cludes— |
| 9 | (i) the results of the evaluation con- |
| 10 | ducted under subparagraph (A); |
| 11 | (ii) a description of current approval |
| 12 | rates for electronic medical devices; |
| 13 | (iii) a description of research efforts |
| 14 | and risk mitigation strategies with respect |
| 15 | to electronic medical devices; and |
| 16 | (iv) recommendations for updating |
| 17 | electronic medical device requirements in |
| 18 | secure compartmented information facili- |
| 19 | ties. |
| 20 | (d) Protection of Information.—In carrying out |
| 21 | this section, the head of each covered entity shall ensure |
| 22 | the protection of personally identifiable information, in- |
| 23 | cluding medical information, in accordance with all appli- |
| 24 | cable laws and policies with respect to confidentiality and |
| 25 | privacy. |
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