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Policy

It is the policy of Bay-Arenac Behavioral Health Authority (BABHA) to provide definitive guidelines and processes for the uses and disclosures of protected health information (PHI) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Michigan Mental Health Code and the Code of Federal Regulations (CFR).

Purpose

This policy and procedure is established to provide general information as well as describe BABHA practices regarding the circumstances and parameters under which uses and disclosures of PHI are permitted. This procedure also describes the disclosure tracking to be used to ensure BABHA is able to provide an accounting of disclosures to a person served upon their request.

Education Applies to:

△ All BABHA Staff	
Selected BABHA Staff, as follows:	
All Contracted Providers: Policy Only	☐ Policy and Procedure
Selected Contracted Providers, as follows:	
Policy Only Policy and Proced	ure

Definitions

- <u>Consent</u>: A written agreement executed by a recipient, a minor recipient's parent, a recipient's legal representative with authority to execute a consent, or a full or limited guardian authorized under the estates and protected individuals code, 1998 PA 386, MCL 700.1101 to 700.8206, with the authority to consent, or a verbal agreement of a recipient that is witnessed and documented by an individual other than the individual providing treatment.
- <u>Disclosure</u>: The release of PHI to a person served, to his/her legal representative, and/or to an outside entity or individual.
- Health Care Operations: Relative to a CMHSP, this included conducting quality assessment and
 improvement activities, including outcomes evaluation and development of clinical guidelines,
 provided that the obtaining of generalizable knowledge is not the primary purpose of any studies
 resulting from such activities; patient safety activities; population-based activities relating to
 improving health or reducing health care costs, protocol development, case management and care

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coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment; reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities; and conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

- Payment: Relative to a CMHSP, this includes the activities undertaken to obtain or provide reimbursement for the provision of health care; and determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication of service claims; billing, claims management, collection activities, and related healthcare data processing; review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges; utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services.
- <u>Person Served</u>: The person served, custodial parent or personal representative (see BABHA policy 13-01-07 Personal Representatives for more information.)
- <u>Privileged Information</u>: A communication made to a psychiatrist or psychologist in connection
 with the examination, diagnosis, or treatment of a patient, or to another person while the other
 person is participating in the examination, diagnosis, or treatment or a communication made
 privileged under other applicable state or federal law.
- <u>Protected Health Information (PHI)</u>: Individually identifiable health information transmitted by or maintained in an electronic media format (e-PHI) or transmitted or maintained in any other form or medium, including oral and/or paper.
- <u>Psychotherapy and Psychological Testing Notes</u>: These notes analyze the contents of discussion during an individual, family or group counseling session, or testing session, and often contain sensitive information relevant only to the licensed professional. They are sometimes referred to as 'process notes' and are distinguished from progress notes in that they capture clinical impressions and details, not progress with goals and objectives, or information for billing services.
- <u>Substance Use Disorder Records</u>: Refers to PHI generated by a SUD service provider. For BABHA this is limited to specific programs providing SUD services, such as co-occurring dualdiagnosis treatment (COD-IDDT). Other BABHA programs may record information about a

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substance use disorder diagnosis, treatment history, medications, etc., but these records are not considered substance use disorder records unless SUD treatment is being provided. Records obtained by BABHA from another SUD service provider retain their characteristic as SUD records, regardless of the BABHA program who obtained the records.

• <u>Treatment</u>: The provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

Procedure

- 1) PHI may be disclosed to entities outside of BABHA direct operations and contracted service providers only in the circumstances and under the conditions set forth in this procedure.
- 2) Unless otherwise prohibited or mandated response timelines do not permit, the Director of Healthcare Accountability, the relevant Director of Healthcare Integration or Medical Record Associate will make a good faith effort to provide notification of the disclosure of PHI containing documents (and provide an opportunity to respond) to staff that authored the PHI documents to be released, including prescribers, and their supervisor, are notified.

3) Important Limitations on Any Disclosure of PHI

- a) For any record disclosure, only the minimum necessary information to comply with the request can be released. See BABHA policy 13-01-10 Reasonable Safeguards for Protected Health Information for more information.
- b) Certain information may not be considered part of the person served's records and therefore not subject to disclosure. See BABHA policy 13-01-20 Designated Record Set for more information. Examples of such records include:
 - i) Records obtained from another service provider (with some limitations).
 - ii) Psychotherapy, SUD counseling notes, and psychological testing notes prepared by a licensed professional when performing testing or providing therapy, which are stored by the assessing or treating clinician. BABHA will not release such records in absence of a court order.
- c) A PHI disclosure may be subject to "privileged communications" status as defined in the Michigan Mental Health Code (MMHC).
 - i) The following disciplines have privileged communications status under the MMHC: Physician/patient; Psychologist/patient; Social worker/client; Mental health professional/patient; and Licensed counselor/patient.

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- i) Unless otherwise specified, privileged communications between licensed healthcare professionals and the person served will not be disclosed by BABHA without:
 - (1) A Consent signed by the consumer, specifying privileged communications may be disclosed (i.e., a waiver of privilege by the person served);
 - (2) A court order. See the section of this procedure addressing subpoenas and court orders for requirements regarding privileged communications.
- d) Records containing HIV/AIDS related information may not be disclosed without:
 - (1) A Consent signed by the consumer, specifying HIV/AIDS information may be disclosed;
 - (2) A court order. See the section of this procedure addressing subpoenas and court orders for requirements regarding HIV/AIDS information.
- e) Unless otherwise specified, substance use disorder records (as defined in this procedure) may not be disclosed without the following:
 - (1) A Consent signed by the consumer, specifying SUD information may be disclosed;
 - (2) A court order. See the section of this procedure addressing subpoenas and court orders for requirements regarding SUD information.
 - (3) Exceptions:
 - (i) PHI may be disclosed to medical personnel to the extent necessary to:
 - 1. Meet a bona fide medical emergency in which a Consent cannot be obtained; or
 - 2. Meet a bona fide medical emergency in BABHA SUD program(s) are closed and unable to provide services or obtain a Consent, during a temporary state of emergency declared by a state or federal authority as the result of a natural or major disaster, until such time that the program resumes operations.
 - (ii) Immediately following disclosure, the BABHA must document, in writing, the disclosure in the person served records, including:
 - 1. The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;
 - 2. The name of the individual making the disclosure;
 - 3. The date and time of the disclosure; and

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- 4. The nature of the emergency (or error, if the report was to FDA).
- f) If a release of PHI includes records which have been restricted by person served, limitations apply. See BABHA policy 13-01-16 Rights of Persons Served Regarding Protected Health Information for more information.
- g) Consent Requirements
 - i) Written Consent
 - (1) BABHA is required by MDHHS to use the MI Dep't of Health and Human Services Consent to Share Behavioral Health Information (MDHHS-5515) as its form for disclosure of PHI. Hereafter in this procedure this form will be referred to as a/the Consent.
 - (a) The Consent includes the following required core elements:
 - (i) A description of the information to be disclosed that identifies the information in a specific and meaningful fashion.
 - 1. If a person served is waiving privilege to permit the disclosure of privileged communications, the Consent must state that privileged communications are to be included.
 - 2. If a person served is consenting to disclosure of substance use disorder information (see definition), the Consent must state that substance use disorder information is included.
 - (ii) A description of the purpose of the disclosure. The statement "at the request of the individual" is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.
 - (iii) Signature of the person served and date.
 - (b) The Consent also includes required notices to the person served:
 - (i) The person served right to revoke the authorization in writing, and any exceptions, and a description of how the person served may revoke the authorization.
 - 1. Revocation of authorizations. An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that:
 - a. The covered entity has taken action in reliance thereon; or

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- b. If the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy or the policy itself.
- (ii) Restrictions on BABHA's ability to condition treatment, payment, enrollment or eligibility for benefits on the authorization.
- (iii) The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this subpart.
- (2) BABHA can accept release forms provided by other service providers, and public, governmental and court-related entities, such as the Social Security Administration, Human Services Departments, Public Health, attorneys, etc., if the core elements are present. Medical Records Associates or the Director of Healthcare Accountability will make this determination.
- (3) Per 42 CFR part 2, if the person served is a minor who has the legal capacity under the Mental Health Code to apply for and obtain substance use disorder treatment, any written consent for use or disclosure authorized under subpart C of this part may be given only by the minor. This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement.

ii) Verbal Consent

(1) Verbal agreement of a recipient that is witnessed and documented by an individual other than the individual providing treatment.

4) Disclosure for Duty to Warn, Child Abuse or Neglect Investigation

- a) BABHA may disclose PHI to a provider of mental or other health services or a public agency without a Consent or court order, if in good faith a determination is made that there is a compelling need for disclosure based upon a substantial probability of harm to the person served or other individuals.
- b) If there is a compelling need for mental health records or information to determine whether child abuse or child neglect has occurred or to take action to protect a minor where there may be a substantial risk of harm, a family independence agency caseworker or administrator directly involved in the child abuse or neglect investigation shall notify a mental health professional that a child abuse or neglect investigation has been initiated involving a person who has received services from the mental health professional and shall request in writing mental health records and information that are pertinent to that investigation.

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- i) Upon receipt of this notification and request, BABHA will review all mental health records and information in the mental health professional's possession to determine if there are mental health records or information that is pertinent to that investigation.
 - (1) Privilege is abrogated when BABHA is disclosing PHI in response to a child abuse and neglect investigation.
- ii) Within 14 days after receipt of a request made under this subsection, the mental health professional shall release those pertinent mental health records and information to the caseworker or administrator directly involved in the child abuse or neglect investigation.
- c) To the extent not protected by the immunity conferred by 1964 PA 170, MCL 691.1401 to 691.1415, an individual who in good faith gives access to mental health records or information under this section is immune from civil or administrative liability arising from that conduct, unless the conduct was gross negligence or willful and wanton misconduct.

5) Disclosures to the Person Served or Family Members

- a) See BABHA policy 13-01-16 Rights of Persons Served Regarding Protected Health Information for information about release of records to persons served.
- b) Consent is required for disclosure of PHI to family members of persons served who are not the personal representative of the person served. See BABHA policy 13-01-07 Personal Representatives for more information.

6) Disclosures for Payment, Treatment, Operations

- a) Where a person served is receiving services from BABHA (i.e., case is not closed):
 - i) Information may be disclosed by the case holder without Consent as necessary for treatment, coordination of care, and payment for the delivery of mental health services, with some exclusions.
 - (1) Inclusions:
 - (a) Disclosure of PHI for the person served to apply for or receive benefits.
 - (b) Disclosure of PHI to schools, if the child or adolescent is being referred for or receiving medical or behavioral health services through the school, and such referral or coordination of care between BABHA and the school is addressed in the plan of service.
 - (2) Exclusions:

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- (a) Information with special protections (see the section of this procedure addressing Limitations for more information)
 - (i) Psychotherapy and psychological testing notes;
 - (ii) Privileged communications between licensed healthcare professionals and the person served;
 - (iii) Records containing HIV/AIDS related information; and
 - (iv) Records containing SUD information.
- (b) Disclosure of PHI to schools not involved in medical or behavioral health services.
- b) Where a person served is no longer receiving services from BABHA (i.e., case is closed):
 - BABHA may disclose PHI to a surviving spouse of the person served or, if there is no surviving spouse, to the individual or individuals most closely related to the deceased recipient within the third degree of consanguinity as defined in civil law, for the purpose of applying for and receiving benefits.
 - ii) Disclosure of PHI will be performed in such instances will be performed by Medical Records Associates.

7) Disclosures to Corrections, Jails

- a) BABHA will disclose PHI to a correctional institution having lawful custody of a person served as an inmate, if the correctional institution or such law enforcement official represents that such PHI is necessary for:
 - The provision of health care to such individuals; i)
 - The health and safety of such individual or other inmates;
 - iii) The health and safety of the officers or employees of or others at the correctional institution.
- b) If substance use disorder records [see definition] are involved, BABHA will obtain a Consent from the person served.

8) Disclosures to Law Enforcement

- a) Where a person served is a potential perpetrator of a crime:
 - BABHA will disclose PHI to a law enforcement official:
 - (1) To report potential criminal conduct:
 - (a) That occurred on the premises of BABHA;
 - (b) That resulted in wounds, other physical injuries, or deaths;

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- (2) To assist with identifying or locating a suspect, fugitive, material witness, or missing person;
- (3) Provided that only the following information is disclosed:
 - (a) Name and address;
 - (b) Date and place of birth;
 - (c) Social security number;
 - (d) Last known whereabouts:
 - (e) Date and time of death, if applicable; and
 - (f) A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.
- b) Where a person served is a potential victim of a crime:
 - BABHA will disclose PHI to a law enforcement if:
 - (1) If a Consent is obtained from the person served; or
 - (2) If BABHA is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:
 - (a) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;
 - (b) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and
 - (c) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

9) Disclosures in Response to Warrants, Subpoenas, Court Orders and Attorneys

- a) See C13-S02-T17 Subpoenas, Search Warrants, and Unannounced Visits by the Government for information about handling requests not involving PHI.
- b) When staff are served with a warrant, a subpoena requesting medical records, a subpoena for a deposition or court testimony regarding a person served, they must notify the Corporate Compliance Officer (CCO), or designee, and their direct supervisor as soon as possible and forward a copy of the subpoena to the CCO or designee.

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- c) The CCO, or designee, in consultation with Directors of Integrated Healthcare as needed, will make a determination as to whether or not the request meets BABHA procedures for disclosure of PHI through submission of records or court testimony, and will advise staff and their supervisor regarding how to respond to the subpoena.
 - i) Any attorney, court or administrative tribunal can issue a subpoena to staff or BABHA requesting disclosure of PHI.
 - (1) BABHA and staff must honor an order to appear which is received via a subpoena from an attorney, prosecutor or judge; however:
 - (2) BABHA can only honor a subpoena for disclosure of records or court testimony if the following are in effect:
 - (a) A judge's order (i.e., Court Order);
 - (b) A subpoena from a Prosecuting Attorney (which is considered equivalent to a judge's order);
 - (c) A subpoena from an attorney, other than prosecuting attorneys, <u>that has been signed</u> (or countersigned) <u>by a judge</u> (i.e., becomes a Court Order);
 - (i) The law requires a subpoena or order from an official of the court that is at a higher level than an attorney (specifically a judge or a prosecuting attorney) for disclosure of PHI via submission of records or court testimony. This provides additional protections for persons receiving mental health or substance use disorder services.
 - (ii) If the attorney was retained or appointed by a court to represent a person served, a court order or Consent will still be required.
 - (d) A court-ordered warrant (i.e., a warrant signed by a judge); or
 - (e) A Consent signed by the person served.
 - ii) Psychotherapy and psychological testing notes will not be disclosed by BABHA without a court order.
 - iii) Privileged communications between licensed healthcare professionals and the person served will not be disclosed by BABHA in response to a Court Order for records if the order does not specify that specifies privileged communications are to be included in the disclosure.

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- (1) The judge is required by law to assess risk and set limits for access to the privileged communications. Legal counsel has advised that BABHA may request a 'protective order' if privileged communications are to be disclosed.
- (2) A prosecuting attorney may be given privileged information without a court order if the privileged communication contains information relating to participation in proceedings under Mental Health Code, including all of the following information:
 - (i) Names of witnesses to acts that support the criteria for involuntary admission; or
 - (ii) Information relevant to alternatives to admission to a hospital or facility.
- (3) Privilege is abrogated when BABHA is disclosing PHI in response to a court order regarding a child abuse or neglect case.
- iv) Records containing HIV/AIDS related information will not be disclosed by BABHA in response to a Court Order for records if the order does not specify that HIV/AIDS information must be disclosed.
 - (1) The judge is required by law to assess the risk of releasing HIV/AIDS information see MCL 333.5131(3)(a). The court order must meet specific requirements – see MCL 333.5131(3)(b).
 - (2) Legal counsel has advised that BABHA may request a 'protective order' if needed to protect the HIV/AIDS information disclosed.
- Records containing substance use disorder information will not be disclosed by BABHA in response to a Court Order for records if the order does not specify that SUD information must be disclosed.
 - (1) The judge must complete a risk assessment of cause and determine to what extent access to the information will be restricted.
- Staff can only testify to, or be deposed regarding, the content of documents they authored in the clinical record and their direct observations. If disclosure of additional PHI is requested, staff will inform their supervisor and the Director of Healthcare Accountability, who will consult with BABHA legal counsel, the involved prosecutor, attorneys, and/or the court regarding next steps.
- vii) BABHA will disclose PHI to private physicians or psychologists appointed or retained to testify in civil, criminal, or administrative proceedings as follows:
 - (1) A physician or psychologist who presents identification and a certified true copy of a court order appointing the physician or psychologist to examine a recipient for the

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purpose of diagnosing the recipient's present condition shall be permitted to review, on the provider's premises, a record containing information concerning the recipient. Physicians or psychologists shall be notified before the review of records when the records contain privileged communication that cannot be disclosed in court under section 750(1) of the act.

- (2) The court or other entity that issues a subpoena or order and the attorney general's office, when involved, shall be informed if subpoenaed or ordered information is privileged under a provision of law. Privileged information shall not be disclosed unless disclosure is permitted because of an express waiver of privilege or because of other conditions that, by law, permit or require disclosure.
- d) After review by the Director of Healthcare Accountability, or designee, Court Orders requesting clinical records containing PHI will be processed by the BABHA Medical Records Associate. If billing records are included, the Director of Healthcare Accountability or designee will obtain the records from the appropriate finance manager for inclusion in the packet of records.
- e) BABHA's Medical Records Associate, or designee, will copy or print the clinical records requested via the subpoena and present the copies to the relevant Director of Integrated Healthcare or the CEO. The Director of Integrated Healthcare (or designee) or the CEO will review the copies prior to release, ensuring there are no risk of harm or safety concerns regarding the release.
- f) If the Director of Integrated Healthcare (or designee), or the CEO deems there is information in the records damaging to the person, the court will be made aware by the CCO of the damaging content in a cover letter accompanying the information or the CEO or CCO will obtain legal counsel regarding a possible protective order for the records.

10) Disclosures for National Security

a) BABHA will disclose PHI to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, protective services for the President, and other persons protected under Federal law, and other national security activities. BABHA personnel receiving such requests will refer the request(s) to the CEO or Director of Healthcare Accountability.

11) Disclosures to Public Health, Coroners, Medical Examiners

- a) Disclosures of PHI to employers of persons served will be performed by the Medical Records Associate. BABHA personnel receiving such requests will refer the request(s) to the Medical Records Associate.
- b) BABHA will disclose PHI to a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability,

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including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions.

- Information pertaining to HIV/AIDS may be disclosed by BABHA to Public Health or another health care provider, without a court order or Consent to protect the health of a person served, to prevent further transmission of disease, or to diagnose and care for a person served.
- c) BABHA will disclose PHI to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law.

12) Disclosures to Employers of Persons Served

- a) Disclosures of PHI to employers of persons served will be performed by the Medical Records Associate. BABHA personnel receiving such requests will refer the request(s) to the Medical Records Associate.
- b) BABHA will disclose PHI An employer of a person served if:
 - i) BABHA provides health care to the individual at the request of the employer:
 - ii) The protected health information that is disclosed consists of findings concerning a workrelated illness or injury or workplace-related medical surveillance;
 - iii) The employer needs such findings in order to comply with its obligations, under 29CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and
 - iv) BABHA provides written notice to the person served that such PHI will be disclosed to the employer.

13) Disclosures for Oversight, Advocacy, Auditing, Accreditation, Research

- a) Disclosure of PHI for oversight, advocacy, accreditation and research will be coordinated through the Director of Healthcare Accountability, unless otherwise delegated to a Director(s) of Integrated Healthcare, the Quality Manager, or the Recipient Rights/Customer Service Manager. Oversight specific to financial auditing or claims review will be coordinated through the Chief Financial Officer.
- b) Access is limited to persons served who receive services or benefits under their jurisdiction and records that are relevant to the inquiry/purpose.

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- c) Disclosures to MDHHS, MSHN, MI Attorney General, MI Dep't of Licensing and Regulatory Affairs (LARA), Centers for Medicaid & Medicare Services (CMS), Federal Office of Civil Rights:
 - Per BABHA legal counsel, a Consent or court order is not required for release of privileged and non-privileged PHI to external entities who have regulatory, contractual or enforcement oversight authority over BABHA under state or federal law.
 - ii) LARA usually provides a subpoena.
- d) Disclosures to MI Protection and Advocacy
 - i) BABHA shall grant a representative of the MI Protection and Advocacy access to the records of all of the following:
 - (1) A person served who has consented to the access.
 - (2) The records of a person served who has died or whose location is unknown, if all of the following apply:
 - (a) Because of mental or physical condition, the person served is unable to consent to the access.
 - (b) The person served does not have a guardian or other legal representative, or the recipient's guardian is the state.
 - (c) The protection and advocacy system has received a complaint on behalf of the recipient or has probable cause to believe based on monitoring or other evidence that the recipient has been subject to abuse or neglect.
 - (3) A recipient who has a guardian or other legal representative if all of the following apply:
 - (a) A complaint has been received by the protection and advocacy system or there is probable cause to believe the health or safety of the recipient is in serious and immediate jeopardy.
 - (b) Upon receipt of the name and address of the recipient's legal representative, the protection and advocacy system has contacted the representative and offered assistance in resolving the situation.
 - (c) The representative has failed or refused to act on behalf of the recipient.
- e) Disclosure for Research or Statistical Compilation
 - i) BABHA does not conduct research projects.

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- ii) BABHA programs may be required to participate in MDHHS research projects. In such instances MDHHS assumes responsibility for compliance with regulatory requirements, including protection of PHI.
- iii) If BABHA intends to participate in a non-state sponsored research project or statistical compilation:
 - (1) The Director of Healthcare Accountability, with the approval of the Chief Executive Officer, and in consultation with the relevant Director(s) of Integrated Healthcare, may disclose records as necessary for the purpose of outside research, or statistical compilation, if:
 - (a) The individual who is the subject of the information is not identifiable in the disclosed information. See BABHA policy 13-01-15 De-Identification of Protected Health Information for de-identification requirements which must be met.
 - (b) If identification is essential in order to achieve the purpose for which the information is sought or if preventing the identification would clearly be impractical, records can be released if the subject of the information is not likely to be harmed by the identification. If there is a risk of harm, the person served must sign a Consent.
 - (2) If BABHA is asked or required to provide protected health information for research by another entity, the Director of Healthcare Accountability will confirm the entity conducting the research is:
 - (a) Subject to the HHS regulations regarding the protection of human subjects (45 CFR part 46), and provides documentation either that the researcher is in compliance with the requirements of 45 CFR part 46, including the requirements related to informed consent or a waiver of consent (45 CFR 46.111 and 46.116) or that the research qualifies for exemption under the HHS regulations (45 CFR 46.104) or any successor regulations.
 - (b) Subject to the FDA regulations regarding the protection of human subjects (21 CFR parts 50 and 56) and provides documentation that the research is in compliance with the requirements of the FDA regulations, including the requirements related to informed consent or an exception to, or waiver of, consent (21 CFR part 50) and any successor regulations; or
 - (c) Any combination of a HIPAA covered entity or business associate.
- 14) Disclosure of PHI for Marketing or Selling of Data

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a) BABHA does not engage in marketing or the sale of protected health information.

Attachments

Related Forms

MDHHS Consent to Share

Related Materials

References/Legal Authority

HIPAA 45 CFR Part 164; Subpart E – Privacy of Individually Identifiable Health Information PA 258 of 1974 Mental Health Code

MI Dep't of Community Health; Mental Health and Substance Abuse Services Administrative Rules 42 CFR Part 2 Confidentiality of Substance Use Disorder Patient Records (Includes Final Rule effective 04/16/24)

PA 368 of 1978 Public Health Code

PA 238 of 1975 Child Protection Law

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SUBMISSION FORM				
			ACTION	
			(Deletion, New, No	
	APPROVING BODY/	APPROVAL/	Changes,	
AUTHOR/	COMMITTEE/	REVIEW	Replacement or	REASON FOR ACTION
REVIEWER	SUPERVISOR	DATE	Revision)	If replacement, list policy to be replaced
K. Amon	Corporate Compliance	7/8/24	New	New policy that incorporates C13-S01-
	Committee			T14 and 17 and updates according to
				new standards. Archive C13-S01-T14
				and 17.