
	NON-REGULATORY STANDARD OPERATING PROCEDURE	SOP Number: PRO-004	
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WRITTEN BY:	Signature	Date
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1.0 OBJECTIVE AND SCOPE

- 1.1 The objective of this standard operating procedure is to define the procedures for preparing the minimum Supplier status requirements (i.e., Approved, Preferred), Supplier qualification and approval processes, and Approved/Preferred Supplier list management.

2.0 RESPONSIBILITY

- 2.1 This policy applies to all employees of the Company and those who act on its behalf for procurement purposes.
- 2.2 The Procurement department is responsible for the maintenance of this SOP.


3.0 REFERENCED DOCUMENTS

- 3.1 Related policies and SOPs regarding expenditure authority, approval and signing authority have been established elsewhere. Important matters 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
 - Procurement Glossary, PRO-005
 - Receiving Goods & Completion of Services SOP
 - Educational Grant Policy
 - Health Professional Consultant Policy
 - Customs–Trade Partnership Against Terrorism Program and Tier-One International Suppliers SOP.
 - Code of Conduct and Ethics
 - 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.


These policies and procedures have been documented to standardize the procurement process. Important matters related to the commitment of Company funds and resources are discussed in these policies. Please become familiar with them prior to engaging in procurement activities.

4.0 GENERAL

- 4.1 The New/Change Supplier Request Form provides specific requirements and identifies exclusions from ASL requirements some of which include:
- 4.1.1 Suppliers of goods and services directly impacting the quality of products, or utilized in support of regulatory submissions, must be on the Approved Supplier List (ASL) and appropriately qualified.
 - 4.1.2 Analytical or Testing laboratories, which generate data in support of a regulatory submission, must be on the ASL and appropriately qualified.

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- 4.1.3 Service providers, who impact the cleanliness, maintenance, or operation of a Sepracor facility, must be on the ASL, and appropriately qualified.
- 4.2 Suppliers required to be on the ASL will sign a Supplier Agreement as required by the Contract Review and Signing Authority Policy and supporting SOPs, in order to be approved.
- 4.3 Suppliers currently being used as of the effective date of this document are "Grandfathered" to the Approved Supplier List for a period of twelve months. If those Suppliers are made inactive for any reason, they will have to follow the current qualification and approval process to be made an Active Supplier, i.e. an Approved Supplier.
- 4.4 **Materials or services must not be ordered from Suppliers that have been disqualified.**
- 4.5 Incoming acceptance activities and requirements are defined in the Receiving Goods and Completion of Services SOP.
- 4.6 The ASL should be reviewed by Procurement and Accounts Payable on a periodic basis.
- 4.7 Definitions
- 4.7.1 Please refer to the associated Procurement Glossary Document, found on the SEPResource Procurement Portal and in the Corporate Standard Operating Procedures (SOP's) and Memorandum of Standards (MOS's) Index.
- 4.8 Roles & Responsibilities
- 4.8.1 Stakeholder is responsible for:
- Identifying Supplier options in collaboration with Procurement prior to new Supplier requests
 - Completing *New/Change Supplier Request Form* and submitting required documentation, to the Procurement Department.
 - Submitting *Supplier Performance Assessment Forms* to the Procurement Department
 - Requesting supplier complete the Supplier Profile Form
- 4.8.2 The Procurement Department is responsible for:
- Performing or approving Supplier qualification process
 - Reviewing and approving new Supplier requests
 - Compiling and publishing Preferred Supplier List on SEPResource Procurement Portal ("Buy Smart")
- 4.8.3 Accounts Payable is responsible
- Setting up Approved Suppliers in Oracle
 - Notifying Procurement that the new Supplier is available
 - Coding Suppliers as Active or Inactive

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5.0 PROCEDURES

5.1 Minimum Requirements

5.1.1 The minimum vetting requirements are contained in the Approved Supplier List Authorization (ASL) Form and the Strategic Sourcing SOP. Minimum Requirements vary by type of service requested, but in general consist of:


- A quality audit or assessment
- Confidentiality agreements and/or contractual documents
- Other requirements in accordance with regulatory requirements
- Financial screen
- Other internal procurement related policies and SOPs

5.1.2 In general vendor evaluations encompass broad areas of inquiry including a supplier's:

- Global reach
- Financial management and stability
- Quality evaluation
- Continuous improvement practices
- Systems assessment
- Technical competence
- Total Cost of Ownership
- Service and responsiveness

5.1.3 In addition to the minimum ASL requirements, the supplier selection team should choose and document their broader supplier evaluation based on the Strategic Sourcing SOP if applicable.

5.1.4 The following information is required for the Procurement Department's review and approval process for Approved Suppliers. All forms are available on SEPRResource Procurement Portal under the tools and templates section and Legal Affairs Portal.

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- New/Change Supplier Request Form
- New/Change Supplier Request Form
- Supplier Profile Form
- Sepracor Confidential Disclosure Agreements
- Approved Contract and/or Master Services Agreement
- Quality Audit or Assessment if required
- Financial Screen

5.1.5 Oracle Supplier classifications:

- Oracle supports two Supplier classifications: Active and Inactive Suppliers.

5.2 Supplier Qualification Process Overview

5.2.1 Prior to Supplier approval, Procurement must perform or approve a qualification process, resulting in Approved Supplier status.


- The qualification process should include, a competitive sourcing event (e.g., RFx) if applicable. A competitive sourcing event varies by spend category, but is characterized by the involvement of multiple Suppliers and includes evaluation against other Suppliers using category relevant criteria.
- Additional qualification efforts may include: financial screens, QA audits, site visits, or feedback from references.
- Refer to the Strategic Sourcing SOP for direction on qualifying Suppliers or contact Procurement.

5.2.2 Approved Supplier status may be assigned or recognized by Procurement without an award of business, execution of a contract, or Requisition.

5.2.3 In Oracle, a supplier assigned an Active classification, is an Approved Supplier.

5.3 Understanding Supplier Status

5.3.1 **Approved:** Supplier status in Oracle is set to Active status based on records for each of the following requirements being completed:

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- Stakeholder Completed and Procurement Signed *New/Change Supplier Request Form* and accompanying documentation.
- Supplier completed profile form.
 - AP uses form to set up Supplier in Oracle.
 - If supplier doesn't provide all required information to complete the supplier profile, Stakeholder should obtain the remaining information and complete the profile form.
- Supplier and Stakeholder signed Supplier Agreements per Legal Affairs Policy and SOPs.
- A quality audit or assessment has been performed by appropriate quality organization with a minimum acceptable quality rating if applicable.
- Documentation of a completed financial assessment which include the following:
 - review of the supplier financial status by Sepracor Treasurer
 - Dun & Bradstreet reports
 - and/or an audit of procedures by Sepracor Finance
- Note: The minimum vetting requirements are contained in the Approved Supplier List Authorization (ASL) Form and the Strategic Sourcing SOP. Minimum Requirements vary by type of service and the above listed items may not be required in all cases. Please refer to the New/Change Supplier Request Form.

5.3.2 **In process of Qualification:** Supplier status in Oracle is set to Inactive based on receipt of records or documents for each of the following requirements:

- Confidential Disclosure Agreement (CDA) or equivalent has been signed and executed as required by Legal Affairs Policy and SOPs.
- On-site Quality Audit is scheduled or Supplier Assessment is initiated.
- Procurement activity is not allowed for high risk categories or Suppliers where regulatory submissions are required.

5.3.3 **Inactive:** Supplier Status is set to Inactive based on the following:

- Supplier is in the process of qualification
- No Procurement or payment activity with a Supplier for 18 months


5.3.4 **Disqualified:** Supplier status, is set to Inactive, in the event of poor performance, financial instability, unacceptable business or legal risk, or any other reason that leads to the decision to exit a Supplier. AP enters a note/comment capturing the reason for disqualification in Oracle. AP removes Suppliers from the ASL or Active status when any of the following occur:

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- Supplier's performance falls below an acceptable level, as determined by Procurement and Stakeholder
- At the discretion of Procurement, any Supplier with no purchase and/or payment history in the previous 18 months may be removed and placed in an Inactive status for one year and then purged unless restored to the Approved Supplier List
- To disqualify a Supplier, Procurement or the Stakeholder should document the disqualification as appropriate, which includes:
 - justification for disqualification
 - scope of the disqualification (specific commodity, supplier site, entire company, etc)
 - specific criteria required for re-qualification of supplier
 - mitigation plan to ensure business continuity
 - approval of a procurement manager or equivalent and the quality manager or equivalent
- Reinstatement from disqualified status require the following activities: Supplier on-site assessment with a minimum acceptable score. All non-conformances are resolved with acceptable and verified corrective actions implemented.
- **Procurement activity is not allowed with suppliers at disqualified status.**

5.4 Supplier Approval Process

- 5.4.1 A Supplier qualified per the Strategic Sourcing SOP and the criteria defined above that has an approved Contract and/or Master Services Agreement and Sepracor Confidential Disclosure Agreement in place as required by Legal Affairs Policy and SOPs or has been "Grandfathered" as noted above are recognized by Procurement as an Approved Supplier.
- 5.4.2 Stakeholders can submit new Supplier requests if an Approved Supplier isn't available or performance/quality issues exist. The Stakeholder needs to provide Procurement with evidence that the gap in capabilities exist before requesting new Suppliers. The Procurement Department works with the Stakeholder to determine the best option for their requirements and follows the appropriate selection process as outlined in the Strategic Sourcing SOP.
- 5.4.3 If Procurement and Stakeholder determine a new Supplier is the best option, the Stakeholder completes an *New/Change Supplier Request Form* and submits it to Procurement to begin the Supplier Approval Process.
- 5.4.4 Procurement reviews the new Supplier request and confirms that the activities described in 5.2 and supporting documentation 5.3.1 are complete prior to Supplier approval.

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- 5.4.5 If the New Supplier Request is approved, Accounts Payable enters the Supplier information into Oracle and activates the supplier as an Active Supplier for new requisitions. Accounts Payable notifies Procurement when the Active Supplier is available in the system.
- 5.4.6 If the New Supplier Request is not approved, Procurement works with the Stakeholder to review the justification for the request and determines whether to approve the new Supplier or recommend alternatives. If issues occur in the approval process, requests are escalated to the Director of Procurement.

5.5 Approved Supplier List Maintenance

5.5.1 Approved Supplier List Additions

- Reference section 5.4 for the process to request new Suppliers.
- Stakeholder completes and submits the New/Change Supplier Request Form to Procurement.
- Procurement reviews, approves or rejects ASI request and notifies Stakeholder..
- Procurement signed and approved forms are directed to AP for processing.
- AP enters Supplier information, codes Supplier to Active, and notifies Procurement of the added Supplier.
- AP archives New/Change Supplier Request Form.

5.5.2 Approved Supplier List Updates

- Stakeholders notify the Procurement Department of changes to existing Approved Suppliers.
- Accounts Payable updates the Approved Supplier information in Oracle and forwards the notification to Finance for any invoice or payment address changes.

5.5.3 Removals from the Approved Supplier List

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- Upon expiration of an Approved Supplier Contract and/or Master Services Agreement, Procurement works with Accounts Payable and Legal Affairs to:
 - suspend the Approved Supplier in Oracle if appropriate
 - sets Supplier status to Inactive which prevents creation of new Purchase Orders but allows any open invoices to be paid.
- If an Approved Supplier is terminated for any reason prior to the completion of its Contract, employees can notify the Procurement Department of changes to the Approved Supplier information by submitting an *New/Change Supplier Request Form*.
- AP makes the appropriate update to suspend the Approved Supplier information in Oracle and forwards the notification to Procurement.

5.5.4 Approved Supplier List Reviews

- Procurement and Accounts Payable conduct periodic reviews of the ASL. Review includes review of PO history to determine if supplier should remain on ASL.
- Procurement reviews the Approved Supplier List with internal stakeholders prior to modification, except where modification is due to procurement inactivity, or other general ASL maintenance.

5.6 Preferred Supplier List and Maintenance

- 5.6.1 Procurement at their discretion may elect to assign a Preferred Supplier Status to an Approved Supplier in accordance with business needs and an overall sourcing strategy.
- 5.6.2 An Approved Supplier that demonstrates a successful track record of performance with appropriate endorsement(s) by relevant category stakeholders can be recognized by Procurement as a Preferred Supplier of a particular product/service.
- 5.6.3 Preferred Supplier Criteria
 - Supplier meets the Approved Supplier Criteria
 - Participation in a supplier performance review program
- 5.6.4 Procurement compiles and publishes a Preferred Supplier List on the SEPResource Procurement Portal ("Buy Smart"). The Preferred Supplier List should be accessible by all Company personnel and searchable/sortable by certain criteria (e.g., Supplier name, location, spend category, and product/service).
- 5.6.5 Preferred Supplier List Reviews

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- The Procurement Department reviews the Preferred Supplier List periodically, but at least every six months.
- Modifications to the Preferred Supplier List are reviewed with the relevant category stakeholders prior to modification.

5.6.6 Removal from Preferred Supplier List


- Upon suspension or removal of Approved Supplier status, the Procurement Department suspends or removes Preferred Supplier status accordingly.
- Should a Preferred Supplier cease to demonstrate a successful track record of performance and/or lack appropriate endorsement(s) by relevant category stakeholders, the Procurement Department makes the appropriate updates to suspend or remove the Preferred Supplier designation.
- Suspension or removal of Preferred Supplier status does not necessarily result in suspension or removal of Approved Supplier status.

5.6.7 In addition to regular, periodic reviews, Preferred Suppliers are required to rebid or participate in a competitive sourcing event after a reasonable tenure, not to exceed two years.

6.0 ATTACHMENTS

6.1 New/Change Supplier Request Form

Insert Form Here

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7.0 DOCUMENT HISTORY

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

The last page of each SOP is a Document History listing that includes each revision number, effective date, and summary of changes corresponding to that revision.

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