

**MED-EL CORPORATION
NOTICE OF PRIVACY PRACTICES**

**THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION
ABOUT YOU MAY BE USED AND DISCLOSED AND
HOW YOU CAN GET ACCESS TO THIS INFORMATION.**

PLEASE REVIEW CAREFULLY

We are required by law to protect the privacy of protected health information (PHI) about you and that identifies you. This PHI may be information about you which we received due to your participation in a clinical trial, information communicated by a member of your implant team to solicit assistance (e.g. programming or surgical support, reimbursement assistance, etc.) or as a cochlear implant user purchasing our product. This PHI may also include information we release to your healthcare providers in order to coordinate your medical services, to federal agencies such as the Food and Drug Administration (for tracking of medical equipment or clinical trial purposes) or healthcare reimbursement entities (e.g. Medicare, Medicaid and private insurers) in order to receive payment for equipment and services.

We are also required by law to provide you with this Notice of Privacy Practices explaining our privacy practices and legal duties with respect to your PHI. We are legally required to follow the terms of this Notice, effective as of the date listed below. In other words, we are only allowed to use and disclose PHI in the manner that we have described in this Notice. We are also required to notify you of any breach of affecting your PHI.

We may change the terms of this Notice in the future. We reserve the right to make changes and to make the new Notice effective for all PHI that we maintain. If we make changes to the Notice, we will:

- Post the new Notice on our website (www.medel.com); and
- Have copies of the new Notice available upon request.

The remainder of this Notice will:

- Discuss how we may use and disclose your PHI.
- Explain your rights with respect to your PHI.
- Describe how and where you may file a privacy-related complaint.

If, at any time, you have questions about information in this Notice or about our privacy practices, or wish to obtain a copy of MED-EL's Notice of Privacy Practices, you can contact MED-EL by toll-free telephone at 1-888-633-3524 or in writing at:

Attention: Privacy Officer
MED-EL Corporation
2645 Meridian Parkway
Durham, North Carolina 27713

**WE MAY USE AND DISCLOSE INFORMATION
ABOUT YOU IN SEVERAL CIRCUMSTANCES**

This section of our Notice explains how we may use and disclose PHI about you in order to provide services related to treatment, obtain payment for products or services and operate our business efficiently. This section then briefly mentions several other circumstances in which we may use or disclose PHI about you as required by law. For more information about any of these uses or disclosures, or about any of our privacy practices, please contact MED-EL at 1-888-633-3524.

1. Treatment

We may use and disclose PHI about you to provide treatment or services to you. In other words, we may use and disclose your PHI to provide, coordinate or manage services related to your implant system. This may include communicating with other health care providers involved in your treatment, including your cochlear implant team (e.g. surgeon, audiologist) or hospital personnel (for your implant surgery). **Example:** Jane is a patient at a cochlear implant program and is currently awaiting her cochlear implant surgery at an affiliated hospital. Jane's surgeon wants to obtain a consultation from MED-EL's Surgical Support staff regarding which of the three available implant arrays (standard, split or compressed) would best meet Jane's need, given her medical condition and physiology. The surgeon reviews preoperative data (e.g. X-ray, MRI and other information from Jane's medical record) with MED-EL's Surgical Support staff to get an opinion as to which implant array would work best for Jane. Jane's audiologist may later contact a MED-EL Clinical staff for consultation regarding Jane's speech processor programming as well as MED-EL Customer Service or Service Repair staff regarding Jane's equipment.

2. Payment

We may use and disclose PHI about you to obtain payment for equipment that you receive; this may include activities such as preparing invoices, insurance claims and managing accounts. We also may disclose PHI about you to others (such as your insurer, or in the event of collection problems, collection agencies or consumer reporting agencies). In some instances, we may disclose PHI about you to an insurance plan before you receive certain health care services. This would be done when an insurance authorization is required before services are rendered in order to ensure that your insurer will cover the costs involved; if not, this information can then be given to you and/or your health care providers so that you can make a decision regarding how you would like to proceed. MED-EL provides assistance to you, your cochlear implant center or hospital, if requested, in obtaining insurance prior authorization for your cochlear implant surgery and equipment. In the event of a denial of coverage, MED-EL Reimbursement staff will assist you in filing an appeal, in accordance with the terms of your insurance plan. **Example:** Jane is a patient at a cochlear implant program and is currently awaiting her cochlear implant surgery at an affiliated hospital. She has private insurance. Before the hospital will schedule the surgery, hospital staff must verify that Jane's insurer will cover the costs of the surgery and all related expenses. If the cochlear implant program or hospital staff needs assistance obtaining this prior authorization of coverage, they may contact MED-EL's Reimbursement staff to request assistance. The same information would be used by MED-EL to file an appeal on behalf of Jane, if requested to do so, in the event that the insurer denied benefits for the surgery. Lastly, this information would be used by the hospital when billing for the implant system or by MED-EL when billing an insurer for Jane's replacement equipment or repairs to her system that are not covered under warranty.

3. Health Care Operations

We may use and disclose PHI about you in performing a variety of business activities that we call "health care operations." These "health care operations" are activities that allow us to continually improve the quality of our products and services as well as those of other providers involved in your treatment. For example, we may use or disclose information about you in performing the following activities:

- Sending you updated information about your equipment and warranty.

- Providing information about new MED-EL products, services and benefits or other health-related information that may be of interest to you as an implant user.
- Providing information about treatment, services, products or health care providers in your area, relating to your medical needs.
- Identifying groups of people with similar medical conditions in order to provide information about available services, treatment, or new procedures in an effort to help manage and coordinate care, improve health care services and lower costs.
- Contacting you regarding participation in a customer satisfaction survey conducted for quality-improvement purposes. This may include feedback on our product and services, information about your experience with your system and any needs you have and will be used only for the purpose of improving quality.
- Face to face communications with you, for example, at a clinic meeting, patient support meeting or national cochlear implant conference. We may also send you a promotional gift of small value from time to time.
- Providing a reminder to you about an upcoming appointment, patient support meeting or other activity related to your treatment or care.
- Reviewing and evaluating the skills, qualifications and performance of personnel working with you.
- Providing training for health care professionals (for example, Audiologists in training) or non-health care professionals (for example, Insurance Support staff).
- Cooperating with outside organizations that assess the quality of the services provided by us and others with whom we work, including private organizations and government agencies (such as the Food & Drug Administration which regulates medical devices including cochlear implants).
- Cooperating with outside organizations that evaluate healthcare providers in a particular field or specialty.
- Reviewing and improving the quality, efficiency and cost of technology and services we provide and planning for MED-EL's future operations in order to better serve our customers.
- Conducting management and administrative activities related to our business, products and services.
- Resolving internal grievances within our organization.
- Reviewing our activities in the event that ownership or corporate control of our organization significantly changes.
- Working with others (such as statisticians, accountants, IT consultants, attorneys and other service providers) who assist us in complying with this Notice and other applicable laws.

Example: MED-EL Customer Service staff, with the support of Administrative Support staff, conducts mailings to MED-EL users to keep them informed about upgrades to their equipment or changes in warranty coverage.

4. Other Uses and Disclosures

When required or permitted by law, we may use or disclose PHI about you without your authorization for various activities that are recognized as "national priorities." In other words, the government has determined that under certain circumstances (described below), it is so important to disclose PHI that it is acceptable to disclose this information without the individual's permission. We will only disclose PHI about you in the following circumstances when we are permitted or required to do so by law. Below are brief descriptions of the "national priority" activities recognized by law. For more information on these types of disclosures, contact MED-EL at 1-888-633-3524.

- **As required by law:** We will use and disclose PHI about you when the use and/or disclosure is required by law, for example, when a disclosure may be required by federal, state or local law or other judicial or administrative proceeding.
- **Public health activities:** As required by law, we may disclose your PHI to public health or legal authorities charged with preventing or controlling disease, injury, or disability. Public health activities require the use of PHI for various activities, including, but not limited to, activities related to investigating diseases (such as Meningitis, by the Centers for Disease Control) and monitoring devices regulated by the Food and Drug Administration (for the purpose of tracking medical devices/ equipment, post-market surveillance, reporting adverse events, etc.).
- **Medical research:** Under certain circumstances, we may use or disclose PHI about you for medical research. This would include activities involved in preparing new research studies or when an institutional review board has given approval.

- **Abuse, neglect or domestic violence:** We may disclose your PHI to a government authority (such as the Department of Social Services) when the disclosure relates to victims of abuse, neglect or domestic violence.
- **Health oversight activities:** We may disclose your PHI to a health oversight agency that is authorized by law to oversee our operations.
- **Court proceedings:** We may disclose your PHI to a court or an officer of the court (such as an attorney) for example, if a judge orders us to do so.
- **Law enforcement:** We may disclose your PHI for law enforcement purposes as required by law or in response to a valid subpoena. Federal law allows your PHI to be released to an appropriate health oversight agency, public health authority or attorney, provided that a work force member or business associate believes in good faith that we have engaged in unlawful conduct or have otherwise violated professional or clinical standards and are potentially endangering one or more patients, workers or the public. We may use or disclose PHI about you if we believe it is necessary to prevent or lessen a serious threat to health or safety.
- **Decedents:** We may disclose PHI about you to a coroner or medical examiner for the purposes of identifying you in the event of your death.
- **Organ procurement organizations:** We may disclose your PHI to organ procurement organizations, funeral directors or other entities engaged in the procurement, banking, or transplantation of organs for the purpose of tissue donation and transplant, in accordance with applicable law.
- **Correctional institution:** Should you be an inmate of a correctional institution, we may disclose to the institution or its agents PHI necessary for your health and the health and safety of other individuals.
- **Workers' compensation:** We may disclose PHI about you in order to comply with workers' compensation laws.
- **Certain government functions:** We may use or disclose PHI about you for certain government functions, including but not limited to military and veterans' activities, national security and intelligence activities.

5. Uses and Disclosures to Which You May Object

Unless you object, we may use or disclose PHI about you in the following circumstances:

- **Persons involved in your care or payment for your care:** We may disclose PHI about you to a relative, personal friend or any other person you identify, if that person is involved in your care or payment for your care and the PHI is relevant to your care. If the patient is a minor, we may disclose PHI about the minor to a parent, guardian or other person responsible for the minor except in limited circumstances. For more information on the privacy of minors' PHI, please contact MED-EL at 1-888-633-3524. We may also use or disclose PHI about you to a relative, another person involved in your care or possibly a national health organization if we need to notify someone about your location or condition.

You may ask us at any time not to disclose PHI about you to persons involved in your care or payment for your care by contacting MED-EL in writing (at the address provided on page 1 of this Notice). We are not required to agree to your request.

Example: Jane's husband contacts MED-EL to place orders and make arrangements for shipment of replacement equipment or request troubleshooting assistance. When the Audiologist or Customer Service staff is handling the order or providing troubleshooting assistance, Jane's husband is on the phone with Jane. The MED-EL staff assisting with the order or trouble-shooting discusses this with both Jane and Jane's husband.

- **Fund raising activities:** We may use or disclose PHI about you for fund raising purposes. We would release only contact information and dates of service from MED-EL. You may ask us at any time not to disclose information about you for fund raising purposes by contacting MED-EL in writing (at the address noted on page 1 of this Notice) or by the opt-out method in each fund raising communication.

6. All Other Circumstances

Under any circumstances other than those listed above, we will ask for your written authorization before we use or disclose PHI about you unless otherwise required by law. This includes situations in which you may contact us to ask us to disclose PHI for specific purposes. This also includes use or disclosure of your PHI for marketing purposes, disclosure for medical research that has not yet been approved by an institutional review board or disclosure of your PHI in exchange for some form of payment. If you sign a written authorization allowing us to disclose PHI about you in a specific situation, you can cancel your authorization at any time by contacting MED-EL in writing (at the address noted on page 1 of this Notice). If you cancel your authorization in writing, we will not disclose PHI about you after we receive your cancellation, except for disclosures that were processed before we received your cancellation.

YOU MAY FILE A COMPLAINT ABOUT OUR PRIVACY PRACTICES

If you believe that your privacy rights have been violated or if you are dissatisfied with our privacy policies or procedures, you may file a complaint either with us or with the federal government. To file a written complaint with MED-EL Corporation, you may mail it to the following address:

Attention: Privacy Officer
MED-EL Corporation
2645 Meridian Parkway
Durham, NC 27713

You may also send a written complaint to the Secretary of the United States Department of Health and Human Services.

We will not take any action against you or change our treatment of you in any way if you file a complaint.

**YOU HAVE RIGHTS WITH RESPECT
TO PROTECTED HEALTH INFORMATION (PHI) ABOUT YOU**

You have several rights with respect to PHI about you. This section of the Notice will briefly mention each of these rights. If you would like to know more about your rights, please contact MED-EL at 1-888-633-3524.

1. Right to a copy of this Notice

You have a right to have a paper copy of our Notice of Privacy Practices at any time, even if you agreed to receive an electronic version. In addition, a copy of this Notice will be posted on our website (www.medel.com). If you would like to have a copy of our Notice please contact MED-EL at 1-888-633-3524, and a copy will be sent to you.

2. Right of access to inspect and copy

You have the right to review and receive a copy of PHI about you that we maintain in certain groups of records. You have the right to receive an electronic copy of these records. If you would like to inspect or receive a copy of PHI about you, you must provide us with a request in writing. We may deny your request in certain circumstances. If we deny your request, we will explain our reason for doing so in writing. We will also inform you in writing if you have the right to have our decision reviewed by another person. If you would like a copy of the PHI, you will be charged for the cost of copying and mailing the information.

We may be able to provide you with a summary or explanation of the PHI. You may request to see and receive a copy of your PHI or obtain more information on this service and any related fees by contacting MED-EL in writing (at the address noted on page 1 of this Notice).

3. Right to have PHI amended

You have the right to have us amend (correct or supplement) certain PHI about you that we maintain in certain groups of records. If you believe that we have information that is either inaccurate or incomplete, we may amend the information to indicate the problem and notify others who have copies of the inaccurate or incomplete information. If you would like us to amend your information, you must provide us with a request in writing and explain why you would like us to amend the information.

We may deny your request in certain circumstances such as if: 1) the information was not created by us (unless you can show that the creator of the information is no longer available to amend the record); 2) the information is not part of the records used to make decisions about you; 3) we have reason to believe the information is correct and complete; or 4) you would not have the right to see and copy the record as described in item 2 above. If we deny your request, we will explain our reason for doing so in writing. You will have the opportunity to send us a statement explaining why you disagree with our decision to deny your amendment request and we will share your statement whenever we disclose the information in the future.

You may request an amendment of PHI about you by contacting MED-EL in writing (at the address noted on page 1 of this Notice).

4. Right to an accounting of disclosures we have made

You have the right to receive an accounting (which means a detailed listing) of certain disclosures of your PHI that we have made for the previous six (6) years. If you would like to receive an accounting, you should make this request in writing to MED-EL (at the address noted on page 1 of this Notice). We are required to provide a listing of all disclosures of your PHI except disclosures for the following purposes:

- For treatment
- For billing and collection of payment for your treatment
- For health care operations
- Made to or requested by you, or that you authorized
- Incidental to permitted uses and disclosures (as outlined within MED-EL Notice of Privacy Practices)
- Made to individuals involved in your care or for notification purposes
- Allowed by law when the use and/or disclosure relates to certain specialized government functions or relates to correctional institutions and in other law enforcement custodial situations
- As part of a limited set of information which does not contain certain information which would identify you

If you request an accounting more than once every twelve (12) months, we may charge a fee to cover the costs of preparing the accounting.

5. Right to request restrictions on uses and disclosures

You have the right to request that we restrict the use and disclosure of PHI about you. We are not required to agree to your request. If we do agree to your request, we must follow your restrictions except for certain situations including emergency treatment, disclosures to the Secretary of the Department of Health and Human Services, and uses and disclosures described under Item 4 of this Notice. You may cancel the restrictions at any time. In addition, we may cancel a restriction as long as we notify you of the cancellation and continue to apply the restriction to PHI collected before the cancellation. You may request a restriction by contacting MED-EL in writing (at the address noted on page 1 of this Notice).

You also have the right to request that we not disclose your PHI to your health plan or insurance company regarding a product, treatment or service provided by MED-EL. Generally, if all of the following requirements are met, MED-EL must comply with your request:

- The disclosure is not otherwise required by law;
- The request is to restrict disclosure of your PHI to your health plan or insurance company;
- The PHI relates solely to a product, treatment, or service for which you (or someone other than your health plan or insurance company) have paid for out-of-pocket in full; and
- The requested disclosure is not for treatment purposes and relates only to payment or health care operations.

If all of the above requirements are not met, including returned or invalid payment, we may be unable to agree to your request. Once PHI about a product or service has been submitted to your health plan or insurance company, we cannot agree to a request to restrict the disclosure so please make your request as soon as possible. You may request a restriction by contacting MED-EL in writing (at the address noted on page 1 of this Notice).

6. Right to request an alternative method of contact

You have the right to request to be contacted at a different location or by a different method. For example, you may prefer to have all written information mailed to your work address rather than to your home address. We will agree to any reasonable request for alternative methods of contact but, when appropriate, may condition this on your providing us with information regarding how payment, if any, will be handled as well as your providing an alternative address or other method of contact. You may request an alternative method of communication by contacting MED-EL in writing (at the address noted on page 1 of this Notice).