

**Post Graduate Diploma in Management (Hospital & Health Management)****PGDM – 2023-25 Batch****2<sup>nd</sup> Year – 3<sup>rd</sup> Semester End Examination**

<b>Subject &amp; Code</b>	<b>: Regulatory Aspects in Digital Health and Cyber Security- HIT 709</b>	<b>Reg. No.:</b>
<b>Semester &amp; Batch</b>	<b>: III, 2023-25</b>	<b>Date : 17-10-2024</b>
<b>Time &amp; Duration</b>	<b>: 10:30 A.M.-01:30 P.M. (3 Hrs.)</b>	<b>Max. Marks : 70</b>

**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.

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**Part A: Q.1 to Q.10 all questions are compulsory (10 X 2 Marks = 20 Marks)**  
**One liner, MCQs, True/False**

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1. When we say software is eating the world. What does it mean?
  - a) Increased role of software in everything we do
  - b) Software is not important anymore
  - c) Software is the root cause of all problems
2. What is CIA?
  - a) Confidentiality, Integrity and Availability
  - b) Confidentiality, Intuition and Accessibility
  - c) Central Investigation Authority
3. Digital Signing is an example of ?
  - a) Confidentiality
  - b) Integrity
  - c) Authority
4. What should be the top most priority for any healthcare organisation?
  - a. Cyber security
  - b. Data privacy
  - c. Patient Safety
  - d. Business

5. Which of the following is NOT a purpose of HIPAA?
- To prevent abuse of information in health insurance and healthcare.
  - To establish continuous healthcare coverage for patients who are switching jobs.
  - To better manage protected health information.
  - All of the above are purposes of HIPAA
6. In which cases can a facility legally share patient information?
- When working with other members of a patient's healthcare team to determine best treatment options.
  - A facility is never allowed to share patient information.
  - When making a legally mandated report or disclosure.
  - A and C
7. How many chapters are there in NABH Digital Health Standards?
- 6
  - 7
  - 8
  - 9
8. When IT and Data processing is Outsourced to Third Party vendors, the responsibility of Data security will
- Still belong to of the hospital
  - Will now belong to the vendor
  - Be that of the Hospital IT manager or whoever has signed the contract.
  - All the above.
9. The proposed DISHA Act is similar to?
- HL7
  - SNOMED CT
  - HIPAA
10. Digital therapeutics and digital health tool are one and the same True or False? \_\_\_\_\_

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**Part B: Q.11 to Q.15 attempt any four questions (4 X 5 Marks = 20 Marks)**

**Short Notes**

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- Explain how digital therapeutics can help in disease outcome?
- Block chain as a digital security tool. Explain how it can benefit healthcare?
- Reducing adverse drug events is a must for patient safety. How do you envisage pharmacovigilance can help?
- What are the digital health standards that NABH include for managing medication in a hospital?
- What are the challenges related to medical device regulation in India.

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**Part C: Q.16 to Q.20 attempt any three questions (3 X 10 Marks = 30 Marks)**  
**Long Notes**

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16. The human papillomavirus (HPV) is one of the most common sexually transmitted infections and is linked to six different cancers, including vulvar, vaginal, anal, penile, oropharyngeal, and cervical. The Centers for Disease Control and Prevention (CDC) recommends HPV vaccination for everyone between the ages of 9 and 26 years. Barriers to HPV vaccination are diverse and are often framed by religious objections and medical mistrust. Factors influencing vaccination decisions include pain, fear, risk, parental and social influence. Social media platforms, such as TikTok, Facebook, and Instagram, facilitate the creation of online communities, offering users opportunities to interact with one another. Misinformation on social media has been found to contribute to vaccine hesitancy, potentially impacting HPV vaccination rates.

How do you propose to address this issue?

17. RXY a digital health company has teamed up with a Pharma giant to address the pain points of breast cancer through digital therapeutics. Pain, nausea, anxiety, lack of understanding of the treatment, and lack of adherence to treatment are the key pain points. Also, very often, the feeling of being alone, not being fully connected with the care team. They are proposing to roll out the product in India after obtaining regulatory approval. Highlight the steps to be taken by the organization to get a regulatory approval in the country.

18. Beta care is a 250 bedded hospital providing geriatric care to the patients. The hospital is planning for a digital transformation to provide quality care to its patients. Suggest some areas where the hospital should target to get accreditation regarding use of digital technology.

19. Tuskan medical college is a premier medical institution catering to a footfall of 15000 patients daily. Recently there was a cyber security related issue faced by the hospital. Two analysts were sacked from the job owing to their negligence. Attackers lurked in the hospital's systems for over 24 hours before the hack, planning their attack. Once they found an administrator account, they could use, they escalated their privileges and pivoted quickly from system to system. Luckily, no data was accessed or acquired, only corrupted or encrypted. The management had set up an enquiry committee and now plans to revamp its entire cyber security under the leadership of a cyber security expert. How will you ensure the cyber security for the hospital as an cyber security expert.

20. Mrs Whitaker was almost completely blind in her right eye since the age of 9. She consulted with Dr Rogers, an ophthalmic surgeon who advised that he could perform surgery on the eye that would improve its appearance and restore significant sight to it. After the operation, not only did Mrs. Whitaker's right eye not improve, she developed inflammation in her left eye, which led to a loss of sight in her left eye. Mrs. Whitaker then sued Dr Rogers in the Supreme Court of New South Wales for damages for medical negligence. Mrs. Whitaker was successful and was awarded over \$800,000.00 in damages. What does this case refer to? How could such happenings be avoided?