

EXTRAORDINARY
GOVERNMENT



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G A Z E T T E

KHYBER PAKHTUNKHWA

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KHYBER PAKHTUNKHWA HEALTH CARE COMMISSION

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NOTIFICATION

Dated: 5th April, 2016

No. HCC/4532/4. In exercise of the powers conferred by the section 31 of the Khyber Pakhtunkhwa Health Care Commission Act, 2015, the Khyber Pakhtunkhwa Health Care Commission has been pleased to approve it's below mentioned regulation in its 6th meeting dated 30.03.2016 held at main Khyber Pakhtunkhwa Health Care Commission office:

KHYBER PAKHTUNKHWA HEALTH CARE COMMISSION CONDUCT OF BUSINESS REGULATIONS 2016

- (1) Regulation of Procedures.
- (2) Registration and Licensing Regulations.
- (3) Complaint Management and Patients' Rights Regulations.
- (4) Human Resource Management Regulations.
- (5) Financial Regulations.

ANNEXURE-A

Health Care Commission Services Regulations 2016.

ANNEXURE-B

ADOPTION BY THE COMMISSION, OF HEALTH CARE STANDARDS, PROCUREMENT RULES AND LAWS /RULES RELATED TO THE HEALTH CARE SYSTEMS

Sd/-x-x-x
Chief Executive Officer/Secretary,
Khyber Pakhtunkhwa Health Care
Commission.

Acronyms

CEO	Chief Executive Officer
CFO	Chief Financial Officer
DFID	Department for International Development, UK
DOH	Department of Health
HCC	Health Care Commission
HCE	Health Care Establishment
HRA	Health Regulatory Authority
HRM	Human Resource Management
HSRU	Health Sector Reform Unit
IMR	Infant Mortality Rate
JD	Job Description
KP	Khyber Pakhtunkhwa
KPHCC	Khyber Pakhtunkhwa Health Care Commission
LHW	Lady Health Workers
MSDS	Minimum Standards of Service Delivery
TRF+	Technical Resource Facility+
U5MR	Under 5 Mortality Rate

3. COMPLAINTS MANAGEMENT AND PATIENTS' RIGHTS REGULATIONS COMPLAINT MANAGEMENT SYSTEM

1. **Complaint Management System.** (1) The Commission shall have a Complaints Management System under the Directorate of Complaints Management and Patients' Rights for receiving, managing and resolving complaints, submitted to it, or such matters as are taken up by the Commission on its own, or as per the provisions of the Act, for welfare of the public, with a view to protect public interest and/or improving healthcare services.
 - (2) The Members of the Commission may constitute a Committee on Complaints Management and Patients' Rights, if needed.
 - (3) All the Healthcare Establishments shall have their own complaint management system as prescribed by the Standards and the Reference Manual.
 - (4) The Commission may provide technical support to facilitate Healthcare Establishments in establishing their complaint management system, in the light of the Reference Manual.
 - (5) The Director of the Directorate of Complaints Management and Patients' Rights or his appointee shall be the Competent Authority to provide decisions in view of the recommendations received from the Complaints Management Committee or the Case Workers, as the case may be, after recording the reasons in writing, on the complaints received.
 - (6) The aggrieved party, Complainant or the Healthcare Establishment, as the case may be, may appeal to the Members of the Commission, if not satisfied with the decision.
 - (7) The aggrieved party may, within thirty days from the date of communication of the order of the Commission, prefer an appeal in writing to the District and Sessions Judge.
2. **Registration of a Complaint.** (1) An aggrieved person shall first make a Complaint to the concerned Healthcare Establishment in line with the Complaint Management System as established under sub-rule 3 of the Rule 44 of these regulations.
 - (2) If the Complaint of the aggrieved person is not addressed by the concerned Healthcare Establishment within thirty (30) days from the date of submission of the complaint, the Aggrieved person may make a Complaint to the Commission as provided in the Act.
 - (3) Every Complaint should be accompanied by an affidavit, bearing signature or the thumb impression, as the case may be, and it should be duly notarized or attested by an authorized member of the staff of the Commission. The Affidavit should clearly indicate that the information provided in the Complaint are true to the best knowledge of the Complainant; no suit, appeal or any proceedings are pending in any court of competent jurisdiction regarding the complaint; no allegation in the Complaint is made without reasonable and justifiable ground(s) and without any malicious intent to defame, harass, embarrass and/or pressurize the party complained against.
 - (4) Every Complaint shall also be accompanied by a copy of the National Identity Card, address of the aggrieved person, Medical records (if any), correspondence with the concerned Healthcare Establishment (if any) and other documents in support of the Complaint.
 - (5) In case the Complaint is proved to be false, the Complainant shall be liable to pay fine, which may extend to two hundred thousand (Rs. 200,000/-).
 - (6) The Khyber Pakhtunkhwa Healthcare Commission shall not entertain the complaint if:

- (a) It is not accompanied by the requisite affidavit as elaborated in these regulations.
- (b) The complaint is anonymous or pseudonymous;
- (c) The Complaint is time barred under sub-rule 2 of the Rule 45;
- (d) The subject matter is sub-judice before a court of competent jurisdiction on the date of receipt of the complaint;
- (e) The subject matter of the Complaint does not fall within the purview of the Act.

3. Receipt and Registration of the Complaint. (1) The Commission after receiving the Complaint shall review it to decide on its maintainability in accordance with the Act and these regulations. If the Complaint is maintainable, the Directorate of Complaints Management and Patient's Rights shall issue acknowledge receipt to the Complainant and notices to the party (ies) complained against.

4. Scope of Complaints. (1) The Commission may accept a Complaint regarding medical negligence, maladministration, malpractice or failure in provision of the healthcare services in accordance with the Act and these regulations.

(2) A Healthcare Service Provider or Healthcare Establishment may be declared guilty of medical negligence on one of the following two findings:-

- (a) The Healthcare Establishment where a Healthcare Service Provider renders services does not have the requisite human resource and equipment which it professes to have possessed; or
- (b) The Healthcare Service Provider or any of his associates do not possess the skills that they claim to possess, or they fail to exercise reasonable competence while rendering Healthcare Services.

(3) The recognized and known complications of a medical or surgical treatment are not considered as medical negligence.

(4) A complaint may be rejected in limine if the same is incompetent and/or is not maintainable under the Act and these regulations, or does not require any other investigation for any other reason in view of the Competent Authority.

(5) If the complaint has been rejected by the Competent Authority under sub-rule 4 of the Rule 47, the Complainant, may within thirty (30) days from the date of the receipt of the decision of the Competent Authority, being other than the Members of the Commission, may file a Representation before the Members of the Commission challenging the same.

(6) The decision of the Members of the Commission on the Representation shall be final.

5. Severity of Complaint. (1) The severity of an act of medical negligence, maladministration, malpractice, or any other act or omission that resulted in compromised healthcare service will be categorized as:

- (a) Severe – which has resulted in or contributed to the death of the patient;
- (b) Moderate – which has resulted in or contributed to the permanent loss of function or a part of body;

- (c) Mild – which has resulted in or contributed to the temporary loss of function of a part of body, or it has delayed the process of recovery from a medical condition

(2) The Commission after ascertaining the severity of a Complaint as per provision in the sub-rule 1 of the Rule 48 of these regulations, may penalise the aggrieved Healthcare Establishment as below:

- (a) For cases of severe and moderate nature due to gross negligence – A fine which may extend up to one million Rupees (Rs. 1,000,000/-) and/or Closure of Healthcare Establishment or both with reference to the professional bodies for taking action under their rules/regulations and laws

In cases where criminal negligence has been proved, the matter may also be referred for criminal proceedings under the PPC and CrPC (existing judicial system) :

- (b) For cases of moderate nature/moderate negligence – A fine which may extend up to five hundred thousand Rupees (Rs. 500,000/-) and/or Closure of Healthcare Establishment.
- (c) For cases of mild nature/mild negligence – A fine which may extend up to five hundred thousand Rupees (Rs. 500,000/-).

6. Competent Authority for handling the complaints. (1) The following will be the competent authority in each type of complaint:

- (a) For cases of severe and moderate nature – the competent authority will be the Director Complaints and Patients' Rights.
- (b) For cases of moderate nature – the competent authority will be the Additional Director Complaints and Patients' Rights.
- (c) For cases of mild nature – the competent authority will be the Assistant Director Complaints and Patients' Rights.

(2) The Competent Authority will dispose of a complaint by issuing a quasi-judicial speaking order, based on the principles of natural justice.

(3) The Competent Authority may seek help and advice from the Panel of Experts, depending on the type of the complaint, as the case may be. The Panel of Experts will provide non-binding advice in writing to the Competent Authority.

(4) The Competent Authority will be supported by Case Workers who will be permanent employees of the Commission and will be qualified professionals from the discipline of relevance to the operations of the Commission.

(5) The Case Workers will report to the Director of Complaints and Patients' Rights who will assign them to work on different cases of complaints for supporting the Competent Authority from time to time.

7. General Welfare of the Public. (1) When the Commission is of the view that it would be in Public interest to probe or look into any instance or allegation, involving any of the Healthcare Establishment(s) or any such matter as provided for under the Act, or the Rules/regulations, which affects or relates to or may affect or relate to the general welfare of the public, as the case may be, it may itself, or direct any Competent Authority to do the needful.

(2) The Commission shall in all such matters take the same as Complaint and shall issue Notices to all the concerned parties directing them to submit their written response to the issue at hand.

8. Complaint Handling. (1) For probing into a Complaint through its Complaints Management and Patients' Rights system, the Competent Authority may do it itself or entrust it to a Case Worker.

(2) If necessary, the Case Worker may call for an initial meeting with the Complainant for clarity of facts and for the purposes of requiring him to provide any document or information in the possession/knowledge of the Complainant.

(3) If the Case Worker concludes after initial meeting with the Complainant that in view of the facts and circumstances of the matter, or the evidence placed on record, there is some other issue which also needs to be looked into by the Commission, he/she may put up a separate note to the Competent Authority in this regard, while stating the reasons for doing so, and if approved by the said authority, the particulars of the allegation or the facts on which they are based shall be added.

9. Response from Party(ies) complained against. (1) In response of every complaint registered, a written response shall be asked from the party(ies) complained against to be filled within ten (10) working days from the date of notice issued to them, in this regard.

(2) A copy of the Complaint along with all its record, if any, shall also be sent with the Notice calling for a written response.

(3) A party complained against shall also file an affidavit, which must include, amongst other assertions, in support of its response, where appropriate, the following information to the effect that:

- (a) The statements made in the response are true to the best knowledge and belief of the said party;
- (b) If any suit, appeal, or any other proceedings in connection with the subject matter of the Complaint are pending before any court of competent jurisdiction or not; and
- (c) The said party undertakes to keep the Commission informed of the its address and contact details and shall regularly attend the dates fixed for hearing by the Commission and understands that if it absents itself, for no sufficient reason despite three consecutive notices, or wilfully delays the proceedings of the Commission, then he/she shall be liable to pay the costs as awarded by the Commission and that the Commission shall decide Complaint as per the governing law;

10. Hearing of Complaints. (1) The concerned party(ies) shall be served Notice for the purpose of hearing by the Case Worker or the Competent Authority, as the case may be.

(2) Summoning orders may be issued to the Complainant and the party(ies) complained against along with their witness(es).

(3) The Competent Authority may after hearing all the concerned parties, order a joint hearing and decision of such complaints which are against the same Healthcare Establishment or relate to same or similar allegations against one or more Healthcare Establishments, provided that the same shall not, in view of the Competent Authority, prejudice the case of any of the said parties.

(4) Prior to administering oath, every witness shall be informed that the statement is to be recorded in writing and that it shall be read over to him in the language that he understands. On confirmation of the statement as recorded in writing, the witness shall put his signatures or thumb impression on the written statement, as the case may be.

(5) The evidence placed on the record shall become the property of the Commission.

(6) Every party shall have the right to ask questions from the witness(es) of the other parties.

(7) The Case Worker or the Competent Authority may ask any question from any of the party or the witnesses or the Expert(s) for the purposes of deciding the issue involved in the matter.

11. Inspection. (1) If necessary an inspection team may visit the Health Care Establishment or the concerned area including but not limited to, for the following purposes:

- a. collect evidence(s); or
- b. inspect any apparatus, appliance, equipment, instrument, product, goods or item used or found in, or any practice or procedure being carried out at the Healthcare Establishment; or
- c. take sample(s) for evaluation; and/or
- d. make sketch(es) or take photographs.

12. Consultation with Expert(s): (1) Opinions of the Expert(s) may be obtained whenever considered necessary by the Competent Authority.

(2) As many Experts as may be considered necessary by the Competent Authority may be engaged on such terms and conditions, as deemed appropriate for carrying out the purposes of the Act and these regulations.

(3) The Expert(s) so appointed shall disclose his/her conflict of interest, if any, to the Competent Authority, as soon as he/she is appointed. If there is any conflict of interest, the Competent Authority shall appoint any other Expert(s), as the case may be, from the relevant field.

(4) The expert opinion submitted to the Competent Authority shall be communicated to all the parties to the complaint.

(5) If any of the parties to the complaint are not satisfied with the expert opinion, it may either, submit his/her questions in writing to the Competent Authority for clarification by the same Expert(s) who provided the opinion, or apply to the Competent Authority to present the matter to other Expert(s) for second opinion. In such a situation where a party apply to the Competent Authority for a second opinion, shall be liable to pay for the fee for the Expert(s) as determined by the Competent Authority.

(6) The Competent Authority, after having gone through the clarifications provided by the Expert(s), for reasons recorded in writing, may seek a second opinion in such a case. If the Competent Authority decides to have a second opinion in such a situation, then the party who submitted the written questions for clarification from the Expert(s), shall not be liable to pay for the second opinion.

(7) At the end of the written opinion of the Expert(s), there must be statement that:

- (i) the Expert(s) understands his/her duty to the Competent Authority; and
- (ii) he/she have complied with that duty.

(8) In case there are difference of opinions between the Experts providing first and second opinion, the Competent Authority may direct that a joint meeting is held between the Experts, for the purpose to identify and discuss expert issues involved in the proceedings; and where possible, reach an agreed position on those issues.

(9) Following the discussion between the Experts, they must submit a statement to the Competent Authority showing those issues on which they agree; and those issues on which they disagree and summary of their reasons for their disagreement.

(10) The Competent Authority may appoint an Expert or panel of experts it deems necessary in cases where the disagreements between the Experts are of serious nature, in order to resolve the controversy. The opinion of such an Expert or panel of experts shall be final.

13. Confidentiality of the Information. It shall be the duty of all involved in any proceedings pending before the Commission to keep all the information brought before the Commission including but not limited to the details of the proceedings of the Commission, confidential.

14. Powers to pass Interim Orders. (1) Where in view of the allegations contained in the Complaint, the Competent Authority may pass including but not limited to, any of the following Interim Orders, ex-parte, while recording the reasons thereof, in view of the facts and circumstances of the matter, in order to protect the public interest and for achieving the purposes of the Act;

- (a) issue orders of restraint;
- (b) issue directions to the Provincial Government;
- (c) issue directions to the Healthcare Establishment;
- (d) issue any directions to any other authority within the scope of the Act;
- (e) pass any conditional orders relating to the manner in which the healthcare services are being delivered or to improve the healthcare delivery system at any given Healthcare Establishment;
- (f) Communicate with the Pakistan Medical and Dental Council (PMDC), Council for Homeopathy, Council for Tibb, Pakistan Nursing Council or any other authority competent to handle the matter and to assist the Commission in deciding the matter, in the larger Public Interest.

(2) The Competent Authority may also further direct that any of the Interim Orders so passed by it may be for a particular period/duration of time or that the same be implemented within a particular time frame and that a report to be submitted before it regarding the compliance of the same.

(3) The Competent Authority shall have the powers to issue, amend, alter, affirm or revoke any Interim Orders after hearing all the parties concerned in the matter, after due Notice.

15. Disposal of the Complaint. The investigation of a Complaint/Case, as the case may be, shall on the orders of the Competent Authority, be closed in any one or more situations as detailed below:

- (a) The Complaint is not maintainable as per the provisions in the sub-rule 6 of the Rule 45 of these regulations;
- (b) The complaint was found incompetent or proved false;

- (c) The Complainant fails to provide evidence and/or record, in his possession, required to decide the Complaint within stipulated period of time or extension thereof;
- (d) The Complainant fails to attend hearing(s) despite issuance of three (3) consecutive notices issued at the address as stated in the Complaint or any new address duly provided by him to the Commission;
- (e) The Complaint is withdrawn by the Complainant during the course of investigation with the approval of the Competent Authority;
- (f) Where decision of the Complaint is declared by the Competent Authority;
- (g) Where the subject matter of the Complaint has already been adjudicated upon by a Court of Competent jurisdiction and there are no further steps required to be taken by the Competent Authority under the Act;
- (h) Where the Competent Authority comes to the conclusion that such steps have been directed to be taken by the Healthcare Establishment for compliance thereof and that no further action is required on the part of the Commission, in the Public Interest.

16. Report by Case Workers. (1) In all instances where a Complaint/Case is proposed to be closed or where the investigation is completed, the Case Worker shall present a comprehensive Report to the Competent Authority for any of the following:

- (a) To pass such orders as it may deem fit and appropriate in the facts and circumstances of the case;
- (b) To present the case to the Complaints Management and Patients' Rights Committee constituted by the Members of the Commission for its recommendations, further instructions or the decision, if needed.

(2) The Complaints Management and Patients' Rights Committee if so desires or on the instructions of the Members of the Commission may order a case to be re-investigated and may also summon and hear parties in a meeting.

17. Decision on Cases/Complaints. (1) The Competent Authority shall decide all the matters after recording reasons in writing.

(2) All the final decisions are to be taken by the Complaints Management and Patients' Rights Committee, through a process of voting.

The appeal against the decision of complaints management and patients' right committee will be made to the members of the commission, while the ultimate appeal against the judgement of HCC will be to the districts and session judge in accordance with the Act.

(3) All decisions shall be communicated to the parties to the Complaint and such other persons as directed by the Competent Authority, in such form or manner as deemed appropriate by the Commission.

Offence: (a) Reference section 28 of the Act, Practice of Quackery is a non-bailable and cognizable offence. Quackery done by a person who does not qualify otherwise any provision of the Act shall be punished as explained in the Act. The said cases will be referred to first class magistrate for criminal proceedings.

KHYBER PAKHTUNKHWA GOVERNMENT GAZETTE, EXTRAORDINARY, 12th JULY, 2016. 51

18. Executive Authorities to aid the Commission. All executive authorities shall aid the Commission pursuant to the provisions in the Section 27 of the Act, for:

- (i) Compliance of the decision or any order issued by the Competent Authority
- (ii) Investigation and inspection in respect of any Complaint; and
- (iii) Any other action required to be taken under Rules /regulations or the Act.