



## **COCHLEAR AMERICAS Comprehensive Compliance Program**

Cochlear Americas (“Cochlear” or the “Company”) has developed a Comprehensive Compliance Program that includes the following:

- Code of Conduct
- Compliance Function and Communication
- Compliance Policies and Procedures
- Compliance Training
- Confidentiality and non-retaliation for identifying compliance issues and asking questions
- Auditing and monitoring programs to ensure Company compliance with policy standards and laws and regulations
- Confidential Hotline and Disclosure Program

All of the components of the Comprehensive Compliance Program follow the Company’s commitment to bring the sounds of life to the ears of those who cannot hear – by providing the tools to hear, and the inspiration to explore the world.

### **Code of Conduct**

The Company’s *Code of Conduct* (the “Code”) describes Cochlear’s standards of conduct for all employees to follow. The Code emphasizes the Company’s commitment to comply with applicable laws and regulations, Company Policies and Procedures and high standards of business ethics.

Cochlear Americas is committed to:

- (a) full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- (b) the requirement that all of its employees and contractors shall be expected to comply with all Federal health care program requirements and with Company Policies and Procedures;
- (c) the requirement that all of the Company’s employees and contractors shall be expected to report to the Compliance Officer or other appropriate individual(s) designated by the Company, suspected violations of any Federal health care program requirements or of the Company’s Policies and Procedures;
- (d) the possible consequences to both the Company and its employees and contractors of failure to comply with Federal health care program requirements and with the Company’s Policies and Procedures and the failure to report such noncompliance; and

- (e) the right of all individuals to use the Compliance Hotline and the Company's commitment to non-retaliation and to maintain, as appropriate, confidentiality and anonymity with respect to disclosures made in the Disclosure Program which includes the Compliance Hotline.

Company employees and others are given training on the Code and Company Policies and Procedures and must acknowledge: (1) that they have received training on and access to the *Code of Conduct*; and (2) that they will comply with the Code and all Company Policies and Procedures.

The Company will periodically review the Code to determine if any revisions are appropriate and will make any necessary revisions based on such review. When the Code is revised, all employees and other interested parties will receive a distribution of the new Code.

## **Compliance Function and Communication**

The Company has a Compliance Officer who is charged with the development, implementation, and modification of the Comprehensive Compliance Program. The Compliance Officer has training, education and certifications in, and is knowledgeable about: applicable federal and state laws; compliance program management; employee training and communication; auditing and monitoring; and health care operations.

The Compliance Officer reports directly to the Senior Vice President – Corporate Services and reports at least quarterly to the Board of Directors of the ultimate parent company.

## **Compliance Committee**

The Company Compliance Committee works with and advises the Compliance Officer to oversee the Compliance Program for the Company. The Committee meets a minimum of twice yearly to address compliance issues. Each member also serves on workgroups and subcommittees as necessary to promote an effective Compliance Program within the Company. The Compliance Officer chairs the Committee and the Committee supports the Chief Compliance Officer in fulfilling his/her responsibilities.

## **Compliance Communication**

Compliance information and issues are communicated to employees through Company newsletters, e-mail, web page information, compliance training, the *Code of Conduct*, and Company Policies and Procedures.

## **Policies and Procedures**

Compliance Policies and Procedures also are available to Company employees and contractors on an in-house weblink. Company Policies and Procedures are available to Company employees on the Company intranet site. Employees also are encouraged to review the Policies and Procedures maintained by the Company's Human Resources Department for information that affects each employee. Employees and contractors receive training on Compliance Policies and Procedures and use the in-house weblink to review any changes to the policies and procedures.

## **Gifts**

The Company does not promote the exchange of gifts between its employees and contractors, recipients, candidates, physicians and vendors. Specifically, Company employees and contractors shall not give or accept any gift in any amount given to induce the referral or recommendation of any item or service payable by Medicare, Medicaid or any other Federal health care program. Cash or cash equivalents shall not be offered or provided in any amount.

On occasion it is permissible to give gifts as long as the gift is not intended to induce a referral or recommendation. Examples include:

- Recipients or candidates may receive a gift from Cochlear of nominal value (\$10 retail per gift, no more than \$50 total per calendar year).
- Physicians and other health care providers may receive a gift from Cochlear less than minimal value (\$100 fair market value per item, no more than \$300 fair market value total of all gifts per calendar year) as long as the gift is related to patient care (e.g., textbooks, educational materials, toolkits for patient education), or related to the health care provider's work (e.g., pens, mouse pads, laser pointers, clip boards). Items such as t-shirts and golf balls not related to the health care provider's work or patient benefit are prohibited.
- Modest meals where business is discussed and held in an environment conducive to business.

## **Donations**

The Company has a policy setting forth guidelines promoting the Company's commitment to providing reasonable donations to charitable organizations in compliance with all federal and state laws and regulations. Contributions may be made by Cochlear to support a charitable purpose, made only to a tax-exempt charity. Donations are made only for charitable, educational and scientific purposes related to cochlear implants and cochlear implant education. Donations are not made for supporting purely social events, funding capital projects, offering general operating support, advertising, or debt retirement. The policy requires the Company to maintain a Donations Committee to consider requests for donations from 501(c)(3) entities. Donation amounts are limited to \$5,000 per organization per Cochlear's fiscal year. The President of Cochlear must approve all requests for any amount over \$5,000 following recommendation from the Donations Committee that the purpose of the request meets policy requirements. Cochlear employees are forbidden from agreeing or promising that Cochlear will make a donation to an entity prior to the Donations Committee's consideration and decision to make such a donation. All requests for donations must be in writing by the charitable organization requesting the donation and the organization must provide proof of its 501(c)(3) status. In considering a request for donation, the Donations Committee will not consider the requesting organization's use, purchase, or referrals for Cochlear's products.

## **Education Support**

The Company maintains Compliance Policies and Procedures related to supporting education programs designed to (i) make the public aware of cochlear implant technology, (ii) provide information to candidates regarding the cochlear implant technology and eligibility criteria, (iii) inform recipients about the use of their implant and other product options; or (iv) inform the professional community about cochlear implant technology, eligibility criteria and available resources to meet patient needs. The program must be educational, scientific, or policy-oriented

with a relationship to Company products or the advancement of cochlear technology and science. Programs and events should be conducted in clinical, educational, conference, or other settings conducive to the effective transmission of knowledge. Cochlear may offer training and education only in a venue where people can learn; may only pay for reasonable travel, modest lodging and modest meals and receptions; and no costs (travel, lodging, meals, etc.) may be paid associated with spouses or other persons without a *bona fide* professional interest in the information being shared.

### **Kickbacks and Rebates**

The Company will not pay or accept any bribe, gratuity, kickback, or similar payment to anyone, including physicians, contractors, agents, patients, or agents of customers or members of agents' families, in connection with any Company services or products. The Company shall not participate in business ventures that can only be obtained by improper or illegal procedures. Kickbacks are not to be given or accepted in any form under any circumstances. Kickbacks are anything of value provided directly or indirectly to another party for the purpose of obtaining or rewarding referrals or recommendations for products or services.

### **Fraud and Abuse**

The government has established "fraud and abuse laws" that are designed to deter businesses or individuals from misusing government funds. The Company and each of its employees must maintain honest and accurate records and never offer, pay or receive any money, gifts or services in return for the referral of patients or to induce the purchase of items or services. The Company and its employees must not engage in any of the following activities, all of which are prohibited by law:

- (a) billing for supplies or services not delivered;
- (b) misrepresenting or duplicate billing of services actually rendered; or
- (c) soliciting, offering or receiving a kickback, bribe or rebate in exchange for patient referrals or recommendations, or to induce the purchase of items or services.

The Company and its employees must be especially vigilant in adhering to the highest ethical standards in conducting business that may implicate the fraud and abuse laws. The Company and its employees must not make false statements or misrepresentations at any time. For employees having claims processing, billing, and reimbursement responsibilities, the consequences of even inadvertent misstatements can be especially serious.

It can be difficult to recognize potential violations of the fraud and abuse laws regarding the prohibition against offering, paying, soliciting or receiving any money, gifts or services in return for the referral of patients; or to induce the purchase of items or services. Problematic situations that may arise include requests from physicians and other providers for special treatment or payments in return for referring patients or other business. Such requests may seek, for example, payment of an incentive each time a patient is referred, provision of free or significantly discounted goods or services, payment for goods or services in excess of their fair market value or payment for goods or services below their market value. Free goods or services in exchange for the purchase of other products also may be a violation.

Remember two important rules on this subject:

1. The Company and its employees do not pay for referrals.
2. The Company and its employees do not accept payment for referrals.

If you are faced with situations which appear to be questionable under the fraud and abuse laws, you should consult the Compliance Officer for guidance and interpretation. If you suspect that a violation of the fraud and abuse laws has occurred, you should disclose the situation directly to the Compliance Officer or the Compliance Hotline (877-543-5401).

## **Consultants**

The Company utilizes consultants experienced in implantable hearing device implant technology to speak at educational forums or to serve on advisory boards. All consultants enter into a consulting agreement with the Company which sets forth fair market value compensation and the requirements for their services. Consultants are reimbursed for modest travel, lodging and meals expenses. No reimbursement (travel, lodging, meals, etc.) may be paid associated with spouses or other persons without a *bona fide* professional interest in the information being shared.

## **Compliance Training**

The Company conducts mandatory compliance training for all employees. The Compliance Training Program includes general compliance information, training on the *Code of Conduct*, Compliance Policies and Procedures, and the entire Company Compliance Program. Annual compliance training updates will be given to all employees and applicable other parties.

## **Confidentiality and Non-Retaliation**

### **Compliance Hotline and the Compliance Disclosure Program**

The Company has established a toll-free Compliance Hotline available 24 hours per day, seven days per week. Company employees and contractors are encouraged to call the Compliance Hotline to report suspected violations of applicable law, the *Code of Conduct*, or Company Policies and Procedures, and to ask questions regarding potential compliance issues or concerns. Employees and contractors may make a report anonymously through Policy IQ, and will receive a report number so that the individual can check Policy IQ to inquire about the ongoing status of their report. Compliance Hotline calls are reviewed promptly by the Compliance Officer to determine what action should be taken.

The Compliance Hotline is advertised to employees and contractors through the *Code of Conduct*, Policy IQ, and during compliance training. Compliance Hotline activity is reported to the Compliance Committee and to the Company Board of Directors.

**The Compliance Hotline number is 1-877-543-5401.**

## **Confidentiality**

Company employees and others are required to report suspected violations of law, the *Code of Conduct*, or Company Policies and Procedures. The Company maintains a Compliance Hotline and Policy IQ system to permit employees and others to ask questions or to report suspected violations in a confidential manner.

Confidentiality will be maintained to the extent possible consistent with laws and regulations and the Company's need to investigate and/or remedy the issue.

The Company prohibits retaliation by anyone against an employee or others who, in good faith, seeks help or reports known or suspected violations. Any person retaliating against an employee or others because that individual, in good faith, sought help or filed a report, will be subject to appropriate disciplinary action, including potential termination of employment.

## **Discipline**

The Company requires all employees and others to conduct Company business in compliance with the *Code of Conduct*, Company Policies and Procedures, and applicable laws and regulations. Employees who fail to meet this commitment to ethical business conduct, are subject to appropriate disciplinary action, up to and including termination. Company managers or supervisors who condone or fail to prevent improper conduct are subject to appropriate disciplinary action, up to and including termination.

## **Ineligible Persons and Entities**

The Company screens physicians, prospective and current employees, independent contractors and vendors against the Office of Inspector General's *List of Excluded Individuals/Entities* and the General Services Administration's *List of Parties Excluded from Federal Programs*. The Company has a policy against employing or contracting with an individual or entity that is excluded or debarred from participating in federal health care programs. The Company also conducts routine background checks prior to employment. Every Company employee, contractor and vendor has an obligation to notify Human Resources if he or she learns of a proposed or implemented exclusion from any health care program. The Company is also prohibited from billing a Federal health care program for any services ordered or provided by an excluded physician or other employee.

## **Monitoring, Auditing and Investigations**

The Company utilizes Compliance Guidance and Fraud Alerts released by the Office of Inspector General (OIG) and other industry guidance along with information obtained from the Compliance Hotline or Policy IQ and inquiries by Company employees to identify potential areas of non-compliance and to develop new compliance initiatives. Monitoring of compliance with regulatory requirements is ongoing.

The Compliance Officer reviews all allegations of non-compliance with laws or policies. The nature of the allegation will determine whether an investigation will be conducted independently by the Compliance Team or with the assistance of legal counsel. Human Resources concerns are referred to members of the Human Resources Department for response.

## **Monitoring and Investigations**

If an investigation, monitoring or audit activity confirms non-compliance with law or Company policy, the Compliance Officer will work with the appropriate managers and employees to resolve the issue, take necessary corrective action, and provide support for any required disciplinary action. The Compliance Officer also works with legal counsel to identify any disclosure or repayment obligations.

## **Audits**

The Company uses self-audits, feedback from the Compliance Hotline and concerned employees, and outside consultants to assess compliance risk. The Compliance Officer conducts proactive audits to monitor compliance with laws and Company Policy and to investigate allegations of non-compliance. The Compliance Officer also reviews self-audit reports generated by Company departments and utilizes external audit consultants as needed. The Compliance Committee approves the annual audit plan developed by the Compliance Officer.

Audit results and recommendations are reported to the Compliance Committee and appropriate operations personnel. Audit reports include the response plan(s) received from operational management. Follow up audits are conducted on the response plans where appropriate.

Many audits will be conducted entirely by Company personnel. Independent auditors will perform other audits. Company employees are expected to cooperate with any Company authorized audit being conducted in their work area(s).

## **Summary**

The Company has established the Comprehensive Compliance Program to assist employees and others in complying with laws and regulations, the *Code of Conduct*, and Company Policies and Procedures. The Comprehensive Compliance Program may be modified, as necessary to prevent and detect violations of the law.

Members of the public wishing to request copies of this document or a copy of the certification required by California Health & Safety Code §119400 may call toll-free, 1-800-523-5798.