

EXHIBIT I

Substance Use Disorder Service Program Requirements and Business Associate Agreement

JULY 1, 2023 – JUNE 30, 2024

1. Services

Services and work provided by Contractor at the County's request under this Agreement will be performed in a timely manner, and in accordance with applicable federal and state statutes and regulations, including, but not limited to, sections 96.126, 96.127, 96.128, 96.131 and 96.132, and all references therefrom, of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reauthorization Act, Public Law 106-310, the State of California Alcohol and/or Other Drug Program Certification Standards, Title 21, CFR Part 1300, et seq., Title 42, CFR, Part 8; Drug Medi-Cal Certification Standards for Substance Abuse Clinics; Title 22, CCR, Section 51341.1; Title 9, CCR, Division 4, Chapter 4, Subchapter 1, Sections 10000, et seq.; 42 CFR Part 438 Managed Care, Fair Employment and Housing Act (Government Code Section 12900 et seq.) and the applicable regulations promulgated thereunder (2 CCR 7285.0 et seq.); Title 2, Division 3, Article 9.5 of the Government Code, commencing with Section 11135; Title 9, Division 4, Chapter 8 of the CCR, commencing with Section 13000; the Hatch Act (Title 5 USC, Sections 1501-1508, Part III, Subpart F, Chapter 73, Subchapter III) which limit the political activities of employees whose principal employment activities are funded in whole or in part with federal funds; and any and all guidelines promulgated by the State Department of Health Care Services' (DHCS) Alcohol and Drug Programs and the Marin County Department of Health and Human Services to serve special populations and groups, as applicable; the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act ("HITECH"), including regulations promulgated thereunder by the U.S. Department of Health and Human Services (45 CFR Parts 160 and 164) to protect the privacy and provide for the security of protected health information; County laws, ordinances, regulations and resolutions; and in a manner in accordance with the standards and obligations of Contractor's profession. Contractor shall devote such time to the performance of services pursuant to this Agreement as may be reasonably necessary for the satisfactory performance of Contractor's obligations. The County shall maintain copies of above-mentioned statutes, regulations, and guidelines for Contractor's use. Copies of Substance Use Disorder Service Programs Policies and Procedures can be found on the Marin County Behavioral Health and Recovery Services (BHRS) website at: www.MarinBHRS.org. Contractor shall adhere to the applicable provisions of the State-County Substance Abuse Prevention and Treatment Block Grant (SABG) Contract and Drug/Medi-Cal Organized Delivery System (DMC-ODS) Intergovernmental Agreement (IA) referenced below in their entirety. This Contract is subject to any additional restrictions, limitations, or conditions enacted by the federal or state governments, the Congress, or any statute enacted by the Congress, which may affect the provisions, terms, or funding of this Contract in any manner. Contractor agrees to comply with all applicable Medicaid laws, regulations, including applicable sub-regulatory guidance and contract provisions [(42 CFR §438.230)].

1.1 Counselor Certification: Any registered or certified counselor providing intake, assessment of need for services, treatment or recovery planning, individual or group counseling to participants, patients, or residents in a DHCS licensed or certified program is required to be registered or certified as defined in Title 9, CCR, Division 4, Chapter 8. [SABG Contract, Enclosure 2; DMC-ODS IA, Exhibit A].

1.2 Medications for Addiction Treatment (MAT): Contractors will have a MAT Policy and procedures for linkage/integration for beneficiaries requiring medications for addiction treatment. All DMC-ODS providers, at all levels of care, shall demonstrate that they either directly offer or have an effective referral mechanism to the most clinically appropriate MAT services for beneficiaries with SUD diagnoses that are treatable with medications or biological products. An effective referral mechanism/process is defined as facilitating access to MAT off-site for beneficiaries while they are receiving services if not provided on-site. Providing a beneficiary the contact information for a treatment program is insufficient. Contractor staff will regularly communicate with physicians of beneficiaries who are prescribed these medications unless the beneficiary refuses to consent to a 42 CFR, Part 2 compliant release of information for this purpose. Beneficiaries shall not be denied access to services based on their use of or need for prescribed MAT for substance use disorders. Beneficiaries cannot be denied services or be required to be tapered off medications as a condition of entering or remaining in the program.

1.3 Cultural and Linguistic Proficiency: To ensure access to quality care by diverse populations, each service provider receiving funds from the State-County Contract shall adopt the federal Office of Minority Health Culturally and Linguistically Appropriate Services (CLAS) national standards as outlined online at: <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53https://thinkculturalhealth.hhs.gov/clas/standards>. The

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Contractor shall participate in the County's efforts to promote the delivery of services in a culturally responsive manner to all beneficiaries, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of gender, sexual orientation or gender identity. [SABG Contract, Enclosure 2; DMC-ODS IA, Exhibit A, BHRS-57; 42 CFR 438.206(c)(2)]

1.4 Information Access for Individuals with Limited English Proficiency: Contractor shall comply with all applicable provisions of the Dymally-Alatorre Bilingual Services Act (Government Code sections 7290-7299.8) regarding access to materials that explain services available to the public as well as providing language interpretation services. Contractor shall also comply with the applicable provisions of Section 1557 of the Affordable Care Act (45 CFR Part 92), including, but not limited to, 45 CFR 92.201, when providing access to: (a) materials explaining services available to the public, (b) language assistance, (c) language interpreter and translation services, or (d) video remote language interpreting services. [SABG Contract, Enclosure 2]

1.5 Perinatal Practice Guidelines: Perinatal programs shall comply with the Perinatal Practice Guidelines until such time new Perinatal Practice Guidelines are established and adopted. All Contractors that serve women and who receive SABG funds shall provide preference to pregnant women and shall publicize the availability of such services and that preference is given to such women. [SABG Contract, Enclosure 2; DMC-ODS IA, Exhibit A; BHRS-66]

1.6 Tuberculosis (TB) Treatment: Contractors receiving SABG funding for substance use treatment shall ensure the following related to TB: routinely make available TB services to each individual receiving treatment for AOD use and/or abuse; reduce barriers to patients accepting TB treatment; and develop strategies to improve follow-up monitoring, particularly after patients leave treatment, by disseminating information through educational bulletins and technical assistance. [SABG Contract, Enclosure 2]

1.7 Intravenous Drug Use (IVDU) Treatment: Contractor shall ensure that individuals in need of IVDU treatment shall be encouraged to undergo AOD treatment (42 USC 300x-23 (45 CFR 96.126(e)).[SABG Contract, Enclosure 2]

1.8 Charitable Choice Requirements: Contractors shall not use funds provided through this contract for inherently religious activities, such as sectarian worship, religious instruction, or proselytization. No federal funds shall be used by Contractors to provide direct, immediate or substantial support to any religious activity. Contractors that are religious organizations shall establish a referral process to a reasonably accessible program for clients who may object to the religious nature of the Contractor's program and contractors shall be required to notify clients of their rights prohibiting discrimination and to be referred to another program if they object to the religious nature of the program at intake. Referrals that were made due to the religious nature of the Contractor's program shall be submitted annually to the County Alcohol and Drug Administrator by June 30 for referrals made during the fiscal year. Contractor shall establish such processes and procedures as necessary to comply with the provisions of USC, Title 42, Section 300x65 and CFR, Title 42, Part 54 pertaining to nondiscrimination and institutional safeguards for religious providers. [SABG Contract, Enclosure 2; DMC-ODS IA, Exhibit A; BHRS-03]

1.9 Trafficking Victims Protection Act of 2000: Contractor shall comply with Section 106(g) of the Trafficking Victims Protection Act of 2000 as amended (22 U.S.C. 7104(g)). The County is authorized to terminate the contract, without penalty, if the Contractor: (a) Engages in severe forms of trafficking in persons during the period of time that the award is in effect; (b) Procures a commercial sex act during the period of time that the award is in effect; or (c) Uses forced labor in the performance of the award or subawards under the award. [SABG Contract, Enclosure 2; DMC-ODS IA, Exhibit A; BHRS-71]

1.10 Tribal Communities and Organizations: Contractor County shall regularly review population information available through Census, compare to information obtained in the California Outcome Measurement System for Treatment (CalOMS-Tx) to determine whether the population is being reached, and survey Tribal representatives for insight in potential barriers to the substance use service needs of the American Indian/Alaskan Native (AI/AN) population within the County geographic area. Contractor shall also engage in regular and meaningful consultation and collaboration with elected officials of the tribe, Rancheria, or their designee for the purpose of identifying issues/barriers

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to service delivery and improvement of the quality, effectiveness, and accessibility of services available to AI/NA communities within the County. [SABG Contract, Enclosure 2]

1.11 Access to Drug/Medi-Cal Services: When a request for non-urgent covered services is made by a beneficiary, services shall be initiated within three business days for Opioid Treatment Programs and within 10 business days for other substance use services of the Contractor's receipt of the request. When a request for urgent covered services is made by a beneficiary, services shall be initiated within 48 hours of the Contractor's receipt of the request. Contractor shall have a documented system for monitoring and evaluating accessibility of care, including a system for addressing problems that develop regarding waiting times and appointments. Contractor shall also have hours of operation during which services are provided to Medi-Cal beneficiaries that are no less than the hours of operation during which the provider offers services to non-Medi-Cal beneficiaries [DMC-ODS IA, Exhibit A; BHRS-73; BHRS-46; CCR, Title 9, § 1810.405]

1.11.1 Follow-Up Appointments: Contractor shall ensure that all clients seeking non-urgent follow-up appointments with a non-physician SUD provider are provided within 10 business days of the prior appointment for those undergoing a course of treatment for an ongoing SUD condition. These timely standards must be followed, except in the following circumstances: a) The referring or treating licensed health care provider, or the health professional providing triage or screening services, as applicable, has determined and noted that in the relevant record that a longer waiting time will not have a detrimental impact on the client's health; b) Preventive care services and periodic follow-up care, including office visits for SUD conditions, may be scheduled in advance consistent with professionally recognized standards of practice as determined by the treating licensed health care provider acting within the scope of their practice.

1.11.2 Rescheduled Appointments: Contractor shall ensure that, if necessary for a client or a provider to reschedule an appointment, the appointment is promptly rescheduled in a manner that is appropriate for the client's health care needs and ensures continuity of care consistent with good professional practice.

1.11.3 Telephone Wait Times: Contractor shall ensure that during normal business hours, the waiting time for a client to speak by telephone with staff knowledgeable and competent regarding the client's questions and concerns does not exceed 10 minutes.

1.12 Contractors that are Drug/Medi-Cal certified shall also comply with the applicable 42 CFR 438 Managed Care requirements, Drug/Medi-Cal Organized Delivery System Special Terms and Conditions (DMC-ODS STCs), and applicable Department of Health Care Services Behavioral Health Information Notices (BHIN), including, but not limited to the following [DMC-ODS IA, Exhibit A]:

1.12.1 Culturally Competent Services: Contractors are responsible to provide culturally competent services. Contractors must ensure that their policies, procedures, and practices are consistent with the principles outlined and are embedded in the organizational structure, as well as being upheld in day-to-day operations. Contractor shall make oral interpretation services in all non-English languages, including use of auxiliary aids such as TTY/TDA and American Sign Language, available at no cost to the beneficiary. Contractor shall submit language line utilization data using the template provided by BHRS detailing monthly use of interpretation services for beneficiaries' face-to-face encounters and telephonic service encounter. Contractor shall make written translation available in prevalent languages. All services, policies and procedures must be culturally and linguistically appropriate. Contractor must participate in the implementation of the most recent Cultural Competency Plan for the County and shall adhere to all cultural competency standards and requirements. Contractor shall participate in the County's efforts to promote the delivery of services in a culturally responsive and equitable manner to all clients, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of gender, sexual orientation, or gender identity. [DMC-ODS IA, Exhibit A; 42 CFR 438, Contract Exhibit I, Section 1.3]

1.12.2 Evidence-Based Practices (EBPs): Contractors will implement and assess fidelity to at least two of the following EBPs per service modality: Motivational Interviewing, Cognitive-Behavioral Therapy, Relapse Prevention, Trauma-Informed Treatment and Psycho-Education.

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1.12.3 Client Informing Materials Basic Information Requirements

1.12.3.1 Contractor shall provide information in a manner and format that is easily understood and readily accessible to clients. (42 C.F.R. § 438.10(c)(1)). Contractor shall provide all written materials for clients in easily understood language, format, and alternative formats that take into consideration the special needs of clients in compliance with 42 C.F.R. § 438.10(d)(6). Contractor shall inform clients that information is available in alternate formats and how to access those formats in compliance with 42 C.F.R. § 438.10.

1.12.3.2 Contractor shall provide the required information in this section to each client receiving SUD services under this Agreement and upon request.

1.12.3.3 Contractor shall utilize the County's website that provides the content required in this section and 42 C.F.R. § 438.10 and complies with all the requirements regarding the same set forth in 42 C.F.R. § 438.10.

1.12.3.4 Contractor shall use DHCS/County developed model beneficiary handbook and client notices. (42 C.F.R. §§ 438.10(c)(4)(ii), 438.62(b)(3)).

1.12.3.5 Client information required in this section may only be provided electronically by the Contractor if all of the following conditions are met:

1.12.3.5.1 The format is readily accessible;

1.12.3.5.2 The information is placed in a location on the Contractor's website that is prominent and readily accessible;

1.12.3.5.3 The information is provided in an electronic form which can be electronically retained and printed;

1.12.3.5.4 The information is consistent with the content and language requirements of this Agreement;

1.12.3.5.5 The client is informed that the information is available in paper form without charge upon request and the Contractor provides it upon request within five business days. (42 C.F.R. § 438.10(c)(6)).

1.12.4 Client Informing Materials Language and Format

1.12.4.1 Contractor shall provide all written materials for potential clients and clients in a font size no smaller than 12 point. (42 C.F.R. § 438.10(d)(6)(ii).)

1.12.4.2 Contractor shall ensure its written materials that are critical to obtaining services are available in alternative formats, upon request of the client or potential client at no cost.

1.12.4.3 Contractor shall make its written materials that are critical to obtaining services, including, at a minimum, provider directories, beneficiary handbook, appeal and grievance notices, denial and termination notices, and the Contractor's SUD health education materials, available in the prevalent non-English languages in the County. (42 C.F.R. § 438.10(d)(3).)

1.12.4.3.1 Contractor shall notify clients, prospective clients, and members of the public that written translation is available in prevalent languages free of cost and how to access those materials. (42 C.F.R. § 438.10(d)(5)(i), (iii); Welfare & Institutions Code § 14727(a)(1); California Code of Regulations, tit. 9 § 1810.410, subd. (e), para. (4))

1.12.4.4 Contractor shall make auxiliary aids and services available upon request and free of charge to each client. (42 C.F.R. § 438.10(d)(3)- (4).)

1.12.4.5 Contractor shall make oral interpretation and auxiliary aids, such as Teletypewriter Telephone/Text Telephone (TTY/TDY) and American Sign Language (ASL), available and free of charge for any language in compliance with 42 C.F.R. § 438.10(d)(2), (4)-(5).

1.12.4.6 Taglines for written materials critical to obtaining services must be printed in a conspicuously visible font size.

1.12.5 Beneficiary Informational Materials: Contractor shall provide and make available at initial contact, and shall notify beneficiaries of their right to request and obtain the following information upon request: DMC-ODS Beneficiary Booklet, Provider Directory, DMC-ODS Formulary, Advance Health Care Directive Form (required for adult clients only), Notice of Language Assistance Services available upon request at no

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cost to the client, Language Taglines, Grievance/Appeal Process and Form, Notice of Privacy Practices, and EPSDT poster (if serving clients under the age of 21). Contractor shall also post notices explaining grievance, appeal and expedited appeal processes in all program sites, as well as make available forms and self-addressed envelopes to file grievances, appeals and expedited appeals without having to make a verbal or written request to anyone. The County will produce required beneficiary informational materials in English and Spanish, and in alternative formats as requested. Contractor shall request materials from the County, as needed. [BHRS-35]

1.12.5.1 Beneficiary Handbook

1.12.5.1.1 Contractor shall provide each client with a beneficiary handbook at the time the client first accesses services. The beneficiary handbook shall be provided to beneficiaries within 14 business days after receiving notice of enrollment.

1.12.5.1.2 Contractor shall give each client notice of any significant change to the information contained in the beneficiary handbook at least 30 days before the intended effective date of change as per BHIN 22-060.

1.12.5.1.3 Required informing materials must be electronically available on the Contractor's website and must be physically available at the Contractor agency facility lobby for clients' access.

1.12.5.1.4 Informing materials must be made available upon request, at no cost, in alternate formats (i.e., Braille or Audio) and Auxiliary Aids (i.e., California Relay Service (CRS) 711 and American Sign Language) and must be provided to clients within five business days. Large print materials shall be in a minimum 18-point font size. Contractor shall request materials from the County, as needed.

1.12.5.1.5 Informing materials will be considered provided to the client if Contractor does one or more of the following: 1) Mails a printed copy of the information to the client's mailing address before the client first receives a SUD service; 2) Mails a printed copy of the information upon the client's request to the client's mailing address; 3) Provides the information by email after obtaining the client's agreement to receive the information by email; 4) Posts the information on the Contractor's website and advises the client in paper or electronic form that the information is available on the internet and includes applicable internet addresses, provided that clients with disabilities who cannot access this information online are provided auxiliary aids and services upon request and at no cost; or 5) Provides the information by any other method that can reasonably be expected to result in the client receiving that information. If the Contractor provides informing materials in person, when the client first receives SUD services, the date and method of delivery shall be documented in the client's file.

1.12.5.2 Provider Directory

1.12.5.2.1 Contractor must follow the County's provider directory policy, in compliance with MHSUDS IN 18-020.

1.12.5.2.2 Contractor must make available to clients, in paper form upon request and electronic form, specified information about its provider network as per 42 C.F.R. § 438.10(h). The most current provider directory is electronically available on the County website (www.MarinBHRS.org) and is updated by the County no later than 30 calendar days after information is received to update provider information. A paper provider directory must be updated as set forth in 42 C.F.R. § 438.10(h)(3)(i).

1.12.5.2.3 Any changes to information published in the provider directory must be reported to the County within two weeks of the change. Notifications can be made in writing to the County Alcohol and Drug Administrator or via the www.MarinBHRS.org website.

1.12.5.2.4 Contractor will only need to report changes/updates to the provider directory for each licensed or certified SUD service provider.

1.12.5.3 Medication Formulary

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1.12.5.3.1 Contractor shall make available in electronic or paper form, the following information about the County's formulary as outlined in 42 C.F.R. § 438.10(i): 1) Which medications are covered (for both generic and name brand); 2) What tier each medication resides on.

1.12.5.3.2 Contractor shall inform clients about County's formulary drug lists availability in a machine-readable file and format on the County's website.

1.12.5.4 Grievances and Appeals: All grievances (as defined by 42 C.F.R. § 438.400) and complaints received by Contractor must be immediately forwarded to the County's BHRS Quality Management Department via a secure method (e.g., encrypted email or by fax) to allow ample time for the Quality Management staff to acknowledge receipt of the grievance and complaints and issue appropriate responses. Contractor shall not discourage the filing of grievances and clients do not need to use the term "grievance" for a complaint to be captured as an expression of dissatisfaction and, therefore, a grievance.

1.12.5.4.1 Contractor must provide clients with any reasonable assistance in completing forms and taking other procedural steps related to a grievance or appeal such as auxiliary aids and interpreter services.

1.12.5.4.2 Contractor must maintain records of grievances and appeals and must review the information as part of its ongoing monitoring procedures. The record must be accurately maintained in a manner accessible to the County and available upon request to DHCS.

1.12.6 Notice of Adverse Benefit Determination (NOABD): Contractor shall immediately notify BHRS of any action that may require a NOABD be issued to a beneficiary, including, but not limited to: failing to provide the beneficiary with an initial face-to-face assessment appointment within three business days of the request for Opioid Treatment Programs or 10 business days of the request for all other substance use services; or determining that a beneficiary does not meet medical necessity for any substance use disorder treatment services. Contractor shall have written procedures to ensure compliance with the County's NOABD Procedure as outlined on the County website MarinBHRS.org including the following: 1) Contractor shall request consent from beneficiaries to issue a NOABD to the address on record should covered services be reduced, denied, modified, delayed or terminated; 2) Contractor shall log the NOABD on the Provider NOABD Log and submit by the 10th of each month via encrypted email to the County with copies of the issued NOABDs. Aligned with MHSUDS 18-010E and 42 C.F.R. § 438.404, the appropriate and delegated NOABD must be issued by Contractors within the specified timeframes using the template provided by the County. [BHRS-33]

1.12.7 Verifying Medi-Cal Eligibility: Contractor shall verify the Medi-Cal eligibility of each beneficiary for each month of service prior to billing for Drug/Medi-Cal services to that beneficiary for that month. Medi-Cal eligibility verification should be performed prior to rendering service, in accordance with and as described in the DHCS's DMC Provider Billing Manual. [DMC-ODS IA, Exhibit A; BHRS-73]

1.12.8 Practice Guidelines: Contractor shall comply with and disseminate the Practice Guidelines to all affected staff and, upon request, to beneficiaries and potential beneficiaries. Practice Guidelines can be accessed at www.MarinBHRS.org. [DMC-ODS IA, Exhibit A]

1.12.9 Advance Directives: Contractor must comply with all County policies and procedures regarding Advanced Directives in compliance with the requirements of 42 C.F.R. §§ 422.128 and 438.6(i) (l), (3) and (4). Copies of these policies are available at the BHRS webpage (www.MarinBHRS.org) and upon request.

1.12.10 Transitions of Care: Contractor shall follow County's transition of care policy [BHRS-58] in accordance with applicable state and federal regulations, MHSUDS IN 18-051: DMC-ODS Transition of Care

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Policy, and any BHINs issued by DHCS for parity in SUD and mental health benefits subsequent to the effective date of this Agreement (42 C.F.R. § 438.62(b)(1)-(2).)

1.12.10.1 Clients shall be allowed to continue receiving covered DMC-ODS services with an out-of-network provider when their assessment determines that, in the absence of continued services, the client would suffer serious detriment to their health or be at risk of hospitalization or institutionalization. DMC-ODS treatment services with the existing provider (out-of-network) provider shall continue for a period of no more than 90 days unless medical necessity requires the services to continue for a longer period of time, not exceeding 12 months. Specific criteria must be met.

1.12.11 The parties agree that failure of the Contractor to comply with W&I section 14124.24, the Special Terms and Conditions, and this Agreement, shall be deemed a breach that results in the termination of this Contract for cause. In the event of a breach, DMC-ODS services shall terminate. The Contractor shall immediately begin providing DMC services to beneficiaries in accordance with the State Plan. [DMC-ODS IA, Exhibit A]

1.12.12 Contractor shall notify County in writing of any change in organizational name, Head of Service or principal business at least 15 business days in advance of the change. DHCS shall certify Contractor to participate in the DMC-ODS program. Contractor cannot reduce or relocate without first receiving approval by DHCS. A DMC certification application shall be submitted to the DHCS Provider Enrollment Division (PED) 60 days prior to the desired effective date of the reduction of covered services or relocation. Contractor shall be subject to continuing certification requirements at least once every five years. Said notice shall become part of this Agreement upon acknowledgment in writing by the County, and no further amendment of the Agreement shall be necessary provided that such change of address does not conflict with any other provisions of this Agreement. [DMC-ODS IA]

1.12.13 Re-Certification Events: Contractor shall notify DHCS and the County Alcohol and Drug Administrator 60 days prior to the desired effective date of the reduction of Medi-Cal covered services or relocation, in addition to applicable federal, state and local regulations and policies of any triggering recertification events, such as change in ownership, organizational status or licensure, change in scope of services or ability to provide the quantity and quality of the contract services in a timely fashion, remodeling of facility, or change in location. [DMC-ODS IA, Exhibit A; BHRS-73]

1.12.14 Voluntary Termination of DMC-ODS Services: The Contractor may voluntarily terminate its obligation to provide DMC-ODS Services, for any reason, by giving 60 days written notice to DHCS and the County Alcohol and Drug Administrator. The Contractor shall be paid for DMC-ODS services provided to beneficiaries up to the date of termination. Upon termination, the Contractor shall immediately begin providing DMC services to beneficiaries in accordance with the State Plan. [DMC-ODS IA]

1.12.15 Nullification of DMC-ODS Services: 1) The parties agree that failure of the Contractor, or its subcontractors, to comply with W&I Code section 14124.24, 14184.100 et seq., BHIN 21-075, this Agreement, and any other applicable statutes, regulations or guidance issued by DHCS, shall be deemed a breach that results in the termination of this Agreement for cause; 2) In the event of a breach, DMC-ODS services shall terminate. The Contractor shall immediately begin providing DMC services to the beneficiaries in accordance with the State Plan. [DMC-ODS IA; BHIN 23-001 (supersedes 21-075)]

1.13 No Unlawful Use or Unlawful Use Messages Regarding Drugs: Contractor agrees that information produced through these funds, and which pertains to drugs and alcohol related programs, shall contain a clearly written statement that there shall be no unlawful use of drugs or alcohol associated with the program. Additionally, no aspect of a drug or alcohol - related program shall include any message on the responsible use, if the use is unlawful, of drugs or alcohol (HSC, Division 10.7, Chapter 1429, Sections 11999-11999.3). By signing this Contract, Contractor agrees that it will enforce, and will require its Subcontractors to enforce, these requirements. [DMC-ODS IA, Exhibit A; SABG Contract, Enclosure 2]

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1.14 Restriction on Distribution of Sterile Needles: No SABG funds made available through this Contract shall be used to carry out any program that includes the distribution of sterile needles or syringes for the hypodermic injection of any illegal drug unless DHCS chooses to implement a demonstration syringe services program for injecting drug users. [SABG Contract, Enclosure 2]

1.15 Limitation on Use of Funds for Promotion of Legalization of Controlled Substances: None of the funds made available through this Contract may be used for any activity that promotes the legalization of any drug or other substance included in Schedule I of Section 202 of the Controlled Substances Act (21 USC 812). [DMC-ODS IA, Exhibit A; SABG Contract, Enclosure 2]

1.16 Adolescent Best Practice Guidelines: Contractor must utilize DHCS guidelines in developing and implementing youth treatment programs funded under SABG Enclosure 2. The Adolescent Best Practices Guidelines can be found at:
https://www.dhcs.ca.gov/Documents/CSD_CMHCS/Adol%20Best%20Practices%20Guide/AdolBestPracGuideOCTOBER2020.pdf [DMC-ODS IA, Exhibit A; SABG Contract, Enclosure 2]

1.17 Byrd Anti-Lobbying Amendment (31 USC 1352): Contractor certifies that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 USC 1352. Contractor shall also disclose to County and DHCS any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award.

1.18 Marijuana Restriction: Grant funds may not be used, directly or indirectly, to purchase, prescribe, or provide marijuana or treatment using marijuana. Treatment in this context includes the treatment of opioid use disorder. Grant funds also cannot be provided to any individual who or organization that provides or permits marijuana use for the purposes of treating substance use or mental disorders. See, e.g., 45 CFR. § 75.300(a) (requiring HHS to “ensure that Federal funding is expended . . . in full accordance with U.S. statutory . . . requirements.”); 21 USC § 812(c) (10) and 841 (prohibiting the possession, manufacture, sale, purchase or distribution of marijuana). This prohibition does not apply to those providing such treatment in the context of clinical research permitted by the DEA and under an FDA-approved investigational new drug application where the article being evaluated is marijuana or a constituent thereof that is otherwise a banned controlled substance under Federal law. [SABG Contract, Enclosure 2]

1.19 Contractors receiving SABG funding are required to comply with the requirements of SABG Contract, Enclosure 2, which can be accessed at www.MarinBHRS.org.

1.20 Advertising Requirements: DHCS licensed substance use recovery or treatment facilities and certified alcohol and other drug programs shall comply with HSC, Section 11831.9, which requires authentic advertisements including license and/or certification number and expiration dates. Contractor shall comply with these requirements and any subsequent regulations around advertising requirements for SUD recovery or treatment facilities issued by DHCS [DHCS BHIN 22-022 and DHCS BHIN 23-007]

1.20.1 Licensed SUD recovery or treatment facilities and certified alcohol or other drug programs shall not do any of the following: 1) Make a false or misleading statement or provide false or misleading information about the entity’s products, goods, services, or geographical locations in its marketing, advertising materials, or media, or on its internet website or on a third-party internet website; 2) Include on its internet website a picture, description, staff information, or the location of an entity, along with false contact information that surreptitiously directs the reader to a business that does not have a contract with the entity; 3) Include on its internet website false information or an electronic link that provides false information or surreptitiously directs the reader to another internet website.

1.21 ASAM Standards of Care

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1.21.1 In accordance with Health and Safety Code section 111834.015, DHCS has adopted the ASAM treatment criteria, or other equivalent evidenced based criteria as the minimum standard of care for AOD facilities

1.21.2 For this Agreement and subsequent services, Contractor shall adopt ASAM as the evidenced based practice standard for LOC.

1.21.3 Contractor shall ensure treatment staff of all SUD treatment programs receive adequate training in ASAM criteria prior to conducting assessments and providing services that includes but is not limited to in person or e-training modules: ASAM Module I- Multidimensional Assessment and ASAM Module II- From Assessment to Service Planning and Level of Care.

1.22 In addition to the insurance requirements in the Professional Services Contract, substance use disorder recovery or treatment facilities licensed by DHCS shall also maintain professional liability and errors and omissions insurance that includes an endorsement for contractual liability, with minimum coverage amounts of one million dollars (\$1,000,000) per occurrence and two million dollars (\$2,000,000) aggregate. If applicable, the contract shall include an endorsement for defense and indemnification of any government entity with which the licensee has contracted. [DHCS BHIN 22-023; HSC 11834.10]

1.23 Participation of County Behavioral Health Director's Association of California: The County AOD Program Administrator shall participate and represent the County in meetings of the County Behavioral Health Director's Association of California for the purposes of representing the counties in their relationship with DHCS with respect to policies, standards, and administration for AOD abuse services. The County AOD Program Administrator shall attend any special meetings called by the Director of DHCS. Participation and representation shall also be provided by the County Behavioral Health Director's Association of California. [DMC-ODS IA; SABG Enclosure 2]

1.24 Additional Contract Restrictions: This Contract is subject to any additional restrictions, limitations, or conditions enacted by the Congress, or any statute enacted by the Congress, which may affect the provisions, terms, or funding of this Contract in any manner.

2. Program Monitoring

2.1 In accordance with 42 C.F.R. § 438.66 and as applicable with 42 C.F.R. §§ 438.604, 438.606, 438.608, 438.610, 438.230, 438.808, 438.900 et seq., County will conduct monitoring and oversight activities to review the Contractor's SUD programs and operations. The purpose of these oversight activities is to verify that medically necessary services are provided to clients, who meet medical necessity and criteria for access to DMC-ODS as established in BHIN 23-001, in compliance with the applicable state and federal laws and regulations, and/or the terms of the Agreement between Contractor and County, and future BHINs which may spell out other specific requirements.

2.2 Formal evaluation of the program shall be made annually through a Provider Self-Audit and on-site visit. This evaluation shall result in a written report to the Contractor within fifteen (15) working days of the site visit. Any report that results from a site visit shall be submitted to the Contractor within fifteen (15) working days. Contractor shall submit a written response within the timeframe outlined in the site visit report, and such response shall be part of the official written report provided for in this section. Marin County submits all DMC-ODS and SABG-related program and fiscal monitoring reports to DHCS within two weeks of issuance.

2.3 Contractor shall maintain proper program, clinical and fiscal records relating to activities and clients served under the terms of this Agreement, as required by the County, DHCS, and all applicable state and federal statutes and regulations. Client records shall include but not be limited to admission records, diagnostic studies and evaluations, client interviews and progress notes, and records of services provided. All such records shall be maintained in sufficient detail to permit evaluation of the services provided and to meet claiming requirements. Contractor shall meet the requirements of and participate in the management information system of BHRS, and maintain fiscal, administrative, and programmatic records and such other data as may be required by the County Alcohol and Drug Administrator for program and research requirements.

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2.4 Contractor shall notify the County Alcohol and Drug Administrator within two business days of receipt of any DHCS report identifying non-compliance services or processes requiring a Corrective Action Plan (CAP). Contractor shall submit the CAP to DHCS with the designated timeframe specified by DHCS and shall concurrently send a copy to the County Alcohol and Drug Administrator.

2.5 County reserves the right to place Contractor on probationary status should Contractor fail to meet performance requirements; including, but not limited to violations such as high disallowance rates, failure to report incidents and changes as contractually required, failure to correct issues, inappropriate invoicing, untimely and inaccurate data entry, not meeting performance outcomes expectations, and violations issued directly from the State. Additionally, Contractor may be subject to Probationary Status or termination if contract monitoring and auditing corrective actions are not resolved within specified timeframes.

2.6 County has the discretion to revoke full or partial provisions of the Agreement, delegated activities or obligations, or application of other remedies permitted by state or federal law when the County or DHCS determines Contractor has not performed satisfactorily.

2.7 In the event the Agreement is terminated, ends its designated term or Contractor ceases operation of its business, Contractor shall deliver or make available to County all financial records that may have been accumulated by Contractor or subcontractor under this Agreement, whether completed, partially completed or in progress within seven calendar days of said termination/end date.

3. Audits and Record Retention

3.1 Contractor and the County mutually agree to maintain the confidentiality of Contractor's participant records, including billings, pursuant to Sections 11812(c) and 11879, Health & Safety Code and Federal Regulations for Confidentiality of Substance Use Disorder Patient Records (42 CFR Part 2, Subparts A - E), the federal Health Insurance Portability and Accountability Act (HIPAA) and all other applicable State and Federal laws and any amendments. Contractor shall inform all its officers, employees, and agents of the confidentiality provisions of said regulations, and provide all necessary policies and procedures and training to ensure compliance. Contractor shall ensure staff participate in information privacy and security training at least annually, and prior to accessing protected health information (hereinafter PHI) or personal information (hereinafter PI), sign a confidentiality statement that includes, at a minimum, General use, Security and Privacy Safeguards, Unacceptable Use, and Enforcement Policies. The statement must be renewed annually and shall be retained for a period of six (6) years following termination of this contract. [DMC-ODS IA, Exhibit F; SABG Contract]

3.2 Where contracts exceed \$10,000 of state funding – the Contractor shall preserve and make available records, and shall be subject to examination and audit of the Department of Auditor General, for a period of ten (10) years from the date of final payment under this agreement, and for such longer period, if any, as required by applicable statute, by any other provision of this agreement, or by subparagraphs 3.2.1 or 3.2.2, below.

3.2.1. If this Agreement is completely or partially terminated, the records relating to the work terminated shall be preserved and made available for a period of three years from the date of any resulting final settlement.

3.2.2. If any litigation, claim, negotiation, audit, or other action involving the records has been started before the expiration of the ten-year period, the records shall be retained until completion of the action and resolution of all issues which arise from it, or until the end of the regular ten-year period, whichever is later. [County of Marin Performance Contract 21-10091, Exhibit A]

3.3 Contractor agrees: 1) The Department, CMS, the Health and Human Services (HHS) Inspector General, the Comptroller General, or their designees, and the County or any subdivision or appointee thereof have the right to audit, evaluate, and inspect any books, records, contracts, computer or other electronic systems of the Contractor, or of the Contractor's subcontractor, that pertain to any aspect of services and activities performed, or determination of amounts payable under this Agreement at any time; 2) The Contractor will make available, for purposes of an audit,

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evaluation, or inspection, its premises, physical facilities, equipment, books, records, contracts, computer or other electronic systems relating to its Medicaid beneficiaries; 3) The Department, CMS, the HHS Inspector General, the Comptroller General, or their designees', and the County or any subdivision or appointee thereof right to audit the Contractor will exist through ten years from the final date of the contract period or from the date of completion of any audit, whichever is later; 4) If the Department, CMS, or the HHS Inspector General determines that there is a reasonable possibility of fraud or similar risk, the Department, CMS, or the HHS Inspector General may inspect, evaluate, and audit the Contractor at any time. Full cooperation shall be given by the Contractor in any auditing or monitoring conducted, according to this Agreement. [DMC-ODS IA; 42 C.F.R. §§ 438.3(h), 438.230(c)(3)(i-iii)]

3.4 Contractor shall cooperate with the County in the implementation, monitoring and evaluation of this Agreement and comply with any and all reporting requirements established by the County. Should the County identify an issue or receive notification of a complaint or potential/actual/suspected violation of requirements, the County may audit, monitor, and/or request information from the Contractor to ensure compliance with laws, regulations, and requirements, as applicable.

3.5 Contractor acknowledges that if a DMC provider is under investigation by DHCS or any other state, local or federal law enforcement agency for fraud or abuse, DHCS may temporarily suspend the provider from the DMC program, pursuant to WIC 14043.36(a). Information about a provider's administrative sanction status is confidential until such time as the action is either completed or resolved. DHCS may also issue a Payment Suspension to a provider pursuant to WIC 14107.11 and Code of Federal Regulations, Title 42, section 455.23. The County is to withhold payments from a DMC provider during the time a Payment Suspension is in effect. The County shall execute the Confidentiality Agreement. The Confidentiality Agreement permits DHCS to communicate with County concerning subcontracted providers that are subject to administrative sanctions.

3.6 Contractor, if applicable, shall maintain medical records and other records showing a Medi-Cal beneficiary's eligibility for services, the service(s) rendered, the Medi-Cal beneficiary to whom the service was rendered, the date of the services, the medical necessity of the service and the quality of care provided. Records shall be maintained in accordance with Title 22 California Code of Regulations, W & I Code, Section 14214.1, 42 CFR 433.32, 438.3(h) and 438.3(u) for a period of time no less than ten (10) years.

3.7 Contractor shall retain, as applicable, the following information: beneficiary grievance and appeal records in 42 CFR 438.416 and the data, information and documentation specified in 42 CFR 438.604, 438606, 438.608 and 438.610 for a period of no less than ten (10) years. [DMC-ODS IA, Exhibit A]

3.8 Reasons for Recoupment: County will conduct periodic audits of Contractor files to ensure appropriate clinical documentation, high quality service provision and compliance with applicable federal, state and county regulations. Such audits may result in requirements for Contractor to reimburse County for services previously paid in the circumstances listed below (3.8.1 – 3.8.2). Contractor shall reimburse County for all overpayments identified by Contractor, County and/or state or federal oversight agencies as an audit exception within the timeframes required by law or Country or state or federal agency.

3.8.1 Identification of Fraud, Waste or Abuse as defined in federal regulation.

C3.8.1.1 Fraud and abuse are defined in Code of Federal Regulations, Title 42, § 455.2 and Welfare & Institutions Code, § 14107.11, subdivision (d). Definitions for "fraud," "waste," and "abuse" can also be found in the Medicare Managed Care Manual available at www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf

3.8.2 Overpayment of Contractor by County due to errors in claiming or documentation.

3.9 Contractor is responsible for the repayment of all audit exceptions and disallowances taken by local, State and Federal agencies, related to activities conducted by Contractor under the Agreement. All overpayments shall be returned to the County within 60 calendar days after the date on which the overpayment was identified, or the date any corresponding cost report is due, if applicable. When a financial audit is conducted by the Federal Government, the

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State, or the California State Auditor directly with Contractor, and if the Contractor disagrees with audit disallowances related to its programs, claims or services, County shall, at the Contractor's request, request an appeal to the State via the County. [DMC-ODS IA, Exhibit B; SABG Contract, Enclosures 3, 5]

3.10 Financial records shall be kept so that they clearly reflect the source of funding for each type of service for which reimbursement is claimed. These documents include, but are not limited to, all ledgers, books, vouchers, time sheets, payrolls, appointment schedules, client data cards, and schedules for allocating costs. Fiscal records shall contain sufficient data to enable auditors to perform a complete audit and shall be maintained in conformance with the procedures and accounting principles set forth in the State Department of Health Care Services' Cost Reporting/Data Collection Systems.

3.11 If Contractor uses electronic medical records, the Contractor agrees to use a system that is consistent with privacy and information security requirements pertaining to technical security controls, audit controls and business continuity/disaster recovery controls outlined in the DMC-ODS IA and SABG Contract. If Contractor does not use electronic medical records, the Contractor agrees to adhere to paper document controls outlined in the DMC-ODS IA, Exhibit F, SABG Contract and BHRS Policy and Procedure BHRS-SUS-06.

3.12 Contractor shall agree to maintain and retain all appropriate service and financial records for a period of at least 10 years from the date of final payment, the final date of the contract period, final settlement, or until audit findings are resolved, whichever is later.

3.13 Contractor shall submit audited financial reports on an annual basis to the County. The audit shall be conducted in accordance with generally accepted accounting principles and generally accepted auditing standards.

3.14 Contractor shall comply with Medical Records/Protected Health Information Article regarding relinquishing or maintaining medical records.

3.15 If Contractor uses electronic medical records, the Contractor agrees to submit staff updates, including changes in roles or new or separated staff, to the Marin Electronic Health Record (EHR) Administrator within the timeframes outlined in the BHRS Policy and Procedure BHRS-SUS-08. The notification shall include submission of the Electronic Signature Agreement and Marin EHR User Request/Change Form, as applicable. If a user suspects that their electronic signature may be comprised, Contractor shall notify the Marin EHR Administrator within the timeframes outlined in the BHRS Policy and Procedure BHRS-SUS-08.

3.16 Contractors funded with SABG dollars for primary prevention services are required to adhere to the Primary Prevention Substance Use Disorder Data Service quality standards as outlined in the SABG Contract, Enclosure 2.

4. Serious Incident Reporting

4.1 Contractor shall report serious incidents (formerly referred to as unusual occurrences) to the County of Marin in accordance with [BHRS Policy 06-Serious Incident Reporting](#). A serious incident is any event that jeopardizes the health and/or safety of clients, staff and/or members of the community, including but not limited to physical injury and death and/or could result in a claim or litigation against the County, its officials, agents, employees, or volunteers.

4.2 Level 1 incidents require immediate reporting and include: 1) Any event that has been reported in the media (including social media), current or recent past regardless of the type of incident; 2) The event has resulted in a death or serious physical injury on the program's premises; 3) The event is associated with a significant adverse deviation from the usual process for providing behavioral health care. All other incidents are reported as Level 2. The serious incident reporting form can be accessed at www.MarinHHS.org/policies-procedures.

4.2.1 A **Level 1** incident report must be e-mailed to BHRSM@marincounty.org or faxed to 415 329-3312 **immediately** upon knowledge of the incident.

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4.2.2 A **Level 2** incident report must e-mailed or faxed within 3 calendar days of knowledge of the incident.

4.3 The County and DHCS retain the right to independently investigate serious incidents and Contractor will cooperate in the conduct of such independent investigations.

4.4 In addition to the above reporting requirements, Residential substance use treatment facilities licensed by DHCS shall also comply with reporting unusual incidents as outlined in Title 9 CCR, Chapter 5, Subchapter 3, Article 1. Contractor shall notify the County Alcohol and Drug Administrator concurrently, which is a telephonic report within one (1) working day of the event, followed by a copy of the written report submitted to DHCS within seven (7) days of the event.

5. Applicable Fee(s)

5.1 Contractor shall charge participant fees. No one shall be denied services based solely on ability or inability to pay.

5.2 Contractor shall perform eligibility and financial determinations in accordance with a fee schedule approved by the County Alcohol and Drug Administrator for this purpose. Individual income, expenses, and number of dependents shall be considered in formulating the fee schedule and in its utilization.

5.3 Contractor agrees to have on file with the County a schedule of Contractor's published charges, if applicable.

5.4 Contractor shall conduct community-centered fundraising activities, as appropriate.

6. Non-Discrimination

6.1 Contractor certifies that under the laws of the United States and the State of California, Contractor will not unlawfully discriminate against any person.

6.2 Contractor shall develop and implement policies and procedures that ensure: non-discrimination in the provision of services based on a diagnosis of Acquired Immune Deficiency Syndrome (AIDS) or AIDS-related Complex (ARC), or upon testing positive for Human Immunodeficiency Virus (HIV); the prohibition of the use of HIV antibody testing as a screening criterion for program participation; training of all staff and all participants regarding high risk behaviors, safer sex practices, and perinatal transmission of HIV infection; and development of procedures for addressing the special needs and problems of those individuals who test positive for antibodies to HIV. No individual shall be required to disclose his or her HIV status.

6.3 The contractor and/or any permitted sub-contractor shall not discriminate in the provision of services because of race, color, religion, marital status, national origin, sex, sexual orientation, gender identity, age, health status or need for health care services, or mental or physical disability as consistent with the requirements of applicable federal law, such as 42 CFR, Part 438.3(d)(3) and (4) and state law. For the purpose of this contract, distinctions on the grounds of race, color, religion, marital status, national origin, sex, sexual orientation, gender identity, age, health status or need for health care services, or mental or physical disability include but are not limited to the following: denying a Medi-Cal beneficiary any service or benefit which is different, or is provided in a different way manner or at a different time from that provided to other beneficiaries under this contract; subjecting a beneficiary to segregation or separate treatment in any matter related to receipt of any service; restricting a beneficiary in any way in the enjoyment, advantage or privilege enjoyed by others receiving a service or benefit; treating a beneficiary differently from others in determining whether the beneficiary satisfied any admission, eligibility, other requirement or condition which individuals must meet in order to be provided any benefit; the assignment of times or places for the provision of services.

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6.4 The Contractor shall take affirmative action to ensure that services to intended Medi-Cal beneficiaries are provided without regard to race, color, religion, marital status, national origin, sex, sexual orientation, gender identity, health status or need for health care services, age or mental or physical disability.

6.5 Contractor shall not unlawfully discriminate against any person pursuant to the following Federal Law Requirements: Title VI of the Civil Rights Act of 1964, Section 2000d, as amended, prohibiting discrimination based on race, color, or national origin in federally funded programs; Title VIII of the Civil Rights Act of 1968 (42 USC 3601 et seq.) prohibiting discrimination on the basis of race, color, religion, sex, handicap, familial status or national origin in the sale or rental of housing; Age Discrimination Act of 1975 (45 CFR Part 90), as amended 42 USC Sections 6101 – 6107), which prohibits discrimination on the basis of age; Age Discrimination in Employment Act (29 CFR Part 1625); Title I of the Americans with Disabilities Act (29 CFR Part 1630) prohibiting discrimination against the disabled in employment; Title II of the Americans with Disabilities Act (28 CFR Part 35) prohibiting discrimination against the disabled by public entities; Title III of the Americans with Disabilities Act (28 CFR Part 36) regarding access; Section 504 of the Rehabilitation Act of 1973, as amended (29 USC Section 794), prohibiting discrimination on the basis of individuals with disabilities; Section 508 of the Rehabilitation Act and the Americans with Disabilities Act of 1973, which requires Contractor to provide physical access, reasonable accommodations, and accessible equipment for Medi-Cal clients with physical or mental disabilities; Executive Order 11246 (42 USC 2000(e) et seq. and 41 CFR Part 60) regarding nondiscrimination in employment under federal contracts and construction contracts greater than \$10,000 funded by federal financial assistance; Executive Order 13166 (67 FR 41455) to improve access to federal services for those with limited English proficiency; The Drug Abuse Office and Treatment Act of 1972, as amended, relating to nondiscrimination on the basis of drug abuse; and Confidentiality of Alcohol and Drug Abuse Patient Records (42 CFR Part 2, Subparts A – E); Title IX of the Education Amendments of 1972 (regarding education and programs and activities), if applicable; and The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism. [SABG Contract, Enclosure 2; DMC-ODS IA, Exhibit A]

6.6 Noncompliance with the requirements of nondiscrimination in services shall constitute grounds for DHCS to withhold payments under this Contract or terminate all, or any type, of funding provided hereunder.

6.7 Contractor shall develop and implement policies and procedures that ensure non-discrimination in access to or the provision of services because of the prescribed use of or need for Medication Assisted Treatment for substance use disorders.

6.8 Nondiscrimination in Employment and Services: County certifies that under the laws of the United States and the State of California, County will not unlawfully discriminate against any person Contractor is obligated to ensure and certifies that under the laws of the United States and the State of California, Contractor will not unlawfully discriminate against any person. [DMC-ODS IA; SABG Enclosure 2].

7. Required Program Submissions

7.1 Contractor agrees to maintain, and provide to County upon request, job descriptions, including minimum qualifications for employment and duties performed, for all personnel whose salaries, wages, and benefits are reimbursable in whole or in part under this Agreement.

7.2 Contractor agrees to maintain, and to provide to County upon request, an organizational chart that reflects the Contractor's current operating structure.

7.3 Contractor shall maintain, and provide to County upon request, the complaint procedure to be utilized in the event that there is a complaint regarding services provided under this Agreement. Contractor shall ensure that recipients of service under this Agreement have access to and are informed of Contractor's complaint procedure.

7.4 Upon Contractor's completion of services under this Agreement to County's satisfaction, payment to Contractor shall be made monthly in accordance with the procedures set forth in Exhibit B. All billings and reports shall clearly reflect and in reasonable detail give information regarding the services for which the claim is being made. It is

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understood and agreed that County may withhold payment until receipt of billings and reports in the prescribed detail and format. Billings and reports shall be made and forwarded to County of Marin Health & Human Services Division of BHRS promptly at the end of each calendar month; no later than the 10th day of the month following the month in which the services, for which billing is made, were rendered. Payments received after that date may result in a delay in payment until the next monthly billing cycle. The payment for the month of September may be withheld pending receipt of the preceding year's Cost Report on continuing services contracts.

7.5 Contractor shall provide County with an annual Cost Report no later than sixty (60) days after the termination of this agreement. In addition to the annual Cost Report, Contractor shall furnish County, within one hundred and eighty (180) days of close of contractor fiscal year, a certified copy of an Audit Report from an independent CPA firm. This Audit Report shall cover Contractor's fiscal year which most nearly coincides with County's fiscal year. Contractors receiving federal funds shall comply with Office of Management and Budget (OMB) Circular Number A133, Uniform administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals, and other Nonprofit Organizations. Cost Report settlements shall be made when a proper Cost Report has been submitted to the County. The findings of the annual Cost Report shall be subject to an audit by County and State. The State of California may make such audits as it deems necessary for the purpose of determining reimbursement due to the County.

7.6 Contractor will have written contractual agreements in place with all approved subcontractors that defines the services to be provided by the subcontractors and is consistent with and fully reflects the services and conditions described in this contract. Such MOUs will be made available to County within a reasonable time upon request. Notwithstanding any relationship(s) that Contractor may have with any subcontractor, the Contractor shall maintain ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of this Agreement.

7.7 Contractor will report all data and outcomes, such as CalOMS and DATAR, as required by state or county and as required by the State-County Contract. DATAR shall be submitted directly to DHCS by the 10th of the month following the report activity month. Contractor shall comply with data reporting compliance standards as established by DHCS and/or SAMHSA depending on the specific source of funding. Contractor shall ensure that all data stored or submitted to the County, DHCS or other data collection sites is accurate and complete.

8. Privacy and Security Safeguards

8.1 The County receives funding from DHCS pursuant to an annual contracting arrangement (hereinafter "State Contract"). The State Contract contains certain requirements pertaining to the privacy and security of PI and/or PHI and requires that County contractually obligate any of its sub-contractors to also comply with these requirements. Contractor hereby agrees to be bound by, and comply with, any and all terms and conditions of the State Contract, the applicable standards and requirements of the HIPAA regulations and this Exhibit "I," pertaining to the privacy and/or security of PI and/or PHI. This include ensuring that all workstations, laptops and removable media devices that process and/or store DHCS PHI or PI must be encrypted using a FIPS 140-2 certified algorithm which is 256bit or higher. A hard copy of the State-County Contract will be provided to the Contractor upon request, and an electronic copy can be found on the BHRS website at www.MarinBHRS.org.

8.2 The County is also required to enter into a contract containing specific requirements with Contractor prior to the disclosure of PHI to the Contractor pursuant to the Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act ("the HITECH Act") and their implementing privacy and security regulations at 45 CFR Parts 160 and 164 (collectively "the HIPAA Regulations").

8.2.1 Contractor is the Business Associate of County, acting on County's behalf, and provides services, arranges, performs or assists in the performance of functions or activities on behalf of County and creates, receives, maintains, transmits, uses or discloses PHI.

8.3 This section is intended to protect the privacy and security of County information, that Contractor may create, receive, access, store, transmit, and/or destroy under this Contract and serves as the Business Associate Agreement

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Contractor agrees as follows:

8.3.1 Obligations of Contractor

8.3.1.1 Permitted Uses and Disclosures. Contractor shall not use or disclose Protected Information except for the purpose of performing Contractor's obligations under the Contract and as permitted under the Contract and this Exhibit "I." Further, and notwithstanding anything to the contrary above, Contractor shall not use or disclose Protected Information in any manner that would constitute a violation of the HIPAA regulations if so used or disclosed by County. However, Contractor may use or disclose Protected Information (i) for the proper management and administration of Contractor, (ii) to carry out the legal responsibilities of Contractor, (iii) as required by law, or (iv) for data aggregation purposes for the Health Care Operations of Contractor, as permitted under 45 C.F.R. § 164.504(e). If Contractor discloses Protected Information to a third party, Contractor must obtain, prior to making any such disclosure, (i) reasonable written assurances from such third party that such Protected Information will be held confidential as provided pursuant to this Exhibit "I" and only disclosed as required by law or for the purposes for which it was disclosed to such third party, and (ii) a written agreement from such third party to immediately notify Contractor of any breaches of confidentiality of the Protected Information, to the extent it has obtained knowledge of such breach.

8.3.1.2 Prohibited Uses and Disclosures. Contractor shall not use or disclose Protected Information for fundraising or marketing purposes. Contractor shall not disclose Protected Information to a health plan for payment or health care operations purposes if the patient has requested this special restriction and has paid out of pocket in full for the health care item or service to which the PHI solely relates). Contractor shall not directly or indirectly receive remuneration in exchange for Protected Information, except with the prior written consent of County and as permitted by the HITECH Act, 42 U.S.C. § 17935(d)(2); however, this prohibition shall not affect payment by County to Contractor for services provided pursuant to the Contract.

8.3.1.3 Appropriate Safeguards. Contractor shall implement appropriate administrative, physical, and technical safeguards as are necessary to prevent the use or disclosure of Protected Information other than as permitted by the Contract that reasonably and appropriately protect the confidentiality, integrity and availability of the Protected Information, in accordance with 45 C.F.R. § 164.308, 164.310, and 164.312. Contractor shall comply with the policies and procedures and documentation requirements of the HIPAA Security Rule.

8.3.1.4 Contractor's Agents. Contractor shall ensure that any agents, including subcontractors, to whom it provides Protected Information, agree in writing to the same restrictions and conditions that apply to Contractor with respect to such PHI and implement the safeguards required by § 8.3.1.3 above with respect to PHI. Contractor shall implement and maintain sanctions against agents and subcontractors that violate such restrictions and conditions and shall mitigate the effects of any such violation.

8.3.1.5 Access to Protected Information. Contractor shall make Protected Information maintained by Contractor or its agents or subcontractors in designated record sets, as defined by the Privacy Rule, including, but not limited to, 45 C.F.R. § 164.501, available to County for inspection and copying within ten (10) business days of a request by County to enable County to fulfill its obligations under the HIPAA Privacy Rule, including, but not limited to, 45 C.F.R. § 164.524. If Contractor maintains an Electronic Health Record, Contractor shall provide such information in electronic format to enable County to fulfill its obligations under the HIPAA Regulations. If any individual, as defined under HIPAA Privacy Rule and HIPAA Security Rule, including but not limited to 45 C.F.R. § 164.103, requests access to Protected Information directly from Contractor or its agents or subcontractors, Contractor shall inform the County of the request without unreasonable delay, in any event no later than three (3) days of receipt of the request. If the County permits the disclosure, the County will inform the Contractor within two (2) days of the receipt of the request from

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Contractor, whereupon the Contractor will be authorized to provide access to the authorized individual.

8.3.1.6 Amendment of PHI. Within ten (10) business days of receipt of a request from County for an amendment of Protected Information or a record about an individual contained in a designated record set, Contractor or its agents or subcontractors shall make such Protected Information available to County for amendment and incorporate any such amendment to enable County to fulfill its obligations under the HIPAA Privacy Rule, including, but not limited to, 45 C.F.R. § 164.526. If any individual requests an amendment of Protected Information directly from Contractor or its agents or subcontractors, Contractor must notify County in writing within five (5) business days of the request. Any approval or denial of amendment of Protected Information maintained by Contractor or its agents or subcontractors shall be the responsibility of County.

8.3.1.7 Accounting Rights. Within ten (10) business days of notice by County of a request for an accounting of disclosures of Protected Information, Contractor and its agents or subcontractors shall make available to Contractor the information required to provide an accounting of disclosures to enable County to fulfill its obligations under the HITECH Regulations as determined by County. Contractor agrees to implement a process that allows for an accounting to be collected and maintained by Contractor and its agents or subcontractors for at least six (6) years prior to the request. At a minimum, the information collected and maintained shall include: (i) the date of disclosure; (ii) the name of the entity or person who received Protected Information and, if known, the address of the entity or person; (iii) a brief description of Protected Information disclosed and (iv) a brief statement of purpose of the disclosure that reasonably informs the individual of the basis for the disclosure, or a copy of the individuals' authorization, or a copy of the written request for disclosure. In the event that the request for an accounting is delivered directly to County or its agents or subcontractors, Contractor shall within five (5) business days of a request forward it to County in writing. However, it shall be Contractor's responsibility to prepare and deliver any such accounting requested and to do so in accordance with law. Contractor shall not disclose any Protected Information except as set forth in § 9.3.1.1 of this Exhibit "I."

8.3.1.8 Governmental Access to Records. Contractor shall make its internal practices, books and records relating to the use, disclosure, and privacy protection of Protected Information available to County and to the DHHS Secretary for purposes of determining County's compliance with the Privacy Rule. Contractor shall provide to County a copy of any Protected Information that Contractor provides to the DHHS Secretary concurrently with providing such Protected Information to the US Department of Health & Human Services ("DHHS") Secretary.

8.3.1.9 Minimum Necessary. Contractor and its agents or subcontractors shall request, use and disclose only the minimum amount of Protected Information necessary to accomplish the purpose of the request, use, or disclosure. Contractor understands and agrees that the definition of "minimum necessary" is in flux and shall keep itself informed of guidance issued by the DHHS Secretary with respect to what constitutes "minimum necessary."

8.3.1.10 Data Ownership. Contractor acknowledges that Contractor has no ownership rights with respect to the Protected Information. The County is the owner of all protected information and/or records containing such PHI provided to Contractor pursuant to the Contract or this Exhibit "I."

8.3.1.11 Notification of Improper Access, Use or Disclosure and Breach. Unless stricter reporting requirements apply in accordance with federal or state laws or regulations, other provisions of the Contract, or this Exhibit "I," Contractor shall report to County any access, use or disclosure of Protected Information not permitted by the Contract and this Exhibit "I," suspected and actual breaches of Protected Information, and security incidents involving Protected Information.

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8.3.1.11.1 An Initial Notice shall be provided to County within twenty-four (24) hours of any suspected or actual breach of security, intrusion or unauthorized use or disclosure of Protected Information of which Contractor becomes aware and/or any actual or suspected access, use or disclosure of data in violation of the Contract and this Exhibit "I" and/or any applicable federal or state laws or regulations, Contractor shall (1) immediately investigate breaches and security incidents involving protected information, (2) take prompt corrective action to mitigate any risks or damages involved with the breach or security incident and to protect the operating environment and (3) take any action pertaining to such unauthorized disclosure required by applicable federal and state laws and regulations. The parties agree that County has the sole discretion to determine whether or not it will undertake such obligations on behalf of Contractor and that, if it does, County has the right to require Contractor to pay for any or all costs associated therewith. Contractor shall provide notice to County as set forth in section 8.3.

8.3.1.11.2 A Complete Report shall be submitted within ten (10) working days of the discovery. The Complete Report of the investigation shall include an assessment of all known factors relevant to the determination of whether a breach occurred under applicable HIPAA provisions and/or other applicable law. The report shall also include a Corrective Action Plan (CAP) that shall include, at minimum, detailed information regarding the mitigation measures taken to halt and/or contain the improper use or disclosure. Contractor shall provide any other relevant requested information.

8.3.1.11.3 Notification of individuals and Regulatory Agencies. When the breach is attributable to the Contractor or its subcontractor and applicable state or federal law requires notification to individuals and reporting of a breach or unauthorized disclosure of protected information, the Contractor shall give the required notice and report pursuant to the applicable state or federal requirements, including but not limited to the requirement that the notifications be made without unreasonable delay and in no event, later than sixty (60) calendar days from discovery.

8.3.1.12 Breach Pattern or Practice. If the Contractor knows of a pattern of activity or practice of the Contractor's subcontractors or vendors that constitutes a material breach or violation of the Contractor's obligations under this Contract or this Exhibit "I" or other arrangement, the Contractor shall require its subcontractor or vendor take reasonable steps to cure the breach or end the violation. If the steps are unsuccessful, the Contractor shall terminate the contract or other arrangement, if feasible, or if termination is not feasible, report the problem to the County.

8.3.1.13 Audits, Inspection and Enforcement. Within ten (10) days of a written request by County, Contractor and its agents or subcontractors shall allow County to conduct a reasonable inspection of the facilities, systems, books, records, agreements, contracts, policies and procedures relating to the use or disclosure of Protected Information pursuant to this Exhibit "I" for the purpose of determining whether Contractor has complied with this Exhibit; provided, however, that (i) Contractor and County shall mutually agree in advance upon the scope, timing and location of such an inspection, (ii) County shall protect the confidentiality of all confidential and proprietary information of Contractor to which County has access during the course of such inspection; and (iii) County shall execute a nondisclosure agreement, upon terms mutually agreed upon by the parties, if requested by Contractor. The fact that County inspects, or fails to inspect, or has the right to inspect, Contractor's facilities, systems, books, records, agreements, contracts, policies and procedures does not relieve Contractor of its responsibility to comply with this Exhibit "I", nor does County's (i) failure to detect or (ii) detection, but failure to notify Contractor or require Contractor's remediation of any unsatisfactory practices, constitute acceptance of such practice or a waiver of County's enforcement rights under the Contract or this Exhibit "I". Contractor shall notify County within ten (10) business days of learning that Contractor has become the subject of an audit, compliance review, or complaint investigation by the Office for Civil Rights.

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8.3.1.14 Offshore Activities. Contractor shall not access or transmit nor permit any agent or subcontractor to access, transmit, move, ship, mail or in any way convey or communicate any protected information to a location outside of the United States of America without the advance written consent of County.

8.4 If Contractor is provided access to, receive or transmit information that is considered DHCS Protected Health Information as defined herein and Personal Information as defined under the California Information Practices Act (CIPA), at California Civil Code Section 1798.3 and under the contracts between the County and DHCS, Contractor shall meet the requirements as identified in Attachment 1, Privacy and Information Security Provisions, Business Associate Security Requirements.

8.5 Notices required pursuant to this section of Exhibit "I" shall be given via the contact details below.

Notice to County:

Marin County Health and Human Services (HHS) Compliance Program
Phone: 415-473-6948
Email: HHSCompliance@marincounty.org

Notice to Contractor:

Name
Address
City, State Zip
Phone / Email

8.6 In the event the State Contract requires the County to pay any costs associated with a breach of privacy and/or security of PII and/or PHI, including but not limited to the costs of notification, Contractor shall pay on County's behalf any and all such costs arising out of a breach of privacy and/or security of PII and/or PHI by Contractor.

8.7 Contractor shall maintain personnel controls to protect PHI or PI, including, but not limited to ensuring all workforce members accessing or disclosing PHI or PI: complete information privacy and security training at least annually; sign a confidentiality statement prior to accessing PHI or PI and annually thereafter; and performing a background check and evaluating the results to assure that there is no indication of a risk to the security or integrity of confidential data. Records shall be retained pursuant to the SABG Contract and DMC-ODS IA.

8.8 All work performed under this Contract is subject to the Health Insurance Portability and Accountability Act (HIPAA) of 1996, County and Contractor shall perform the work in compliance with all applicable provisions of HIPAA. As identified in Exhibit E in the SABG Contract and Exhibit F in the DMC-ODS IA, DHCS and County shall cooperate to assure mutual agreement as to those transactions between them, to which this provision applies. Refer to Exhibit E in the SABG Contract and Exhibit F in the DMC-ODS IA for additional information. Hard copies of Exhibits E and F will be provided to the Contractor upon request and electronic copies can be found on the BHRS website at www.MarinBHRS.org.

8.8.1 Trading Partner Requirements

8.8.1.1 No Changes. County hereby agrees that for the personal health information (Information), it will not change any definition, data condition or use of a data element or segment as proscribed in the Federal Health and Human Services (HHS) Transaction Standard Regulation (45 CFR 162.915 (a)).

8.8.1.2 No Additions. County hereby agrees that for the Information, it will not add any data elements or segments to the maximum data set as proscribed in the HHS Transaction Standard Regulation (45 CFR 162.915 (b)).

8.8.1.3 No Unauthorized Uses. County hereby agrees that for the Information, it will not use any code or data elements that either are marked "not used" in the HHS Transaction's

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Implementation specification or are not in the HHS Transaction Standard's implementation specifications (45 CFR 162.915 (c)).

8.8.1.4 No Changes to Meaning or Intent. County hereby agrees that for the Information, it will not change the meaning or intent of any of the HHS Transaction Standard's implementation specification (45 CFR 162.915(d)).

8.8.2 Concurrence for Test Modifications to HHS Transaction Standards: County agrees and understands that there exists the possibility that DHCS or others may request an extension from the uses of a standard in the HHS Transaction Standards. If this occurs, County agrees that it will participate in such test modifications.

8.8.3 Adequate Testing: County is responsible to adequately test all business rules appropriate to their types and specialties. If the County is acting as a clearinghouse for enrolled providers, County has obligations to adequately test all business rules appropriate to each and every provider type and specialty for which they provide clearinghouse services.

8.8.4 Deficiencies: County agrees to correct transactions, errors, or deficiencies identified by DHCS, and transactions errors or deficiencies identified by an enrolled provider if the County is acting as a clearinghouse for that provider. When County is a clearinghouse, County agrees to properly communicate deficiencies and other pertinent information regarding electronic transactions to enrolled providers for which they provide clearinghouse services.

8.8.5 Code Set Retention: Both parties understand and agree to keep open code sets being processed or used in this Contract for at least the current billing period or any appeal period, whichever is longer.

8.8.6 Data Transmission Log: Both parties shall establish and maintain a Data Transmission Log which shall record any and all Data Transmissions taking place between the Parties during the term of this Contract. Each party will take necessary and reasonable steps to ensure that such Data Transmission Logs constitute a current, accurate, complete, and unaltered record of any and all Data Transmissions between the parties, and shall be retained by each Party for no less than twenty-four (24) months following the date of the Data Transmission. The Data Transmission Log may be maintained on computer media or other suitable means provided that, if it is necessary to do so, the information contained in the Data Transmission Log may be retrieved in a timely manner and presented in readable form.

8.9 Termination of Contract

8.9.1 Material Breach. A breach by Contractor of any provision pertaining to its obligations as a Business Associate under this Exhibit "I," as determined by County, shall constitute a material breach of the Contract and shall provide grounds for immediate termination of the Contract, any provision in the Contract or this Agreement to the contrary notwithstanding.

8.9.2 Judicial or Administrative Proceedings. Notwithstanding any provision in the Contract to the contrary, County may terminate the Contract, effective immediately, if (i) Contractor is named as a defendant in a criminal proceeding for a violation of HIPAA, the HITECH Act, the HIPAA Regulations or other security or privacy laws or (ii) a finding or stipulation that the Contractor has violated any standard or requirement of HIPAA, the HITECH Act, the HIPAA Regulations or other security or privacy laws is made in any administrative or civil proceeding in which the party has been joined.

8.9.3 Effect of Termination. Upon termination of the Contract for any reason, Contractor shall, at the option of County, return or destroy all Protected Information that Contractor or its agents

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or subcontractors still maintain in any form, and shall retain no copies of such Protected Information. If return or destruction is not feasible, as determined by County, Contractor shall continue to extend the protections of section 8 of this Exhibit "I" to such information, and limit further use of such PHI to those purposes that make the return or destruction of such PHI infeasible. If County elects destruction of the PHI, Contractor shall certify in writing to County that such PHI has been destroyed.

8.10 The terms used in this section have the following meanings:

8.10.1 Breach shall have the meaning given to such term under the HIPAA Regulations (45 CFR § 164.402), and the California Information Practices Act (Cal Civ Code § 1798.29(f)).

8.10.2 Business Associate shall have the meaning given to such term under the HIPAA Regulations including but not limited to, 42 U.S.C. § 17938 and 45 C.F.R. § 160.103. For purposes of this Exhibit "I", use of the term Business Associate, when applicable, includes all Contractor agents, employees, contractors or other associates providing services or assistance to Contractor under the Contract.

8.10.3 HIPAA Privacy Rule or HIPAA Security Rule shall both mean the HIPAA Regulation that is codified at 45 C.F.R. Parts 160 and 164, Subparts A, C and E.

8.10.4 Protected Health Information or PHI means any information, whether oral or recorded in any form or medium: (i) that relates to the past, present or future physical or mental condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the Individual, and shall have the meaning given to such term under the Privacy Rule, including, but not limited to, 45 C.F.R. § 164.501. Protected Health Information includes Electronic Protected Health Information, i.e., PHI maintained in or transmitted by electronic media.

8.11 Business Continuity: Contractor shall have in place, and shall provide to the County, upon request, its plan for the referral and/or treatment of clients in case of a disaster.

9. Compliance with Anti-Kickback Statute

Contractor shall comply with the provisions of the "Anti-Kickback Statute" (42 U.S.C. § 1320a-7b) as they pertain to Federal healthcare programs.

10. Davis-Bacon Act

Contractor must comply with the provisions of the Davis-Bacon Act, as amended (40 U.S.C. § 3141 et seq.). When required by Federal Medicaid Program legislation, all construction contracts awarded by the Contractor and its subcontractors of more than \$2,000 must include a provision for compliance with the Davis-Bacon Act (40 U.S.C. § 3141 et seq.) as supplemented by Department of Labor regulations (Title 29, CFR Part 5, "Labor Standards Provisions Applicable to Contracts Governing Federally Financed and Assisted Construction").

11. Conditions for Federal Financial Participation

11.1 Contractor shall meet all conditions for Federal Financial Participation, consistent with 42 CFR 438.802, 42 CFR 438.804, 42 CFR 438.806, 42 CFR 438.808, 42 CFR 438.810, 42 CFR 438.812.

11.2 Pursuant to 42 CFR 438.808, Federal Financial Participation (FFP) is not available to the Contractor if the Contractor:

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- 11.2.1 Is an entity that could be excluded under section 1128(b)(8) as being controlled by a sanctioned individual;
- 11.2.2 Is an entity that has a substantial contractual relationship as defined in section 431.55(h)(3), either directly or indirectly, with an individual convicted of certain crimes described in section 1128(8)(B); or
- 11.2.3 Is an entity that employs or contracts, directly or indirectly, for the furnishing of health care utilization review, medical social work, or administrative services, with one of the following:
 - i. Any individual or entity excluded from participation in federal health care programs under section 1128 or section 1126A; or
 - ii. An entity that would provide those services through an excluded individual or entity.

12. Certification of Non-Exclusion or Suspension from Participation in Federal Health Care Program

12.1 Federal and State Excluded, Suspension and Debarment List: The County and the Contractor shall comply with the provisions of Title 42 § 438.610 and Executive Orders 12549 and 12689, "Debarment and Suspension," which excludes parties listed on the General Services Administration (GSA) list of parties excluded from federal procurement or non-procurement programs from having a relationship with the County or Contractor. County shall not subcontract with or employ any party listed on the government wide exclusions in the System for Award Management (SAM), in accordance with the OMB guidelines at 2 CFR 180 that implement Executive Orders 12549 (3 CFR part 1986 Comp. p. 189) and 12689 (3 CFR part 1989., p. 235), "Debarment and Suspension." SAM exclusions contain the names of parties debarred, suspended, or otherwise excluded by agencies, as well as parties declared ineligible under statutory or regulatory authority other than Executive Order 12549. The County shall advise all subcontractors of their obligation to comply with applicable federal debarment and suspension regulations, in addition to the requirements set forth in 42 CFR Part 1001. If a County subcontracts or employs an excluded party, DHCS has the right to withhold payments, disallow costs, or issue a CAP, as appropriate, pursuant to HSC Code 11817.8(h).

12.2 Prior to the effective date of this Contract, Contractor must certify that it is not excluded from participation in Federal Health Care Programs under either Section 1128 or 1128A of the Social Security Act. Failure to so certify will render all provisions of this Contract null and void and may result in the immediate termination of the Contract.

12.3 Contractor shall certify, prior to the execution of the contract, that the Contractor does not employ staff or sub-contractors who are excluded from participation in federally funded health care programs. Contractor shall conduct initial and monthly Exclusion & Suspension searches of the following databases and provide evidence of these completed searches when requested by County, CA Department of Health Care Services or the US Department of Health & Human Services.

- 12.3.1 www.oig.hhs.gov/exclusions - LEIE Federal Exclusions
- 12.3.2 www.sam.gov/portal/SAM - GSA Exclusions Extract
- 12.3.3 www.Medi-Cal.ca.gov – Suspended & Ineligible Provider List
- 12.3.4 <https://nppes.cms.hhs.gov/#/> - National Plan and Provider Enumeration System (NPPES)
- 12.3.5 Any other database required by DHCS or DHHS.

12.4 Contractor shall certify, prior to the execution of the contract that the Contractor does not employ staff or sub-contractors that are on the Social Security Administration's Death Master File. Contractor shall check the following database prior to employing staff or sub-contractors, and provide evidence of these completed searches when requested by County, CA Department of Health Care Services or the US Department of Health & Human Services.

- 12.4.1 <https://www.ssdmf.com/> - Social Security Death Master File

12.5 Contractor is required to notify County immediately if they become aware of any information that may indicate their (including employees and subcontractors) potential placement on an exclusions list.

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12.6 If a Contractor finds a provider that is excluded, it must promptly notify the DMC-ODS as per 42CFR §438.608(a)(2), (4). The Contractor shall not certify or pay any excluded provider with Medi-Cal funds, an any such inappropriate payments or overpayments may be subject to recovery.

12.7 Contractor and its subcontractors shall not knowingly have a relationship with: a) An individual or entity that is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in non-procurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549; or b) An individual or entity who is an affiliate, as defined in the Federal Acquisition Regulation at 48 CFR 2.101, of a person described in paragraph (a)(1) of this section; or c) An individual or entity that is excluded from participation in any Federal Health Care Program under section 1128 or 1128A of the Act. Relationships are defined as: 1) A director, officer, or partner of the Contractor; b) a subcontractor, as governed by 42 CFR 438.230; c) a person with beneficial ownership of five percent or more of the Contractor's equity; or d) a network provider or person with an employment, consulting, or other arrangement with the Contractor for the provision of items and services that are significant and material to the Contractor's obligations under this Agreement . [42 CFR 438.610]

12.8 DMC-ODS Contractors shall have a Medical Director who, prior to the delivery of services, has enrolled with DHCS under applicable state regulations, has been screened in accordance with 42 CFR 455.450(a) as a "limited" categorical risk within a year prior to serving as a Medical Director under this contract, and has signed a Medicaid provider agreement with DHCS as required by 42 CFR 431.107.

12.9 Contractor shall screen and periodically revalidate all network providers in accordance with the requirements of 42 C.F.R., Part 455, Subparts B and E.

12.10 Contractor must confirm the identity and determine the exclusion status of all its providers, as well as any person with an ownership or control interest, or who is an agent or managing employee of the contracted agency through routine checks of federal and state databases. This includes the Social Security Administration's Death Master File, NPPES, the Office of Inspector General's List of Excluded Individuals/Entities (LEIE), the Medi-Cal Suspended and Ineligible Provider List (S&I List) as consistent with the requirements of 42 C.F.R. § 455.436.

13. Credentialing and Re-Credentialing

13.1 Contractor shall ensure that all staff and subcontractors providing services will have all necessary and valid professional certification(s) or license(s) to practice the contracted services. This includes implementing procedures of professional license checks, credentialing and re-credentialing, monitoring limitations and expiration of licenses, and ensuring that all providers have a current National Provider Identifier (NPI) through the National Plan and Provider Enumeration System (NPPES). Contractor shall provide evidence of these completed verifications when requested by County, DHCS or the US Department of Health & Human Services.

13.2 Contractors must follow the uniform process for credentialing and re-credentialing of network providers established by BHRS and pursuant to Title 42 CFR, Part 438.214. The contractor, at minimum, must verify and document specified items listed on the credentialing and re-credentialing procedure for all of its providers through a primary source and must verify and document all the specified items on the credentialing and re-credentialing procedure through a non-primary source.

13.3 Upon request, contracted agencies/individuals must demonstrate to BHRS that each of its providers are qualified in accordance with current legal, professional, and technical standards, and that they are appropriately licensed, registered, waived, and/or certified.

13.4 Contractors must ensure that all of their network providers, delivering covered services, sign and date an attestation statement provided by BHRS in which each provider attests to the following:

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13.4.1 Any limitations or inabilities that affect the provider's ability to perform any of the position's essential functions, with or without accommodation;

13.4.2 A history of loss of license or felony convictions;

13.4.3 A history of loss or limitation of privileges or disciplinary activity;

13.4.4 A lack of present illegal drug use; and

13.4.5 The application's accuracy and completeness

13.5 Contractor must file and keep track of attestation statements for all of their providers and must make those available to BHRS upon request at any time.

13.6 Contractors are required to verify and document at a minimum every three years that each network provider that delivers covered services continues to possess valid credentials, including verification of each of the credentialing requirements as per BHRS' uniform process for credentialing and re-credentialing. If any of the requirements are not up-to-date, updated information should be obtained from network providers to complete the recredentialing process.

13.7 Contractor is required to sign an annual attestation statement at the time of Agreement renewal or at least annually in which they will attest that they will follow County's Credentialing Policy and MHSUDS IN 18-019 and ensure that all of their rendering providers are credentialed as per established guidelines.

13.8 Contractors must ensure that they follow BHRS' uniform process for credentialing and re-credentialing, including disciplinary actions such as reducing, suspending, or terminating provider's privileges. Failure to comply with specified requirements can result in suspension or termination of a provider.

14. Additional Program Integrity Requirements

14.1 Compliance Program, Including Overpayments and Preventing Fraud, Waste and Abuse: As a condition of receiving payment under a Medi-Cal managed care program, the Contractor shall comply with the provisions of 42 C.F.R. §§ 438.604, 438.606, 438.608 and 438.610. (42 C.F.R. § 438.600 (b)).

14.2 Contractor shall implement and maintain procedures designed to detect, prevent and report fraud, waste, and abuse of Federal or state health care funding (42 C.F.R §438.608 (a)(7)). Contractor must report fraud and abuse information to the County pursuant to 42CFR §455.1(a)(1) which include:

14.2.1 Any potential fraud, waste, or abuse as per 42CFR §438.608(a), (a)(7),

14.2.2 All overpayments identified or recovered, specifying the overpayment due to potential fraud (42CFR §438.608(a), (a)(2),

14.2.3 Information about change in a beneficiary's circumstances that may affect the beneficiary's eligibility including changes in the beneficiary's residence or the death of the beneficiary (42 CFR §438.608(a), (a)(3),

14.2.4 Information about a change in the provider's circumstances that may affect the network provider's eligibility to participate in the managed care program, including the termination of the provider agreement with the Contractor as per 42CFR §438.608(a), (a)(6).

14.3 The Contractor shall have in place a compliance program designed to detect and prevent fraud, waste and abuse, as per 42 C.F.R. § 438.608 (a)(1), that must include:

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14.3.1 Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable requirements and standards under the contract, and all applicable Federal and state requirements.

14.3.2 A Compliance Office (CO) who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements of the contract and who reports directly to the CEO and the Board of Directors.

14.3.3 A Regulatory Compliance Committee on the Board of Directors and at the senior management level charged with overseeing the organization's compliance program and its compliance with the requirements under the contract.

14.3.4 A system for training and education for the Compliance Officer, the organization's senior management, and the organization's employees for the federal and state standards and requirements under the contract.

14.3.5 Effective lines of communication between the Compliance Officer and the organization's employees.

14.3.6 Enforcement of standards through well-publicized disciplinary guidelines.

14.3.7 The establishment and implementation of procedures and a system with dedicated staff for routine internal monitoring and auditing of compliance risks, prompt response to compliance issues as they are raised, investigation of potential compliance problems as identified in the course of self-evaluation and audits, corrections of such problems promptly and thoroughly to reduce the potential for recurrence and ongoing compliance with the requirements under the contract as per 42 CFR §438.608(a), (a)(1).

14.4 Contractor shall report to the County all identified overpayments and reason for the overpayment, including overpayments due to potential fraud, immediately upon discovery and no later than 5 calendar days when it has identified payments in excess. Contractor shall return any overpayments to the County within 60 calendar days after the date on which the overpayment was identified, or the date any corresponding cost report is due, if applicable. ((42 C.F.R. § 438.608 (a)(2), (c)(3), MHSUDS IN 19-034, Public Law 111-148, Contract Exhibit I, Section 3.8)

14.5 Contractor shall implement written policies for that provide detailed information about the False Claims Act ("Act") and other Federal and State Laws described in section 1902(a)(68) of the Act, including information about rights of employees to be protected as whistleblowers.

14.6 Contractor shall make prompt referral of any potential fraud, waste or abuse to County or potential fraud directly to the State Medicaid Fraud Control Unit.

14.7 County may suspend payments to Contractor if the State Department of Health Care Services or County determine that there is a credible allegation of fraud in accordance with C.F.R §455.23 (C.F.R §438.608 (a)(8))

14.8 Screening and Enrollment Requirements

14.8.1 County shall ensure that all Contractor providers are enrolled with the state as Medi-Cal providers consistent with the provider disclosure, screening, and enrollment requirements of 42 C.F.R. Part 455, subparts B and E. (42 C.F.R. § 438.608(b)).

14.8.2 County may execute this Agreement, pending the outcome of screening, enrollment, and revalidation of Contractor, of up to 120 days but must terminate this Agreement immediately upon determination that Contractor cannot be enrolled, or the expiration of one 120-day period without enrollment of the Contractor, and notify affected clients (42 C.F.R. § 438.602(b)(2)).

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- 14.8.3 Contractor shall ensure that all Providers and/or subcontracted Providers consent to and undergo a criminal background check, including fingerprinting to the extent required under state law and 42 C.F.R. § 455.434(a). Contractor shall provide evidence of completed consents when requested by the County, DHCS or the US Department of Health & Human Services (US DHHS). (Attachment I, Section 1D)
- 14.8.4 Contractor shall comply with the conflict of interest safeguards described in 42 CFR §438.58 and with the prohibitions described in section 1902(a)(4)(C) of the Act applicable to contracting officers, employees, or independent contractors.
- 14.9 Provider Application and Validation for Enrollment (PAVE)
- 14.9.1 Contractor shall ensure that all of its required clinical staff, who are rendering SUD services to Medi-Cal clients on behalf of Contractor, are registered through DHCS' Provider Application and Validation for Enrollment (PAVE) portal, pursuant to DHCS requirements, the 21st Century Cures Act, and the CMS Medicaid and Children's Health Insurance Program (CHIP) Managed Care Final Rule.
- 14.10 Integrity Disclosures
- 14.10.1 Contractor shall provide information on ownership and controlling interests, disclosures related to business transactions, and disclosures related to persons convicted of crimes in the form and manner requested by the County, by the Effective Date, each time the Agreement is renewed and within 35 days of any change in ownership or controlling interest of Contractor. (42 C.F.R. §§ 455.104, 455.105, and 455.106)
- 14.10.2 Upon the execution of this Agreement, Contractor shall furnish County a Provider Disclosure Statement, which, upon receipt by County, shall be kept on file with County and may be disclosed to DHCS. If there are any changes to the information disclosed in the Provider Disclosure Statement, an updated statement should be completed and submitted to the County within 35 days of the change. (42 C.F.R. § 455.104).
- 14.10.3 Contractor must disclose the following information as requested in the Provider Disclosure Statement:
- 14.10.3.1 Disclosure of 5% or More Ownership Interest:
- 14.10.3.1.1 In the case of corporate entities with an ownership or control interest in the disclosing entity, the primary business address as well as every business location and P.O. Box address must be disclosed. In the case of an individual, the date of birth and Social Security Number must be disclosed.
- 14.10.3.1.2 In the case of a corporation with ownership or control interest in the disclosing entity or in any subcontractor in which the disclosing entity has a five percent (5%) or more interest, the corporation tax identification number must be disclosed.
- 14.10.3.1.3 For individuals or corporations with ownership or control interest in any subcontractor in which the disclosing entity has a five percent (5%) or more interest, the disclosure of familial relationship is required.
- 14.10.3.1.4 For individuals with five percent (5%) or more direct or indirect ownership interest of a disclosing entity, the individual shall provide evidence of completion of a criminal background check, including fingerprinting, if required by law, prior to execution of Agreement. (42 C.F.R. § 455.434)
- 14.10.3.2 Disclosures Related to Business Transactions:

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14.10.3.2.1 The ownership of any subcontractor with whom Contractor has had business transactions totaling more than \$25,000 during the 12-month period ending on the date of the request.

14.10.3.2.2 Any significant business transactions between Contractor and any wholly owned supplier, or between Contractor and any subcontractor, during the 5-year period ending on the date of the request. (42 C.F.R. § 455.105(b).)

14.10.3.3 Disclosures Related to Persons Convicted of Crimes:

14.10.3.3.1 The identity of any person who has an ownership or control interest in the Contractor or is an agent or managing employee of the Contractor who has been convicted of a criminal offense related to that person's involvement in any program under the Medicare, Medicaid, or the Title XXI services program since the inception of those programs. (42 C.F.R. § 455.106.)

14.10.3.3.2 County shall terminate the enrollment of Contractor if any person with five percent (5%) or greater direct or indirect ownership interest in the disclosing entity has been convicted of a criminal offense related to the person's involvement with Medicare, Medicaid, or Title XXI program in the last 10 years.

14.10.4 Contractor must provide disclosure upon execution of Contract, extension for renewal, and within 35 days after any change in Contractor ownership or upon request of County. County may refuse to enter into an Agreement or terminate an existing Agreement with a Contractor if the Contractor fails to disclose ownership and control interest information, information related to business transactions and information on persons convicted of crimes, or if the Contractor did not fully and accurately make the disclosure as required.

14.10.5 Contractor must provide the County with written disclosure of any prohibited affiliations under 42 C.F.R. § 438.610. Contractor must not employ or subcontract with providers or have other relationships with providers Excluded from participating in Federal Health Care Programs, including Medi-Cal/Medicaid or procurement activities, as set forth in 42 C.F.R. § 438.610.

15. Clean Air and Water

15.1 This section is applicable only if the Contract exceeds \$100,000, or the Federal Contracting Officer, the State or County has determined that orders under an indefinite quantity contract in any one year will exceed \$100,000, or a facility to be used has been the subject of a conviction under the Clean Air Act [42 U.S.C. 7413 (c) (1)] or the Federal Water Pollution Control Act (33 U.S.C. 1319[c]) and is listed by EPA, or the contract is not otherwise exempt.

Contractor agrees as follows:

15.1.1 To comply with all the requirements of § 114 of the Clean Air Act, as amended (42 U.S.C. 7401 et seq.) and § 308 of the Federal Water Pollution Control Act (33 USC 1251 et seq.) respectively relating to inspection monitoring, entry, reports, and information, as well as other requirements specified in § 114 and § 308 of the Air Act and the Water Act, respectively, and all regulations and guidelines issued thereunder before the award of this Contract;

15.1.2 No obligation required by this Contract will be performed in a facility listed on the Environmental Protection Agency List of Violating Facilities on the date when this contract was executed unless and until the EPA eliminates the name of such facility or facilities from such listing;

15.1.3 To use its best efforts to comply with clean air standards and clean water standards at the facility in which the services are being performed; and

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15.1.4 To insert the substance of the provisions of this Paragraph 3.0 into any written delegation.

15.2 The terms used in this section have the following meanings:

15.2.1 The term "Air Act" means the Clean Air Act, as amended (42 U.S.C. 7401 et seq.).

15.2.2 The terms "Water Act" means Federal Water Pollution Control Act, as amended (33 U.S.C. 1251 et seq.).

15.2.3 The term "clean air standards" means any enforceable rules, regulations, guidelines, standards, limitations, orders, controls, prohibitions, or other which are contained in, issued under, or otherwise adopted pursuant to the Air Act or Executive Order 11738, an approved implementation procedure or plan under § 110(d) of the Clean Air Act [42 U.S.C. 7410 (a)] an approved implementation procedure or plan under § 111(c) [42 U.S.C.7411 (c)] or § 111(d) [42 U.S.C. 7411(d)] or an approved implementation procedure under § 112(d) of the Air Act [42 U.S.C. 7412(d)].

15.2.4 The terms "clean water standards" means any enforceable limitation, control, condition, prohibition, standard, or other requirement which is promulgated pursuant to the Water Act or contained in a permit issued to a discharger by the Environmental Protection Agency or by a state under an approved program, as authorized by § 402 of the Water Act (33 U.S.C. 1342).

15.2.5 The term "compliance" in this section means compliance with clean air or water standards. Compliance shall also mean compliance with a schedule or plan ordered or approved by a court of competent jurisdiction, the Environmental Protection Agency or an air or water pollution control agency in accordance with the requirements of the Air Act or Water Act and regulations issued pursuant thereto.

15.2.6 The term "facility" means any building, plan, installation, structure, mine, vessel or other floating craft, location, or site of operations, owned, leased, or supervised by a Contractor or delegate, to be utilized in the performance of a contract of delegation. Where a location or site of operations contains or includes more than one building, plant, installation, or structure, the entire location or site shall be deemed to be a facility except where the Director, Office of Federal Activities, Environmental Protection Agency, determines that independent facilities are collected in one geographical area.

16. Independent Contractor

16.1 Contractor understands and agrees that the services performed hereunder by its officer, agents, employees, or contracting persons or entities are performed in an independent capacity and not in the capacity of officers, agents, or employees of the County for any purpose, including workers' compensation, tax withholding, and employee benefits. Contractor shall determine the method and manner of performing its duties under this Agreement, and County may monitor the work performed by Contractor.

16.2 Contractor shall provide all personnel, supplies, and operating expenses of any kind required for the performance of this Agreement.

16.3 Contractor shall immediately report to the County Alcohol and Drug Administrator any changes in status that may impact the ability to perform the contracted duties, including, but not limited to: changes in status of a driver's license; change in status of registration, certification or licensure; or any change in circumstances that would impact Credentialing status or ability to perform services for the County.

17. Quality Improvement Program

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17.1 Quality Improvement Activities and Participation

17.1.1 Contractor shall comply with the County's ongoing comprehensive Quality Assessment and Performance Improvement (QAPI) Program (42 C.F.R. § 438.330(a)) and work with the County to improve established outcomes by following structural and operational processes and activities that are consistent with current practice standards.

17.1.2 Contractor shall participate in quality improvement (QI) activities, including clinical and non-clinical performance improvement projects (PIPs), as requested by the County in relation to state and federal requirements and responsibilities, to improve health outcomes and clients' satisfaction over time. Other QI activities include quality assurance, collection and submission of performance measures specified by the County, mechanisms to detect both underutilization and overutilization of services, client and system outcomes, utilization management, utilization review, provider appeals, provider credentialing and re-credentialing, and client grievances. Contractor shall measure, monitor, and annually report to the County its performance.

17.1.3 Contractor shall implement mechanisms to assess client/family satisfaction based on County's guidance. The Contractor shall assess client/family satisfaction by: 1) Surveying client/family satisfaction with the Contractor's services at least annually; 2) Evaluating client grievances, appeals and State Hearings at least annually; 3) Evaluating requests to change persons providing services at least annually; 4) Informing the County and clients of the results of client/family satisfaction activities.

17.1.4 Contractor, if applicable, shall implement mechanisms to monitor the safety and effectiveness of medication practices. This mechanism shall be under the supervision of a person licensed to prescribe or dispense prescription drugs, at least annually.

17.1.5 Contractor shall implement mechanisms to monitor appropriate and timely intervention of occurrences that raise quality of care concerns. The Contractor shall take appropriate follow-up action when such an occurrence is identified. The results of the intervention shall be evaluated by the Contractor at least annually and shared with the County.

17.1.6 Contractor shall collaborate with County to create a QI Work Plan with documented annual evaluations and documented revisions as needed. The QI Work Plan shall evaluate the impact and effectiveness of its quality assessment and performance improvement program.

17.1.7 Contractor shall attend and participate in the County's Quality Improvement Committee (QIC) to recommend policy decisions, review and evaluate results of QI activities, including PIPs, institute needed QI actions, and ensure follow-up of QI processes. Contractor shall ensure that there is active participation by the Contractor's practitioners and providers in the QIC.

17.1.8 Contractor shall assist County, as needed, with the development and implementation of Corrective Action Plans.

17.1.9 Contractor shall participate, as required, in annual, independent external quality reviews (EQR) of the quality, timeliness, and access to the services covered under this Contract, which are conducted pursuant to Subpart E of Part 438 of the Code of Federal Regulations. (42 C.F.R. §§ 438.350(a) and 438.320)

17.2 Network Adequacy

17.2.1 Contractor shall ensure that all services covered under this Agreement are available and accessible to clients in a timely manner and in accordance with the network adequacy standards required by regulation. (42 C.F.R. § 438.206 (a),(c)).

17.2.2 Contractor shall submit, when requested by County and in a manner and format determined by the County, network adequacy certification information to County, utilizing a provided template or other designated format.

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17.2.3 Contractor shall submit updated network adequacy information to the County any time there has been a significant change that would affect the adequacy and capacity of services. Significant changes include, but are not limited to, changes in services or providers available to clients, and changes in geographic service area.

17.2.4 If Contractor reaches or exceeds 90 percent of their dedicated treatment capacity, this information must be reported to the County Alcohol & Drug Administrator and to DHCSPerinatal@dhcs.ca.gov within seven days of reaching capacity. The subject line in the email must read "Capacity Management".

17.3 Treatment Perceptions Survey: Contractor shall participate in the annual Treatment Perception Survey (TPS) consistent with DMC-ODS requirements and under the direction of County. Contractors shall implement at least one performance improvement project annually utilizing feedback from the TPS.

17.4 Physician Incentive Plan: If Contractor wants to institute a Physician Incentive Plan, Contractor shall submit the proposed plan to the County which will in turn submit the Plan to the State for approval, in accordance with the provisions of 42 C.F.R. § 438.6(c).

18. Services and Access Provisions

18.1 Certification of Eligibility: Contractor will, in cooperation with County, comply with 42 C.F.R. § 455.1(a)(2) and BHIN 23-001, to obtain a certification of a client's eligibility for SUD services under Medi-Cal.

18.2 Access to Substance Use Disorder Services

18.2.1 In collaboration with the County, Contractor will work to ensure that individuals to whom the Contractor provides SUD services meet access criteria and medical necessity requirements, as per DHCS guidance specified in BHIN 23-001. Specifically, the Contractor will ensure that the clinical record for each client includes information as a whole indicating that client's presentation and needs are aligned with the criteria applicable to their age at the time of service provision as specified below.

18.2.2 Contractor shall have written admission criteria for determining the client's eligibility and suitability for treatment and services. All clients admitted shall meet the admission criteria and this shall be documented in the client's record.

18.2.3 Programs shall ensure that their policies, procedures, practices, and rules and regulations do not discriminate against the above special populations. Whenever the needs of the client cannot be reasonably accommodated, efforts shall be made to make referral(s) to appropriate programs.

18.2.4. Contractor should recognize and educate staff and collaborative partners that Parole and Probation status is not a barrier to SUD services.

18.2.5 Contractor will ensure that the clinical record for each client includes information as a whole indicating that client's presentation and needs are aligned with the criteria applicable to their age at the time-of-service provision as outlined in this Agreement.

18.2.6 The initial assessment shall be performed face-to-face, by telehealth or by telephone by a Licensed Practitioner of the Healing Arts (LPHA) or registered or certified counselor and may be done in the community or the home, except for residential treatment services and narcotic treatment programs (NTPs). If the assessment of the client is completed by a registered or certified counselor, then an LPHA shall evaluate that assessment with the counselor and the LPHA shall make the final diagnosis. The consultation between the LPHA and the registered or certified counselor can be conducted in person, by video conferencing, or by telephone.

18.2.7 Contractor shall comply with beneficiaries' access criteria and services provided during the initial assessment process requirements:

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18.2.7.1 For beneficiaries 21 years of age and older, a full assessment using the ASAM Criteria shall be completed within 30 days of the beneficiary's first visit with an LPHA or registered or certified counselor, or Peer Support Specialist (except for residential treatment services)

18.2.7.2. For beneficiaries under the age of 21, a full assessment using the ASAM Criteria shall be completed within 60 days of the beneficiary's first visit with an LPHA or registered or certified counselor (except for residential treatment services).

18.2.7.3 For beneficiaries experiencing homelessness and where the provider documents that due to homelessness additional time is required to complete the assessment, a full assessment using the ASAM Criteria shall be completed within 60 days of the beneficiary's first visit with an LPHA or registered or certified counselor (except for residential treatment services).

18.2.7.4 If a client withdraws from treatment prior to completion of the assessment or prior to establishing a DSM diagnosis for Substance-Related and Addictive Disorder, and later returns, the 30-day or 60-day time period starts over.

18.2.8 Contractor shall comply with beneficiaries' access criteria after initial assessment requirements:

18.2.8.1 Beneficiaries 21 years of age and older, to qualify for DMC-ODS services after the initial assessment, must meet one of the following criteria:

18.2.8.1.1 Have at least one diagnosis from the most current edition of the Diagnostic and Statistical Manual (DSM) of Mental Disorders for Substance-Related and Addictive Disorders, except for Tobacco-Related Disorders and Non-Substance-Related Disorders, OR

18.2.8.1.2 Have had at least one diagnosis from the most current edition of the DSM for Substance-Related and Addictive Disorders, except for Tobacco-Related Disorders and Non-Substance-Related Disorders, prior to being incarcerated or during incarceration, determined by substance use history.

18.2.8.2 Beneficiaries under the age of 21, qualify for DMC-ODS medically necessary services after the initial assessment, in the following circumstances:

18.2.8.2.1 All services that are Medi-Cal-coverable, appropriate, and medically necessary, needed to correct and ameliorate health conditions shall be provided, as per federal Early & Periodic Screening, Diagnostic and Treatment (EPSDT) statutes and regulations.

18.2.8.2.2 Services need not be curative or completely restorative to ameliorate a health condition, including substance misuse and SUDs, consistent with federal guidance.

18.2.8.2.3 Services that sustain, support, improve, or make more tolerable substance misuse or an SUD are considered to ameliorate the condition and are thus covered as EPSDT services.

18.3. ASAM Level of Care Determination

18.3.1 Contractor shall use the ASAM Criteria to determine placement into the appropriate level of care (LOC) for all beneficiaries, which is separate and distinct from determining medical necessity. LOC determinations shall ensure that beneficiaries are able to receive care in the least restrictive LOC that is clinically appropriate to treat their condition.

18.3.2 A full ASAM Criteria assessment and an SUD diagnosis is not required to deliver prevention and early intervention services for beneficiaries under the age of 21; a brief screening ASAM Criteria tool is sufficient for these services.

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18.3.3 For clients who withdraw from treatment prior to completing the ASAM Criteria assessment or prior to establishing a diagnosis from the DSM for Substance-Related and Addictive Disorders, and later return, the time period for initial assessment starts over.

18.3.4 A full ASAM Criteria assessment, or brief screening ASAM Criteria tool for preliminary LOC recommendations, shall not be required to begin receiving DMC-ODS services.

18.3.5 A full ASAM Criteria assessment does not need to be repeated unless the client's condition changes.

18.3.6 Requirements for ASAM LOC assessments apply to NTP clients and settings.

18.4 Medical Necessity

18.4.1 Pursuant to BHIN 23-001 and consistent with Welfare & Institutions Code § 14059.5, DMC-ODS services must be medically necessary.

18.4.2 For beneficiaries 21 years of age and older, a service is "medically necessary" or a "medical necessity" when it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain.

18.4.3 For beneficiaries under the age of 21, a service is "medically necessary" or a "medical necessity" if the service is necessary to correct or ameliorate screened health conditions. Consistent with federal guidance, services need not be curative or completely restorative to ameliorate a health condition, including substance misuse and SUDs. Services that sustain, support, improve, or make more tolerable substance misuse or an SUD are considered to ameliorate the condition and are thus covered as EPSDT services.

18.5 Additional Coverage Requirements and Clarifications

18.5.1 The target population for DMC-ODS SUD services includes clients who are enrolled in Medi-Cal, reside in Marin County, and meet the criteria for DMC-ODS services as per established requirements above.

18.5.2 Consistent with Welfare & Institutions Code § 14184.402(f), covered SUD prevention, screening, assessment, treatment, and recovery services are reimbursable Medi-Cal services when:

18.5.2.1 Services are provided prior to the completion of an assessment or prior to the determination of whether DMC-ODS access criteria are met, or prior to the determination of a diagnosis.

18.5.2.1.1 Clinically appropriate and covered DMC-ODS services provided to clients over the age of 21 are reimbursable during the assessment process. Similarly, if the assessment determines that the client does not meet the DMC-ODS access criteria after initial assessment, those clinically appropriate and covered DMC-ODS services provided are reimbursable.

18.5.2.1.2 All Medi-Cal claims shall include a current CMS approved International Classification of Diseases (ICD) diagnosis code. In cases where services are provided due to a suspected SUD that has not yet been diagnosed, options are available in the CMS approved ICD-10 code list, for example, codes for "Other specified" and "Unspecified" disorders, or "Factors influencing health status and contact with health services".

18.5.2.2 Prevention, screening, assessment, treatment, or recovery services were not included in an individual treatment plan, or if the client signature was absent from the treatment plan.

18.5.2.3 While most DMC-ODS providers are expected to adopt problem lists as specified in BHIN 22-019, treatment plans continue to be required for some services in accordance with

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federal law. Treatment plans are required by federal law for: Narcotic Treatment Programs (NTPs) and Peer Support Services.

18.5.2.4 Medically necessary covered DMC-ODS services delivered by Contractor shall be covered and reimbursable Medi-Cal services whether or not the client has a co-occurring mental health condition.

18.6 Diagnosis During Initial Assessment

18.6.1 Contractor may use the following options during the assessment phase of client's treatment when a diagnosis has yet to be established as specified in BHIN 22-013:

18.6.1.1 ICD-10 codes Z55-Z65 Potential health hazards related to socioeconomic and psychological circumstances: may be used by all providers as appropriate during the assessment period prior to diagnosis and do not require certification as, or supervision, of, an LPHA.

18.6.1.2 ICD-10 code Z03.89 Encounter for observation for other suspected diseases and conditions ruled out: may be used by an LPHA during the assessment phase of a client's treatment when a diagnosis has yet to be established.

18.6.1.3 CMS approved diagnosis code on the ICD 10 tabular, available in the CMS 2022 ICD-10-CM page at: <https://www.cms.gov/medicare/icd-10/2022-icd-10-cm>, which may include Z codes. LPHAs may use any clinically appropriate ICD-10 code, for example, codes for "Other specified" and "Unspecified" disorders, or "Factors influencing health status and contact with health services".

18.7 Coordination and Continuity of Care

18.7.1 Contractor shall comply with the care and coordination requirements established by the County and per 42 C.F.R. § 438.208.

18.7.2 Contractor shall ensure that all care, treatment, and services provided pursuant to this Agreement are coordinated among all providers who are serving the client. Coordination and continuity of care procedures shall meet the following requirements:

18.7.2.1 Ensure that each client has an ongoing source of care appropriate to their needs and a person or entity formally designated as primarily responsible for coordinating the services accessed by the client. The client shall be provided information on how to contact their designated person or entity.

18.7.2.2 All services provided to clients shall be coordinated:

18.7.2.2.1 Between settings of care, including appropriate discharge planning for short-term and long-term hospital and institutional stays.

18.7.2.2.2 With the services the client receives from any other managed care organization.

18.7.2.2.3 With the services the client receives in FFS Medi-Cal.

18.7.2.2.4 With the services the client receives from community and social support providers.

18.7.3 Share with other providers serving the client, as allowed by regulations, the results of any identification and assessment of that client's needs to prevent duplication of those activities.

18.7.4 Ensure that each provider furnishing services to clients maintains and shares, as appropriate, a client health record in accordance with professional standards.

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18.7.5 Ensure that in the process of coordinating care, each client's privacy is protected in accordance with the privacy requirements in 45 C.F.R. Parts 160 and 164 subparts A and E and 42 C.F.R. Part 2, to the extent that they are applicable.

18.7.6 Contractor shall engage in care coordination activities beginning at intake and throughout the treatment and discharge planning processes.

18.7.7 To facilitate care coordination, Contractor will request a 42 CFR Part 2, HIPAA and California law compliant client authorization to share client information with and among all other providers involved in the client's care, in satisfaction of state, and federal privacy laws and regulations.

18.8 Site Licenses, Certifications, Permits, Requirements

18.8.1 As specified in BHIN 21-001 and in accordance with Health and Safety Code § 11834.015, DHCS adopted the ASAM treatment criteria as the minimum standard of care for licensed AOD facilities. All licensed AOD facilities shall obtain at least one DHCS LOC Designation and/or at least one residential ASAM LOC Certification consistent with all of its program services. If an AOD facility opts to obtain an ASAM LOC Certification, then that facility will not be required to obtain a DHCS LOC Designation. However, nothing precludes a facility from obtaining both a DHCS LOC Designation and ASAM LOC Certification.

18.8.2 Contractor shall obtain and comply with DMC site certification and ASAM designation or DHCS Level of Care Designation for each type of contracted service being delivered, as well as any additional licensure, registration or accreditation required by regulations for the contracted service being delivered.

18.8.3 Contractor shall obtain and maintain all appropriate licenses, permits, and certificates required by all applicable federal, state, and county and/or municipal laws, regulations, guidelines, and/or directives.

18.8.4 Contractor shall have and maintain a valid fire clearance at the specified service delivery sites where direct services are provided to clients.

18.9 Medications

18.9.1 If Contractor provides or stores medications, the Contractor shall store and monitor medications in compliance with all pertinent statutes and federal standards.

18.9.2 Contractor shall have written policies and procedures regarding the use of prescribed medications by clients, and for monitoring and storing of medications.

18.9.3 Prescription and over the counter medications which expire and other bio-hazardous pharmaceuticals including used syringes or medications which are not removed by the client upon termination of services shall be disposed of by the program director or a designated substitute, and one other adult who is not a client. Both shall sign a record, to be retained for at least one year.

18.9.4 Contractor shall have at least one program staff on duty at all times trained to adequately monitor clients for signs and symptoms of their possible misuse of prescribed medications, adverse medication reactions and related medical complications.

18.10 Alcohol and/or Drug-Free Environment

18.10.1 Contractor shall provide an alcohol and/or drug-free environment for clients. The use of medications for the treatment of SUD, mental illness, or physical conditions, shall be allowed and controlled as per Contractor's written policies and procedures.

18.10.2 Contractor shall have written policies regarding service delivery for when clients experience relapse episodes. These policies shall be supportive of and consistent with the alcohol and/or drug-free environment of the program.

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18.11 Assessment of Tobacco Use Disorder

18.11.1 As required by Assembly Bill (AB) 541 and BHIN 22-024, all licensed and/or certified SUD recovery or treatment facilities shall conduct an assessment of tobacco use at the time of the client's initial intake. The assessment shall include questions recommended in the most recent version of Diagnostic and Statistical Manual of Mental Disorders (DSM) under Tobacco Use Disorder, or County's evidence-based guidance, for determining whether a client has a tobacco use disorder.

18.11.2 The licensed and/or certified SUD recovery or treatment facility shall do the following:

18.11.2.1 Provide information to the client on how continued use of tobacco products could affect their long-term success in recovery from SUD.

18.11.2.2 Recommend treatment for tobacco use disorder in the treatment plan.

18.11.2.3 Offer either treatment, subject to the limitation of the license or certification issued by DHCS, or a referral for treatment for tobacco use disorder.

18.11.4 Licensed and/or certified SUD recovery or treatment facilities can also adopt tobacco free campus policies, to change the social norm of tobacco use, promote wellness, and reduce exposure to secondhand smoke.

18.12 Naloxone Requirements

18.12.1 As required by AB 381, Health and Safety Code, § 11834.26, and BHIN 22-025, all licensed and/or certified SUD recovery or treatment facilities shall comply with the following requirements:

18.12.1.1 Maintain, at all times, at least 2 unexpired doses of naloxone, or any other opioid antagonist medication that is approved by the FDA for the treatment of an opioid overdose, on the premises of the licensed SUD recovery or treatment facility.

18.12.1.2 Have at least one staff member, at all times, on the premises who knows the specific location of the naloxone, or other FDA-approved opioid antagonist medication, and who has been trained in its administration. Training shall include review of online resources and the National Harm Reduction Coalition's Opioid Overdose Basics website to respond effectively to an opioid-associated overdose emergency. Staff shall certify that they have reviewed and undergone training in opioid overdose prevention and treatment.

18.12.1.3 The proof of completion of such training shall be documented in the staff member's individual personnel file, in accordance with California Code of Regulations (CCR), Title 9, § 10564(k).

19. Service Authorization

19.1 Contractor will collaborate with County to complete authorization requests in line with County and DHCS policy and Contract Exhibit A. [BHRS-77: Substance Use Residential Authorization]

19.2 Contractor shall respond to County within 24 hours when consultation is necessary for County to make appropriate authorization determinations.

19.3 County shall provide Contractor with written notice of authorization determinations within the timeframes set forth in BHIN 23-001, or any subsequent DHCS notices.

19.4 For SUD Non-Residential and Non-Inpatient Levels of Care service authorization:

19.4.1 Contractor shall follow County's policies and procedures around non-residential/non-inpatient levels of care according to BHIN 23-001.

19.4.2 Contractor is not required to obtain service authorization for non-residential/non-inpatient levels of care. Prior authorization is prohibited for non-residential DMC-ODS services.

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19.5 For SUD Residential and Inpatient Levels of Care service authorization:

19.5.1 Contractor shall have in place, and follow, County written authorization policies and procedures for processing requests for initial and continuing authorization, or prior authorization, for residential treatment services, including inpatient services, but excluding withdrawal management services.

19.6.2 County will review the DSM and ASAM Criteria to ensure that the beneficiary meets the requirements for the service.

19.6.3 Prior authorization for residential and inpatient services (excluding withdrawal management services) shall be made within 24 hours of the prior authorization request being submitted by the provider.

19.6.3.1 County will ensure that prior authorization processes are completed in a manner that assures the provision of a covered SUD service to a client in a timely manner appropriate for the client's condition.

19.6.4 Contractor shall alert County when an expediated service authorization decision is necessary due to a client's specific needs and circumstances that could seriously jeopardize the client's life or health, or ability to attain, maintain, or regain maximum function. Expediated service authorizations shall not exceed 72 hours after receipt of the request for service, with a possible extension of up to 14 calendar days if the client or provider requests an extension.

19.6.5 Contractor shall alert County when a standard authorization decision is necessary. Standard service authorizations shall not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days if the client or provider requests an extension.

19.7 Contractor, if applicable, shall ensure that length of stay (LOS) in residential program complies with the following:

19.7.1 LOS shall be determined by individualized clinical need (statewide LOS goal is 30 days). LOS for clients shall be determined by an LPHA and authorized by the County as medically necessary.

19.7.2 Clients receiving residential treatment must be transitioned to another LOC when clinically appropriate based on treatment progress.

19.7.3 Perinatal clients may receive a longer LOS than those described above, if determined to be medically necessary.

19.7.4 Nothing in this section overrides any EPSDT requirements. EPSDT clients may receive a longer length of stay based on medical necessity.

20. Documentation:

20.1 Documentation Requirements

20.1.1 Contractor agrees to comply with documentation requirements for non-hospital services as specified in Article 4.2-4.9 inclusive in compliance with federal, state and County requirements.

20.1.2 All Contractor documentation shall be accurate, complete, legible, and shall list each date of service. Contractor shall document the face-to-face duration of the service, including travel and documentation time for each service. Services must be identified as provided in-person, by telephone, or by telehealth.

20.1.3 All services shall be documented utilizing County-approved templates and contain all required elements. Contractor agrees to satisfy the chart documentation requirements set forth in BHIN 22-019, or BHIN that supersedes BHIN-22-019, and the contract between County and DHCS. Failure to comply with documentation standards specified in this Article require corrective action plans.

20.2 Assessment

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20.2.1 Contractor shall use the American Society of Addiction Medicine (ASAM) Criteria assessment for DMC-ODS clients to determine the appropriate level of SUD care.

20.2.2 The assessment shall include a typed or legibly printed name, signature of the service provider and date of signature. Assessment shall include the provider's LOC determination and recommendation for services. If the assessment of the client is completed by a registered or certified counselor, then the LPHA shall evaluate that assessment with the counselor and the LPHA shall make the initial diagnosis. The consultation between the LPHA and the registered or certified counselor can be conducted in person, by video conferencing, or by telephone.

20.2.3 The problem list and progress note requirements shall support the medically necessary services or medical necessity of each service provided.

20.2.4 Assessments shall be updated as clinically appropriate when the beneficiary's condition changes. Additional information on assessment requirements can be found in Access to Substance Use Disorder Services within Exhibit I or BHIN 23-001.

20.3 ICD-10

20.3.1 Contractor shall use the criteria set forth in the current edition of the DSM as the clinical tool to make diagnostic determinations.

20.3.2 Once a DSM diagnosis is determined, the Contractor shall determine the corresponding diagnosis in the current edition of ICD. Contractor shall use the ICD diagnosis code(s) to submit a claim for SUD services to receive reimbursement from County.

20.3.3 Under the EPSDT mandate, for youth under the age of 21, a diagnosis from the ICD-10 for Substance-Related and Addictive Disorders is not required for early intervention services.

20.3.4 The ICD Tabular List of Diseases and Injuries is maintained by CMS and may be updated during the term of this Agreement. Changes to the lists of ICD diagnoses do not require an amendment to this Agreement, and County may implement these changes as provided by DHCS.

20.4 Problem List

20.4.1 Contractor will create and maintain a Problem List for each client served under this Agreement. The problem list is a list of symptoms, conditions, diagnoses, and/or risk factors identified through assessment, psychiatric diagnostic evaluation, crisis encounters, or other types of service encounters.

20.4.2 Contractor must document a problem list that adheres to industry standards utilizing at minimum SNOMED International, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, March 2021 Release, and ICD-10-CM 2023.

20.4.3 A problem identified during a service encounter may be addressed by the service provider (within their scope of practice) during that service encounter and subsequently added to the problem list.

20.4.4 The problem list shall be updated on an ongoing basis to reflect the current presentation of the client.

20.4.5 The problem list shall include, but is not limited to the following:

20.4.5.1 Diagnoses identified by a provider acting within their scope of practice, if any. Diagnosis-specific specifiers from the current DSM shall be included with the diagnosis, when applicable.

20.4.5.2 Problems identified by a provider acting within their scope of practice, if any.

20.4.5.3 Problems or illnesses identified by the client and/or significant support person, if any.

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20.4.5.4 The name and title of the provider that identified, added, or removed the problem, and the date the problem was identified, added, or removed.

20.4.6 Contractor shall add to or remove problems from the problem list when there is a relevant change to a beneficiary's condition.

20.4.7 County does not require the problem list to be updated within a specific timeframe or have a requirement about how frequently the problem list should be updated after a problem has initially been added. However, Contractor shall update the problem list within a reasonable time such that the problem list reflects the current issues facing the client, in accordance with generally accepted standards of practice and in specific circumstances specified in BHIN 22-019.

20.5 Progress Notes

20.5.1 Contractor shall create progress notes for the provision of all DMC-ODS services provided under this Agreement.

20.5.2 Each progress note shall provide sufficient detail to support the service code selected for the service type as indicated by the service code description.

20.5.3 Progress notes shall include all elements specified in BHIN 22-019, whether the note be for an individual or group service, and shall include:

20.5.3.1 The type of service rendered

20.5.3.2 A narrative describing the service, including how the service addressed the client's behavioral health need (e.g., symptom, condition, diagnosis, and/or risk factors)

20.5.3.3 The date that the service was provided to the beneficiary

20.5.3.4 Duration of the service, including travel and documentation time

20.5.3.5 Location of the client at the time of receiving the service

20.5.3.6 A typed or legibly printed name, signature of the service provider and date of signature

20.5.3.7 ICD-10 code

20.5.3.8 Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code

20.5.3.9 Next steps, including, but not limited to, planned action steps by the provider or by the client, collaboration with the client, collaboration with other provider(s) and any update to the problem list as appropriate.

20.5.4 Contractor shall complete progress notes within three business days of providing a service, with the exception of notes for crisis services, which shall be completed within 24 hours.

20.5.5 Contractor shall complete a daily progress note for services that are billed on a daily basis, such as residential and inpatient services, if applicable.

20.5.6 When a group service is rendered by the Contractor, the following conditions shall be met:

20.5.6.1 A list of participants is required to be documented and maintained by the Contractor.

20.5.6.2 If more than one provider renders a group service, one progress note may be completed for a group session and signed by one provider. Contractor shall ensure that in this case, the progress note clearly documents the specific involvement and the specific amount of time of involvement of each provider during the group activity, including documentation time.

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20.6 Plan of Care

20.6.1 As specified in BHIN 22-019, when a plan of care is required, Contractor shall follow the DHCS requirements outlined in the Alcohol and/or Other Drug Program Certification Standards document, available in the DHCS Facility Certification page at: <https://www.dhcs.ca.gov/provgovpart/Pages/Licensing-and-Certification-Facility-Certification.aspx>

20.6.2 Contractor is not required to complete a plan of care for clients under this Agreement, except in the below circumstances:

20.6.2.1 Peer Support Services require a specific care plan based on an approved Plan of Care. The plan of care shall be documented within the progress notes in the client's clinical record and approved by any treating provider who can render reimbursable Medi-Cal services.

20.6.2.2 Narcotic Treatment Programs (NTP) are required to create a plan of care for clients as per federal law. This requirement is not impacted by the documentation requirements in BHIN 22-019. NTPs shall continue to comply with federal and state regulations regarding plans of care and documentation requirements.

20.7 Telehealth

20.7.1 Contractor may use telehealth, when it deems clinically appropriate, as a mode of delivering behavioral health services in accordance with all applicable County, state, and federal requirements, including those related to privacy/security, efficiency, and standards of care. Such services will conform to the definitions and meet the requirements included in the Medi-Cal Provider Manual: Telehealth, available in the DHCS Telehealth Resources page at: <https://www.dhcs.ca.gov/provgovpart/Pages/TelehealthResources.aspx> and as outlined in BHIN 23-018.

20.7.2 All telehealth equipment and service locations must ensure that client confidentiality is maintained.

20.7.3 Licensed providers and staff may provide services via telephone and telehealth as long as the service is within their scope of practice.

20.7.4 Medical records for clients served by Contractor under this Agreement must include documentation of written or verbal consent for telehealth or telephone services if such services are provided by Contractor. Such consent must be obtained at least once prior to initiating applicable health care services and consent must include all elements as specified in BHIN 22-019 and BHIN 23-018. Contractor shall also provide an explanation that beneficiaries have the right to access covered services that may be delivered via telehealth through an in person, face-to-face visit; an explanation that use of telehealth is voluntary and that consent for the use of telehealth can be withdrawn at any time by the Medi-Cal beneficiary without affecting their ability to access covered Medi-Cal services in the future; an explanation of the availability of Medi-Cal coverage for non-medical transportation services to in-person visits when other available resources have been reasonably exhausted; and the potential limitations or risks related to receiving services through telehealth as compared to an in-person visit, to the extent any limitations or risks are identified by the provider. The provider must document in the patient record the provision of this information and the patient's verbal or written acknowledgment that the information was received.

20.7.5 County may at any time audit Contractor's telehealth practices, and Contractor must allow access to all materials needed to adequately monitor Contractor's adherence to telehealth standards and requirements.

20.7.6 Effective no sooner than January 1, 2024, all providers furnishing applicable covered services via synchronous audio-only interaction must also offer those same services via synchronous video interaction to preserve beneficiary choice. Also, effective no sooner than January 1, 2024, to preserve a beneficiary's right to access covered services in person, a provider furnishing services through telehealth must do one of the following: 1. Offer those same services via in-person, face-to-face contact; or 2. Arrange

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for a referral to, and a facilitation of, in-person care that does not require a beneficiary to independently contact a different provider to arrange for that care [BHIN 23-018].

20.8 Discharge Planning

20.8.1 Contractor shall have written policies and procedures or shall adopt the County's policies and procedures regarding discharge. These procedures shall contain the following:

20.8.1.1 Written criteria for discharge defining: Successful completion of program; Administrative discharge; Involuntary discharge; Transfers and referrals.

20.8.1.2 A discharge summary that includes:

20.8.1.2.1 Reason for discharge, including whether the discharge was voluntary or involuntary and whether the client successfully completed the program;

20.8.1.2.3 Description of treatment episodes;

20.8.1.2.4 Description of recovery services completed;

20.8.1.2.4 Current alcohol and/or other drug usage;

20.8.1.2.5 Vocational and educational achievements;

20.8.1.2.6 Client's continuing recovery or discharge plan signed by an LPHA, or registered or certified counselor and client;

20.8.1.2.7 Transfers and referrals; and

20.8.1.2.8 Client's comments.

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Attachment I

Privacy and Information Security Provisions

Business Associate Data Security Requirements

I. Personnel Controls.

A. Employee Training. All Contractor workforce members who assist in the performance of functions or activities on behalf of DHCS, or access or disclose DHCS PHI or PI must complete information privacy and security training, at least annually, at Business Associate's expense. Each Contractor workforce member who receives information privacy and security training must sign a certification, indicating the member's name and the date on which the training was completed. These certifications must be retained for a period of six (6) years following contract termination.

B. Employee Discipline. Appropriate sanctions must be applied against Contractor workforce members who fail to comply with privacy policies and procedures or any provisions of these requirements, including termination of employment where appropriate.

C. Confidentiality Statement. All persons that will be working with DHCS PHI or PI must sign a confidentiality statement that includes, at a minimum, General Use, Security and Privacy Safeguards, Unacceptable Use, and Enforcement Policies. The statement must be signed by the Contractor workforce member prior to access to DHCS PHI or PI. The statement must be renewed annually. The Contractor shall retain each person's written confidentiality statement for DHCS inspection for a period of six (6) years following contract termination.

D. Background Check. Before a member of the Contractor workforce may access DHCS PHI or PI, a thorough background check of that worker must be conducted, with evaluation of the results to assure that there is no indication that the worker may present a risk to the security or integrity of confidential data or a risk for theft or misuse of confidential data. The Contractor shall retain each workforce member's background check documentation for a period of three (3) years following contract termination.

II. Technical Security Controls.

A. Workstation/Laptop encryption. All workstations and laptops that process and/or store DHCS PHI or PI must be encrypted using a FIPS 140-2 certified algorithm which is 128bit or higher, such as Advanced Encryption Standard (AES). The encryption solution must be full disk unless approved by the DHCS Information Security Office.

B. Server Security. Servers containing unencrypted DHCS PHI or PI must have sufficient administrative, physical, and technical controls in place to protect that data, based upon a risk assessment/system security review.

C. Minimum Necessary. Only the minimum necessary amount of DHCS PHI or PI required to perform necessary business functions may be copied, downloaded, or exported.

D. Removable media devices. All electronic files that contain DHCS PHI or PI data must be encrypted when stored on any removable media or portable device (i.e. USB thumb drives, floppies, CD/DVD, smartphones, backup tapes etc.). Encryption must be a FIPS 140-2 certified algorithm which is 128bit or higher, such as AES.

E. Antivirus software. All workstations, laptops and other systems that process and/or store DHCS PHI or PI must install and actively use comprehensive anti-virus software solution with automatic updates scheduled at least daily.

F. Patch Management. All workstations, laptops and other systems that process and/or store DHCS PHI or PI must have critical security patches applied, with system reboot if necessary. There must be a documented patch

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management process which determines installation timeframe based on risk assessment and vendor recommendations. At a maximum, all applicable patches must be installed within 30 days of vendor release.

G. User IDs and Password Controls. All users must be issued a unique user name for accessing DHCS PHI or PI. Username must be promptly disabled, deleted, or the password changed upon the transfer or termination of an employee with knowledge of the password, at maximum within 24 hours. Passwords are not to be shared. Passwords must be at least eight characters and must be a non-dictionary word. Passwords must not be stored in readable format on the computer. Passwords must be changed every 90 days, preferably every 60 days. Passwords must be changed if revealed or compromised. Passwords must be composed of characters from at least three of the following four groups from the standard keyboard:

- Upper case letters (A-Z)
- Lower case letters (a-z)
- Arabic numerals (0-9)
- Non-alphanumeric characters (punctuation symbols)

H. Data Destruction. When no longer needed, all DHCS PHI or PI must be cleared, purged, or destroyed consistent with NIST Special Publication 800-88, Guidelines for Media Sanitization such that the PHI or PI cannot be retrieved.

I. System Timeout. The system providing access to DHCS PHI or PI must provide an automatic timeout, requiring re-authentication of the user session after no more than 20 minutes of inactivity.

J. Warning Banners. All systems providing access to DHCS PHI or PI must display a warning banner stating that data is confidential, systems are logged, and system use is for business purposes only by authorized users. User must be directed to log off the system if they do not agree with these requirements. Contractor's email transmissions shall display a warning banner stating that data is confidential, systems activities are monitored and logged for administrative and security purposes, systems use is for authorized users only, and that users are directed to log off the system if they do not agree with these requirements. Contractors that utilize an EHR shall maintain all parts of the clinical record that are not stored in the EHR, including but not limited to the following examples of client signed documents: discharge plans, informing materials, and health questionnaire

K. System Logging. The system must maintain an automated audit trail which can identify the user or system process which initiates a request for DHCS PHI or PI, or which alters DHCS PHI or PI. The audit trail must be date and time stamped, must log both successful and failed accesses, must be read only, and must be restricted to authorized users. If DHCS PHI or PI is stored in a database, database logging functionality must be enabled. Audit trail data must be archived for at least 3 years after occurrence.

L. Access Controls. The system providing access to DHCS PHI or PI must use role-based access controls for all user authentications, enforcing the principle of least privilege.

M. Transmission encryption. All data transmissions of DHCS PHI or PI outside the secure internal network must be encrypted using a FIPS 140-2 certified algorithm which is 128bit or higher, such as AES. Encryption can be end to end at the network level, or the data files containing PHI can be encrypted. This requirement pertains to any type of PHI or PI in motion such as website access, file transfer, and E-Mail.

N. Intrusion Detection. All systems involved in accessing, holding, transporting, and protecting DHCS PHI or PI that are accessible via the Internet must be protected by a comprehensive intrusion detection and prevention solution.

III. Audit Controls.

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- A. **System Security Review.** All systems processing and/or storing DHCS PHI or PI must have at least an annual system risk assessment/security review to provide assurance that administrative, physical, and technical controls are functioning effectively and providing adequate levels of protection. Reviews should include vulnerability scanning tools.
- B. **Log Reviews.** All systems processing and/or storing DHCS PHI or PI must have a routine procedure in place to review system logs for unauthorized access.
- C. **Change Control.** All systems processing and/or storing DHCS PHI or PI must have a documented change control procedure that ensures separation of duties and protects the confidentiality, integrity and availability of data.
- IV. **Business Continuity / Disaster Recovery Controls**
- A. **Emergency Mode Operation Plan.** Contractor must establish a documented plan to enable continuation of critical business processes and protection of the security of electronic DHCS PHI or PI in the event of an emergency. Emergency means any circumstance or situation that causes normal computer operations to become unavailable for use in performing the work required under this Agreement for more than 24 hours.
- B. **Data Backup Plan.** Contractor must establish documented procedures to backup data to maintain retrievable exact copies of DHCS PHI or PI. The plan must include a regular schedule for making backups, storing backups offsite, an inventory of backup media, and an estimate of the amount of time needed to restore DHCS PHI or PI should it be lost. At a minimum, the schedule must be a weekly full backup and monthly offsite storage of DHCS data.
- V. **Paper Document Controls.**
- A. **Supervision of Data.** DHCS PHI or PI in paper form shall not be left unattended at any time, unless it is locked in a file cabinet, file room, desk or office. Unattended means that information is not being observed by an employee authorized to access the information. DHCS PHI or PI in paper form shall not be left unattended at any time in vehicles or planes and shall not be checked in baggage on commercial airplanes.
- B. **Escorting Visitors.** Visitors to areas where DHCS PHI or PI is contained shall be escorted and DHCS PHI or PI shall be kept out of sight while visitors are in the area.
- C. **Confidential Destruction.** DHCS PHI or PI must be disposed of through confidential means, such as cross cut shredding and pulverizing.
- D. **Removal of Data.** DHCS PHI or PI must not be removed from the premises of the Contractor except with express written permission of DHCS.
- E. **Faxing.** Faxes containing DHCS PHI or PI shall not be left unattended and fax machines shall be in secure areas. Faxes shall contain a confidentiality statement notifying persons receiving faxes in error to destroy them. Fax numbers shall be verified with the intended recipient before sending the fax.
- F. **Mailing.** Mailings of DHCS PHI or PI shall be sealed and secured from damage or inappropriate viewing of PHI or PI to the extent possible. Mailings which include 500 or more individually identifiable records of DHCS PHI or PI in a single package shall be sent using a tracked mailing method which includes verification of delivery and receipt, unless the prior written permission of DHCS to use another method is obtained.