

US Notice of Patient Privacy Practices

Pacific Edge Diagnostics USA, Ltd. together with its affiliates, including Pacific Edge Ltd. and Pacific Edge Diagnostics New Zealand Ltd. (collectively called “Pacific Edge, “we” or “us”) are committed to maintaining the privacy of your personal information provided to us.

We are required under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) to maintain the privacy of health information about you (“Protected Health Information”), and to notify you of our legal duties and privacy practices in relation to your Protected Health Information. Notice will take effect on 07 January 2021, and will remain in effect until it is amended or replaced by us.

This Notice of Privacy Practices (“Notice”) is given in accordance with our obligations under HIPAA, and in compliance with the HIPAA regulations setting forth the Standards for Privacy of Individually Identifiable Health Information, (“HIPAA Privacy Standards”). We are required under these HIPAA Privacy Standards to abide by the terms of this Notice.

Information Collected from Our Websites

For information about how we use and disclose information collected from our websites, including the websites www.pacificedgedx.com and www.cxbladder.com (“Websites”), please refer to our Notice of Website Privacy Practices.

Your Protected Health Information

In order to provide you with laboratory services, we will receive your Protected Health Information from your healthcare provider or another laboratory that asked us to test your sample. The HIPAA Privacy Standards require us to protect any health information that will identify you, such as your name, Social Security Number, telephone number, or address. We protect this information regardless of the form in which we receive it (e.g. oral, written, or recorded in other media).

Examples of Allowable Uses or Disclosures of Your Protected Health Information

The HIPAA Privacy Standards allow us to receive and disclose your Protected Health Information for three (3) routine purposes without first obtaining your authorization or giving you an opportunity to object. These routine uses include disclosures necessary for treatment, payment, and healthcare operations purposes. Each of these purposes is explained below.

1. **Treatment:** When we receive a request for laboratory services by your healthcare provider or a referring laboratory, it may contain your name, age, and other identifiable information.

The disclosure of this information to us is considered treatment, as is our subsequent disclosure of the laboratory results to the referring laboratory or your healthcare provider.
2. **Payment:** We may legitimately use and disclose your Protected Health Information to seek payment for services we provide for you. For example, we may send your information to a billing service to file claims for us with health plans, billing collection agencies or other payers.
3. **Healthcare Operations:** We may disclose your Protected Health Information as part of our internal operations to maintain the high quality of our laboratory services and to keep our organization operable. For example, we may use or disclose Protected Health Information in connection with quality assurance, accreditation and certification, licensing, or credentialing activities.

Other Legitimate Uses and Disclosures of Protected Health Information

The HIPAA Privacy Standards specify certain other non-routine circumstances where we may legally use or disclose your Protected Health Information without your consent. More information about these circumstances is set out below.

1. **Required by law:** We may disclose your Protected Health Information when we are required to do so by law pursuant to a judicial or administrative proceeding (court or administrative orders, subpoena, discovery request or other lawful process.)
2. **Personal Representatives:** We may disclose Protected Health Information about you to your authorized personal representative, as defined by applicable law, or to an administrator, executor or other authorized person responsible for your estate.
3. **Minors:** As permitted by federal and state law, we may disclose Protected Health Information about minors to their parents or guardians.
4. **Persons Involved in Your Care or Payment for Your Care:** We may disclose your Protected Health Information to a person involved in your care or payment for your care, such as a family member or close friend.
5. **Communications about our Products and Services:** We may use and disclose your Protected Health Information to contact you about our products and services which we believe may be of interest to you, only if you have signed an authorization that permits use of medical information.

6. Disclosures to Business Associates: We may disclose your Protected Health Information to other companies or individuals who need your information to provide services to us. For example, we may use another company to perform billing services on our behalf. Our business associates are required to protect the privacy of your Protected Health Information.

To protect the information that is disclosed, each business associate is required to sign an agreement whereby they agree to appropriately safeguard the information and not to redisclose the information unless specifically permitted by law.

7. Public health: As required by law, we may disclose your Protected Health Information to public health or legal authorities and other entities charged with preventing or controlling disease, injury, or disability. We may also disclose Protected Health Information for health oversight activities, such as audits, investigations, inspections and licensure activities. For example, we may disclose your Protected Health Information to agencies responsible for ensuring compliance with the rules of government health programs such as Medicare or Medicaid.
8. Research: We may disclose Protected Health Information to researchers in connection with a study, if an institution's review board (a committee that reviews the ethics of research projects) has reviewed the proposed study and established protocols to ensure the privacy of the Protected Health Information to be used in the study, and has determined that the researcher does not need to obtain your authorization prior to using your Protected Health Information for research purposes. The information that we may disclose is limited to the information necessary to make a transplant possible.
9. Organ procurement organizations: We may disclose Protected Health Information consistent with applicable law to organ procurement organizations or other entities for the purposes of tissue donation and transplant.
10. Food and Drug Administration ("FDA"): We may disclose to the FDA Protected Health Information relating to adverse events with respect to product defects, and may post marketing surveillance information to enable product recalls, repairs, or replacement.
11. Workers compensation: We may disclose Protected Health Information to the extent authorized by, and necessary to comply with, laws relating to workers compensation or other similar programs established by state law.
12. Correctional institution: If you are an inmate of a correctional institution, we may disclose to the institution or its agents Protected Health Information necessary for the health and safety of other individuals.
13. Disclosures to Coroners, Medical Examiners and Funeral Directors: We may disclose Protected Health Information to coroners or medical examiners for the purpose of identifying an individual, determining cause of death or other duty authorized by law.

14. Law enforcement: We may disclose Protected Health Information for law enforcement purposes as required by law. We may also disclose Protected Health Information to appropriate agencies if we believe there is the possibility of abuse, neglect, or domestic violence.
15. Judicial proceedings: We may disclose Protected Health Information to courts or administrative agencies in response to a court order, or a discovery request. In the case of the latter, we will not disclose the information unless we are satisfied that you have been given notice of the request and have not objected, or the party seeking the information obtains an order protecting the information from further disclosure.

No Other Uses and Disclosures Without Authorization

Except as otherwise permitted or required under this Notice, we do not use or disclose your Protected Health Information without your written authorization, and then we use or disclose it only in a manner consistent with the terms of that authorization. You may revoke the authorization to use or disclose any Protected Health Information at any time, by writing to the Privacy Officer listed at the bottom of this Notice, unless we have already acted under that authorization.

Your Rights

Under the HIPAA Privacy Standards, you or your authorized designated personal representative have certain rights with respect to your Protected Health Information. As a clinical laboratory we are also governed by the Clinical Laboratories Improvement Amendments (“CLIA”) Pursuant to CLIA, Pacific Edge does not, as a matter of practice, deal directly with patients. Our contact for Protected Health Information is usually your healthcare provider or another clinical laboratory that ordered the specific testing. There may be unique circumstances in which Pacific Edge responds directly to patients, but these circumstances are limited.

In accordance with CLIA, you (the patient) have the right to receive test results directly if you provide us with written authorization. Without explicit consent no results will be disclosed.

To the extent possible and appropriate, you should contact your healthcare provider to exercise the rights listed in this Notice. We will try to accommodate requests from our healthcare provider clients, if legally permissible, and clinically appropriate to respond to your exercise of these rights, which include the rights listed below.

1. Right to Inspect and Copy Personal Health Information: You have the right to request a copy of your Protected Health Information as we have received it. However, we are not permitted to disclose your test results directly to you. You may ask your healthcare provider for a copy of your test results, if you wish.

2. Right to Receive Personal Health Information via Confidential Communications:

You have the right to request that we communicate with you about your Protected Health Information by alternative means or to an alternative address. Your request must be in writing and must specify the alternative means or location. We will accommodate reasonable requests for confidential communications. Additionally, upon request from your healthcare provider we will send them your Protected Health Information in a confidential manner.

3. Right to Receive this Notice of Privacy Practices: You can request and receive a free copy of this Notice in printed or electronic form, by contacting our Privacy Officer listed at the bottom of this Notice.

4. Right to Request Restrictions on Use or Disclosure: You can request restrictions on certain uses and disclosures of your Protected Health Information. We are not required to agree with the request. If we do agree, we will not violate that restriction except in certain emergency situations.

5. Right to Amend Protected Health Information: You can request that we amend your Protected Health Information or your clinical record. The HIPAA Privacy Standards provide that we can deny the request for amendment under certain specified circumstances. If we do deny your request to amend, we will explain to you why, and explain your rights to seek review of that decision, if required under the HIPAA Privacy Standards.

6. Right to Receive an Accounting of Disclosures of Protected Health Information: You can get a written accounting of all of our disclosures of your Protected Health Information made by us or our business associates for purposes other than treatment, payment, healthcare operations and certain other activities. Your request must be in writing and made to our Privacy Officer. Unless you designate a shorter time period, the list will include disclosures made within the prior six years.

7. Right to Complain: We are committed to complying with the privacy practices described in this Notice. If you believe that we have violated any of them, you may file a complaint with us and/or with the Department of Health and Human Services, Office of Civil Rights. To file a complaint with us, please send a letter to the Privacy Officer listed at the bottom of this Notice. We will not retaliate in any way if you file a complaint with the Office of Civil Rights or with us.

8. Right to Notice of a Breach: You [the patient] have the right to be notified of a data breach.

Amendments

We may amend this Notice from time to time, provided such amendments are permitted by applicable law. Notice of any such amendments will be announced on the Websites and will be effective immediately, unless we state otherwise. You should review the Websites regularly to obtain timely notice of any such amendments.

If we amend this Notice, we may make the amended Notice terms effective for all Protected Health Information that we maintain, including any information created or received prior to issuing the amended Notice.

You may also request a copy of the current Notice by contacting our Privacy Officer listed at the bottom of this Notice.

Contacting us or our Privacy Officer

If you:

- a. have any questions about this Notice or our privacy or Protected Health Information practices; or
- b. want to make a request under this Notice, please contact our Privacy Officer: privacy@pacifedgedx.com.