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### 3. MEDICAL RECORDS REQUIREMENTS

#### A. Provider Medical Record Requirements

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**APPLIES TO:**

A. This policy applies to all IEHP Covered Providers.

**POLICY:**

A. All Provider offices must comply with IEHP, local, state, and federal regulatory standards for maintenance of Member medical records.

**PROCEDURES:**

**IEHP Medical Record Standards<sup>1</sup>**

- A. **Individual Medical Records** – An individual medical record is created for each Member treated by an IEHP Provider. The medical record is designed to maintain a Member’s documented medical information of the care provided, as well as all ancillary services/diagnostic tests ordered by a Provider and all referred diagnostic and therapeutic services in a consistent, logical, and uniform manner. The same medical record may be used by other treating Providers within the same group to provide conformity and coordination of Member care. This unique medical record must be updated by the Provider or their office staff with each Member visit or contact. Sensitive medical information, such as detailed behavioral health and substance use records, may be filed separately to maintain confidentiality. Medical records must meet, at minimum, the following requirements:
1. Correct Beneficiary;
  2. Acceptable risk adjustment Provider type, source, and Provider specialty providing the face-to-face encounter;
  3. Dates of service within the data collection period under review;
  4. Valid signatures and credentials; and
  5. Coded according to the official conventions and instructions provided within ICD-CM.
- B. **Member (Patient) Identification** – Members should be linked to their individual medical records through an assigned unique identifier for filing purposes and to distinguish that record from any other Member record. Each page, test result, letter, and item of correspondence regarding that individual Member must contain the unique identifier, and Member (patient) name as a means of Member identification.
- C. **Member Demographics** – Each medical record must contain a section for Member identification that includes name, age, employer, occupation, work and home telephone numbers, address, insurance information, marital status, and emergency contact person and name of parent(s)/legal guardian, if Member is a minor.

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<sup>1</sup> National Committee for Quality Assurance (NCQA), 2024 Health Plan Standards and Guidelines, MED 3, Element A, Factor 5

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- D. **Responsible Party** – Providers designate individuals responsible for record maintenance. Responsible parties must follow established protocols for the daily collection, research, retrieval, securing, maintaining, and transporting of medical records within the Provider setting.
- E. **Legal Document** – The medical record is a legal document, and all contents must be maintained in a confidential manner.
- F. **Medical Record Maintenance** – The Member medical record must be maintained in a current and detailed organized manner that reflects effective care of the Member and facilitates quality review.
- G. **Legibility and Maintenance** – Providers must establish a uniform format to organize medical records and maintain all medical records in a consistent and comprehensive manner. Medical record entries are to be legible, made in a timely manner, dated, and signed by the appropriate Provider/Practitioner or staff. Records may be maintained in hard copy format or electronically as long as they are easily accessible, have sufficient backup to prevent loss of information and have a unique electronic identifier for the author. The medical record must be legible to a person other than the author.
- H. **Protection and Confidentiality** – Providers must limit medical records access to authorized and associated staff. Records must be maintained in a protective and confidential manner and are not readily accessible to unauthorized persons or visible to the general public. Providers must maintain policies and procedures to ensure appropriate record processing to prevent breach of protection or confidentiality or the unauthorized release of Member information to any internal or external person. Providers must educate staff regarding confidentiality and record maintenance policies and procedures and ensure that confidentiality statements are signed.
- I. **Storage, Filing and Availability** – Providers must maintain an organized record-keeping system to make the individual medical record available for each Member visit or contact including: collection, processing, maintenance, storage, retrieval, identification, and distribution. Providers must maintain procedures to assign the unique identifier to each individual record and ensure that the appropriate record is pulled for each Member. Filing of records must be done in a consistent manner either alphabetically or by Member identifier number. In addition, procedures must outline the methodology for pulling requested records, methodology for tracking, the amount of notification time required, and system of distribution and collection. Providers must have provisions for obtaining medical records on an emergency basis. Medical records are to be kept in a clean, secure environment and in good condition.
- K. **Record Retention** – Providers must retain medical records pertaining to Members for a period of 10 years from the end of the fiscal year in which IEHP’s contract expires or is terminated. Pediatric medical records must be maintained for a minimum of 10 years or until the Member’s 19<sup>th</sup> birthday, but in no event for less than 10 years. All medical records, medical charts and prescription files, and other documentation pertaining to medical and non-medical services rendered to Members are subject to this requirement.

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L. **Informed Consent for Treatment** – Providers must obtain appropriate written consent for treatment prior to actual procedure performance including the human sterilization consent procedures. If someone other than the Member signs the consent, the legal relationship should be noted on the consent form. Provider/Practitioner staff must witness, sign, and date consent forms.<sup>2</sup> See Policy 3C, “Informed Consent,” for more information.

M. **Release of Information** – Medical records contain confidential information that is not to be released to another party without the expressed consent, written in ink, of the Member or legal representative. Any adult patient, or any minor patient who by law can consent to medical treatment is entitled to inspect patient records upon written request within five (5) working days after receipt of the written request.<sup>3</sup> Members are also entitled to copies of all or any portion of his or her records upon written request.<sup>4</sup>

Providers must provide Members with copies within 15 days of the receipt of a written request.<sup>5</sup> Providers receiving medical records request from other Providers must submit the medical records within 15 days of receiving the written request to avoid any delay in the Member’s care.<sup>6</sup> See Policy 3B, “Information Disclosure and Confidentiality of Medical Records” for more information. As it is customary for Providers not to charge, IEHP encourages its Providers to offer this as a complimentary service to other Providers. When absolutely necessary to charge another Provider, the law allows only \$0.25 per page and to limit a total charge to \$20.<sup>7</sup>

N. **Exam Information** - Each medical record entry must contain all pertinent information related to the Member contact including: complaints, symptoms, examination results, medical impressions, treatments, Member conditions, test results, and proposed follow-up. A subjective complaints, objective findings, assessment, and plan (SOAP) format may be used to satisfy this requirement.

O. **Medical Record Contents**<sup>8</sup> – Providers must maintain a complete and comprehensive medical record for each Member. The record must include all Provider services rendered including all but not limited to: examinations, Member contacts, health maintenance or preventive services, laboratory and radiology test results or reports, procedures, ancillary services, off-site treatments, missed appointments, emergency room records, and hospital admission and discharge information. Correspondence regarding the Member’s medical condition, such as consultation records, specialist reports, and referrals, must also be included in the Member record. Pathology and laboratory/radiology reports must be included in the record with a special notation for all abnormal findings. Each page, insert, test, and lab entry must be identified by Member name and/or Member identifier. The medical record must

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<sup>2</sup> Title 22 of the California Code of Regulations (CCR), §§ 51305.1-51305.4

<sup>3</sup> California Health & Safety Code (Health & Saf. Code), § 123110

<sup>4</sup> Ibid.

<sup>5</sup> Ibid.

<sup>6</sup> Ibid.

<sup>7</sup> Ibid.

<sup>8</sup> NCQA, 2024 HP Standards and Guidelines, MED 5, Element B, Factors 1-4

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include Member identification, biographical data, emergency contact information, and informed consents.<sup>9</sup>

P. **Documentation Standards** – The IEHP documentation standards and goals for medical record maintenance are as follows:<sup>10</sup>

1. Each page in the record contains the Member's name and a second identifier.
2. Medication allergies and adverse reactions are noted in a consistent, prominent place; otherwise, no known allergies or history of adverse reactions is noted.
3. Appropriate initial and subsequent risk assessment(s).
4. Past medical history for the Member is documented. This documentation includes serious accidents, operations, and childhood illnesses. For children and adolescents (20.99 years and younger), past medical history relates to prenatal care, birth, operations, and childhood illnesses.
5. The use of cigarettes, alcohol and history of substance use noted for Members age 11 and older (substance use history is queried for Members seen three (3) or more times).
6. Problem lists are maintained for Members with significant illnesses and/or conditions that are monitored. A chief complaint and diagnosis or probable diagnosis is included.
7. The history and physical examination records must include appropriate subjective and objective information pertinent to the Member's presenting complaints.
8. Documentation of exams is appropriate for the medical condition.
9. Copies of signed informed consent forms, as appropriate.
10. All medications prescribed include the name, dosage, frequency, and route unless medication only comes in oral form.
11. Medications given on-site must document name, dosage, route, and whether the Member had a reaction to the medication.
  - a. Immunizations administered on-site must document name, dosage, and route, as well as the injection site, manufacturer's name, lot number, and VIS publication date.
12. Laboratory and other studies are ordered and documented, as appropriate.
13. All treatments, procedures, and tests, with results, are documented.
14. Working diagnoses are consistent with findings.
15. Treatment plans are consistent with diagnoses.

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<sup>9</sup> Ibid.

<sup>10</sup> NCQA, 2024 HP Standards and Guidelines, MED 5, Element B, Factors 1-4

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16. Notes have a notation, when indicated, regarding needed follow-up care, calls or visits. The specific time of return is noted in weeks, months, or as needed.
  17. Unresolved problems from previous office visits are addressed in subsequent visits.
  18. Member education, recommendations and instructions given are included.
  19. Pediatric Members' (age 20.99 and under) records have a completed immunization record or notation of immunizations up to date.
  20. An immunization history has been noted for adults.
  21. Immunization(s) administered must be recorded in the Member's medical record and into the appropriate immunization registry (i.e. CAIR).
  22. There is no evidence that the Member is placed at inappropriate risk by a diagnosis or therapeutic procedure.
  23. Preventive screening and services are offered and documented in accordance with DHCS and IEHP standards.
  24. Referrals for specialty care or testing are noted, when appropriate.
  25. Consultant notes are present, as applicable.
  26. Consultation, lab, and imaging reports filed in the chart are initialed by the Provider who ordered them to signify they have been reviewed. A Provider may also designate this task to a non-physician medical practitioner under their supervision only if it is part of their practice agreement. If the reports are presented electronically or by some other method, there is also representation of review by the ordering Provider. Consultation, abnormal lab and imaging study results have an explicit notation in the record of follow-up plans.
  27. Evidence of practitioner review of referral reports and diagnostic test results.
  28. Evidence of follow-up of specialty referrals made, and results/reports of diagnostic tests, when appropriate.
  29. Missed primary care appointments and outreach efforts/follow-up contacts are documented.
  30. For Members age 18 years and older, as well as Emancipated Minors, documentation of Advance Directives discussion or offered is present.
- Q. **Completeness of the Medical Record** – The medical record must be checked to assure that all ordered procedure and referral notes are returned and filed in the chart within three (3) working days of the visit, procedure, or receipt of the report/progress notes from any outside Provider or Practitioner into the Provider office. The Provider/Practitioner must review and initial all test results and consultations and document follow-up treatment for abnormal lab results.
- R. **Laboratory and Radiology Results** – Providers must maintain procedures for filing laboratory and radiology results in the Member's medical record. STAT tests are to be

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performed and reported within 24 hours. Providers must have procedures for review of test results, notation of normal and abnormal results in the medical record, and documentation of instructions for follow-up. Providers must have guidelines identifying which staff member is authorized to notify Members of test results. Tests performed by the Provider or Practitioner must have results documented in the medical record.

- S. **Language Preference** – Each medical record must include designation of primary language and documentation of request or refusal of language interpretation services. Person or entity providing medical interpretation is identified for each encounter. Provider/Practitioner documentation must be in English.
- T. **Providers and Staff Entries and Signatures** – Each entry including chief complaint and vital signs or Member contact, including telephone conversation/advice noted in a Member’s medical record must be dated and signed by the Provider and/or staff, if applicable, including the title of the person making the chart entry. This includes all therapies, procedures, and medications administered to a Member. When documentation errors occur, the person that makes the error must correct the error in the following manner:
1. A single line is drawn through the error;
  2. The corrected information is written as a separate entry and includes the following:
    - a. Date of the entry;
    - b. Signature (or initials, if authenticated in other area of chart); and
    - c. Title.
  3. There are to be no unexplained cross-outs, erased entries or use of correction fluid or tape. Both the original entry and corrected entry are to be clearly preserved. One method used for correcting documentation errors is the S.L.I.D.E Rule: Single Line, Initial, Date and Error.
- U. **Follow-Up Care Documentation** – Specific follow-up care instructions and a definite time for return visit or other follow-up care is appropriately documented in the Member’s medical record. The time period for return visit or other follow-up care is definitively stated in number of days, weeks, months or as needed (PRN).
- V. **Advance Directives** – Adult medical records that contain information regarding the offer of information or the execution of advance directives such as a living will or Advance Health Care Directive, for Members 18 years or older, as well as Emancipated Minors, must be prominently noted. See Policy 3D, “Advance Health Care Directive,” for more information.
- W. **Preventive Health Screening** – Providers must maintain documentation of any appropriate screening tests and/or screening tools in the Member’s medical records. See policy 5A, “Initial Health Assessment.”
- X. **Follow-up Care for Referrals, Emergency Treatment, Hospitalization, Home Health Care, Skilled Nursing Facility (SNF) or Surgical Treatment Rendered at Surgical Center** – The medical record must reflect continuity of care for any treatment, emergency or

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otherwise, rendered in a hospital, emergency room, urgent care, home health, SNF, or surgical center setting. Documentation must include the provisions for follow-up or continued treatment. Providers must document referrals to specialists or waiver programs, treatments rendered, or recommendations made and follow-up care to be instituted.

#### Monitoring

##### A. Facility Site Review (FSR) and Medical Record Review (MRR)

1. New and current Providers are required to undergo a full scope FSR and MRR survey initially and at a minimum of every three (3) years.
2. The MRR consists of an evaluation of a Provider’s medical record system and information kept in the medical record to ensure Provider’s medical record compliance with IEHP and regulatory standards.
3. Medical record reviews for any other contracted or specialty care Providers are conducted as directed by the IEHP Chief Medical Officer, Quality Management and Health Equity Transformation (QMHE) Committee, Quality Improvement Subcommittee (QISC), Peer Review Subcommittee, Member Safety Subcommittee, or Credentialing Subcommittee.

B. Other monitoring includes focused audits and Interim FSR Reviews, as well as the use of both internal quality management systems and external sources of information All deficiencies require the completion of a corrective action plan according to established timelines.

C. Medical record compliance is monitored through the Annual Delegation Oversight Audit (DOA). See Policy 18A2, “Delegation Oversight - Audit” for more information.

INLAND EMPIRE HEALTH PLAN		
<b>Regulatory/ Accreditation Agencies:</b>	<input type="checkbox"/> DHCS	<input type="checkbox"/> CMS
	<input type="checkbox"/> DMHC	<input type="checkbox"/> NCQA
<b>Original Effective Date:</b>	January 1, 2024	
<b>Revision Effective Date:</b>		

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#### B. Information Disclosure and Confidentiality of Medical Records

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**APPLIES TO:**

- A. This policy applies to all IEHP Covered Members and Providers.

**POLICY:**

- A. IEHP and its Delegates implement and maintain policies and procedures that ensure the Member’s right to confidentiality of medical information.
- B. IEHP, Delegates, Providers and their staff must fully comply with all applicable sections of the Health Insurance Portability and Accountability Act (“HIPAA”), the California Civil Code, Section 56 et seq., the Confidentiality of Medical Information Act (“CMIA”); California Health and Safety Code Section 1364.5; the Insurance Information and Privacy Protection Act (“The Act”); Code 791, et. seq.; and all other applicable State, Federal and local regulations pertaining to confidentiality, privacy, and information disclosure of medical records.

**DEFINITIONS:**

- A. Delegate – A health plan, medical group, or any contracted organization delegated to perform the activities described in this policy.
- B. Member – For the purpose of this policy, a Member is defined as a protected individual, an adult or minor Member, who can consent to a health care service without the consent of a parent or legal guardian. This definition does not include an individual that lacks the capacity to give informed consent for health care.<sup>1</sup>
- C. Sensitive Services - All health care services related to mental or behavioral health, sexual and reproductive health, sexually transmitted infections, substance use disorder, gender affirming care, and intimate partner violence, and minor consent services.<sup>2</sup> See Policy 4E, “Access to Services with Special Arrangements.”
- D. “Genetic characteristics” is defined as:
1. Any scientifically or medically identifiable gene or chromosome, or combination or alteration thereof, that is known to be the cause of a disease or disorder in a person or his or her offspring, or that is determined to be associated with a statistically increased risk of development of a disease or disorder and presently not associated with any symptoms of any disease or disorder; or
  2. Inherited characteristics that may derive from the individual or family member, that are known to be a cause of a disease or disorder in a person or his or her offspring, or that are determined to be associated with a statistically increased risk of development of a disease

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<sup>1</sup> California Civil Code (Civ. Code) § 56.05(l)

<sup>2</sup> CA Civ. Code § 56.05(n)



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or disorder and presently not associated with any symptoms of any disease or disorder.

#### **PROCEDURES:**

##### **Confidentiality of Medical Records**

- A. IEHP, Delegates, and Providers are responsible for orienting all office staff, Practitioners and committee members to IEHP medical records standards including:
1. The maintenance of confidentiality of Member medical records;
  2. The protection of medical record information including the documentation used in utilization and case management processes; and
  3. The protection of medical record information used in the claims process.
- B. IEHP, Delegates and Providers are responsible for maintaining signed confidentiality statements as follows:
1. Provider office staff are required to sign a confidentiality statement protecting the privacy of Member medical records and information;
  2. IEHP committee members and all other attendees of committee meetings are required to sign a Member medical record confidentiality statement; and
  3. Providers must have policies and procedures in place that require Practitioners and other subcontractors to maintain confidentiality by signing confidentiality statements.
- C. Members have the right to inspect or correct any personal or medical information held by their Provider.<sup>3</sup>
- D. Members have the right to develop a written addendum for inclusion in their medical record if they believe that the records are incomplete or inaccurate. Providers must include this addendum as a permanent part of the Member's medical record and must disclose it to other parties when records are requested.<sup>4</sup>
- E. Members have the right to request an accounting of disclosures of Protected Health Information (PHI) made by IEHP, Delegates, and/or Providers for the prior six (6) years.<sup>5</sup>
- F. At no time shall Delegates, Providers, their staff, medical facilities, Practitioners or affiliates, obtain personal or otherwise deemed confidential information under false pretenses.
- G. Providers who create, maintain, preserve, store, transmit or destroy medical records must do so in a manner that preserves the confidentiality of the information contained in the records.<sup>6</sup>

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<sup>3</sup> Title 45 Code of Federal Regulations (CFR) § 164.524

<sup>4</sup> 45 CFR § 164.526

<sup>5</sup> 45 CFR § 164.528

<sup>6</sup> 45 CFR § 164.310

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##### Release of Medical Records

- A. Providers are responsible for orienting all their office staff, Practitioners, and committee members to IEHP Policies and Procedures regarding the release of Member medical records including:
1. The release of medical record information at the request of the Member and in response to legal requests for information;
  2. The release of a Member's behavioral health records without the Member's written consent, in ink; and
  3. The release of a Member's genetic testing records without the Member's written consent in ink.
- B. Providers and their office staff may release medical record information only if a signed authorization of consent has been obtained from the Member, the parent or legal guardian or authorized representative who is legally responsible for making medical decisions for the Member. However, a Provider may allow for the release of medical records without authorization to health plans for the purposes of:<sup>7,8</sup>
1. Administering benefits under IEHP programs, including determination of responsibility for payment, Member's eligibility for benefits, provision of services to eligible recipients and payment of claims;
  2. Coordination of care between providers as necessary;
  3. Professional peer review or utilization review and quality management; and
  4. Conducting actuarial or research studies.
- C. Written authorization for the release of health information must meet the following criteria:<sup>9,10</sup>
1. Is handwritten in plain language by the person who signs it or is in typeface no smaller than 14 point type;
  2. Is clearly separate from any other language on the same page and is executed by a signature which serves no other purpose than to execute the authorization;
  3. Is dated and signed by the Member, the Member's legal representative, the Member's spouse or person financially responsible for the Member, or the beneficiary or personal representative of a deceased Member;
  4. Specifies the uses and limitations on the types of medical information to be disclosed;
  5. Specifies the names or functions of persons authorized to disclose the information about

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<sup>7</sup> 45 CFR § 164.506

<sup>8</sup> CA Civ. Code § 56.10

<sup>9</sup> CA Civ. Code § 56.11

<sup>10</sup> 45 CFR § 164.508

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- the Member;
6. Specifies the names or functions of persons authorized to receive the disclosed information;
  7. Specifies the uses and limitations for persons receiving the information;
  8. Specifies a date after which the authorization is no longer valid;
  9. If a covered entity seeks an authorization, the covered entity must provide the Member with a copy of the authorization they signed;
  10. The authorization must include the Member's individual right to revoke the authorization in writing; and
- D. The Member may revoke an authorization at any time if this is done in writing and the covered entity has not taken action in reliance of that authorization.<sup>11</sup>
- E. Should the requesting party need an extension to the timeframe mentioned above, they must notify the Provider in writing. This information should include:
1. The specific reason for the extension;
  2. The intended use or uses of information during the extended time; and
  3. The expected destruction date of the information.
- F. Upon request, Providers must disclose Member medical information to independent medical review organizations and their reviewers without specific authorization by the Member.<sup>12,13</sup> Independent medical review organizations may include public or private licensing or accrediting entities such as the California Department of Managed Health Care (DMHC) or its contractors.
- G. Protected Health Information (PHI) that is electronically transmitted to another entity must be sent in compliance with the Health Insurance Portability and Accountability Act (HIPAA) Security Rule, as required by the Health Information Technology for Economic and Clinical Health Act (HITECH Act) as part of the American Recovery and Reinvestment Act of 2009.
- H. Any person in the Provider office staff making copies of Member medical record information must note the release in the departmental, medical, or computer record, sign and date the entry, and document what information was copied.
- I. Providers and their office staff must disclose Member medical information when requested by a coroner, in the course of an investigation for the purpose of identifying the Member or locating next of kin.<sup>14</sup> Disclosure must also be provided when the coroner's office is

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<sup>11</sup> 45 CFR § 164.508

<sup>12</sup> 45 CFR § 164.506

<sup>13</sup> CA Civ. Code § 56.10

<sup>14</sup> 45 CFR § 164.512

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investigating deaths that may involve public health concerns, organ or tissue donation, child abuse, elder abuse, suicides, poisonings, accidents, sudden infant death, suspicious deaths, unknown deaths, or criminal deaths, or when otherwise authorized by the Member's representative. Medical information shall be limited to information regarding the patient who is the Member and who is the subject of the investigation. This information must be given to the coroner without delay.

- J. Except to the extent permitted by law, and notwithstanding a Member's legal or court appointed representative, confidential information pertaining to a Member's medical records must not be released to family members, unless written authorization is on file. The disclosure authorization must allow for release of information to family members, or a court document must be presented that substantiates the family member's right to obtain confidential medical record information on the Member.<sup>15</sup>
- K. Member questions regarding release of medical information to insurance carriers and other healthcare providers and staff must be directed to their Provider.
- L. Subpoenas are handled according to IEHP policies and procedures and in accordance with state and federal regulatory requirements.<sup>16</sup>
- M. Upon request, all Providers are required to make available to Members the Provider's policy of Information Disclosure and Confidentiality of Medical Records.<sup>17</sup>
- N. IEHP makes available to its Members its policies and procedures for preserving the confidentiality of medical records. Any request for IEHP's policy of Information Disclosure and Confidentiality of Medical Records must be directed to IEHP Member Services at (800) 440-4347 or (800) 718-4347 for the speech or hearing impaired.<sup>18</sup>
- O. Providers must develop and implement a disclosure authorization form that is compliant with State and Federal regulations.<sup>19,20</sup> An example of acceptable language is as follows:

"I, the undersigned, hereby authorize (Releasing Entity) to release to (Receiving Entity), any and all medical records pertaining to (Patient's Name) specifically relating to (Type of Information/Date Parameters). This authorization of the medical information specified herein is to be used solely for the purpose of (Uses/Limitations) and will expire after (Date). I also understand that I have the right to receive a copy of this authorization. I also understand that I have the right to revoke this authorization in writing."

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

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<sup>15</sup> 45 CFR § 164.510

<sup>16</sup> 45 CFR § 164.512

<sup>17</sup> CA Health and Safety Code (Health & Saf. Code) § 1364.5

<sup>18</sup> Ibid.

<sup>19</sup> 45 CFR § 164.508

<sup>20</sup> CA Civ. Code § 56.11

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Print Name: \_\_\_\_\_

Relationship to Patient: \_\_\_\_\_

- P. Providers must not require a Member, as a condition of receiving health care services, to sign a release or consent that would permit the disclosure of medical information.<sup>21</sup>
- Q. Providers are prohibited from intentional sharing, selling, or using medical information for any purpose not necessary to provide health care services to the Member, except as otherwise authorized.<sup>22</sup>
- R. Delegates and Providers must monitor Provider sites for compliance with IEHP requirements for the protection of Member medical records.

#### **Sensitive Services Information**

- A. Medical information related to sensitive services must only be disclosed to the Member receiving care, absent an express authorization of the Member.<sup>23</sup>
- B. In special circumstances for treatment of sensitive services such as sexually transmitted infection, human immunodeficiency virus (HIV), and family planning, Members have the right to sign a Limited Release of Information Form that prohibits the release of medical records but does allow release of sufficient information for billing purposes, see Policy 10H, “Sexually Transmitted Infection Services.”
- C. Except in cases where Providers are disclosing the results of HIV tests for purposes directly related to the health care of the Member, all IEHP network Providers must obtain written consent from the Member to disclose results of an HIV test.

#### **Genetic Testing Information**

- A. The release of information related to sensitive services must meet the same specifications as noted in the “Release of Medical Records” section above.
- B. In addition, the person or entity requesting the medical record information must submit a copy of the written request to the Member within 30 days of receipt of the requested information, unless the Member has signed a written waiver in the form of a letter that is submitted by the Member to the Provider waiving this notification.
- C. A person who negligently or willfully discloses the results of a test for genetic characteristics to any third party is subject to those penalties described in Section 56.17 of the California

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<sup>21</sup> CA Civ. Code § 56.37

<sup>22</sup> 45 CFR § 164.502

<sup>23</sup> Department of Managed Health Care (DMHC) All Plan Letter (APL) 22-010, “Guidance Regarding AB 1184”

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Civil Code.<sup>24</sup>

##### **Behavioral Health Information**

- A. Providers, including Behavioral Health Practitioners, may not release medical information to persons or entities authorized to receive that information if the requested information specifically relates to a Member's participation in behavioral health treatment, unless the following requirements have been met:<sup>25</sup>
1. The person or entity requesting that information submits a written request to the Provider, whichever is applicable, signed by the requestor. The request must include:
    - a. The specific information relating to a Member's participation in behavioral health treatment and its specific use(s);
    - b. A statement that the information is not to be used for any purpose other than its intended use;
    - c. The length of time that the information will be kept before being destroyed or disposed of. A requestor may extend the timeframe if they notify the appropriate Provider of the extension. An extension notice must include the specific reason for the extension, the intended use of the information during the extension, and the expected date that the information is to be destroyed; and
    - d. A statement that the requestor will destroy the information and all copies in their possession or control, will cause it to be destroyed or will return the information and all copies of it before or immediately after the length of time specified in paragraph (c.) has expired.
- B. In addition, the person or entity requesting the medical record information must submit a copy of the written request to the Member within 30 days of receipt of the requested information, unless the Member has signed a written waiver in the form of a letter that is submitted by the Member to the health care Provider waiving this notification.<sup>26</sup>
- C. This section does not apply to the disclosure or use of medical information by a law enforcement agency or a regulatory agency when required for an investigation of unlawful activity or for licensing, certification, or regulatory purposes, unless otherwise prohibited by law.<sup>27</sup>
- D. This section does not apply to the disclosure or use of behavioral health information when IEHP is the payer and IEHP requests clinical information, records for coordination of care, quality studies or risk adjustment activities.
- E. A covered entity must obtain an authorization for any use or disclosure of psychotherapy notes

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<sup>24</sup> CA Civ. Code § 56.17

<sup>25</sup> CA Civ. Code § 56.104

<sup>26</sup> Ibid.

<sup>27</sup> CA Civ. Code § 56.104

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### 3. MEDICAL RECORDS REQUIREMENTS

#### B. Information Disclosure and Confidentiality of Medical Records

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except to carry out the following treatment, payment, or health care operations:<sup>28</sup>

1. Use of the originator of the psychotherapy notes for treatment;
2. Use or disclosure by the covered entity for its own training programs; and
3. To defend itself in a lawsuit.

#### **IEHP Oversight and Monitoring**

- A. IEHP monitors the confidentiality of Member medical records and the appropriate release of confidential information through the PCP Facility Site Review and Medical Record Review Surveys.
- B. IEHP monitors compliance with Member medical record confidentiality policies and procedures through annual Delegation Oversight Audits.
- C. IEHP monitors compliance with medical record confidentiality by ensuring that committee members have signed a confidentiality statement protecting Member information.

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<sup>28</sup> 45 CFR § 164.508

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### 3. MEDICAL RECORDS REQUIREMENTS

#### C. Informed Consent

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##### **APPLIES TO:**

- A. This policy applies to all IEHP Covered Members and Providers.

##### **POLICY:**

- A. Informed consent for treatment, procedures or other interventions must be obtained by IEHP Providers prior to initiation of the procedure.

##### **DEFINITIONS:**

- A. IEHP Providers – IEHP Providers, in this policy, are defined as but not limited to: Primary Care Providers (PCPs), Specialists, Behavioral Health Providers, Behavioral Health Treatment Providers (BHT), Vision Providers, Urgent Care Centers, Ancillary Providers, Facilities, Pharmacies, and other Providers (e.g. Nurse Practitioners, Physician Assistants, Acupuncturists, Certified Nurse Midwives, and Dentists).

##### **PROCEDURES:**

- A. IEHP Providers must obtain appropriate written consent from Members before the actual performance of any diagnostic or treatment procedure of an intrusive nature. See “Attachments/Consent for Special Procedure – English” and “Consent for Special Procedure – Spanish” in found in the IEHP website.<sup>1,2</sup>
- B. In the event the appropriate consent form is unavailable in the Member’s primary language, Members have the right to request an interpreter at no charge. See Policies 4G1, “Cultural and Linguistic Services – Language Capabilities” and 4D, “Access to Care for Members with Access and Functional Needs.”
- C. The consent form may be either of the following:
1. A written consent document that embodies the elements of informed consent required by 45 CFR § 46.116 (discussed in section E below). This form may be read to the Member or the Member’s legally authorized representative, but in any event, the investigator shall give either the Member or the Member’s legally authorized representative adequate opportunity to read it before it is signed;<sup>3</sup> or
  2. A short form written consent document stating that the elements of informed consent required by 45 CFR § 46.116 (discussed in section E below) have been presented orally to the Member or the Member’s legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the Internal Review Board (IRB) shall approve a written summary of what is to be said to the Member or the

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<sup>1</sup> Title 45 Code of Federal Regulations (CFR) § 46.116(a)

<sup>2</sup> <https://www.iehp.org/en/providers/provider-resources?target=forms>

<sup>3</sup> 45 CFR § 46.117(b)(1)



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### 3. MEDICAL RECORDS REQUIREMENTS

#### C. Informed Consent

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Member's legal authorized representative. Only the short form itself is to be signed by the Member or the Member's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the Member or the Member's legally authorized representative, in addition to a copy of the short form.<sup>4</sup>

D. In the event a Member lacks legal authority to sign the consent due to either the Member's legal status as a minor or because of mental incapacitation, Member's legally authorized representative<sup>5</sup> may sign the consent on behalf of the Member. The signing agent must document their relationship to the Member on the consent form. A copy of any authorizing document or court order should be maintained in the Member's file. Examples of authorized agents include:

1. A person appointed pursuant to a valid advance health care directive.
2. A conservator, guardian, or interested person with a court order authorizing the particular treatment of the Member.
3. A conservator or guardian authorized by a court to make health care decisions for the Member.
4. The Member's parents, spouse, registered domestic partner, or close family relatives.

E. The basic elements of an informed consent form must include the following information:<sup>6,7</sup>

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the Member's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A statement that the invasive procedure involves an explanation of the purposes of the procedure, a description of the procedure to be followed, and identification of alternative options, as appropriate;
3. A description of any reasonably foreseeable risks or discomforts to the Member;
4. A description of any benefits to the Member or to others which may reasonably be expected from the research;
5. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the Member;
6. A statement describing the extent, if any, to which confidentiality of records identifying the Member will be maintained;<sup>8</sup>

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<sup>4</sup> 45 CFR § 46.117(b)(2)

<sup>5</sup> 45 CFR § 46.102

<sup>6</sup> 45 CFR § 46.116(b)

<sup>7</sup> Title 22 California Code of Regulations (CCR) § 73524

<sup>8</sup> 22 CFR § 51009

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### 3. MEDICAL RECORDS REQUIREMENTS

#### C. Informed Consent

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7. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
  8. An explanation of whom to contact for answers to pertinent questions about the research and research Members' rights, and whom to contact in the event of a research-related injury to the Member; and
  9. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the Member is otherwise entitled, and the Member may discontinue participation at any time without penalty or loss of benefits to which the Member is otherwise entitled.
- F. Informed consent is required whenever any surgical or invasive diagnostic procedure is to be performed or when general, local, or regional anesthesia is to be used.
- G. Informed consent information must be provided with consideration of the Member's linguistic needs and literacy level.
- H. A special informed consent procedure must be followed in the case of sterilization for Members enrolled in Medi-Cal Managed Care. See "Attachments/PM 330 Sterilization Consent Form" found on the IEHP website.<sup>9</sup>
- I. Providers must provide informed consent forms in English and Spanish. See "Attachment/ Consent for Special Procedures" found on the IEHP website.<sup>10</sup>
- J. An informed consent procedure must be in place for Medi-Cal Members who seek out-of-plan Sexually Transmitted Infection (STI), Family Planning, and HIV testing services, and who wish to maintain medical record confidentiality but allow for transmission of information necessary for billing purposes.
- K. Providers are required to keep copies of signed informed consent forms in the Member's medical record as well as submit these with any claim forms.
- L. Providers must obtain voluntary written consent prior to examination and treatment, with appropriate regard to the patient's age and following State and Federal laws. Consent also must be obtained prior to release of patient information.<sup>11,12</sup>
- M. Adults, parents/legal guardians of a minor or emancipated minors may sign consent forms for operative and invasive procedures. Persons under 18 years of age are emancipated if they have entered into a valid marriage, are on military active duty, or have received a court declaration of emancipation.<sup>13</sup>

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<sup>9</sup> <https://www.iehp.org/en/providers/provider-resources?target=forms>

<sup>10</sup> Ibid.

<sup>11</sup> 45 CFR § 164.524

<sup>12</sup> 22 CCR § 51009

<sup>13</sup> California Code, Family Code (FAM) §7122

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### 3. MEDICAL RECORDS REQUIREMENTS

#### C. Informed Consent

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### 3. MEDICAL RECORDS REQUIREMENTS

#### D. Advance Health Care Directive

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##### **APPLIES TO:**

A. This policy applies to all IEHP Covered Members and Providers.

##### **POLICY:**

- A. IEHP requires that all Health Care Providers (i.e., healthcare facilities and Practitioners) comply with the Patient Self Determination Act (PSDA) of 1990, which states that all Health Care Providers must:<sup>1</sup>
1. Inform Members of their right to formulate an advance directive in writing. This policy, regarding PSDA, applies to all Health Care Providers and Members age 18 and older, as well as Emancipated Minors.
  2. Periodically inquire as to whether a Member executed an advance directive and document the Member wishes regarding their medical care;
  3. Not to condition the provision of care or otherwise discriminate against persons who have or have not executed an advance directive;
  4. Ensure that legally valid advance directives and documented medical care wishes are implemented to the extent permitted by State law; and
  5. Provide education to staff, Members and the community on ethical issues concerning patient self-determination and advance directives.

##### **DEFINITION:**

- A. **Advance Health Care Directive** - Written legal document that details treatment preferences for any health care decisions when a Member is unable to speak for his or herself. Examples of advance directives include (but are not limited to): an Advance Health Care Directive form, a living will, a Durable Power of Attorney for Health Care form, a health care proxy, a Physician Orders of Life Sustaining Treatment (POLST), Five Wishes, and surrogate decision maker. This document must comply with State and Federal law.
- B. **Health Care Decision**- A health care decision does not include consent by a patient's agent, conservator, or surrogate to convulsive treatment, psychosurgery, sterilization, or abortion.

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<sup>1</sup> Patient Self Determination Act (PSDA) of 1990

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### 3. MEDICAL RECORDS REQUIREMENTS

#### D. Advance Health Care Directive

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**PROCEDURES:**

- A. The provisions of the PSDA that affect Health Care Providers (i.e., healthcare facilities and Practitioners) are as follows:<sup>2,3</sup>
1. Every Health Care Provider that receives payments from Medicare or Medi-Cal must give each Member a statement of rights regarding making healthcare decisions.
  2. The Health Care Provider must offer information to all Members age 18 and older, as well as Emancipated Minors regarding advance directives. A response must be documented in the Member's medical record. Healthcare may not be withheld or delayed for lack of an advance directive.
  3. If the Member has an advance directive, the Health Care Provider must request that the Member bring the Provider a copy to be placed in the Member's medical record.
  4. If the Member does not have an advance directive and requests further information, the Health Care Provider must have written educational materials on hand regarding the PSDA. See Attachments, "Advance Health Care Directive FAQs – English" and "Advance Health Care Directive FAQs – Spanish" found on the IEHP website.<sup>4</sup>
  5. Health Care Providers are not required to assist Members with formulating advance directives. They are only required to offer information to Members 18 and older, as well as Emancipated Minors of advance directives.
  6. A Member may change, cancel and/or amend an advance directive at any time.
  7. The "Advance Health Care Directive" form can be utilized in the medical record to satisfy the advance directive requirement. See "Attachments/Advance Health Care Directive – English" and "Advance Health Care Directive – Spanish" found on the IEHP website.<sup>5</sup>
- B. Neither IEHP nor the plan is required to provide care that conflicts with an advance directive.
- C. IEHP allows a Member's representative/caregiver to facilitate care or treatment decisions for a Member who is unable to do so. IEHP and/or will allow the Member or the Member's representative/caregiver to be involved in decisions about withholding resuscitative services or declining/withdrawing life-sustaining treatment.
- D. Through its written Member materials, IEHP must periodically inform Members of their right to accept or refuse treatment and to complete an advance directive and inform the Member how to implement that right.

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<sup>2</sup> Ibid.

<sup>3</sup> California Probate Code § 4670 et. Seq

<sup>4</sup> <https://www.iehp.org/en/providers/provider-resources?target=forms>

<sup>5</sup> Ibid.

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### 3. MEDICAL RECORDS REQUIREMENTS

#### D. Advance Health Care Directive

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- E. IEHP must have a policy for medical record documentation of advance directives that require:
1. Documentation of whether the Member has been offered Advance Care Directives or has executed an Advance Health Care Directive.<sup>6,7,8</sup>
  2. The Physician Orders for Life-Sustaining Treatment (POLST) form<sup>9</sup> and Five (5) Wishes are acceptable if appropriately completed and signed by necessary parties.
  3. Advanced Health Care Directive information is reviewed with the Member at least every five (5) years and as appropriate to the Member's circumstances.
- F. IEHP shall demonstrate that it provides education for staff on issues concerning advance directives.

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<sup>6</sup> California Probate Code § 4701

<sup>7</sup> Title 42 Code of Federal Regulations (CFR) § 422.128

<sup>8</sup> 42 CFR § 489.100

<sup>9</sup> California Probate Code § 4780