Site Visits to Outsourced I.V. Admixture Services Suppliers: Rationale and Process
PharMEDium Lunch and Learn Series

LUNCH AND LEARN

Site Visits to Outsourced I.V. Admixture Services Suppliers:
Rationale and Process
June 12, 2015

Featured Speaker: Karen E. Bertch, PharmD, FCCP
Independent Pharmacy Consultant

CE Activity Information & Accreditation

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1.0 contact hour

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Ask a Question

- Submit your questions to your site manager.
- Questions will be answered at the end of the presentation.
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Resources

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  - Handouts
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PharMEDium Webinar Series
June 12, 2015

Karen Bertch, PharmD, FCCP
Learning Objectives

- At the end of this session, the participant should be able to:
  - Discuss key factors that personnel from an institution/healthcare system or other organization should consider when evaluating an outsourced IV admixture services supplier.
  - State several reasons as to why personnel from an institution/healthcare system or other organization would conduct a site visit to an outsourced IV admixture services supplier.
  - List the typical personnel from an institution/healthcare system or other organization that would go on a site visit to an outsourced IV admixture services supplier.
  - Identify specific areas that are addressed during a site visit conducted by personnel from an institution/healthcare system or other organization to an outsourced IV admixture services supplier.
  - Describe how the personnel from an institution/healthcare system or other organization should prepare for a site visit to an outsourced IV admixture services supplier.

Speaker’s Background

- Current
  - Independent consultant
  - Per diem clinical pharmacist for national provider of home infusion therapy services
- Previous
  - Director, Pharmacy Drug Intelligence at Premier, Inc. (national Group Purchasing Organization)
    - Liaison to the Medical/Surgical Product Planning Group and Pharmacy Contracting Group, involved in the upfront clinical analysis of products prior to the contracting stage as a part of Premier’s strategic sourcing process
    - Specific areas of content focus included the intravenous therapy products portfolio, USP chapter <797>/<800>/sterile compounding product categories, and medication and supply automation categories
Definition of Outsourced Intravenous (IV) Admixture Services

- Health-system pharmacy is challenged by changes in the structure and financing of health care
  - Reduce costs
  - Improve performance
- An option used to achieve these goals is outsourcing
- Outsourcing is a formal arrangement by which a healthcare organization contracts with an outside company/supplier to obtain
  - Selected pharmaceutical services
  - Comprehensive management of the organization’s pharmacy
- Rationale related to IV therapy is that healthcare organizations may not have the resources (e.g., staff, equipment) to prepare all compounded sterile preparations (CSPs) in the pharmacy so will contract with an outside vendor/supplier to provide some of the product preparation (“outsourcing”)
  - The outsourced IV admixture service provider must comply with all USP chapter <797> and chapter <800> guidelines and other regulatory body requirements

Definition of Outsourced IV Admixture Services (continued)

- Traditional, prescription-based compounding pharmacies*
  - Known as 503A compounding pharmacies or compounding pharmacies
  - Entities that fall into this category include
    - Most healthcare organization pharmacies
    - Pharmacies that fill prescriptions or medication orders within a prescriber-pharmacist-patient professional relationship
  - All pharmacies are regulated by state boards of pharmacy, except federal facilities
  - May be subject to Food and Drug Administration (FDA) inspection to enforce Section 503A of the Food, Drug, and Cosmetic (FD&C) Act
  - Must follow regulatory requirements related to prescription/medication orders for compounded preparations and comply with applicable United States Pharmacopeia (USP) chapters on compounding (USP chapters <795>, <797>, <800>); additional FDA Compliance Policy Guide recommendations

* Based on Drug Quality and Security Act (DQSA) of 2013.
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**Definition of Outsourced IV Admixture Services (continued)**

- Human drug compounding outsourcing facilities*
  - Frequently referred to as registered 503B outsourcing facilities or outsourcing facilities
  - Permitted to engage in the manufacture and interstate shipment of larger quantities of compounded sterile drug products
    - Without prescriptions or medication orders
  - Federally regulated by the Food and Drug Administration (FDA), and inspected by the FDA
  - Must comply with applicable Current Good Manufacturing Practices (CGMPs) established under section 503B by the FDA
    - Differ from those for manufacturers
  - States may establish additional requirements with which outsourcing facilities must comply
  - PharMEDium falls into this category

* Based on Drug Quality and Security Act (DQSA) of 2013.

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**Group Purchasing Organization Contract Sourcing Process**

- Contract sourcing process
  - Rationale is to provide a standardized, evidence-based, transparent, member-driven process to give all suppliers equal opportunity to be awarded a contract for the category
    - Also called product planning process
  - Pharmacy process for non-pharmaceutical agents (e.g., automation and technology, USP chapters <797> and <800> categories, service categories) is modeled after the medical/surgical model
  - Other individual healthcare organization/institution/hospital and Integrated delivery network (IDN)/system staff can easily emulate this model/process
Sourcing Process to Identify Suppliers

- Needs of the healthcare organization should guide identification of potential suppliers with appropriate expertise and capabilities
  - Requires completion of an internal assessment of needs and capabilities
- Sourcing process may be conducted by
  - Individual healthcare organization/institution/hospital
  - Integrated delivery network (IDN)/system for healthcare organizations
    - Usually at a corporate system level
    - Covers several hospitals at a system level/multi-hospital system
  - Group purchasing organization (GPO) on behalf of individual healthcare organization and/or IDN
- Pathway for sourcing process
  - Healthcare organization staff oftentimes identifies and contacts suppliers directly to participate in contract bidding process
  - Healthcare organization staff may delegate process to GPOs
    - GPO process usually conducted through an on-line supplier portal

Processes and Tools Used to Make Contract Award Decisions

- Request for Information (RFI) responses
  - Variety of questions asked in the RFI document
- American Society of Health-System Pharmacists (ASHP) “Outsourcing Sterile Products Preparation Contractor Assessment Tool” review
  - Suppliers may complete as part of RFI response
    - 92 questions in the tool
  - Information in tool validated at supplier site visits by organization staff
- Supplier site visit(s) observations
- Request for Proposal/Pricing (RFP) responses
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Recommendations Related to Suppliers to Move Forward in Sourcing Process

- Consider suppliers that responded to the RFI
  - Incumbent
    - History as a supplier with healthcare organization (e.g., relationship, problem resolution)
  - New Supplier
- Initial recommendations regarding suppliers
  - Short list of suppliers
    - Review recommendations with pertinent healthcare organization staff and committees
    - Send RFP to noted suppliers
  - Suppliers that did NOT make the short list
    - Provide justification/rationale

Goals of Contract for Sourcing Cycle (New or Repeat/Renewal)

- Contract focus
  - Contract(s) to cover strictly outsourced intravenous admixture compounding (sterile-to-sterile), not high-risk sterile compounding (from bulk active pharmaceutical ingredients), versus
  - May include sterile-to-sterile compounding and high-risk sterile compounding
- Award contract(s) to a high-quality service provider
- Geographic focus is to achieve a contract(s) with
  - Local and/or regional coverage → individual healthcare organizations and/or IDN viewpoint
  - National geographic coverage → usually perspective of GPO
- Offer a contract(s) to a supplier(s) that provides a broad breadth of products and services
- Provide contract(s) that offer services in niche areas (e.g., oncology agents, total parenteral nutrition [TPN]) if possible
Key Factors When Evaluating Outsourced IV Admixture Services Suppliers

- Due diligence review of company/supplier
- Depth of their product line and list of products offered as part of the services
- Characteristics of the off-site compounding pharmacy
- Required documentation
- Regulatory and/or accreditation compliance
- Ability to meet USP chapters <797> and/or <800> guidelines, and/or Section 503A and/or 503B of the FD&C Act, as applicable
- Specifics related to the compounding process

Key Factors When Evaluating Outsourced IV Admixture Services Suppliers (continued)

- Features of compounded products (e.g., labeling, bar coding capabilities, storage, delivery)
- Simplicity of the inventory management process
- Assess quality issues and reporting (e.g., custom reports available)
- Specifics of the compounding pharmacy agreement
- Discuss business growth over the last 5 years; ability to handle increased business if awarded a contract
- Geographic regions/territories that the company serves
Sample Questions in a Request for Information (RFI): Supplier Characteristics and Performance

- History: How many years has your company provided this service?
- Covered geographic regions: List the primary metropolitan areas and states for which your company provides services specifically noting states and areas NOT serviced by your company.
- Company business model: Describe your company’s business model (e.g., are the majority of compounded sterile preparations for patient-specific compounding, or anticipatory compounding?).
- Licenses, certifications, and accreditations: List the licenses, certifications, and accreditations held by your company.
- Food and Drug Administration (FDA)/Drug Enforcement Administration (DEA) designation: Provide the designation(s) or categorization of your organization with the FDA and DEA.
- Product recalls: Describe any product recalls occurring in the previous 3 years. Also, please describe your recall procedure.
- Government investigation: Has your company received any 483 citation(s) or other applicable citation(s) from the Food and Drug Administration within the last 5 years (if applicable)?

Sample Questions in an RFI: Service Attributes

- Service offerings: List and describe the services and breadth of products that will be offered to Premier members.
- New services: Identify any new services, products, or product lines related to this category scheduled for release within the next 12 – 24 months.
- Beyond-use dating: What is your company’s process for assigning beyond-use dates?
- Beyond-use dating Part II: Is your company willing to provide X organization with a paper and/or electronic copy of a chart containing a list of all of your products and services offered along with the assigned beyond-use dates so that this document can be used in the decision-making process related to sourcing this category?
- Product bar coding: Describe the bar-code packaging and labeling used for products and/or services which advance patient safety.
Sample Questions in an RFI: Service Performance

- USP chapters <797> and/or <800> specifications, and/or Section 503A and/or 503B of the FD & C Act: Provide the type of supportive documentation you maintain for assurance the products meet current USP chapters <797> and/or <800> guidelines and requirements, and/or Section 503A and/or 503B of the FD & C Act, as applicable.

- Location for services provided: Provide detailed information regarding the facility/pharmacy locations(s) where the product preparation and service of your company are performed; what processes or disaster preparation plans are undertaken to ensure no interruption in product preparation or services occurs for customers in the event of an emergency situation with any of the facility/pharmacy locations? do any of your facility/pharmacy locations serve as redundant locations to the others?

- Responsiveness to product and/or service request: Timeframe between customer placement of a product or service order and actual customer receipt; describe procedures and processes undertaken, as well as typical timeframe for implementation of any new products and/or services requested by a customer.

Sample Questions in an RFI (continued)

- Service Performance
  - Ordering capabilities: List and describe the procedure(s) used by customers to order your products and services.
  - Reporting capabilities: List and describe the types of custom reports available from your system.
  - Service delivery: How are your company’s products and services delivered to the customer (e.g., via FedEx, UPS, local delivery service, company courier, etc.)?
  - Quality control processes: Describe your quality control and cGMP processes and programs, and the personnel dedicated to these programs.

- Service Implementation and Customer Service
  - Customer service process: In general, describe your customer service process and documentation.
Sample Questions in an RFI: Agreement

- Payment options: Does your company offer a ship to/bill to option for payment?
- Shipping and handling charges: Do the prices that your company offers for its products and services include shipping and handling charges? If not, what would a typical shipping and handling cost be?

Reasons to Conduct Site Visits to Outsourced IV Admixture Services Suppliers

- To ensure that the suppliers have addressed the factors and considerations used by pharmacy staff when evaluating an outsourced IV admixture services supplier
  - Look at some questions addressed in RFI and RFP processes if need further exploration during the on-site visits
  - Clarify any questions addressed in the RFI process
  - Clarify any responses to questions in the ASHP assessment tool, if applicable
- To assist with contract award decisions that will be made upon completion of site visits at the suppliers
  - Site visits are considered part of the supplier qualification process
  - Observations and information gathered at site visits should be used as part of the process to make contract award recommendations
Healthcare Organization/IDN Personnel Participation in Site Visits

- **Required participants**
  - Director of Pharmacy (individual healthcare organization and/or system level) and/or other pharmacy leaders
  - Pharmacy Operations Supervisor/Manager
  - Pharmacy IV Room/Clean Room Supervisor/Manager

- **Additional potential participants**
  - Director of Materials Management
  - Director of Nursing
  - Risk Management Director/Officer
  - Medication Safety Officer
  - Chief of Medical Staff
  - Chairperson of Pharmacy and Therapeutics Committee
  - Staff with chemistry and/or microbiology background (Director of Laboratory)

Group Purchasing Organization Personnel Participation in Site Visits

- **Required participants**
  - Clinical pharmacist that participates in upfront clinical analysis of product(s)/services
  - Pharmacy contracting staff
  - Staff that wrote RFI questions

- **Additional potential participants**
  - Pharmacy department senior leadership
  - Staff with chemistry and/or microbiology background
  - GPO member representative(s)
Issues to Consider Before Site Visits

- Organization staff should set the agenda with the supplier staff before arriving for the site visit
  - Clearly articulate what personnel expect to see and/or be shown
- Determine the time needed/length of the day(s) for the site visits
- If supplier has multiple sites, anticipate visiting the appropriate sites
- Expenses related to site visits should be paid by healthcare organization to eliminate any bias
- Timing of site visits to supplier in relation to sourcing cycle
  - Initially before contracting with a supplier
  - Periodically throughout contract agreement (e.g., annually)
  - Periodic unannounced site visits should be conducted after selecting the supplier(s) you will do business with
    - Supplier should be comfortable with and support this

Specific Areas/Factors Addressed During a Site Visit: Agenda Information

- Used a standardized agenda for each site visit
- Suggest the agenda be two-fold
  - An abbreviated version
  - A more detailed version
- Delineate anticipated time allowance for specific components of the site visit on the agenda
  - Attempt to adhere to the agenda outline and time frames in order to:
    - Conduct a thorough visit
    - Ensure all necessary observations are made
    - Complete all facets of evaluation process
Example Site Visit Agenda

## Agenda for Outsourced I.V. Admixture Service Company Site Visit:

### Overview
- Supplier overview of company and philosophy
  - [Example: 15 minutes; site leadership present; time allowance = 1 hour]
- Visit follows CPR guideline: Comprehension, Planning, Risk Management, and Documentation

### Site Visit Agenda:
- Discussions with supplier leadership staff
- Discussions with supplier sales force and/or account director team, marketing staff, call center staff
- Ask to see documentation of suppliers’ product recalls and/or regulatory actions
- Obtain a listing of product line offered as part of services
  - Should include generic drug name, diluent, concentration, size of finished preparation, dosage form delivery system, beyond-use date information

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Specific Areas/Factors Addressed During a Site Visit (continued)

- Discussions with supplier leadership staff
- Discussions with supplier sales force and/or account director team, marketing staff, call center staff
- Ask to see documentation of suppliers’ product recalls and/or regulatory actions
- Obtain a listing of product line offered as part of services
  - Should include generic drug name, diluent, concentration, size of finished preparation, dosage form delivery system, beyond-use date information
Specific Areas/Factors Addressed During a Site Visit: Copies of Specific Documentation

- Current liability insurance
- State pharmacy licenses, manufacturing licenses, 503B registration/application (if applicable), DEA registration
- Pharmacists’ and technicians’ licenses
- Education and training processes for staff
- Standard operating procedures manual
- Methods used to validate sterility, stability, and potency; beyond-use dating information
- Any work related to labeling of compounded sterile preparations
- Custom reports related to quality issues and anticipated frequency

Specific Areas/Factors Addressed During a Site Visit (continued)

- Examination of the suppliers’ buildings/facilities
  - Outside of the building
    - Appearance, signage, security
  - Examination of the pharmacy and clean room
    - Cleanliness, security
    - Work flow procedures
    - Observe staff performing admixture processes
    - Gowning and gloving procedures
    - Supplies and equipment being used
    - Meeting or exceeding USP chapters <797> and/or <800 guidelines, and/or Section 503A and/or 503B of the FD&C Act, as applicable
Specific Areas/Factors Addressed During a Site Visit: Examination of the Warehouse

- Cleanliness
- Organization
- Safety
- Security
- Shipping and delivery processes
  - Packaging materials
  - Use of containers that maintain proper storage temperature

Specific Areas/Factors Addressed During a Site Visit (continued)

- Examination of compounded sterile preparations
  - Professional appearance
  - Labeling in accordance with state and federal laws; bar-code capabilities
    - Label features related to safety, uniqueness
  - Packaging

- Review of overall use of various automation and technology methods
  - Specific equipment utilized
  - Patient/product and staff safety issues
Personnel Preparation for a Site Visit

- Review pertinent clinical literature related to outsourced IV admixture services
- Be familiar with USP chapters <797> and/or <800> guidelines, and/or Section 503A and/or 503B of the FD&C Act, as applicable
- Review RFI responses from respective supplier
  - Examine any supporting documents/attachments provided with the RFI responses (e.g., product brochures, policies and procedures, standard operating procedures, etc.)
  - Highlight responses that need clarification
- Review responses to questions in the ASHP assessment tool, if applicable
  - Highlight responses that need clarification

Personnel Preparation for a Site Visit (continued)

- Gather feedback on experience/relationship with respective supplier from colleagues, other healthcare organization personnel, and GPO personnel and/or members
- Examine abbreviated and detailed site visit agenda
- Assess RFP responses, pricing information, contract agreement offer, terms and conditions (if available) from respective supplier
Follow-up After Site Visits

- Discuss observations with site visit(s) participants from organization
- Summarize highlights of observations for all organization project team members
- Generate key contract award attributes list
- Create written document with summary of observations of site visits
- Formulate recommendations for contract award
  - Attributes table
  - Decision scorecard
- Review all clinical and contract award recommendations with organization team assigned to project
- Present recommendations to various committees affiliated with organization

Follow-up: Supplier A Site Visits

Observations and Findings

- Visited 2 facilities: one each in City A and in City B; also visited corporate office in City C where the majority of paperwork for standard operating procedures and product testing is created and processed, as well as the Customer Service Center is located
- Both facilities are large-size operations
  - Large-sized clean rooms in both compounding centers
  - City A facility has capacity to expand to more than double its current clean room size
- Facilities were extremely clean, including the warehouse and shipping and delivery areas
- Meets or exceeds USP chapter <797> requirements
- Workflow process was stellar with use of Lean principles evident
  - Staff use sporicidal agents to sanitize vials and ports of containers
Follow-up: Supplier A Site Visits
Observations and Findings (continued)

- Extensive use of automation procedures including automated compounders, automated filling devices, bar-code verification system, automated labeling and packaging systems; bar-code scanning used in warehouse to verify picking of initial products and ingredients to be used in the compounding process
- Excellent computer system for processing orders from customers
  - Use of LCD television monitors throughout the facilities to monitor staging process for products being prepared
- Supplier Web site is robust; has comprehensive information for customers including order history reports, customizable usage reports, and an on-line catalog with searchable view of complete line of admixing services
  - User-friendly order templates available and ability to create institution formulary listing of outsourced products
  - Beyond-use dating information available for all product offerings
  - Product and/or preparation container latex status available along with product information and educational materials

Follow-up: Supplier A Site Visits
Observations and Findings (continued)

- Labeling of product includes bar-codes, TALLman lettering, ASTM color-coded syringe labels; tamper-resistant packaging
  - Continuously updating label; large-size print and color enhancements recently introduced
  - Work with staff at Institute for Safe Medication Practices (ISMP) on labeling features
- Redundant facilities available due to X large scale compounding centers located in X distinct areas across the United States
- Customer service support provided by separate Customer Service Center staff 24 hours a day, 7 days a week, 365 days a year
Follow-up: Supplier A Site Visits Observations and Findings (continued)

- Building and employee access is secure
  - Check-in with a security guard required for visitors at both facilities visited
  - City A site has a wrought iron fence around perimeter of premises and visitors have to be buzzed in by security staff to open gate
  - Controlled substances are very secure; employees use fingerprint technology to sign products in and out
  - Labels are locked in a separate cabinet in the warehouse

- Documentation manual is ready-to-go for institutions that request information for State Board of Pharmacy, Department of Public Health, and/or Centers for Medicare and Medicaid inspections
### Contract Award Scorecard (continued)

#### Product Utilization
- X X Revenue and Expense - Net Income
- X X Clinical Support and Service Agreement
- X X Network Management - Cost Reduction Program

#### Product Acquisition/Budget
- X X Product Quality Management - Compliance
- X X Product Provenance - Product Traceability
- X X Product Traceability and Safety
- X X Product Labeling and Compendia
- X X Product Shelf Life and Capital Equipment
- X X Product Disposal

#### Product performance
- X X Customer Development and Relationships
- X X Product Supply and Arrive
- X X Product Compliance and Change
- X X Client Service Quality

#### Product implementation
- X X Product Implementation Programs - Acute & Non-Acute Care Settings
- X X Product Implementation Programs - Commercial and Technical Support - Commercial and Technical Support - Commercial and Technical Support

### Terms & Conditions Considerations
- Allow for the purchasing of "best in class" without price penalties

### Key
- 1. Not impacted enough to weigh in the evaluation
- 2. Mildly important to weigh in the evaluation
- 3. Moderately important to weigh in the evaluation
- 4. Highly important to weigh in the evaluation

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[Image of the scorecard]
### Outsourced IV Admixture Services: Supplier Attributes

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* If sole source award
Follow-up After Site Visits (continued)

- Contract award notification process
  - Awarded suppliers
  - Non-awarded suppliers
- Anticipated launch materials
  - Clinical and contracting toolkit
  - Contract abstract summary overview
  - List of services and pricing list
  - Depending upon number of supplier(s) awarded, a cross-reference of products

Contact Information

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