



NOTICE OF PRIVACY PRACTICES

Version: August 2021

THIS NOTICE DESCRIBES HOW HEALTH INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

This Notice is being provided to you by Ark Laboratory, LLC d/b/a Helix Diagnostics (“Helix Diagnostics”) as a requirement of a federal law, the Health Insurance Portability and Accountability Act (HIPAA) 42 U.S.C. §1320d et seq., 45 C.F.R. Parts 160 & 164. For purposes of this Notice, your “protected health information” (PHI) means any of your written and oral health information, including demographic data that can be used to identify you. This is health information that is created or received by your health care provider, and that relates to your past, present or future physical or mental health or condition.

USE AND DISCLOSURE OF YOUR PHI WITHOUT AUTHORIZATION OR AN OPPORTUNITY TO OBJECT

Your PHI, linked with your name and other identifying information is used in many ways such as providing care, obtaining payment for your care and running our business. Disclosures of your PHI for purposes described in this Notice may be made in writing, orally, electronically, or by facsimile. As permitted by HIPAA and Michigan State Law, we may use or disclose your PHI for several purposes. Here are some examples of how we may use or disclose your PHI. Not every possible use or disclosure is specifically mentioned. However, all of the ways we are permitted to use and disclose your medical information without your authorization will fit within one of these general categories:

TREATMENT. We will use and disclose your PHI to provide, coordinate, or manage your health care and any related services. This includes the coordination or management of your health care with a third party for treatment purposes. For example, we may disclose your PHI to other providers who may be treating you or consulting with your provider with respect to your care. In some cases, we may also disclose your PHI to an outside treatment provider for purposes of the treatment activities of the other provider.

PAYMENT: We may use and disclose your PHI as needed to get paid for the medical care that we provide to you or to assist others who care for you to get paid for that care. For example, we may share your PHI with a billing company or with your health insurance plan to obtain prior approval for your testing or make sure your plan will cover your testing. We may also disclose PHI to another provider involved in your care for the other provider’s payment activities.

HEALTH CARE OPERATIONS: We may use and disclose your PHI for our own health care operations, general administrative activities, and quality assurance activities and as needed to run our health care facilities. We may use your PHI in combination with other patients’ PHI to



compare our efforts and to learn where we can improve our care and services. We may also use or disclose your PHI for legal, auditing, accounting, compliance reviews, medical reviews, accreditation, certification, licensing, credentialing, and compliance program purposes. We may use or disclose your PHI for employee review activities, training and teaching, business management, and planning purposes. We may disclose your information to businesses and individuals (e.g. medical transcription service) who perform services for us involving health information as long as they agree to protect the privacy of that information. In certain situations, we may also disclose PHI to another provider or health plan for their health care operations.

APPOINTMENT REMINDERS: We may use and disclose your PHI to contact you as a reminder that you have an appointment for treatment or medical care at our laboratory.

TREATMENT ALTERNATIVES: We may use and disclose your PHI to tell you about or recommend possible treatment options or alternatives that may be of interest to you.

HEALTH-RELATED BENEFITS AND SERVICES: We may use and disclose your PHI to tell you about health-related benefits or services that may be of interest to you.

WHEN LEGALLY REQUIRED: We will disclose your PHI when we are required to do so by any federal, state or local law. We may also release your PHI to comply with worker's compensation laws or similar programs.

WHEN THERE ARE RISKS TO PUBLIC HEALTH: We may disclose your PHI for the following public activities and purposes:

- To prevent, control, or report disease, injury or disability as permitted by law;
- To report vital events such as birth or death as permitted or required by law;
- To conduct public health surveillance, investigations and interventions as permitted or required by law;
- To collect or report adverse events and product defects, track FDA regulated products, enable product recalls, repairs or replacements to the FDA and to conduct post marketing surveillance;
- To notify a person who has been exposed to a communicable disease or who may be at risk of contracting or spreading a disease as authorized by law; and
- To report to an employer information about an individual who is a member of the workforce as legally permitted or required.

TO REPORT ABUSE, NEGLECT OR DOMESTIC VIOLENCE: We may notify government authorities if we believe that a patient is the victim of abuse, neglect or domestic violence. We will make this disclosure only when specifically required or authorized by law or when the patient agrees to the disclosure.

TO CONDUCT HEALTH OVERSIGHT ACTIVITIES: We may disclose your PHI to a health oversight agency for activities including audits; civil, administrative, or criminal investigations,



proceedings, or actions; inspections; licensure or disciplinary actions; or other activities necessary for appropriate oversight as authorized by law. We will not disclose your PHI if you are the subject of an investigation and your PHI is not directly related to your receipt of health care or public benefits.

IN CONNECTION WITH JUDICIAL AND ADMINISTRATIVE PROCEEDINGS: We may disclose your PHI in the course of any judicial or administrative proceeding in response to an order of a court or administrative tribunal as expressly authorized by such order or in response to a signed authorization. In certain circumstances and, as permitted by state law, we may be able to disclose your PHI in response to a subpoena, but only where we receive satisfactory assurances that reasonable efforts have been made to notify you or to obtain a protective order.

FOR LAW ENFORCEMENT PURPOSES: We may disclose your PHI to a law enforcement official for law enforcement purposes as follows:

- As required by law for reporting of certain types of wounds or other physical injuries;
- Pursuant to court order, court-ordered warrant, subpoena, summons or similar process;
- For the purpose of identifying or locating a suspect, fugitive, material witness or missing person;
- Under certain limited circumstances, when you are the victim of a crime;
- To a law enforcement official if we have a suspicion that your death was the result of criminal conduct; and
- In an emergency in order to report a crime.

TO CORONERS, FUNERAL DIRECTORS, AND FOR ORGAN DONATION: We may disclose your PHI to a coroner or medical examiner for identification purposes, to determine cause of death or for the coroner or medical examiner to perform other duties authorized by law. We may also disclose your PHI to a funeral director, as authorized by law, in order to permit the funeral director to carry out their duties. We may disclose such information in reasonable anticipation of death. PHI may be used and disclosed for cadaveric organ, eye or tissue donation purposes.

FOR RESEARCH PURPOSES: We may use or disclose your PHI for research when the use or disclosure for research has been approved by an institutional review board or privacy board that has reviewed the research proposal and research protocols to address the privacy of your PHI.

IN THE EVENT OF A SERIOUS THREAT TO HEALTH OR SAFETY: We may, consistent with applicable law and ethical standards of conduct, use or disclose your PHI if we believe, in good faith, that such use or disclosure is necessary to prevent or lessen a serious and imminent threat to your health or safety or to the health and safety of the public.

FOR SPECIFIED GOVERNMENT FUNCTIONS: In certain circumstances, the federal regulations authorize us to use or disclose your PHI to facilitate specified government functions relating to military and veterans activities, national security and intelligence activities, protective



services for the President and others, medical suitability determinations, correctional institutions, and law enforcement custodial situations.

USES AND DISCLOSURES PERMITTED WITHOUT AUTHORIZATION BUT WITH OPPORTUNITY TO OBJECT

INDIVIDUALS INVOLVED IN YOUR CARE OR PAYMENT FOR CARE: We may disclose your PHI to your family member or a close personal friend if it is directly relevant to the person's involvement in your care or payment related to your care. We can also disclose your PHI in connection with trying to locate or notify family members or others involved in your care concerning your location, condition or death.

You may object to these disclosures. If you do not object to these disclosures or we can infer from the circumstances that you do not object or we determine, in the exercise of our professional judgment, that it is in your best interests for us to make disclosure of information that is directly relevant to the person's involvement with your care, we may disclose your PHI as described.

FUNDRAISING ACTIVITIES: Although we currently do not engage in any fundraising activities, in the future we may contact you in order to raise funds for Helix Diagnostics or an institutional foundation related to Helix Diagnostics. Should we send you any fundraising communications, you will be provided with an opportunity to opt-out of receiving any future communications. If you do not wish to be contacted regarding fundraising, please contact our Privacy Officer.

MEDIA: We will not disclose your information to any Media source if requested.

USES AND DISCLOSURES WHICH YOU AUTHORIZE

Other uses and disclosures of your medical information not covered by this Notice will be made only with your written authorization. If you provide us such an authorization in writing to use or disclose your PHI, you may revoke that authorization, in writing, at any time, except to the extent that we have acted in reliance of it. If you revoke your authorization, we will no longer use or disclose your PHI for the reasons covered by your written authorization. The following are examples of uses and disclosures requiring an authorization:

PSYCHOTHERAPY NOTES: If we maintain psychotherapy notes, we will require your written authorization for the use or disclosure of psychotherapy notes other than by the creator of those notes, by Helix Diagnostics for its training programs, or for Helix Diagnostics to defend itself in a



legal action brought by you.

MARKETING: We are required by law to receive your written authorization before we use or disclose your health information for marketing purposes, except if the communication is in the form of: (i) a face-to-face communication made by us to you; or (ii) a promotional gift of nominal value we provide. If the marketing involves direct or indirect remuneration to us from a third party, the authorization must state that such remuneration is involved. If the marketing involves financial remuneration to us from a third party, the authorization must state that such remuneration is involved.

SALE OF PHI: Under no circumstances will we sell our patient lists or your PHI to a third party without your written authorization. Such authorization must state if the disclosure will result in remuneration to us.

YOUR RIGHTS REGARDING HEALTH INFORMATION ABOUT YOU

ACCESS AND COPIES: In most cases you have the right to look at or get a copy of health information. You may inspect and obtain a copy of your PHI that is contained in a designated record set for as long as we maintain the PHI. A “designated record set” contains medical and billing records and any other records that your provider(s) and Helix Diagnostics uses for making decisions about you. If information in a “designated record set” is maintained electronically, you may request an electronic copy in a form and format of your choice that is readily producible or, if the form/format is not readily producible, you will be given a readable electronic copy. Under federal law, however, you may not inspect or copy the following records: psychotherapy notes; information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and PHI that is subject to a law that prohibits access to PHI. Depending on the circumstances, you may have the right to have a decision to deny access reviewed.

To inspect or copy your medical information, you must submit a written request to the Privacy Officer whose contact information is listed on the last page of this Notice. If you request copies of the PHI, however, we may charge a fee for cost of copying mailing or other related supplies. We may deny your request to inspect or copy your PHI if, in our professional judgment, we determine that the access requested is likely to endanger your life or safety or that of another person, or that it is likely to cause substantial harm to another person referenced within the information. If we deny your request to look at the information or get a copy of it, you may give us a written request for a review of that decision. In some instances, your health information may not be available due to our retention policy.

CORRECT OR UPDATE: If you believe that information in our records about you is incorrect or if important information is missing, you have the right to request that we change the records if your PHI is maintained by us in a designated record set for as long as we maintain this information, by submitting a request in writing directed to our Privacy Officer and including your



reason for requesting the change. We may deny your request to change a record if the information was not created by us; if it is not part of the health information kept by us; or if we determine the record is complete and correct. If we deny your request to change, you may submit a written request to review that denial and we may prepare a rebuttal to your statement and will provide you with a copy of any such rebuttal.

ACCOUNTING OF DISCLOSURES: You have the right to ask for an accounting of certain disclosures made by Helix. This list will not include the times that information was disclosed for treatment, payment, or health care operations, or information provided directly to you or your family, or information that was disclosed with your authorization.

We are also not required to account for disclosures that you requested, disclosures that you agreed to by signing an authorization form, disclosures for a facility directory, to friends or family members involved in your care, or certain other disclosures we are permitted to make without your authorization. The request for an accounting must be made in writing to our Privacy Officer. The request should specify the time period sought for the accounting. Accounting requests may not be made for periods of time in excess of six (6) years. We will provide the first accounting you request during any 12-month period without charge. Subsequent accounting requests may be subject to a reasonable cost-based fee.

CONFIDENTIALITY: You have the right to request that we communicate with you in certain ways. We will accommodate reasonable requests. We may condition this accommodation by asking you for information as to how payment will be handled or specification of an alternative address or other method of contact. We will not require you to provide an explanation for your request. Requests must be made in writing to our Privacy Officer.

RESTRICT USES OR DISCLOSURES OF YOUR PHI: You may request that we not share health information with your health plan about care or services you received, **if you pay in full out of pocket for those services and make the request in writing at the time services are provided.** You may ask us not to use or disclose certain parts of your PHI for the purposes of treatment, payment or health care operations. You may also request that we not disclose your PHI to family members or friends who may be involved in your care or for notification purposes as described in this Notice. Your request must state the specific restriction requested and to whom you want the restriction to apply.

Helix Diagnostics is not required to agree to a restriction that you may request unless your request relates to a disclosure to a health plan for services that were paid in full by you or someone other than the health plan and the disclosure is not required by law. We will notify you if we deny your request to a restriction. If we do agree to the requested restriction, we may not use or disclose your PHI in violation of that restriction unless it is needed to provide emergency treatment. Under certain circumstances, we may terminate our agreement to a restriction. You may request a restriction by contacting the Privacy Officer.



COPIES OF OUR NOTICE OF PRIVACY PRACTICES: You may ask for a copy of our current Notice at any time. If the Notice was sent to you electronically, you may request a paper copy.

COMPLAINTS: If you have any questions about this Notice, or questions or complaints about the handling of your PHI, you may contact the Privacy Officer in writing or call to submit a report to our Compliance Line. You may also send a written complaint to the Secretary of the United States Department of Health and Human Services. You will not be penalized or retaliated against in any way for filing a complaint.

WHO TO CONTACT: To exercise any of the rights described above, please send a written request to our Privacy Officer at the address listed below. If you do not have access to a computer, then you may call our Compliance Line at the number listed below and request that the Privacy Officer return your call. compliance@helixmdx.com

Helix Diagnostics
Privacy Officer
6620 Highland Rd.
Waterford, Michigan 48327
(888) 275-5221 x 135

OUR DUTIES: Helix Diagnostics is required by law to maintain the privacy of your health information and report to you any breach of unsecured PHI. We are also required to provide you with this Notice of our duties and privacy practices and shall abide by the terms of this Notice as may be amended from time to time. We reserve the right to revise this Notice. Any revised Notice will be effective for medical information we already have about you as well as any information we receive in the future. We will post a copy of any revised Notice in our office. Any revised Notice will contain an effective date. In addition, each time you visit the office we will offer you a copy of the current Notice in effect.

EFFECTIVE DATE: This Notice is effective August 16, 2021.