International Institute of Health Management Research (IIHMR)

NEW DELHI

HIT 709 - Regulatory Aspects in Healthcare IT

Sept-2022 **Total Marks 70**

Long Questions (10 marks each, do any 4) **10 x 4 = 40 marks**

1. What is HIPPA? What are the essential components of compliance to HIPAA?
2. What is medical consent? What are the types of consent? When is consent not required?
3. What is a medical device? How are medical devices classified? What is the most common eHealth Device? Give examples of eHealth Devices.
4. What is a medical record? What is the importance of medical records? What are active and inactive health records? What are the retention periods for medical records in India?
5. What is Pharmacovigilance and how is it implemented in India?
6. What do you understand by medical negligence? What are the elements of medical negligence? What are the types of medical negligence?

Write Short Notes on the following (5 marks each, do any 4) **5 x 4 = 20 marks**

1. Major laws that apply to Pharmacy shop and their compliance.
2. Contract Act and rules
3. Laws governing Biomedical Research
4. PCPNDT Act & its Compliance
5. BMW Act & Rules
6. Disaster Management Act & its compliance

Multiple Choice Questions (1 mark each) **1 x 10 = 10 marks**

a. Medico Legal Case files have to be preserved for
   i. 2 years
   ii. 5 years
   iii. 10 years
   iv. permanently

b. Indian Code of Medical Ethics
   i. Allows Euthanasia
   ii. Allows signing of certificates
   iii. Allows a doctor to advertise his services
   iv. Allows a doctor to sell medicines to the public

c. Electronic record management must include (all except)
    i. Tracking and storing records
    ii. Appropriate classification of the records
    iii. Retention and purging polices / procedures
    iv. User access charges
d. HIPAA was necessitated by
    i. Medical / healthcare insurance
    ii. Patient demand
    iii. Software vendors
    iv. Demand from Medical staff
e. Digital health data is ownership belongs to
    i. Healthcare institution collecting the data
    ii. Software and Server companies
    iii. Government
    iv. Individual patient whose data is captured
f. Clinical nomenclature is most commonly based on
    i. PACS
    ii. ICD
    iii. SNOMED - CT
    iv. DICOM
g. Medical Devices Rules 2017
    i. Is meant to restrict use of medical devices
    ii. Was issued under the Drugs and Cosmetics Act, 1940
    iii. Is meant to make use of medical devices easier
    iv. Places an unnecessary burden on the medical devices industry
h. Consent is not required for
    i. Minor surgery
    ii. Local anaesthesia
    iii. Recording of videos / photographs for training
    iv. Psychiatric examination / treatment under court orders
i. HITECH Act covers all the following except
    i. Hacking with computer systems
    ii. Breach of confidentiality
    iii. Offences committed outside India involving Indian networks
    iv. Infringement of copyright laws
j. The laws governing the safety of the patient in a hospital include
    i. Explosive Act 1884
    ii. Food Safety and Standards Act 2006
    iii. Environment Protection Act 1986
    iv. All of the above