



August 2019

BPL's U.S. Compliance Program

I. Introduction

Bio Products Laboratory USA, Inc. ("BPL") has established and maintains a Comprehensive U.S. Compliance Program on behalf of itself and its affiliates that market and sell plasma-derived products in the U.S. (the "Program").¹

The Program has been developed in accordance the "*Compliance Program Guidance for Pharmaceutical Manufacturers*," published by the Office of Inspector General, U.S. Department of Health and Human Services (the "OIG Guidance"). The Program reflects BPL's commitment to the highest standards of conduct.

As recommended in the OIG Guidance, the Program is tailored to BPL's size, organizational structure, and available resources. While the OIG Guidance recognizes that even an effective compliance program may not completely eliminate all misconduct by individuals, BPL's Program is reasonably designed to prevent and detect violations. The Program is dynamic, and in order to address evolving compliance needs, BPL assesses and updates the Program annually.

The key elements of the Program are:

¹ This document describes the material elements of the Program, effective as of August 2019 and updates and replaces prior documents describing the program.

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- A Chief Compliance Officer
- Written Standards of Conduct
- On-going compliance training
- Open lines of communication, including a Compliance Hotline
- Targeted monitoring and auditing, and
- A process for promptly implementing corrective action

II. Leadership and Structure

BPL's Chief Compliance Officer is Matt Boucher, U.S. General Counsel & Chief Compliance Officer. The Chief Compliance Officer reports directly to the Chief Executive Officer of Bio Products Laboratory, Ltd., and has the authority to report to BPL's Board of Directors.

The Chief Compliance Officer is responsible for developing, operating, and monitoring the Program. The Chief Compliance Officer has the authority and capability to effectuate change within BPL and to exercise independent judgment.

III. Written Standards of Conduct

The U.S. Healthcare Compliance Policies are the main compliance resource for employees of BPL and its affiliates who are engaged in the sale and marketing of BPL products in the U.S or working with U.S. healthcare professionals. Employees are required to certify at or about the time of hire and annually that

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they have reviewed and will comply with the U.S. Healthcare Compliance Policies.

The U.S. Healthcare Compliance Policies include standards of conduct that address the areas of potential risk described in the OIG Guidance.²

IV. Education and Training

BPL educates its employees on the elements of the Program. BPL employees receive initial compliance training at or about the time of hire, annual training, and periodic training as may necessary to address changes in the law, specific areas of risk, or new policies. The training materials are developed by the Chief Compliance Officer and cover the U.S. laws that are relevant to the areas of risk identified in the OIG Guidance. BPL regularly reviews and updates its training materials.

V. Effective Internal Lines of Communication

BPL is committed to promoting an open dialogue between management and employees. Our goal is that all employees with questions or concerns will know who to turn to for a meaningful response, without fear of retaliation.

BPL requires its employees to report any actual or suspected violations of law or policy. Employees can report actual or suspected violations or raise their concerns in a number of ways, including with any manager, Human Resources, a

² The U.S. Healthcare Compliance Policies are in accordance with the material aspects of the *PhRMA Code on Interactions with Healthcare Professionals*.

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member of the law and compliance departments, or by calling BPL's Compliance Hotline 1-844-863-1823.

VI. Auditing and Monitoring

BPL monitors, audits, and evaluates compliance with its policies and the law. BPL's approach includes targeted monitoring and auditing based on identified and prioritized risk areas in accordance with the OIG Guidance.

VII. Investigations and Corrective Action

The Chief Compliance Officer will promptly investigate suspected violations of Company policy or the law. The scope and manner of the investigation will depend upon the severity, materiality and nature of the allegation. All employees are expected to comply with internal investigations as a condition of employment.

The Chief Compliance Officer is authorized to consider whether interim compliance measures are required during the pendency of an investigation and, in consultation with management, implement appropriate interim measures to protect BPL.

VIII. Enforcing Policies

Employees that intentionally, repeated or materially violate BPL's policies or the law are subject to appropriate disciplinary action up to termination of employment.

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IX. Declaration under California Health & Safety Code

BPL has established an aggregate, annual dollar limit of \$2,500 on promotional items and/or meals provided to healthcare professionals who reside or practice in the State of California.

BPL declares, to the best of its knowledge, and based on its good faith understanding of the statutory requirements, that as of January 1, 2015, it is in compliance with the Program and the California Health & Safety Code.

X. BPL's Commitment

BPL is committed to the maintenance of an effective, comprehensive U.S. compliance program, and will update this document as necessary to reflect changes to the Program. The Chief Compliance Officer is available to answer questions concerning the Program at 512-993-8355.

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