

Proprietary and Confidential

INDIAN MEDICAL ASSOCIATION

and

NATHEALTH
Healthcare Federation of India

Code of Ethics for Healthcare

Declaration

We, the members of IMA and NATHEALTH and signatories to the Code of Ethics for Healthcare, do hereby solemnly declare that we have read and understood the Code of Ethics and shall abide by it to maintain ethical and transparent professional conduct and practices to ensure improved access to and better quality of the healthcare ecosystem in India.

- (i) A voluntary and collective commitment to follow ethical practices to ensure that patients are provided access to high quality, cost effective, safe and efficient technologies, products and services.
- (ii) Comply with all applicable laws and members' internal policies on the subject and create a mechanism to address violations appropriately.
- (iii) Recognize and champion the sanctity of patient confidentiality.
- (iv) Maintain accurate and complete records and ensure their safety and access.
- (v) Refrain from offering or accepting any payments/gifts with the objective of influencing a decision making process within the healthcare community.
- (vi) Desist from engaging in any activity, practice or act which conflicts with, or appears to conflict with the interests of the healthcare community, end users or patients.
- (vii) Maintain a safe and healthy work environment.
- (viii) Provide donations only for charitable purposes and not with the intent to influence the healthcare community to purchase, lease or recommend the use of specific products and services or treatment modalities.
- (ix) Meet all applicable quality standards and accreditations as may be required to provide the appropriate delivery of healthcare services.
- (x) Undertake appropriate dissemination of the Code for full applicability and accountability.

Section I

The Preamble

"The practice of medicine is not a business and can never be one...our fellow creatures cannot be dealt with as a man deals in corn and coal; the human heart by which we live must control our professional relations."

- Sir William Osler

- (i) The fundamental objective of the medical profession is to maintain the trust reposed by individuals and enhance the overall quality of life, dignity and wellbeing of every individual requiring healthcare services; and to create a more equitable, accessible, affordable, effective and efficient healthcare system. To meet this objective, it is the duty of every Healthcare Professionals (as defined hereafter) to act in the best interest of patients by maintaining high ethical standards, observing transparency in their interactions within the medical fraternity as well as with patients and conducting themselves within the parameters prescribed under law.
- (ii) The Indian Medical Association (IMA) and NATHEALTH are dedicated to the advancement of medical science leading to the improvement of patient care and are committed; not only to provide patients with high quality healthcare technologies and services, but also to provide such technologies and services faster, better, easier and in compliance with the highest ethical and legal standards.
- (iii) The IMA and NATHEALTH They represent, *amongst others*, medical professionals and caregivers, Healthcare Institutions, Medical Device Companies, Diagnostic Centres and Healthcare Insurers (as defined hereafter).
- (iv) The Members of IMA and NATHEALTH (as defined hereafter) believe that healthcare related decisions should be taken keeping in mind the welfare and wellbeing of patients. Regulatory bodies across the world have become increasingly stringent in the enforcement of laws and regulations governing the interactions of Healthcare Professionals to ensure that medical decisions and outcomes are based keeping in mind the best interest of the patient(s). The Members recognize their obligation to facilitate the highest standards of integrity and ethical standards in interactions of Healthcare Professionals.
- (v) Towards this end, the Members adopt this voluntary Code of Ethics for Healthcare (the "**Code**"), which represents their collective commitment to follow ethical and appropriate practices in their day to day interactions within the healthcare community as well as with patients/ end users, leading to increased transparency, reduced cost and improved quality of healthcare for the Indian patient.
- (vi) This Code is intended to provide Members with guidelines for professional conduct that fulfils this commitment. Members must use the Code as a yardstick for their

own conduct and behaviour. Adherence to the Code will enable society to have greater trust and confidence in the medical profession.

- (vii) The Code is supplementary to the mission and vision of IMA and NATHEALTH. In the event of any questions regarding this Code, please feel free to reach out to Padma Shri awardee Dr. K.K Aggarwal, Honorary Secretary General, IMA or Mr. Anjan Bose, Secretary General, NATHEALTH at the following website <http://www.ima-india.org/ima/> and www.nathealthindia.org respectively.

Section II

A. Applicability & Scope:

1. This Code applies to all the Members who are signatories to this Code as on the Effective Date (“**Original Signatories**”) and have taken a voluntary step to monitor their conduct and actions in the provision of healthcare technology, medical care and services in India. The Code is open for ratification by other entity(ies), who upon such ratification shall become signatories to the Code for the purposes of this Code and its application thereof.
2. This Code shall apply to the Members within the territory of the Republic of India.
3. The Code is intended to provide guidance to the Members as regards their conduct and interactions inter se, with patients/ end users, and with Third Parties (as defined hereafter) so as to ensure that their daily activities, efforts and interactions are undertaken in an ethical, honest manner within the parameters of Law for the advancement of healthcare and improved patient care in India.
4. This Code shall be supplement to a Member’s existing Internal Code (as defined hereafter). A Member may consider amending such Internal Code to be in consonance with this Code.

B. Effective Date:

The Code shall come into effect on and from { ____ 2016_5}.

C. Definitions:

- ~~1. “Code Monitoring Committee” shall mean a committee comprising of 3(three) members, nominated by the Governing Council and representing the Members on a six (6) monthly/annual rotational basis as may be agreed upon by the Governing Council;~~

~~2.1.~~ **“Diagnostic Centres”** shall mean and include centres both Government and in the private sector which are equipped to conduct and provide a broad range of tests that are essential to the management of patient care ~~and which, allowing~~ physicians to detect disease earlier, make diagnoses, prescribe therapies and monitor patient results;

~~3.2.~~ **“Governmental Authority”** shall mean any statutory authority, government department, agency, commission, board, tribunal, court or other entity set up by an Act of Parliament or a State Legislature or established by the Government;

~~4.3.~~ **“Healthcare Institutions”** shall mean hospitals, clinics and those healthcare outfits, both Government and in the private sector, that provide health care and related services, including but not limited to the provision of inpatient and outpatient care, diagnostic or therapeutic services, laboratory services and nursing care;

~~5.4.~~ **“Healthcare Insurers”** shall mean and include an Insurer (as defined under section 2(9) of the Insurance Act, 1938, as amended from time to time) carrying on health insurance business in India under applicable Law(s);

~~5.~~ **“Healthcare Professionals”** shall mean and collectively include entities both Government and in the private sector such as Healthcare Institutions, Diagnostic Centres, Healthcare Insurers, Medical Device Companies, Third Parties and other entities; and medical professionals and caregivers that are engaged in the provision of medical care, healthcare products and/or services to patients/end users.

~~6.~~ **“IMA Code Monitoring Committee”** shall mean a committee set up by IMA as it deems appropriate for the purposes of monitoring the Code in a fair and transparent manner;

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7. **“Internal Code”** shall mean the existing internal policy(ies), code of conduct(s), and related procedures of each Member, as amended from time to time;

8. **“Law(s)”** shall include all applicable statutes, enactments, acts of legislature or Parliament, laws, ordinances, rules, by-laws, regulations, notifications, guidelines, policies, directions, directives and orders of any Governmental Authority and amendments thereto, as may be applicable;

9. **“Medical Device Companies”** shall mean and include companies or entities both Government and in the private sector, that design, develop, produce, manufacture, market and distribute medical devices as defined under the Drugs and Cosmetics Act 1940 as amended; medical imaging and diagnostic equipment, technologies and related services; and any other medical devices and related services used to diagnose, treat, monitor, manage and alleviate health conditions

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of patients/ end users to enable them to live longer and healthier lives;

10. "Member(s)" shall mean and include Healthcare Professionals, who are signatories to the Code as on the Effective Date and other entity(ies) who subsequently subscribe and by ratification of the Code become signatory/ies thereto.

~~10.11.~~ "NATHEALTH Code Monitoring Committee" shall mean a committee comprising of three (3) members, nominated by the Governing Council and representing the Members on a six (6) monthly/annual rotational basis as may be agreed upon by the Governing Council for the purposes of monitoring the Code in a fair and transparent manner;

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~~12.4.~~ "Third Party(ies)" shall mean and include independent contractors, vendors, consultants, TPAs and the like for the purposes of its application thereof.

D. Applicable Laws and Regulations:

1. This Code is not intended to supplant or supersede any applicable Law/s or professional codes of conduct including the Internal Code(s) to which a Member may be subject to and which may impose particular requirements on such Member.
2. In the event of any conflict between the provisions of this Code and those prescribed under any applicable Law/s, the latter shall prevail.
3. This Code is not intended to define or create legal rights or standards nor should it be construed as legal advice. All Members have an independent obligation to ensure that their interactions at all levels are in compliance with the Laws.
4. In the event of any violation of this Code the standards mandated by the Laws shall be applied to corroborate such violation.

E. Amendments:

1. This Code may be amended or modified, including for purposes of accommodating other classes of Healthcare Professionals, as and when such persons intend to be signatories to this Code, provided however that any amendment, variation or modification to the Code should be in writing and duly signed by a majority of the persons comprising the Code Monitoring Committee.
2. Any and all references to this Code shall include any amendments or modifications to the Code carried out in accordance with the immediately preceding clause.

F. General Principles:

The following general principles shall apply to and govern the conduct and interactions of Member(s) with one another and with Healthcare Professionals, as applicable:

1. Ethical Professional Practices

- (i) Members should be committed to the delivery of high quality, cost effective, safe, efficient, compassionate and satisfying technologies, other healthcare products and services to improve patient care in India. Patient(s)/end user(s) should be treated with warmth, respect and dignity and care should be administered to the extent necessary and appropriate. To this end, each Member(s) shall encourage ethical practices and socially responsible professional conduct.
- (ii) Members shall conduct their respective businesses with honesty, integrity and accountability, within the limits prescribed by Law and shall not participate in or conceal any unethical, fraudulent or deceptive activity.

2. Legal and Regulatory Compliance

Members are subject to numerous Laws pertaining to various aspects of their operations and professional conduct, including but not limited to those which regulate accreditation, licenses, permits, medical ethics, access to treatment, consent to treatment, medical record-keeping, access to medical records and confidentiality and patients' rights. Members shall be and remain fully compliant with all the Law(s).

3. Prohibition of Retaliation

Members shall ensure zero tolerance towards any form of illegal discrimination or retaliation against any person including any Member who, in good faith, reports suspected violations of any Law(s), this Code or any Internal Code. Further, Members shall not discharge, demote, suspend, threaten, harass, or in any manner discriminate against any employee, individual or entity as the case may be because such employee, individual or entity reports or participates in the investigation initiated by any Governmental Authority related to one or more violations of any Law(s), this Code and/or any Internal Code.

4. Conflict of Interest

IMA and NATHEALTH value ethical decision making and trust Members to make choices in the best interests of patient(s) and end user(s). A conflict of interest may be said to exist when the interests of a Member (including financial interests) are in conflict with the interests of patients(s) and end user(s). Members shall therefore desist from engaging in any activity, practice or act which conflicts with, or appears to conflict with the interests of patient(s) and

end user(s). Further, Members shall ensure that their acts and actions are not induced by personal gain or to cause any detriment to patient(s)/end user(s).

5. Gifts, Entertainment and Professional Meetings

- (i) Each Member shall have a policy to clarify its rules and regulations on gifts and entertainment, to be used for the guidance of its employees.
- (ii) Members shall ensure that they refrain from giving, soliciting or receiving and shall not offer to give, solicit or receive money, services, gifts, commission, personal gratuities, other items of value or inducement of any kind to Healthcare Professionals, other Member(s) and/or Third Parties, directly or indirectly, whether or not in consideration for or with the objective of influencing such person's or entity's judgment, recommendation or decision making process against the interests of patient(s) and/or end user(s).
- (iii) Members will not provide any entertainment or recreation in the context of interactions with one another or with Healthcare Professionals in connection with sales, provision of services including any advisory/consulting services and promotional meetings, third-party educational conferences or product training and continued medical education.
- (iv) Members are permitted to give and receive non-monetary gratuities or gifts of a value of upto INR 5000 such as medical books, journals, diaries, pens and the like, to and from Healthcare Professionals, other Members, and/or Third Parties that either benefit patients/end user(s) or serve a genuine educational function for such Healthcare Professional or a Member(s).
- (v) Members may interact and host professional meetings with/for Healthcare Providers other Member(s) and/or Third Parties for discussion on scientific topics, sales and service terms, contracts, patient access to therapies, professional consultation and such like professional activities. Such meetings shall be held at an appropriate location, where (a) the meeting is primarily to promote business, scientific and educational activities and discourse and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. Such meetings shall not be used in any manner whatsoever, by a Member to act with the objective of influencing the judgment, recommendation or decision making process of other Members, Healthcare Professionals and Third Parties to act against the interests of patient/s, end user/s. Members shall refrain from making any payment for meals and refreshments of guests of Healthcare Professionals or any other person who does not have a bona fide professional interest in the information being shared at such professional meeting(s).
- (vi) Members shall maintain record of all costs associated with giving and receiving such gifts and hosting such professional meetings and if required shall disclose the same under any Internal Code or applicable Law(s).

6. Privacy and Confidentiality of Sensitive Information

- (i) Members shall ensure that they maintain strict confidentiality in respect of the professional and/or technical information, protected health information both in print and electronically, including without limitation medical records, patient data, financial data, know-how, trade secrets, plans, reports, pricing information and materials related to professional activities, information relating to existing, previous and potential customers, suppliers, end users and patients, marketing, technology and technical documentation and information, results of research, product or service specifications or strategies, contracts and products, inventions, software applications, design and performance specifications, which are owned, controlled or possessed by each Member and considered confidential and proprietary information ("**Sensitive Information**") in accordance their respective Internal Code(s) and applicable Law(s).
- (ii) Members should take appropriate steps to avoid improper or accidental disclosures of, and unauthorized access to the Sensitive Information including protected health information both in written and/or digital/electronic form unless the same is required by an authorized person or may be required to be disclosed under applicable Law.

7. Accurate and Complete Records and Reports

In the normal course of their professional activity and as may be applicable, Members may create multiple documents, emails, reports, and other records and documentation (collectively the "**Records**"). In this regard, Members must ensure the following:

- (i) provision of full, fair, accurate, complete and timely information to every person in receipt of Records;
- (ii) Records must not provide false, fraudulent, or misleading information; and
- (iii) Appropriate level of privacy/security protection must be accorded to the Records and the same must be protected and maintained in accordance with applicable Laws and the Member's Internal Code.

8. Retention of Documents

In order to satisfy applicable regulatory and legal requirements, it may be necessary for a Member to retain Records for a prescribed period of time, in print and/or in electronic version. Additionally, such applicable requirements may also indicate when the Records should be destroyed and/or handed over to the relevant authority. In this regard, Members shall ensure that the Records are

maintained in a secure and safe environment and in the manner prescribed under applicable Law and Internal Code.

9. Training and Communication about the Code

Members should develop and undertake comprehensive training and education programs to ensure that their employees, directors, agents, contractors, vendors, suppliers, customers and consultants are aware of the Code and accordingly the standards that are applicable to them especially in their responsibilities towards patients and end users.

10. Protection of Intellectual Property

Trademarks, copyrights, patents, trade name, trademarks, trade secrets, know how (collectively "**Intellectual Property**") belonging to a Member(s) is an extremely valuable asset and needs to be properly protected at all times. It is also equally important for Members to ensure that there is no infringement of the Intellectual Property of third parties in violation of any applicable Law(s).

11. Environment, Health & Safety

Members shall be committed to maintaining a safe, clean and healthy environment for Healthcare Professionals, patients/end users and Third Parties as the case may be. Members shall ensure the appropriate disposal of all waste and other materials and store all chemicals and substances in accordance with applicable Laws. In addition to meeting applicable provisions under Law and their respective Internal Code in this regard, the following acts (amongst others) should be strongly discouraged by Members on their premises:

- (i) violence of any kind, including, but not limited to, threats, verbal abuse, bullying, harassment including sexual harassment, and physical attacks;
- (ii) unlawful manufacture, distribution, dispensation, possession or use of any controlled substance or other illegal drugs on the premises of any Member ("**Premises**"), including by an employee thereof while discharging his duties;
- (iii) carrying of any firearms or other weapons on the Premises, including by a Member employee while discharging his duties, except as may be permitted by Law.

12. Inquiries from the Media and the Government

In the normal course of their work, Members may interact with the media and the public. In this regard Members shall ensure that such interactions are conducted by authorized personnel as per Members' internal policies and procedure and applicable Law(s) in this regard. Members shall refrain from citing

Sensitive Information or releasing Records about Healthcare Professionals, patients and end users, or other Members, unless and to the extent required by Law.

13. Competition

Competition is the cornerstone of any country's free-market economy and growth, and Members shall compete in the marketplace without engaging in unfair trade practices that may potentially deprive patients/end users of healthcare choices. A Member shall market its products and services on their own merits and shall not make unfair and misleading statements about competitors' products and services. Members must conduct their professional affairs in accordance with applicable Laws including more specifically the Competition Act, 2002.

14. Fair Professional Transactions

Members shall ensure that professional interactions between Members inter se, with Healthcare Professionals and with Third Parties must be transparent and in compliance with the applicable Laws and their respective Internal Code(s). Members must also ensure that decisions are taken fairly and objectively following established bidding, negotiating and contracting procedures and must not be influenced by any subjective considerations.

15. Bribery and Corrupt Practices

(i) Bribery and corrupt practices may potentially erode the integrity of Members and compromise patients' and end users trust, as the burden of such improper payments is ultimately borne by the patient/end user. Members must ensure that they follow ethical practices at all times as required under applicable Law(s) and their respective Internal Code and do not engage in offering/accepting bribes or kickbacks, whether in cash or kind to any person including but not limited to Government officials, Healthcare Professionals, other Members and or Third Parties.

(ii) No financial benefit or benefit-in-kind may be provided or offered (other than legitimate consideration/professional fees) to a Healthcare Professional, to another Member and/or a Third Party in exchange for prescribing, recommending, purchasing, supplying or administering products and/or services or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a Member's professional integrity and autonomy or will compromise patients' and or end users interest in any manner.

16. Charitable Donations

Members may make donations for charitable purposes such as providing funds or products for indigent care, patient education, public education or the sponsorship of events where proceeds are intended for charitable purposes. Donations may be made only to organizations which are involved in such charitable activities. Charitable donations should not be made to induce Healthcare Professionals, other Members and/or Third Parties to purchase, lease, recommend the use of Members' products and services or be linked to the past, present or future recommendation, purchase or lease of Members' products or services. Transparency must be maintained in making charitable donations by documenting in writing the planned use of such donations and the reasons for making such donations, in accordance with applicable Laws and Members' respective Internal Code.

17. Soliciting and Advertising

~~Soliciting of patients directly or indirectly (including through agent(s) is unethical and in violation of applicable Law. More specifically Members shall:~~

~~(i) refrain from using their name in any form or manner for advertising and publicity through any mode (including social media) either alone or in conjunction with others which is of such character as would ordinarily result in benefit to such Member, and~~

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~~(ii) will not lend their name, signature or photograph to endorse or advertise any drug, remedy, articles, apparatus or appliance or commercial product with respect to any property, quality or use thereof or any test, demonstration or trial thereof and the like through any mode except as may be permitted under applicable Law.~~

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~~Soliciting of patients by doctors/medical practitioners directly or indirectly (including through agent(s) is unethical and in violation of applicable Law. Doctors/medical practitioners will not lend their name, signature or photograph to endorse or advertise any drug, remedy, articles, apparatus or appliance or commercial product with respect to any property, quality or use thereof or any test, demonstration or trial thereof and the like through any mode except as may be permitted under applicable Law. Members shall follow prescribed guidelines under applicable law for the purposes of undertaking advertising in any form or manner.~~

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18. Quality Assurance and Accreditations

Members agree to meet all applicable quality standards and accreditations as may be required for the sale of their respective products/services and service delivery. Securing additional voluntary accreditation(s) is a good practice and is encouraged by Members.

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G. Specific Principles:

1. Healthcare Institutions: In addition to the General Principles set out above, Healthcare Institutions should also comply and should encourage their directors, employees, agents, dealers and distributors, contractors, consultants, vendors and suppliers as the case may be comply with the following Specific Principles, as may be applicable:
 - (i) encourage the practice of medicine with honesty, integrity, and accountability;
 - (ii) balance the human and patient-centred values of the health profession with the very real and practical demands of the business aspects of healthcare delivery;
 - (iii) consider the well-being and interest of the patient first;
 - (iv) treat patients with utmost compassion, respect and to the best of their abilities;
 - (v) respect the patient's right to choose their doctor freely, to accept or reject advice and to make their own decisions about treatment or procedures;
 - (vi) to protect the patient's right to give informed consent and to ensure patients are provided with adequate, sufficient and relevant information about the potential outcome of the consequences of their care prior to their giving consent;
 - (vii) continue lifelong self-education to improve the standard of medical care;
 - (viii) should ensure that paramedical services such as, pharmacy and nursing adhere to the principles of duty of care and ensure the well-being of the patient by applying the highest principles of ethical practices;
 - (ix) build a comprehensive system for handling and disposal of hazardous and bio medical waste;
 - (x) maintain accurate contemporaneous clinical records;
 - (xi) ensure that selection of doctors and other health professionals is unbiased, based purely on merit and there is a consistent effort to review the performance of such health professionals with the aim of maintaining the standard of care to patients;
 - (xii) ensure that doctors and other health professionals have the necessary qualifications and continue to do so;
 - (xiii) not discriminate against and refrain from treating a patient without good cause;
 - (xiv) maintain strict confidentiality as regards information pertaining to a patient and ensure security of storage, access and utilization of such patient information;
 - (xv) upon request by a patient, make available to another doctor a report of the findings and treatment;
 - (xvi) recognize that in case of clinical trials, considerations relating to the well-being of individual participants in research take precedence over the interests of science or society;

- (xvii) ensure that all research participants or their agents are fully informed and have consented to participate in a clinical study and refrain from using coercion or unconscionable inducements as a means of obtaining consent;
 - (xviii) with respect to clinical trials, respect the participant's right to withdraw from a study at any time without prejudice to medical treatment;
 - (xix) be cognizant that a patient's decision not to participate in a clinical study should not compromise the doctor-patient relationship or appropriate treatment and care;
 - (xx) recognize a patient's applicable rights and extend physical, psychological, emotional, and spiritual support for the patient, the family and other care givers when they need to exercise such rights;
 - (xxi) remember the obligation to preserve life; but, where death is deemed to be imminent, try to ensure that death occurs with dignity and comfort;
 - (xxii) refrain from practicing euthanasia, which shall constitute unethical conduct and be in violation of applicable Law(s);
 - (xxiii) in case where a patient is declared brain dead, the medical institution/hospital shall follow the law, rules and regulations pertaining to organ transplant, offering the relations of such a patient an option to donate his organs;
 - (xxiv) refrain from using coercion when obtaining consent to any or all organ donations;
 - (xxv) inform a donor and his family fully of the proposal to transplant organs, the purpose and the risks of the procedure and exercise sensitivity and compassion while discussing the option to donate organs;
 - (xxvi) will not differentiate between poor and rich patient as far as medical services are concerned
 - (xxvii) when referring a patient, make available to their colleague, with the patient's knowledge and consent, all relevant information and indicate whether or not they are to assume the continuing care of the patient during their illness;
 - (xxviii) inform and guide patients towards making informed health choices for individuals and society (e.g. lifestyle changes, voluntary blood donation, etc.);
 - (xxix) educate and guide their staff in the safe handling and disposal of all wastes in line with health and safety and infection control requirements;
 - (xxx) make available treatment records of patients to Health Insurers with whom the patient has privity of contract;
 - (xxxi) ensure that patients covered under health insurance are not discriminated on pricing or procedure being advised; and
 - (xxxii) follow the Law(s) relating to any cuts and commissions (fee splitting).
2. Healthcare Insurers: In addition to the General Principle set out above, Healthcare Insurers should also apply and should insist that their directors, employees, agents, dealers and distributors, contractors, consultants, vendors

and suppliers as the case may be comply with the following principles, as may be applicable:

- (i) ensure health insurance benefits, including all medically necessary and emergency care must be available to all enrollees on a timely basis, as per the terms and conditions of the contract;
- (ii) provide accurate and easily accessible information should be provided to patients pertaining to physicians (including hospital based physicians), hospitals and other health care providers which are in-network and accepting new patients;
- (iii) ensure that a decision to cancel a person's coverage must be subject to an independent review. Rescission of coverage should not be permitted for innocent mistakes on applications. Further, they shall not cancel policies of patients who have become severely ill/injured after the policy was issued, provided that there are no non-disclosures at the time of proposal by the person;
- (iv) ensure that any claim should not be denied on the grounds that it is not a medical necessity, except by a physician qualified by education, training and expertise to evaluate specific clinical issues;
- (v) ensure that claims should be paid accurately and in a timely manner, and clear and comprehensive explanation of how each claim was handled, including the specific reason for any denial or deduction in payment should be provided;
- (vi) protect the confidentiality of each enrollee's medical information; and
- (vii) ensure clear information as regards benefit restrictions etc., be readily available to patients in a timely manner and Health Insurers must eliminate complexity and confusion from their processes and communication.
- (viii) Notwithstanding anything contained in this Code, Health Insurers may hold conferences, educational trainings, seminars, contests etc. for their agents/ intermediaries as per industry practice and subject to applicable Laws in this regard. Such conferences, educational trainings, seminars, contests etc. will be excluded from the restriction, if any, under the Code.

3. Diagnostic Centres: In addition to the General Principle set out above, Diagnostic Centres should also apply and should insist that their directors, employees, agents, dealers and distributors, contractors, consultants, vendors and suppliers as the case may be comply with the following principles, as may be applicable:

- (i) provide accurate, reliable, pertinent and cost effective diagnostic information, in addition to the test results;
- (ii) provide patients with written information on all diagnostics (in this case pertaining to Radiology/Imaging) being administered and obtain their consents prior to such procedures;
- (iii) be committed to staying abreast with new developments in the fields of medicine and law and provide compliance training, guidance and education to employees;

- (iv) ensure that there is a proper complaint mechanism in place to record complaints and respond at an appointed time;
- (v) make available treatment records of patients to Health Insurers with whom the patient has privity of contract;
- (vi) constantly review, upgrade and improve infrastructure and equipment; and
- (vii) establish, implement and maintain a quality management system which conforms to accepted national/ international standards.
- (viii) Protect the confidentiality of the patient's medical information.

4. Medical Device Companies: In addition to the General Principle set out above, Medical Device Companies shall, in their interaction with Healthcare Professionals apply and comply with and ensure that their directors, employees, agents, dealers and distributors, contractors, consultants, vendors and suppliers as the case apply and comply with as the case may be, the following additional specific principles, as may be applicable:

(A) Medical Technology: endeavor to develop cutting edge medical technology that potentially improves quality of products and related services to provide accessible and cost effective healthcare to the Indian patient and end user.

(B) Product Trainings and Education

(i) Location: may organize training and educational sessions at large scientific sites as well as at regional and local patient care institutions. In case of necessity, the educational programs for specialists are allowed to be conducted at a "working place" - in a real clinical or laboratory environment in hospitals, laboratories, institutes and other places if it does not contradict with applicable regulations. Venues for Medical Device Company organized product trainings and education must be modest and appropriate, and secondary to the main purpose for which the meeting is provided. Resort locations are not appropriate for company-organized meetings.

(ii) Well-qualified Educators: The educators should be appropriately trained and qualified for conducting such programs. In cases where educational programmes require a license, permission, and/or other approvals under applicable Law(s), the Medical Device Companies can only conduct such educational programs after having received the required license, permission or approval. In this regard Medical Device Companies may engage Healthcare Professionals as consultants to conduct such educational programmes under a consulting agreement and subject to applicable Laws. Each such Healthcare Professional and the respective Medical Device Company shall be responsible for ensuring compliance with any such consulting agreement.

- (iii) *Costs:* Educational programmes and trainings may take place in various regions of India as well as abroad and in this case modest expenses for accommodation, food and transportation of participants may be paid for by organizers. This reimbursement of costs should meet the aim of the educational and training programs organized. Medical Device Companies will not invite any person without a professional interest to a meeting. Medical Device Companies will not pay for the travel and lodging, meals and hospitality of any such guests or individuals (spouse, family members etc.) and should make this clear in the invite.

(C) Sponsorship (third party educational and /or other conferences)

- (i) Medical Device Companies may support conferences organized by third parties through financial grants to cover costs of venue hire, catering subject to the following:

- (a) Conference is primarily dedicated to promoting objective scientific and educational activities;
- (b) Conference organizer is responsible for and controls the selection of program content, faculty, educational methods and materials; and

- (c) Medical Device Company's support of the conference should be clearly stated in advance of and at the conference/meeting.

- (ii) *Conference Support:*

Medical Device Companies may provide financial grants directly to the conference organizer to help reduce the registration fees of the participants and to cover reasonable honoraria, travel, meals and accommodation expenses of Healthcare Professionals who are bona fide conference faculty members. A written request must be made by the conference organizer to the Medical Device Company and any sponsorship must be paid directly to the conference organizer or training institution. The conference organizer alone is responsible for the programme content and the faculty selection. Medical Device Companies may not have any detailed involvement in determining the content of the conference other than recommending speakers or commenting on the programme where requested to do so.

- (iii) *Satellite Symposia:*

Medical Device Companies may sponsor satellite symposia at third party conferences and provide presentations on subjects that are consistent with the overall content of the third party conference provided that all information presented is fair, balanced and scientifically rigorous. Medical Device Companies may determine the content of these events and comment on faculty selection when requested to do so. The arrangement must be documented by written contract and the support of the Medical

Device Company must be disclosed in all materials relating to the satellite event.

(iv) *Advertisements and Demonstrations:*

Medical Device Companies may purchase advertisements and lease booth space for company displays at conferences.

(v) *Fellowships/Scholarships:*

Medical Device Companies may also provide educational grants to training institutions, healthcare institutions or professional societies of Healthcare Professionals for medical education programmes by providing financial support for fellowships and similar scholarship awards. The selection of the grantee should be within the discretion of the institution at which such grantee is enrolled or the teaching institution at which they will be trained. Grants must be provided to the teaching or professional institution and not to individual fellows, save at the prior written request of the institution. In no way should the funding be tied to an institution's purchase of a Medical Device Company's products and services, or otherwise be based on an institution's past or potential future use of the Medical Device Company's products or services.

(D) Advisory/Consulting Arrangements

(i) Medical Device Companies may engage Healthcare Professionals in advisory capacities (as consultants, as speakers, as proctors, as researchers, as treating doctors or in any other professional capacity) to provide services that support research and development to advance medical science, develop new technologies, improve existing products and services, or enhance the quality and efficacy of patient care. Medical Device Companies may not engage Healthcare Professionals as a means of inappropriate inducement.

(ii) Medical Device Companies should engage only the number of Healthcare Professionals reasonably needed to perform services for which a pre-existing need has been identified by the Medical Device Company. Healthcare Professionals in advisory capacities should be selected based on their qualifications and expertise to perform the required services and not be influenced by volume of business that may be generated by such Healthcare Professionals. Advisory/consulting services should be engaged pursuant to written agreements describing the services to be performed and the compensation to be provided. Such agreements should only be entered into by Medical Device Companies where a legitimate need has been identified and there is a requirement for contracting such services.

(iii) Advisory/consulting arrangements must be written and should specify all services to be provided. Wherever applicable under the Law, such agreements should be disclosed in advance and in writing to the

Healthcare Professional's institution or employer, unless applicable Law, regulations or institutional rules specifically require disclosure to a different body, in which case disclosure should be made in accordance with the applicable Law. Wherever applicable, such agreements should be approved by the management of the institution with which the Healthcare Professional is affiliated.

- (iv) Payments for services should be at fair market value. Payments in advance of services rendered should be avoided. Fees should not be based on or influenced by the volume of or value of the consultant's business. Payments should be appropriately documented and should be made against a proof of service e. g. a report from the consultant containing details of service. Any reimbursement of permissible expenses under applicable Law should be subordinate in time and focus to the scientific or business purpose for which services have been engaged. It must be transparent and appropriately documented. There should not be any reimbursement for side trips, extended stays or meetings at luxury locations.
- (v) In undertaking the above mentioned advisory/consulting arrangements, Medical Device Companies must ensure that:
 - (a) The professional integrity and the freedom of the Healthcare Professional is maintained;
 - (b) The patient's interests are not compromised in any manner whatsoever;
 - (c) The arrangements and affiliations are within applicable Law; and
 - (d) Where required under applicable Law, such arrangements and affiliations are fully transparent and appropriately disclosed.

(E) Research and Educational Grants

- (i) To promote independent medical research, medical education and advancement of medical care, research and educational grants may be provided by Medical Device Companies in areas of legitimate interests of the Medical Device Companies. Grants may also be made for initiatives supporting education of patients and/or the public on important healthcare issues. While encouraging this important function, it is imperative to ensure that such grants do not place Medical Device Companies and Healthcare Professionals at undue risk of legal liability.
- (ii) The said grant should not be viewed as a price concession, inducement for promoting business interests of the Medical Device Company or as a reward to favoured Healthcare Professionals. Therefore, the purpose of the grant must be captured in a written agreement with well-defined objectives, milestones and deliverables. Research and/or educational

funding should not be linked to sales of Medical Device Company's products or services.

- (iii) Any research and/or educational grant shall not be made directly to the individual Healthcare Professional but shall be received only through approved institutions under applicable Laws and rules/guidelines adopted by such approved institutions, in a transparent manner.

Section III

Monitoring and Compliance

1. The respective NATHEALTH and IMA Code Monitoring Committees shall :
 - (i) identify and recommend optimal means to their respective the Members/members to promote and publicize the Code within the medical community, amongst Healthcare Professionals, Governmental Authorities and regulators and other relevant stakeholders in the healthcare industry;
 - (ii) work with their respective the Members/members to ensure that publicity campaigns are undertaken to increase awareness about the Code through media and other outlets;
 - (iii) ensure that the Code is available on the IMA and NATHEALTH website and encourage their respective Members/members to provide references and links to the Code on their websites;
 - (iv) encourage their respective Members/members to promote the Code and its implementation on a regular basis in consonance with applicable Law(s) and their respective Internal Codes;
 - (v) encourage their respective Members/members to engage a third party independent certification agency to help measure public perception to the adherence to the Code by Members (such as a Public Trust Index). Such a third party agency will be an independent, appropriately qualified consultant or a panel of independent, qualified and experienced persons;
 - (vi) on receipt of a complaint of violation of the Code by their respective a Member/member, shall forward the complaint to the concerned Member/member to provide an appropriate response, within sixty (60) days of receipt of such complaint. The concerned Member shall undertake an appropriate investigation subject to applicable Law(s) and the Internal Code as the case may be and provide a detailed report of the investigation and

steps (remedial or proactive as the case may be) undertaken in accordance with the same;

(vii) the NATHEALTH and IMA Code Monitoring Committee as the case may be shall review the response and the actions undertaken by the concerned Member/member and if satisfied that it meets applicable Law(s) and is in consonance with the Member's Internal Code as the case may be, the complaint shall be treated as closed; and

(viii) In the event the NATHEALTH and IMA Code Monitoring Committee as the case may be is not in agreement on the appropriateness of the concerned Member's/member's response and steps undertaken in accordance thereto, it shall present the matter at the next upcoming meeting of the NATHEALTH Governing Council or the IMA Governing Council as the case may be for its consideration. The respective NATHEALTH or IMA Governing Council shall review the matter and provide its response within thirty (30) days by a majority vote, maintaining confidentiality in the matter to avoid any misuse of the outcome to the detriment of the concerned Member/member. The decision of the respective NATHEALTH or the IMA Governing Council shall be final subject to applicable Law(s).