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

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. 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. Right to records Every patient or his caregiver has the right to access originals / copies of case 1) Annexure 8 of standards for 2 and reports indoor patient records, investigation reports (during period of Hospital level 1 by National Clinical papers, admission, preferably within 24 hours and after discharge, within 72 hours). This Establishments Council set up as may be made available wherever applicable after paying appropriate fees for per Clinical Establishment Act 2010 2) MCI Code of Ethics section1.3.2 photocopying or allowed to be photocopied by patients at their cost. 3) Central Information Commission

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

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

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

		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.	
7	Right to	Every patient and their caregivers have a right to information on the rates to be	1) MCI Code of Ethics section
	transparency in	charged by the hospital for each type of service provided and facilities available	1.8 regarding Payment of Professional
	rates, and care	on a prominent display board and a brochure. They have a right to receive an	Services
	according to	itemized detailed bill at the time of payment. It would be the duty of the	2) Section 9(i) and 9(ii) of Clinical
	prescribed rates	Hospital / Clinical Establishment to display key rates at a conspicuous place in	establishments (Central
	wherever relevant	local as well as English language, and to make available the detailed schedule of	Government) Rules 2012
		rates in a booklet form to all patients / caregivers.	3) Annexure 8 of standards for
		Every patient has a right to obtain essential medicines as per India	Hospital level 1 by National Clinical
		Pharmacopeia, devices and implants at rates fixed by the National	Establishments Council set up as
		Pharmaceutical Pricing Authority (NPPA) and other relevant authorities. Every	per Clinical Establishment Act 2010
		patient has a right to receive health care services within the range of rates for	4) Various Drug price control orders
		procedures and services prescribed by Central and State Governments from	5) The Consumer Protection Act, 1986
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		time to time, wherever relevant. However, no patient can be denied choice in	6)	Drugs Price Control Order (DPCO)
		terms of medicines, devices and standard treatment guidelines based on the		section 3 of the Essential
		affordability of the patients' right to choice.		Commodities Act, 1955
		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.		
8	Right to non-	Every patient has the right to receive treatment without any discrimination	1)	Annexure 8 of standards for
	discrimination	based on his or her illnesses or conditions, including HIV status or other health		Hospital level 1 by National Clinical
		condition, religion, caste, ethnicity, gender, age, sexual orientation, linguistic or		Establishments Council set up as
		geographical /social origins.		per Clinical Establishment Act 2010
		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.		
		The hospital management must regularly orient and instruct all its doctors and		

		staff regarding the same.		
9	Right to safety and	Patients have a right to safety and security in the hospital premises. They have a	1)	Clinical establishments (Central
	quality care	right to be provided with care in an environment having requisite cleanliness,		Government) Rules 2012
	according to	infection control measures, safe drinking water as per BIS/FSSAI Standards and	2)	The Consumer Protection Act, 1986
	standards	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.		
		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		
			<u> </u>	

		delivery system in any form.		
10	Right to choose	Patients and their caregivers have a right to choose between alternative	1)	Annexure 8 of standards for
	alternative	treatment / management options, if these are available, after considering all		Hospital level 1 by National Clinical
	treatment options	aspects of the situation. This includes the option of the patient refusing care		Establishments Council set up as
	if available	after considering all available options, with responsibility for consequences		per Clinical Establishment Act 2010
		being borne by the patient and his/her caregivers. In case a patient leaves a	2)	The Consumer Protection Act, 1986
		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.		
		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.		
11	Right to choose	When any medicine is prescribed by a doctor or a hospital, the patients and	1)	Various judgments by the National
	source for	their caregivers have the right to choose any registered pharmacy of their		Consumer Dispute Redressal

	obtaining	choice to purchase them. Similarly when a particular investigation is advised by		Commission
	medicines or tests	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	2)	The Consumer Protection Act, 1986
		personnel and accredited by National Accreditation Board for Laboratories		
		(NABL).		
		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.		
12	Right to proper	A patient has the right to continuity of care, and the right to be duly registered	1)	Medical Council of India code of
	referral and	at the first healthcare facility where treatment has been sought, as well as at		ethics section 3.6
	transfer, which is	any subsequent facilities where care is sought. When being transferred from	2)	World Health Organisation –
	free from perverse	one healthcare facility to another, the patient / caregiver must receive a		Referral Notes
	commercial	complete explanation of the justification for the transfer, the alternative options	3)	Various IPHS documents

	influences	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.	
		In regard to all referrals of patients, including referrals to other hospitals,	
		specialists, laboratories or imaging services, the decision regarding facility to	
		which referral is made must be guided entirely by the best interest of the	
		patient. The referral process must not be influenced by any commercial	
		consideration such as kickbacks, commissions, incentives, or other perverse	
		business practices.	
13	Right to protection	Every person / patient who is approached to participate in a clinical trial has a	Protocols and Good Clinical
	for patients	right to due protection in this context. All clinical trials must be conducted in	Practice Guidelines issued by
	involved in clinical	compliance with the protocols and Good Clinical Practice Guidelines issued by	Central Drugs Standard Control
	trials	Central Drugs Standard Control Organisation, Directorate General of Health	Organisation, Directorate General
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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:

- 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.
- 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.
- The patient should also be informed in writing about the name of the drug / intervention that is undergoing trial along with dates, dose and

- of Health Services, Govt. of India

 2) Amended Drugs and Cosmetics Act,
- 1940 and Rules, 1945 especially schedule Y
- 3) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Indian Council of Medical Research, New Delhi, 2017
- 4) World Medical Assembly
 Declaration of Helsinki: Ethical
 Principles for Medical Research
 Involving Human Subjects available
 at

www.wma.net/en/30publications/
10policies/b3/17c.pdf

duration of administration.

- 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.
- 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.
- f) Ancillary care may be provided to clinical trial participants for nonstudy/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

		appropriate.		
		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.		
		h) After the trial, participants should be assured of access to the best		
		treatment methods that may have been proven by the study.		
		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.		
14	Right to protection	Every patient who is taking part in biomedical research shall be referred to as	1)	National Ethical Guidelines for
	of participants	research participant and every research participant has a right to due protection		Biomedical and Health Research
	involved in	in this context. Any research involving such participants should follow the		Involving Human Participants,
	biomedical and	National Ethical Guidelines for Biomedical and Health Research Involving Human		Indian Council of Medical Research,

	1.1		l	N D II : 2017
h	nealth research	Participants, 2017 laid down by Indian council for Medical Research and should		New Delhi, 2017
		be carried out with prior approval of the Ethics Committee.	2)	World Medical Assembly
				Declaration of Helsinki: Ethical
		Documented informed consent of the research participants should be taken.		Principles for Medical Research
		Additional safeguards should be taken in research involving vulnerable		Involving Human Subjects available
		population. Right to dignity, right to privacy and confidentiality of individuals		at
		and communities should be protected.		www.wma.net/en/30publications/
				10policies/b3/17c.pdf
		Research participants who suffer any direct physical, psychological, social, legal	3)	Drugs & Cosmetic Act, Rules 2016
		or economic harm as a result of their participation are entitled, after due		on Clinical Trails
		assessment, to financial or other assistance to compensate them equitably for		
		any temporary or permanent impairment or disability.		
		The benefits accruing from research should be made accessible to individuals,		
		communities and populations whenever relevant.		

		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	Right to take	A patient has the right to take discharge and cannot be detained in a hospital,	1)	Prohibition of wrongful
	discharge of	on procedural grounds such as dispute in payment of hospital charges. Similarly,		confinement under Sec. 340-342 of
	patient, or receive	caretakers have the right to the dead body of a patient who had been treated in		IPC.
	body of deceased	a hospital and the dead body cannot be detailed on procedural grounds,		Statements of Mumbai High Court.
	from hospital	including nonpayment/dispute regarding payment of hospital charges against	2)	Consumer Protection Act 1986
		wishes of the caretakers.		
		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.		
1.5	Bishing Ballani		4)	The Common Part of the Art 4000
16	Right to Patient	Patients have the right to receive education about major facts relevant to	1)	The Consumer Protection Act, 1986
	Education	his/her condition and healthy living practices, their rights and responsibilities,	2)	Standards for Hospital level 1 by
		officially supported health insurance schemes relevant to the patient, relevant		National Clinical Establishments
		entitlements in case of charitable hospitals, and how to seek redressal of		Council set up as per Clinical

		grievances in the language the patients understand or seek the education.		Establishment Act 2010
		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.		
17	Right to be heard	Every patient and their caregivers have the right to give feedback, make	1)	The Consumer Protection Act, 1986
	and seek redressal	comments, or lodge complaints about the health care they are receiving or had	2)	NHS - Charter of Patient Rights and
		received from a doctor or hospital. This includes the right to be given		Responsibilities
		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'		

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.

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.

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.

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.