

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 IT CAREFULLY.

Purpose of This Notice

We understand that information about your health is personal. We are committed to protecting the privacy of your health information. This Notice describes how we may use and disclose Protected Health Information or PHI about you. Please note that not every possible use or disclosure within a category of uses or disclosures is included. This Notice will also describe our obligations and your rights regarding the use and disclosure of your PHI. We are required by the HIPAA¹ Privacy Rule² to:

- Protect the privacy of your PHI.
- Provide you notice of our legal duties and privacy practices with respect to PHI.
- Follow the terms of the Notice currently in effect.

Definitions

“Protected Health Information” or “PHI,” generally, is information about your physical or mental health or condition, health care provided to you, or the payment for health care provided to you, whether past, present, or future and that identifies you or could be used to identify you.

The terms “we,” “our,” and “us” refer to CoaguChek® Patient Services and the terms “you” and “your” refer to the individual receiving treatment.

Effective Date of this Notice

The original effective date of this Notice is June 24, 2004. The Notice governs our privacy practices on or after that date. The effective date of any changes to this Notice will be located in the upper right hand corner of the first page.

Changes to Privacy Practices and this Notice

We will follow the privacy practices described in this Notice, however, we reserve the right to change our privacy practices and this Notice at any time. Any changes will apply both to PHI we already have and to PHI we receive or generate after the change. At your request, we will give you an updated Notice. We will also post the most current Notice at our web site, www.coaguchekpatientservices.com.

For Questions, Additional Information Regarding Privacy Practices, and Complaints

Contact the HIPAA Privacy Contact Person by calling or writing:

HIPAA Privacy Contact Person
CoaguChek Patient Services
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457
(800) 780-0675

If you believe your privacy rights have been violated, you may file a

complaint in writing with the Privacy Contact Person at the address listed above. You may also file written complaints with the Office for Civil Rights of the U.S. Department of Health and Human Services (HHS).

We will not retaliate against you for filing a complaint either with us or with HHS.

Your Health Information Rights

You have certain rights regarding your PHI. For details, including the procedures that you must follow to enforce your rights and the procedures we must follow in responding to your requests, please contact the Privacy Contact Person.

• *Obtain a copy of the Notice.*

If we provide treatment directly to you, you have the right to receive a written copy of this Notice at the date of our first service delivery to you, except in an emergency treatment situation. If our first service delivery takes place in an emergency situation, then we will provide the Notice to you as soon as possible. If our services to you are provided indirectly through another health care provider, we will provide the Notice to you upon request.

You also have the right to obtain a copy of the Notice at any time (even if you have agreed to receive the Notice electronically). Contact the Privacy Contact Person for a copy of the Notice.

• *Request our consideration of your request for restriction on certain uses and disclosures of PHI.*

You may ask us to limit or not to use or disclose any part of your PHI for the purposes of payment, treatment or health care operations. We are not required to agree to these requested restrictions unless the request is to restrict a disclosure to a health plan for purposes of carrying out payment or health care operations, the disclosure is not required by law and the information pertains solely to a health care item or service for which you or someone on your behalf (other than the health plan has paid us out of pocket in full). However, if we agree, we must honor the restrictions you request. To ask for a restriction, send a written request to the HIPAA Privacy Contact Person at the address shown at the beginning of this Notice.

• *Inspect and obtain a copy of your PHI.*

You have the right to review and copy PHI in a designated record set about you for as long as we maintain the PHI. A designated record set might include information such as medical records and billing records about individuals. You must send a written request to the HIPAA Privacy Contact Person. We may charge you for the costs of copying, mailing, or other costs we incur that are necessary to grant your request. We may deny your request to inspect and copy in certain limited circumstances. If you are denied access to your PHI, you may request that the denial be reviewed by us.

- *Request correction of PHI.*

You have the right to request us to correct your PHI that is held in a designated record set. A designated record set might include information such as medical records and billing records about individuals. You may request a correction for as long as we maintain the PHI. You must send a written request to the HIPAA Privacy Contact Person which must include a reason that supports your request. In certain cases, we may deny your request. If we deny your request for correction, you have the right to file a statement of disagreement with the decision.

- *Receive a list of disclosures of PHI.*

You have the right to receive a list of certain disclosures of your PHI made by us (subject to exceptions, restrictions, and limitations noted in the Privacy Rule). To request a disclosure list, submit a written request to the HIPAA Privacy Contact Person and specify the time period (which may not be longer than six years). You may be charged for the cost of providing a disclosure list if you make more than one request within a 12-month period. We will notify you of the cost in advance and you may choose to withdraw or modify your request at that time.

- *Request our consideration of your request for communications of PHI by alternative means or at alternative locations.*

You may request in writing that we communicate with you by alternative means or at alternative locations. You should send your request to the Privacy Contact Person at the address at the beginning of this Notice. We will accommodate your request if we consider it to be reasonable. You may be charged for the cost of providing alternative means of communications. We may refuse to accommodate your request if you have not provided information as to how payment, if applicable, will be handled and specify how or where you wish to be contacted.

Required Disclosures of Protected Health Information

We will disclose PHI to you in accordance with your right to access your PHI or to receive an accounting of disclosures of your PHI as specified in this Notice. We will also disclose PHI to the Department of Health and Human Services when required by that department to investigate or determine our HIPAA compliance with the requirements of HIPAA.

Reasons We May Use and Disclose Your Protected Health Information Include:

- *Treatment:*

We will use and disclose your PHI to permit the provision, coordination or management of your health care and related services by us and other health care providers, including consulting with other health care providers about your health care or referring you to another health care provider for treatment. For example, information we obtain from your physician(s) may be used to suggest the most suitable products to treat your condition or may be disclosed to other distributors to ensure you receive the highest level of benefits available

through your insurance carrier. Also, we may disclose your PHI to a health care provider who has questions regarding the use of our products as it pertains to your condition for which you are receiving treatment.

- *Payment:*

We will use and disclose your PHI, as needed, to obtain payment for the health care we or other health care providers deliver to you. For example, prior to providing services, we may disclose to your insurance carrier information regarding the treatment you are going to receive, which may include your diagnosis and equipment or supplies that will be provided to you in the course of that treatment, to ensure that your insurance carrier will cover such costs. Additionally, we may disclose to your insurance carrier, as necessary, information regarding the treatment you received, which may also include your diagnosis and equipment or supplies provided to you, to ensure that we are paid or you are reimbursed for the cost of your treatment.

- *Health Care Operations:*

We may use or disclose your PHI in order to support our business activities. These activities include, but are not limited to, quality assessment and improvement activities, business planning and development, business management and general administrative activities. For example, we may use your PHI to evaluate the performance of our staff, assess outcomes in your case and similar cases, and determine how to improve the quality and effectiveness of our products and services.

- *Business Associates:*

Some activities are performed for us by our business associates, for example, our contracted trainers, accountants, or attorneys. We may disclose PHI to our business associates so that they can provide services to us, or perform functions on our behalf. We will amend or enter into contracts with our business associates to obtain certain promises to safeguard PHI as required by the Privacy Rule.

- *Individuals involved in your care or payment for your care:*

Unless you object, we may release PHI about you to a family member, other relative, or a close personal friend of yours or any other person identified by you, who is present with you. Disclosure to individuals not present with you will be made if, in our professional judgement, the disclosure is in your best interest. We will disclose only PHI that is directly relevant to the person's involvement with your health care or payment related to your health care.

- *Shipment Reminders:*

We may use or disclose your PHI in order to contact you and remind you of a scheduled shipment.

- *Health-Related Benefits and Services:*

We may use and disclose your PHI to inform you about health-related benefits and services we provide that may be of interest to you.

• *Food and Drug Administration (FDA):*

Our products are subject to regulation by the FDA. We may disclose your PHI to the FDA for the purpose of activities related to the quality, safety, or effectiveness of our products.

• *As Required by Law:*

We will disclose PHI when the law requires.

• *Public Health:*

We may disclose your PHI to a public health authority authorized to collect such information for certain purposes, such as preventing or controlling disease, injury or disability, reporting disease or injury, and public health investigations.

• *Abuse, Neglect or Domestic Violence:*

We may disclose your PHI to a government authority authorized to receive reports of abuse, neglect or domestic violence if we reasonably believe that you are a victim of abuse, neglect or domestic violence as required by law, or if, in our professional judgement, such disclosure is necessary to prevent serious harm to you or others.

• *Health Oversight Activities:*

We may disclose your PHI to a government agency authorized by law to conduct health oversight activities such as audits, investigations, inspections, disciplinary actions or other activities necessary for the oversight of the health care system, government benefit programs, compliance with government regulatory program standards or compliance with applicable civil rights laws.

• *Judicial and Administrative Proceedings:*

We may, upon certain conditions, disclose your PHI in the course of a judicial or administrative proceeding in response to a

court order or administrative judge, a subpoena, or other lawful process.

• *Law Enforcement Purposes:*

We may disclose your PHI to a law enforcement official for certain purposes, such as, in response to a warrant or subpoena; for the purpose of identifying or locating a suspect, witness or missing person; or in certain emergency circumstances.

• *Coroners, Medical Examiners and Funeral Directors:*

We may disclose your PHI to a coroner or medical examiner for the purpose of identifying you, determining a cause of death or other duties authorized by law. We may disclose your PHI to a funeral director, consistent with all applicable laws, in order to allow the funeral director to carry out his or her duties.

• *Medical Research:*

We may disclose your PHI for research purposes, provided that an institutional review board authorized by law or a privacy board waives the authorization requirement and provided that the researcher makes certain representations regarding the use and protection of the PHI to be disclosed.

• *Serious Threat to Health or Safety:*

We may disclose your PHI, in a manner which is consistent with applicable laws, if the disclosure is necessary to prevent or lessen a serious threat to health or safety or the information is necessary to apprehend an individual.

• *Military and Veterans Activities:*

We may, if you are a member of the United States or foreign Armed Forces, disclose your PHI for activities that are deemed necessary by appropriate military command authorities to assure the proper execution of a military mission.

Notice of Privacy Practices

By completing the information below, you acknowledge you have received your copy of CoaguChek Patient Services' Notice of Privacy Practices.

First Name: _____ Last Name: _____ Date of Birth: _____

CoaguChek Patient Services ID number: _____

(this is the number you provide when you call to report your rest results)

Signature: _____ Date: _____

Thank you!

• *National Security:*

We may disclose your PHI to authorized federal officials for the conduct of lawful intelligence, counter-intelligence and other national security activities authorized by law. Additionally, we may disclose your PHI to authorized federal officials for the provision of protective services to the President, foreign heads of state, or other people to conduct investigations authorized by law.

• *Correctional Institutions:*

If you are an inmate, we may disclose your PHI to a correctional institution if the institution informs us that the information is necessary for your health care or the health and safety of others.

• *Workers' Compensation:*

We may disclose your PHI as authorized by, and in compliance with, laws relating to workers' compensation and other similar programs established by law that provide benefits for work-related illnesses and injuries without regard to fault.

Email Communications

In some circumstances, if requested, authorized or otherwise initiated by you, we may communicate with you via email. Email, like most non-encrypted internet communications, may be accessed and viewed without your knowledge or permission while in transit. Therefore, while we take reasonable precautions to safeguard the confidentiality of emails, we cannot guarantee the security of email communications. If you have requested, authorized or initiated

email communication with us and you would like us to cease email communication, you may revoke your authorization at any time.

Uses and Disclosures With Your Written Authorization

PHI Will Not Be Used or Disclosed for Other Purposes Without Your Written Permission.

We will obtain your written permission before using or disclosing your PHI for purposes other than those provided in this Notice or if required by a state or federal law that is more stringent than HIPAA.

You May Revoke Your Permission.

In the event that you grant your permission for other uses or disclosures, you may revoke your permission at any time but must do so in writing to the HIPAA Privacy Contact Person at the address shown at the beginning of this notice. Upon receipt of the written revocation, we will stop using or disclosing PHI in accordance with the written permission, except to the extent we have already acted in reliance on your written permission.



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Opt-in to receive email updates from us!

CoaguChek Patient Services and Roche Diagnostics may use email to send me treatment-related information and information about Patient Self-Testing and CoaguChek Patient Services.

Yes **No**

Please note that email, like most internet communications, may be accessed and viewed without your knowledge or permission while in transit. Therefore, while we take reasonable precautions to safeguard the confidentiality of emails, we cannot guarantee the security of email communications. If you have requested, authorized or initiated email communication with us and you wish to no longer receive email communications, you may opt-out at any time.

First Name: _____ Last Name: _____

Email: _____

Thank you!