AS INTRODUCED IN THE RAJYA SABHA
ON THE 6TH FEBRUARY, 2026

Bill No. XIII of 2026

THE ARTIFICIAL INTELLIGENCE (HUMAN HEALTH AND MEDICAL EDUCATION) REGULATION BILL, 2026

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BILL

to provide for a comprehensive, scientific and patient-centric statutory framework for the ethical, safe and disciplined use of Artificial Intelligence in human health, clinical research and medical education; to enable Government and private hospitals, research institutions and medical colleges to utilize Artificial Intelligence to enhance patient care, prescription safety, clinical trials, drug discovery and medical education under strict human oversight; to ensure patient safety, data protection, accountability and transparency; to establish a statutory regulatory authority for the purpose and for matters connected therewith or incidental thereto.

BE it enacted by Parliament in the Seventy-seventh Year of the Republic of India as follows:—

Short title and commencement.

1. *(1)* This Act may be called the Artificial Intelligence (Human Health and Medical Education) Regulation Act, 2026.

(2) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

Definitions.

2. In this Act, unless the context otherwise requires,—

(a) "Artificial Intelligence" means any computational system that uses algorithms, models, or rule-based techniques to analyse data or information and produce outcomes or actions**,** and which may operate with varying degrees of autonomy, adaptiveness, or human oversight;

(b) "Artificial Intelligence system" means any machine-based system that, for explicit or implicit objectives, infers from input data to generate outputs such as predictions, recommendations or analyses influencing diagnosis, prescription review, treatment, clinical research, patient management or medical education;

(c) "Authority" means the National Authority for Artificial Intelligence in Human Health and Medical Education established under section 13;

(d) "Fund" means the Artificial Intelligence Harm Compensation Fund established under section 17;

(e) "high-risk Artificial Intelligence system" means an Artificial Intelligence system whose failure, misuse or error may result in death, serious bodily injury, psychological harm, unethical experimentation, discrimination or grave clinical, research or educational consequences;

(f) "Human-in-the-Loop" means a governance mechanism ensuring meaningful human oversight, intervention and final responsibility over the outputs of an Artificial Intelligence system;

(g) "medical education" includes undergraduate, postgraduate and super-specialty medical education, faculty development, assessment, certification and continuing professional development; and

(h) "prescribed" means prescribed by rules made under this Act.

Application of the Act.

3. This Act shall apply to all Artificial Intelligence systems developed, deployed, imported, sold or used in India for —

(a) diagnostics, screening, treatment, prognosis and clinical decision support;

(b) prescription review, medication safety analysis and clinical audit;

(c) drug discovery, therapeutics and biomedical research involving human data;

(d) clinical trials, including protocol design support, patient eligibility assessment, safety monitoring and data analysis, subject to applicable laws and ethical approvals;

(e) mental and behavioural healthcare;

(f) public health surveillance and epidemiology;

(g) hospital and clinic management systems; and

(h) medical education, training, simulation, assessment and certification.

Disciplined and patient-centric use of Artificial Intelligence in human health, clinical research and medical education.

4. *(1)* Notwithstanding anything contained in this regard in any other law for the time being in force, the use of Artificial Intelligence in human health, clinical research and medical education shall be:-

(i) strictly as a supportive scientific tool intended to enhance, and not replace, human clinical judgment, ethical reasoning, compassion and professional accountability; and

(ii) permitted only in a regulated, supervised and disciplined manner, as provided under this Act recognising that human life, dignity and safety are paramount.

(2) The Central Government may encourage innovation in such use of artificial intelligence, in such manner as may be prescribed, subject to protection of patient safety, research ethics, student competence or professional responsibility.

Permissible use of Artificial Intelligence system in healthcare institutions.

5. *(1)* Subject to the provisions of section 4, any Government or private hospital or any other healthcare institution may utilise any Artificial Intelligence system to enhance diagnosis, treatment planning, patient monitoring, prescription review, clinical audit, quality assurance, public health functions and operational efficiency, subject to human oversight and informed consent, in such manner as may be prescribed:

Provided that Artificial Intelligence systems may be utilised for prescription and clinical audit purposes, including detection of medication errors, drug–drug interactions, contraindications, dosage deviations and non-compliance with standard treatment guidelines, only as clinical decision-support tools.

(2) No Artificial Intelligence system shall be deployed to autonomously generate, modify or finalise any prescription, and the final responsibility for a prescription shall at all times vest with a registered medical practitioner.

(3) The Artificial Intelligence system may suggest evidence-based treatment protocols, care pathways and risk stratification models subject to the final decision regarding diagnosis, initiation, modification or discontinuation of treatment being vested exclusively with a registered medical practitioner, who shall remain professionally and legally accountable.

(4) The Artificial Intelligence system may assist in clinical documentation, discharge summaries and follow-up planning, subject to verification and authentication by a human clinician.

Mandatory human-in-the-loop.

6. No Artificial Intelligence system shall operate as the sole or final authority in diagnosis, prescription, treatment, prognosis, patient triage or clinical decision-making; and the final authority and accountability shall at all times vest with a qualified human medical professional.

Permissible use of Artificial Intelligence system in medical education institutions.

7. (*1*) Any Government or private medical college or any other medical education institution may utilise Artificial Intelligence systems to supplement teaching, clinical simulations, curriculum planning, faculty support, assessment analytics and continuing medical education:

Provided that such use shall not replace hands-on clinical training, bedside teaching, clinical reasoning or ethical judgment.

(*2*) Artificial Intelligence systems may be used to analyse learning outcomes, identify competency gaps and suggest modifications or updates to medical syllabi, curricula and training methods, in alignment with emerging scientific evidence and national health priorities, in such manner as may be prescribed.

Safeguards in medical education.

8. *(1)* Notwithstanding anything contained in this Act, no Artificial Intelligence system shall be used to replace faculty judgment, certify clinical competence autonomously or dilute ethical and clinical training standards.

(2) Any syllabus or curriculum modification suggested with the aid of Artificial Intelligence shall be advisory in nature and shall be implemented only after due human review, expert deliberation and approval by the National Medical Commission or such other competent authority in such manner as may be prescribed.

Permissible use of Artificial Intelligence system in clinical research.

9. *(1)* Any Artificial Intelligence system may be utilized to assist in drug discovery, molecule screening, protocol design, patient recruitment support, safety signal detection and data analysis in clinical trials, subject to compliance with any applicable law for the time being in force or ethical guidelines and regulatory approvals, as may be prescribed:

Provided that all decisions relating to clinical trials shall remain under the control and responsibility of qualified investigators and such ethics committees, as may be appointed or constituted by the Central Government.

(2) No Artificial Intelligence system shall independently determine trial participation, dose escalation, adverse event management or trial termination.

(3) The use of any Artificial Intelligence system in clinical trials shall be transparent, auditable and subject to continuous oversight to prevent bias, unsafe experimentation or violation of participant rights, in such manner as may be prescribed.

Safety, validation and monitoring.

10. Every Artificial Intelligence system covered under this Act shall undergo scientific validation in clinical, research or educational settings of the country and shall be subject to continuous post-deployment monitoring, bias assessment and performance review, in such manner as may be prescribed.

Informed consent.

11. Explicit, informed and Artificial Intelligence-specific consent shall be mandatory for the use of any Artificial Intelligence system involving identifiable human health, clinical trial or educational data, in such manner as may be prescribed:

Provided that refusal to provide such content shall not, in any circumstance, result in denial of healthcare services or educational opportunities.

Data governance.

12. The collection, storage, processing and sharing of data by means of any Artificial Intelligence system shall be limited to necessity, and any unauthorised re-identification, profiling or secondary use of such data without consent shall be prohibited.

Establishment of National Authority for Artificial Intelligence in Human Health and Medical Education.

13. ***(1)*** **The Central Government shall, by notification in the Official Gazette, establish an authority, to be known as the National Authority for Artificial Intelligence in Human Health and Medical Education, consisting of a Chairperson and such number of other Members to assist it in performing any of the functions under this Act.**

(2) **The Authority shall be a body corporate by the name aforesaid, having perpetual succession and a common seal, with power to acquire, hold and dispose of property, both movable and immovable, and to contract, and shall, by the said name, sue and be sued.**

(3) **The head office of the Authority shall be at New Delhi and it may with the prior approval of the Central Government, establish offices at other places in the country as it may deem necessary for carrying out the purposes of this Act.**

(4) The Authority shall have the power to regulate its own procedure.

(5) **The Central Government may prescribe the following, namely:-**

(a) **appointment of the Chairperson;**

(b) **composition and qualification for appointment of Members;**

(c) **salary, allowances payable to Chairperson and Members and their term of office;**

(d) **disqualification for appointment and continuation as Chairperson and Members;**

(e) **resignation by Members and filling of vacancy;**

(f) **proceedings of the Authority;**

(g) **officers and employees of the Authority;**

(h) **powers to be exercised by the Chairperson; and**

***(i)* any other matter to further the objectives of this Act.**

Powers and functions of the Authority.

14. The Authority shall be the central regulatory, supervisory and enforcement body for Artificial Intelligence systems governed under this Act and shall exercise the following powers and functions:-

(a) to register, scrutinise and approve Artificial Intelligence systems intended for development, deployment, import, sale or use in human health, clinical research and medical education, in such manner as may be prescribed;

(b) to classify Artificial Intelligence systems**,** including identification and designation of high-risk Artificial Intelligence systems**,** based on potential harm, complexity, autonomy and impact on human safety, ethics or rights;

(c) to recommend to the Central Government regarding the conditions, limitations or safeguards that may be prescribed for approval, deployment or continued operation of Artificial Intelligence systems;

(d) to formulate technical, ethical, clinical and educational standards for the safe, transparent and accountable use of Artificial Intelligence systems;

(e) to require pre-deployment scientific validation of Artificial Intelligence systems in the clinical, research or educational settings of the country;

(f) to mandate and oversee continuous post-deployment monitoring, performance review and bias assessment;

(g) to order suspension, modification, recall or withdrawal of Artificial Intelligence systems found to be unsafe, unethical, misleading or non-compliant.

(h) to investigate complaints, incidents, adverse events or whistle-blower disclosures relating to Artificial Intelligence systems.

(i) to impose penalties for minor, serious or grave violations in accordance with section 15 of the Act;

***(j)* to establish and maintain a national registry of approved Artificial Intelligence systems**, **including their risk classification and permitted uses;**

(k) to administer and manage the Artificial Intelligence Harm Compensation Fund established under section 17;

(l) to advise the Central Government on policy, legislative and regulatory measures relating to Artificial Intelligence in health and medical education; and

(m) to perform such other functions, as may be prescribed.

Penalties.

15. *(1)* Any person who contravenes or violates any provision of this Act shall be guilty of an offence and shall be liable for a fine of upto rupees ten lakh which may extend upto rupees five crore for violations of grave nature.

(2) Whoever, causes death either directly or indirectly due to violation of any provisions of this Act shall be liable for imprisonment for a term which may extend up to seven years or a fine up to rupees ten crore or both.

Offences by companies.

16. *(1)* Where an offence under this Act has been committed by a company, every person who at the time the offence was committed, was in charge of and was responsible to the company for the conduct of the business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section *(1)*, where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation. — For the purposes of this section-

(a) "company" means a body corporate, and includes a firm or other association of individuals; and

(b) "director" in relation to a firm means a partner in the firm.

Establishment of Artificial Intelligence Harm Compensation Fund.

17. ***(1)*** **The Central Government shall, by notification in the Official Gazette, establish a fund to be called the Artificial Intelligence Harm Compensation Fund.**

(2) **The Fund shall be credited with—**

(a) **such sums as may be provided by the Central Government;**

(b) **contributions, fees, or levies imposed on developers, deployers, or operators of Artificial Intelligence systems, in such manner as may be prescribed;**

(c) **penalties recovered under this Act; and**

(d) **any other source as may be prescribed by the Central Government.**

(3) **The Fund shall be administered by the Authority, subject to rules made by the Central Government in this behalf.**

(4) **Every victim of harm caused by use of Artificial Intelligence systems shall be entitled to receive compensation from the Fund, in such manner as may be prescribed.**

Whistleblower protection.

18. No person who, in good faith, reports or discloses any violation of the provisions of this Act, shall suffer retaliation, discrimination, or adverse action of any kind; and such person shall be entitled to protection in such manner as may be prescribed.

Power to make rules.

19. *(1)* The Central Government may, by notification in the Official Gazette, make rules to carry out the provisions of this Act.

(2) Every rule made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both the Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

Overriding effect.

20. The provisions of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force.

Central Government to provide funds.

21. The Central Government shall, after due appropriation made by Parliament by law in this behalf, pay to the Authority, by way of grants such sums of money as the Central Government may think fit for carrying out the purposes of this Act.

Accounts and audit.

22. *(1)* The Authority shall maintain proper accounts and other relevant records and prepare an annual statement of accounts in such form as may be prescribed by the Central Government in consultation with the Comptroller and Auditor-General of India.

(2) The accounts of the Authority shall be audited by the Comptroller and Auditor-General at such intervals as may be specified by him and any expenditure incurred in connection with such audit shall be payable by the Authority to the Comptroller and Auditor-General.

(3) The Comptroller and Auditor-General and any person appointed by him in connection with the audit of the accounts of the Authority under this Act shall have the same rights and privileges and the authority in connection with such audit as the Comptroller and Auditor-General generally has in connection with the audit of Government accounts and, in particular, shall have the right to demand the production of books, accounts, connected vouchers and other documents and papers and to inspect any of the offices of the Authority;

(4) The accounts of the Authority, as certified by the Comptroller and Auditor-General or any other person appointed by him in this behalf, together with the audit report thereon shall be forwarded annually to the Central Government by the Authority.

Annual Report.

23 The Authority shall prepare, in such form and at such time, for each financial year, as may be prescribed, its annual report, giving a full account of its activities during the previous financial year and forward a copy thereof to the Central Government.

Annual report and audit report to be laid before Parliament.

24. The Central Government shall cause the annual report together with a memorandum of action taken on the recommendations contained therein, in so far as they relate to the Central Government, and the reasons for the non-acceptance, if any, of any of such recommendations and the audit report to be laid as soon as may be after the reports are received, before each House of Parliament.

Power to remove difficulties.

25. If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions, not inconsistent with the provisions of this Act, as appear to it to be necessary or expedient for removing the difficulty.

STATEMENT OF OBJECTS AND REASONS

Artificial Intelligence has emerged as a transformative scientific tool with significant potential to enhance diagnostic accuracy, treatment planning, prescription safety, patient monitoring, public health surveillance, clinical research, drug development and the quality of medical education. Government and private hospitals, research institutions and medical colleges across India are increasingly adopting AI-based systems to support clinical decision-making, optimise healthcare delivery, conduct clinical audits, improve prescription safety and strengthen teaching–learning processes. At the same time, it is now well recognised that the application of Artificial Intelligence in human health, clinical trials and medical education is fundamentally different from its use in other sectors, as it directly affects human life, bodily integrity, mental health, dignity, autonomy, research ethics and professional medical judgment. Errors, bias, opacity, lack of validation or excessive reliance on automated systems may result in serious patient harm, misdiagnosis, unsafe prescriptions, unethical experimentation, erosion of clinical reasoning, dilution of professional accountability and long-term risks to public trust in the healthcare system.

The Indian Council of Medical Research (ICMR), as the apex body for biomedical research in the country, has issued detailed ethical and scientific guidance emphasising that Artificial Intelligence in healthcare and clinical research must adhere to the highest standards of safety, validation, transparency, accountability, data protection and human oversight, and must function strictly as a supportive tool rather than a substitute for human clinical judgment. Similarly, the National Medical Commission is mandated to ensure that medical education in India produces doctors who are clinically competent, ethically grounded and professionally accountable, which requires that Artificial Intelligence be used in medical education only in a supervised, supplementary and disciplined manner, without replacing hands-on training, ethical reasoning or faculty judgment.

At present, however, India lacks a comprehensive statutory framework specifically governing the use of Artificial Intelligence in human health, clinical trials and medical education. Existing laws relating to information technology, data protection, drugs, clinical research or professional regulation are fragmented and do not adequately address the unique scientific, ethical, safety and liability issues posed by AI systems that influence diagnosis, prescriptions, treatment decisions, clinical trials or medical training. Ethical guidelines, though valuable, remain advisory in nature and do not provide enforceable safeguards, accountability mechanisms or effective remedies for harm.

This Bill seeks to fill this critical regulatory gap by establishing a balanced, science-based and patient-centric statutory framework for the use of Artificial Intelligence in human health, clinical research and medical education. The Bill aims to—

(a) enable the responsible use of Artificial Intelligence by Government and private hospitals, research institutions and medical colleges to enhance patient care, prescription safety, clinical research and medical education;

(b) mandate strict human-in-the-loop oversight, ensuring that final authority and accountability for diagnosis, prescription, treatment decisions, clinical trial conduct and educational certification always rest with qualified medical professionals and educators;

(c) ensure patient safety and risk minimization through scientific validation, bias assessment, transparency, continuous monitoring and post-deployment surveillance of Artificial Intelligence systems;

(d) protect patient autonomy, dignity and data privacy, including mandatory informed consent for the use of Artificial Intelligence involving human health, clinical trial or educational data;

(e) safeguard the integrity of medical education by preventing the replacement of clinical reasoning, hands-on training and ethical judgment with

automated systems, while permitting advisory use of Artificial Intelligence for curriculum and syllabus development subject to statutory approval;

(f) provide a regulated framework for the use of Artificial Intelligence in drug discovery and clinical trials, including protocol design support, safety monitoring and data analysis, subject to human oversight, ethics committee approval and existing clinical trial laws, ensuring that innovation does not compromise participant safety or research ethics;

(g) establish clear accountability and liability, including penalties and compensation mechanisms, for harm caused by misuse, negligence or failure of Artificial Intelligence systems; and

(h) create a statutory regulatory authority to oversee registration, approval, audit and enforcement in respect of Artificial Intelligence systems used in human health, clinical research and medical education.

The Bill does not seek to stifle innovation. On the contrary, it seeks to foster responsible and trustworthy innovation by providing legal certainty, public confidence and robust patient protection, while making it unequivocally clear that human life, dignity, safety, ethics and professional responsibility are paramount and non-negotiable. The enactment of this legislation is therefore considered necessary in the national interest to ensure that Artificial Intelligence strengthens healthcare, clinical research and medical education in India as a scientifically sound and ethically governed aid, and not as an unregulated force capable of causing unintended harm to patients, students and society at large.

Hence, this Bill.

AJEET MADHAVRAO GOPCHADE.

FINANCIAL MEMORANDUM

Clause 13 of the Bill provides for the establishment of a National Authority for Artificial Intelligence in Human Health and Medical Education and appointment of Chairperson, Members and staff for its efficient discharge of functions. Clause 14, sub-clause *(k)* provides for establishment and maintenance of a national registry of approved artificial Intelligence systems. Clause 17 provides for establishment of an Artificial Intelligence Harm Compensation Fund. Clause 21 provides that the Central Government shall provide adequate funds to the Authority for carry out the purposes of this Act.

This Bill, therefore, if enacted would involve recurring and non-recurring expenditure from the Consolidated Fund of India. However, at this juncture, it is difficult to estimate the actual expenditure likely to be involved.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 19 of the Bill empowers the Central Government to make rules for carrying out the provisions of the Act. Clause 25 empowers the Central Government to make such provisions through an order for removing any difficulty that might arise in giving effect to the provisions of the Bill.

As the rules will relate to matters of procedural and administrative detail only, the delegation of legislative power is of a normal character.

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to provide for a comprehensive, scientific and patient-centric statutory framework for the ethical, safe and disciplined use of Artificial Intelligence in human health, clinical research and medical education; to enable Government and private hospitals, research institutions and medical colleges to utilize Artificial Intelligence to enhance patient care, prescription safety, clinical trials, drug discovery and medical education under strict human oversight; to ensure patient safety, data protection, accountability and transparency; to establish a statutory regulatory authority for the purpose and for matters connected therewith or incidental thereto.

(Dr. Ajeet Madhavrao Gopchade, M.P.)