



<b>QUALITY SYSTEM</b> <b><i>STANDARD OPERATING PROCEDURE (SOP)</i></b>	Document Number <b>SOP 101475</b>	Revision <b>01</b>	Page 1 of 6
<b>CALIFORNIA 2022 COMPLIANCE POLICY AND DECLARATION</b>			

## **I. INTRODUCTION**

Vivani Medical, Inc. including our affiliated entities (referred to collectively as “Vivani,” “we,” “our,” or “us”) have established a program designed to materially comply with applicable federal and state laws and industry standards relating to the marketing and promotion of its products. Additionally, we recognize that adherence to these standards can be furthered through a compliance program that is informed by the Compliance Program Guidance for Pharmaceutical Manufacturers, published by the Office of Inspector General of the U.S. Department of Health and Human Services (the “OIG Guide”). The OIG Guide advises that effective compliance programs are comprised of seven elements. As described below, these elements form the basis of Vivani’s program for compliance with the standards regulating the marketing and promotion of its products. In addition, we have implemented and maintained on our website (<http://www.vivanimedical.com/>) information related to California State requirements, and a phone number (818-833-5000) to request further information related to California State requirements.

## **II. OVERVIEW OF COMPLIANCE PROGRAM**

### **1. Written Policies and Procedures**

Vivani has written policies to assure substantial compliance with the applicable laws and regulations and standards governing the marketing and promotion of our products. Among these standards are recognized industry codes of conduct including the Code of Ethics on Interactions with Health Care Professionals (“AdvaMed Code”), published by the Advanced Medical Technology Association (“AdvaMed”). We have established written policies that govern activities involving communicating with customers about the appropriate use of our products, including appropriate instruction, education, training, service, and technical support required for the safe and effective use of our products. We also have policies governing activities involving the advancement of scientific and educational activities supporting medical research and education. These policies include:

- **Policy on Educational Grants and Research Grants**

We may provide grants for specific educational purposes that benefit patients and customers. These may include, but are not limited to, continuing medical and paraprofessional education programs, fellowships provided to teaching institutions and similar organizations with a demonstrated commitment to scientific and technical education, and programs operated by organizations that provide high-quality, nationally recognized patient education. Funding of educational programs will generally be provided only to organizations and institutions and not to individual practitioners. Research grants to support customer-initiated research may be provided



<b>QUALITY SYSTEM</b> <i>STANDARD OPERATING PROCEDURE (SOP)</i>	Document Number <b>SOP 101475</b>	Revision <b>01</b>	Page 2 of 6
<b>CALIFORNIA 2022 COMPLIANCE POLICY AND DECLARATION</b>			

for programs involving research in areas of legitimate interest to the company. All requests are subject to committee review prior to funding approval.

- **Policy on Charitable Contributions and Patient Assistance**

We will consider charitable contributions consistent with our policies.

- **Policy on Travel Expense Reimbursement for CME, Promotional or Product Training Meetings**

We will not, with very limited exceptions that are in accordance with nationally recognized standards, reimburse for travel and lodging expenses of attendees at promotional and educational programs.

We may reimburse attendees for reasonable travel and lodging expenses associated with attendance at product training meetings. Product training meetings will be conducted in locations conducive to the exchange of information, such as educational or conference settings. Where face-to-face or hands-on customer training reasonably necessary for the safe and effective use of our products is required, we may provide training at our company facilities, at independent teaching centers such as medical institutions, or in other appropriate clinical settings.

- **Policy on Business Meals**

We may occasionally offer a modest meal, consistent with the standards of the AdvaMed Code as part of an educational presentation or a business discussion. Venues that feature entertainment or recreation, and attendance by spouses or guests, are not permitted.

- **Policy on the Provision of Educational and Practice-Related Items**

On occasion, our representatives may provide items that benefit patients or serve a genuine educational function for Health Care Professionals, consistent with the standards of the AdvaMed Code. Examples may include patient care and education-related items up to \$100.00, textbooks up to \$300.00, and medical equipment up to \$400.00.

- **Total Annual Dollar Limit for Meals, Educational or Practice-Related Items, Product Training Expenses, and Expense Reimbursement for Product Training Meetings**

We have established an annual limit of \$1,500.00 for meals and educational items as the aggregate value of the items or activities that may be provided to California health care professionals pursuant to the requirements of Cal. Health & Safety Code § 119402 (S.B. 1765).

- **Policy Prohibiting Entertainment**



<b>QUALITY SYSTEM</b> <b><i>STANDARD OPERATING PROCEDURE (SOP)</i></b>	Document Number <b>SOP 101475</b>	Revision <b>01</b>	Page 3 of 6
<b>CALIFORNIA 2022 COMPLIANCE POLICY AND DECLARATION</b>			

It is our policy not to provide Entertainment (e.g., sporting events, golf outings, concerts, hunting, etc.) to customers.

## **2. Assigned Compliance Officer**

Vivani has appointed a Compliance Officer. Our Compliance Officer has been empowered with appropriate authority to exercise independent judgment and has free and unencumbered access to senior management.

We have appointed a Health Care Compliance Committee. The committee is comprised of the company's Compliance Officer and members appointed by the Compliance Officer. The Health Care Compliance Committee is the Compliance leadership team. We have also established Board-level compliance oversight.

## **3. Training**

Vivani has a Health Care Compliance training process that, when required, includes testing and annual certification of appropriate employees. New associates receive training at the time of hire and annually thereafter. The training covers applicable guidelines governing our compliance program. Employees will also be trained on the consequences of failure to comply with the requirements of our compliance program.

## **4. Communication**

Vivani encourages open and candid discussion between management and employees regarding any compliance concerns. Our employees are encouraged to report their concerns to their manager, to the Human Resources Department, or to our Compliance Officer. Employees also have the option to report potential violations anonymously using a Compliance Hotline at (844) 301-0008, administrated by Lighthouse, or the Lighthouse website at [www.lighthouse-servies.com/vivani](http://www.lighthouse-servies.com/vivani).

## **5. Auditing and Monitoring**

Vivani self-assesses and periodically audits its compliance with its policies and procedures. Audit observations are reviewed and tracked to ensure timely and effective closure of identified items.

## **6. Enforcement and Disciplinary Guidelines**

Vivani will take disciplinary actions in response to violation of our compliance policies or procedures. We will conduct a fair and diligent investigation of matters that are brought to our attention to ensure the consistent application of our standards.

## **7. Responses To Detected Problems, and Actions To Correct Issues**

Vivani requires a prompt and diligent response to potential violations of our compliance program, including standards regulating the marketing and promotion of our products.



<b>QUALITY SYSTEM</b> <b><i>STANDARD OPERATING PROCEDURE (SOP)</i></b>	Document Number <b>SOP 101475</b>	Revision <b>01</b>	Page 4 of 6
<b>CALIFORNIA 2022 COMPLIANCE POLICY AND DECLARATION</b>			

Actions in response to detected problems may include improving policies, procedures, training, communication, and monitoring, or may require disciplinary action to prevent future violations.

### **III. CALIFORNIA CONSUMER PRIVACY ACT OF 2018**

The California Consumer Privacy Act of 2018 (“CCPA”) gives certain consumers that reside in California (“California Consumers”) the right to know what categories of Personal Information Vivani collects about them and how and for what purposes we use and share that information. “Personal Information” means information that identifies, relates to, describes, is reasonably capable of being associated with, or could reasonably be linked, directly or indirectly, with a particular individual or household. Personal Information includes, but is not limited to, the categories of Personal Information identified below if such information identifies, relates to, describes, is reasonably capable of being associated with, or could be reasonably linked, directly or indirectly, with a particular individual or household. If you are not a California Consumer, the CCPA does not apply to you.

We are for-profit business that does collect Personal Information of California Consumers; however, we do not have annual gross revenues more than \$25 million, we do not annually obtain Personal Information of 50,000 or more California Consumers, households and/or devices, and we do not derive 50% or more annual revenue from selling California Consumers’ Personal Information. For these reasons, Vivani is currently considered exempt from complying with CCPA provisions.

In addition, provisions of the CCPA do not apply to certain medical information that is collected pursuant to the California Confidentiality of Medical Information Act (“CMIA”) or protected health information under Health Insurance Portability and Accountability Act (“HIPAA”), and its implementing regulations. We do collect Personal Information from some California Consumers that is considered protect health information governed under CMIA and HIPPA. The CCPA also exempts most clinical trial data.

We may collect Personal Information that may pertain to a company or business entity. The CCPA is not applicable to Personal Information processed solely in the business-to-business context, for example, information about an individual acting in his or her capacity as a representative of a company or business, and other data that is exempt from the requirements of the CCPA.

We also collect Personal Information about California Consumers during a California Consumer acting as a job applicant, employee, owner, director, officer, or contractor of ours where that information is exclusively used within the context of his or her role as a current or former job applicant, employee, owner, director, officer, or contractor. Please note that, at



QUALITY SYSTEM <i>STANDARD OPERATING PROCEDURE (SOP)</i>	Document Number <b>SOP 101475</b>	Revision <b>01</b>	Page 5 of 6
<b>CALIFORNIA 2022 COMPLIANCE POLICY AND DECLARATION</b>			

this time, consumer rights under the CCPA to request access to and deletion of all such personal information we may hold do not apply to such information.

Any questions regarding compliance with CCPR, or our exemption, should be directed to Vivani's Privacy Official at [privacy@vivani.com](mailto:privacy@vivani.com).

#### **IV. DECLARATION FOR CALIFORNIA COMPLIANCE LAW**

***As part of Vivani's ongoing efforts in compliance, we have developed a Comprehensive Compliance Program that is designed to comply with applicable federal and state laws and industry standards relating to the marketing and promotion of our products. To our knowledge as of the date of this declaration, Vivani is following our Comprehensive Compliance Program, as described here, and with California Health & Safety Code sections 119400-119402.***

A handwritten signature in black ink, appearing to read "Scott Dunbar", is written over a horizontal line.

Scott Dunbar  
Compliance Officer  
Last Updated: August 30, 2022



<b>QUALITY SYSTEM</b> <i><b>STANDARD OPERATING PROCEDURE (SOP)</b></i>	Document Number <b>SOP 101475</b>	Revision <b>01</b>	Page 6 of 6
<b>CALIFORNIA 2022 COMPLIANCE POLICY AND DECLARATION</b>			

This page intentionally left blank