

	THE HEALTH TECHNOLOGY ASSESSMENT BOARD BILL (2019)	
	A	
	BILL	
	<i>to provide for the constitution of a Board for providing evidences related to cost-effectiveness, clinical-effectiveness and safety of medicines, devices, vaccines and health programmes by means of Health Technology Assessment (HTA) studies for decision making. It will evaluate affordability, appropriateness and cost effectiveness of the available and new health technologies in India. It will work on the objectives of maximizing health, reducing out of pocket expenditure and reducing inequality so that maximum people can have access to quality healthcare at minimum cost in the country.</i>	
	Be it enacted by Parliament in the Seventieth Year of the Republic of India as follows:-	
	CHAPTER I PRELIMINARY	
	1. (1) This Bill may be called the Health Technology Assessment Board Bill ,2019	Short title, extent and commencement.
	(2) It extends to the whole of India	
	(3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.	
	2. In this Bill, unless the context otherwise requires,—	Definitions.
	(a) "Board" means the Health Technology Assessment Board constituted under sub-section (1) of section 3;	
	(b) "Chairperson" means the Chairperson of the Board;	
	(c) "Fund" means the Fund for Health Technology Assessment constituted under sub-section (1) of section 10;	
	(d) "Health Technology or Health Intervention" means as application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives. This includes pharmaceuticals, devices, procedures, and organizational systems used in the	

	healthcare system, as well as computer-supported information systems.	
	(e)“Health Technology Assessment” (HTA): means a multidisciplinary process that gathers policy relevant evidence about the medical (clinical effectiveness), economic (cost effectiveness), social and ethical issues related to the use of a health technology in a systematic, inclusive, transparent and robust manner to assist policy makers in decision making while formulating policies for incorporating or excluding health interventions from the health system.	
	(f) "member" means a member of the Board and includes the Chairperson;	
	(g) “notification” means a notification published in the Official Gazette;	
	(h) "prescribed" means prescribed by rules made under this Bill;	
	(i) “regulation” means regulations made by the Board under this Bill;	
	(j) "Secretary" means the Secretary of the Board appointed under sub-section (1) of section 4	
	(k) “Technical Appraisal Committee" means the Committee of Experts constituted under sub-section (1) of section 5	
	CHAPTER II HEALTH TECHNOLOGY ASSESSMENT BOARD	
	3. On and from the date of commencement of this Bill,—	
	(1) The Central Government shall, by notification in the Official Gazette, constitute, for the purposes of this Bill, a Board to be called the Health Technology Assessment Board.	Constitution and Incorporation of the Board
	(2) The Board shall be a body corporate by the name aforesaid having perpetual succession and a common seal with power, subject to the provisions of this Bill, to contract and shall, by the said name, sue and be sued.	
	(3) The Board shall consist of the following persons, namely: (a) Member,Health,NITIAayog, <i>ex officio</i> -Chairperson (b) Secretary to the Government of India in the Department of	

	<p>Health Research, <i>ex officio</i>- Vice Chairperson;</p> <p>(c) Secretary, Ministry of Health and Family Welfare, <i>ex officio</i>-Member;</p> <p>(d) Secretary to the Government of India in the Ministry of Ayush, <i>ex officio</i>-Member;</p> <p>(e) Secretary to the Government of India in the Department of Biotechnology, <i>ex officio</i>-Member;</p> <p>(f) Secretary to the Government of India in the Department of Scientific and Technology, <i>ex officio</i>-Member;</p> <p>(g) Secretary to the Government of India in the Ministry of Chemicals and pharmaceuticals, <i>ex officio</i>-Member;</p> <p>(h) Secretary, Ministry of Micro, Small and Medium enterprises <i>ex officio</i>-Member;</p> <p>(i) Director General of Health Services, <i>ex officio</i>-Member;</p> <p>(j) AS and FA, Ministry of Health and Family Welfare, <i>ex officio</i>-Member;</p> <p>(k) not more than five senior members to be appointed by the Central Government from amongst persons having experience in scientific research related to Health Technology Assessment in government research/academic institutions</p> <p>(l) not more than 2 Principal Health Secretaries from Ministry of Health and Family Welfare from State/Union Territories on rotation, <i>ex officio</i>, Member;</p> <p>(m) Secretary of the Secretariat, Member</p> <p>(n) Joint Secretary from Department of Health Research Dealing with Health Technology Assessment as, Member Secretary</p>	
	<p>(4) The Head Office of the Board shall be at Department of Health Research, Delhi</p>	
	<p>(5) The qualifications and experience, term of office and allowances of the members specified in clauses (h) of sub-section (3) shall be for a period of 5 years and as may be prescribed</p>	

	(6)The Chairperson shall,in addition to presiding over the meetings exercise and discharge such powers and duties, as may be prescribed or delegated to him by the Board.	
	(7) The meetings will be conducted by the Chairperson and in his/her absence by the Vice Chairperson	
	(8) No act or proceeding of the Board shall be invalidated merely by reason of (a) any vacancy in, or any defect in the constitution of the Board; (b) any defect in the appointment of a person acting as a member of the Board; (c) any irregularity in the procedure of the Board not affecting the merits of the case.	
	4.(1) The Board may appoint an officer not below the rank of Joint Secretary as Secretary of the Secretariat, in consultation with the Central Government	Secretary of Secretariat
	(2) The Board may appoint such other Scientists, Economists, officers and employees as it considers necessary for the efficient discharge of its functions under this Bill.	Secretariat Officers
	(3) The qualifications and experience, terms and conditions of service including salary and allowances of the Secretariat and other officers and employees of the Board shall be such as may be specified in the regulations made by the Board.	
	(4) The Board may engage the services of Research Institutes, Medical Colleges,visiting scientists on such terms and conditions and remunerations as may be specified in the regulations made by the Board and shall facilitate their operations within the country.	
	5.(1) Subject to the rules made in this behalf, the Board shall constitute one or more Technical Appraisal Committee of Experts consisting of experts, eminent scientists and academics to submit scientific evidence based HTA reports to the Board.	Committees of Board.
	(2) The Committee shall consist of the following persons, namely:	
	(i) a scientist of eminence and repute to be appointed by the Board as-Chairperson;	

	(ii) not more than ten members to be appointed by the Board from amongst distinguished experts in different areas of Research related to Health Technology Assessment, as members	
	(iii) the period of appointment will be for three years or as decided by the Board and deliberation of duties will be as prescribed	
	6.(1) Subject to the rules made in this behalf, the Board may appoint other committees as may be necessary for the efficient discharge of its duties and performance of its functions under this Bill.	
	(2) The Board shall have the power to co-opt as members of any committee appointed under sub-section (1), such number of persons who are not members of the Board as it may think fit, and the person so co-opted shall have the right to attend the meetings of the committee, and take part in the proceedings of the committee.	
	7(1) The Board will be a National Advisory Body for providing robust evidence for decision making on (i)Health Technologies and Interventions (ii)Clinical ,public health, social care guidelines (iii)Quality evaluation in health and Social sector for implementation in public health and social care sectors in Central and State Governments	Powers and Functions of the Board
	(2) The powers and functions of the Board shall, <i>inter alia</i> , include (i) considering and ratifying the recommendations and suggestions made by the Technical Appraisal Committee;	
	(ii) identifying major inter-disciplinary research areas for undertaking research;	
	(iii) evolving nationally coordinated programmes in various identified areas for promoting evidence based research;	
	(iv) provide the overall direction/ guidance in using evidence	

	for healthcare in improving the quality and standard of public health care deliveries	
	(v) achieving synergy between State Government/Union Territories, Central Government research and development laboratories and industry for promoting real world evidence to support public health care funding	
	(vi) evolving a management system to speedily monitor and evaluate new and cost effective technologies in Health Care models	
	(vii) evolving participation in international collaborative projects, wherever necessary or desirable; and	
	(viii) any other role as may be prescribed	
	(3) The Board may provide financial assistance for the purposes specified in sub section (1) and (2), in the form of grants and loans to individuals, academic institutions, research and development laboratories and other organisations for research related activities for evidence based decision making for the health care development	
	CHAPTER III APPLICATION FOR SANCTION OF FINANCIAL ASSISTANCE	
	8.(1) An application for availing of financial assistance for the purposes specified in section 7 shall be made to the Board in such form as may be prescribed.	
	(2) The Board may through the committees, examine the application and after making such enquiries or seeking such clarifications as it considers necessary, by order in writing, either sanction the financial assistance or refuse the same.	
	CHAPTER IV FINANCE, ACCOUNTS AND AUDIT	
	9. The Central Government may, after due appropriation made by Parliament by law, in this behalf, make to the Board grants and loans of such sums of money as that Government may consider necessary.	Grants and loans by Central Government clinics.
	10. (1) There shall be constituted a Fund to be called the Fund for Health Technology Assessment and there shall be credited to the Fund	Fund for Health Technology Assessment

	(a) any grants and loans made to the Board by the Central Government under section 9;	
	(b) all sums received by the Board including donations from any other source;	
	(c) recoveries made of the amounts granted from the Fund; and	
	(d) any income from investment of the amount of the Fund.	
	(2) The Fund shall be applied for meeting	
	(a) expenses on the object and for the purposes authorised by this Bill;	
	(b) salaries, allowances and other expenses of the members, officers and other employees of the Board, Committees and Secretariat	
	(c) remunerations of the consultants and visiting scientists; and	
	(d) expenses of the Board in the discharge of its functions under this Bill.	
	11. The Board with the Support of Secretariat shall prepare, in such form and at such time in each financial year, as may be prescribed, its budget for the next financial year, showing the estimated receipts and expenditure of the Board and forward the same to the Central Government.	Budget
	12. The Board with the support of Secretariat shall prepare, in such form and at such time in each financial year, as may be prescribed, its annual report, giving a full account of its activities during the previous report financial year, and submit a copy thereof to the Central Government.	Annual Report.
	13. (1) The Secretariat shall maintain proper accounts and other relevant records and Accounts and prepare an annual statement of accounts in such form as may be prescribed by the Central audit, Government in consultation with the Comptroller and Auditor-General of India.	
	(2) The Comptroller and Auditor-General of India or any other person appointed by him in connection with the auditing of the accounts of the Board under this Bill shall have the same rights and privileges and the authority in connection with such audit as the Comptroller and Auditor-General of India has in connection with the auditing of the 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 office of the Board under this Bill.	
	(3) The accounts of the Board shall be audited by the Comptroller and Auditor General of India annually and any expenditure incurred in connection with such audit shall be payable by the Board to the Comptroller and Auditor-General.	
	(4) The Board shall furnish to the Central Government, before such date as may be prescribed, its audited copy of accounts together with auditor's report.	
	14. The Central Government shall cause the annual report and auditor's report to be laid, as soon as may be after they are received, before each House of Parliament.	Annual report and auditor's report to be laid before Parliament
	CHAPTER V MISCELLANEOUS	
	15. (1) Any institution as mentioned in Section 8 receiving financial assistance from the Board shall furnish return to the Board/Secretariat in such form and at such time as may be specified by regulations.	Returns to be furnished to Board
	(2) The Board may authorise an officer to visit any institution referred to in sub-section (1) of Section 8 at any time to verify the accuracy of any return made under this section.	
	16. (1) Without prejudice to the foregoing provisions of this Bill, the Board shall, in the discharge of its functions and duties under this Bill, be bound by such directions on questions of policy as the Central Government may give in writing to it from time to time:	Power of Central Government to issue directions
	Provided that the Board shall, as far as practicable, be given an opportunity to express its views before any direction is given under this sub-section.	
	17. (1) If at any time the Central Government is of the opinion (a) that on account of grave emergency, the Board is unable to discharge the functions and the duties imposed on it by or under the provisions of this Bill;	Power of central government to supersede Board

	(b) that circumstances exist which render it necessary in the public interest so to do, the Central Government may, by notification in the Official Gazette, supersede the Board for such period, not exceeding six months, as may be specified in the notification.	
	(2) Upon the publication of a notification under sub-section (1) superseding the Board - (a) all the members shall, as from the date of supersession, vacate their offices as such;	
	(b) all the powers, functions and duties which may, by or under the provisions of this Bill, be exercised or discharged by or on behalf of the Board shall, until the Board is reconstituted under sub-section (3), be exercised and discharged by such person or persons as the Central Government may direct; and	
	(c) all property owned or controlled by the Board shall, until the Board is reconstituted under sub-section (3), vest in the Central Government.	
	(3) On the expiration of the period of supersession specified in the notification issued under sub-section (1), the Central Government may reconstitute the Board by a fresh appointment and in such case any person or persons who vacated their offices under clause (a) of sub-section (2), shall not be deemed to be disqualified for appointment:	
	Provided that the Central Government may, at any time, before the expiration of the period of supersession, take action under this sub-section.	
	4) The Central Government shall cause a notification issued under sub-section (1) and a full report of any action taken under this section and the circumstances leading to such action to be laid before each House of Parliament at the earliest.	
	18. The Board may, by general or special order in writing, delegate to the Chairperson or any other member or to any officer of the Board subject to such conditions and limitations, if any, as may be specified in the order, such of its powers and functions under this Bill (except the power under section 21) as it may deem necessary.	Delegation.

	19. No prosecution or other legal proceeding shall lie against the Central Government or the Board or any committee appointed by it or any member of the Board or such committee, or any officer or employee of the Government or the Board or any other person authorised by the Central Government or the Board for anything which is in good faith done or intended to be done under this Bill or the rules or regulations made thereunder.	Protection of Action taken in full faith
	20. (1) The Central Government may, by notification in the Official Gazette, make rules Central to carry out the provisions of this Bill.	Government to make rules.
	(2) Without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely: (a) the qualifications and experience, term of office and other allowances of the members of the Board, under sub-section (5) of section 3;	
	(b) the powers and duties of the Chairperson under sub-section (6) of section 3;	
	(c) the constitution of Technical Appraisal Committee under section 5	
	(d) the qualifications and experience, term of office and other allowances of the members of the Technical Appraisal Committee, under sub-section (2) of section 5;	
	(e) the constitution of committees under sub-section (1) of section 6;	
	(f) any other role for the Board under Clause (viii) sub section (2) of Section 7	
	(g) the form of application under sub-section (1) of section 8;	
	(h) the form in which, and the time at which the Board shall prepare its budget under section 11 and its annual report under section 12;	
	(i) the form of annual statement of accounts under sub-section (1) of section 13 and the date before which audited copy of the accounts may be furnished to the Central Government under	

	sub-section (1) of that section;	
	(j) any other matter which is to be or may be prescribed or in respect of which provision is to be, or may be made by rules.	
	21. (1) The Board may, with the previous approval of the Central Government, by Power of notification in the Official Gazette, make regulations consistent with this Bill and the rules Board to generally to carry out the provisions of this Bill.	Provision to make regulations
	(2) In particular, and without prejudice to the generality of the foregoing power, such regulations may provide for all or any of the following matters, namely:-- (a) the qualifications and experience, terms and conditions of service including salaries and allowances of the Secretary and other officers and employees of the Board under sub-section (3) of section 4;	
	(b) the form in which and the time at which the returns may be furnished to the Board under sub-section (1) of section 15.	
	22. Every rule and every regulation made under this Bill shall be laid, as soon as may Rules and 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 regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation 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 or regulation.	Rules and Regulations to be laid in the Parliament