

Implement and Manage a Best Practice Pharmaceutical Waste Management Program

DESCRIPTION

Ensure management procedures and requirements for pharmaceutical waste handling, collection, storage and disposal are established. Implement a program that properly manages expired drugs, controlled substances, RCRA hazardous and non-hazardous drugs, and trace and bulk chemotherapeutics.

TRIPLE BOTTOM LINE BENEFITS

Cost benefits

- Where possible, prevention of pharmaceutical waste is the best strategy to achieve cost savings.
- EPA Regulatory fines can be in excess of \$450,000 (\$37,000/day/per occurrence.).
- Hazmat Implementation – Average fine is \$30,000 per violation and range up to \$100,000

Environmental benefits

- Improved environmental conditions (water & aquatic species) through the proper management and disposal of pharmaceuticals.

Health and safety benefits

- A pharmaceutical waste management program will improve human health through a reduction in drinking water and food supply contamination.


PROJECT TALKING POINTS

- Pharmaceutical waste is not a “new” waste stream as the US Environmental Protection Agency’s (EPA) Resource Conservation and



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- Recovery Act (RCRA) was written in 1976. However, hospitals and healthcare organizations have flown under the radar for years drain-dumping and otherwise improperly disposing of pharmaceuticals.
- In 2008, the Associated Press report highlighted the finding that trace amounts of pharmaceuticals were found in the drinking water affecting 46 million Americans. This prompted an immediate call to action to develop programs focused on preventing pharmaceuticals from reaching national water supplies. As hospitals were recognized as a major source of pharmaceutical use, regulators began to target hospitals’ pharmaceutical waste programs in their inspections.
 - The once-common practice of flushing pharmaceuticals is no longer considered best practice. The challenge to healthcare facilities is to reduce occupational and environmental risks by safely managing and disposing of



pharmaceuticals waste, while producing less upfront waste and reducing toxicity

- While patients should be allowed access to the best available pharmaceutical treatment, other things being equal, we should consider the medicine's PBT (persistence, bioaccumulation and toxicity) disposing of medicines. Our collective aim should be to protect people and the environment.
- A hospital pharmacy can easily have several thousand distinct pharmaceutical materials in inventory. Any of these materials can enter the waste stream, and some must be managed as hazardous wastes.
- Some pharmaceuticals can be extremely toxic in order to function while other drugs have properties, unrelated to their intended action, which can make them hazardous.
- Pharmaceuticals in the waste stream can pose several different types of risk.
 - Toxicity: Preservatives and other ingredients can pose a toxicity hazard over and above the effect of the main active ingredient
 - Ignitability: Some common solvents can pose a fire hazard
 - Corrosivity: A few compounding agents are corrosive, including strong acids with pH less than 2 (such as glacial acetic and carboic acids) and strong bases with pH greater than 12.5 (such as sodium hydroxide)
 - Reactivity: Reactive wastes include wastes that are unstable, react with water and are

capable of releasing toxic gases.

- Some compounds are radioactive, including certain chemotherapy drugs, and certain agents that are used as tracers or markers.
- Where possible, prevention of pharmaceutical waste is the best strategy, and efforts to generate less pharmaceutical waste can result in significant savings.
 - To support hospitals in this endeavor, the Joint Commission published a Booster-Pak entitled "Management of Hazardous Waste in Healthcare Facility" [[LINK to PDF - BP_HazardousWasteFINALlinked \(2\).pdf](#)] (this report was sponsored by Stericycle who brought in independent subject matter experts to provide an unbiased viewpoint).
- The Joint Commission has begun training its surveyors to ask questions about proper pharmaceutical management, and today, healthcare facilities are either actively addressing this complex and expensive waste stream or their programs are in the early stages of implementation.
- The following regulatory bodies have oversight on pharmaceuticals:
 - [Federal DOT](#)
 - [Federal EPA \(RCRA\)](#)
 - [State EPA&DOT](#)
 - [OSHA](#)
 - [DEA](#)
 - The Joint Commission
 - Publicly Owned Treatment Works (POTW)
- A 2013 survey of 453 hospitals, conducted by Pharmacy Purchasing & Products² noted that 81% of health systems placed a high priority on pharmaceutical waste management. The survey also found that 86% of the surveyed pharmacists had policies and procedures in place to capture RCRA hazardous pharmaceutical waste, up 11% from 2011 but only slightly gaining from the previous year. However only 60% of those surveyed felt their programs to be fully RCRA compliant. This highlights the need for much more work to be done. The top five challenges the pharmacists listed in this 2013 survey were as follows:
 1. Staff training challenges

2. Complexity of regulation
 3. Lack of storage space
 4. Lack of in-house expertise
 5. Unclear regulations for controlled substances
- Understand the challenges faced by hospitals. Some include getting buy in from key stakeholders, lack of training resources and lack of expertise with handling pharmaceutical waste.

PURCHASING CONSIDERATIONS

- Does the vendor provide a formulary review and process to track, as your formulary changes, to ensure changes are documented and new pharmaceuticals are disposed of properly?
- Ask the vendor to provide samples and ensure the information is easy to read and complete.
 - Does the vendor have the ability to easily update the formulary characterizations as new meds are added to the formulary. A compliance requirement is to update the formulary whenever adding new medications.
- Determine the level of detail the vendor can provide regarding reporting on volumes and costs of specific waste streams, i.e. RCRA Hazardous, non-hazardous, incompatibles.
- Does the vendor participate in transportation efficiency programs (e.g., Smartway)
- How will the vendor help you maximize pickups and container utilization to maximize transportation efficiencies and reduce related emissions and associated costs.
- Does the vendor provide the latest regulatory updates and technology advancements are provided to your organization within an agreed upon timeframe, i.e., new materials that have to be disposed of as hazardous pharmaceutical waste.
- What education, training and staff engagement support does the vendor provide and how often. Will they provide tune-ups if you have a problem. Be specific as this is a primary component of a successful program.
- Does the vendor provide on-going program support in the form of waste audits, re-

training, tools, resources, and other ongoing improvement activities. Again, be specific.

HOW-TO

1. Develop a Pharmaceutical Waste Management team to oversee the development of a comprehensive program. The following departments should be involved:
 - Nursing: The nursing representative can act as a project lead and assist with education program development, process development and sorting procedures and location of containers. (In particular high use areas such as OR and ER). If nursing is not involved from the start they understandably will delay implementation until they do understand why a pharmaceutical program is necessary and the basic regulatory requirements that for example, answers the question of why we can't have hazardous waste containers in the patient rooms.
 - Operating Room Department Managers: Even though they may be small in number, they will undoubtedly be the most vocal department regarding their particular needs prior to implementing a program. Also, the way the program is run throughout the hospital will not be the same for the Operating Room, so adjustments are almost always made to meet their needs. In most hospitals, if you do not include the OR early in the process and keep them informed, they will opt out of the program when it comes time to implement.
 - Emergency Department: the ED will be a high volume department with many unique needs. Similar to the Operating Room you will want to make sure they understand the need for the program from the start. The placement of containers is especially going to be a collaborative process as well as proper training of the staff since they normally don't follow the same scheduling as the hospital.
 - Pharmacy: The pharmacy representative can act as a project lead and assist with

process development, sorting procedures, labeling and the formulary review process.

- Environmental Services: The environmental services representative can assist with determining the collection process, DOT training, container location/placement and identifying a hazardous waste storage area.
 - Supply Chain: The supply chain representative can assist with product logistics.
 - Also consider the following departments as resources when developing your program: Sustainability, Safety, and Process Improvement & Infection Control. Re-evaluate team and add members and impacted departments as necessary.
2. Determine pharmaceutical waste vendor to assist with program development. Although this can be done internally, with the complexity of hazardous waste regulations, outside experts are often engaged.
 3. Determine whether to use reusable pharmaceutical waste containers or not. To help reduce the carbon footprint of the hospital, the use of reusable pharmaceutical waste containers helps to divert waste from landfills, and typically saves money.
 - a. Estimate the number and cost of disposable pharmaceutical waste containers used annually.
 - b. Determine the additional costs of waste disposal.
 - c. Understand the differences in procedures. For example, for a pharmaceutical container to be reusable, it must contain a plastic liner (as shown below) that is replaced as needed. Per OSHA regulations, containers with plastic liners cannot receive any sharps due to the risk of needlesticks in the exchange process. Once the liner is pulled, it is packed into a box or larger container for shipment to an incinerator permitted to process pharmaceutical waste
 4. Understand and anticipate the challenges.
- Although laws have been in place since 1976, only recently have hospitals addressed the disposal of pharmaceutical waste. Pharmacists and safety departments often lack the experience for handling pharmaceutical waste. Aware of the complexity of the hazardous waste regulations, hospitals often look to outside consultants to acquire expertise. Training time must be appropriately included in your program implementation.
5. Understand the regulations.
 - a. Pharmaceutical waste consists of any pharmaceutical that is not longer used for its intended purpose, is designated for discard or is not returnable for credit.
 - b. Refer to Practice Greenhealth's 10-Step Blueprint for Managing Pharmaceutical Waste to better understand regulations pertinent to your organization.
 - c. Identify the RCRA hazardous pharmaceuticals on their formulary. RCRA has two ways medications can be hazardous.
 - i. (1) A- Listed: Listed hazardous medications are easy to identify as they are on either a "P" or "U" list supplied by the EPA. Unfortunately, this list has not been updated since 1980, so it captures approximately only 25% of the hazardous drugs. If hospitals only use this list to identify hazardous medications on their formularies, they will have missed identification of the vast majority of hazardous wastes and not dispose of them properly. This list is a great first step, but must be supplemented with the "characteristically" defined hazardous waste.
 - ii. (2) Characteristically hazardous waste identifies pharmaceuticals that fall into one of the following four categories as defined by the Department of Energy and Environmental Protection:
 - a) Ignitability - A wastes is *ignitable* if:
 - (1) it is liquid and has a flash point below 140 degrees Fahrenheit; (2)

- it is a flammable solid; (3) it is an ignitable compressed gas; or, (4) it is classified by the U.S. Department of Transportation as an oxidizer.
- b) Corrosivity - A waste is *corrosive* if: (1) it is aqueous (i.e., water-based) and has a pH of 2.0 or lower (i.e., a strong acid) or 12.5 or more (i.e., a strong alkali); or (2) it can corrode steel at a rate of greater than ¼ inch per year.
 - c) Reactivity - There are many ways that a waste may be defined as a *reactive* waste. To briefly summarize, reactive wastes include wastes that are unstable, react with water or form hazardous mixtures with water, are capable of releasing toxic cyanide or sulfide gases under certain conditions, are explosive, or are capable of detonating under certain conditions.
 - d) Toxicity - A waste is *toxic* if it contains any of 40 different hazardous constituents at a concentration equal to or greater than a certain amount. These 40 constituents include 8 metals, 6 pesticides, 2 herbicides, 10 volatile organic compounds (VOCs), and 14 semi-volatile organic compounds (SVOCs).
- d. For example a drug can meet the hazardous definition of corrosives if the aqueous medication's PH is ≤ 2.5 or ≥ 12.5 and would therefore need to be labeled as a corrosive. An additional layer that must also be factored is the Department of Transportation (DOT) requirements. Many aerosol containers must be shipped as hazardous to comply with DOT regulations even though the medications themselves may not be considered hazardous.
 - e. This identification step is the cornerstone of the pharmaceutical waste program. However, the complexity to identify the thousands of pharmaceuticals coupled with a lack of expertise and internal resources have compelled hospitals to seek outside expertise. Unfortunately, the required information to make the determination is not available on the Safety Data Sheets (SDS).
 - f. Incompatible waste – that which is considered both hazardous chemical and bio-hazardous-- must be separated and handled differently. A proper waste identification report identifies these Rx categories. The staff needs to be trained on how to properly identify and dispose of these incompatible wastes.
 - g. Understand the differences and overlaps between OSHA, EPA and DOT regarding pharmaceutical material and waste management.
6. Receive senior leadership approval
 - a. Present to your leadership team the cost & waste impact analysis, community image benefits, regulatory issues and environmental/human health impacts associated with pharmaceutical waste management.
 7. Develop an implementation and maintenance strategic plan
 - a. A pharmaceutical waste management plan is a requirement so must be accomplished, but its implementation is not simple and takes time. For that reason, create an accountability plan that lists action items, the responsible person and a timeline for completion
 - b. Ensure the training program starts from day one and is ongoing. Your program will surely fail if training and education is not assigned and adequately managed.
 - c. Report successes, problems and milestones throughout the process to keep team morale high, as this can be a long, detail oriented process.
 8. Complete a formulary review to develop

waste profiles for end disposal at your facility. The formulary review will enable the pharmacy to properly identify pharmaceuticals.

- a. There are several ways to go about a formulary review process--ranging from partnering with a service provider who may offer the formulary review in exchange for later providing service via a "turn-key" program, to hiring a consultant, to tackling this project with internal resources.
- b. If you are partnering with a vendor, they will be able to provide the analysis for you. The analysis should define which pharmaceuticals are non-hazardous, hazardous, controlled substances and incompatibles.
- c. [Click here](#) to learn more about how to conduct a hazardous waste characterization internally.

9. Develop strategy for segregation of Non-Hazardous Waste vs. Hazardous Waste.

- a. Typically, hospitals have two options: 1. Treat all pharmaceuticals as hazardous waste or 2. Sort between hazardous and non-hazardous pharmaceuticals. The second approach is less expensive, but requires more education and training. Incompatibles must be labeled and disposed of separate from the non-hazardous and hazardous waste streams.
- b. Not all pharmaceutical waste is considered EPA RCRA "hazardous." Currently EPA regulations do not require that certain pharmaceutical wastes known to have a negative environmental impact be captured as hazardous waste. For example, endocrine disruptors, some antibiotics and chemotherapeutic agents.
- c. However, given the nature of most pharmaceuticals, it is now considered an environmental best practice to not only capture RCRA designated dangerous waste, but also all pharmaceutical waste whether designed hazardous or non-hazardous.
- d. From a cost perspective, the most expensive option is waste to be incinerated at an incineration facility for hazardous

waste. Due to environmental regulation, only a small number of incinerators remain operational in the US. Hospitals that over-classify all of their waste as hazardous will pay about 50-75% more than if they properly segregated. The least expensive disposal option is for incineration of non-hazardous pharmaceutical waste, which makes up approximately 95% of all pharmaceutical waste in a hospital that can be disposed in a non-hazardous incinerator licensed to dispose of pharmaceuticals. If hospitals properly segregate non-hazardous and hazardous waste, hospitals can save substantially while following best demonstrated practices.

- i. Work with your vendor to ensure which process works best at your hospital.

10. Develop strategy to manage Controlled Substances

- a. Controlled substances are managed by the DEA to ensure a closed loop system which tracks to final use or disposal. Controlled substance cannot be disposed of using pharmaceutical waste containers.
- b. Clinicians need to dispose of unused controlled substances in such a manner as it is non-retrievable. Unfortunately, the non-retrievable standard is not well defined by the DEA. In a written statement, DEA remarked that mixing a controlled substance with kitty litter or coffee grounds does not meet the definition of non-retrievable. The DEA released final regulations for handling and disposal of controlled substances September of 2014 and will become law as of October.
- c. Hospitals have dealt with this grey area with different approaches. Some have instructed staff to dispose of controlled substances into sharps containers. This does not prevent diversion, as well as the sharps disposal company is not licensed to take controlled substances. Hospitals can also send unused controlled substance back to the pharmacy or by drain

disposal (state specific). Neither is optimal.

11. Labeling of Drugs for Proper Segregation

- a. Consider using the Pyxis, Omnicell, and other dispensing systems to identify whether or not the drug being dispensed is hazardous and relay instructions on how to properly dispose.
- b. Many hospitals are using their electronic record systems (EMR's) such as Cerner and Epic to insert medication disposal instructions for their nursing staff.
- c. Incompatible medications such as unused silver nitrate sticks or aerosols are given special labels and most often are returned to the pharmacy for proper disposal.

12. Containers

- a. Pharmaceutical waste containers used for collecting drug waste are either one use disposables or reusable. If sharps are placed into a container, OSHA regulations require that they be disposable.
- b. Reusable containers are preferred since they benefit the environment and save on the cost of purchasing disposable containers.
- c. Pharmaceutical waste containers can be any color, however, most hospitals will use a black container to collect hazardous medications and either a blue or possibly white container to collect non-RCRA.

13. Understand why a Reverse Distributor is not appropriate to handle pharmaceutical waste disposal.

- a. A pharmaceuticals reverse distributor is used by pharmacies to return unused *products* for credit. Notice use of the word 'products'. The reverse distributor would then issue wholesaler credits or checks for these returns.
- b. Reverse distributors CAN NOT take waste in the form of used, open, or outdated medications. This is illegal. Unused medications should be sent back to the

pharmacy who then needs to work with the reverse distributor to understand what is acceptable.

- c. This is an important distinction because EPA regulations do not allow for any hazardous pharmaceutical waste to be sent back to a reverse distributor.
- d. So it is extremely important to understand when the product becomes a waste. The answer is when pharmacies no longer receive credit for the item returned then that item is considered to be waste and must be handled under hazardous waste regulations. The hospital hazardous waste coordinator/compliance officer must work with the pharmacy to understand what is collected throughout the hospital as hazardous waste and what can be returned to the pharmacy.
- e. The EPA is interested in making sure that pharmaceutical hazardous waste is properly manifested, tracked and disposed of from individual generators. The EPA loses that capability if reverse distributors are used as substitute hazardous waste companies.

14. Conduct a facility walkthrough to (often done with your vendor):

- a. Determine pharmaceutical waste container placement
- b. Define the Environmental Services collection process
- c. Identify a hazardous waste storage room and necessary requirements
- d. Create program awareness
- e. Identify any possible barriers and challenges that the team/program will face

15. Finalize container placement and determine the definition of "empty" defined by the EPA/RCRA as less than 3% of the contents original volume or when all contents have been removed via commonly employed practices (pouring, pumping, aspirating).

- a. Finalize container placement based on nursing/staff input

- b. Define “empty” for IV Bags, tubing, vials, etc. Some hospitals choose to error on the side of caution and have all products (regardless of “empty”) placed in the appropriate pharmaceutical waste container. This however does increase program costs.
16. Develop collection and removal processes
- a. Define the Environmental Services collection process
 - i. Determine if the collection of pharmaceutical waste can be added to a current waste stream route system
 - ii. Consider using soiled utility rooms as collection points on the nursing units
 - b. Identify a centralized hazardous waste collection room
 - i. The collection room:
 - a) Can’t have open drains
 - b) Must be properly labeled
 - c) Needs to be equipped with a phone and eye wash or portable eye wash station
 - d) Must contain the proper PPE
 - ii. RCRA requirements plus the need to be near the dock area are balanced with managing number of the waste pick-ups. Many hospitals have re-allocated dedicated space in their bio-hazardous room in the dock area to accommodate pharmaceutical waste.
 - iii. Regularly inspect the room to ensure all requirements are being met.
17. Assess ways to minimize pharmaceutical waste.
- a. As you design and implement your pharmaceutical waste management program, it is important to ask what pharmaceuticals are being “wasted,” why they are being wasted and how wasting can be minimized.
 - b. Waste segregation is critical in managing costs. While it may seem simpler to opt for dual waste (placing all compatible pharmaceutical waste into one container), however this is the most expensive option costing 50%-75% more to combine bio-hazardous and hazardous pharmaceutical waste.
- c. A small investment in training staff can lead to a safer, compliant and cost effective program. See training #22
 - d. In addition to being the most environmentally preferable alternative to waste management, source reduction practices can minimize compliance hassles, reduce costs and ultimately reduce the liability. Refer to [Practice Greenhealth’s 10-Step Blueprint for Managing Pharmaceutical Waste](#) for a number of minimization opportunities to consider and explore.
18. Understand Supply Chain logistics
- a. Define warehousing, distribution and par levels for Containers, bags, stickers, labels and absorbent pads
19. Work with vendor to determine an efficient pick up schedule to maximize cost efficiencies and reduce transportation impacts. See [Maximize waste equipment utilization and hauling efficiencies](#) PIM for more information.
20. Create and finalize a pharmaceutical waste management policy
- a. The policy should outline the purpose, responsibility, on-site storage and handling and disposal procedures.
21. Develop and implement staff training program
- a. First, take advantage of the available vendor training and educational materials, including signage. Identify departmental champions as “train-the-trainers.” If available and feasible, consider online modules with online tests to track aptitude.
 - b. All waste generators must be trained to ensure proper implementation of waste segregation and disposal techniques. Often, due to a lack of experience in handling pharmaceutical waste, hospitals will error on the side of classifying all their

waste as hazardous – an expensive route. By investing initially in training regarding properly segregating waste, hospitals can ensure compliance and save money.

- c. Initial training should focus on the differentiation between hazardous waste and bio-hazardous waste. If bio-hazardous waste is disposed of in hazardous containers, it may result in large fines. Once staff are trained in the different types of waste, proper disposal containers can be used effectively and optimally.
- d. Develop a training program for new staff and annually, with reinforcement occurring multiple times during the year. In order to ensure compliance and safety, hospitals must monitor their programs through periodic audits. These audits should include random checking of waste container contents to ensure proper segregation as well as a weekly inspection of the storage area. These audits will help to identify departments/shifts that may need additional training support. They will also allow the hospital to identify areas that need improvement prior to a regulatory inspection.
- e. OSHA, DOT and EPA require training on handling hazardous pharmaceutical waste. DOT training is required within 90 days of hire (and then every 3 years) for those individuals preparing waste for transport or signing the shipping papers. If the hospital is a large quantity hazardous waste generator, then EPA/RCRA regulations require annual refresher courses in addition to ongoing waste stream training.

22. Launch program and a continuous improvement strategy

- a. The continuous improvement strategy should incorporate tools such as rounding, visual management, education and training, managing for daily improvement, etc.

TOOLS

If you have an ROI tool, calculator, or similar resources to share, please [contact us](#) or participate

in the discussion below.

CASE STUDIES

- “Do the Right Thing”, A case study at Northwestern Memorial Hospital [[LINK to PDF](#)]. Gerry VanDormelen, Stericycle. August 2014. This case study is a *PIM in Practice*, addressing the challenges and opportunities and imperative for environmental compliance.

REGULATIONS, CODES AND STANDARDS, POLICIES

- [HealthCare Environmental Resource Center – Pharmaceutical Waste Compliance in Health Care Facilities](#)
- Federal and state regulations exist for the management of pharmaceutical waste. Review the [hazardous waste under RCRA](#) resource for federal regulations and for information on state requirements; consult the [HERC Hazardous Waste State Locator](#).

CROSS REFERENCES: GGHC

GGHC Operations

Credit 3: Chemical Discharge: Pharmaceutical Management & Disposal

PIM SYNERGIES

- [Maximize waste equipment utilization and hauling efficiencies](#)
- [Establish baseline for current waste generation and program for ongoing waste metrics reporting](#)
- [Conduct a waste assessment](#)
- [Improve waste-handling, container utilization and management process. Audit all hazardous waste related activities for compliance and beyond](#)

EDUCATION RESOURCES

The Roadmap is collecting sample training programs and posters, if you have anything to add, please contact us.

RESOURCES

- [Practice Greenhealth’s 10-Step Blueprint for Managing Pharmaceutical Waste](#)

- [Practice Greenhealth's webpages on Pharmaceutical Waste](#)
- [Pharmaceutical Waste in Health Care Facilities](#). Webpages on the HealthCare Environmental Resource Center website sponsored by the USEPA Compliance Division.
- [Pharmaceuticals Found in Drinking Water](#). An Associated Press Investigation.
- Charlotte Smith, *Journal of the Pharmacy Society of Wisconsin*, November-December, 2002)
- US Geological Survey: [Emerging Contaminants in the Environment](#)
- Washington State [Department of Ecology](#) has a useful website, among many resources, a good index page to pharmaceutical waste management resources
- The Minnesota Pollution Control Agency provides several useful factsheets, with links to additional resources:
 - [Evaluating pharmaceutical waste](#)
 - [Regulatory Consensus on Health Care Issues](#) (MN specific)
 - [Reverse distribution of pharmaceuticals](#)
- Environmentally Classified Pharmaceuticals 2014-2015 [[LINK - Environmentally classified pharmaceuticals 2014-2015 booklet.pdf](#)]
- Health Care Research Collaborative – [Minding the Gaps Research Priorities to Address Pharmaceuticals in the Environment](#) [[LINK -Minding_the_Gap_Research.pdf](#)]
- Preventing Damage to the Environment from Pharmaceuticals: A Primer – A Fact Sheet by Health Care Without Harm Europe [[LINK -Prevent_Damage_from_Pharma.pdf](#)]

The Sustainability Roadmap for Hospitals provides access to reliable, unbiased resources that can help organizations integrate sustainable practices into the health care environment.

Find out more about the Sustainability Roadmap for Hospitals by contacting 415-364-7266 or roadmap@mazzetti.com

