California Declaration of Compliance

ACell, Inc. has established and maintains a Corporate Compliance Program in accordance with the Compliance Program Guidance issued by the Office of Inspector General, U.S. Department of Health and Human Services. Our Corporate Compliance Program is just one attribute that demonstrates our commitment to high standards of corporate conduct and ethical practices and is tailored to ACell’s size, organizational structure and resources to reasonably meet the specific needs of ACell. Our compliance policies and procedures are built upon the various laws, regulations, industry code (the Advanced Medical Technology Association or AdvaMed Code of Ethics on Interactions with Healthcare Professionals) and other requirements relevant to ACell’s business. The AdvaMed Code was developed to provide guidance specifically to the medical device industry. The AdvaMed Code is the medical device industry’s equivalent to the voluntary Pharmaceutical Research and Manufacturers of America’s Code on Interactions with Healthcare Professionals (PhRMA Code), which was developed to provide guidance to the pharmaceutical industry.

As a part of ACell’s Corporate Compliance Program, an annual aggregate dollar limit has been established concerning appropriate items covered by the California Health and Safety Code, §§ 119400-119402, that are provided to Healthcare Professionals. Examples of these items include a modest meal provided while ACell products, indications, or efficacy are presented or items or activities permitted under the OIG’s Compliance Program Guidance and AdvaMed Code. ACell’s annual dollar limit is $2,500 per individual healthcare professional. This limit is a maximum amount, not an average.

Based upon ACell’s good faith understanding of the California Health and Safety Code, ACell excludes certain items and payments from its annual dollar limit, which are listed below.

- Financial support for continuing medical education forums, including independent education
- Financial support for health educational scholarships
- Payments for legitimate professional services, and any meals or expenses associated with the provision of such services, that are based on the fair market value of the services provided
- Educational items that are provided to physicians to give to their patients to assist and enhance the patient’s understanding or management of their condition

Annual Declaration for Purposes of California Health and Safety Code §§ 119400-19402

ACell maintains a comprehensive Corporate Compliance Program and declares, to the best of its knowledge and based upon a good faith understanding of the applicable statutory requirements, that the indicated program encompasses the compliance requirements in all material respects stated in the California Health and Safety Code. ACell further affirms that the program is designed to detect, prevent, and address misconduct appropriately.
As of July 1, 2019, ACell declares that it is in fundamental compliance with the Corporate Compliance Program described above as it relates to the marketing and promotion of our products and the California Health and Safety Code, §§ 119400-119402. ACell will continue to assess the Corporate Compliance Program and the overall effectiveness of the program at least annually.

Confidential Reporting of Policy Violations and Misconduct

Information on ACell’s Corporate Compliance Program can be accessed at https://acell.com/ethics-and-compliance/. ACell’s Ethics and Integrity Hotline can be reached via the same website or by dialing 844-620-0004 or emailing reports@lighthouse-services.com. Please note: You must include the company name with your report.

For a written copy of this declaration or Corporate Compliance Program description please call 1-800-826-2926.