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<b>WRITTEN BY:</b>	<b>Signature</b>	<b>Date</b>
Type Author's Title Here Policy and SOP workgroup	Michael Casati, Chairman	30 June 10
<b>APPROVED BY:</b>	<b>Signature</b>	<b>Date</b>
Department Head or designee, Authoring Department	Phil G. [Signature]	6/18/10
Department Head or designee, Affected Department	Brian [Signature]	6/29/10
Other Staff		

## 1.0 OBJECTIVE AND SCOPE:

### 1.1. SOP Statement:


Sepracor Procurement is responsible for authorizing external goods and services spend commitments and related activities, prior to any financial or legal commitment of funds, except as otherwise described in this Standard Operating Procedure.

To derive the maximum value to Sepracor, Stakeholders must advise Sepracor Procurement, Legal Affairs, and Financial Planning and Analysis/Accounting of any transaction involving the procurement or outsourcing of relevant activities and/or critical or important operational functions at the earliest opportunity as described in the below sections.

### 1.2. Purpose:

To ensure that expenditures of company funds follow established best in class procurement practices in a way that engages consistent, effective and appropriate procurement activities so that Sepracor obtains the best value and is in compliance with applicable rules, regulations and internal policies and Standard Operating Procedures. Procurement's mandate is to:

- Drive procurement best practices and consistency across the organization.
- Leverage Sepracor's spend and Supplier base.
- Proactively manage value and total cost of ownership.
- Establish the procedures and practices required to manage price and supply risk.
- Lead and instill a culture that embraces cost and demand management.
- Reduce Sepracor's cost structure.
- Ensure appropriate Supplier selection and Contractual protection.
- Provide appropriate tools and sourcing process expertise.

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- Establish a link between payment obligation and deliverables.

1.3. **Purchases governed by this Standard Operating Procedure:**

- 1.3.1. This Standard Operating Procedure applies to purchases of goods, equipment, and services.

**2.0 DEFINITIONS:**


- 2.1. Please refer to the associated Procurement Glossary, PRO-005 Document, found on the SEPResource Procurement Portal and in the Corporate Standard Operating Procedures (SOP's) and Memorandum of Standards (MOS's) Index.

- 2.2. Purchases can be characterized into four basic segments:

- 2.2.1. **Transactional or Non-critical Purchases:** Low Spend, Low Market Complexity. Many alternate products and services exist, many Suppliers exist. Denoted by small dollar values, and frequency of transactions. Items for everyday use, requirements not specified. Procurement doesn't need to be engaged.
- 2.2.2. **Guided Purchases:** Low Spend, High Market Complexity. Few alternate products or services, few Suppliers, purchase may have a big impact on operations or maintenance, very complex specifications. Procurement should be consulted. Stakeholder should utilize the sourcing process and tools.
- 2.2.3. **Competitive Purchases:** High Spend, Low Market Complexity. Many alternate Suppliers exist, commodity or standards for product or services exist. Stakeholder must consult Procurement for negotiations and to leverage existing arrangements, and utilize the sourcing process and tools.
- 2.2.4. **Strategic Sourcing:** High Spend, High Market Complexity. Few qualified Suppliers exist, product or service requirements or specifications are unique or complex. Characterized by high dollar expenditures, purchase is critical to operations and profitability. Procurement must lead or co-lead sourcing activity.

**3.0 REFERENCED DOCUMENTS:**

- 3.1. Related policies and SOPs regarding expenditure authority, approval and signing authority have been established elsewhere. Important matters

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related to the commitment of Sepracor funds and resources are discussed in these policies. Please refer to the following as appropriate:

- Procurement Policy
- Strategic Sourcing SOP, PRO-002
- Supplier Relationship Management SOP, PRO-003
- Supplier List Management SOP, PRO-004
- Procurement Glossary, PRO-005
- Purchasing Requisitions SOP, PRO-006
- Expenditure Commitment and Invoice/Payment Approval Policy
- Invoice/Payment Approval SOP, FIN-001
- Approval Authority SOP, FIN-002
- Receiving Goods & Completion of Services SOP, PRO-008
- Contract Review and Signing Authority Policy
- Contract Signing Authority Procedure
- Contract Management SOP, PRO-009
- Supplier Qualification of Hardware, Software, and IT-Service Providers SOP
- Travel Policy
- External Communications Policy
- Educational Grant Policy
- Health Professional Consultant Policy
- Customs–Trade Partnership Against Terrorism Program and Tier-One International Suppliers SOP.
- Code of Conduct and Ethics

3.2. Note that new and revised policies and SOPs may be approved by Sepracor from time to time and should also be referred to, as applicable. All policies and procedures can be found on the Compliance Portal of the SEPResource.


#### 4.0 APPLICABILITY:

4.1. This Standard Operating Procedure applies to all employees of the Company and those who act on its behalf for procurement purposes

4.2. **Exceptions and Waivers:** The only exceptions to this Standard Operating Procedure, are noted in below.

4.2.1. The Executive Director of Procurement or their designee may re-delegate responsibility under the Procurement Policy and Procedures in the rare circumstance where there is a resource or knowledge gap within Procurement or as part of an overall strategic procurement plan or as documented in business justification provided by the Stakeholder. Those



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receiving an exception must apply Supplier selection and negotiation techniques that have been approved by Procurement and adhere to all other aspects of this Standard Operating Procedure. Exceptions are documented on the Procurement authorization log.

- 4.2.2. Stakeholders using purchasing cards and travel cards must follow supporting Standard Operating Procedures and related guidance documents.
- 4.2.3. Stakeholders utilizing procurement designated preferred Suppliers must follow the supporting Standard Operating Procedures and related guidance documents.
- 4.2.4. The Executive Committee or the Sepracor Board of Directors may authorize external spend commitments that will be outside the remit of this process for reasons of emergency, business continuity, merger & acquisition, or confidentiality.

## 5.0 GENERAL:

When making a commitment to external Suppliers, the following applies:

### 5.1. Expenditure Commitments

- 5.1.1. Stakeholders must involve Procurement, Financial Planning and Analysis/Accounting and Legal Affairs at the **earliest opportunity** where external spending with a single Supplier exceeds \$100,000 during a calendar or contract year or where the total commitment is reasonably anticipated to exceed \$100,000. Procurement works with the Stakeholder:


- To determine the best sourcing solution/strategy based on business project needs and timelines.
- To establish Service Level Agreements (SLAs) with finite milestones/deliverables that coincide with payment obligations documented as part of the Contract and clearly define what constitutes performance failures and corresponding penalties.

- 5.1.2. Where the commitment is under \$100,000, it is the responsibility of the Stakeholder to manage the commitment process in accordance with applicable Procurement related policies and procedures and other applicable policies and procedures. This includes all Contract renewals, changes, or modifications, as well as, new Suppliers and new agreements.

- 5.1.3. **The following defines the Procurement method and coordination requirements when initiating a purchase.**

#### **Annual Spend less than \$100,000.**

- Allowed Purchase methods: Purchase requisition and Purchasing Card.

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- Stakeholders should utilize Preferred Suppliers or
- Obtain approval for new Suppliers.

**Annual Spend of \$100,000 or more.**


- Stakeholders should consult Procurement regarding purchases from new Suppliers or
- Suppliers with an expired or expiring Contract.
- Allowed Purchase methods: Purchase requisition.
- Stakeholders should utilize Preferred Suppliers or
- Obtain Procurement approval for a new Supplier.
- Engage Procurement to coordinate a Strategic Sourcing event and select Suppliers using strategic sourcing best practices.

**Supply Chain and GMP Inventory Spend.**

- Allowed Purchase methods: Purchase Orders generated by Operations Planning and Chemical and Pharmaceutical Sciences group.
- Coordination requirements: Stakeholder should utilize Preferred Suppliers or
- Obtain approval for new Suppliers.
- Prior to selection of a inventory Supplier, engage Procurement to support Supplier selection and Contract negotiations.

**Stakeholder should also coordinate their purchases with the appropriate organizations for special purchases i.e. facilities related equipment, capital lab equipment and lab safety equipment, controlled or radioactive chemicals, hazmat waste for example.**


- 5.1.4. Stakeholders do not need to contact Procurement where:
- Stakeholder is engaging a Procurement defined Preferred Supplier.
  - Spend with a single Approved Supplier that is less than \$100,000, and commitment is reasonably anticipated to NOT exceed \$100,000 annually.
  - Stakeholder is releasing orders against a Blanket or Contract Purchase Order.
  - For a transactional or non-critical purchases.
- 5.1.5. Use Procurement Preferred Suppliers and Purchase to Pay channels where available.
- If goods or services can be procured through a requisition system, no other channel of Procurement is permitted (e.g. retail store, internet purchases, direct order, etc.)

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- For all other transactions that can be completed using a credit card, employees are required to use the Sepracor Travel Card to pay for the goods or services consistent with the spending limits and terms outlined in the Travel Policy.
- Use of personal credit cards is prohibited.
- A list of Preferred Suppliers is available on the SEPResource Procurement Portal.

## 5.2. Contract Management

- 5.2.1. Stakeholders must use existing Contracts established by Procurement and Legal Affairs where possible. For sourcing events, Procurement will serve as the business' liaison with Legal Affairs and Financial Planning and Analysis/Accounting. Stakeholders must include Procurement at the earliest opportunity in all price/Contract negotiations that meet the expenditure approval thresholds listed in Section 5.1.
- 5.2.2. Procurement will facilitate the inclusion of appropriate business terms and Supplier controls, and make use of appropriate sourcing levers and tactics to benefit from market opportunities.
- 5.2.3. Stakeholder must follow existing Legal Affairs and Financial Planning and Analysis/Accounting processes and guidelines and make use of Legal Affairs and Procurement approved Contract templates where appropriate.
- 5.2.4. Legal Affairs will not approve new Contracts without Procurement participation. Stakeholder failure to include appropriate Procurement, Legal Affairs or Financial Planning and Analysis/Accounting oversight may result in having to re-start the negotiation/Contract process and a delay to your project.
- 5.2.5. For budgeted items Stakeholders must obtain required Management approval prior to engaging Procurement and Legal Affairs in the requisition process.
- 5.2.6. For unbudgeted items Stakeholders must provide written Management approval prior to initiating any purchasing activity to Procurement and Legal Affairs.
- 5.2.7. Stakeholder cannot commit to business or start Supplier engagement without Contract signature and purchase document authority in place.

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5.2.8. Stakeholders must follow existing Legal Affairs Contract processes and consult with Procurement on Contract renewals. Legacy Contracts may have to be revised to current legal, regulatory and business standards.

5.2.9. Sepracor no longer permits “evergreen” clauses. Any Contracts expiring with “evergreen” clauses will not be renewed. Stakeholders must engage Procurement and Legal Affairs to evaluate Contract renewal or Supplier alternatives.

5.2.10. Stakeholders must use a confidentiality agreement consistent with Legal Affairs policies and procedures with a potential Supplier, which must be signed prior to commencing discussions where such discussions may involve sharing of confidential information.

5.2.11. Stakeholders must use standard forms of Contract or Purchase Orders (obtained from Sepracor Procurement and/or Sepracor Legal Affairs), when making commitments below \$100,000. Stakeholder must not make verbal agreements which may be legally binding.

### 5.3. Preferred Suppliers

5.3.1. Sepracor has negotiated favorable Contracts with a set of Preferred Suppliers; Stakeholders must utilize them for all goods and services unless there is a demonstrable performance or quality issue or a gap in capability exists. Where a capability gaps exist, Stakeholders must follow the Supplier approval process per the Supplier List Management SOP, PRO-004.

5.3.2. Procurement designates Preferred Supplier status to an Approved Supplier in accordance with business needs and an overall sourcing strategy based on established criteria.


5.3.3. A list of preferred Suppliers is available on the SEPResource Procurement Portal.

### 5.4. Contracts and Purchase Orders

5.4.1. Stakeholders are prohibited from signing a Supplier’s sales Contract or agreement.

5.4.2. Stakeholder must use a company approved Purchase Order and Contract (if required) when purchasing goods or services, unless specific exception is granted in writing from the Executive Director of Procurement.



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5.4.3. If the Executive Director of Procurement has granted an exception, all Supplier Contract forms must still be reviewed by Legal Affairs and Financial Planning and Analysis/Accounting.

5.4.4. Stakeholder must coordinate goods returns with Procurement.

#### 5.5. No Personal Purchases

5.5.1. Sepracor Conflict of Interests Policy prohibits personal purchases for employees by Procurement personnel. Other employees who buy goods or services as part of their job are prohibited from making personal purchases using the company's name or accounts.

#### 5.6. Conduct


5.6.1. Reciprocal transacting with Suppliers purely on the basis of them being a customer of Sepracor is prohibited. Reciprocity refers to arrangements between purchasers and Suppliers to deal exclusively with one another.

5.6.2. Commit to conducting business with Suppliers in a fair and honest manner, with openness and integrity. For further guidance refer to the Sepracor Code of Conduct and Ethics.

5.6.3. As detailed in the Conflict of Interest Policy, employees, officers and others acting on Sepracor's behalf should be free of any interest that could adversely influence their judgment, objectivity or loyalty to the Company in conducting Sepracor's business activities and assignments. Employees must act in the best interests of Sepracor when engaging in Sepracor business.

Sepracor requires that employees and others acting on Sepracor's behalf disclose to the company any situation, transaction, activity, relationship or matter that reasonably may give rise to, create the appearance of, a conflict of interest. Any employee acting on Sepracor's behalf who suspects that s/he may have a conflict of interest, or has involvement in a situation that others could reasonably perceive as a conflict of interest, should report that matter to a supervisor, or to a member of the Compliance, Legal Affairs, or Human Resources Departments. It is the responsibility of the employee's line management to determine whether the situation, transaction, activity, relationship, or matter constitutes a conflict of interest and what, if any, measures would be required to manage the conflict appropriately. In the



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event there is any doubt whatsoever; the matter shall be determined by the Compliance Department in consultation with line management.

Please refer to the [Conflict of Interest Policy](#) for further information.

5.6.4. Employees should ensure compliance with applicable laws and regulations, industry guidance, and the [Sepracor Meals, Medically Relevant and Other Items, and Entertainment Policy 3.05](#) related to Healthcare Professional interactions. Policy 3.05 defines the parameters to which Sepracor employees may provide a meal, medically relevant item, and/or entertainment to a Healthcare Professional.

5.6.5. No Policy can cover all circumstances or eventualities an employee may meet, and every employee is expected to use good judgment, common sense and generally accepted business principles in applying this Policy. In case of doubt in the application of this Policy, employees should contact Procurement, Legal Affairs and/or Compliance


## 5.7. Procurement Contacts

5.7.1. If you have specific questions about this standard operating procedure or other Procurement related policies and SOPs, contact the Executive Director of Procurement at [sourcing@sepracor.com](mailto:sourcing@sepracor.com).

## 6.0 Supplier Qualification

6.1. Approved Supplier is any Supplier who has been qualified through the quality and Supplier selection process per the [Strategic Sourcing SOP, PRO-002](#) and applicable Quality SOPs. Approved Suppliers will be maintained in Oracle as the system of record. The minimum vetting requirements are contained in the [Supplier List Management SOP PRO-004](#). These requirements generally consist of a quality audit or assessment, financial screen, minimum confidentiality agreements and/or Contractual documents but may vary by type of product or service requested and Supplier risk.

6.2. Supply Chain must evaluate any international purchase of goods from a Tier 1 Supplier shipping products into the United States to a Sepracor or Sepracor partnered facility for compliance to Customs-Trade Partnership Against Terrorism (C-TPAT) regulations. Stakeholder is responsible to notify their Supplier of the requirement and provide either the Suppliers status verification ID (SVI) or submit their Supplier completed security questionnaire for approval prior to doing business with the Supplier per the requirements contained in the


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Customs–Trade Partnership Against Terrorism Program and Tier-One International Suppliers Standard Operating Procedures. Suppliers that can't meet minimum security requirements are disqualified from use. Your failure to comply with the Customs–Trade Partnership Against Terrorism Program and Tier-One International Suppliers Standard Operating Procedures requirements may result in Sepracor losing its own C-TPAT certification impacting our customs clearing for commercial drug products and others imported goods.

- 6.3. Stakeholders must follow the Standard Operating Procedures for strategic sourcing activities, best practices, process methodology and the process to engage procurement in sourcing related activities is defined in the Strategic Sourcing SOP, PRO-002.
- 6.4. Stakeholders requesting IT purchases must follow the IT SOP entitled, Supplier Qualification of Hardware, Software, and IT-Service Providers.

## **7.0 Supplier Management**

- 7.1. The Stakeholder is responsible for the day-to-day conduct of Supplier oversight and performance management.
- 7.2. If the Supplier and business can not resolve performance issues, the issues require escalation, or the issues are the result of systemic failures of the Supplier, Procurement will coordinate the appropriate level of response in collaboration with the business, based on the performance criteria established during the Contract phase.
- 7.3. Procurement may lead or co-lead a standard best-in-class Performance Review process of strategic Suppliers as defined in the Supplier Relationship Management (SRM) SOP, PRO-003. Determination as to which Suppliers require recurring performance reviews and the appropriate frequency may be determined by Supplier risk, amount of spend and criticality to the business as outlined in the SRM Standard Operating Procedure. The specific performance metrics are identified or developed in collaboration with the business users within each category. Key components generally include quality, pricing adherence, delivery, innovation, and service & responsiveness.
- 7.4. Supplier Rationalization will occur through the SRM and Procurement process.
- 7.5. Procurement will apply a structured process within each category to solicit innovative ideas and evaluate them for applicability and size of benefit.

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## 8.0 Roles and Responsibilities:

8.1. Primary responsibility for the implementation, monitoring and enforcement of an effective Procurement related policies and Standard Operating Procedures rests with each Stakeholder in consultation with Procurement personnel.

### 8.2. Procurement Task Roles & Responsibility Matrix

Sec	Role	Procurement	Legal Affairs	Compliance	FP&A /Accounting	Stakeholder	Steering	Quality	Management
	<b>Task</b>								
	Project Lead*	A/R/C				A/R/C			
	Profile Category	A/R				C			
	Scope Definition	C				A/R	I		
	Develop Sourcing Strategy	A/R				C	I		
	Sourcing Event	A/R				C			
	Assess Suppliers	A/R				R		C	
	Supplier Selection	R				A/R			
	Negotiations	A/R	C		C	A/C	I		
	Contract Development/ Management	A/R	A/R			C			
	Purchase Documents	A/R			C	R			
	SRM	A/R							
	Supplier Oversight (day-to-day)					A/R		C	
	Internal Communication	A/R				R	C		
	Supplier Communications	A/R				I			
	Implementation	A/R				A/R	C		
	Transition Management	A/R				A/R			
	Results Validation	I		A/R	A/R	A/I			
	Executive Sourcing Reports	A/R			R		I		I
<b>Comments</b>		*Depending on the category requirements, projects may be led by Procurement or the Stakeholder or Co-led.							
<b>Legend:</b>		A = Accountable for result; R = Responsible for work tasks; C = Contribute / Consult; I = Inform							



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## 9.0 RECORD RETENTION:

9.1. Procurement will maintain Supplier selection records including RFx documents, Supplier proposals and presentations, evaluation forms, financial screens, etc in uncontrolled files as appropriate and consistent with Sepracor record retention policies.

9.2. Legal will maintain Supplier Contract documents.

## 10.0 COMPLIANCE:

10.1. **Failure to Comply**  
**EMPLOYEES WHO VIOLATE ANY SEPRACOR POLICIES AND PROCEDURES WILL BE SUBJECT TO DISCIPLINARY ACTION, UP TO AND INCLUDING TERMINATION OF EMPLOYMENT.**

10.2. Employees will be held accountable for adherence to this policy, associated policies, and supporting Procurement SOPs. Any commitment of funds that do not meet the requirements set forth in this policy will be considered non-compliant.


10.3. Violation of this policy or procedures will result in employee loss of expenditure privileges, non-payment to Suppliers, and cancellation of unauthorized Supplier Contracts. Suppliers not approved through the appropriate process for use in Oracle and appropriately qualified will not be paid and/or may be placed on payment hold, conditional use, or disqualified for use.

10.4. **Violations**  
 Reports concerning wrongful behavior, violations or suspected violations of this or any other policy, the Code of Conduct and Ethics, law or regulation may be submitted on a confidential basis or may be submitted anonymously through Sepracor's Compliance Hotline. Reports of violations or suspected violations of alleged misconduct or wrongful behavior will be maintained as confidential as practicable under the circumstances, and as necessary to conduct a full and fair investigation.

Toll free telephone number. 866-886-1348  
 Via the internet at: [www.ethicspoint.com](http://www.ethicspoint.com)

10.5. **Amendment**



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Management reserves the right to amend this policy as appropriate at any time without prior notice, pursuant to Sepracor Corporate Policy 1.0, "Origination, Revision, Communication and Archiving of Sepracor Corporate Policies."

10.6. **Approval:**

Ownership and maintenance of this policy is the responsibility of Sepracor Procurement. Sepracor Procurement will review the policy annually and make revisions as necessary. This policy, and significant changes to this policy, will be approved by Sepracor Procurement and all appropriate Sepracor boards and committees as required by tier level designation.


10.7. **Audit:**

Each department; shall perform periodic reviews of the implementation of this Policy, under the oversight and guidance of the Chief Compliance and Ethics Officer.

Procurement will provide non-compliance reports and notify individuals, managers, and the Management as appropriate.

10.8. **Governance:**

Internal Audit has responsibility for independently auditing the effectiveness of the company's regulatory compliance management program by its performance of routine internal audits in which compliance with major laws and regulations are regularly tested, and through targeted regulatory compliance audits as warranted.

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**Document History**

<u>Revision</u>	<u>Date Effective</u>	<u>Comment</u>
00		<b>New SOP.</b>