HHP Law Firm.

Client Alert

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Indonesia: Key updates on medical devices provision

In brief

On 2 March 2023, Indonesia's Minister of Health enacted Minister of Health Regulation on Maintenance of Medical Devices in Healthcare Facilities ("**MOH Regulation 15/2023**"). Under the new regulation, healthcare facilities of hospitals, local governments or communities are required to allocate certain amount of budget to carry out medical device maintenance. This new requirement is aimed to ensure the availability of medical devices that meet service standards and requirements for quality, security, benefits, safety and feasibility of use in healthcare facilities, and to ensure the safety of users, patients and the environment in healthcare facilities.

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Key takeaways

MOH Regulation 15/2023 features a new scope and requirements for medical device maintenance. We summarize the key provisions below.

1. **Scope of medical device maintenance activities**

   Every medical device used in healthcare facilities must meet service standards and requirements for quality, security, benefits, safety and feasibility of use. To meet these standards and requirements, healthcare facilities must implement medical device maintenance.

   Medical device maintenance in healthcare facilities include the following activities:

   a. Stock-taking: Data recording on all medical devices inventory in the healthcare facilities that will be scheduled for maintenance.

   b. Promotive maintenance: Activities that are meant to provide instructions for the use or operation of medical devices in the healthcare facilities.

   c. Function monitoring/inspection maintenance: Activities that are related to the monitoring on the function of each medical device that will be used or operated.

   d. Preventive maintenance: Activities that are related to cleaning, lubrication, replacement of parts and accessories that have to be replaced within a certain time period.

   e. Corrective/repair maintenance: Activities that are related to the repair of mild to heavy damage (overhaul).

2. **Financing for medical device maintenance activities**

   Under Article 8 of MOH Regulation 15/2023, healthcare facilities are required to spend at least 4% of the value of medical device assets on maintenance per year.

3. **Recordation and reporting of medical device maintenance activities**

   Medical devices maintenance in hospitals is organized by hospital-owned medical device maintenance units, either in the form of installation, unit, division, or dedicated field in the hospital tasked with medical device maintenance ("**Hospital MD Maintenance Unit**"). In addition to Hospital MD Maintenance Unit, MOH Regulation 15/2023 also allows hospitals to also seek out outsourced help from medical device maintenance unit owned by regional governments or from third party service

provider companies. In the latter's case, we presume it will also include medical device wholesalers providing after-sales services to hospitals, and not exclusively open for pure maintenance service providers.

In Hospital MD Maintenance Units must maintain a record and report on the implementation of their maintenance activities every six months through the application for facilities, infrastructure and medical devices managed by the Ministry of Health (i.e., ASPAK (kemkes.go.id)).

The above mentioned record and report must at least contain the following information:

a. Type of medical devices.

b. Number of medical devices.

c. Condition of medical devices.

Conclusion

MOH Regulation 15/2023 requires healthcare facilities to implement medical device maintenance activities in the form of inventory, promotional maintenance, function monitoring/inspection maintenance, preventive maintenance and corrective maintenance to ensure the quality of the medical devices being used. In implementing MOH Regulation 15/2023, healthcare facilities are required to conduct routine maintenance on medical devices (and to record and report such maintenance) every six months. The relevant minister, governors and regents/mayors supervise and provide guidance on the implementation of medical device maintenance in accordance with their authority.

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