



राष्ट्रीय आयुर्विज्ञान आयोग National Medical Commission

Expert Training Module by Ethics & Medical Registration Board



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राष्ट्रीय आयुर्विज्ञान आयोग

National Medical Commission

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MESSAGE

The Ethics and Medical Registration Board (EMRB) of the National Medical Commission has prepared the Expert Training Module to help the experts to give opinion on the cases related to patient-doctor conflicts that come for appeals to the National Medical Commission. The module has been carefully and meticulously drafted by experts from both medical and legal specialities.



I congratulate the team of the EMRB for achieving this significant outcome. It is notable that the contents of the module have a wider application for use by the experts who are helping similar cases at all the State Medical Council as well. As a result, the decisions with regards to conflicts between doctors and patients can be resolved on the basis of sound evidence and expert opinion. It is a module which has to be read by each of the experts who help such conflict resolution even in other situation.

I wish the team the very best in their similar future endeavour.


(Dr. B.N. Gangadhar)
Chairman



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Editor's Note

Let's learn, unlearn, and relearn continuously!

There is a basic difference between the Indian Medical Council (IMC) Act and National Medical Commission (NMC) act, 2019 in dealing with the appeal cases at the National level. Earlier there was an appeal committee of experts and its decision was to be ratified by MCI. However, in NMC there is an autonomous board Ethics and Medical Registration Board (EMRB) which must decide the appeal and its decision is final and there is provision of further appeal at NMC level.



It is impossible to decide the variety of cases coming to EMRB by 2-3 members and president of the board who can obviously represent only their own specialty. So, use of domain experts is inevitable in nearly all cases.

EMRB ethics section has devised very clear-cut Standard operative Procedures for dealing with all appeal cases. However, it was felt that an expert needs not only the subject knowledge but also possess the basic knowledge of act, rules and regulations and understand functioning of regulatory bodies and courts. They also need to see and understand various implications of the opinions they give in such cases. This will help resolve most of his/her queries and they will be able to give their opinions in a non-biased and comprehensive manner.

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With this background in mind EMRB thought of training the experts working with State Medical Councils (SMCs), EMRB and national Medical Commission (NMC) for ethics, conduct and negligence related complaints or appeals. This module is the result of the hard work of a group of experts over months. We have also conducted a trail training to firm up the module.

EMRB will train all such experts at SMCs and Medical colleges in due course of time. In this fast-changing world we must continuously learn, unlearn, and relearn. This module and the presentations prepared based on this module will help the experts in building confidence and knowledge required to give expert opinions.

I request all the stakeholders to critically analyze the content and send us their comments for further improvements.

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National Medical Commission

**Expert Training
Module**

2023

★★★★★

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Part-I: Substantive Legal Framework

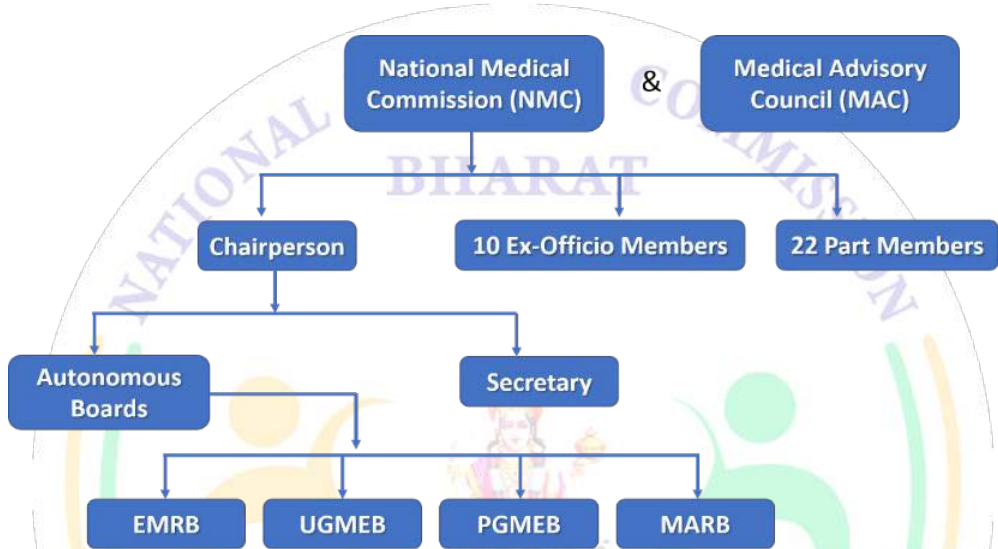
1. INTRODUCTION TO THE NATIONAL MEDICAL COMMISSION ACT, 2019

The National Medical Commission Act, 2019 (hereinafter NMCA) is an important legislation in India that was passed by the Parliament and received the assent of President on August 8, 2019. An Act to provide for a medical education system that improves access to quality and affordable medical education, ensures availability of adequate and high quality medical professionals across all parts of the country; that promotes equitable and universal healthcare which encourages community health perspective and makes services of medical professionals accessible to all the citizens; that promotes national health goals; that encourages medical professionals to adopt latest medical research in their work and to contribute to research; that has an objective periodic and transparent assessment of medical institutions and facilitates maintenance of a medical register for India and enforces high ethical standards in all aspects of medical services; that is flexible to adapt to changing needs and has an effective grievance redressal mechanism and for matters connected therewith or incidental thereto.

The NMC Act replaces the previous regulatory body, the Medical Council of India (MCI)¹, with a new overarching body called the National Medical Commission (NMC hereinafter). Apart from NMC, a Secretariat for administrative assistance, Medical Advisory Council (MAC) to advise on

¹ The National Medical Commission Act, sections 60, 61

different matters to NMC and four Autonomous Boards (UGMEB²; PGMEB³; MARB⁴; EMRB⁵) to perform various kinds of functions have been established under the Act which are shown below:



A. Powers and Functions of the National Medical Commission: The Commission has several important functions specifically mentioned under section 10 (a-j), apart from other provisions in the Act, which are as follows:

- (a) lay down policies for maintaining a high quality and high standards in medical education and make necessary regulations in this behalf;
- (b) lay down policies for regulating medical institutions, medical researches and medical professionals and make necessary regulations in this behalf;

² Under-Graduate Medical Education Board

³ Post-Graduate Medical Education Board

⁴ Medical Assessment and Rating Board

⁵ Ethics and Medical registration Board

- (c) assess the requirements in healthcare, including human resources for health and healthcare infrastructure and develop a road map for meeting such requirements;*
- (d) promote, co-ordinate and frame guidelines and lay down policies by making necessary regulations for the proper functioning of the Commission, the Autonomous Boards and the State Medical Councils;*
- (e) ensure co-ordination among the Autonomous Boards;*
- (f) take such measures, as may be necessary, to ensure compliance by the State Medical Councils of the guidelines framed and regulations made under this Act for their effective functioning under this Act;*
- (g) exercise appellate jurisdiction with respect to the decisions of the Autonomous Boards;*
- (h) lay down policies and codes to ensure observance of professional ethics in medical profession and to promote ethical conduct during the provision of care by medical practitioners;*
- (i) frame guidelines for determination of fees and all other charges in respect of fifty percent of seats in private medical institutions and deemed to be universities which are governed under the provisions of this Act;*
- (j) exercise such other powers and perform such other functions as may be prescribed.*

Apart from the above-stated functions, under section 14, NMC to conduct the National Eligibility-cum-Entrance Test (NEET) for admission to undergraduate, postgraduate and super-speciality medical courses across the country. It also conducts the National Exit Test (NEXT), which has been introduced for final year undergraduate students and serves as a licensing

examination for medical practitioners, for enrolment in the State/National Register and to determine their eligibility for postgraduate broad speciality medical education.⁶

B. Under Chapters-III and V of the NMCA, the Medical Advisory Council and Autonomous Boards have been discussed in detail. Their functions have been explained briefly hereunder:

a. Medical Advisory Council (MAC): The MAC advises the NMC on various matters related to medical education, training and research including maintenance of minimum standard of medical education and enhance its equitable access. It provides the primary platform through which views and concerns of States and Union Territories are put forth and helps in shaping the overall agenda, policy and action related to medical education and training.⁷

b. Under-Graduate Medical Education Board (UGMEB): The UGMEB is responsible for overseeing and regulating undergraduate medical education in India. It sets standards for the curriculum, assessment, and quality of under-graduate medical courses, along with framing of guidelines for the institutions and facilitating the development and training of faculty members teaching these courses.⁸

c. Post-Graduate Medical Education Board (PGMEB): The PGMEB determines the standards of medical education at postgraduate and super-speciality levels in the country, apart from developing curriculum, setting

⁶ The National Medical Commission Act, 2019, Section-15.

⁷ *Ibid.* section 12.

⁸ For details see, section 24 of the National Medical Commission Act.

standards and norms for setting up of medical institutions, infrastructure and facilitating the development and training of faculty members teaching these courses.⁹

d. Medical Assessment and Rating Board (MARB): The MARB determine the procedure for assessing and rating medical institutions for their compliance with the standards laid down by UGMEB and PGMEB, apart from granting permission to establish new institution, carry out inspections etc. or to start any postgraduate course or increase the number of seats.¹⁰

e. Ethics and Medical Registration Board (EMRB): The EMRB performs the following functions as per section 27 of the NMCA:

27. (1) The Ethics and Medical Registration Board shall perform the following functions, namely: —

(a) maintain National Registers of all licensed medical practitioners in accordance with the provisions of section 31;

(b) regulate professional conduct and promote medical ethics in accordance with the regulations made under this Act:

Provided that the Ethics and Medical Registration Board shall ensure compliance of the code of professional and ethical conduct through the State Medical Council in a case where such State Medical Council has been conferred power to take disciplinary actions in respect of professional or ethical misconduct by medical practitioners under respective State Acts;

⁹ *Ibid.*, section 25.

¹⁰ *Ibid.*, section 26.

(c) develop mechanisms to have continuous interaction with State Medical Councils to effectively promote and regulate the conduct of medical practitioners and professionals;

(d) exercise appellate jurisdiction with respect to the actions taken by a State Medical Council under section 30. (2) The Ethics and Medical Registration Board may, in the discharge of its duties, make such recommendations to, and seek such directions from, the Commission, as it deems necessary.

Powers to take Disciplinary Action has been provided under section 30 of the NMCA, which has been reproduced as under:

30. (1) The State Government shall, within three years of the commencement of this Act, take necessary steps to establish a State Medical Council if no such Council exists in that State.

(2) Where a State Act confers power upon the State Medical Council to take disciplinary actions in respect of any professional or ethical misconduct by a registered medical practitioner or professional, the State Medical Council shall act in accordance with the regulations made, and the guidelines framed, under this Act:

Provided that till such time as a State Medical Council is established in a State, the Ethics and Medical Registration Board shall receive the complaints and grievances relating to any professional or ethical misconduct against a registered medical practitioner or professional in that State in accordance with such procedure as may be specified by the regulations:

Provided further that the Ethics and Medical Registration Board or, as the case may be, the State Medical Council shall give an opportunity of hearing to the medical practitioner or professional concerned before taking any action, including imposition of any monetary penalty against such person.

(3) A medical practitioner or professional who is aggrieved by any action taken by a State Medical Council under sub-section (2) may prefer an appeal to the Ethics and Medical Registration Board against such action, and the decision, if any, of the Ethics and Medical Registration Board thereupon shall be binding on the State Medical Council, unless a second appeal is preferred under sub-section (4).

(4) A medical practitioner or professional who is aggrieved by the decision of the Ethics and Medical Registration Board may prefer an appeal to the Commission within sixty days of communication of such decision.

Explanation. - For the purposes of this Act —

(a) "State" includes Union territory and the expressions "State Government" and "State Medical Council", in relation to a Union territory, shall respectively mean the "Central Government" and "Union territory Medical Council";

(b) the expression "professional or ethical misconduct" includes any act of commission or omission as may be specified by the regulations.

2. THE INDIAN MEDICAL COUNCIL (PROFESSIONAL CONDUCT, ETIQUETTE AND ETHICS) REGULATIONS, 2002

The Indian Medical Council had notified the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations for registered medical practitioners. These Regulations were framed under section 20A read with section 33(m) of the Indian Medical Council Act, 1956. These Regulations are applicable till the time, new Regulations/Guidelines/Code of Conduct are drafted/notified under the NMCA.

The precise summary of the relevant Regulations, 2002 is given as under:

These Regulations introduced professional and ethical standards for doctors with qualification of MBBS or MBBS with postgraduate degree/diploma or with equivalent qualification in medical discipline in India. Under Chapters-1-5 of the Regulations, various kinds of duties and responsibilities of doctors towards patients, public, para-medical professionals and towards each other have been explained. It has been said that the prime objective of the medical profession is to render service to humanity, any reward or financial gain is a subordinate consideration. A physician should be an upright man, of pure character and diligent in caring for the sick. He should be modest, sober, patient and prompt in discharging his duties without anxiety. He is required to maintain a high standard of professional conduct, show respect towards patients, and uphold the dignity and honour of the medical profession. He should merit the confidence of patients and should try continuously to improve medical

knowledge and skills, as the responsibility of the medical profession extends not only to individuals but also to the society. The main duties and responsibilities of a physician include the maintenance of medical records, display of registration number, use of generic names of drugs, highest quality assurance of patient care and treatment with patience, delicacy and secrecy without any neglect and maintaining dignity of relationship between doctors and patients, apart from specifying the unethical conduct on the part of doctors.

Medical practitioners are prohibited from receiving or giving any commission, fee, or other similar inducements for referring patients or prescribing specific treatments or drugs. They are obligated to maintain confidentiality of patients and not to disclose any information acquired during the course of treatment, unless required by law or in the patient's best interest. Prior informed consent of the patient or their legal guardian is necessary before undertaking any investigation, treatment, or surgical procedure. The doctor must explain the nature, purpose, risks, and benefits of the procedure to the patient.

Unethical acts such as advertising, making patents and copyrights useful for patients unavailable, exploitation by selling medicines or surgical appliances and prescribing or dispensing secret medicines etc. have been clearly prohibited.¹¹ Code of conduct for doctors and their professional associations in dealing with the pharmaceutical and allied health sector industry was specifically incorporated in detail in 2009. According to the Regulations, if a registered medical practitioner fails to adhere to the prescribed Regulations and

¹¹ The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, Chapter-6.

is found guilty of professional misconduct, the concerned State Medical Council / National Medical Commission has the authority to take disciplinary action against him/her.¹²

3. IMPORTANT CONCEPTS AND PRINCIPLES

Important concepts and principles, and tests have been defined and explained as under:

A. Negligence:

The Latin word '*negligentia*,' means 'to fail to pick up,' is the source of the English word 'negligence,' which refers to a lack of care. Negligence is a synonym for carelessness. Accordingly, failure to take the necessary steps that should have been taken under the circumstances to avoid or prevent that harm is negligence as opposed to knowingly or deliberately creating that harm.

Negligence as a tort is defined as the breach of a legal duty to take care which results in damage to the claimant.¹³ Therefore, to constitute 'negligence' there must be a legal duty on the part of the doer, breach of which results into some damage, injury or loss to the claimant, directly attributable to the conduct of the doer. Negligence becomes actionable on account of injury or damage resulting from the act or omission to the person sued. The essential components of negligence are:

¹² For details see, *Ibid.*, Chapters 7 & 8.

¹³ Winfield and Jolowicz, *Torts*, Sixteenth edition (2002), p.103.

- (a) duty to take care;
- (b) breach of that duty;
- (c) resulting harm/injury/damage and;
- (d) direct causation (foreseeable injury)

B. **Medical Negligence:**

Medical negligence can be defined as a breach of duty to take care by a medical professional resulting into injury to the patient. It may be due to an act or omission to do something expected of a medical professional, which a prudent and reasonable professional would do or not do, guided by those considerations which ordinarily regulate the conduct of human affairs.

A medical professional owes duties towards his/her patients. A medical professional, who holds himself/herself out as ready to give medical advice or treatment impliedly undertakes that he/she is possessed of skill, competence and knowledge for that purpose. Such a medical professional, when is consulted by a patient, owes him certain duties, namely, a duty of care in deciding whether to undertake the case; a duty of care in deciding what treatment to give; and a duty of care in his administration of that treatment. A breach of any of these duties will support an action for negligence by the patient.¹⁴

¹⁴ *Kusum Sharma v. Batra Hospital and Medical Research Centre*, (2010) 3 SCC 480.

While deciding whether the medical professional is guilty of medical negligence following well-known principles must be kept in view:

- a.** A medical professional is expected to bring a reasonable degree of skill, competence and knowledge and must exercise a reasonable degree of care. Neither the highest nor a very low degree of care and competence judged in the light of the particular circumstances of each case is what the law requires.
- b.** The medical professionals are entitled to get protection so long as they perform their duties with reasonable skill and competence and in the interest of the patients. Medical professionals must not be unnecessarily harassed or humiliated so that they can perform their duties without fear and apprehension. It is not conducive for the society and to the efficiency of the medical profession if no doctor could administer medicine without a halter round his neck.
- c.** The interest and welfare of the patients have to be paramount for the medical professionals. A medical practitioner would be liable only where his/her conduct fell below that of the standards of a reasonably competent practitioner in his/her medical field.
- d.** The existence of doctor–patient relationship is a prerequisite to fasten liability on the doctor. The relationship is fiduciary in nature, and the obligation is there on the medical practitioner to make patient understand ordinarily regarding the ailment, diagnostic process, treatment, and all its consequences.
- e.** A medical professional must secure the consent of the patient, and such consent should be ‘real and valid.’ ‘Adequate information’ is to be furnished to the patient to enable him/her to make a balanced judgment.

f. The term “negligence” has no defined boundaries and if any medical negligence happens at any stage, whether pre or post-operative medical care or in the follow-up care, or at any point of time by the treating doctors or anyone else, it is always open to be considered by the Courts/Commission, but each case has to be examined on its own merits in accordance with law.

g. Negligence i.e., lack of care is an essential ingredient of wrong committed against the patient. It has to be established by the patient/family, which must be culpable or gross and not merely based upon an error of judgment.

h. A medical practitioner would be liable only where his/her conduct fell below the standards of a reasonably competent practitioner in the field. While adopting a course of treatment, the medical practitioner is under duty to ensure that the medical protocol being followed by him/her is to the best of his/her skill and competence. He/she cannot be held liable for genuine difference of opinion.

i. In the realm of diagnosis and treatment, there is scope for genuine difference of opinion and one professional doctor is clearly not negligent merely because his conclusion differs from that of another professional doctor.

j. A doctor cannot be said to be negligent so long as he/she performs his/her duties with reasonable care, skill and competence. Merely because he/she chooses one course of action in preference to the other one available, he/she would not be liable if the chosen course of action is acceptable to the medical profession.

k. If a medical professional, looking at the gravity of illness adopts a particular procedure involving higher element of risk, but honestly believes that

it will provide greater chances of success than a procedure, which may be lesser risky but having higher chances of failure cannot be said to be negligent.

l. A medical practitioner is not to be held liable simply because things went wrong from mischance or misadventure or accident or through an error of judgment in choosing one reasonable course of treatment in preference to another.

m. A doctor following routine practice/procedure/line of treatment acceptable to the medical profession of that day and by using due care and reasonable caution, he cannot be said to be negligent, merely because a better alternative course or method of treatment was also available. A failure to use special or extraordinary precautions which might have prevented the particular happening cannot be the standard for judging the alleged negligence. The standard of care must be reasonable which any prudent medical professional is expected to take, in the light of knowledge available at the time of the incident.

n. The medical professional is not considered negligent if he/she acts in accordance with a practice accepted at the time as proper by a responsible body of professional opinion skilled in the particular type of activity, even though there is a body of competent professional opinion which might adopt a different technique.¹⁵ The courts are not supposed to choose between the schools of professional thought.

o. The burden of proving that the injury or harm, would not have occurred if the negligence, had not been committed rests upon the patient claimant.

p. The causal relationship between breach and injury is a must for fastening the liability of negligence, and such cause must be ‘direct’ or

¹⁵ *Bolam v. Friern Hospital Management Committee*, (1957) 1 WLR 582.

‘proximate.’ It is important to note that the test is an ‘or’ one, and therefore the casual link can be either direct causation or proximate causation, and in both cases, negligence can be ascribed.

q. Difference between civil liability and criminal liability is clearly indicated by the Apex Court. For conviction of a doctor for alleged criminal offence, the standard should be proof of recklessness and deliberate wrong doing i.e. a higher degree of morally blameworthy conduct, showing negligence or rashness of such a higher degree as to indicate a mental state which can be described as totally apathetic towards the patient.¹⁶ To hold liability for ‘the criminal rashness or criminal negligence, it shall have to be found out that the rashness was of such a degree as to amount to taking a hazard knowing that the hazard was of such a degree that injury was most likely imminent.’¹⁷ Such gross negligence alone is punishable. Mere lack of proper care, precaution and attention or inadvertence might create civil liability but not a criminal one.¹⁸ Indiscriminate prosecution of medical professionals for criminal medical negligence is counter-productive and does no service or good to the society.

r. It has been emphasized by the Supreme Court of India in several cases that extreme care and caution should be exercised while initiating criminal proceedings against medical professionals for alleged medical negligence and had drawn up elaborate safeguards for them, including avoiding arrest unless it was inevitable. A simple lack of care, an error of judgment or an accident is not proof of negligence on the part of the medical professional. Negligence

¹⁶ *Dr. Suresh Gupta v. Govt. of NCT Delhi*, (2004) 6 SCC 422.

¹⁷ *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1.

¹⁸ *Dr. Suresh Gupta v. Govt. of NCT Delhi*, (2004) 6 SCC 422.

would amount to an offence only if there is a clear mental intention backed by strong evidence attributable to the doctor to make him/her criminally liable. The relevant provisions for imputing criminal liability to doctors and associated medical professionals have been provided under the Indian Penal Code (IPC), 1860, depending upon the facts and circumstances of the case, a complaint may be registered against a medical practitioner for alleged criminal medical negligence.¹⁹ Please read Supreme Court Guidelines on page 23.

s. The Constitution of India does not provide any special rights to the patient. The patient's rights are basically indirect rights, which arise or flow from the obligations of a physician or medical professionals under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. Apart from that, patient's rights flow from the fundamental right to life and personal liberty enunciated under Article 21 of the Constitution of India, such as the right to know about the patient's condition, right to give consent for the treatment/surgery or the right to participate in treatment decision-making etc. Therefore, patients' rights must be protected and medical professionals

¹⁹ Indian Penal Code (IPC), 1861, Section 304-A: Causing death by negligence: Whoever causes the death of any person by doing any rash or negligent act not amounting to culpable homicide, shall be punished with imprisonment of either description for a term which may extend to ten years, or with fine, or with both.

Section 337: Causing hurt by act endangering life or personal safety of others: Whoever causes hurt to any person by doing any act so rashly or negligently as to endanger human life, or the personal safety of others, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to five hundred rupees, or with both.

Section 338: Causing grievous hurt by act endangering life or personal safety of others: Whoever causes grievous hurt to any person by doing any act so rashly or negligently as to endanger human life, or the personal safety of others, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine which may extend to one thousand rupees, or with both.

must conduct themselves according to the obligations given under the above-stated Ethics Regulations, to avoid any mis-hap.

C. Medical Malpractice V/s Medical Negligence:

The term ‘malpractice’ has been derived from two Latin terms, ‘*malus*’ means ‘bad’ and ‘*practicare*,’ which means ‘to practice.’ Any action or inaction by a doctor during the course of treating a patient that varies from the accepted standards of care and results in harm to the patient may be referred to as ‘medical malpractice.’ The term ‘malpractice’ is generally not used in India. In India, the term ‘medical negligence’ is used, whereas in USA, the term ‘medical malpractice’ is used.

Medical malpractice specifically is said to have happened when a medical professional is aware of the possible consequences before making a mistake that led to an injury, whereas in cases of medical negligence, the medical professional makes an honest mistake that leads to an injury, loss or damage to the patient. In our daily lives, we tend to use the two terms ‘negligence’ and ‘malpractice’ interchangeably. However, these are legally two distinct concepts. Both may indicate that a doctor is responsible for the patient’s losses, but depending on whether the patient is claiming negligence or malpractice, the elements that need to be proved and the nature of the claim may change.

D. Different Facets of Negligence and Malpractice:

- a.** Negligence occurs when one person fails to exercise the standard of care that of a reasonable and prudent man would take in a similar situation, may be despite his/her best efforts, and as a result causes harm, damage, injury, or loss to the other person.
- b.** Negligence is the result of an unintentional action that occurs due to a failure to take the necessary steps that should have been taken under the circumstances to avoid or prevent that harm. Malpractice is the result of an intentional and unreasonable lack of skill causing harm, damage, injury, or loss.
- c.** In cases of negligence, there may or may not be the presence of intent. But in cases of malpractice, the intent is usually present, i.e., knowing that harm may be caused.
- d.** Negligence is a failure to exercise appropriate care. In medical malpractice, the degree of professional misconduct is severe or a gross lack of competency or wilful wrong-doing by the healthcare provider, resulting in harm to the patient.
- e.** A medical professional should never try to cause harm. But if he/she is aware of the potential consequences before undertaking the procedure, it could be considered medical malpractice.
- f.** If a medical professional endangers the life or safety of a patient due to negligence, there can be civil or criminal liability, depending upon the severity

of the wrong committed, and accordingly the compensation or punishment may be ordered against the erring medical professional or hospital.²⁰

E. Principles of Natural Justice (PsNJ):

Natural justice or *Jus Naturale* or *lex naturale* (equivalent to Roman or Greek law, found in *Kautilya's Arthashastra*) is a branch of law which is closely associated with the principles of common law and several moral practices. These Principles of Natural Justice have existed in the natural environment for a very long time and in simple terms, they establish the differences between right and wrong.

Principles of Natural Justice cannot be restricted to mere fairness or procedure alone. These principles are widely used in the Constitutional law, administrative law, and the procedural aspects of these principles are embedded in the decision-making process of every judicial and quasi-judicial

²⁰ Indian Penal Code (IPC), 1861, Section 304-A: Causing death by negligence: Whoever causes the death of any person by doing any rash or negligent act not amounting to culpable homicide, shall be punished with imprisonment of either description for a term which may extend to ten years, or with fine, or with both.

Section 337: Causing hurt by act endangering life or personal safety of others: Whoever causes hurt to any person by doing any act so rashly or negligently as to endanger human life, or the personal safety of others, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to five hundred rupees, or with both.

Section 338: Causing grievous hurt by act endangering life or personal safety of others: Whoever causes grievous hurt to any person by doing any act so rashly or negligently as to endanger human life, or the personal safety of others, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine which may extend to one thousand rupees, or with both.

organization. Different facets and applications of Principles of Natural Justice are extremely important to any democratic country. There are three different and very important rules associated with the Principles of Natural Justice, which have been briefly explained hereunder:

a. Rule of giving an Opportunity of Hearing or ‘Audi Alteram Partem’: The literal meaning of ‘*Audi Alteram Partem*’ is that both parties should be given a fair chance to present themselves with their relevant points and a fair trial should be conducted. No person should be condemned or punished without giving a fair opportunity of being heard. This ‘*hearing rule*,’ or ‘*rule of fair hearing*’ posits that before arriving at any decision or judgment, the decision-making authority or the court must make sure that both/all the parties in any dispute or any legal proceeding have been given a sufficient chance of being heard and any decision is not arrived at, without any of the parties having a fair opportunity to express their opinion. Prior notice should be given to a person so as to know what all charges are framed against him/her.

b. Rule against Bias or Rule of ‘Nemo Judex in Causa Sua’: According to this rule against bias, it is stated that ‘*no one should be a judge in his/her own case*,’ because it may lead to unfair activity whether in a conscious or unconscious stage in relation to the party or a particular case. Therefore, it provides that the decision-making authority must not be unfairly inclined towards the interest of any one particular party to the dispute, and must be neutral towards both/all the parties and consequently, the decision of such a dispute or legal proceeding must be on the facts and merits of the circumstances and on the basis of evidence recorded, and not be influenced by any other reason.

c. Rule of Speaking Order or Reasoned Decisions: This Principle of Natural Justice provides that the arbiter or deciding authority or judge deliberating and giving any decision, must give a detailed well-reasoned and legally acceptable decision, so that the parties subject to such decision can understand the reasons behind such decision. Moreover, in case the decision is to be appealed, the appellate authority/ judge overseeing such appeal would be able to understand the decision-making process of the previous authority.

F. Important Tests/Maxims used in cases of medical negligence are as follows:

a. *Bolam Test*²¹ and the *Bolitho Test*²² make up the twin pillars of all assessments of medical negligence. They state that a doctor is not negligent if he/she acts in accordance with a responsible body of medical opinion, provided that the court finds such an opinion to be logical.

In the *Bolam Test* (1957), it has been laid down that no doctor can be found guilty of negligence if they are deemed to have acted ‘in accordance with a responsible body of medical opinion.’ *Bolam test* is considered merely a rule of practice or of evidence and not a rule of law. It lays down the standards for judging cases of medical negligence.

The *Bolitho Test* (1997) helped to clarify further and elaborated that the opinion of the responsible body must have a ‘logical basis’ behind that opinion.

²¹ *Bolam v. Friern Hospital Management Committee*, (1957) 1 WLR 582.

²² *Bolitho v. City and Hackney H.A.*, (1997) AC 232.

The Bolam Test has been applied in India in majority of the cases and has been accepted by the judiciary. Only in few cases, the court has applied Bolitho Test, when it is not satisfied that the body of expert opinion can be logically supported and hence, it should not accept a defence argument without first assessing whether such opinion is subjected to logical analysis.

b. *Res ipsa loquitur*: This is a Latin term, which means- the thing speaks for itself. It essentially means the incident alone is enough to prove medical negligence happened or the mere fact of the happening of the accident should tell its own story so as to establish a prima facie case against the wrongdoer/medical professional.

Ordinarily, in case of medical negligence, the burden is on the complainant to prove breach of duty, injury and causation. But in cases where the '*res ipsa loquitur*' is applied, the legal burden of proof shifts to the medical professional and he/she has to rebut that by some cogent and plausible explanation and prove that he/she exercised all due care and done his/her duty to repel the charge of negligence.

This doctrine has to be seen on the basis of facts and circumstances of the case and is a rule of evidence.



Part-II: Procedural Framework

1. THE PROCEDURE FOLLOWED DURING AN INQUIRY

Here is a general overview of the procedure involved in an inquiry into a complaint received:

- A. **Receipt of Complaint:** The SMC/EMRB/NMC receives a complaint regarding alleged medical negligence or misconduct. The complaint may come from the patient or their representatives, another healthcare professional, or even from the Board's own initiative if it becomes aware of the potential wrongdoing.
- B. **Examination of the Complaint:** The SMC/EMRB/NMC examines the complaint to determine if it falls within the jurisdiction. Apart from that, it will also examine the supporting documents, and consider the relevant laws or regulations depending upon the facts given in that complaint.
- C. **Notice to the Registered Medical Practitioner:** If the SMC/EMRB/NMC entertains the complaint, notice is given to the other party/parties, which are usually medical practitioner(s).
- D. **Gathering of Information:** The SMC/EMRB/NMC begins gathering the relevant information related to the complaint. This may include obtaining medical records, relevant documents, and any other evidence that can shed light on the allegations. They may also request statements or interviews from the complainant, witnesses, and the healthcare providers.
- E. **Expert Opinion:** In any complaint, the SMC/EMRB/NMC may seek the opinion of one or more subject experts. These experts are usually from the

same medical specialty who will consider the compliance of accepted standards of practice, and provide his/her/their professional medical opinion.

F. **Hearing of the Case:** The parties involved, including the medical practitioner, should participate in the hearing of the case. This may involve providing statements, answering questions, and participating in depositions made. Based on the information and evidences gathered, the SMC/EMRB/NMC will analyse the case to determine if there is sufficient evidence to substantiate the allegations of medical negligence/misconduct or not. They will evaluate the care provided, compare it to applicable standards, and assess whether the provider's actions deviated from those standards and resulted in harm to the patient, which has to be the direct cause of that harm.

G. **Process of taking Decision:** It is important to conduct a thorough analysis of the facts, relevant laws, and applicable legal principles. Here are some steps, which may be helpful to decide the issues properly:

- i. **Review of the Facts:** Start by thoroughly reviewing and understanding the facts of the case. This includes examining the documents, contracts, agreements, or other evidences which are relevant to the case at hand. Also identify key events, actions, and individuals involved in the case.
- ii. **Analyse Ethical and Legal Issues:** Identify and analyse the ethical and legal issues arising from the case. For each issue, SMC/EMRB/NMC must consider the applicable ethics, laws, rules, and legal precedents, and assess how they apply to the facts of the case.
- iii. **Consider Argument and Counter-Arguments:** Evaluate the strengths and weaknesses of arguments made, from both/all the sides. The SMC/EMRB/NMC evaluates the evidence presented by both/all the parties and

determines, based on the balance of probabilities, whether the defendant's negligence caused the harm or injury alleged by the patient.

H. **Disciplinary Actions:** If the SMC/EMRB/NMC concludes that medical negligence or misconduct has occurred, they may take disciplinary action against the RMP or refer the case for further action.

I. **Decision:** The decision must be self-explanatory and well-reasoned. The SMC/EMRB/NMC must provide a thorough analysis of the evidences, relevant laws, and applicable precedents to support its decision. It outlines the considerations taken into account, the arguments presented by the parties involved, and the rationale behind the final decision taken.

J. **Appeal:** Appeal may be filed against the decision as per the provisions of the NMCA.²³

2. BASIC GUIDELINES IN CRIMINAL CASES

There is need to emphasize the need for care and caution in the interest of society, as the services which the medical profession renders to human beings is probably the noblest of all, and hence there is a need to protect doctors from frivolous or unjust prosecutions. Recourse to criminal process to pressurize the medical professional for extracting uncalled for or unjust compensation must be condemned and guarded against. Some Statutory Rules or Executive Instructions incorporating certain guidelines by the Government of India and/or the State Governments in consultation with the medical professionals are the need of the hour. As the cases of doctors (surgeons and physicians) being

²³ The National Medical Commission Act, sections-10 (1) (g); 27 (d); 30 (3) & (4).

subjected to criminal prosecution are on an increase, there is an urgent need to follow Hon'ble Supreme Court guidelines, which are as follows:

- a.** A private complaint should not be entertained unless the complainant has produced prima facie evidence before the court as a credible opinion given by another competent doctor to support the charge of rashness or negligence by the accused doctor.
- b.** The investigating officer should, before proceeding against the doctor accused of rash or negligent act or omission, get an independent and competent medical opinion preferably from a doctor in government service, qualified in that branch of medical practice who can normally be expected to give an unbiased opinion applying the Bolam test to the facts collected in the investigation.
- c.** A doctor accused of rashness or negligence may not be arrested routinely (simply because a charge has been levelled against him). Unless his arrest is necessary for furthering the investigation or for collecting evidence or unless the investigating officer feels satisfied that the doctor proceeded against him would not make himself available to face the prosecution unless arrested, the arrest may be withheld.
- d.** The private complainant and the investigating officer are not supposed to have knowledge of medical science so as to determine whether the act of the accused medical professional amounts to rash or negligent act within the domain of criminal law. Therefore, a private complaint should not be entertained unless a prima facie case is made out, based upon the evidences tendered in the Court and a credible opinion given by some competent doctor

is annexed to support the charge of gross rashness or negligence on the part of the accused doctor.

e. The process of investigating medical negligence or malpractice can be challenging, but it is important to ensure that all of the relevant evidence, documents and medical records are considered before any decision is made, based on logic and law. It is important to involve medical experts who have relevant expertise and experience in the specific medical issue at hand.

f. As the criminal process once initiated subjects the medical professional to serious embarrassment, harassment and loss of reputation which can never be compensated by any standards, criminal complaints must be entertained after taking due caution and as per the laid down guidelines by the Courts from time to time in several cases.

g. In cases of criminal negligence, it must be investigated that the degree of negligence committed must be much higher i.e., gross or of a very high degree. Negligence which is neither gross nor of a higher degree may provide a ground for action in civil law but cannot form the basis for prosecution. The expression 'rash or negligent act' as occurring in Section 304-A IPC has to be read as qualified by the word 'grossly'. This word 'grossly' has not been defined in any law or in the case law. Usually, it is defined based upon the circumstances around the incident, behaviour of the medical practitioners, the degree of deviation from the standard of care and the hazard taken by the accused doctor, which should be of such a nature that the injury resulted was most likely imminent.

h. The investigating officer or the aggrieved person cannot always be supposed to have knowledge of medical science to determine whether the act amounts to a rash or negligent act within section 304-A IPC, invariably the

investigating agencies seek help from the State Medical Council or from the medical expert(s) to provide expert opinion before arresting the medical practitioner.²⁴



²⁴ *Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1.

Part-III: Medical Expert: Attributes, Responsibilities, Rights and Entitlements

1. MEDICAL EXPERT

Any individual who possesses specialized knowledge, expertise, and experience in a specific area of medicine or healthcare can be a medical expert. He/she has to be highly qualified, experienced and recognized professional in that field. Medical expert plays a crucial role in various aspects of the healthcare system, including clinical practice, research, teaching, and legal proceedings.

In the context of legal cases involving medical negligence or malpractice, a medical expert is often called upon to provide opinions and testimony regarding the standard of care, causation, and other medical aspects of the case. These experts are typically physicians or other healthcare professionals who have extensive experience and expertise in the relevant field of medicine.

Medical experts are usually required to have the following qualifications and characteristics:

A. Education, Certification and Training: Medical experts have completed medical school education and obtained a medical degree or other relevant healthcare professional degree. They typically hold advanced medical degrees, such as a Doctor of Medicine (MD) or Post-graduate degree in Surgery (MS) or super-specialty degrees, Doctorate of Medicine (DM) or Master of

Chirurgiae (Surgery-MCh). They have also undergone specialized residency training and may have pursued additional fellowship, sub-specialty or super-specialty education and training in their area of expertise. The expert should be working in the related speciality and preferably, with designation. He/she should be a trained academician and sound in academics.

B. Clinical Experience: Medical experts have a significant amount of practical experience gained through clinical practice in their specific fields. They must have treated a large number of patients and encountered a wide range of medical conditions and scenarios related to their specialty. Their experience gives them a broad perspective and the ability to decide on complex cases.

C. Research and Publications: Medical experts often engage in research and scholarly activities, which may include publishing articles in medical journals, presenting at medical conferences, or contributing to the medical textbooks. Their research and publications demonstrate their expertise and ongoing engagement in their field.

It is important to note that the requirements and qualifications for being considered a medical expert may vary depending on the jurisdiction, subject matter of the case and the legal context in which their expertise is sought.

2. PROVIDING MEDICAL EXPERT OPINION

Medical expert opinions are sought in various situations where specialized medical knowledge and expertise are required to assess or provide insights on medical issues. The process of investigating a medical negligence or malpractice case can be complex and time-consuming.

Providing a medical expert opinion typically involves the following steps:

- a. Gathering information:** The first step is to gather as much information as possible about the case. This may include copy of the complaint, complainant's letter, respondent's letter, other attachments and medical records. Expert is free to look into text books, scientific literatures, case laws, precedents and other relevant materials. The experts may consider listing all the sources referred before writing their opinions.
- b. Noting the facts of the case:** The expert will present a summary of the key facts which may include a neutral and objective account of the events as per the complainant and also as per the registered medical practitioner i.e., the facts of the entire case according to the perspective of both/all the parties.
- c. Analysing the information:** Once the information regarding the facts has been gathered, it needs to be analysed to determine whether there is a case for medical negligence/malpractice. This involves considering the standard of care in the given situation and whether it was sufficient or to the extent as required, whether there is any breach of duty to take care, and whether patient's injury/damage is due to that breach to take requisite care etc.
- d. Circumstances around the incident:** The expert should make efforts to look into the circumstances around the alleged incident such as timing, location of the incident, reliable and adequate history behind the incident, availability of the human resources and the quality of available infra-structural facilities, supply of medicines, behaviour of the patient and patient's family members towards treating team and proposed treatment, distance from the higher healthcare centres, need for emergency intervention and other factors etc. All these factors are required to be considered before making assessment

of ‘degree or standard of care’ provided by the alleged medical practitioner/treating team.

e. Providing a report: Depending upon the facts and other circumstances of the case, the expert may conclude whether a case of medical negligence or of malpractice could be made out or not and accordingly, he/she will provide a report to the relevant SMC/EMRB/NMC. This report will set out the findings of the complaint and also logical explanation on the basis of which the conclusion is arrived at by the expert along with the references, if any and are available in the context of Indian settings.

f. Important points to be noted: Experts should refrain from giving verdict. They need to focus, whether the ‘requisite standard of care’ was provided or not? Was there any damage/loss/injury caused directly due to the lack of that care? Are there any other contributory factor(s) responsible for causing damage/loss/injury?

3. ATTRIBUTES OF A MEDICAL EXPERT

It is important to note that while medical experts possess extensive knowledge and skills, they are also fallible. Medicine is a complex field, and uncertainties and risks are inherent. Hence, the expert should strive to keep himself/herself updated and open for new-learning. Following attributes are essential for a medical expert to provide a rational and well-founded opinion:

i. Sound Knowledge and Experience: Medical experts profoundly understands the subject matter they specialize in. They possess comprehensive knowledge and experience of the theories, principles, concepts, and facts

relevant to their field, and in the locally relevant socio-cultural contextual setting. The experts must have accumulated significant expertise by practically applying their knowledge. They have spent considerable time working in their field, solving problems, and gaining insights contributing to their expertise.

ii. Contributions to the Field: Experts make significant contributions to their field through research, innovation, or developing new methodologies. They push the frontiers of knowledge and drive progress within their domain.

iii. Consistency and Reliability: Experts consistently demonstrate their knowledge and skills over time. Their expertise is reliable, and they can consistently deliver high-quality results or advice.

iv. Continuous Learning: Medicine is an ever-evolving field, and medical experts must understand the importance of continuous learning. They should engage in ongoing professional development, attending conferences, reading medical journals, participating in research and publications. They must stay informed about advancements in medical technology and treatment modalities and must have an updated knowledge regarding the latest innovations in the medical field, diagnostic tests and procedures etc., while giving an expert medical opinion.

v. Critical Thinking and Problem-Solving: Experts should possess the necessary skills, enabling them to evaluate information objectively, identify biases or fallacies, and make informed decisions. They can assess the strengths and weaknesses of various approaches within their field. They must excel in solving complex problems related to their domain. They are capable of analysing situations, identifying underlying issues, and provide practical solutions based on their knowledge and experience.

vi. Reputation and Recognition: Experts are recognized by their peers, colleagues, and the broader community as authorities in their fields. They often have a track record of successful contributions, publications, awards, or accolades that validate their expertise and enhances their reputation.

vii. Effective Communication: Experts can convey complex ideas and information in a simple and clear way which is easily understandable. They have excellent communication skills, enabling them to explain concepts, provide guidance, and educate others.

viii. Mentorship and Teaching: Experts often play a role in mentoring and teaching others. They can guide and inspire younger generation and those less experienced to develop their expertise.

ix. Commitment Towards Obligation/Duty: Experts must be committed towards the due discharge of their obligations and duties, especially when called as an expert, knowing that such societal obligation overrides any fiduciary relationships that they may be in, with any third parties.

x. Ethical, Moral and Professional Conduct: Medical experts must adhere to the highest standards of ethical, moral and professional conduct. They should prioritize privacy and confidentiality, honesty and integrity and should make impartial, objective and unbiased evidence-based decisions. The expert should never have been punished for moral turpitude and should bear a good moral character.

xi. Impartiality and Ability to Listen: Medical experts should demonstrate impartial attitude and conduct. Partial conduct based upon any kind of bias may be a hurdle to justice and stereotypic judgements can influence decision making. People can easily become biased or may have an unfair

preference, for small things like friendship, food, or flattery etc., which may influence the decision. Sincere efforts must be made to avoid any kind of bias or undue influence from all quarters while giving an expert opinion. Expert should have adequate experience, research and healthcare achievements and exposure, including the ability to listen and capability to give an unbiased opinion. The expert may have well rounded experience of being in an arbitration committee, ethics committee or the like.

xii. Conflict of Interest: A conflict of interest occurs when an entity or individual becomes unreliable because of a clash between personal (or self-serving) interests and professional duties or responsibilities, which often has legal implications. Most conflicts can be based upon varying considerations viz. financial or non-financial, gift issuance or acceptance, or nepotism etc. Transparency (being completely open and frank) and disclosure becomes important when dealing with cases of conflicts of interest. It is always desirable for the medical experts to be transparent and they must disclose if any kind of personal or professional interest is involved in a particular case. As they are going to be responsible and accountable for any kind of issues relating to conflict of interest in a given case, in which their expert opinion is sought, they should be very cautious and clear from the very beginning or before they undertake that particular case. In case there is any conflict of interest involved, the experts must declare it at the outset or/and they should recuse themselves from that case. Some examples and case studies depicting conflict of interest, wherein the concerned medical expert should avoid giving opinion, are as follows:

- Doctor was asked for an expert opinion regarding the side-effects of medicines manufactured by a pharmaceutical company, in which he/she was

having substantial financial interest and backing for attending medical conferences and scientific journal publications

- Expert opinion was sought from a doctor, in a case of food poisoning of the patient who had meals in a restaurant owned by the spouse of that doctor
- Medical expert opinion was sought on the authenticity and correctness of the report of a testing facility or diagnostic centre, which was owned (completely or partially) by the expert who earns financial benefits from that facility or diagnostic centre

Case Study- 1:

AB is an osteopath who runs a clinic where she also rents out few rooms to other medical practitioners. One acupuncturist XT has taken one of AB's rooms on rent and also agreed to give her 25% share of the patient fees, when working from that premises. AB frequently used to refer her patients to XT. Those referrals were influenced by the fact that she has a commercial interest in the XT seeing as many patients as possible.

Case Study- 2:

In 1999, the University of Pennsylvania conducted a trial aimed to test a gene therapy treatment for a rare metabolic disorder called Ornithine Transcarbamylase deficiency (OTC). Jesse Gelsinger was a young man who tragically lost his life during a clinical trial for gene therapy in 1999. At the time, he was 18 years old and suffering from OTC deficiency, which affects the liver's ability to process ammonia.

Gelsinger volunteered for the clinical trial at the University of Pennsylvania's Institute for Human Gene Therapy, hoping that the experimental treatment would help him and others with the same condition.

Dr. Wilson, who was one of the principal investigators held equity in the biotechnology company that owned the rights to the gene therapy technology being tested. He also had consulting agreements and stood to gain financially if the therapy received FDA approval. The researchers involved did not fully disclose all the potential risks associated with the treatment to Gelsinger or his family.

Gelsinger's condition was not as severe as initially portrayed. The researchers failed to obtain proper informed consent from Gelsinger and made procedural errors during the administration of the gene therapy. During the trial, Gelsinger experienced a severe immune response to the vector, an adenovirus and multiple organ failures, leading to his death just a few days after receiving the experimental gene therapy.

xiii. Medical Bias: Medical bias is the systematic and often unconscious prejudices or stereotypes that influence medical decision-making, treatment and outcome. Bias and discrimination may occur at both the interpersonal and the institutional level of healthcare. It can lead to lower quality healthcare among people from certain groups. As everyone has a right to receive good healthcare, regardless of personal characteristics, identities, considerations of caste, community, gender or traits etc., it is important to eliminate 'bias' in healthcare to avoid its detrimental effects. It is crucial to ensure equitable and patient-centred care for all individuals, regardless of their background or

characteristics. The bias or discrimination could be inherent to the expert or could creep in (due to external factors), but it must be ensured that it does not affect the diagnosis or treatment and is not detrimental or result into any kind of harm to any patient. Following are some examples and case studies of how ‘bias’ plays out in healthcare:

- Patients from caste-X receive fewer cardiac issues and fewer renal transplants.
- Tribal women are more likely to die after being diagnosed with breast cancer.
- Men are viewed as ‘brave’ or ‘stoic,’ when in chronic pain, but women with chronic pain are viewed as ‘emotional’ or ‘hysterical.’ Most of the doctors treat women’s pain as a product of a mental health condition, rather than a physical condition as they feel that women often exaggerate their pain.
- As transgender people face different forms of discrimination viz. interpersonal prejudice, insults, refusal of treatment, stigmatisation, discrimination, mental stress, physical aggression, sexual harassment, and abuse etc., a separate entry and queue may be provided for easy access to healthcare facilities.

Case Study-1:

A 50-year-old obese woman visits her primary care physician complaining of chest pain and shortness of breath. Despite her symptoms aligning with potential signs of a heart condition, the doctor dismisses her concerns, attributing the discomfort to anxiety, stress, and obesity. Over the next few months, her symptoms persisted and worsened, leading her to seek a second

opinion. Eighteen months later, not finding relief with her first doctor, she consulted another doctor for a second opinion. During the angiography and other investigations, the doctor suggests a bypass since he finds more than 90% block in three coronary arteries. The second doctor asked why the patient was not subjected to angiography since the symptoms were from nearly one and a half years ago. The husband of the patient is suing the primary healthcare physician for not diagnosing the condition and not referring her to a higher center despite the patient/family's insistence.

Case Study-2:

Before being diagnosed with an auto-immune disease several years ago, Tom was a skinny patient, but due to steroid treatment taken for his autoimmune condition, he gained around 25 kgs of weight in one year. The doctors failed to recognize the relationship between the auto-immune condition, his medication, and the weight gain. Instead, the doctor routinely told him to count calories as being overweight is his main problem.

Such like instances and stories of implicit biases are very common, which are based upon unconscious assumptions regarding skin colour, gender, sexual preference, or appearance etc. affecting patient care.

4. RESPONSIBILITIES OF A MEDICAL EXPERT

Medical expert plays a multifaceted role being an expert in medico-legal cases. They usually have experience of working for years in various facilities and hospitals, which enormously add to their skill and expertise. Expert opinions

are cornerstone in medical negligence cases as they provide an unbiased assessment of the standard of care exercised by healthcare professionals. They provide objective assessments of the standard of care expected from healthcare professionals, the cause of injuries and long-term impact of medical conditions etc. and also clarify the unique aspects of medical practice and evidence, which helps in arriving at an informed decision. To perform the role of a medical expert, he/she must remain independent and neutral in their discussions and reports. They must be free from any biases or prejudices and must give a fair and balanced opinion on the nature of the objective facts of the given case that lies within their expertise. They must be aware of, and clearly illustrate consideration of, alternative professional views offering a logical and reasonably held opinion on the management of that case.

Experts must have an updated knowledge in the specific medical field, for which they have been asked to give an expert opinion. They must be fully aware of the probable opposing views put forward by other side and are able to deal with it professionally. Full care, caution and consideration is required to draft an expert opinion, so that the pertinent medico-legal issues are competently addressed and form a solid basis for future discussions and decisions.

Apart from knowledge and experience in the concerned medical field, it is better to have a clear working knowledge of basic legal principles, doctrines and tests that may be applied to particular case.

A medical expert should strive to cultivate:

- a) The ability for in-depth study of documents and exhibits. The expert should have patience, be hard-working and resilient.
- b) Giving an expert opinion must be considered as a learning opportunity of having potential for self-growth through professional improvement.
- c) The expert should not harbour bias which may come in the way of interpreting the facts of the case and have an open mind.
- d) The expert should be just and fair, and also affirm that he/she does not discriminate on the basis of gender, caste, creed, religion, race or socio-economic status.

Before accepting responsibility, a medical expert may consider the following:

- i. Exact role and responsibilities of the medical expert should be defined prior to the acceptance.
- ii. The timeline and commitment expected from the expert on that particular case should be clearly spelt out.
- iii. After acceptance of the assignment, the expert must work with promptitude and adhere to the timeline.
- iv. A Confidentiality Agreement and Conflict of Interest Declaration should be signed by the medical expert upon acceptance of a particular case/assignment.

(Annexure-1).

5. RIGHTS OF A MEDICAL EXPERT

Medical experts have some rights, which are as follows:

- i. **Expert Opinions:** Experts can agree or refuse to give an expert opinion, when contacted, depending upon their preferences or schedules. They may agree to review medical cases, provide second opinions, or expert opinions in medical negligence. They can refuse to give opinion, due to some cogent reason or some issue relating to conflict of interest or otherwise.
- ii. **Professional Autonomy:** Medical experts have the right to exercise professional autonomy, which allows them to make independent decisions regarding cases allocated to them by using their experience, expertise, scientific evidence and ethical guidelines.
- iii. **Confidentiality:** Doctor and patient relationship is based upon trust, therefore, the privacy and confidentiality in healthcare has to be maintained by the medical professionals. Experts are bound by the obligation of confidentiality and they must protect patient and hospital information. This right ensures that parties in the complaints have their confidentiality protected.
- iv. **Access to Medical Records:** Experts have the right to access the relevant medical records of the cases and the care given (OPD slips, case sheets, feedback, complaints etc.). Access to accurate and detailed patient and hospital information is essential for making informed decisions.
- v. **Right to Remuneration:** Experts have the right to remuneration for discharging their professional services.

vi. **Protection from Liability:** Experts are entitled to legal protection from unwarranted lawsuits and liabilities arising from the expert opinions given by them based upon the medical records.

vii. **Liability of a Medical Expert:** In case of legal complications, the appropriate legal support should be provided to the medical expert. As the medical expert has given a *bonafide* opinion in good faith, legal expenditure, if any, must be taken care of, by the concerned SMC/EMRB/NMC.

6. ENTITLEMENTS OF A MEDICAL EXPERT

The travel and dearness allowance (TA/DA) along with the honorarium and sitting fees etc. should be given to the medical experts, commensurate to their designation and be decided by NMC similar to what is paid by various government organisations. Regarding TA/DA, the set guidelines of NMC should be followed and TA/DA fixation document be decided by EMRB for NMC. (Annexure-2)

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Part IV - Processing of Complaint and Standard Operating Procedure

1. PROCESSING OF COMPLAINT: EXAMINING & ANALYZING, PREPARING THE BRIEF & FRAMING THE OPINION

- I. **Chronology:** Chronology i.e., the time-line and sequence of events must be written so that it will give the overall situation in the present time.
- II. **Date and Time of Complaint:** Actual date and time when the complaint is received, must be noted clearly. List of all the documents and annexures received along with the complaint must also be mentioned along with that entry. The mode of receipt of complaint (by hand, by post, via email or any other) may also be specifically added.
- III. **Statement of Facts:** It must be checked that the statement of facts given in the complaint are comprehensive and complete. Since, the patient is the complainant, he may state complaints in a very generic way, and miss many specific and technical processes and procedures. Therefore, a detailed note of the documents or things required may be prepared beforehand and should be asked for, from the complainant/other party during the process of hearing which may have a bearing on the final decision to be given. In other words, it must be used as an opportunity to bring additional facts on record if the same could not have been so brought before the SMC/EMRB/NMC. All factual mistakes/ errors/ incorrect observations of the previous deciding authority must be specifically mentioned with reason, wherever possible. The correct position

of the case should be expressly mentioned. The statement of fact should however be clean and not be influenced by opinion.

IV. Grounds of appeal: The grounds of appeal represent those issues that show the nature of the dispute between the two parties. Grounds of appeal are in fact in the nature of a claim. Thus, these may be distinguished from arguments because arguments are made in support of the claim. There may be several arguments in support of a claim, but all the arguments cannot form grounds of appeal. Following factors must be kept in mind while drafting and analysing the grounds of appeal:

- a. All causes of grievance are required to be included in the grounds of appeal.
- b. Grounds of appeal should be simple, concise, and specific.
- c. Grounds of appeal should be specifically numbered.
- d. It must avoid arguments.

V. Records or exhibits to be perused, if any:

If any additional records or exhibits are produced during the appeal, the description of the same should be included in the brief.

VI. Framing opinion:

- a. An opinion is a form of legal opinion written by an expert in the course of resolving a medical dispute, it includes providing the decision reached to resolve the dispute and usually indicating the facts which led to the dispute and an analysis of the rules used to arrive at the decision.

- b. Opinion should be given point-wise on the basis of the grounds of appeal. At this stage, no new issue/matter should be taken up which was not there initially in the ground of appeal.
- c. Opinion should be given after mentioning the point of view, of both/all the parties on a certain ground of dispute.
- d. Opinion given should be, if possible, supported by the rules/regulations/law etc.

VII. **Conclusion:**

The conclusion should be a summary of the opinion with the decision on whether medical negligence has been proved or not, and if proved what has/will be the impact on the patient/relative/dependent/legal heir, which will form the ground for compensation for patient/relative/ dependent/ legal heir, and penalty to the medical professional or treating team/facility/hospital.

2. STANDARD OPERATING PROCEDURE (SOP)

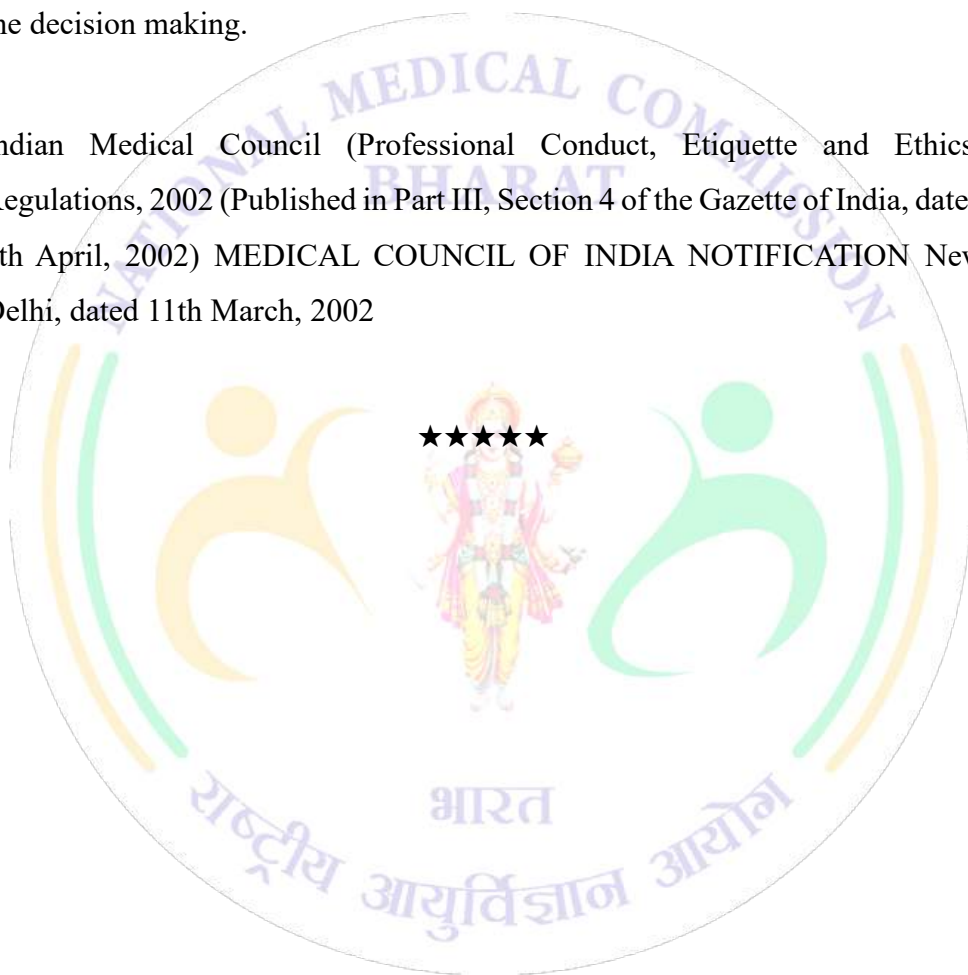
- i. When a doctor is considered to be chosen as an expert, someone from the EMRB contacts telephonically to ascertain willingness to be an expert.
- ii. Further communication is via emails. After receiving the email, an expert is expected to acknowledge receiving of such official email, and also acknowledge the receipt of the attachments, if any.
- iii. If the expert is willing to review the appeal, then he/she should promptly send willingness and consent form. If not, then should also communicate the same promptly.
- iv. The expert should give his/her opinion within specified time.

- v. The expert should mention opinion of speciality/subspecialty/ super-speciality opinion required, if any.
- vi. The expert should intimate the EMRB immediately, as soon as he/she comes to know about any conflict of interest.
- vii. The expert should give unbiased expert opinion, with reason, and without passing judgement.
- viii. The expert should attend the hearing of the case, as and when required at EMRB/NMC.
- ix. The expert is expected to also consider the point of view given by other experts.
- x. The expert is expected to empathetically consider representation by both/all the parties.
- xi. The expert is expected to maintain the dignity and honour of office during proceedings.
- xii. Dissent, if any, has to be communicated politely to the Chairman.
- xiii. If the expert has any questions to be asked to any/both/all the parties, that must be communicated through the Chairman.
- xiv. The expert must refrain from communicating any kind of intentions of either parties, either verbally or non- verbally.
- xv. The expert is expected to intimate Chairman, if at any point of time any of the parties approaches him/her.
- xvi. An expert is expected to reach a decision based on the information available. The expert is expected not to presume anything and to base the decision solely on the information available.

xvii. The committee should have at least three experts. But may have more in number but the number should be odd i.e., 5, 7, 9 etc.

xviii. The expert is expected to focus solely on the procedural aspects of the case. The outcome of the case, positive or negative, should have no bearing on the decision making.

Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (Published in Part III, Section 4 of the Gazette of India, dated 6th April, 2002) MEDICAL COUNCIL OF INDIA NOTIFICATION New Delhi, dated 11th March, 2002



Annexure – 1 Certificate on Willingness cum Conflict of Interest

दूरभाष/Phone :25367033, 25367035, 2536703

ई-मेल/E-mail: ethics@nmc.org.in

वेबसाइट/Website :www.nmc.org.in

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राष्ट्रीय आयुर्विज्ञान आयोग
NATIONAL MEDICAL COMMISSION
आचार और चिकित्सा पंजीकरण बोर्ड
ETHICS & MEDICAL REGISTRATION BOARD

WILLINGNESS CUM CONFLICT OF INTEREST

I Dr. _____ hereby inform

that I am willing to be appointed as an expert in _____

_____ and offer my comments within the prescribed time limit.

2. I also declare that I don't know the doctor, the patient or any other party in this case and have no conflict of interest in offering my expert comments.

3. I acknowledge that the existence and the terms of this Willingness Cum conflict of Interest and any oral, written information or digitalized information exchanged from EMRB with reference to the preparation of opinion shall be regarded as confidential information.

4. I shall not disclose any confidential information to any third parties, disclosure of any confidential information by me and my staff members or agencies hired by me shall be deemed disclosure of such confidential information, which I shall be held liable for breach of this Willingness Cum conflict of Interest.

(Signature)

Date: _____

Name: _____

Place: _____

Designation: _____

Name of the Institution:- _____

Department: _____

Annexure – 2 Office Order on Honorarium (sitting fee) to Subject Experts

दूरभाष/Phone : 25367033 35 36 17 41
25366650, 1800111154
ई-मेल/ E-mail: admin@nmc.org.in
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राष्ट्रीय आयुर्विज्ञान आयोग National Medical Commission (General Administration)

No. A-11013/01/2022/Gen. Misc./Accounts 001146-51 Dated: 11th January, 2023

OFFICE ORDER

Sub: Honorarium (sitting fee) to Experts engaged individually by the Commission or Boards for carrying out specific tasks including tendering expert opinion.

The committee constituted with the approval of Chairman, NMC, under the Chairmanship of President, PGMEB has conveyed their recommendation along with the minutes of the meeting was conveyed on 30.11.2022.

2. The competent authority has approved the following decisions:-
 - i.) All pending bills upto December, 2022 should be paid at the rate of Rs. 5000/- per day in line with the payment made since December, 2020 to all the experts at par Memorandum dated 24th December, 2020.
 - ii.) Honorarium (sitting fee) for physical meeting of the experts should be Rs.5000/- per day.
 - iii.) Honorarium (sitting fee) for virtual meeting of the experts should be Rs. 3000/- per day.
 - iv.) Honorarium (sitting fee) for a maximum of five days in a calendar month shall be permitted. In this regard, it is clarified that expert engaged will get fee payment for five days sitting in a calendar month. In case of special circumstances, if engagement of same expert is continued beyond 5 days, he shall not be entitled for any fee beyond five sittings in a calendar month.
 - v.) Travel, stay arrangements and food/refreshment shall be arranged/borne by the NMC in line with the Department of Expenditure guidelines as well as NMC's regulations. Travel by air shall be permitted by economy class only.
 - vi.) Professionals fee(honorarium) are taxable.
 - vii.) This Office Order shall be effective from 1.1.2023.
3. All the concerned may kindly take a note of above decisions for necessary compliance.
4. This supersedes Office Order of even no. dated 19th December, 2022.
5. This issues with the approval of the Chairman, NMC vide Dy. No. 9 dated 11.1.2023.


(Pankaj Agrawal)
Director, NMC

Copy to:-

1. PPS to Chairman, NMC, New Delhi.
2. PPS to President- PGMEB/MARB/UGMEB/EMRB.
3. Member(s)-EMRB/UGMEB/PGMEB/MARB.
4. PPS to Secretary, NMC, New Delhi.
5. Directors/DSs and USs of all Boards and NMC.
6. Guard file.

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The National Medical Commission (NMC) is India's premier regulatory body overseeing medical education and practice. Committed to upholding the highest standards in healthcare education, NMC ensures the delivery of quality medical education and training across the nation.

For more information about NMC, please visit
www.nmc.org.in



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National Medical Commission

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