

**Post Graduate Diploma in Management (Hospital & Health Management)**  
**PGDM – 2022-24 Batch**

**Term – 2<sup>nd</sup> Year - 4<sup>th</sup> Term Examinations**

Course & Code	: Regulatory Aspects in Digital Health & Cyber Security-HIT 709	Reg. No.	:
Term & Batch	: IV, 2022-24	Date	: October 06, 2023
Duration	: 3 Hrs.	Max. Marks	: 70

**Instructions:**

- Budget your time as per the marks given for each question and write your answer accordingly.
- Don't write anything on the Question Paper except writing your Registration No.
- Mobile Phones are not allowed even for computations.

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

**10 x 4 = 40 marks**

1. What is medical consent? What are the types of consent? What are the components of a proper medical consent?
2. What constitutes medical negligence? How to prevent it? What are the remedies to the aggrieved person who has suffered due to medical negligence?
3. What is HIPAA? What is PHI and what are its permitted disclosures and uses? What measures are required to implement HIPAA compliance?
4. Write about biomedical waste act and its implementation?
5. Write about Indian Contract Act and its implications in healthcare/
6. Write about medical device and their classification. How are medical devices controlled and regulated in India?

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

**5 x 4 = 20 marks**

1. Medical Ethics
2. PCPNDT Act
3. Medical Records
4. Telemedicine
5. Software as a medical device
6. HIS

**Multiple Choice Questions (1 mark each)**

**1 x 10 = 10 marks**

- a. HITECH Act
  - i. Requires patients to be notified of any unauthorised access or disclosure of their data
  - ii. Specifies the eHealth standards to be followed
  - iii. Makes to compulsory for healthcare institutions to maintain all health records in digital format
  - iv. Physicians & hospital must pay the govt for using eHealth data

**Contd...2..**

- b. Digital Health record management must include (all except)
  - i. Tracking and storing records
  - ii. Appropriate classification of the records
  - iii. Retention and purging policies / procedures
  - iv. User access charges
- c. Digital health data ownership belongs to
  - i. Healthcare institution collecting the data
  - ii. Software and Server companies
  - iii. Government
  - iv. Individual patient whose data is captured
- d. Consent is required for all the following except
  - i. Minor surgery
  - ii. Local anaesthesia
  - iii. Recording of videos / photographs for training
  - iv. Psychiatric examination / treatment under court orders
- e. 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
- f. Biomedical Waste Rules specify the following colours of waste bins
  - i. Red & Yellow
  - ii. Green & Blue
  - iii. Red, Yellow, Blue, White and Black
  - iv. Red, Yellow, Green, Blue and Black
- g. Medico Legal Case files have to be preserved for
  - i. 2 years
  - ii. 5 years
  - iii. 10 years
  - iv. permanently
- h. SaMD examples include
  - i. Smart watch
  - ii. Diabetic Monitoring System
  - iii. AI Radiology
  - iv. All of the above
- i. eHealth Systems Include
  - i. wearable devices
  - ii. Mobile Health
  - iii. Telemedicine
  - iv. All of the above
- j. Hospital Information system uses include
  - i. Administrative
  - ii. Financial
  - iii. Clinical
  - iv. All of the above