



## 340B Compliance Audit Statement of Work

**Vizient, Inc.**, a Delaware corporation, ("**Vizient**"), will provide the services detailed in this **340B Compliance Audit Services Statement of Work** ("**SOW**") to **County of Ventura**, a political subdivision of the State of California ("**Member**"), for the Service Fees indicated hereunder. **This SOW is made pursuant to the terms and conditions set forth in the Master Services Agreement between the Parties dated November 1, 2022, including any amendments or addendums thereto** (collectively, the "**Master Agreement**"). As such, all capitalized terms used herein and not otherwise defined in this SOW will have the meanings ascribed to such terms in the Master Agreement. **This SOW is effective as of January 15, 2024** (the "**Effective Date**"). Vizient and Member are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

### 1. **Services.**

**1.1 Services Description.** Vizient will assess Member's 340B program compliance and Member's 340B program compliance review and pharmacy operations in an effort to support Health Resources and Service Administration ("**HRSA**") audit readiness. The services are designed to identify any compliance risks associated with Member's 340B program as it is currently implemented and provide support for an official HRSA audit. A mock audit similar in scope and sample size to an actual Office of Pharmacy Affairs ("**OPA**") audit will be included as part of the review. Vizient will provide an onsite assessment that includes both Member and contract pharmacy relationships for the following to Member (collectively, the "**Services**"). Specifically, the Services include:

**A. 340B Compliance Audit.** The Services are designed to identify any compliance risks associated with Member's 340B program as it is currently implemented and provide support for an official HRSA audit. Vizient will provide, at a time and with a deadline for completion to be mutually agreed upon by the Parties, a comprehensive assessment, quality assurance, and simulation of a mock audit conducted by HRSA auditors for hospital-based, clinic-based, and contract pharmacy-based programs that includes the following:

- i. Registration – Current adherence to database accuracy;
- ii. Program governance – Current resources allocated to provide proper 340B oversight and management;
- iii. Covered entity eligibility – Eligibility and accuracy of current registration through review of the Medicare cost report, facility information, patient eligibility and OPA database;
- iv. Diversion prevention – Review system, and/or process in place that precludes dispensing 340B drugs to non-340B patients;
- v. GPO prohibition or orphan drugs as applicable – Review system and/or process in place to ensure these are handled properly;
- vi. Duplicate discount – Review system and or process in place that prevents accessing duplicate discounts;
- vii. Policy and procedure – Completeness of and adherence to written policies and procedures and assess compliance to HRSA guidelines, including evaluating the current 340B processes and update/develop enhancements to policies and procedures as appropriate, including but not limited to a) the Member's current self-auditing process and b) revising or developing a master checklist of key monthly, quarterly, and annual activities to be performed by the Member;
- viii. Eligible providers – Review system and/or process, in place to select and maintain a 340B provider list;
- ix. Internal controls – Scope of internal compliance monitoring and performance improvement documentation; and
- x. Audit preparation – Ensure readiness elements in place by:

- a. Verifying that prescription dispensing data reflects actual activity in the pharmacy by confirming:
  - (i) Historical dispensing data is listed for all prior days of operation of the pharmacy;
  - (ii) All prescription data contains National Drug Code ("NDC");
  - (iii) Quantity dispensed;
  - (iv) Reversals appear in the prescription claims data and are reflected as negative quantities; and
  - (v) Duplicate dispensing data is not present unless accompanied by a prescription reversal.
- b. Review the process for tracking utilization and procurement of drugs on 340B pricing;
- c. Review 340B procurement and utilization for:
  - (i) Ambulatory clinics and infusion centers;
  - (ii) Emergency department utilization;
  - (iii) Day surgery utilization;
  - (iv) Retail pharmacy;
  - (v) Areas outside of the scope of pharmacy that may dispense drugs or supplies that may have a 340B contract; and
  - (vi) Areas that require the implementation of a process outside the normal scope of tracking methods of pharmacy to identify a corresponding 340B savings opportunity.
- d. Review process(es) to articulate Member 340B eligibility tracking methodology and procurement replenishment process, including data capture and validation, updating and maintenance procedures, and reporting. This will include but not be limited to a) fulfillment processes for all identified eligible areas including clinics and physician offices; b) prescription fulfillment areas for take-home medications; c) wholesaler reporting and price updates and 340B usage report; d) revenue reports for identification of drugs dispensed; and e) review of purchases as they relate to HRSA guidelines for the entity type;
- e. Review the pharmacy services agreements for signature execution, HRSA registration accuracy and completion;
- f. Review current internal auditing procedures and findings/reporting;
- g. Identify and conduct an assessment of the process which eliminates duplicate Medicaid rebates, including verifying that Member is consistent with Member's inclusion and exclusion of 340B-eligible dispensations on Medicaid or Managed Medicaid (if appropriate) claims;
- h. Verify provider's information such as:
  - (i) Name;
  - (ii) Key contacts;
  - (iii) Child site;
  - (iv) Addresses;
  - (v) Drug Enforcement Agency ("DEA") registration number;
  - (vi) National Provider Identifier ("NPI");
  - (vii) Hire/termination date;
  - (viii) Work is exclusively for Member in provider-based settings; and
  - (ix) Contract pharmacy listings.
- i. Review structure, business relationships, and business plans affecting the 340B compliance program;
- j. Select a random sample of qualified prescriptions (30-90) and confirm the prescription was not paid by traditional Medicaid, the conversion from quantity dispensed to partial (or full) packages is correct and reflects the quantity dispensed divided by the total number of units contained in a package of the specific NDC;
- k. Verify that the patient received the prescription from a physician that has been identified as only serving 340B qualified patients, received care within a provider-based location and the care was related to the specific prescription filled. The Parties agree and acknowledge that testing may require reviewing patient medical records to verify the relationship of the prescription to the patient treatment(s);
- l. Review and validate all eligible departments of the covered entities feeding contract pharmacies, per the Member's related Medicare cost report(s);

- m. Review 340B policies and procedures that address procurement, distribution, dispensing, inventory, management, audit documentation procedures, patient eligibility, accumulation and administration of the 340B program;
- n. Evaluate adherence to the patient definition, eligible physician and prescription relationship to entity;
- o. Evaluate the Member's ability to provide auditable documentation for review;
- p. Provide a mid-point output and review of findings;
- q. Provide a detail report and presentation within one (1) month of assessment and mock audit completion at a mutually agreeable time to Member leadership of all findings and recommendations, including but not limited to the following:
  - (i) areas of partial or incomplete compliance and recommendations for corrective action including:
    - a. Recommendations and support for ensuring compliant 340B process to mitigate diversion and duplicate discounts;
    - b. Provide proposed updates to policies and procedures based on Vizient recommendations;
    - c. Recommendations for ensuring staff are compliant in the new procedures; and
    - d. Provide current and future state operating procedures and diagrams that describe the 340B process at Member site.
  - (ii) Recommended master checklist of key monthly, quarterly, and annual activities to be performed by Member to maintain compliant utilization of 340B contracts;
  - (iii) Recommended changes to 340B procurement process, including software, for accurate representation of utilization and corresponding purchases; and
  - (iv) Updates to Self-Auditing Plan and provision of a "Briefing Manual" for HRSA Audit preparation.
- r. Serve as a resource for questions and guidance post audit.

**B. Protected Health Information.** The Parties acknowledge that Services include the use of Protected Health Information ("PHI") and thus, any PHI disclosed hereunder shall be subject to the Parties' Business Associate Agreement dated January 15, 2024.

**1.2 Member Duties.** Vizient's ability to complete Services within the Term is based upon Member's cooperation and the timely performance of the following Member duties:

- A. Vizient Access.** Member will provide Vizient personnel with timely access to Member's facilities, network, personnel, equipment, and software as required by Vizient to perform the Services described herein.
- B. Member Data.** Member will provide accurate and complete data upon Vizient's request. This includes any and all interview requests with key Member personnel. Should Member fail to provide accurate and/or complete Member data, Vizient will have no obligation to re-perform or correct Services.
- C. Services Coordinator.** Member will designate an employee to: (i) coordinate Services; (ii) ensure Member data is accurate, complete, and submitted in a timely manner; and (iii) obtain any internal approvals needed for Vizient to perform Services ("Services Coordinator").
- D. Reimbursable Expenses.** Member and Vizient acknowledge and agree that Reimbursable Expenses, as defined by and subject to the Master Agreement, are in addition to the Service Fees set forth hereunder.

## **2. Term and Termination.**

**2.1 Term.** The term of this SOW will commence on the Effective Date and continue for a period of two (2) months (the "Term")

**2.2 Termination for Convenience.** This SOW may not be terminated for convenience. If the Master Agreement expires or is terminated for convenience prior to the expiration of this SOW, the applicable terms and conditions of the Master Agreement survive for the limited purpose of governing this SOW for its remaining Term.

**2.3 Termination for Cause.** The Parties may terminate this SOW for material breach in accordance with the terms of the Master Agreement.

**3. Insurance.**

**3.1** Vizient, at Vizient's sole cost and expense, will obtain and maintain in full force during the term of this SOW the following types of insurance:

- 3.1.1 General liability "occurrence" coverage in the minimum amount of one million dollars (\$1,000,000) combined single limit ("CSL") bodily injury and property damage each occurrence and two million dollars (\$2,000,000) aggregate, including personal injury, broad form property damage, products/completed operations, broad form blanket contractual and \$50,000 fire legal liability;
- 3.1.2 Commercial automobile liability coverage in the minimum amount of one million dollars (\$1,000,000) CSL bodily injury and property damage, including owned, non-owned, and hired automobiles. Also to include uninsured/underinsured motorists coverage in the minimum amount of one hundred thousand dollars (\$100,000) when there are owned vehicles;
- 3.1.3 Workers' compensation coverage, in full compliance with California statutory requirements, for all employees of Vizient and employer's liability coverage in the minimum amount of one million dollars (\$1,000,000). Workers' compensation coverage is not required if Vizient provides written verification it has no employees and has other medical coverage;
- 3.1.4 Professional liability/technology errors & omissions coverage in the minimum amount of one million dollars (\$1,000,000) each occurrence and two million dollars (\$2,000,000) aggregate; and
- 3.1.5 Cyber liability/security and privacy insurance coverage, which may be maintained within a technology errors & omissions policy) in the minimum amount of two million dollars (\$2,000,000) per claim and four million dollars (\$4,000,000) annual aggregate.

**3.2** All insurance coverage Vizient is required to obtain and maintain will be primary coverage as respects Member, and any insurance or self insurance maintained by Member will be excess of Vizient's insurance coverage and except with respect to professional liability coverage, will not contribute to it.

**3.3** Member is to be notified immediately if any aggregate insurance coverage is lowered below required limits. Vizient must purchase additional coverage to meet requirements.

**3.4** For the general liability insurance required above, Member is to be named as additional insured as respects work done by Vizient under the terms of this SOW.

**3.5** Vizient agrees to waive all rights of subrogation against Member and its boards, agencies, departments, officers, employees, agents and volunteers for losses arising directly or indirectly from the services, work and/or activities performed under the terms of this SOW.

**3.6** Policies will not be canceled, non-renewed or reduced in scope of coverage until after thirty (30) days' written notice has been given to Member. Vizient will provide prompt written notice of non-renewal, termination or diminution below required limits to Member's Risk Management Division, located at 800 S. Victoria Ave., Ventura, CA 93009.

**3.7** Vizient agrees to provide Member with the following insurance documents on or before the commencement date of this SOW:

- 3.7.1 Certificates of insurance for all required coverage;
- 3.7.2 Additional Insured endorsement for general liability insurance; and
- 3.7.3 Waiver of subrogation endorsement (also known as waiver of transfer rights of recovery against others, waiver of our right to recover from others) for workers' compensation insurance.

Failure to timely provide these documents, upon Member's request, will be, at Member's sole discretion, grounds for immediate termination of this SOW or suspension of the commencement date.

#### 4. Service Fees and Invoicing.

**4.1 Service Fees.** Vizient will provide the Services described herein to Member for a total service fee of **\$17,500** ("Service Fees").

**4.2 Invoicing and Payment.** Commencing on the Effective Date, Vizient will invoice Service Fees in 2 equal monthly installments, and Vizient will invoice Reimbursable Expenses, as incurred, on a monthly basis. Member will pay invoiced balances directly to Vizient within 30 days of receipt.

Invoices will be addressed to:

<b>Name/Title/Dept.:</b>	VCMC Accounts Payable
<b>Address:</b>	800 South Victoria Ave., L #4610
	Ventura, CA 93009
<b>Member Contact Information</b>	
<b>Name/Title:</b>	
<b>Phone:</b>	
<b>Email:</b>	VCMC.AccountsPayable@ventura.org

If Member requires specific information (i.e. purchase order number) to be included in each invoice, Member will select the appropriate box below and provide the required information, ***at the time Member executes this Order Form***, and annually (or as required) thereafter:

- ☐ Purchase Order Number \_\_\_\_\_
- ☐ Contract Identification Number \_\_\_\_\_
- ☐ Other Information \_\_\_\_\_

**4.3 Member Statement Offset Option.** If adequate funds are available, Member may elect to have invoiced Service Fees and/or Reimbursable Expenses offset from Member's available cash distributions. If Member intends to elect this option, Member will request, complete, and return the Offset Authorization Form via email to [MSD@vizientinc.com](mailto:MSD@vizientinc.com).

[Signatures on next page]

## County of Ventura – 340B Compliance Audit

(MID# 3745219)

IN WITNESS WHEREOF, the Parties have caused this SOW to be executed by their duly authorized representatives as of the Effective Date.

### Vizient, Inc.

By: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

### County of Ventura

By: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

***Please sign, scan and email to: [executedagreements@vizientinc.com](mailto:executedagreements@vizientinc.com). Vizient will provide a fully executed electronic copy to Member.***