

## **Charter of Patients' Rights for adoption by NHRC**

### ***Patients' rights are Human rights!***

#### **Preamble**

The Universal Declaration of Human Rights (1948) emphasizes the fundamental dignity and equality of all human beings. Based on this concept, the notion of Patient Rights has been developed across the globe in the last few decades. There is a growing consensus at international level that all patients must enjoy certain basic rights. In other words, the patient is entitled to certain amount of protection to be ensured by physicians, healthcare providers and the State, which have been codified in various societies and countries in the form of Charters of Patient's Rights. In India, there are various legal provisions related to Patient's Rights which are scattered across different legal documents e.g. The Constitution of India, Article 21, Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002; The Consumer Protection Act 1986; Drugs and Cosmetic Act 1940, Clinical Establishment Act 2010 and rules and standards framed therein; various judgments given by Hon'ble Supreme Court of India and decisions of the National Consumer Disputes Redressal Commission.

This Charter of Patient's Rights adopted by the National Human Rights Commission draws upon all relevant provisions, inspired by international charters and guided by national level provisions, with the objective of consolidating these into a single document, thereby making them publicly known in a coherent manner. There is an expectation that this document will act as a guidance document for the Union Government and State Governments to formulate concrete mechanisms so that Patient's Rights are given adequate protection and operational mechanisms are set up

to make these rights functional and enforceable by law. This is especially important and an urgent need at the present juncture because India does not have a dedicated regulator like other countries and the existing regulations in the interest of patients, governing the healthcare delivery system is on the anvil, some States have adopted the national Clinical Establishments Act 2010, certain other States have enacted their own State level legislations like the Nursing Homes Act to regulate hospitals, while a few other States are in the process of adopting / developing such regulation. The Charter of Patient's Rights has been drafted with the hope that it shall be incorporated by policy makers in all existing and emerging regulatory legislations concerning the health care sector. This charter would also enable various kinds of health care providers to actively engage with this framework of patients' rights to ensure their observance, while also benefiting from the formal codification of patients responsibilities.

Another objective of this Charter is to generate widespread public awareness and educate citizens regarding what they should expect from their governments and health care providers—about the kind of treatment they deserve as patients and human beings, in health care settings. NHRC firmly believes that informed and aware citizens can play a vital role in elevating the standard of health care, when they have guidance provided by codified rights, as well as awareness of their responsibilities.

NHRC believes that this Charter of Patients' Rights will be an enabling document to ensure the protection and promotion of Human rights of those who are among some of the most vulnerable sections of society – ordinary patients and citizens seeking health care across India.

Rights of patients	Description of rights and associated duty bearers	Reference
1 Right to information	<p>Every patient has a right to adequate relevant information about the nature, cause of illness, provisional / confirmed diagnosis, proposed investigations and management, and possible complications To be explained at their level of understanding in language known to them.</p> <p>The treating physician has a duty to ensure that this information is provided in simple and intelligible language to the patient to be communicated either personally by the physician, or by means of his / her qualified assistants.</p> <p>Every patient and his/her designated caretaker have the right to factual information regarding the expected cost of treatment based on evidence. The hospital management has a duty to communicate this information in writing to the patient and his/her designated caretaker. They should also be informed about any additional cost to be incurred due to change in the physical condition</p>	<p>1) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010</p> <p>2) MCI Code of Ethics</p> <p>3) Patients Charter by National Accreditation Board for Hospitals (NABH)</p> <p>4) The Consumer Protection Act, 1986</p>



		<p>of the patient or line of treatment in writing. On completion of treatment, the patient has the right to receive an itemized bill, to receive an explanation for the bill(s) regardless of the source of payment or the mode of payment, and receive payment receipt(s) for any payment made.</p> <p>Patients and their caretakers also have a right to know the identity and professional status of various care providers who are providing service to him / her and to know which Doctor / Consultant is primarily responsible for his / her care. The hospital management has a duty to provide this information routinely to all patients and their caregivers in writing with an acknowledgement.</p>	
<p>2</p>	<p><b>Right to records and reports</b></p>	<p>Every patient or his caregiver has the right to access originals / copies of case papers, indoor patient records, investigation reports (during period of admission, preferably within 24 hours and after discharge, within 72 hours). This may be made available wherever applicable after paying appropriate fees for photocopying or allowed to be photocopied by patients at their cost.</p>	<p><b>1)</b> Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010</p> <p><b>2)</b> MCI Code of Ethics section 1.3.2</p> <p><b>3)</b> Central Information Commission</p>

		<p>The relatives / caregivers of the patient have a right to get discharge summary or in case of death, death summary along with original copies of investigations.</p> <p>The hospital management has a duty to provide these records and reports and to instruct the responsible hospital staff to ensure provision of the same are strictly followed without fail.</p>	<p>judgment, Nisha Priya Bhatia Vs. Institute of HB&amp;AS, GNCTD, 2014</p> <p><b>4)</b> The Consumer Protection Act, 1986</p>
3	<p><b>Right to</b></p> <p><b>Emergency</b></p> <p><b>Medical Care</b></p>	<p>As per Supreme Court, all hospitals both in the government and in the private sector are duty bound to provide basic Emergency Medical Care, and injured persons have a right to get Emergency Medical Care. Such care must be initiated without demanding payment / advance and basic care should be provided to the patient irrespective of paying capacity.</p> <p>It is the duty of the hospital management to ensure provision of such emergency care through its doctors and staff, rendered promptly without compromising on the quality and safety of the patients.</p>	<p><b>1)</b> Supreme court judgment</p> <p>Parmannand Katara v. Union of India (1989)</p> <p><b>2)</b> Judgment of National Consumer Disputes Redressal Commission</p> <p>Pravat Kumar Mukherjee v. Ruby General Hospital &amp; Others (2005)</p> <p><b>3)</b> MCI Code of Ethics sections 2.1 and 2.4</p> <p><b>4)</b> Article 21 of the Constitution 'Right to Life'</p>

4	<b>Right to informed consent</b>	<p>Every patient has a right that informed consent must be sought prior to any potentially hazardous test/treatment (e.g. invasive investigation / surgery / chemotherapy) which carries certain risks.</p> <p>It is the duty of the hospital management to ensure that all concerned doctors are properly instructed to seek informed consent, that an appropriate policy is adopted and that consent forms with protocol for seeking informed consent are provided for patients in an obligatory manner.</p> <p>It is the duty of the primary treating doctor administering the potentially hazardous test / treatment to explain to the patient and caregivers the main risks that are involved in the procedure, and after giving this information, the doctor may proceed only if consent has been given in writing by the patient / caregiver or in the manner explained under Drugs and Cosmetic Act Rules 2016 on informed consent.</p>	<p>1) MCI Code of Ethics section 7.16</p> <p>2) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010</p> <p>3) The Consumer Protection Act, 1986</p> <p>4) Drugs and Cosmetic Act 1940, Rules 2016 on Informed Consent</p>
5	<b>Right to confidentiality,</b>	<p>All patients have a right to privacy, and doctors have a duty to hold information about their health condition and treatment plan in strict confidentiality, unless</p>	<p>1) MCI Code of Ethics sections 2.2, 7.14 and 7.17.</p>

<p><b>human dignity and privacy</b></p>	<p>it is essential in specific circumstances to communicate such information in the interest of protecting other or due to public health considerations.</p> <p>Female patients have the right to presence of another female person during physical examination by a male practitioner. It is the duty of the hospital management to ensure presence of such female attendants in case of female patients. The hospital management has a duty to ensure that its staff upholds the human dignity of every patient in all situations. All data concerning the patient should be kept under secured safe custody and insulated from data theft and leakage.</p>	<p><b>2)</b> Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010</p>
<p><b>6 Right to second opinion</b></p>	<p>Every patient has the right to seek second opinion from an appropriate clinician of patients' / caregivers' choice. The hospital management has a duty to respect the patient's right to second opinion, and should provide to the patients caregivers all necessary records and information required for seeking such opinion without any extra cost or delay.</p> <p>The hospital management has a duty to ensure that any decision to seek such</p>	<p><b>1)</b> Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010</p> <p><b>2)</b> The Consumer Protection Act, 1986</p>



		<p>second opinion by the patient / caregivers must not adversely influence the quality of care being provided by the treating hospital as long as the patient is under care of that hospital. Any kind discriminatory practice adopted by the hospital or the service providers will be deemed as Human Rights' violation.</p>	
7	<p><b>Right to transparency in rates, and care according to prescribed rates wherever relevant</b></p>	<p>Every patient and their caregivers have a right to information on the rates to be charged by the hospital for each type of service provided and facilities available on a prominent display board and a brochure. They have a right to receive an itemized detailed bill at the time of payment. It would be the duty of the Hospital / Clinical Establishment to display key rates at a conspicuous place in local as well as English language, and to make available the detailed schedule of rates in a booklet form to all patients / caregivers.</p> <p>Every patient has a right to obtain essential medicines as per India Pharmacopeia, devices and implants at rates fixed by the National Pharmaceutical Pricing Authority (NPPA) and other relevant authorities. Every patient has a right to receive health care services within the range of rates for procedures and services prescribed by Central and State Governments from</p>	<p><b>1) MCI Code of Ethics section 1.8 regarding Payment of Professional Services</b></p> <p><b>2) Section 9(i) and 9(ii) of Clinical establishments (Central Government) Rules 2012</b></p> <p><b>3) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010</b></p> <p><b>4) Various Drug price control orders</b></p> <p><b>5) The Consumer Protection Act, 1986</b></p>



		<p>time to time, wherever relevant. However, no patient can be denied choice in terms of medicines, devices and standard treatment guidelines based on the affordability of the patients' right to choice.</p> <p>Every hospital and clinical establishment has a duty to ensure that essential medicines under NLEM as per Government of India and World Health Organisation, devices, implants and services are provided to patients at rates that are not higher than the prescribed rates or the maximum retail price marked on the packaging.</p>	<p><b>6)</b> Drugs Price Control Order (DPCO) section 3 of the Essential Commodities Act, 1955</p>
<b>8</b>	<b>Right to non-discrimination</b>	<p>Every patient has the right to receive treatment without any discrimination based on his or her illnesses or conditions, including HIV status or other health condition, religion, caste, ethnicity, gender, age, sexual orientation, linguistic or geographical/social origins.</p> <p>The hospital management has a duty to ensure that no form of discriminatory behaviour or treatment takes place with any person under the hospital's care.</p> <p>The hospital management must regularly orient and instruct all its doctors and</p>	<p><b>1)</b> Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010</p>

9	<p><b>Right to safety and quality care according to standards</b></p>	<p>staff regarding the same.</p> <p>Patients have a right to safety and security in the hospital premises. They have a right to be provided with care in an environment having requisite cleanliness, infection control measures, safe drinking water as per BIS/FSSAI Standards and sanitation facilities. The hospital management has a duty to ensure safety of all patients in its premises including clean premises and provision for infection control. Patients have a right to receive quality health care according to currently accepted standards, norms and standard guidelines as per National Accreditation Board for Hospitals (NABH) or similar. They have a right to be attended to, treated and cared for with due skill, and in a professional manner in complete consonance with the principles of medical ethics. Patients and caretakers have a right to seek redressal in case of perceived medical negligence or damaged caused due to deliberate deficiency in service delivery.</p> <p>The hospital management and treating doctors have a duty to provide quality health care in accordance with current standards of care and standard treatment guidelines and to avoid medical negligence or deficiency in service</p>	<p>1) Clinical establishments (Central Government) Rules 2012</p> <p>2) The Consumer Protection Act, 1986</p>
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		delivery system in any form.	
10	<b>Right to choose alternative treatment options if available</b>	<p>Patients and their caregivers have a right to choose between alternative treatment / management options, if these are available, after considering all aspects of the situation. This includes the option of the patient refusing care after considering all available options, with responsibility for consequences being borne by the patient and his/her caregivers. In case a patient leaves a healthcare facility against medical advice on his / her own responsibility, then notwithstanding the impact that this may have on the patient's further treatment and condition, this decision itself should not affect the observance of various rights mentioned in this charter.</p> <p>The hospital management has a duty to provide information about such options to the patient as well as to respect the informed choice of the patient and caregivers in a proper recorded manner with due acknowledgement from the patient or the caregivers on the communication and the mode.</p>	<p>1) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010</p> <p>2) The Consumer Protection Act, 1986</p>
11	<b>Right to choose source for</b>	<p>When any medicine is prescribed by a doctor or a hospital, the patients and their caregivers have the right to choose any registered pharmacy of their</p>	<p>1) Various judgments by the National Consumer Dispute Redressal</p>



	<p>obtaining medicines or tests</p>	<p>choice to purchase them. Similarly when a particular investigation is advised by a doctor or a hospital, the patient and his caregiver have a right to obtain this investigation from any registered diagnostic centre/laboratory having qualified personnel and accredited by National Accreditation Board for Laboratories (NABL).</p> <p>It is the duty of every treating physician / hospital management to inform the patient and his caregivers that they are free to access prescribed medicines / investigations from the pharmacy / diagnostic centre of their choice. The decision by the patient / caregiver to access pharmacy / diagnostic centre of their choice must not in any ways adversely influence the care being provided by the treating physician or hospital.</p>	<p>Commission</p> <p>2) The Consumer Protection Act, 1986</p>
12	<p><b>Right to proper referral and transfer, which is free from perverse commercial</b></p>	<p>A patient has the right to continuity of care, and the right to be duly registered at the first healthcare facility where treatment has been sought, as well as at any subsequent facilities where care is sought. When being transferred from one healthcare facility to another, the patient / caregiver must receive a complete explanation of the justification for the transfer, the alternative options</p>	<p>1) Medical Council of India code of ethics section 3.6</p> <p>2) World Health Organisation – Referral Notes</p> <p>3) Various IPHS documents</p>

influences	<p>for a transfer and it must be confirmed that the transfer is acceptable to the receiving facility. The patient and caregivers have the right to be informed by the hospital about any continuing healthcare requirements following discharge from the hospital. The hospital management has a duty to ensure proper referral and transfer of patients regarding such a shift in care.</p>	
13	<p><b>Right to protection for patients involved in clinical trials</b></p> <p>Every person / patient who is approached to participate in a clinical trial has a right to due protection in this context. All clinical trials must be conducted in compliance with the protocols and Good Clinical Practice Guidelines issued by Central Drugs Standard Control Organisation, Directorate General of Health</p>	<p>1) Protocols and Good Clinical Practice Guidelines issued by Central Drugs Standard Control Organisation, Directorate General</p>

	<p>Services, Govt. of India as well as all applicable statutory provisions of Amended Drugs and Cosmetics Act, 1940 and Rules, 1945, including observance of the following provisions related to patients rights:</p> <p>a) Participation of patients in clinical trials must always be based on informed consent, given after provision of all relevant information. The patient must be given a copy of the signed informed consent form, which provides him / her with a record containing basic information about the trial and also becomes documentary evidence to prove their participation in the trial.</p> <p>b) A participant's right to agree or decline consent to take part in a clinical trial must be respected and her/his refusal should not affect routine care.</p> <p>c) The patient should also be informed in writing about the name of the drug / intervention that is undergoing trial along with dates, dose and</p>	<p>of Health Services, Govt. of India</p> <p>2) Amended Drugs and Cosmetics Act, 1940 and Rules, 1945 especially schedule Y</p> <p>3) National Ethical Guidelines for Biomedical and Health Research</p> <p>Involving Human Participants, Indian Council of Medical Research, New Delhi, 2017</p> <p>4) World Medical Assembly</p> <p>Declaration of Helsinki: Ethical Principles for Medical Research</p> <p>Involving Human Subjects available at <a href="http://www.wma.net/en/30publications/10policies/b3/17c.pdf">www.wma.net/en/30publications/10policies/b3/17c.pdf</a></p>
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	<p>duration of administration.</p> <p>d) At all times, the privacy of a trial participant must be maintained and any information gathered from the participant must be kept strictly confidential.</p> <p>e) Trial participants who suffer any adverse impact during their participation in a trial are entitled to free medical management of adverse events, irrespective of relatedness to the clinical trial, which should be given for as long as required or till such time as it is established that the injury is not related to the clinical trial. In addition, financial or other assistance must be given to compensate them for any impairment or disability. In case of death, their dependents have the right to compensation.</p> <p>f) Ancillary care may be provided to clinical trial participants for non-study/trial related illnesses arising during the period of the trial. This could be in the form of medical care or reference to facilities, as may be</p>	
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		<p>appropriate.</p> <p>g) Institutional mechanisms must be established to allow for insurance coverage of trial related or unrelated illnesses (ancillary care) and award of compensation wherever deemed necessary by the concerned Ethics Committee.</p> <p>h) After the trial, participants should be assured of access to the best treatment methods that may have been proven by the study.</p> <p>Any doctor or hospital who is involved in a clinical trial has a duty to ensure that all these guidelines are followed in case of any persons / patients involved in such a trial.</p>	
14	<b>Right to protection of participants involved in biomedical and</b>	<p>Every patient who is taking part in biomedical research shall be referred to as research participant and every research participant has a right to due protection in this context. Any research involving such participants should follow the National Ethical Guidelines for Biomedical and Health Research Involving Human</p>	<p>1) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Indian Council of Medical Research,</p>

<p><b>health research</b></p>	<p>Participants, 2017 laid down by Indian council for Medical Research and should be carried out with prior approval of the Ethics Committee.</p> <p>Documented informed consent of the research participants should be taken.</p> <p>Additional safeguards should be taken in research involving vulnerable population. Right to dignity, right to privacy and confidentiality of individuals and communities should be protected.</p> <p>Research participants who suffer any direct physical, psychological, social, legal or economic harm as a result of their participation are entitled, after due assessment, to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability.</p> <p>The benefits accruing from research should be made accessible to individuals, communities and populations whenever relevant.</p>	<p>New Delhi, 2017</p> <p>2) World Medical Assembly Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects available at</p> <p><a href="http://www.wma.net/en/30publications/10policies/b3/17c.pdf">www.wma.net/en/30publications/10policies/b3/17c.pdf</a></p> <p>3) Drugs &amp; Cosmetic Act, Rules 2016 on Clinical Trails</p>
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		Any doctor or hospital who is involved in biomedical and health research involving patients has a duty to ensure that all these guidelines are followed in case of any persons / patients involved in such research.	
15	<b>Right to take discharge of patient, or receive body of deceased from hospital</b>	<p>A patient has the right to take discharge and cannot be detained in a hospital, on procedural grounds such as dispute in payment of hospital charges. Similarly, caretakers have the right to the dead body of a patient who had been treated in a hospital and the dead body cannot be detailed on procedural grounds, including nonpayment/dispute regarding payment of hospital charges against wishes of the caretakers.</p> <p>The hospital management has a duty to observe these rights and not to indulge in wrongful confinement of any patient, or dead body of patient, treated in the hospital under any circumstances.</p>	<p>1) Prohibition of wrongful confinement under Sec. 340-342 of IPC.</p> <p>Statements of Mumbai High Court.</p> <p>2) Consumer Protection Act 1986</p>
16	<b>Right to Patient Education</b>	<p>Patients have the right to receive education about major facts relevant to his/her condition and healthy living practices, their rights and responsibilities, officially supported health insurance schemes relevant to the patient, relevant entitlements in case of charitable hospitals, and how to seek redressal of</p>	<p>1) The Consumer Protection Act, 1986</p> <p>2) Standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical</p>

		grievances in the language the patients understand or seek the education. The hospital management and treating physician have a duty to provide such education to each patient according to standard procedure in the language the patients understand and communicate in a simple and easy to understand manner.	Establishment Act 2010
17	<b>Right to be heard and seek redressal</b>	Every patient and their caregivers have the right to give feedback, make comments, or lodge complaints about the health care they are receiving or had received from a doctor or hospital. This includes the right to be given information and advice on how to give feedback, make comments, or make a complaint in a simple and user-friendly manner. Patients and caregivers have the right to seek redressal in case they are aggrieved, on account of infringement of any of the above mentioned rights in this charter. This may be done by lodging a complaint with an official designated for this purpose by the hospital / healthcare provider and further with an official mechanism constituted by the government such as Patients'	1) The Consumer Protection Act, 1986 2) NHS - Charter of Patient Rights and Responsibilities

	<p>rights Tribunal Forum or Clinical establishments regulatory authority as the case may be. All complaints must be registered by providing a registration number and there should be a robust tracking and tracing mechanism to ascertain the status of the complaint resolution.</p> <p>The patient and caregivers have the right to a fair and prompt redressal of their grievances. Further, they have the right to receive in writing the outcome of the complaint within 15 days from the date of the receipt of the complaint.</p>	
	<p>Every hospital and clinical establishment has the duty to set up an internal redressal mechanism as well as to fully comply and cooperate with official redressal mechanisms including making available all relevant information and taking action in full accordance with orders of the redressal body as per the Patient's Right Charter or as per the applicable existing laws.</p>	

**Responsibilities of patients and caretakers**

Along with promoting their rights, patients and caretakers should follow their responsibilities so that hospitals and doctors can perform their work satisfactorily.

- 1) Patients should provide all required health related information to their doctor, in response to the doctor's queries without concealing any relevant information, so that diagnosis and treatment can be facilitated.
- 2) Patients should cooperate with the doctor during examination, diagnostic tests and treatment, and should follow doctor's advice, while keeping in view their right to participate in decision making related to treatment.
- 3) Patients should follow all instructions regarding appointment time, cooperate with hospital staff and fellow patients, avoid creating disturbance to other patients, and maintain cleanliness in the hospital.
- 4) Patients should respect the dignity of the doctor and other hospital staff as human beings and as professionals. Whatever the grievance may be, patient / caregivers should not resort to violence in any form and damage or destroy any property of the hospital or the service provider.
- 5) The Patients should take responsibility for their actions based on choices made regarding treatment options, and in case they refuse treatment (not clear??).

**Recommended mechanism for implementation of Charter of Patient's Rights and Grievance redressal mechanism**



NHRC recommends to the Government of India, all State Governments and Administration of all the Union Territories that they should seriously consider the adoption of the charter and incorporate this Charter of Patients' Rights in the entire range of existing and emerging regulatory frameworks concerning the health care sector, under their jurisdiction.

Further NHRC recommends that all State Human Rights Commissions should adopt the Charter of Patients' Rights to be treated as a reference document in all cases related to human rights violations concerning patients and all users of health care services.

NHRC further recommends that all administrative and regulatory authorities completely or partially related with the healthcare sector, including but not limited to the following should incorporate and promote implementation of the Charter of Patient's Rights within their jurisdiction wherever applicable.

1. Ministry of Health and Family Welfare, Government of India
2. Public Health and Family Welfare Departments in all States and UTs
3. Medical Education Department of States and UTs, wherever they exist
4. Executive/Managing authorities of all publicly funded healthcare insurance schemes and Public-Private-Partnership arrangements in healthcare by Government of India, all State Governments and administrations in all UTs
5. National Council for Clinical Establishments
6. State Councils for Clinical Establishments, wherever applicable

7. Authorities established under State Nursing Home Acts or equivalent acts, wherever applicable
8. Medical Council of India / National Medical Commission or equivalent body
9. State Medical Councils in all States and UTs
10. Central Council of Indian Medicine
11. State Councils for Indian Medicine in all States and UTs
12. Any other healthcare related statutory councils established in all States and UTs
13. Central Consumer Protection Council, all State and District consumer protection councils
14. Registrar of Societies in all States and UTs, in the context of non-profit clinical establishments
15. Charity Commissioner in those States wherever applicable, in the context of non-profit clinical establishments
16. Department of Religious and Charitable Endowments in those States wherever applicable, in the context of non-profit clinical establishments
17. Registrar of Companies, in the context of for-profit hospitals run by companies and non-profit clinical establishments run by companies registered under Section 25
18. Central Drugs and Standard Control Organisation, Ministry of Health & Family Welfare, Government of India

19. Quality Council of India, New Delhi

20. Department of Consumer Affairs, Ministry of Consumer Affairs, Food & Public Distribution, Government of India

Once the Patients' Rights Charter has been adopted by the Govt. of India, State Governments and the Administration of the Union Territories, they may stipulate/ensure that all types of Clinical Establishments (both therapeutic and diagnostic) display this Charter prominently within their premises, orient all their staff and consultants regarding the Charter, and observe the Charter of Patients'

Rights in letter and spirit irrespective of whether such clinical establishment is owned, controlled or managed by-

- i. the Government or a department of the Government;
- ii. a trust, whether public or private;
- iii. a corporation (including a society) registered under a Central, Provincial or State Act, whether or not owned by the Government;
- iv. a privately owned enterprise;
- v. a local authority

Further, NHRC recommends to the Government of India, all State Governments and administration of Union Territories to ensure the setting up of a grievance redressal mechanism for patients, as a component of their existing or emerging regulatory frameworks for clinical establishments, by making required modifications in rules, regulations and acts where required. Observance of patients' rights and setting up of grievance

redressal mechanism for protection of these Rights should be made an integral component of the implementation of Clinical Establishment (Registration and Regulation) Act 2010 in those states who have adopted it, or as a component of state specific regulatory frameworks for clinical establishments in other states, which have equivalent state specific legislations, or are planning to enact state specific legislations to regulate clinical establishments.

NHRC recommends that Patients' rights grievance redressal mechanisms should have the following components-

1. Every clinical establishment should set up an internal grievance redressal mechanism. First, patients may file a complaint with an authorized representative who can be named 'Internal Grievance Redressal Officer' of the clinical establishment, either individually in person through an authorized representative or collectively through a consumer group or civil society organization. The clinical establishment's Internal Grievance Redressal Officer shall consider the complaint and try to find an appropriate solution, keeping in view the provisions of the Patients' Rights Charter and promptly acknowledge the receipt of the complaint within 24 hours by assigning a registration number for tracking and tracing the status of the complaint.
2. If a solution acceptable to the patient is not found at the level of the clinical establishment and the patient/representative is not satisfied, then he/she may approach the office of the district level registering authority set up under Clinical Establishment (Registration and Regulation) Act 2010 in those States who have adopted it, or equivalent district level authorities created under the State specific clinical establishments act or similar regulatory frameworks for clinical establishments in other states which have other State specific legislations. The district level registering authority shall verify the facts of the matter, and where there is clear violation of patient's



rights as brought out facts, the registering authority may issue necessary executive orders to the clinical establishment for rectification.

If there is any dispute over interpretation of Charter of Patient's Rights and provisions in the regulatory framework, the registering authority may clarify the procedure, rules, regulations and attempt to resolve the complaint through mediation between both parties within 30 days from the date of receipt of the appeal.

3. In case of any particular complaint, if even after completing the above mentioned procedure, the patient or his/her representative is not satisfied, then he/she can file appeal before the State Council of Clinical Establishments under Clinical Establishment (Registration and Regulation) Act 2010 in those states who have adopted the Act. Section 8(5)(e) empowers the 'State Council for Clinical Establishments' to hear appeals against the orders of the District Registering Authority set up under CEA 2010. 'State Council of Clinical Establishment' can set up a three or five member sub-committee / cell (with multi-stakeholder participation) which can be named as 'Healthcare Grievance Redressal Authority' for resolution of patient's grievances, and pass rectification orders or disciplinary orders or punitive orders which would be binding upon the clinical establishments within the framework of CEA within 30 days from the date of receipt of the appeal. The complaints procedure to be set up under the State Council of Clinical Establishments should explicitly state that it is not intended as a means of achieving monetary compensation.

4. Apart from the above mentioned grievance redressal mechanisms, patients/representatives would always be free to approach the State Medical Council to seek disciplinary action against unethical conduct of any specific doctor, and also free to approach Consumer Forums at

various levels to seek financial compensation, or approach Civil/Criminal Courts keeping in view the nature of the complaint i.e., creation of a separate grievance redressal machinery to deal with violations of Patients' Rights Charter shall in no way either extinguish or affect adversely the existing legal remedies both civil and criminal available to patients and their caregivers under the existing legal framework.

