Discovering the Possibilities

What Vendors Need to Know About HTM

....But Don't

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Introduction

20+ years in the healthcare technology management (HTM) industry with extensive experience in operations, sales, marketing, and strategic planning.

- **Currently President of Heidi Horn HTM Consulting LLC**
- **Treasurer of the AAMI Board of Directors**
- **Vice President of HTM at SSM Health** for 13 years – system-wide responsibility for HTM at 22 hospitals – managed $35M in annual expenses and 120 HTM employees.
- **Executive at Nuvolo** (a CMMS software provider) for 4 years as its VP of Healthcare Industry Solutions and VP of Healthcare Marketing Strategy.

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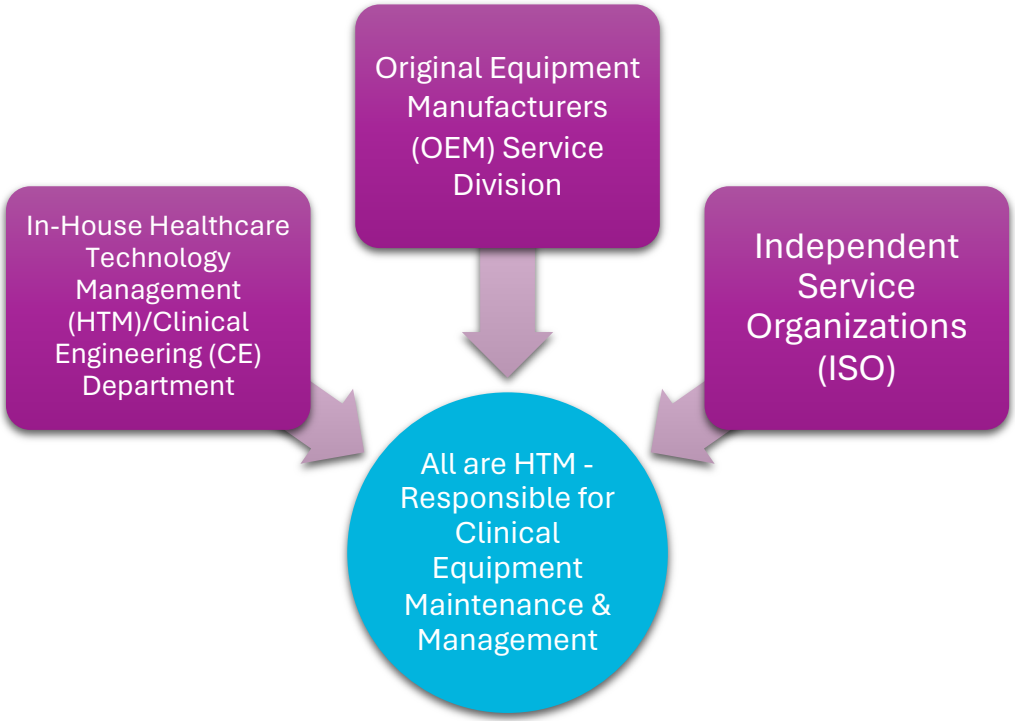
Objectives of Presentation:

Vendor participants will learn:

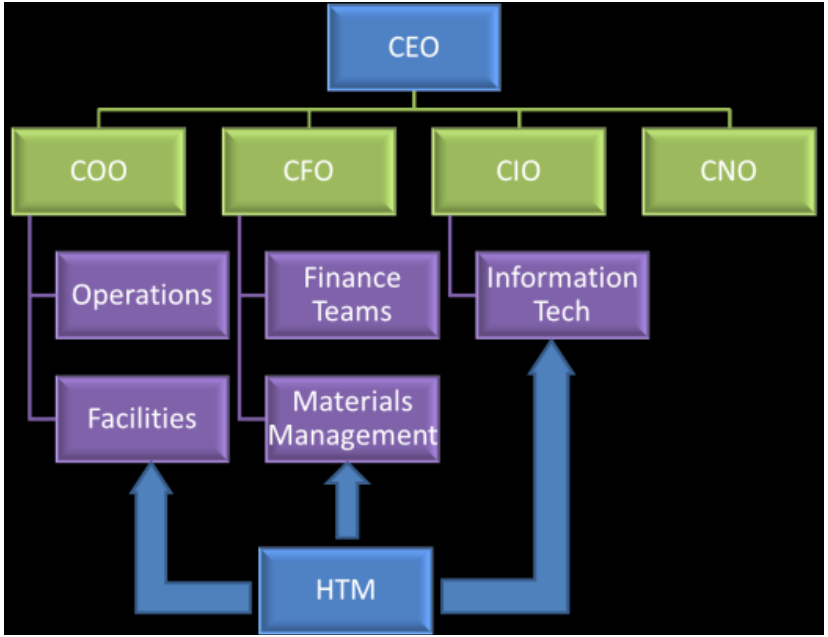
- What are the priorities of your HTM customers and what keeps them up at night?
- Understanding the different sophistication levels within the HTM industry.
- Understanding HTM's responsibilities and culture.
- How to build trust and rapport with your HTM customers.
- Words and acronyms you must understand when talking to your HTM customers (the appendix of this presentation contains a glossary of common HTM words and acronyms).

Who Is Healthcare Technology Management (HTM)?



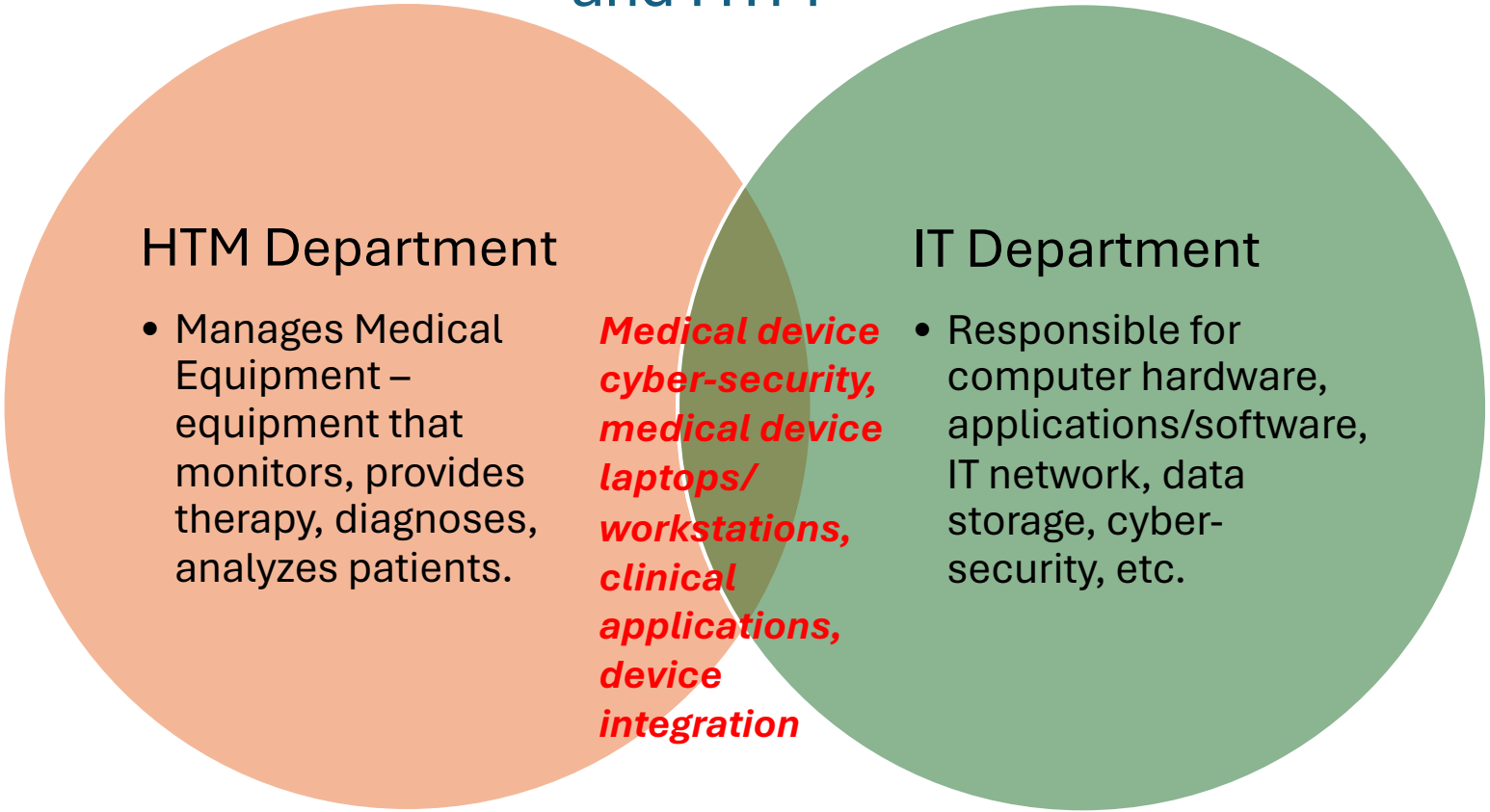
Priorities for All HTM Providers

- Ensure the safety, security, and reliability of the medical equipment they manage.
- Repair equipment as quickly as possible so that it's available for patient use.
- Control labor, parts, service contract, overhead, and capital costs.
- Ensure regulatory compliance of the medical equipment.
- Promote high employee and internal/external customer satisfaction.
- Provide expertise on medical equipment-related projects, such as capital planning, network integrations, renovations, etc.



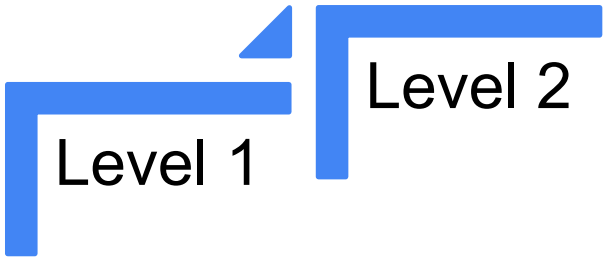
For hospital-employed HTM departments, their priorities are impacted by their reporting structure.

Many Products Require Support From Both Healthcare IT and HTM



Hospital Employed HTM Sophistication Levels

Each level manages the responsibilities all levels below them.



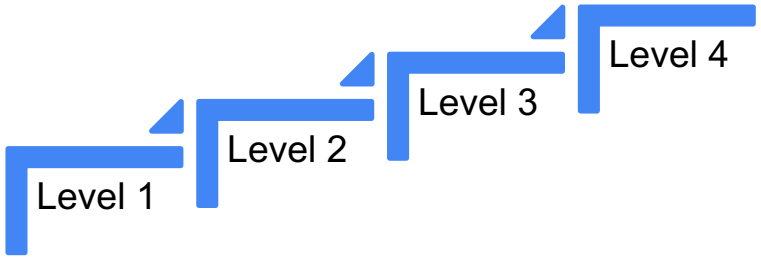
Level 1

- Only maintains non-imaging/non-lab equipment (aka biomedical equipment). Responsible for biomedical equipment regulatory compliance. Do not use data very often in decision-making.

Level 2

- Maintains and manages most equipment (including imaging equipment) in-house and manages the service vendors' service quality. Responsible for all medical equipment regulatory compliance.

Hospital Employed HTM Sophistication Levels



Level 3

- Manages all clinical equipment maintenance budgets for the hospital, inclusive of in-house labor, service contracts, and non-contracted labor and parts. Negotiates and manages equipment service contracts. Utilizes basic data analytics for some decision-making.

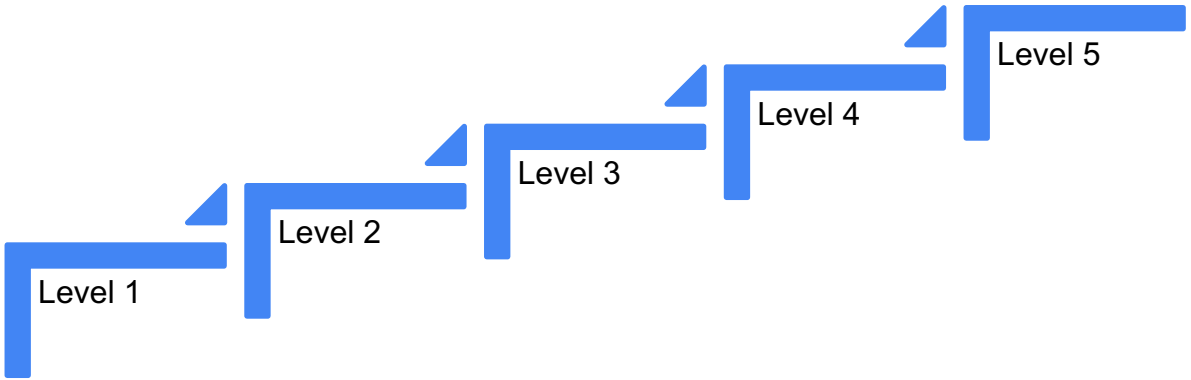
Level 4

- Responsible for medical device cybersecurity and HTM/IT hybrid projects, i.e. device integration, device server management, some clinical applications. Utilizes clinical engineers. Participates regularly as a SME in equipment purchasing evaluations.

Hospital Employed HTM Sophistication Levels

Level 5

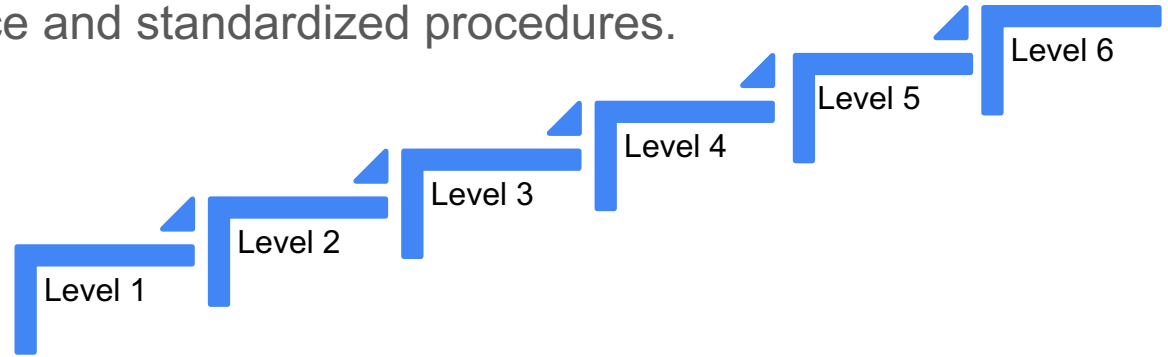
- Participates as a decision-maker in capital equipment purchasing process. Negotiates with vendors on equipment purchases. Uses data analytics extensively in decision-making.



Hospital Employed HTM Sophistication Levels

Level 6 (highest level)

- “Owns” all medical equipment-related responsibilities. They are the key decision-makers (versus contributors) in all medical equipment-related projects, but also responsible for: helping to decide which departments get clinical equipment capital; provide asset management reports regularly to C-suite; involved with strategic planning of new equipment needs and markets; develop equipment workflows for clinical users. Will have centralized governance and standardized procedures.



Responsibilities and Skills of People in the HTM Department

A Day in the Life of an HTM Director/VP and HTM Manager

Has department meeting/huddle with his/her team to share info and answer questions.

Reviews service contracts and evaluates equipment for purchase

Attends project, budget, strategy, capital and EOC meetings.

A Day in the Life of an HTM Director/VP and HTM Manager (cont.)

Meets with service vendors to address equipment issues

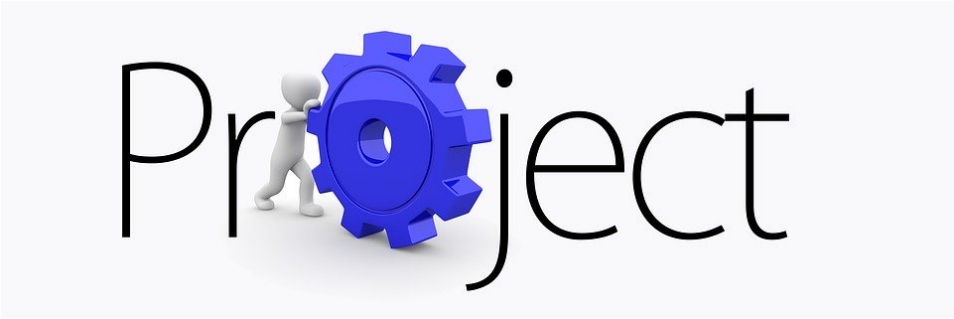
Addresses technician questions and concerns throughout the day

Rounds in hospital(s) to hear clinician feedback and concerns

Meets with multiple vendors to negotiate and discuss contracts and support

A Day in the Life of an HTM Director/VP and HTM Manager (cont.)

Reviews department performance and regulatory compliance in CMMS



Works on projects they are managing/implementing

Meets with various hospital leaders to provide updates and address medical device-related concerns

HTM Technicians and other HTM Support Functions

- **Biomedical Equipment Technician (BMET) –** is a technician trained to maintain clinical equipment (usually non-imaging). Typically, the training includes electronics, mechanical and basic physiology, as well as some IT and networking training. BMETs usually maintain non-imaging equipment (aka **biomedical equipment**). While some organizations have titled their BMETs "clinical engineers", officially, the title "clinical engineer" is reserved for degreed engineers who perform more planning, analyzing, and engineering responsibilities.
- **Certified Biomedical Equipment Technicians (CBET) -** some HTM organizations – but not many – require their BMETs to be certified. This requires them to take a test to prove their competency and take courses every year to maintain their accreditation.

HTM Technicians and other HTM Support Functions (cont.)

- Different levels of BMETs:
  - **BMET I** – is usually an entry level BMET with less than two years of experience. They will typically work on less complicated equipment.
  - **BMET II** – typically are generalists and maintain a broad range of equipment.
  - **BMET III** – depending on the organization, this will be the more senior BMETs or those with specialized skills or both.
  - **BMET Lead Tech** – Not all organizations have Lead Techs, but those that do use them to coordinate the maintenance work within the HTM department. They help the HTM manager in providing non-HR related supervisory support, i.e. assigning corrective and planned maintenance work to other technicians. They usually also are working technicians themselves.

HTM Technicians and other HTM Support Functions (cont.)

- **Field Service Equipment Specialists** – often have other titles. They tend to specialize on certain equipment types – usually higher-end equipment (i.e. imaging equipment) and often travel between hospitals and even regions. Many organizations add “Senior” to the title of their specialists who work on the high-end equipment (i.e. CTs, MRIs, linear accelerators).

HTM Technicians and other HTM Support Functions (cont.)

- **Clinical Engineers** – are often mistakenly thought of as BMETs, but true clinical engineers have a college degree (often an advanced degree in clinical or biomedical engineering) and assist the organization with clinical equipment project planning, pre-sales product analysis and comparison, provide the bridge role between HTM and IT on device integration work, are responsible for data analytics, and performance measurement, and often provide other high-level skill sets (i.e. device cyber-security, device end user work flow analysis, etc.). Only more sophisticated HTM organizations employ true clinical engineers.

- More sophisticated HTM organizations also may have **contract managers, equipment buyers, parts purchasers, business analysts, medical device cyber-security analyst and Computerized Maintenance Management System (CMMS) administrators.**

Factors Impacting the HTM Department

- **Shrinking hospital net income** and hospital-wide budget cuts.
- **Increasing pressure to control clinical equipment maintenance costs** while parts and service labor costs increase.
- More demand from hospital leadership for **medical device data and the ability to measure program performance** (i.e. equipment utilization, maintenance cost, regulatory compliance, staff productivity, cost of ownership, etc.).
- Medical device **cyber-security** needs (and often a lack of understanding how to solve this problem).
- **Shortage in HTM industry labor pool**. A large percentage of people will be retiring this decade. Hard to find qualified people.
- **New and different skill**s are now being required from these roles than in the past: IT knowledge, ability to budget, strategize, motivate, manage projects, provide business analytics, etc. Not everyone in HTM has these skills.

The HTM Culture

- “Get ‘er done” work philosophy - don’t have much patience for departments that may try to slow them down with “red tape processes” (i.e. IT department).
- They have LONG memories and will hold a grudge.
- Data entry seen as a necessary evil (if they can take short-cuts, they will). The fewer keystrokes, the better.
- Deep sense of pride in the work they do. Believe they are an integral part of providing quality patient care (which they are).
- In general, may resist change (especially if the team is older).
- The profession is slowly becoming more “white collar.”

Building Positive Relationships with HTM

- Don’t make it difficult to get answers or support.
- Don’t force your HTM customers to work with a herd of people from your company. Companies (especially large ones) should have a single point of contact that can help navigate support within your corporation.
- Salespeople, don’t think your work is done once the sale is made.
- Don’t say your product can do something it can’t and keep your promises. Remember….long memories.
- Respond quickly to requests – this is healthcare.
- Understand the priorities and challenges of your HTM prospects and deliver solutions that make their jobs easier and better.
- And…..

Don’t Be This Person at an HTM Meeting

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Q&A

Appendix A
Common Terms and Acronyms Used in HTM

- **AEM**: Alternative Equipment Maintenance – AEM is an acronym created by The Joint Commission (TJC). Most medical devices require some planned maintenance (PM) to prevent failures and ensure it is still safe to use. The equipment manufacturers detail their recommended PM activities and frequencies in their service manuals. CMS and TJC require all imaging devices, lasers and new asset types to follow the manufacturers' PM guidelines/frequencies. However, all other clinical devices can be put on an Alternative Equipment Maintenance (AEM) plan from the manufacturers service manual if a proper review occurs to ensure the AEM will not negatively impact the performance of the equipment. If a hospital is not performing every PM task in the manufacturer's service manual at the specified frequencies, by definition, it is on an AEM. TJC requires the hospital to document its evaluation allowing the device to be on an AEM and identify in CMMS that the device is on an AEM.

- **AAMI** (pronounced Amy) - **The Association for the Advancement of Medical Instrumentation (AAMI)** is the not-for-profit trade association that provides voluntary standards and guidelines supporting safe medical devices. AAMI often provides guidelines that interprets CMS and Joint Commission regulations and offers best practices to operationalizes them.

- **American College of Clinical Engineers (ACCE):** ACCE is another trade association for HTM professionals. It's smaller than AAMI and its membership tends to be HTM leadership and actual clinical engineers (versus BMETs and technicians).

- **Biomed Department:** the official industry name is Healthcare Technology Management (HTM)), but many hospitals still call the department that maintains and manages the clinical equipment by the name of CES or Biomedical/Biomed.

- **Biomedical Equipment Technician (BMET) –** is a technician trained to maintain clinical equipment. Typically, the training includes electronics, mechanical and basic physiology, as well as some IT and networking training. BMETs usually maintain non-imaging equipment (aka **biomedical equipment**). Some – but not many – organizations require their BMETs to be **Certified Biomedical Equipment Technicians (CBET)**, which requires them to take a test to prove their competency and take so many courses a year to maintain their accreditation. However, most do not make certification mandatory. While some organizations have titled their BMETs "clinical engineers", officially, the title "clinical engineer" is reserved for people who perform more planning, analyzing and engineering responsibilities (see below). There are different levels of BMETs:
    - **BMET I** – is usually an entry level BMET with less than two years of experience. They will typically work on less complicated equipment.
    - **BMET II** – typically are generalists and maintain a broad range of equipment.
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- **Clinical Engineers** – are often mistakenly thought of as BMETs, but true clinical engineers have a college degree (often an advanced degree in clinical or biomedical engineering) and assist the organization with clinical equipment project planning, pre-sales product analysis and comparison, provide the bridge role between HTM and IT on device integration work, are responsible for data analytics and performance measurement, and often provide other high-level skill sets (i.e. device cyber-security, device end user work flow analysis, etc.). Only more sophisticated HTM organizations employ true clinical engineers, but if they have them, they may be involved in product analysis and implementation. In some hospitals, BMETs mistakenly use the title clinical engineer.

Common Healthcare Terms & Acronyms (cont.)

- **CES**: Clinical Engineering Services. The official industry name is Healthcare Technology Management (HTM)), but many hospitals still call the department that maintains and manages the clinical equipment by the name of CES or Biomedical/Biomed.
- **CM**: Corrective Maintenance. This is work to repair something that is broken.
- **CM/PM**: Corrective Maintenance/Planned Maintenance
- **CMMS**: Computerized Maintenance Management System. CMMS is the software HTM teams use to manage the medical equipment inventory and work.
- **CMS: The Centers for Medicare & Medicaid Services (CMS)** is a federal agency within the United States Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid, the Children's Health Insurance Program (CHIP), and health insurance portability standards.
  - Most hospitals get a significant amount of income from Medicare and Medicaid patients.
  - CMS has standards it requires hospitals to meet in order to receive these funds. The Joint Commission (TJC) surveys and accredits hospitals to make sure they are adhering to these standards.
  - In addition to these programs, CMS has other responsibilities, including administering provisions from the Health Insurance Portability and Accountability Act of 1996 (HIPAA),
- **COE**: Center of Excellence
- **DNV GL-Healthcare** and the **American Osteopathic Association** are the other agencies - but much less common than Joint Commission - that accredit for CMS.
- **ECRI Institute** (pronounced EK-ree) - is an independent nonprofit organization that provides standards, best practices and services to improve practices and products in support of safe and cost-effective care. Many hospitals contract with ECRI to provide them with standardized equipment type identification and to provide a centralized resource for medical equipment safety alerts and recalls.
- **EOC: Environment of Care:** Are the Joint Commission standards that cover the building or space - including how it is arranged - and the special features that protect patients, visitors, and staff. Also includes clinical equipment and equipment used to support patient care or to safely operate the building or space. Many hospitals have an EOC committee to monitor and govern adherence to EOC regulations.
- **ERP** – Enterprise Resource Planning application – in a hospital setting, this usually describes the software the hospital uses for purchasing supplies and capital, tracking expenses, paying invoices, and other financial transactions. An ERP also may have an HR, marketing, strategic planning function. Common ERP's are Lawson, SAP, Workday.
- **Field Service Equipment Specialists** – another common technician in the HTM field. They often have other titles. They tend to specialize on certain equipment types – usually higher end equipment (i.e. imaging equipment) and often travel between hospitals and even regions. Many organizations add "Senior" to the title of their specialists who work on the high-end equipment (i.e. CTs, MRIs, linear accelerators). It is not unusual for the Imaging Specialists to have a different supervisor than the BMETs. They may also sometimes report directly to the Radiology Department. It's worth noting that Sr. Imaging Equipment Specialists are in extreme high demand and are paid accordingly ($100k+). Their opinion will carry a lot of weight in the department.

Common Healthcare Terms & Acronyms (cont.)

- **FDA:** The US Food and Drug Administration (FDA) monitors medical device alerts/recalls and patient incidents involving medical devices. A typical hospital will have dozens of medical device safety alerts and recalls every year impacting hundreds of devices. It is not unusual for the FDA to have an unplanned inspection after an alert or recall has occurred to verify the hospital has responded to it.
- **FSR: Field Service Report** – an FSR is the report that a vendor technician will provide the hospital after they complete maintenance work. It will include what the reported problem was, the work they completed to resolved the problem, their hours and travel time, parts used and cost. The FSR or its information needs to be entered into the CMMS.
- **HTM:** (the official industry name is **Healthcare Technology Management** (HTM)), but many hospitals still call the department that maintains and manages the clinical equipment by the name of CES or Biomedical/Biomed.
- **HL7:** Set of international standards for transfer of clinical and administrative data between software applications used by various healthcare providers.
- **Initial Inspection** – The Joint Commission requires all new clinical devices to undergo an initial inspection before it is put into use to ensure it is safe to use and working as intended. This is performed during the onboarding process and requires an initial inspection work order to document it took place.
- **IR**: Internal Requisition
- **Independent Service Organization (ISO)/Third Party** - ISOs can be large, national organizations - like TriMedx, Crothall and Sodexxo – or small local "mom and pop" organizations that provide general HTM services or specialize on specific device types (i.e. ultrasounds, anesthesia, etc.). Hospitals may contract with these organizations to maintain and manage all of their clinical equipment or just some locations or asset types. In order to be competitive, ISOs typically tend to cost less than OEM service.
- **The Joint Commission**, aka **TJC**, aka JCAHO (pronounced JACO) aka JCO - is a not-for-profit organization that creates its own regulations and standards – known as Elements of Performance (EPs) – in support of CMS' regulations and accredits hospitals so that they can receive Medicare and Medicaid reimbursement.
  - The TJC EPs that cover medical equipment and Facilities are in the **Environment of Care (EOC)** sections of the TJC standards. Note there are many other EPs a hospital must adhere to that do not directly impact the HTM or Facilities departments (i.e. Infection Prevention).
  - Approximately 22,000 hospitals, ambulatory care, nursing care, behavioral health, home care and laboratory services facilities in the United States contract with TJC to accredit them on behalf of CMS so that they can receive Medicare and Medicaid reimbursements. This is about 91% of all healthcare providers. Note: if a healthcare provider isn't receiving federal reimbursements for Medicare/Medicaid patients, they do not need to participate in accreditation programs. However, they still will be regulated by the state and other regulatory bodies.
  - TJC will conduct planned surveys at its accredited facilities every 3 years and unplanned surveys if there is a complaint or a significant patient event occurs at the facility or if it identified issues during its planned survey. .

Common Healthcare Terms & Acronyms (cont.)

- **NFPA – National Fire Protection Association (NFPA) 99** – Currently, CMS and Joint Commission reference NFPA 99 2012 edition in establishing procedures for electrical safety checks on medical equipment, definition of what is considered a patient care vicinity, as well as requirements for establishing medical device risk.

- **OEM: original equipment manufacturer - OEMs** are the companies that make the devices. Every OEM offers maintenance support on the equipment it sells, either directly or through its distributors. Note: the terms Manufacturer and Vendor are often confused. The manufacturer is the company that makes the equipment. The Vendor is who services it. A manufacturer can also be a vendor if they service the equipment. OEMS may offer different kinds of support contracts:
  - full service – for a flat fee, all service is covered during Normal Working hours or the contracted time period and most parts are covered.
  - shared service - requires the in-house HTM department to take first look when a repair is needed, and the OEM covers more complicated repairs and most parts.
  - Planned Maintenance (PM) Only service – the hospital contracts with the OEM to perform PMs only. This is typically done if the OEM has a proprietary PM kit with parts that can't be purchased from anyone other than the OEM.
  - Depot Service – for smaller devices or components of devices, the manufacturer may have the HTM department ship the broken device/part to them for repair. In these cases, they will often provide a loaner or replacement device either at no cost or for a rental fee.
  - Time & Material (aka Parts & Labor) – this contract offers the hospital discounts on parts and hourly labor rates. If a device does not fail frequently, this tends to be more economical than a flat rate contract.
  - Master Service Agreements (MSA) – in facilities that have a large quantity of equipment made by the same manufacturer, it is common for the hospital to enter into an MSA with that manufacturer to service their equipment. The MSA could include some or all the coverage levels above. Note that it is not uncommon for individual devices on MSAs to have different coverage start and end times, coverage levels, cost, etc.

- **PHI: Protected Health Information**. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) makes it a serious offense if patients' PHI is accessed by unauthorized people, including hospital staff and anyone outside the hospital. If there is a PHI breach, the hospital could face serious fines and public relations damage.
  - **ePHI – Electronic Protected Health Information**

- **PM: Planned Maintenance –** it's also commonly referred to as Preventive Maintenance. However, HTM/Facilities experts will argue that PMs never prevent a device failure. PMs are scheduled activities - vs. corrective maintenance (CM) that are unscheduled - that are designed to ensure equipment is safe and reliable to use. During PMs, a technician will physically check a device to make sure it is not damaged, check that it's operating properly, replace disposable or worn parts (i.e. filters), and tighten components and calibrate if needed. Regulations require that written PM procedures are followed. See AEM definition for more details.

- **RASMAS** – in addition to ECRI, RASMAS is another organization that collects all the safety alerts/recalls from many different sources and sends them to hospitals that subscribe to them and provides software for these to be tracked.

- **RPT – Relocatable Power Tap** (aka extension cord). RPTs in the hospital have regulations governing how they're inventoried, used and maintained.

- **RTLS: Real-time Location System** – these are systems that track the location of mobile assets, such as wheelchairs, infusion pumps, etc. so they can be easily found. Some RTLS systems also will track whether the device is in use.

- **UDI:** Unique numeric or alphanumeric code specific to a model of medical device: Device Identifier (DI) + Production Identifier (PI) = Unique Device Identifier (UDI) and that is also used as the "access key" to the information stored in UDID.