



KERN HEALTH SYSTEMS

KERN HEALTH SYSTEMS					
POLICY AND PROCEDURES					
SUBJECT: Facility Site Review and Medical Record Review			POLICY #: 2.71-P		
DEPARTMENT: Quality Improvement					
Effective Date: 01/01/2022	Review/Revised Date: 3/31/2023	DMHC	X	PAC	X
		DHCS	X	QI/UM COMMITTEE	X
		BOD		FINANCE COMMITTEE	

Emily Duran
Chief Executive Officer

Date _____

Chief Operating Officer

Date _____

Chief Medical Officer

Date _____

Director of Quality Improvement

Date _____

POLICY:

Per Department of Health Care Services (DHCS) All Policy Letter (APL)22-017, Kern Health Systems (KHS) is responsible for oversight of the site review policies whether KHS retains site review functions, delegates them to another Managed Care Plan (MCP), or subcontracts site review. KHS develops and maintains a standardized system-wide process for conducting reviews of provider facility sites and medical records that minimize evaluation criteria and guidelines in compliance with the State Department of Health Care Services (DHCS) contractual requirements. KHS' Chief Medical Officer or designee is accountable for the Facility Site Survey process.

Kern Health Systems (KHS) personnel will perform a facility site and medical record review on all contracted primary care providers (PCP) (including OB/GYNs, IPAs, clinics, and hospital ambulatory care clinics serving as PCPs). Physical Access Reviews (PARs) will also be completed for providers who serve a high volume of Seniors and People with Disabilities (SPD) beneficiaries, in accordance

with Letters, MMCD Policy Letter 02-02 and 10-016, Title 22, CCR Section 53856, and W & I Code 14182(b)(9).

KHS makes the results of the FSR Attachment C tool available to members via Provider Directories. The Provider Directories display the accessibility indicator per Medi-Cal Managed Care Division (MMCD) Policy Letter 11-009. The Provider Directories identify whether the provider site has access in the following categories: Parking (P), Exterior Building (EB), Interior Building (IB), Restroom (R), Exam Room (E), and Exam Table/Scale (T).

Only a Certified Master Trainer (CMT) or Certified Site Reviewer (CSR) conduct initial and subsequent site reviews, consisting of a Facility Site Review (FSR) and Medical Records Review (MRR), regardless of a PCP site's other accreditations and certifications.

KHS conducts an initial and subsequent site review, consisting of an FSR and MRR, for all contracted Primary Care Provider (PCP) sites receive regardless of the site's other accreditations and certifications. KHS ensures the following:

- A. Each PCP site has passed an initial FSR and, as applicable, corrects all deficiencies in order to close their Corrective Action Plan (CAP) prior to adding the provider(s) to the MCP's network and assigning MCP members to the provider(s).
- B. Each PCP completes an initial MRR after the PCP is assigned members, and, as applicable, submits all appropriate documentation to address all deficiencies to close their CAP.
- C. Each PCP site completes a periodic subsequent site review, consisting of both an FSR and MRR, at least every three years after the initial FSR.
- D. DHCS' most current FSR and MRR tools and standards are being utilized when conducting site reviews
- E. All PCP sites are held to the same standards.
- F. The site review status of each contracted PCP site is properly tracked.
- G. KHS collaborates with Health Net or any other local MCP to determine how we notify each other of site review statuses and results for shared providers.

KHS issues a Certified Quality Provider Site certificate to providers that successfully pass a site review. This certificate is valid for up to three years and affirms that the site has been deemed a DHCS Certified Quality Provider Site. Certificates are issued and revoked to shared provider sites in coordination with the county collaborative partner.

KHS notifies its providers in advance for scheduled site reviews. However, inspection of an MCP's facilities or other elements of a review may be conducted without prior notice, in conjunction with other medical surveys or as part of an unannounced inspection program¹.

KHS may choose to delegate site review responsibilities to another MCP. However, KHS retains ultimate responsibility for oversight of site review completion, results, any necessary corrective action plan (CAP), and monitoring of assigned PCP sites per county collaboration.

DEFINITIONS:

Ancillary Service Providers: Free standing facilities that provide diagnostic and therapeutic services, such as, but not limited to laboratory, infusion, radiology, imaging, cardiac testing, renal dialysis, occupational therapy, speech therapy, physical therapy, pulmonary testing, and cardiac rehabilitation.

High Volume Specialists: Ancillary and CBAS Providers as a whole. Specialty, Ancillary and CBAS types, whose claim numbers exceed the established average, will be considered High Volume SPD Specialties, Ancillary and CBAS Providers.

PROCEDURES:

1.0 SITE REVIEW PROCESS

A. Initial Site Review

An initial site review consists of an initial FSR and an initial MRR. The initial FSR and the initial MRR might not occur on the same date. The FSR is conducted first to ensure the PCP site operates in compliance with all applicable local, state, and federal laws and regulations. KHS does not assign members to providers until their PCP sites receive a passing FSR score and completes all CAPs. An initial FSR is not required when a new provider joins a PCP site that has a current passing FSR score.

A DHCS Site Identification Number (“DHCS Site ID”) is a unique identifier and must be assigned by designated MCPs to each PCP site reviewed. DHCS releases sets of DHCS Site ID numbers for each county. In the event of an ownership change at an established PCP site, a new DHCS Site ID will be assigned. The new DHCS Site ID may be the existing Site ID but with a modifier to represent a change of ownership at the site. Local county MCPs collaborate to manage and assign the DHCS Site ID numbers specific to the county.

Once a PCP site passes the initial FSR’s and completes all Corrective Action Plans (CAPs), KHS begins assigning members to the PCPs at that site. KHS will complete the initial MRR of a new PCP site within 90 calendar days of the date that KHS first assigns members. KHS may defer this initial MRR for an additional 90 calendar days only if the new PCP does not have enough assigned MCP members to complete the MRR on the required minimum number of medical records (see Subsequent Site Reviews below for details regarding the required minimum number of medical records). If, after 180 days following assignment of members, the PCP still has fewer than the required number of medical records, KHS will complete the MRR using the total number of medical records it has available and adjust the scoring according to the number of medical records reviewed.

KHS may choose to conduct the MRR Review portion of the site review on site or virtually. The virtual process must comply with all applicable Health Insurance Portability Accountability Act (HIPAA) standards at all-times.

There are additional scenarios that require KHS to conduct an initial site review. Examples of these scenarios include, but are not limited to, instances when:

- a. A new PCP site is added to KHS's network.
- b. A newly contracted provider assumes a PCP site with a previous failing FSR and/or MRR score within the last three years.
- c. A PCP site is returning to the Medi-Cal managed care program and has not had a passing FSR in the last three years.
- d. At the discretion of KHS, a separate site review may be conducted for solo practices/organizations.
- e. Upon identification of multiple independent practices that occupy the same site, a separate site review must be completed for all PCP practices at that site and a unique alphanumeric DHCS Site ID must be assigned for each independent PCP practice at the site if ownership is different. MCPs must develop processes within their local county collaborative in regard to conducting separate site reviews for shared sites.
- f. There is a change of ownership of an existing provider site.
- g. A PCP site relocates. When a PCP site relocates, KHS:
 - Completes an initial FSR within 60 days of notification or discovery of the completed move.
 - Allows assigned KHS members to continue to see the provider at the new location, but not assign new Members until the initial site review is completed.
 - i. Upon passing the initial FSR and closing CAPs, if applicable, the following will occur: The PCP site may be formally added to the Network.
 - ii. New and established relocating Members can be formally assigned to the new Provider location.
 - If the relocated PCP site does not pass the initial FSR within two attempts, or does not complete required CAPs per established timelines, the following will occur:
 - i. The relocated PCP site may not be added to the MCP's Provider Network.
 - ii. The previous PCP site must be removed from the Network if the site has closed.
 - iii. Current assigned membership must be reassigned to another Network PCP, if the previous site has closed.
 - iv. The relocated PCP site may reapply six months from the last FSR survey.
- h. Does not assign new members to providers at the site until the PCP site receives passing FSR and MRR scores.
- i. If KHS were to expand to a new service area, KHS will complete an initial site review on a specified number of PCP sites as outlined in the bulleted list below. The FSR portion of the initial site review must be completed prior to the start of KHS expanding its operations.
 - Five percent of the PCP sites in KHS' proposed network, or on thirty PCP sites, whichever is greater in number.
 - All remaining proposed PCP sites within the first six months of operation or expansion.

- All PCP sites in the network if there are thirty or fewer PCP sites in the network.
- New and/or expanding MCPs may use site reviews of existing county MCPs as evidence of completion of the required initial site reviews.
- MCPs must submit data and relevant information to DHCS, in a format and timeframe to be specified by DHCS, for the instances described above.

PCP sites that are subject to site reviews must include a variety of PCP types (Family Medicine, Internal Medicine, Pediatric, etc.) and subcontracted entities (solo practice, Medical Group, etc.) from throughout the provider network.

B. Supplemental Facilities – Mobile, Satellite, School Based, and Other Extension Clinics

Supplemental facilities assist in the care delivery of primary care services to geographically remote areas that lack health care services, as well as assist the underserved population in areas where there may be access to care concerns.

- Supplemental facilities may offer a variety of clinical services including, but not limited to preventive care, immunizations, screenings, and/or chronic care management (excluding specialty services).
- Mobile clinics are self-contained units including vans, recreational vehicles, and other vehicles that have been repurposed to provide space for various clinic services and may also serve to deliver equipment to locations that operate temporary clinics.
- In general, supplemental facilities that provide primary care services may serve as an extension of a PCP site, a community-based clinic, a Federally Qualified Health Center (FQHC) county facility, or a standalone clinic with Members assigned.
- KHS must conduct an initial site review and subsequent site reviews of supplemental facilities at least every three years thereafter, with a focus on areas relevant to the services being provided by the supplemental facilities.
- KHS must establish a process to complete the oversight of supplemental facilities and collaborate with MCPs within a given county.

C. Subsequent Site Reviews

KHS conducts subsequent site reviews, consisting of an FSR and MRR, at least every three years, beginning no later than three years after the initial FSR. KHS may conduct site reviews more frequently per county collaborative decisions, or when determined necessary based on monitoring, evaluation, or CAP follow-up issues.

D. Scoring

KHS will base FSR and MRR scores on available documented evidence, demonstration of the criteria, and verbal interviews with site personnel. If a site reviewer chooses to review additional criteria not included on the FSR or MRR tools, the site reviewer will not include the additional criteria in the existing scoring method. KHS will not alter scored criteria or assigned weights in any way.

Critical elements have the largest potential for adverse effects on patient health or safety and therefore have a scored weight of two points while all other review elements have a scored

weight of one point. The PCP site must correct all critical element deficiencies identified during a site review, focused review, or monitoring visit within ten calendar days of those reviews or visits. KHS will verify that CAPs related to critical elements are completed within 30 calendar days of the site review, focused review, or monitoring visit. KHS will ensure that PCP sites found to be deficient in any critical element during an FSR have fully corrected all deficiencies, regardless of the PCP site's FSR score. Any MRR section score of less than 80 percent requires a CAP for the entire MRR regardless of the total MRR score.

All MRR tool review elements have a scored weight of one-point each. The MRR score is based on a standard review of ten randomly selected KHS member medical records per provider, consisting of five pediatric and five adult or obstetric medical records. For PCP sites serving only pediatric or only adult patients, all ten medical records will be reviewed using the appropriate preventive care criteria. For OB/GYNs acting as PCPs, all medical records will be reviewed using preventive care criteria for adults or pediatrics (pregnant under age 21 years) and obstetrics. During the MRR, site reviewers have the option to request additional medical records for review. If the site reviewer chooses to review additional medical records, KHS will calculate the scores accordingly.

If a PCP site documents patient care performed by multiple PCPs in the same medical record, KHS will consider these medical records as a shared medical record system. KHS will consider shared medical records as those that are not identifiable as separate records belonging to any specific PCP. KHS will review a minimum of ten medical records if two or three PCPs share records, twenty medical records if four to six PCPs share records, and thirty medical records if seven or more PCPs share records. If there are multiple providers in one office that do not share medical records, each PCP will be reviewed separately and receive a separate score. If a minimum number of records are not available for review due to limited patient population, the reviewer will complete the MRR, document the rationale, and adjust the score as needed.

In the event that there are multiple Providers in one office that do not share medical records, each PCP must be reviewed separately and receive a separate score. A minimum of ten medical records must be reviewed per Provider.

During the MRR, site reviewers have the option to request additional medical records for review to ensure adequate review of all Provider specialties, Member populations, etc. If the site reviewer chooses to review additional medical records, the MCP must calculate the scores accordingly.

MCPs may choose to conduct the MRR portion of the site review onsite or virtually. The virtual process must comply with all applicable HIPAA standards at all times, regardless of the chosen method. Both onsite and virtual MRRs may include the review of medical records for Members belonging to another MCP, and may include the viewing, collection, storage, and transmission of Protected Health Information (PHI).

If a PCP site receives a failing score from one MCP, all other MCPs will consider the PCP site as having a failing score. KHS will use the county collaborative process to identify shared

providers and to determine methods for sharing site review information, including CAPs and provider terminations (See Policy 4.39 for Provider Terminations).

When a PCP site receives a failing score on an FSR or MRR, KHS will notify the PCP site of the score, all cited deficiencies, and all CAP requirements. KHS may choose to remove any PCP site with a failing FSR or MRR score from its network. If KHS allows a PCP site with a failing FSR or MRR score to remain in its network, KHS will require and verify that the PCP site has corrected the identified deficiencies within the CAP timelines established in this policy. KHS will not assign new members to network PCP sites that receive a failing score on an FSR or MRR until KHS has verified that the PCP site has corrected the deficiencies and the CAP is closed.

PCP sites that receive a failing score on either the FSR or MRR for two consecutive site reviews must receive a minimum passing score on the next FSR and MRR (including PCP sites with open CAPs in place) to remain in the MCP’s provider network. If the PCP site fails on its third consecutive attempt, despite KHS’ ongoing monitoring and assistance, the PCP site will be removed from KHS’ provider network, and its members will be reassigned to other network providers, as appropriate and as contractually required.

E. Corrective Action Plan (CAP)

A CAP is required for all cited deficiencies for PCP sites that have a deficiency in a critical element or receive a conditional passing score on the FSR or MRR tool, on a focused review, or for deficiencies identified by KHS or DHCS through oversight and monitoring activities. CAPs are required as indicated:

Review	Exempted Pass	Conditional Pass	Fail
FSR	<ul style="list-style-type: none"> a. Score of 90% and above with no deficiencies in critical elements, infection control, or pharmacy b. CAP not required 	<ul style="list-style-type: none"> a. Score of 90% and above with deficiencies in critical elements, infection control, or pharmacy b. Score of 80% and above. c. CAP required 	<ul style="list-style-type: none"> a. Score below 80% b. CAP required

Review	Exempted Pass	Conditional Pass	Fail
MRR	<ul style="list-style-type: none"> a. Score of 90% and above, with all section scores at 80% and above b. CAP not required 	<ul style="list-style-type: none"> a. Score of 90% and above with one or more section scores below 80% b. Score of 80% and above c. CAP required. 	<ul style="list-style-type: none"> a. Score below b. 80% c. CAP required
MCPs may require a CAP regardless of score for other findings identified during the survey that require correction.			

KHS will not assign new Members to Providers who fail to correct site review deficiencies within the established CAP timelines. For Providers that fail to comply with their CAP, the MCP must verify that the PCP site has corrected the deficiencies and the CAP is closed before assigning new Members. Ultimately, KHS must remove any Provider from their Network that does not come into compliance with review criteria and CAP requirements within the established timelines, and the MCP must expeditiously reassign that Provider’s Members to other Network Providers

KHS may decide to provide additional training and give technical assistance when a PCP site fails an FSR prior to contracting with KHS. Precontracted providers who do not pass the initial FSR within two attempts may reapply to KHS after six months.

When conducting the site review, KHS is responsible for follow-up, re-review, closure of CAPs, and monitoring re-reviews. CAP documentation will identify:

- a. The specific deficiency,
- b. Corrective actions needed,
- c. Projected and actual dates of the deficiency correction,
- d. Reevaluation of timelines and dates. And
- e. Responsible persons

CAPs for non-critical elements may be verified via document submission. CAPs for critical elements will be verified onsite. Closed CAP documentation will include:

- a. Documentation of problems in completing corrective actions (if any),

- b. Resources and technical assistance provided by the MCP,
- c. Evidence of the corrections,
- d. Completion and closure dates, and
- e. Name and title of the MCP reviewer.

KHS will follow the timeline below for CAP notification and completion:

CAP Timeline	CAP Action(s)
FSR and/or MRR Completion Day	<p>KHS will provide the PCP site a report containing:</p> <ul style="list-style-type: none"> a. Verbal notification of any CE findings and a signed attestation by the PCP/site designee and KHS staff confirming that a discussion regarding CE findings occurred. (This serves as the start of the CE-CAP timeline.) b. A formal written request for CAPs to address all CEs, if applicable, the day of the site visit but no later than one business day after site visit completion c. The FSR and/or MRR scores site visit but no later than one business day after site visit completion. d. A formal written request for CAPs for all critical elements, if applicable the day of the site visit but no later than one business day after site visit completion
Within 10 calendar days of the FSR and/or MRR	<ul style="list-style-type: none"> a. The PCP site will submit a CAP and evidence of corrections to KHS for all deficient critical elements, if applicable. b. KHS will provide a report to the PCP site containing FSR and/or MRR findings, along with a formal written request for CAPs for all non-critical element deficiencies. c. KHS will provide educational support and technical assistance to PCP sites as needed. d. KHS must review, approve, or request additional information on the submitted CAP(s) for CE findings
Within 30 calendar days from the date of the FSR and/or MRR report	<ul style="list-style-type: none"> a. KHS will conduct a focused review to verify that CAPs for critical elements are completed. b. The PCP site must submit a CAP for all non-critical element deficiencies to KHS. c. KHS will provide educational support and technical assistance to PCP sites as needed.

CAP Timeline	CAP Action(s)
Within 60 calendar days from the date of the FSR	<ul style="list-style-type: none"> a. For those sites that were granted an extension for CE CAPs, the MCP must verify that all CE CAPs are closed
Within 60 calendar days from the date of the FSR and/or MRR report	<ul style="list-style-type: none"> a. KHS will review, approve, or request additional information on the submitted CAP(s) for non-critical findings. b. KHS will continue to provide educational support and technical assistance to PCP sites as needed.
Within 90 calendar days from the date of the FSR and/or MRR report	<ul style="list-style-type: none"> a. All CAPs must be closed. b. Providers can request a definitive, time-specific extension period to complete the CAP(s), not to exceed 120 calendar days from the date of the initial report of FSR and/or MRR findings.
Beyond 120 days from the date of the FSR and/or MRR report	<ul style="list-style-type: none"> a. KHS will request approval from DHCS to complete a CAP review for any extenuating circumstances that prevented completion of a CAP within the established timeline. b. KHS will conduct another FSR and/or MRR, as applicable, within 12 months of the applicable FSR and/or MRR date(s).

KHS will not assign new members to providers who do not correct site review deficiencies within the established CAP timelines. KHS will verify that the PCP site has corrected the deficiencies and the CAP is closed. KHS will remove any provider from the network who does not come into compliance with review criteria and CAP requirements within the established timelines, and KHS will appropriately reassign that provider’s KHS members to other network providers.

F. Re-Credentialing

For a new provider on a site that has not previously been reviewed, initial provider credentialing and site review will occur simultaneously. Providers at a site are credentialed according to DHCS contractual and policy requirements. A site review shall be completed as part of the initial credentialing process if a new provider at a site that has not previously been reviewed is added to a contractor's provider network. A site review need not be repeated as part of the initial credentialing process if a new provider is added to a provider site that has a current passing site survey score. A site review survey need not be repeated

as part of the recredentialing process if the site has a current passing site survey score. A passing Site Review Survey shall be considered "current" if it is dated within the last three years and need not be repeated until the due date of the next scheduled site review survey, as determined necessary from monitoring activities.

G. Monitoring

KHS will monitor all PCP sites between each regularly scheduled site review. Monitoring methods may include site reviews, but KHS also uses additional methods such as information gathered through established internal KHS systems (e.g., quality improvement), as well as provider and program-specific reports from external sources of information. KHS will monitor and evaluate all critical elements for all PCP sites between scheduled site reviews. When KHS identifies deficiencies through monitoring, KHS will determine the appropriate course of action, such as conducting a site review or additional focused reviews, to educate and correct the deficiencies according to established CAP timelines.

H. Physical Access Reviews (PARs)

The Physical Accessibility Review Survey (Attachment C) assesses the physical accessibility of provider sites for PCPs and high-volume specialist, ancillary, and CBAS providers who serve KHS SPD members. Physical accessibility reviews are available to any contracted provider that requests to be evaluated, regardless of whether they are determined to be high volume.

KHS conducts PARs for new PCP sites at the time of initial credentialing or contracting, and every three years thereafter as a requirement for participation in the California State Medi-Cal Managed Care (MMCD) Program. PARS are conducted for PCP sites regardless of the status of other accreditation and/or certifications.

The following types of providers will be excluded from PAR site visits:

- Non-contracted providers;
- Transportation providers;
- Durable Medical Equipment (DME) pick-up sites;
- Laboratories out of service area;
- Licensed and State-certified long-term care facilities; and
- Delegated entities, including Vision Services Plan (VSP), Managed Behavioral Health Services, and Pharmacy Benefit Managers (PBMs).

A PAR will be conducted utilizing the DHCS MMCD Facility Site Survey Tool, APL 15-023 Attachments C, D, or E when appropriate. Assessment includes, but is not limited to, parking, building, elevator and clinic areas, exam rooms, lobbies, and restrooms. Medical equipment assessed may include, but is not limited to, height adjustable exam tables, member accessible weight scales, infusion chairs and/or beds, physical therapy equipment, and imaging equipment such as for mammography or Magnetic Resonance Imaging

(MRI). KHS staff members are trained to conduct the PAR utilizing the requirements and process as described in MMCD PL 12-006 and DHCS APL 15-023.

KHS will utilize the following methodology to identify high-volume specialist, ancillary, and CBAS providers who serve KHS SPD members. At least annually, KHS will use internal claims data from the past 12 months to identify all specialist, Ancillary, and CBAS Providers who served a KHS SPD member; at a minimum, the report will include the following data categories:

1. Provider name, NPI number,
2. KHS internal provider ID number;
3. Medi-Cal specialty description.
4. Place of service, and
5. Number of SPD related claims.

KHS will total the number of claims for each specialty types and, determine the average number of claims for all specialties, Ancillary and CBAS Providers as a whole. Specialty, Ancillary and CBAS types, whose claim numbers exceed the established average, will be considered High Volume SPD Specialties, Ancillary and CBAS Providers. The provider sites in each of these specialties will then be required to undergo a Physical Accessibility Review Survey.

I. Focused Review

A focused review is a targeted review of one or more specific areas of the FSR or MRR. KHS will not substitute a focused review for a site review. KHS may use focused reviews to monitor providers between site reviews to investigate problems identified through monitoring activities or to follow up on corrective actions. Reviewers may utilize the appropriate sections of the FSR and MRR tools for the focused review, or other methods to investigate identified deficiencies or situations. All deficiencies identified in a focused review require the completion and verification of corrective actions according to CAP timelines established in this policy and procedure.

J. County Collaboration

KHS will collaborate locally within each Medi-Cal managed care county to establish systems and implement procedures for the coordination and consolidation of site reviews for mutually shared PCPs.² KHS and Health Net have equal responsibility and accountability for participation in the site review collaborative processes.

The Collaborative Process are:

- 1) Standardize policy and procedures for FSR's and MRR's
- 2) Standardize tolls for CAP's
- 3) Standardize Protocols which will limit access to audit results only to authorized health plan representatives
- 4) Standardized certified reviewers training and certification programs
- 5) Standardized protocols for designated vendor's responsibility and reporting (if applicable)

KHS submits an initial written description and periodic update reports as requested and instructed by DHCS describing the county collaboration processes, which will include, but are not limited to, the following:

- 1) Names and titles of each MCP's participating personnel.
- 2) A work plan that includes goals, objectives, activities, and timelines.
- 3) Scheduled meeting dates, times, and locations.
- 4) Meeting processes and outcomes.
- 5) Communication and information-sharing processes.
- 6) Roles and responsibilities of each MCP.
- 7) Delegated activities and use of delegated or sub-delegated entities.
- 8) Memorandum of Agreement requirements established KHS and Health Net.

KHS will establish policies and procedures to define local collaborative methodology for:

- 1) Identification of shared providers,
- 2) Confidentiality, disclosure, and release of shared provider review information and site review results,
- 3) Site review processes,
- 4) Issuance of Certified Quality Provider Site certificates,
- 5) Oversight and monitoring of review processes,
- 6) Site review personnel and training processes, and
- 7) Collection and storage of site review results

K. MCP Site Review Personnel

KHS will designate a minimum of one physician, Nurse Practitioner (NP), Physician Assistant (PA), or Registered Nurse (RN), to be certified by DHCS as the MCP's CMT. The CMT has the overall responsibility for the training, supervision, and certification of site reviewers, as well as monitoring site reviews and evaluating site reviewers for accuracy.

KHS will determine the composition of the teams performing site reviews. Each site review will have a designated CSR who is responsible for and signs the FSR and MRR tools. Only physicians, NPs, PAs, or RNs are eligible to become CSRs. A variety of personnel may be part of the site review team, including pharmacists, dietitians, and others to provide assistance and clarification.

An RN³ is the minimal level of site reviewer acceptable for independently performing site reviews. RN reviewers can independently make determinations regarding implementation of appropriate reporting or referral of abnormal review findings to initiate peer review procedures. An RN can only delegate site review tasks to a subordinate based on the subordinate's legal scope of practice and on the degree of preparation and ability required by the site review tasks that the RN would delegate.

KHS has written policies and procedures that clearly define the duties and responsibilities of all site review personnel. KHS ensures that site review activities established for CSRs comply with the CSR's scope of

practice as defined by state law, in accordance with the state licensing and certification agencies and are appropriate to the site reviewers' level of education and training by completing a minimum of 10 FSR's and 10 MRR' s for recertification, attending a DHCS sponsored Inter rated workshop in person every two years, and achieving a 10% variance on FSR and MRR.

L. MCP Site Review Training and Certification

Physicians, NPs, PAs, and/or RNs that are designated by KHS to be CMTs or site reviewers will meet the certification and recertification requirements outlined in the respective table below to be certified as a CMT or CSR. CMT candidates must apply for certification directly to DHCS using Attachments 1-41 of this policy and procedure, Application for DHCS Site Review Master Trainer Certification. Applications will be submitted to KHS's assigned DHCS Nurse Evaluator. Upon certification and recertification, CMTs will receive a certificate signed by DHCS. CMTs must be recertified every three years.

KHS is responsible for ensuring that all site reviewers are appropriately trained, evaluated, certified, and monitored. KHS may collaborate with another MCP to determine local systems for training and certifying site reviewers. Training must include DHCS seminars, KHS classes, individual or small group training sessions provided by a CMT, and self-study learning programs. KHS can only certify physicians, PAs, or RNs as CSRs, and recertify them every three years thereafter. Upon certification and recertification, CSRs will receive written verification of certification by KHS.

M. Inter-rater Review Process

Candidates for CMT and CSR certifications will complete an inter-rater review process as part of both the initial certification and recertification processes. The inter-rater for CMT candidates is a DHCS Nurse Evaluator. The inter-rater review process requires the CMT candidate to concurrently complete and score a site review with the DHCS Nurse Evaluator using the DHCS FSR and MRR tools and standards. The inter-rater for CSR candidates is KHS' CMT. The inter-rater review process requires the CSR candidate to participate with KHS' CMT to concurrently complete and score a site review utilizing the DHCS FSR and MRR tools and standards. The CMT or CSR candidate must achieve the required inter-rater score as described in the tables below to be certified.

If the CMT or CSR candidate does not meet the appropriate inter-rater score variance, they may repeat the process one time. The appropriate inter-rater (DHCS Nurse Evaluator or KHS' CMT) and the candidate with the failing inter-rater score will jointly assess training needs and implement a training plan prior to conducting the second inter-rater review. CMT and CSR candidates that do not meet the appropriate inter-rater variance score for the second inter-rater review must wait 6 months to reapply for certification.

Initial Certification Requirements	CMT	CSR
Possess a current and valid California RN, Doctor of Medicine (MD), Doctor of Osteopathic Medicine (DO), NP, or PA license.	X	X

Initial Certification Requirements	CMT	CSR
Be employed by or subcontracted with an MCP.	X	X
Submit Attachment A, Application for DHCS Site Review Master Trainer Certification.	X	
Have experience in conducting training in a health-related field, or conducting quality improvement activities such as medical audits, site reviews, or utilization management activities within the past three (3) years.	X	
Complete twenty (20) FSRs and twenty (20) MRRs, and one (1) year of experience as a CSR.	X	
Achieve an inter-rater score within 5% of FSR and 5% of MRR from the DHCS Nurse Evaluator.	X	
Attend didactic site review training or completion of DHCS site review training modules on the current site review tools under supervision of a CMT.		X
Complete ten (10) FSRs and ten (10) MRRs with a CSR or CMT.		X
Achieve an inter-rater score of 10% in FSR and 10% in MRR with designated CMT.		X

Recertification Requirements	CMT	CSR
Possess a current and valid California RN, MD, DO, NP, or PA license.	X	X
Be employed by or subcontracted with an MCP.	X	X
Be responsible for staff training on the most current DHCS site review tools and standards.	X	
Participate in DHCS-sponsored site review trainings as well as site review work group (SRWG) meetings and teleconferences.	X	
Maintain CMT certification.	X	
Complete a minimum of twenty (30) site reviews following initial certification or recertification.	X	X
Attend DHCS-sponsored inter-rater workshops in person or virtually every three years.	X	X

Achieve a 10% variance on the MRR, on the interrater score as defined by the SRWG and DHCS.		X
Achieve an inter-rater score within 5% of FSR and 5% of MRR from the DHCS Nurse Evaluator.	X	

KHS will develop policies and procedures for ongoing supervision and monitoring of site review personnel to ensure reliability of site review findings and data submitted to DHCS. Each MCP must maintain certification records including, but not limited to, site review training activities and supporting documentations to support the certification requirements.

N. Data Submission Procedures

KHS will submit site review data to DHCS every six months (July 31 for the period January - June, and January 31 for the period July - December) in an approved format uploaded to a designated DHCS secure site. KHS may submit data more frequently than every six months. For preoperational and expansion site reviews, KHS will submit site review data to DHCS at least six weeks prior to site operation. DHCS will make available the database containing all necessary tables and data input forms for the mandatory bi-annual submission of site review data. DHCS will reject site review data if KHS submits it in nonconforming formats.

KHS is required to collect PHI as part of the MRR process and must include the PHI in the bi-annual data submission to DHCS.

O. DHCS-Conducted Site Reviews

DHCS conducts separate site reviews to validate KHS’ FSR and MRR processes. Prior to an expansion to a new county by KHS, DHCS conducts initial FSRs, followed by initial MRRs upon KHS beginning operations and assignment of KHS members, as outlined in APL22-017, of randomly chosen PCP sites in KHS’ network. DHCS also conducts subsequent site reviews on PCP sites within KHS networks. DHCS will notify KHS of critical findings in writing via email within 10 business days following the date of the FSR and/or MRR and provide a written report summarizing all of DHCS’ review findings within 30 calendar days following the date of the FSR and/or MRR.

Within 30 calendar days from the date of the DHCS-conducted site review report, KHS must provide a CAP to DHCS responding to all cited deficiencies documented in the report. KHS’ CAP response must include:

- a. The identified deficiency(ies) and
- b. A description of action(s) taken to correct the deficiency(ies)

If a deficiency is determined to require long-term corrective action, KHS’ CAP response must include indication that KHS has:

- a. Initiated remedial action(s)
- b. Developed a plan to achieve an acceptable level of compliance, and

- c. Documented the date the provider is in full compliance or when full compliance will be achieved.

Additional supporting documentation and remedial action may be required if DHCS determines CAPs are insufficient to correct deficiencies.

KHS will be notified approximately four weeks in advance of DHCS-conducted site reviews. KHS must notify its providers in advance of site reviews, whether the site review is conducted by DHCS or by KHS. However, inspection of KHS' facilities or other elements of a review may be conducted without prior notice, in conjunction with other medical surveys or as part of an unannounced inspection program.

KHS is responsible for ensuring that our delegates and/or subcontracted entities comply with all applicable state and federal laws and regulations, contract requirements, and other DHCS guidance, including APLs and Plan Letters (PLs). These requirements must be communicated by KHS to all delegated entities and subcontractors.

All contracting plans within a county have equal responsibility and accountability for the coordination and consolidation of provider site reviews and therefore are expected to participate in these collaborative activities.

All Health Plans within the county shall collaborate to determine processes for scheduling facility site reviews, notification of survey status and/or results on shared providers. Site review responsibilities may be shared equally by all plans within a county, delegated to one or more plans or individual physician practices (e.g., IPA) and/or subcontracted to other agencies or entities. The Chief Medical Officer or their designee is ultimately responsible for site review activities.

A Full Scope Site Review Survey can be waived for a pre-contracted provider site if the provider or another local plan has documented proof that a current full scope survey with a passing score was completed by the other Health Plan within the past 3 years. Prior to initiating plan operation in a service area, an initial full scope survey shall be completed on 5% of the provider network, or on 30 PCP sites, whichever is greater in number. The 5% or 30 PCP sample sites shall include a variety of providers from throughout the provider network and/or from each subcontracted entity. If there are 30 or fewer PCP sites in the network, 100% of the sites must be completed prior to beginning plan operations. Corrective actions shall be completed per APL 20-006. An initial full scope survey shall be completed on 100% of the remaining proposed PCP sites within the first six (6) months of plan operation or expansion.

The most current site review and medical record surveys shall be shared with and accepted by all Health Plans both intra and inter-county contracting with the provider(s). Each Health Plan is responsible for tracking the survey status of all contracted Medi-Cal managed care provider sites.

Delegation or site review responsibilities are a determination made by each plan. However, each collaborating health plan shall determine the acceptance of surveys completed by the entities delegated or subcontracted by another local plan.

2.0 INTERIMREVIEW

Each Health Plan is responsible for systematic monitoring of all PCP sites between each regularly scheduled full scope site review surveys which includes the fourteen (14) critical elements. PCP office self-assessment system may be considered as part of the overall monitoring. Other performance assessments may include previous deficiencies, patient satisfaction, grievance, and utilization management data.

A. Deficiencies identified during the monitoring process will be noted in a Corrective Action Plan to assist the PCP in meeting requirements. This Corrective Action Plan (CAP) includes deficiencies noted during the monitoring review, specified corrective actions, their actions, their evidence of corrections, date corrections, date corrections were implemented, physician or designee responsible for corrective actions and name and title of Reviewer. In addition, there is a section for Health Plan verification of Corrections.

The CAP includes Disclosure and Release statements regarding CAP submission timeline and authorization to furnish results of the reviews and corrective actions to Health Plans participating in the collaboration, government agencies that have authority over the Health Plans and authorized county entities in the state of California.

The signed Corrective Action Plan documents are placed in the PCP's file that is maintained by the Health Plan responsible for completing the review.

As providers at a site may change over time, the timeline for provider recredentialing and subsequent site review surveys may become independent processes that are not on a synchronized schedule.

3.0 FULL SCOPE SITE REVIEW

A Full Scope Site Review shall be the system-wide standard for conducting the initial and subsequent periodic reviews of contracted Primary Care Physician sites.

A full scope review consists of the DHCS Facility Site Review Survey and Medical Record Review Survey. Reviewers shall only review criteria that are appropriate to their level of education expertise, training and professional licensing scope of practice as determined by the California statute. The responsible reviewer for each survey shall be at minimum an RN, who shall sign the site review and/or medical record survey.

Facility Site and Medical Record Reviews are performed at least every three (3) years.

3.1 INITIAL SITE REVIEW

The initial site review is the first onsite inspection of a site that has not previously had a full scope survey or a PCP site that is returning to the Medi-Cal managed care program and has not had a passing full scope survey within the past three (3) years. It is the responsibility of the Health Plan

that performed the Facility Site and Medical Record Review to follow-up and close any provider Corrective Action Plan(s).

Health Plans may review sites more frequently when determined necessary based on monitoring, evaluation, or corrective action plan (CAP) follow-up issue.

4.0 FACILITY SITE REVIEW PROCESS

The Site Reviewer will conduct the Facility Site review with the DHCS Site Review tool and accompanying interpretive guidelines.

There are fourteen (14) critical survey elements identified to have potential for adverse effect on patient health or safety. The elements include:

- A. Exit doors and aisles are unobstructed and egress (escape) accessible.
- B. Airway management equipment: oxygen delivery system, nasal cannula or mask, bulb syringe, Ambu bag, appropriate to practice and populations served are present on site
- C. Emergency medicine such as asthma, chest pain, hypoglycemia, and anaphylactic reaction management: Epinephrine 1:1000 (injectable), and Benadryl 25 mg. (oral) or Benadryl 50 mg./ml (injectable), Naloxone, chewable Aspirin 81 mg, Nitroglycerine spray/tablet, bronchodilator medication (solution for nebulizer or metered dose inhaler), and glucose. Appropriate sizes of ESIP needles/syringes and alcohol wipes.
- D. Only qualified/trained personnel retrieve, prepare or administer medications.
- E. Physician review and follow-up or referrals/ consultation reports and diagnostic test results.
- F. Only lawfully authorized persons dispense drugs to patients;
- G. Drugs and Vaccines are prepared and drawn only prior to administration.
- H. Personal protective equipment (PPE) for Standard Precautions is readily available for staff use.
- I. Needlestick safety precautions are practiced on-site.
- J. Blood, other potentially infectious materials (specimens) and regulated wastes (sharps/biohazardous non-sharps) are placed in appropriate leak-proof, labeled containers for collection, processing, storage, transport, or shipping.
- K. Cold chemical sterilization/high level disinfection
 - a. Staff demonstrate/verbalize necessary steps/process to ensure sterility and/or high-level disinfection of equipment.
 - b. Appropriate PPE is available, exposure control plan, MSDS and clean up instructions in the event of a cold chemical sterilant spill.
- L. Autoclave steam sterilization Spore testing of autoclave/steam sterilizer is completed (at least monthly), with documented results.
- M. Management of positive mechanical, chemical, and/or biological indicators of the sterilization process

The PCP and/or site contact will be notified of all critical element deficiencies found during a full scope site survey, focused survey or monitoring visit.

All critical element deficiencies shall be corrected by the provider within ten (10) business days of the survey date. All corrected critical element deficiencies will be verified as completed by the site reviewer within thirty (30) calendar days of the survey date. Sites found deficient in any critical element during the Full Scope Site Review shall be required to correct 100% of the survey deficiencies regardless of the survey score.

The Site Reviewer will calculate the Facility Site Survey tool score and at the exit interview discuss the findings with the PCP and/or site contact focusing on those area that are critical elements, other areas requiring improvement and the need for a corrective action plan.

ATTACHMENTS:

- A. Medical Record Review Standards
- B. Medical Record Review Tool
- C. Facility Site Review Standards
- D. Facility Site Review Tool
- E. Attachment C: Physical Accessibility Review Survey

REFERENCES:

Department of Health Care Services (DHCS) Policy Letter (PL) 12-006

Department of Health Care Services (DHCS) All-Plan Letter (APL) 15-023

Department of Health Care Services (DHCS) All-Plan Letter (APL) 22-017

DHCS All Plan Letter 15-023 – Facility Site Review Tools for Ancillary Service and Community Based Adult Services Providers

DHCS Medi-Cal Contract Exhibit A, Attachment III, Subsection 5.2.14

Revisions 2022.10 to 2022.12: Policy updated to comply with DHCS APL 22-017. The DHCS approved revisions on 2/1/2023. **10.2022:** DMHC Approved, Filing No. 20223599. **9.2022:** Policy accepted under the DHCS File and Use criteria. **Revision 2022.08:** Policy updated to comply with All-Plan Letter (APL) 20-006 and PARs survey. **Revision 2021.11:** Policy was approved by PAC and QI-UM Committees. **Revision 2021.10:** Policy created by Director of Quality Improvement and RN, DHCS Certified Master Trainer to comply with DHCS All-Plan Letter (APL) 20-006.

¹See Title 28 CCR, section 1300.80

² Health and Safety Code (HSC), section 1342.8.

³ Business and Professions Code (BPC), section 2725.

Medical Record Review Standards

Purpose: The Medical Record Review (MRR) Standards provide instructions, rules, regulations, parameters, and indicators for conducting medical record reviews using the MRR Tool. The site reviewer must use these Standards for measuring, evaluating, assessing, and making decisions.

Medical Record Selection: Medical records shall be randomly selected using methodology decided upon by the reviewer. Ten (10) medical records are reviewed for each primary care physician (PCP) site. For sites with *only* adult or *only* pediatric patient members, all ten records reviewed will be in *only* one preventive care criteria. For sites with adult and pediatric members, five (5) adults and five (5) pediatrics preventive criteria will be reviewed. For PCP sites where the OB-GYN providers both specialty and preventive services, based on the age of the patient, reviewer must review either adult or pediatric preventive criteria as well as OB Comprehensive Perinatal Services Program (CPSP) criteria.

PCP sites that document patient care performed by multiple PCPs in the same medical record are considered "shared." The MCP must consider shared medical records as those that are not identifiable as "separate" records belonging to any specific PCP. Scores calculated on shared medical records apply only to PCPs sharing the records. A minimum of ten shared records shall be reviewed for 2-3 PCPs, 20 records for 4-6 PCPs, and 30 records for 7 or more PCPs based on specialty and/or population served.

Example for determining the number of medical records to review:

A site that has three (3) providers, two (2) providers see only adults and share records, and one (1) only see pediatrics and does not share records, 10 medical records on the two providers who share medical records and 10 medical records on the provider who does not share records will be conducted and scored separately. A total of 20 medical records shall be reviewed for this site. Two (2) scores will be reported for this site.

Reviewers are expected to determine the most appropriate method(s) on each site to ascertain information needed to complete the review. Review criteria that shall be reviewed *only* by a registered nurse (RN), nurse practitioner (NP), physician (MD), physician assistant (PA), Certified Nurse Midwife (CNM), or Licensed Midwife is labeled "👤📁
RN/NP/MD/PA/CNM/LM".

Reviewers must ensure confidentiality on Protected Health Information (PHI) or Personally Identifiable Information (PII).

Scoring: The review score is based on a review standard of 10 records per individual primary care provider (PCP). Documented evidence found in the hard copy (paper) medical records and/or electronic medical records, including immunization registries, are used for review criteria determinations. Compliance levels are:

An Exempted Pass is 90%.

Conditional Pass is 80-89%.

Failure is below 80%.

The minimum passing score is 80%. A corrective action plan (CAP) is required for a total MRR score below 90%. Also, any section score of less than 80% requires a CAP for the entire MRR, regardless of the total MRR score.

Not Applicable (N/A) applies to any criterion that does not apply to the medical record being reviewed and must be explained in the comment section.

Directions: Score one point if criterion is met. Score zero points if criterion is not met. Do not score partial points for any criterion.

If 10 shared records are reviewed, score calculation shall be the same as for 10 records reviewed for a single PCP.

If 20 records are reviewed, divide total points given by the “adjusted” total points possible.

If 30 records are reviewed, divide total points given by the “adjusted” total points possible.

Multiply by 100 to calculate percentage rate.

Reviewers have the option to request additional records to review but must calculate scores accordingly.

Scoring Example:

Step 1: Add the points given in each section.

Step 2: Add the points given for all six sections.

(Format points given)

(Documentation points given)

(Coordination of Care points given)

(Pediatric Preventive points given)

(Adult Preventive points given)

+ (OB/CPSP Preventive points given)

= (Total points given)

Step 3: Subtract the “N/A” points from total points possible.
(Total points possible)
– (N/A points)
= (“Adjusted” total points possible)

Step 4: Divide total points given by the “adjusted” points possible, then multiply by 100 to calculate percentage rate.

$\frac{\text{Total points given}}{\text{“Adjusted” total points possible}}$	Example:	$\frac{267}{305} = 0.875 \times 100 = 88\%$
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Rationale: A well-organized medical record keeping system supports effective patient care, information confidentiality and quality review processes.

I. Format Criteria	
An individual medical record is established for each member.	Practitioners are able to readily identify each individual treated. A medical record is started upon the initial visit. ¹ “Family charts” are not acceptable.
A. Member identification is on each Page.	<ul style="list-style-type: none"> • Member identification includes first and last name, and a unique identifier established for use on clinical site. • Electronically maintained records and printed records from electronic systems must contain member identification.
B. Individual personal biographical information is documented.	<p>Personal biographical information includes:</p> <ul style="list-style-type: none"> ○ Date of birth ○ Current address ○ Home/work phone numbers ○ Name of parent(s)/legal guardian if member is a minor <p>If member refused to provide information, “refused” is documented in the medical record. Do not deduct points if member has refused to provide all personal information requested by the practitioner.</p>
C. Emergency “contact” is identified.	<p>The name and phone number of an “emergency contact” person is identified for all members. Listed emergency contacts may include:</p> <ul style="list-style-type: none"> ○ Spouse, relative or friend, and must include at least one of the following: ○ Home, work, pager, cellular, or message phone number. <ul style="list-style-type: none"> • If the member is a minor, the primary (first) emergency contact person must be a parent or legal guardian and then other persons may be listed as additional emergency contacts. • Adults and emancipated minors may list anyone of their choosing. • If a member refuses to provide an emergency contact, “refused” is noted in the record. Do not deduct points if member has refused to provide personal information requested by the practitioner.

¹ See the U.S. Department of Health and Human Services Summary of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, available at: <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html>.

I. Format Criteria	
	<ul style="list-style-type: none"> • Next of kin category is not considered as an emergency contact. The member's emergency contact may be different from the next of kin.
D. Medical records are maintained and organized	<ul style="list-style-type: none"> • Contents and format of printed and/or electronic records within the practice site are uniformly organized, securely fastened, attached or bound to prevent medical record loss. • Hard copy printed documents shall belong to the medical record established for each member (e.g., reusing the blank side of printed documents from another member is not acceptable and should be scored a "0"). • Medical Record information should be readily available.
E. Member's assigned and/or rendering PCP is identified.	<ul style="list-style-type: none"> • The assigned and/or rendering PCP is <i>always</i> identified when there is more than one PCP on site and/or when the member has selected health care from a non-physician medical practitioner. • Various methods can be used to identify the assigned PCP, reviewers must identify specific method(s) used at each individual site such as Health Plan ID Card, practitioner stamp, etc. • If there is only one PCP/Practitioner onsite and is not identified, reviewer may score "N/A".
F. Primary language and linguistic service needs of non-or of limited-English proficiency (LEP) or hearing/speech-impaired persons are prominently noted.	<ul style="list-style-type: none"> • The primary language is prominently documented at least once in the medical record. • Language documentation is not necessary, score "N/A," if English is the primary language. However, if "English" is documented, the point may be given. <p>Note: Title VI of the Civil Rights Act of 1964 prohibits recipients of federal funds from providing services to LEP persons that are limited in scope or lower in quality than those provided to others. Since Medi-Cal is partially funded by federal funds, <i>all</i> Plans with Medi-Cal LEP members must ensure that these members have equal access to all health care services.²</p>

² See All Plan Letter (APL) 21-004: Standards for Determining Threshold Languages, Nondiscrimination Requirements, and Language assistance Services, or any superseding APL. APLs are searchable at: <https://www.dhcs.ca.gov/formsandpubs/Pages/AllPlanLetters.aspx>

I. Format Criteria

G. Person or entity providing medical interpretation is identified.

- Requests for language and/or interpretation services by a non-or limited-English proficient member are documented.
- Member refusal of interpreter services may be documented at least once and be accepted throughout the member's care unless otherwise specified.
- If bilingual staff are asked to interpret or translate, they should be qualified to do so. Assessment of ability, training on interpreter ethics and standards, and clear policies that delineate appropriate use of bilingual staff, staff or contract interpreters and translators, will help ensure quality and effective use of resources.
- Those utilizing the services of interpreters and translators should request information about certification, assessments taken, qualifications, experience, and training. Quality of interpretation should be a focus of concern for all recipients.
- Family or friends should not be used as interpreters, unless specifically requested by the member and documented in the member's chart.
- Minors (under 18 years old) accompanying member shall not be used as an interpreter.
- The Affordable Care Act (ACA) 2010 section 1557: prohibits from using low-quality video remote interpreting services or relying on unqualified staff, translators when providing language assistance services.
- Sign language interpreter services may be utilized for medically necessary health care services and related services such as obtaining medical history and health assessments, obtaining informed consents and permission for treatments, medical procedures, providing instructions regarding medications, explaining diagnoses, treatment and prognoses of an illness, providing mental health assessment, therapy or counseling.

Various documents can be accepted to document linguistic service needs such as Individual Health Education Behavior Assessment (IHEBA)/Staying Healthy Assessment (SHA), intake form, demographic form, Electronic Medical Record (EMR) fields, consent forms, etc.

I. Format Criteria	
	<p>Note: See Commonly Asked Questions and Answers Regarding LEP Individuals, available at: https://www.lep.gov/faq/faqs-rights-lep-individuals/commonly-asked-questions-and-answers-regarding-limited-english. See also Title 22 California Code of Regulations (CCR) Section 51309.5. The CCR is searchable at: https://govt.westlaw.com/calregs/Search/Index.</p>
H. Signed Copy of the Notice of Privacy	<p>The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The right to inspect, review and receive a copy of the medical records is covered by the Privacy Rule.³</p>

³ See the U.S. Department of Health and Human Services Understanding of Some of HIPAA's Permitted Uses and Disclosures, available at: <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/permitted-uses/index.html>.

Rationale: Well-documented records facilitate communication and coordination and promote efficiency and effectiveness of treatment.

  RN/NP/MD/PA/CNM/LM

II. Documentation Criteria	
A. Allergies are prominently noted.	<ul style="list-style-type: none"> Allergies and adverse reactions are listed in a prominent, easily identified, and consistent location in the medical record. If member has no allergies or adverse reactions, “No Known Allergies” (NKA), “No known Drug Allergies” (NKDA), or ∅ is documented.⁴
B. Chronic problems and/or significant conditions are listed.	<ul style="list-style-type: none"> Documentation may be on a separate “problem list,” or a clearly identifiable problem list in the progress notes. All chronic or significant problems are considered current if no “end date” is documented. <p>Note: Chronic conditions are current long-term, on-going conditions with slow or little progress.⁵</p>
C. Current continuous medications are listed.	<ul style="list-style-type: none"> Documentation may be on a separate “medication list,” or a clearly identifiable medication list in the progress notes. List of current, on-going medications identifies the medication name, strength, dosage, route (if other than oral), and frequency. Discontinued medications are noted on the medication list or in progress notes.⁶
D. Appropriate Consents are present.	<ol style="list-style-type: none"> Consent must be obtained prior to release of patient information.⁷ Adults, parents/legal guardians of a minor or emancipated minor may sign consent forms for operative and invasive procedures.⁸ Persons under 18 years

⁴ 22 CCR 70527 and 28 CCR 1300.80

⁵ 22 CCR 70527 and 28 CCR 1300.80

⁶ 22 CCR 70527 and 28 CCR 1300.80

⁷ 22 CCR 73524, 22 CCR 51009, and Title 45, Code of Federal Regulations Section 164.524. The CFR is searchable at: <https://www.ecfr.gov>.

⁸ An invasive procedure is a medical procedure that invades (enters) the body, usually by cutting or puncturing the skin or by inserting instruments into the body. Very minor procedures such as drawing blood testing, umbilical cord blood donations and a few other very specific

II. Documentation Criteria	
	<p>of age are emancipated if they have entered into a valid marriage, are on military active duty, or have received a court declaration of emancipation under the CA Family Code, Section 7122.⁹</p> <p>Note: Human sterilization requires the Department of Health Care Services (DHCS) Consent Form PM 330 if services are performed at the site.</p>
<p>E. Advance Health Care Directive information is offered. (Adults 18 years of age or older; emancipated minors).</p>	<ul style="list-style-type: none"> • Adult medical records include documentation of whether the member has been <i>offered</i> information or has executed an Advance Health Care Directive.¹⁰ <p>The Physician Orders for Life-Sustaining Treatment (POLST) form and Five Wishes are acceptable if appropriately completed and signed by necessary parties.¹¹</p> <p>Note: Advance Health Care Directive Information is reviewed with the member at least every 5 years and as appropriate to the member’s circumstance.</p>
<p>F. All entries are signed, dated and legible.</p>	<p>Signature includes:</p> <ul style="list-style-type: none"> • First initial, last name, and title of health care personnel providing care, including Medical Assistants. • Initials and titles may be used only if signatures are specifically identified elsewhere in the medical record (e.g. signature page). • Stamped signatures are acceptable, but must be authenticated, meaning the stamped signature can be verified, validated, confirmed, and is countersigned or initialed. <p>Dated entries include:</p> <ul style="list-style-type: none"> • Month/day/year. • Entries are in reasonably consecutive order by date.

tests are not considered invasive and do not require a consent. Consent is implied by entering the provider’s office or lab and allowing blood to be drawn. (Ref: National Institutes of Health; American Cancer Society)

⁹ California Law is searchable at: https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml.

¹⁰ See Probate Code, Section 4701, 42 CFR 422.128, 42 CFR 489.100, and APL 05-010.

¹¹ See AB 3000, Chapter 266, Statutes of 2008, available at:

https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=200720080AB3000.

II. Documentation Criteria

- Handwritten documentation does not contain skipped lines or empty spaces where information can be added. Entries are not backdated or inserted into spaces above previous entries.
- Omissions are charted as a new entry.
- Late entries are explained in the medical record, signed and dated.

Legibility means the record entry is readable by a person other than the writer. Handwritten documentation, signatures, and initials are entered in ink that can be readily/clearly copied. Only standard abbreviations are used. All medical record documentation must be in English.¹²

Note:

- In EMR, methods to document signatures (and/or authenticate initials) will vary and must be individually evaluated.
- Signature page may be in the member's medical record or available elsewhere onsite and all previous and current employees who document in medical records need to be included on the signature page.
- Reviewers should assess the log-in process and may need to request printouts of entries.

See the Centers for Medicare and Medicaid Services' (CMS) Guidance on Medicaid Documentation for Medical Office Staff, available at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/docmatters-officestaff-factsheet.pdf>.

G. Errors are corrected according to legal medical documentation standards.

- The person that makes the documentation error corrects the error.

Example correction methods:

- Single line drawn through the error, with the writer's initial and date written above or near the lined-through entry.
- Single line and initial.

¹² ACA Section 1557

II. Documentation Criteria

- The corrected information is written as a separate entry and includes date of the entry, signature (or initials), and title.

There are no unexplained cross-outs, erased entries or use of correction fluid. Both the original entry and corrected entry are clearly preserved.

Note: Reviewers must determine the method used for error corrections for EMR on a case by case basis. This should include the log-in process and whether the EMR allows for corrections to be made after entries are made.

Rationale: Medical records support coordination and continuity-of-care with documentation of past and present health status, medical treatment and future plans of care.

  RN/NP/MD/PA/CNM/LM

III. Coordination Criteria	
A. History of present illness or reason for visit is documented.	Each focused visit (e.g., primary care, follow-up ER/urgent care, hospital discharge, etc.) includes a documented history of present illness or reason for visit.
B. Working diagnoses are consistent with findings.	<p>Each visit has a documented “working” diagnosis/impression derived from a physical exam, and/or “Subjective” information such as chief complaint or reason for the visit as stated by member/parent. The documented “Objective” information (such as assessment, findings and conclusion) relate to the working diagnoses.</p> <p>Note: For scoring purposes, reviewers shall <i>not make determinations</i> about the “<i>rightfulness or wrongfulness</i>” of documented information but shall initiate the peer review process or internal investigation per health plan policy as appropriate.</p>
C. Treatment plans are consistent with diagnoses.	<p>A plan of treatment, care and/or education related to the stated diagnosis is documented for each diagnosis.</p> <p>Note: For scoring purposes, reviewers shall <i>not make determinations</i> about the “<i>rightfulness or wrongfulness</i>” of treatment rendered or care plan but shall initiate the peer review process or internal investigation per health plan policy as appropriate.</p>
D. Instruction for follow-up care is documented.	<ul style="list-style-type: none"> • Specific follow-up instructions and a definite time for return visit or other follow-up care is documented. • Time period for return visits or other follow-up care is definitively stated in number of days, weeks, months, or PRN (as needed). • Every visit with the provider shall have follow-up instructions.
E. Unresolved continuing problems are addressed in subsequent visit(s).	<ul style="list-style-type: none"> • Previous complaints and unresolved or chronic problems are addressed in subsequent notes until problems are resolved or a diagnosis is made.

III. Coordination Criteria

	<ul style="list-style-type: none">• Each problem need not be addressed at every visit as long as the provider documents a reason for deferring the unresolved problem(s) for subsequent visits.• Documentation demonstrates that the practitioner follows up with members about treatment regimens, recommendations, and counseling.
F. There is evidence of practitioner review of specialty/consult/referral reports and diagnostic test results.	<ul style="list-style-type: none">• There is documented evidence of practitioner review of records such as diagnostic studies, lab tests, X-ray reports, consultation summaries, inpatient/discharge records, emergency and urgent care reports, and all abnormal and/or “STAT” reports.• Evidence of review may include the practitioner’s initials or signature on the report, notation in the progress notes, or other site-specific method of documenting practitioner review. <p>Note: Electronically maintained medical reports must also show evidence of practitioner review and may differ from site to site. Evidence of practitioner review on any page of the report(s) or diagnostic result(s) that have multiple pages is acceptable.</p>
G. There is evidence of follow-up of specialty/consult/referrals made, and results/reports of diagnostic tests, when appropriate.	<p>Documentation includes:</p> <ul style="list-style-type: none">• Consultation reports and diagnostic test results for ordered requests.• <u>Abnormal test</u> results/diagnostic reports have explicit notation in the medical record or separate system, including attempts to contact the member/guardian, follow-up treatment, instructions, return office visits, referrals and/or other pertinent information.• Missed/broken appointments for diagnostic procedures, lab tests, specialty appointments and/or other referrals are noted, and include attempts to contact the member/parent and results of follow-up actions. <p>If diagnostic appointments or referrals are documented in a separate system from medical records, they must be readily accessible and meet the medical retention requirements.</p> <p>Note:</p>

III. Coordination Criteria

- Abnormal test results/diagnostic reports without follow-up documentation for specific pediatric or adult preventive screening criteria/diagnostic tests will be scored under this criterion.
- If results are normal and there are no missing reports, then the reviewer may score “N/A” for this criterion.
- If specific pediatric or adult preventive screenings are ordered and there is no documentation of normal results and/or follow-up, the reviewer shall score this under the appropriate preventive services criteria.
- If the provider/staff does not follow up or attempt outreach to the member regarding a missed specialty referral, give a zero “0” score.

Reviewer must assess the process of outreach efforts/follow-up contacts and documentation of attempts. The process must include at least one attempt for outreach/follow-up contact.

H. Missed primary care appointments and outreach efforts/follow-up contacts are documented.

Documentation includes:

- Incidents of missed/broken appointments, cancellations or “No shows” with the PCP office.
- Attempts to contact the member or parent/guardian and the results of follow-up actions. Missed and/or canceled appointments and contact attempts must be documented in the patient’s medical record.

Note: Reviewer must assess the process of outreach efforts/follow-up contacts and documentation of attempts. The process must include at least one attempt for outreach/follow-up contact.

Rationale: Pediatric preventive services are provided to members under 21 years of age in accordance with current American Academy of Pediatrics (AAP) bright future and US Preventive Task Force (USPSTF) recommendations. See the DHCS Boilerplate contract, available at: <https://www.dhcs.ca.gov/provgovpart/Documents/2-Plan-Non-CCI-Boilerplate-Final-Rule-Amendment.pdf>.

 **RN/NP/MD/PA/CNM/LM**

IV. Pediatric Preventive Criteria	
A. Initial Health Assessment (IHA) includes H&P and IHEBA	<p><u>New Members</u> IHA must be completed within 120 days of plan enrollment or PCP effective date (whichever is more recent) or documented within the 12 months prior to Plan enrollment/PCP effective date.</p> <p>A complete IHA enables the PCP to assess current acute, chronic, and preventive needs and to identify those Members whose health needs require coordinated services with appropriate community resources/other agencies not covered by the Plan.</p> <p>References: Policy Letter (PL) 08-003 or current version and PL 13-001 or current version</p>
1) Comprehensive History and Physical	<p><u>New members</u> The history must be comprehensive to assess and diagnose acute and chronic conditions it includes:</p> <ul style="list-style-type: none"> ○ History of present illness ○ Past medical history ○ Social history ○ Review of Organ Systems (ROS) <p>If an H&P is not found in the medical record, the reasons (e.g., member/parent refusal, missed appointment) and contact attempts to reschedule are documented.</p>
2) Individual Health Education Behavioral Assessment (IHEBA)	<p><u>New members</u> An age-appropriate IHEBA (“Staying Healthy” or other DHCS-approved tool such as AAP Bright Future is a screening tool that may assist in screening for risk factors for many preventive care criteria (e.g., alcohol misuse, STI, HIV, Tobacco, etc.) is completed by the member or parent/guardian within 120 days of the effective date of enrollment into the Plan or PCP effective date (whichever is more recent), or within the 12 months prior to Plan enrollment/PCP effective date. Staff may assist.</p>

IV. Pediatric Preventive Criteria

	<p>The IHEBA shows evidence of practitioner review:</p> <ul style="list-style-type: none"> ○ Printed name ○ Signature ○ Date ○ Interventions, which may be documented on the IHEBA form, in progress notes, or other areas of the paper or electronic medical record system. <p>If an initial IHEBA is not found in the medical record, the reasons (e.g., member/parent refusal, missed appointment) and contact attempts to reschedule are documented.</p> <ul style="list-style-type: none"> • <u>Give a point</u>: 1) IHEBA is complete, reviewed, and signed by the provider. • <u>Give a N/A</u>: 2) The Provider documents patient refusal of IHEBA in Electronic Health Record chart notes. • <u>Give a zero</u>: 1) IHEBA was not reviewed/signed by the provider, 2) IHEBA is refused by the patient (“refused” box checked) and the provider has not signed the form. <p>SHA Questionnaires are available at: http://www.dhcs.ca.gov/formsandpubs/forms/pages/stayinghealthy.aspx</p>
<p>B. Subsequent Comprehensive Health Assessment</p>	<p><u>Existing/Current Members</u> The examination must be comprehensive, focus on specific assessments that are appropriate for the child’s or adolescent’s age, developmental phase, and needs building on the history gathered earlier. The physical examination provides opportunities to identify silent or subtle illnesses or conditions and time for the health care professional to educate children and their parents about the body and its growth and development. See the AAP/Bright Futures Recommendations for Preventive Pediatric Health Care, available at: https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf</p>
<p>1) Comprehensive History and Physical Exam completed at age-appropriate frequency</p>	<ul style="list-style-type: none"> • Health assessments containing age-appropriate requirements are provided per the most recent AAP periodicity schedule. • Assessments and identified problems are documented in the progress notes.

IV. Pediatric Preventive Criteria	
	<ul style="list-style-type: none"> • Follow-up care or referral is provided for identified physical health problems as appropriate. <p>Note: The AAP periodicity exam schedule is more frequent than the Child Health and Disability Prevention Program (CHDP) periodicity examination schedule. The AAP scheduled visit must include all assessment components required by the CHDP program for the lower age nearest to the current age of the child.¹³</p>
2) Subsequent Periodic IHEBA	<ul style="list-style-type: none"> • An age-appropriate IHEBA is re-administered when the member has reached the next specific age interval designated by DHCS' Managed Care Quality and Monitoring Division. • The PCP must review previously completed IHEBA questionnaires with parent, guardian, or adolescent annually before reaching the next age group. • Documentation requirements are the same as the initial IHEBA. <p>The SHA Questionnaires are available at: http://www.dhcs.ca.gov/formsandpubs/forms/pages/stayinghealthy.aspx</p>
c. Well-child Visit	<p>The Bright Futures/AAP developed a set of comprehensive health guidelines for well-childcare, known as the "periodicity schedule."¹⁴ It is a schedule of screenings and assessments recommended at each well-child visit from infancy through adolescence.</p> <p>Screening pertains to an assessment of the eligible population for presence of risk factors.</p> <ul style="list-style-type: none"> • If the patient is positive for risk factors, (e.g., obesity, menstrual status, etc.) age and gender parameters of the criterion the provider shall offer and document appropriate follow-up intervention(s) (e.g., diagnostic testing, counseling, referral to specialist, documentation of patient refusal, etc.).

¹³ See the AAP/Bright Futures Recommendations for Preventive Pediatric Health Care, available at: https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf

¹⁴ The Bright Futures/AAP periodicity schedule is available at: https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf.

IV. Pediatric Preventive Criteria

- Providers who fail to document the presence or absence of risk factors shall receive zero points since the patient's risk status could not be determined and the preventive care criterion was not addressed.
- Evidence of risk assessments and screenings for other preventive care criteria may be found in the ***IHEBA***, progress notes, comprehensive history forms, or elsewhere in the medical record.

Note: The AAP does not approve nor endorse any specific tool for screening purposes.

Examples of screening tools are available at: <https://screeningtime.org/star-center/#/screening-tools>

<https://www.healthychildren.org/English/family-life/health-management/Pages/Well-Child-Care-A-Check-Up-for-Success.aspx>

1) Alcohol Use Disorder Screening and Behavioral Counseling

Per AAP recommendations, alcohol use disorder screening and behavioral counseling should begin at 11 years of age. If the patient is positive for risk factors, provider shall offer and document appropriate follow-up intervention(s).

Brief Assessment and Screening

When a screening is positive, validated assessment tools should be used to determine if unhealthy alcohol use is present. Validated assessment tools may be used without first using validated screening tools. The AAP recommended assessment tool is available at: <http://crafft.org>.

Brief Interventions and Referral to Treatment

When brief assessments reveal unhealthy alcohol use, brief misuse counseling with appropriate referral for additional evaluation and treatment options, referrals, or services must be offered.

Brief interventions must include the following:

- [Providing feedback to the patient regarding screening and assessment results;](#)

IV. Pediatric Preventive Criteria

- [Discussing negative consequences that have occurred and the overall severity of the problem;](#)
- [Supporting the patient in making behavioral changes; and](#)
- [Discussing and agreeing on plans for follow-up with the patient, including referral to other treatment if indicated.](#)

The AAP/Bright Futures periodicity schedule is available at: https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf

For details on Alcohol and Drug Screening, Assessment, Brief Interventions and Referral to Treatment, refer to APL 21-014 or any superseding APL.

Please refer to the link below to The Medi-Cal Provider Manual: <https://www.dhcs.ca.gov/formsandpubs/publications/Pages/Manuals.aspx>

2) Anemia Screening

Per AAP, perform risk assessment or screening at 4, 15, 18, 24, and 30 months, 3 years old, and then annually thereafter. Test serum hemoglobin at 12 months old. If the patient is positive for risk factors, provider shall offer and document appropriate follow-up intervention(s).

Acceptable evidence of anemia screening: evaluate patient's diet, nutrition supplement intake, menstrual status, medical history for chronic conditions, etc.

Chronic conditions to assess that are associated with anemia:

- A diet consistently low in iron, vitamin B-12 and folate
- Heavy Menstruation. See link for signs of heavy menstrual bleeding: <https://www.acog.org/womens-health/faqs/heavy-menstrual-bleeding>
- Pregnancy
- Slow, chronic blood loss from an ulcer; Crohn's disease, celiac disease, cancer, kidney failure, diabetes, etc.

The Bright Futures/AAP periodicity schedule is available at: https://www.aap.org/en-us/documents/periodicity_schedule.pdf.

IV. Pediatric Preventive Criteria

	<p>See the National Institutes of Health information on Anemia, available at: https://www.nhlbi.nih.gov/health-topics/anemia#:~:text=Some%20people%20are%20at%20a,such%20as%20chemotherapy%20for%20cancer.</p> <p>See the Center for Disease Control and Prevention’s (CDC) information on heavy menstrual bleeding, available at: https://www.cdc.gov/ncbddd/blooddisorders/women/menorrhagia.html.</p>
3) Anthropometric measurements	<p>For each well exam:</p> <ul style="list-style-type: none">• <u>Infants up to 24 months old</u>: assess for length/height and head circumference (HC). Measurements are plotted in a World Health Organization (WHO) growth chart.• <u>2-21 years old</u>: assess for height, weight, and body mass index (BMI) measurements are plotted in a CDC growth chart.• Provider should measure and track BMI to identify patient at risk for <u>being</u> overweight, obese, or underweight. Patients identified as overweight and/or obese are provided counseling for nutrition to promote healthy eating habits and regular physical activity. <p>For additional information on anthropometric measurements, refer to the following link: https://www.dhcs.ca.gov/services/chdp/Documents/HAG/4AnthropometricMeasure.pdf</p> <p>Note: Site is deficient if anthropometric measurements are not plotted on the appropriate growth chart.¹⁵</p>
4) Anticipatory Guidance	<ul style="list-style-type: none">• Must be documented at each well child visit.• Is given by the health care provider to assist parents or guardians in the understanding of the expected growth and development of their children.• Specific to the age of the patient, includes information about the benefits of healthy lifestyles and practices that promote injury and disease prevention

¹⁵ CDC growth charts are available at: <https://www.cdc.gov/growthcharts/>.

IV. Pediatric Preventive Criteria

https://brightfutures.aap.org/Bright%20Futures%20Documents/BF_PreventiveServices_Tipsheet.pdf#search=document%20anticipatory%20document

5) Autism Spectrum Disorder (ASD) Screening

ASD screening must be performed at 18 months and 24 months of age based on AAP periodicity “Bright Futures”. If the patient is positive for risk factors, provider shall offer and document appropriate follow-up intervention(s).

ASD screening tools examples:

- Ages and Stages Questionnaires (ASQ)
- Communication and Symbolic Behavior Scales (CSBS)
- Parents' Evaluation of Developmental Status (PEDS)
- Modified Checklist for Autism in Toddlers (MCHAT)
- Screening Tool for Autism in Toddlers and Young Children (STAT)
- Survey of Well-being of Young Children (SWYC) screening tools (assess three domains of child functioning: developmental domain, emotional/behavioral domain, and family context)

Refer to APL 19-014, Responsibilities for Behavioral Health Treatment Coverage for Members Under the Age of 21, and APL 19-010, Requirements for Coverage of Early and Periodic Screening, Diagnostic, and Treatment Services for Medi-Cal Members Under the Age of 21, or any superseding APLs for more information on ASD.

Screening should occur per “Identification, Evaluation, and Management of Children With Autism Spectrum Disorder”

Screening should occur per “Promoting Optimal Development: Identifying Infants and Young Children With Developmental Disorders Through Developmental Surveillance and Screening”, available at:

<https://pediatrics.aappublications.org/content/145/1/e20193449>.

See the AAP publication regarding Identification, Evaluation, and Management of Children with ASD, available at:

<https://pediatrics.aappublications.org/content/145/1/e20193447>.

IV. Pediatric Preventive Criteria

See the Tufts Children's Hospital Survey of Well-being of Young Children, available at: <https://www.tuftschildrenshospital.org/The-Survey-of-Wellbeing-of-Young-Children/Overview>.

See the AAP Screening Tools, available at: <https://screeningtime.org/star-center/#/screening-tools>

6) Blood Lead Screening

- Children receiving health services through publicly funded programs must receive anticipatory guidance on lead poisoning prevention at each periodic health assessment, starting at 6 months of age and continuing until 72 months of age.
- Provider shall offer and document appropriate follow-up intervention(s) for patient whose screen reveals elevated Blood Lead Levels. Medi-Cal managed care health plans (MCPs) must ensure that the providers provide oral or written anticipatory guidance to the parent(s) or guardian(s) of a child member that, at a minimum, includes information that children can be harmed by exposure to lead, especially deteriorating or disturbed lead-based paint and the dust from it, and are particularly at risk of lead poisoning from the time the child begins to crawl until 72 months of age.

Childhood Lead Poisoning Prevention Branch (CLPPB) anticipatory guidance includes information about other common sources of lead exposure for children.¹⁶

Spanish version:

[https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/CLPPB/CDPH%20Document%20Library/CLPPB-antguid\(S\).pdf](https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/CLPPB/CDPH%20Document%20Library/CLPPB-antguid(S).pdf).

Order or perform blood lead screening tests on all child members in accordance with the following:

- At 12 months and at 24 months of age.
- When the network provider performing a PHA becomes aware that a child member who is 12 to 24 months of age has no documented evidence of a blood lead screening test taken at 12 months of age or thereafter.

¹⁶ The CLPPB Guidance is available at: https://vchca.org/images/public_health/VCCHDP/Chapter6.pdf.

IV. Pediatric Preventive Criteria

- When the network provider performing a PHA becomes aware that a child member who is 24 to 72 months of age has no documented evidence of a blood lead screening test taken.
- At any time, a change in circumstances has, in the professional judgement of the network provider, put the child member at risk.
- If requested by the parent or guardian.

Follow the CDC Recommendations for Post-Arrival Lead Screening of Refugees contained in the CLPPB issued guidelines.¹⁷

Note: Network providers are not required to perform a blood lead screening test if either of the following applies:

- In the professional judgment of the network provider, the risk of screening poses a greater risk to the child member's health than the risk of lead poisoning.
- If a parent, guardian, or other person with legal authority to withhold consent for the child refuses to consent to the screening.

Evidence of provider compliance of blood lead screening test if not performed:

- The provider must document the reason(s) for not performing the blood lead screening test in the child member's medical record.
- In cases where consent has been withheld, the provider must obtain a signed statement of voluntary refusal by parent or guardian.

If the provider is unable to obtain a signed statement of voluntary refusal because the party that withheld consent, refuses or declines to sign it, or is unable to sign it (e.g., when services are provided via telehealth modality), it is acceptable for the provider to document the refusal.

See APL 20-016, Blood Lead Screening of Young Children, or any superseding APL for more information.

¹⁷ The CDC Recommendations are available at: <https://www.cdc.gov/immigrantrefugeehealth/guidelines/lead-guidelines.html>.

IV. Pediatric Preventive Criteria

Please refer to California Department of Public Health (CDPH) CLPPB and the CDC for recommended actions based on BLL levels:

- Information on how to report blood lead screening test results to CLPPB can be found at:
https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/CLPPB/Pages/report_results.aspx.
- Health care providers using a point-of-care device are considered laboratories and must report.¹⁸
- See the CDC Guidance on Childhood Lead Poisoning Prevention, available at:
<https://www.cdc.gov/nceh/lead>.
- See the California Management Guidelines on Childhood Lead Poisoning for Health Care Providers publication, available at:
<https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/CLPPB/Pages/prov.aspx>
- For children at risk of lead exposure, see “Prevention of Childhood Lead Toxicity”, available at: <http://pediatrics.aappublicatons.org/content/138/1/e20161493>, and “Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention”, available at:
https://www.cdc.gov/nceh/lead/acclpp/final_document_030712.pdf

7) Blood Pressure Screening

- Per AAP, blood pressure screening starts at 3 years old.
- In infants and children with specific risk conditions, blood pressure measurements should be performed at visits before age 3 years.
- Provider shall offer and document appropriate follow-up intervention(s) for patient whose screening reveals elevated blood pressure.

¹⁸ See Health and Safety Code Section 124130. State law is searchable at: <https://leginfo.legislature.ca.gov/faces/home.xhtml>.

IV. Pediatric Preventive Criteria

	<p>In persons aged 3-18 years, the prevalence of hypertension is 3.6 %. Evidence suggests that elevated blood pressure in childhood increases the risk for adult Hypertension and Metabolic Syndrome.</p> <p>Screening should occur per “Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents”, available at: http://pediatrics.aappublications.org/content/140/3/e20171904</p> <p>See the Bright Futures Medical Screening Reference Table, available at: https://brightfutures.aap.org/Bright%20Futures%20Documents/MSRTable_InfancyVisits_BF4.pdf.</p> <p>See the AAP guidance on Clinical Practice Guidelines for Screening and Management of High Blood Pressure in Children and Adolescents, available at: https://publications.aap.org/pediatrics/article/140/3/e20171904/38358/Clinical-Practice-Guideline-for-Screening-and</p>
8) Dental/Oral Health Assessment	<ul style="list-style-type: none">• Per DHCS contracts, the provider is responsible for ensuring that dental screening/oral health assessment for all members are included as part of the IHA.¹⁹• Inspection of the mouth, teeth, and gums is performed at every health assessment visit and refer to a dentist if a dental problem is detected or suspected.• Per AAP, referral to a dental home begins at 12 months. If patients do not have an established dental home after 12 months, continue performing an oral health risk assessment and refer to a dental home.²⁰• Documentation of “HEENT” is acceptable. <p>See the Caries-risk Assessment and Management for Infants, Children, and Adolescents, available at: https://www.aapd.org/media/Policies_Guidelines/BP_CariesRiskAssessment.pdf</p> <p>See the AAP guidance on Fluoride Use in Caries Prevention in the Primary Care Setting, available at: http://pediatrics.aappublications.org/content/134/3/626.</p>

¹⁹ For additional information, see the MCP Contract, Exhibit A, Attachment 11, Provision 15.

²⁰ See the AAP Oral Health Practice Tools, available at: <https://www.aap.org/en/patient-care/oral-health/oral-health-practice-tools/>.

IV. Pediatric Preventive Criteria

a. Fluoride Supplementation

- The AAP and USPSTF recommends that primary care clinicians prescribe oral fluoride supplementation starting at age 6 months for children whose water supply is deficient in fluoride.
- Parents or legal guardian should be encouraged to check with local water utility agency if water has fluoride.
- If local water does not contain fluoride, provider may recommend the purchase of fluoridated water or give prescription for fluoride drops or tablets.
- Per AAP, fluoride supplementation for all children ages 6 months until their fifth-year birthday (age range according to the most current AAP periodicity schedule) whose daily exposure to systemic fluoride is deficient.

For the fluoridation status of a community water supply, contact the local water department or the link for “My Water’s Fluoride”, available at:

https://nccd.cdc.gov/doh_mwf/default/default.aspx

See the AAP’s guidance on Maintaining and Improving the Oral Health of Young Children, available at: <http://pediatrics.aappublications.org/content/134/6/1224>.

See the USPSTF guidance on Dental Caries in Children Younger Than 5 Years, available at:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-dental-caries-in-children-younger-than-age-5-years-screening-and-interventions1>

Comment: USPSTF changed their recommendation as of 12/7/21 which is what AAP is referencing in the AAP periodicity schedule footnote 35 and 36.

See guidance on fluoride supplementation, available at:

<https://publichealth.nc.gov/oralhealth/library/includes/IMBresources/2020-FluorideSupplementation.pdf#:~:text=Pediatric%20Dentistry%20%28AAPD%29%20recommend%20the%20daily%20administration%20of,years%20of%20age%20to%20provide%20the%20maximum%20benefits.>

IV. Pediatric Preventive Criteria

b. Fluoride Varnish

- Fluoride varnish is a dental treatment that can help prevent tooth decay, slow it down, or stop it from getting worse by strengthening the tooth enamel (outer coating on teeth).
- AAP recommends that fluoride varnish be applied to the teeth of infants and children starting at tooth eruption until their fifth-year birthdate (age range according to the most current AAP periodicity schedule). All children in this category should receive fluoride varnish application at least once every 3-6 months in the primary care or dental office.

Note: Documentation of “seeing a dentist” without specific notation that fluoride varnish was applied at the dentist office does not meet the criterion. Not all dentists routinely apply fluoride varnish during routine dental visits.

See the USPSTF guidance on Dental Caries in Children Younger Than age 5 Years, available at:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-dental-caries-in-children-younger-than-age-5-years-screening-and-interventions1>.

See APL 19-010, Requirements for Coverage of Early and Periodic Screening, Diagnostic, and Treatment Services for Medi-Cal Members Under the Age of 21, for additional guidance on fluoride varnish.

See the AAP publication on Maintaining and Improving the Oral Health of Young Children, available at:

<https://publications.aap.org/pediatrics/article/134/6/1224/33112/Maintaining-and-Improving-the-Oral-Health-of-Young>.

9) Depression Screening

- AAP recommends screening for major depressive disorder (MDD) in adolescents aged 12 to 20 years.
- Screening should be implemented with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up if screening is positive and a follow up plan is documented.

IV. Pediatric Preventive Criteria	
	<ul style="list-style-type: none"> • Provider shall offer and document appropriate follow-up intervention(s) for patient whose screening is positive for depression. • Depression screening must be done using a validated screening tool. <p>Per AAP, screen using the Patient Health Questionnaire (PHQ)-2 or other tools available in the GLAD-PC toolkit, and available at: https://downloads.aap.org/AAP/PDF/Mental_Health_Tools_for_Pediatrics.pdf and https://screeningtime.org/star-center/#/screening-tools.</p>
a) Suicide Risk Screening	<ul style="list-style-type: none"> • Pending AAP guidance
b) Maternal Depression Screening	<ul style="list-style-type: none"> • Maternal mental health condition is defined as a mental health condition that occurs during pregnancy or during the postpartum period and includes, but is not limited to, postpartum depression. • Maternal depression screen at 1-, 2-, 4-, and 6-month visits. • Maternal depression screening must be done using a validated screening tool, such as the Edinburgh Postnatal Depression Scale (EPDS), Postpartum Depression Screening Scale, or Patient Health Questionnaire (PHQ) 9.²¹ • As with any screening test, results should be interpreted within the clinical context and when appropriate referral to the PCP and/or to mental health care providers for follow up.²² • Provider shall offer and document appropriate follow-up intervention(s) for women whose screening is positive for maternal depression. <p>Assembly Bill (AB) 2193 requires provider who provides prenatal or postpartum care for a patient to offer to screen or appropriately screen a mother for maternal mental health conditions.²³ It also requires interpregnancy care providers to do the same when the patient has experienced a stillbirth or miscarriage. (Health and Safety Code, section 123640 (https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=1236</p>

²¹ See the American College of Obstetricians and Gynecologists (ACOG) guidance on Screening for Perinatal Depression, available at: <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/11/screening-for-perinatal-depression>.

²² For additional resources on perinatal depression, see: <http://www.acog.org/More-Info/PerinatalDepression>.

²³ AB 2193 (Chapter 755, Statutes of 2018) is available at: https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180AB2193.

IV. Pediatric Preventive Criteria

40.&lawCode=HSC), with the most recent version effective 1/1/2022, as amended by AB 1477.

Per AAP, “screening should occur per ‘Incorporating Recognition and Management of Perinatal and Postpartum Depression into Pediatric Practice’, available at: <https://pediatrics.aappublications.org/content/143/1/e20183259>

See the ACOG Frequently Asked Questions on Postpartum Depression, available at: <https://www.acog.org/Patients/FAQs/Postpartum-Depression>.

See the USPSTF recommendation on Screening Depression in Adults, available at: <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/depression-in-adults-screening1>

See the U.S. Department of Health and Human Services guidance on Postpartum Depression, available at: <https://www.womenshealth.gov/mental-health/mental-health-conditions/postpartum-depression>.

10) Developmental Disorder Screening

- Screen for developmental disorders at the 9th, 18th, and 30th month visits.
- 30th month screening can be done at 24 months.
- Providers must use an AAP validated screening tool that must also be a global, not domain specific, consistent with criteria set forth in the CMS Technical Specifications.
- Provider shall offer and document appropriate follow-up intervention(s) for patient whose screening is positive for developmental disorder.
- The CMS Technical Specifications are consistent with age recommendations and use of a validated screening tool; however, tech spec excludes MCHAT tool which AAP allows. CMS determined that the ASQ: SE and M-CHAT screening tools were too specific because they screen for a domain-specific condition (social emotional development or autism, respectively), rather than a full, general assessment of developmental delays.

IV. Pediatric Preventive Criteria

	<p>For detailed information on the CMS Technical Specifications please refer to the link: https://www.medicaid.gov/license/form/6466/4391. The developmental screening measure starts on page 65.</p> <p>Screening should occur per “Promoting Optimal Development: Identifying Infants and Young Children with Developmental Disorders Through Developmental Surveillance and Screening”, available at: https://pediatrics.aappublications.org/content/145/1/e20193449.</p>
11) Developmental Surveillance	Developmental surveillance is a component of every well care visit. If the patient is positive for potential delays, provider shall offer and document appropriate follow-up intervention(s).
12) Drug Use Disorder Screening and Behavioral Counseling	<p>Per AAP recommendations, drug use screening and behavioral counseling should begin at 11 years of age. Provider shall offer and document appropriate follow-up interventions for patient whose screening reveals unhealthy drug use.</p> <p><u>Brief Assessment and Screening</u> When a screening is positive, validated assessment tools should be used to determine if unhealthy drug use is present. Validated drug assessment tools may be used without first using validated screening tools. The AAP recommended assessment tool is available at: http://craftt.org.</p> <p><u>Brief Interventions and Referral to Treatment</u> When brief assessments reveal unhealthy drug use, brief misuse counseling with appropriate referral for additional evaluation and treatment options, referrals, or services must be offered.</p> <p><u>Brief interventions must include the following:</u></p> <ul style="list-style-type: none">• Providing feedback to the patient regarding screening and assessment results;• Discussing negative consequences that have occurred and the overall severity of the problem;• Supporting the patient in making behavioral changes; and• Discussing and agreeing on plans for follow-up with the patient, including referral to other treatment if indicated.

IV. Pediatric Preventive Criteria

	<p>See APL 21-014 or any superseding APL for details on Alcohol and Drug Screening, Assessment, Brief Interventions and Referral to Treatment. See the AAP guidance on Substance Use Screening, Brief Intervention, and Referral to Treatment, available at: https://pediatrics.aappublications.org/content/138/1/e20161211.</p>
13) Dyslipidemia Screening	<p>Family history of obesity, diabetes, hypertension, and heart disease is commonly associated with a combined dyslipidemia. Provider shall offer and document appropriate follow-up intervention(s) for patient whose screening reveals dyslipidemia.</p> <p>Per AAP perform a risk assessment at:</p> <ul style="list-style-type: none">○ 2, 4, 6, and 8 years old, then annually thereafter.○ Order one lipid panel between 9 and 11.○ Perform again between 17 and 21 years old to identify children with genetic dyslipidemia or more lifestyle-related dyslipidemia. <p>For more information see “Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents”, available at: https://www.nhlbi.nih.gov/health-topics/integrated-guidelines-for-cardiovascular-health-and-risk-reduction-in-children-and-adolescents</p> <p>For more information on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents, see: https://www.nhlbi.nih.gov/node/80308 https://brightfutures.aap.org/Pages/default.aspx</p>
14) Hearing Screening	<p>Per AAP audiometric screenings are performed at:</p> <ul style="list-style-type: none">○ Birth to 2 months old, 4, 5, 8, and 10 years old○ Once between 11-14 years old○ Once between 15-17 years old○ Once between 18-21 years old <p>Per AAP, clinicians must confirm initial screen was completed, verify results, and follow up, as appropriate. Newborns should be screened, per “Year 2007 Position</p>

IV. Pediatric Preventive Criteria

Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs”, available at: <http://pediatrics.aappublications.org/content/120/4/898.full>.

A failed audiometric screening is followed-up with a repeat screening at least two weeks and no later than 6 weeks after the initial screening. If the second screening also fails, the primary care provider must make a referral to a specialist.

- Non-audiometric assessments shall be performed at each health assessment visit until the child reaches 21 years old and includes an assessment of birth/family history (hearing loss in the family), history of ear infection and the signs and symptoms of hearing loss (i.e. does not startle at loud noises, does not turn to the source of a sound after 6 months of age, speech is delayed and unclear, often says, “Huh?”, turns the TV volume up too high, etc.).
- Audiometric testing is performed using a newborn hearing screening test (e.g. Automated Auditory Brainstem Response [AABR] or Otoacoustic Emission [OAE] technology) at the birth hospital or specialty facility; or a Behavioral Audiometry Evaluation with an audiometer at the primary care facility starting at 4 years old and includes follow-up care as appropriate.

See the AAP periodicity schedule, available at: www.aap.org/periodicityschedule.

See the CDC recommendations and guidelines on Hearing Loss in Children, available at: <https://www.cdc.gov/ncbddd/hearingloss/recommendations.html>.

See the CDC guidance on Hearing Screenings for Children, available at: <https://www.cdc.gov/ncbddd/hearingloss/screening.html>.

For more information on Hearing Loss in Children, see: <https://www.cdc.gov/ncbddd/hearingloss/facts.html>.

15) Hepatitis B Virus Infection Screening

- Pending guidance from AAP
- Per AAP, all individuals 18 and older should be assessed for risk of hepatitis C virus (HCV) infection.

IV. Pediatric Preventive Criteria

16) Hepatitis C Virus Infection Screening

- Provider shall offer and document appropriate follow-up intervention(s) for patient whose screening reveal potential for Hepatitis C Virus infection.
- Per USPSTF and CDC, test at least once between the ages of 18 and 79. Persons with increased risk of HCV infection, including those who are persons with past or current injection drug use, should be tested for HCV infection and reassessed annually.²⁴

For more information refer to Hepatitis C Virus Infection in Adolescents and Adults: Screening, available at:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-c-screening>.

17) Human Immunodeficiency Virus (HIV) Infection Screening

- Per AAP, risk assessment for HIV shall be completed at each well child visit starting at 11 years old.
- Adolescents should be tested for HIV according to the USPSTF recommendations once between the ages of 15 and 18, making every effort to preserve confidentiality of the adolescent.²⁵
- Those at increased risk of HIV infection, including those who are sexually active, participate in injection drug use, or are being tested for other STIs, should be tested for HIV and reassessed annually.

If the patient is positive for risk factors, provider shall offer and document appropriate follow-up intervention(s). Recommendations for STD screening are listed in Box 3 at:

https://www.cdc.gov/mmwr/volumes/68/rr/rr6805a1.htm#B3_down. Additional

information on screening recommendations is available

at: <https://www.cdc.gov/std/treatment-guidelines/screening-recommendations.htm>;

<https://stacks.cdc.gov/view/cdc/82088>.

The CDC Recommendations for Providing Quality STD Clinical Services is available

at: <https://www.cdc.gov/mmwr/volumes/68/rr/rr6805a1.htm>.

²⁴ See the USPSTF recommendations on HCV screening, available at:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-c-screening>, and the CDC recommendations on HCV screening, available at: <https://www.cdc.gov/mmwr/volumes/69/rr/rr6902a1.htm>.

²⁵ See the USPSTF recommendation on HIV screening, available at:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening>

IV. Pediatric Preventive Criteria

For additional information on clinical considerations for risk assessment, screening intervals, treatment, and prevention, see:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening>

The AAP periodicity schedule is available at:

https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf

For those at risk, look for documented evidence that pre-exposure prophylaxis (PrEP) was offered.

18) Psychosocial/Behavioral Assessment

- Psychosocial/Behavior Assessment should be done at each well child visit.
- This assessment should be family centered and may include an assessment of child social-emotional health, caregiver depression, and social determinants of health.
-
- **Note: Social Determinants Of Health (SDOH)**
- Per AAP, social determinants of health (SDOH) are the web of interpersonal and community relationships experienced by children, parents, and families.
- Per CDC, social determinants of health (SDOH) are conditions in the places where people live, learn, work, and play that affect a wide range of health and quality of life risks and outcomes.

https://brightfutures.aap.org/Bright%20Futures%20Documents/BF_IntegrateSDoH_Tip_sheet.pdf

<https://www.cdc.gov/socialdeterminants/about.html>

See the AAP publication titled “Promoting Optimal Development: Screening for Behavioral and Emotional Problems”, available at:

<http://pediatrics.aappublications.org/content/135/2/384>.

See the AAP publication titled “Poverty and Child Health in the United States”,

available at: <http://pediatrics.aappublications.org/content/137/4/e20160339>

https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf.

IV. Pediatric Preventive Criteria

19) Sexually Transmitted Infection (STI) Screening and Counseling

Per AAP, adolescents should be screened for STIs per recommendations in the current edition of the AAP Red Book: Report of the Committee on Infectious Diseases.

- Sexual activity shall be assessed at every well child visit starting at 11 years old.
- If adolescents are identified as sexually active (by report or on the IHEBA form), the provider shall offer and provide contraceptive care with the goals of helping teens reduce risks and negative health consequences associated with adolescent sexual behaviors, including unintended pregnancies and STIs.
- For adolescents that have been pregnant, provider should engage in a discussion of counseling on inter-pregnancy intervals and contraceptive care, such as moderately and most effective contraceptive options.

Provider shall offer and document appropriate follow-up intervention(s) for patient whose screening reveals STI. AAP refers to CDC for full list of STIs, available at:

<https://www.cdc.gov/std/treatment-guidelines/screening-recommendations.htm>

<https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/California-STI-Treatment-Guidelines.aspx>

- **Risk assessments for Adolescents and 24 years and younger:** Annual chlamydia and gonorrhea screenings should be done for sexually active women under age 25 as well as older women who are at risk. Screening for syphilis, HIV, chlamydia, and Hepatitis B should be given to all pregnant women, and gonorrhea screening for all pregnant women.²⁶
- **Men Who Have Sex with Men (MSM):** These men have higher rates of STIs, such as HIV and syphilis and should be tested for these as well as chlamydia, and gonorrhea.
- **Men Who Have Sex with Women:** There is insufficient evidence for screening among heterosexual men who are at low risk for infection, however, screening young men can be considered in high prevalence clinical settings (adolescent clinics, correctional facilities, and STI/sexual health clinic).

²⁶ See the AAP guidance on Screening and Nonviral STIs in Adolescents and Young Adults:

<https://publications.aap.org/pediatrics/article/134/1/e302/62344/Screening-for-Nonviral-Sexually-Transmitted>, the AAP periodicity schedule, available at: https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf, and the AAP guidance on Adolescent Sexual Health, available at: <https://www.aap.org/en/patient-care/adolescent-sexual-health/>.

IV. Pediatric Preventive Criteria

- **Sex Workers:** This population is at higher risk for HIV and other STIs than others, and should be tested at least annually for HIV.
- **Transgender and Gender Diverse Persons:** Screening recommendations should be adapted based on anatomy, (i.e., annual, routine screening for Chlamydia in cis-gender women < 25 years old should be extended to all transgender men and gender diverse people with a cervix. Consider screening at the rectal site based on reported sexual behaviors and exposure. **Persons with HIV:** For sexually active individuals, screen at first HIV evaluation, and at least annually thereafter. More frequent screening might be appropriate depending on individual risk behaviors and the local epidemiology.

Syphilis

- People who are pregnant
- Male adolescents and young adults in settings with high prevalence rates (e.g. jails or juvenile correction facilities)
- MSM at least annually (every 3 to 6 months if high risk because of multiple or anonymous partners, sex in conjunction with illicit drug use, or having sex partners who participated in these activities)

See the AAP guidance on Adolescent Sexual Health, available at:

<https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/adolescent-sexual-health/Pages/default.aspx>

See the DHCS webpage on the Staying Healthy Assessment, available at:

<https://www.dhcs.ca.gov/formsandpubs/forms/Pages/StayingHealthy.aspx>.

For information on chlamydia and gonorrhea screening. see:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/chlamydia-and-gonorrhea-screening>.

For USPSTF information on syphilis screening, see:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/syphilis-infection-in-nonpregnant-adults-and-adolescents>.

[Senate Bill \(SB\) 306](#) (Pan, Chapter 486, Statutes of 2021)

https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220SB306

IV. Pediatric Preventive Criteria

	<p>https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=120685&lawCode=HSC</p>
<p>20) Sudden Cardiac Arrest and Sudden Cardiac Death Screening</p>	<p>Pending guidance from AAP</p>
<p>21) Tobacco Use Screening, Prevention, and Cessation Services</p>	<p>Tobacco Use Screening, Prevention, and Cessation Services</p> <ul style="list-style-type: none"> • Screen all children 11 years and older at each well child visit for tobacco products use. • Tobacco products include but not limited to smoked cigarettes, chewed tobacco, electronic cigarette, and vaping products use, and/or exposure to secondhand smoke. • If patient answered “yes” to the smoke/tobacco questions in the IHEBA or at any time the PCP identifies a potential tobacco use problem, then the provider shall document prevention and/or cessation services to potential/active tobacco users. • Provider shall offer and document appropriate follow-up intervention(s) for patient whose screening reveal tobacco use. <p>Tobacco cessation services must be documented in the patient’s medical record as follows:</p> <ol style="list-style-type: none"> 1) Initial and annual assessment of tobacco (e-cigarette, vaping products, and/or secondhand smoke) use for each adolescent (11-21 years of age). 2) FDA-approved tobacco cessation medications (for non-pregnant adults of any age). 3) Individual, group, and telephone counseling for members of any age who use tobacco products. 4) Services for pregnant tobacco users. 5) Prevention of tobacco use in children and adolescents (including counseling and pharmacotherapy). <p>For information on comprehensive tobacco prevention and cessation services for Medi-Cal beneficiaries is available at, see APL 16-014, Comprehensive Tobacco</p>

IV. Pediatric Preventive Criteria

	<p>Prevention and Cessation Services for Medi-Cal Beneficiaries, or any superseding APL.</p> <p>Smoking status can be assessed through the use of the SHA, which is DHCS's IHEBA. The AAP recommended assessment tool is available at: http://crafft.org.</p>
<p>22) Tuberculosis Screening</p>	<ul style="list-style-type: none"> • Per AAP, Committee on Infectious Diseases, published in the current edition of the AAP Red Book: Report of the Committee on Infectious Diseases, testing should be performed on recognition of high-risk factors. • All children are assessed for risk of exposure to tuberculosis (TB) at 1, 6, and 12-months old and annually thereafter. • Provider shall offer and document appropriate follow-up intervention(s) for patient whose screening reveals positive risk factors for TB. • Two tests that are used to detect TB bacteria in the body: the TB skin test (TST) (Mantoux) and TB blood tests QuantiFERON-TB Gold Plus. A positive TB skin test or TB blood test only tells that a person has been infected with TB bacteria. TB infection screening test is administered to children <i>identified at risk</i>, if there has not been a test in the previous year. The Mantoux is not given if a previously positive Mantoux is documented. Documentation of a positive test includes follow-up care (e.g. further medical evaluation, chest x-ray, diagnostic laboratory studies and/or referral to specialist). • Providers are required to follow current CDC and American Thoracic Society guidelines for TB diagnosis and treatment. <p>The California Pediatric Tuberculosis Risk Assessment tool is available at: https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/TBCB-CA-Pediatric-TB-Risk-Assessment.pdf.</p> <p>CDC guidance on TB testing and diagnosis is available at: https://www.cdc.gov/tb/topic/testing/default.htm.</p>
<p>23) Vision Screening</p>	<ul style="list-style-type: none"> • Age-appropriate visual screening occurs at each health assessment visit, with referral to optometrist/ophthalmologist as appropriate.

IV. Pediatric Preventive Criteria

- Per AAP, visual acuity screenings using optotypes (figures or letters of different sizes used for vision screening) are to be performed at ages 3 (if cooperative), 4, 5, 6, 8, 10, 12, and 15 years old.
- Instrument-based screening may be used to assess risk at ages 12 and 24 months, in addition to the well visits at 3 through 5 years of age.
- Documentation of “PERRLA” is acceptable for children below the age of 3 years.
- If the patient is positive for risk factors, provider shall offer and document appropriate follow-up intervention(s).
-
- AAP recommended eye charts are:
 - LEA Symbols (3-5 years old)
 - HOTV Chart (3-5 years old)
 - Sloan Letters (preferred) or Snellen Letters (over 5 years old)

See the AAP publications titled “Visual System Assessment in Infants, Children, and Young Adults by Pediatricians” available at: <http://pediatrics.aappublications.org/content/137/1/e20153596> and “Procedures for the Evaluation of the Visual System by Pediatricians”, available at: <http://pediatrics.aappublications.org/content/137/1/e20153597>.

Note: Although specific screening details are not generally documented in the medical record, screening for infants and children (birth to 3 years) may consist of evaluations such as external eye inspection, ophthalmoscopy red reflex examination, or corneal penlight evaluation. Visual acuity screening usually begins at age 3 years. AAP guidance on Visual System Assessment in Infants, Children, and Young Adults by Pediatricians is available at: <https://pediatrics.aappublications.org/content/137/1/e20153596>.

D) Childhood Immunizations

Every visit should be an opportunity to update and complete a child’s immunizations. Childhood Immunizations Schedules, per the AAP Committee on Infectious Diseases, are available at: https://redbook.solutions.aap.org/SS/immunization_Schedules.aspx.

IV. Pediatric Preventive Criteria

	<p>For reference, see the CDC's ACIP webpage, available at: https://www.cdc.gov/vaccines/acip/index.html, also see APL 18-004, Immunization Requirements, or any superseding APL For details on Immunization Requirements.</p>
1) Given according to ACIP guidelines	<p>Immunization status is assessed at each health assessment visit. Practitioners are required to ensure the provision of immunizations according to CDC's most recent ACIP guidelines, unless medically contraindicated, vaccine shortage or refused by the parent.</p> <p>Refer to the following link for more information on ACIP Vaccine Recommendations and Guidelines: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html.</p>
2) Vaccine administration documentation	<p>The name, manufacturer, date of administration, and lot number of each vaccine given is recorded in the medical/electronic record or on medication logs, including immunization registries, in accordance with the National Childhood Vaccine Injury Act.</p> <p>For additional details on the National Childhood Vaccine Injury Act, refer to: https://www.congress.gov/bill/99th-congress/house-bill/5546</p>
3) Vaccine Information Statement (VIS) documentation	<ul style="list-style-type: none">• VISs are information sheets produced by the CDC that explain both the benefits and risks of a vaccine to the vaccine recipients.• Federal law requires that healthcare staff provide a VIS to a patient, parent, or legal representative before each dose of certain vaccines. <p>VIS documentation in the medical/electronic record, medication logs, or immunization registries include the date the VIS was given or presented/offered <i>and</i> the VIS publication date.</p> <p>Refer to the following link from the CDC for the current VISs: https://www.cdc.gov/vaccines/hcp/vis/current-vis.html.</p> <p>Note: Federal law allows up to 6 months for the updated VIS to be distributed.</p>

Rationale: Current Guide to Clinical Preventive Services, U.S. Preventive Services Task Force (USPSTF) Report is the minimum standard for adult preventive health services.

  RN/NP/MD/PA/CNM/LM

V. Adult Preventive Criteria	
A. Initial Health Assessment (IHA): Includes H&P and IHEBA	<p><u>New Members:</u> The IHA (comprehensive history and IHEBA “Staying Healthy Assessment” or other DHCS-approved tool) enables the PCP to assess current acute, chronic, and preventive needs <i>and</i> to identify those Members whose health needs require coordinated services with appropriate community resources/other agencies not covered by the Plan.</p> <p>IHA must be completed within 120 days of plan enrollment or PCP effective date (whichever is more recent) or documented within the 12 months prior to Plan enrollment/PCP effective date.</p> <p>Reference: PLs 08–003 and 13-001, or any superseding APL.</p>
1) Comprehensive History and Physical	<p><u>New members:</u> The history must be comprehensive to assess and diagnose acute and chronic conditions it includes:</p> <ul style="list-style-type: none"> ○ History of present illness ○ Past medical history ○ Social history ○ Review of Organ Systems (ROS) including <u>dental assessment</u> <p>Referrals for any abnormal findings must be documented.</p> <p>If an H&P is not found in the medical record, the reasons (e.g., member/parent refusal, missed appointment) and contact attempts to reschedule are documented. A review of the organ systems that include documentation of “inspection of the mouth” or “seeing dentist” meets the criteria for dental assessment during a comprehensive history and physical.</p>
	<p><u>New members:</u> An age-appropriate IHEBA (“Staying Healthy” or other DHCS-approved tool) is completed by the member within 120 days of the effective date of</p>

V. Adult Preventive Criteria

<p>2) Individual Health Education Behavioral Assessment (IHEBA)</p>	<p>enrollment into the Plan or PCP effective date (whichever is more recent), or within the 12 months prior to Plan enrollment/PCP effective date. Staff may assist.</p> <p>The IHEBA has evidence of practitioner review:</p> <ul style="list-style-type: none"> ○ Printed name ○ Signature ○ Date ○ Interventions, which may be documented on the IHEBA form, in progress notes, or other areas of the paper or electronic medical record system. <p>If an initial IHEBA is not found in the medical record, the reasons (e.g., member's refusal, missed appointment) and contact attempts to reschedule are documented.</p> <p>SHA Questionnaires are available at: http://www.dhcs.ca.gov/formsandpubs/forms/pages/stayinghealthy.aspx</p>
<p>B. Periodic Health Evaluation according to most recent USPSTF guidelines</p>	<p>The type, quantity, and frequency of preventive services is based on the most recent USPSTF recommendations.</p>
<p>1) Comprehensive History and Physical Exam completed at age-appropriate frequency.</p>	<ul style="list-style-type: none"> • Periodic health evaluations occur in accordance with the frequency that is appropriate for individual risk factors. • In addition to USPSTF recommendations, periodic health evaluations are scheduled as indicated by the member's needs and according to the clinical judgment of the practitioner. <p>Example: A patient with elevated cholesterol levels and other risk factors for coronary heart disease (CHD) may be evaluated more frequently than other persons of the same age without similar risk factors.</p>
<p>2) Subsequent Periodic IHEBA</p>	<ul style="list-style-type: none"> • The adult or senior assessment must be re-administered every 3 to 5 years, at a minimum. • The PCP must review previously completed SHA questionnaires with the patient every year, except years when the assessment is re-administered.

V. Adult Preventive Criteria

- Documentation requirements are the same as the initial IHEBA.
- For subsequent annual reviews, PCP must sign, print name, and date “SHA Annual Review” section (last page) to verify the annual review was conducted and discussed with the patient.

SHA Questionnaires are available at:

<http://www.dhcs.ca.gov/formsandpubs/forms/pages/stayinghealthy.aspx>

c. Adult Preventive Care Screenings

The following adult preventive care screenings are based on USPTSF Grade A and B recommendations.

- If the patient falls within the eligible condition (e.g. obesity, post-menopausal, etc.), age and gender parameters of the criterion, the provider shall assess for risk factors.
- The IHEBA screening tool may assist in screening for risk factors for many preventive care criteria (i.e. Alcohol misuse, STI, HIV, Tobacco, etc.).
- Evidence of risk assessments and screenings for other preventive care criteria may be found elsewhere in the medical record if the IHEBA was completed, reviewed, and signed by the provider, and the patient is negative for risk, the provider may be given a point.
- If the patient is positive for risk factors, the provider shall offer and document follow-up intervention(s).
- Providers who fail to document the presence or absence of risk factors shall receive zero (0) points.
- An “NA” score is warranted if the patient falls outside of the eligible condition, age and gender parameters of the specific criterion.

If specific preventive care screening tests are ordered, but results are not found in the member’s record, and no documentation of follow-up is documented, these deficiencies will be cited under the appropriate preventive care criteria. The Follow-up of Specialty Referrals criteria pertain to referrals/lab tests that are not specified under preventive care criteria (i.e. ophthalmology, nephrology, etc.).

Use the following scoring methodology under adult preventive care screenings:

- If ordered and result found, score as 1.

V. Adult Preventive Criteria	
	<ul style="list-style-type: none"> ○ If ordered and patient refused, score as 1. ○ If ordered and no result found, but outreach efforts are documented, score as 1. ○ If ordered but no result or outreach efforts documented, score as 0.
1) Abdominal Aneurysm Screening	<p>Assess all individuals during well adult visits for past and current tobacco use. USPSTF recommends that medical providers should perform a one-time screening for abdominal aortic aneurysm by ultrasonography in men ages 65 to 75 years who have ever smoked 100 or more cigarettes in their lifetime. Indirect evidence shows that smoking is the strongest predictor of Abdominal Aortic Aneurysm (AAA) prevalence, growth, and rupture rates.²⁷ There is a dose-response relationship, as greater smoking exposure is associated with an increased risk for AAA.</p> <p>The USPSTF Grade A and B Recommendations are available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-and-b-recommendations.</p>
2) Alcohol Use Disorder Screening and Behavioral Counseling	<p>Assess all adults at each well visit for alcohol misuse. If at any time the PCP identifies a potential alcohol misuse problem (e.g., patient answered “yes” to the alcohol questions in the IHEBA), the provider shall:</p> <ul style="list-style-type: none"> • Refer any member identified with possible alcohol use disorders to the alcohol and drug program in the county where the member resides for evaluation and treatment. • Use the Alcohol Use Disorder Identification Test (AUDIT) or Alcohol Use Disorder Identification Test-Consumption (AUDIT-C). • Complete at least one expanded screening, using a validated screening tool every year and additional screenings can be provided in a calendar year if medical necessity is documented by the member’s provider. • Offer behavioral counseling intervention(s) to those members that a provider identifies as having risky or hazardous alcohol use. <ol style="list-style-type: none"> 1) A member responds affirmatively to the alcohol questions in the IHEBA.

²⁷ See the USPSTF recommendation on AAA Screening, available at:
<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/abdominal-aortic-aneurysm-screening>.

V. Adult Preventive Criteria

- 2) Member provides responses on the expanded screening that indicate hazardous use, or when otherwise identified.

When a member responds affirmatively to the alcohol questions in the IHEBA, provides responses on the expanded screening that indicate hazardous use, or when otherwise identified.

Behavioral counseling intervention(s) typically include one to three sessions, 15 minutes in duration per session, offered in-person, by telephone, or by telehealth modalities.

See the NIH guidance on Screening Tests, available at:

<https://pubs.niaaa.nih.gov/publications/arh28-2/78-79.htm>

See APL 21-014, Alcohol and Drug Screenings, Assessment, Brief Interventions and Referral to Treatment, or any superseding APL, for additional information.

The USPSTF uses the term “unhealthy alcohol use” to define a spectrum of behaviors, from risky drinking to alcohol use disorder (AUD) (e.g., harmful alcohol use, abuse, or dependence). Risky or hazardous alcohol use means drinking more than the recommended daily, weekly, or per-occasion amounts, resulting in increased risk for adverse health consequences but not meeting criteria for AUD (e.g. the National Institute on Alcohol Abuse and Alcoholism (NIAAA) defines “risky use” as exceeding the recommended limits of 4 drinks per day (56 g/d based on the US standard of 14 g/drink) or 14 drinks per week (196 g/d) for healthy adult men aged 21 to 64 years or 3 drinks per day or 7 drinks per week (42 g/d or 98 g/week) for all adult women of any age and men 65 years or older).

Screening

Unhealthy alcohol use screening must be done with validated screening tools.

The US Surgeon General, NIAAA, CDC, and ASAM recommend routinely screening adult patients for unhealthy alcohol use and providing them with appropriate interventions, <https://www.niaaa.nih.gov/guide>

Brief Assessment

V. Adult Preventive Criteria

When a screen is positive, providers should use validated assessment tools to determine if an alcohol use disorder is present. Validated alcohol assessment tools may be used without first using validated screening tools. Validated assessment tools include, but are not limited to:

- CRAFFT (Car, Relax, Alone, Forget, Friends, Trouble)
- NIDA-modified Alcohol, Smoking and Substance Involvement Screening Test (NM-ASSIST)
- Alcohol Use Disorders Identification Test (AUDIT)

Brief Interventions and Referral to Treatment

For recipients with brief assessments revealing alcohol misuse, brief misuse counseling should be offered. Appropriate referral for additional evaluation and treatment, including medications for addiction treatment (MAT), should be offered to recipients whose brief assessment demonstrates probable alcohol use disorder. Alcohol brief interventions includes alcohol misuse counseling and counseling a member regarding additional treatment options, referrals, or services. Brief interventions must include the following:

- Providing feedback to the patient regarding screening and assessment results.
- Discussing negative consequences that have occurred and the overall severity of the problem.
- Supporting the patient in making behavioral changes.
- Discussing and agreeing on plans for follow-up with the patient, including referral to other treatment if indicated.

Documentation Requirements

Member medical records must include the following:

- The service provided, for example: screen and brief intervention.
- The name of the screening instrument and the score on the screening instrument (unless the screening tool is embedded in the electronic health record).
- The name of the assessment instrument (when indicated) and the score on the assessment (unless the screening tool is embedded in the electronic health record).
- If and where a referral to an alcohol or substance use disorder program was made.

V. Adult Preventive Criteria

	<p>A recommended substance abuse assessment tool is available at http://crafft.org.</p> <p>Please refer to the following link to The Medi-Cal Provider Manual: https://www.dhcs.ca.gov/formsandpubs/publications/Pages/Manuals.aspx.</p>
<p>3) Breast Cancer Screening</p>	<p>A routine screening mammography for breast cancer is completed every 1-2 years on all women starting at age 50, concluding at age 75 unless pathology has been demonstrated.²⁸</p>
<p>4) Cervical Cancer Screening</p>	<ul style="list-style-type: none"> • Screen for cervical cancer in women ages 21 to 65 years with cytology (Pap smear) every 3 years. • Women ages 30 to 65 years who want to lengthen the screening interval, screen with a combination of cytology and human papillomavirus (HPV) co-testing every 5 years OR with high-risk human papillomavirus (hrHPV) testing alone every 5 years. • Follow-up of abnormal test results are documented. <p>Routine Pap testing may not be required for the following:</p> <ul style="list-style-type: none"> • Women who have undergone hysterectomy in which the cervix is removed (TAH - Total Abdominal Hysterectomy), unless the hysterectomy was performed because of invasive cancer. • Women 66 years and older who have had regular previous screening in which the Pap result have been consistently normal. <p>The USPSTF recommendation on Cervical Cancer Screening is available at: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/cervical-cancer-screening.</p>
<p>5) Colorectal Cancer Screening</p>	<p>All adults are screened for colorectal cancer beginning at age 45 years old and concluding at age 75 years to include:</p> <ul style="list-style-type: none"> • High sensitivity gFOBT or FIT every year • sDNA-FIT every 1 to 3 years

²⁸ See the USPSTF recommendation on Breast Cancer Screening, available at:
<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening>.

V. Adult Preventive Criteria

- CT colonography every 5 years
- Flexible sigmoidoscopy every 5 years
- Flexible sigmoidoscopy every 10 years + FIT every year
- Colonoscopy screening every 10 years.

When abnormal results are found on flexible sigmoidoscopy or CT colonography, follow-up with colonoscopy is needed for further evaluation. Rates of colorectal cancer incidence are higher in Black adults and American Indian and Alaskan Native adults, persons with a family history of colorectal cancer (even in the absence of any known inherited syndrome such as Lynch syndrome or familial adenomatous polyposis), men, and persons with other risk factors (such as obesity, diabetes, long-term smoking, and unhealthy alcohol use). The decision to screen for colorectal cancer in adults **aged 76 to 85 years** should be an individual one, taking into account the patient's overall health and prior screening history.

The USPSTF recommendation on Colorectal Cancer Screening is available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening>.

6) Depression Screening

- Per USPSTF, screen for depression in the general adult population, including pregnant and postpartum women.
- Screening should be implemented at each well visit with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up.
- Providers should screen all adults who have not been previously screened using a validated screening tool. If the depression screening is positive, a follow up plan must be documented.
- Providers should use clinical judgment in consideration of risk factors, comorbid conditions, and life events to determine if additional screening of high-risk patients is warranted.

Recommended screening tools include:

- Patient Health Questionnaire (PHQ) in various forms
- Hospital Anxiety and Depression Scales in adults
- Geriatric Depression Scale in older adults

V. Adult Preventive Criteria

- The Edinburgh Postnatal Depression Scale (EPDS) pregnant and postpartum

IHEBA forms when used solely for depression screening do not have psychometric properties and may not be reliable screening tools for depression.

The USPSTF Grade A and B Recommendations are available at:

<https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations>.

The USPSTF recommendation on Screening for Depression in Adults is available at:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/depression-in-adults-screening>.

7) Diabetic Screening and Comprehensive Care

- Per USPSTF, screen for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 35 to 70 years who are overweight or obese.
- Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity.
- Glucose abnormalities can be detected by measuring HbA1c or fasting plasma glucose or with an oral glucose tolerance test.
- Hemoglobin A1C (HbA1c) is a measure of long-term blood glucose concentration and is not affected by acute changes in glucose levels due to stress or illness. HbA1c measurements do not require fasting, they are more convenient than using a fasting plasma glucose or oral glucose tolerance test. The oral glucose tolerance test is done in the morning in a fasting state; blood glucose concentration is measured 2 hours after ingestion of a 75-g oral glucose load.
- The diagnosis of IFG, IGT, or type 2 diabetes should be confirmed; repeated testing with the same test on a different day is the preferred method of confirmation.

See the USPSTF recommendation on Prediabetes and Type 2 Diabetes Screening, available at:

V. Adult Preventive Criteria

<https://uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes>.

See APL 18-018, Diabetes Prevention Program, or any superseding APL for additional information.

- When reviewing medical records of patients with a diagnosis of Diabetes, the reviewer should score based on documented routine comprehensive diabetic care/screening: retinal exams, podiatry, nephrology, etc.
- Proper diabetes management is essential to control blood glucose, reduce risks for complications, and prolong life. With support from health care providers, patients can manage their diabetes with self-care, taking medications as instructed, eating a healthy diet, being physically active, and quitting smoking.

See the National Community for Quality Assurance guidance on Comprehensive Diabetes Care, available at: <https://www.ncqa.org/hedis/measures/comprehensive-diabetes-care/>.

See the USPSTF recommendation on Prediabetes and Type 2 Diabetes Screening, available at:

<https://uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes>.

8) Drug Use Disorder Screening and Behavioral Counseling

Assess all adults at each well visit for drug misuse. If at any time the PCP identifies a potential drug use problem (e.g., patient answered “yes” to the drug use questions in the IHEBA), the provider shall:

- Refer any member identified with possible drug use disorders to the drug treatment program in the county where the member resides for evaluation and treatment.
- Complete at least one expanded screening, using a validated screening tool, every year and additional screenings can be provided in a calendar year if medical necessity is documented by the member’s provider.
- Offer behavioral counseling intervention(s) to those members that a provider identified as having as having risky or hazardous drug use.

V. Adult Preventive Criteria

- 1) A member responds affirmatively to the drug use questions in the IHEBA.
- 2) Member provides responses on the expanded screening that indicate hazardous use, or when otherwise identified.

When a member responds affirmatively to the drug use questions in the IHEBA, provides responses on the expanded screening that indicate hazardous use, or when otherwise identified.

Behavioral counseling intervention(s) typically include one to three sessions, 15 minutes in duration per session, offered in-person, by telephone, or by telehealth modalities.

See APL 21-014, Alcohol and Drug Screenings, Assessment, Brief Interventions and Referral to Treatment, or any superseding APL, for additional information.

The term “unhealthy drug use” is defined as the use of illegally obtained substances, excluding alcohol and tobacco, or the use of nonmedical prescription medications that differ than the parameters for which they were prescribed such as duration, frequency, and amount.

Brief Assessment

When a screen is positive, providers should use validated assessment tools to determine if a drug use disorder is present. Validated drug assessment tools may be used without first using validated screening tools. Validated assessment tools include, but are not limited to:

- CRAFFT (Car, Relax, Alone, Forget, Friends, Trouble)
- NIDA-modified Alcohol, Smoking, and Substance Involvement Screening Test (NM-ASSIST)
- Drug Abuse Screening Test (DAST-20)

Brief Interventions and Referral to Treatment

For recipients with brief assessments revealing drug misuse, brief misuse counseling should be offered. Appropriate referral for additional evaluation and treatment, including medications for addiction treatment (MAT), should be offered to

V. Adult Preventive Criteria

	<p>recipients whose brief assessment demonstrates probable substance use disorder. Drug brief interventions includes misuse counseling and counseling a member regarding additional treatment options, referrals, or services. Brief interventions must include the following:</p> <ul style="list-style-type: none"> • Providing feedback to the patient regarding screening and assessment of results. • Discussing negative consequences that have occurred and the overall severity of the problem. • Supporting the patient in making behavioral changes. • Discussing and agreeing on plans for follow-up with the patient, including referral to other treatment if indicated. <p><u>Documentation Requirements</u> Member medical records must include the following:</p> <ul style="list-style-type: none"> • The service provided, for example: screen and brief intervention. • The name of the screening instrument and the score on the screening instrument (unless the screening tool is embedded in the electronic health record). • The name of the assessment instrument (when indicated) and the score on the assessment (unless the screening tool is embedded in the electronic health record). • If and where a referral to an alcohol or substance use disorder program was made. <p>A recommended substance abuse assessment tool is available at: http://crafft.org.</p> <p>Please refer to the following link to the Medi-Cal Provider Manual: https://www.dhcs.ca.gov/formsandpubs/publications/Pages/Manuals.aspx.</p>
<p>9) Dyslipidemia Screening</p>	<p>USPSTF recommends that adults without a history of cardiovascular disease (CVD) (e.g., symptomatic coronary artery disease or ischemic stroke) use a low- to moderate-dose statin for the prevention of CVD events and mortality when all the following criteria are met:</p> <ol style="list-style-type: none"> 1) They are aged 40 to 75 years; 2) They have one or more CVD risk factors (e.g., dyslipidemia, diabetes, hypertension, or smoking); and

V. Adult Preventive Criteria	
	<p>3) They have a calculated 10-year risk of a cardiovascular event of 10% or greater.</p> <p>Screen universal lipids at every well visit for those with increased risk of heart disease and at least every 6 years for healthy adults.</p> <p>The USPSTF Grade A and B Recommendations are available at: https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations.</p>
10) Folic Acid Supplementation	<ul style="list-style-type: none"> • The USPSTF recommends that all women who are planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.²⁹ • USPSTF and WHO categorize women in the age range of 12-49 years as “women who are capable of becoming pregnant”.
11) Hepatitis B Virus Screening	<p>Assess all adults for risk of acquiring Hepatitis B Virus (HBV) at each well visit. Screening those at risk should include testing to three HBV screening seromarkers (HBsAg, antibody to HBsAg [anti-HBs], and antibody to hepatitis B core antigen [anti-HBc]) so that persons can be classified into the appropriate hepatitis B category and properly recommended to receive vaccination, counseling, and linkage to care and treatment.</p> <p>Important risk groups for HBV infection with a prevalence of ≥2% that should be screened include:</p> <ul style="list-style-type: none"> • Persons born in countries and regions with a high prevalence of HBV infection (≥2%), such as sub-Saharan Africa and Central and Southeast Asia (Egypt, Algeria, Morocco, Libya, Afghanistan, Vietnam, Cambodia, Thailand, Philippines, Malaysia, Indonesia, Singapore, etc.). • U.S.-born persons not vaccinated as infants whose parents were born in regions with a very high prevalence of HBV infection (≥8%).

²⁹ See the USPSTF recommendation on Folic Acid to Prevent Neural Tube Defects, available at:
<https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/folic-acid-to-prevent-neural-tube-defects-preventive-medication>.

V. Adult Preventive Criteria

- HIV-positive persons
- Injection drug users
- MSM
- Household contacts or sexual partners of persons with HBV infection

See the CDC guidance on Viral Hepatitis, available at:
<https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm>

12) Hepatitis C Virus Screening

- All adults 18 to 79 years old shall be assessed for risk of Hepatitis C Virus (HCV) exposure at each well visits.
- Testing should be initiated with anti-HCV. For those with reactive test results, the anti-HCV test should be followed with an HCV RNA.

Persons for whom HCV Testing is recommended:

- All Adults ages 18 to 79 years should be tested once.
- Currently, or had history of, ever injecting drugs.
- Medical Conditions: Long term hemodialysis, persons who received clotting factor concentrates produced before 1987; HIV infection; Persistent abnormal alanine aminotransferase levels (ALT).
- Prior recipients of transfusions or organ transplant before July 1992 or donor who later tested positive for HCV infection.

Persons with continued risk for HCV infection (e.g., injection drug users) should be screened periodically. There is limited information about the specific screening interval that should occur in persons who continue to be at risk for new HCV infection or how pregnancy changes the need for additional screening.

See the USPSTF recommendation on Screening for HCV in Adolescents and Adults Practice Considerations, available at:
<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-c-screening#bootstrap-panel--6>.

See the CDC Recommendations for Hepatitis C Screening Among Adults in the United States, available at: <https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm>.

V. Adult Preventive Criteria	
	<p>See the USPSTF Grade A and B Recommendations, available at: https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/.</p>
13) High Blood Pressure Screening	<ul style="list-style-type: none"> • All adults including those without known hypertension are screened. • A blood pressure (B/P) measurement for the normotensive adult is documented at least once every 2 years if the last systolic reading was below 120 mmHg and the diastolic reading was below 80 mmHg. • B/P is measured annually if the last systolic reading was 120 to 139 mmHg and the diastolic reading was 80 to 89 mmHg. <p>See the USPSTF Grade A and B Recommendation, available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hypertension-in-adults-screening.</p>
14) HIV Screening	<p>USPSTF recommends risk assessment shall be completed at each well visit for patients 65 years old and younger:</p> <ul style="list-style-type: none"> • Those at high risk (regardless of age) i.e., having intercourse without a condom or with more than one sexual partner whose HIV status is unknown. • IV drug users. • MSM. <p>All shall be tested for HIV and offered pre-exposure prophylaxis (PrEP).³⁰ Lab results are documented.</p> <p>https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening</p>
	<ul style="list-style-type: none"> • Per the USPSTF, clinicians shall screen for Intimate Partner Violence (IPV) on asymptomatic women of reproductive age, which is defined across studies as

³⁰ See the USPSTF recommendation on Prevention of HIV Infection, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

V. Adult Preventive Criteria

15) Intimate Partner Violence Screening for Women of Reproductive Age

ranging from 12 to 49 years, with most research focusing on women age 18 years or older.

- Provide or refer those who screen positive to ongoing support services.

The SHA is an incomplete tool to screen for IPV, however, per USPSTF the following instruments accurately detect IPV in the past year among adult women:

- Humiliation, Afraid, Rape, Kick (HARK)
- Hurt, Insult, Threaten, Scream (HITS)
- Extended–Hurt, Insult, Threaten, Scream (E-HITS)
- Partner Violence Screen (PVS)
- Woman Abuse Screening Tool (WAST)

The USPSTF A and B recommendations are the minimum that is required by DHCS. The term “intimate partner violence” describes physical, sexual, or psychological harm by a current or former partner or spouse. This type of violence can occur among heterosexual or same-sex couples and does not require sexual intimacy.

See the CDC guidance on IPV, available at:

<https://www.cdc.gov/violenceprevention/intimatepartnerviolence/>

16) Lung Cancer Screening

- Assess all individuals during well adult visits for past and current tobacco use.
- Per USPSTF, screen annually for lung cancer with low-dose computed tomography in adults ages 50 to 80 years who have a 20 pack-year smoking history and currently smoke or have quit within the past 15 years.
- Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.

See the USPSTF recommendation on Lung Cancer Screening, available at:

<https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lung-cancer-screening>.

V. Adult Preventive Criteria

17) Obesity Screening and Counseling

- USPSTF recommends that clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.
- Documentation shall include weight and BMI
- There is fair to good evidence that high-intensity counseling—about diet, exercise, or both—together with behavioral interventions aimed at skill development, motivation, and support strategies produces modest, sustained weight loss (typically 3-5 kg for 1 year or more) in adults who are obese (as defined by BMI \geq 30 kg/m²).

Although the USPSTF did not find direct evidence that behavioral interventions lower mortality or morbidity from obesity, the USPSTF concluded that changes in intermediate outcomes, such as improved glucose metabolism, lipid levels, and blood pressure, from modest weight loss provide indirect evidence of health benefits.

See the USPSTF recommendation on Screening and Counseling for Obesity in Adults, available at:

<https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/obesity-in-adults-screening-and-counseling-2003>.

18) Osteoporosis Screening

Assess all postmenopausal women during well adult visits for risk of osteoporosis.

USPSTF recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in postmenopausal women younger than 65 years who are at increased risk of osteoporosis, or who have at least one risk factor, as determined by a formal clinical risk assessment tool.³¹ These risk factors include:

- Parental history of hip fracture
- Smoking
- Excessive alcohol consumption
- Low body weight.

³¹ See the USPSTF recommendations on Screening for Osteoporosis to Prevent Fractures, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/osteoporosis-screening>.

V. Adult Preventive Criteria

	<p>USPSTF recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women 65 years and older.</p> <p>For postmenopausal women younger than 65 years who have at least 1 risk factor, a reasonable approach to determine who should be screened with bone measurement testing is to use a clinical risk assessment tool.</p>
19) Sexually Transmitted Infection (STI) Screening and Counseling	<p>Assess all individuals during well adult visits for risk of STI.³²</p> <p><u>Chlamydia & Gonorrhea:</u></p> <ul style="list-style-type: none">• Test all sexually active women under 25 years old• Older women who have new or multiple sex partners• MSM regardless of condom use or persons with HIV shall be tested at least annually <p><u>Syphilis:</u></p> <ul style="list-style-type: none">• MSM or persons with HIV shall be screened at least annually <p><u>Trichomonas:</u></p> <ul style="list-style-type: none">• Sexually active women seeking care for vaginal discharge• Women who are IV drug users• Exchanging sex for payment• HIV+, have History of STD, etc. <p><u>Herpes:</u></p> <ul style="list-style-type: none">• Men and women requesting STI evaluation who have multiple sex partners shall be tested.• HIV+• MSM w/ undiagnosed genital tract infection.

³² See the USPSTF recommendation on STIs: Behavioral Counseling, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/sexually-transmitted-infections-behavioral-counseling>.

V. Adult Preventive Criteria	
	Intensive behavioral counseling for adults who are at increased risk for STIs includes counseling on use of appropriate protection and lifestyle.
20) Skin Cancer Behavioral Counseling	USPSTF recommends that young adults and parents of young children should be counseled to minimize exposure to Ultraviolet (UV) radiation for persons aged 6 months to 24 years to reduce their risk of skin cancer. ³³
21) Tobacco Use: Screening, Counseling, and Intervention	<ul style="list-style-type: none"> • Assess all individuals during well adult visits for tobacco use and document prevention and/or counseling services to potential/active tobacco users. • If the PCP identifies tobacco use (e.g. Patient answered “Yes” on IHEBA). <ul style="list-style-type: none"> ○ Per USPSTF, providers can document any combination of the following since not all may apply especially to pregnant tobacco users: tobacco cessation services, behavioral counseling and/or pharmacotherapy. <p>See APL 16-014, Comprehensive Tobacco Prevention and Cessation Services for Medi-Cal Beneficiaries, or any superseding APL, for additional information.</p> <p>If the PCP identifies tobacco use (i.e., Patient answered “Yes” on IHEBA), documentation that the provider offered tobacco cessation services, behavioral counseling, and/or pharmacotherapy to include any or a combination of the following must be in the patient’s medical record:</p> <ul style="list-style-type: none"> • FDA-approved tobacco cessation medications (for non-pregnant adults of any age). • Individual, group, and telephone counseling for members of any age who use tobacco’s products. • Services for pregnant tobacco users. <p>See APL 16-014, Comprehensive Tobacco Prevention and Cessation Services for Medi-Cal Beneficiaries, or any superseding APL, for additional information.</p>
22) Tuberculosis Screening	<ul style="list-style-type: none"> • Adults are assessed for TB risk factors or symptomatic assessments upon enrollment and at periodic physical evaluations.

³³ See the USPSTF Grade A and B Recommendations, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/skin-cancer-counseling>.

V. Adult Preventive Criteria	
	<ul style="list-style-type: none"> • The Mantoux skin test, or other approved TB infection screening test,³⁴ is administered to all asymptomatic persons at increased risk of developing TB irrespective of age or periodicity if they had not had a test in the previous year. • Adults already known to have HIV or who are significantly immunosuppressed require annual TB testing. <p>The Mantoux is not given if a previously positive Mantoux is documented. Documentation of a positive test includes follow-up care, for example:</p> <ul style="list-style-type: none"> ○ Further medical evaluation ○ Chest x-ray ○ Diagnostic laboratory studies ○ Referral to specialist <p>Practitioners are required to follow current CDC and American Thoracic Society guidelines for TB diagnosis and treatment.</p> <p>See the CDPH guidance on California Adult TB Risk Assessment, available at: https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/TBCB-CA-TB-Risk-Assessment-and-Fact-Sheet.pdf.</p> <p>See the USPSTF recommendation on Latent TB Infection Screening, available at: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/latent-tuberculosis-infection-screening.</p> <p>See the CDC publications on TB, available at: www.cdc.gov/tb/publications/.</p>
D) Adult Immunizations	

³⁴ Per June 25, 2010, CDC MMWR, the FDA approved IGRA serum TB tests, such as QuantiFERON®-TB Gold (QFT-G and QFT-GIT) and T-SPOT®.TB (T-Spot).

V. Adult Preventive Criteria

<p>1) Given according to ACIP guidelines</p>	<p>Immunization status is assessed at periodic health evaluations. Practitioners are required to ensure the provision of immunizations according to CDC’s most recent ACIP guidelines, unless medically contraindicated or refused by the member.³⁵</p> <p>Vaccination status must be assessed for the following:</p> <ul style="list-style-type: none"> ○ Td/Tdap (every 10 years) ○ Flu (annually) ○ Pneumococcal (ages 65 and older; or anyone with underlying conditions) ○ Zoster (starting at age 50) ○ Varicella and MMR Documented evidence of immunity (i.e. titers, childhood acquired infection) in the medical record meets the criteria for Varicella and MMR. <p>The name of the vaccines and date the member received the vaccines must be documented as part of the assessment.</p> <p>See APL 18-004, Immunization Requirements, or any superseding APL for additional information.</p>
<p>2) Vaccine administration documentation</p>	<p>The name, manufacturer, date of administration, and lot number of each vaccine given is recorded in the medical/electronic record or on medication logs, including immunization registries, in accordance with the National Childhood Vaccine Injury Act.</p>
<p>3) Vaccine Information Statement (VIS) documentation</p>	<p>The date the VIS was given (or presented and offered) and the VIS publication date are documented in the medical record.</p>

³⁵ See the CDC ACIP Guidance on Immunization Schedules, available at: <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html>.

Rationale: Perinatal assessments are provided according to the current American College of Obstetrics and Gynecologists (ACOG) standards and Comprehensive Perinatal Services Program (CPSP) Guidelines.³⁶ Reviewers please note, if the OB-GYN provider is also acting as the member's PCP and the member is/was pregnant during the review period (e.g. the last three years), the appropriate preventive services criteria, based on the members' age, i.e. Pediatric or Adult shall ALSO be reviewed and scored.

 RN/NP/MD/PA/CNM/LM

VI. OB/CPSP Preventive Criteria	
A. Initial Comprehensive Prenatal Assessment (ICA)	<p>Initial Prenatal Visit - First entry to OB Care: During the initial Comprehensive assessment, provider gathers baseline information on the pregnant woman, such as:</p> <ul style="list-style-type: none"> ○ Obstetric and medical history, including medical documentation from prior visits with other providers. ○ Nutrition status ○ Health education ○ Psychosocial needs <p>Based on the information gathered, the provider and the pregnant woman develop an individualized care plan (ICP) to meet her unique needs. Documentation of ICP services received, or reasons why not received, must be provided.</p> <p>See VI, B, below, for the First Trimester Comprehensive Assessment, which may be completed over more than one visit during the trimester. See the CDPH CPSP Provider Handbook, available at: https://custom.cvent.com/C506006261F8428CB7CCB91AAA9A05B4/files/8a01c5b0dd744c0aa06f0dece9dec3f1.pdf.</p>
1) Initial Prenatal Visit	Documentation of initial prenatal visit completed within four weeks of entry to prenatal care. Optimally within the first trimester.
2) Obstetrical and Medical History	Obstetric/medical: The H&P exam must be consistent with the most recent ACOG Guidelines for Perinatal Care. ³⁷

³⁶ See the CDPH webpage on CPSP, available at: <https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/Pages/default.aspx>

³⁷ See the ACOG Guidelines for Perinatal Care, available at: <https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c>.

VI. OB/CPSP Preventive Criteria	
3) Physical Exam	Physical exam: includes breast and pelvic exam and calculation of estimated date of delivery. https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx
4) Dental Assessment	Dental Screening and referral as indicated must be documented. Oral health problems are associated with other diseases including heart disease, diabetes, and respiratory infections. ³⁸
5) Healthy Weight Gain and Behavior Counseling	The USPSTF recommends that clinicians offer pregnant women effective behavioral counseling interventions aimed at promoting healthy weight gain and preventing excess gestational weight gain in pregnancy. ³⁹ Effective behavioral counseling interventions promotes healthy weight gain and decreases risk of gestational diabetes mellitus, emergency cesarean delivery, infant macrosomia, and LGA infants.
6) Lab tests	
a) Bacteriuria Screening	USPSTF recommends screening for asymptomatic bacteriuria with urine culture for pregnant women at 12 to 16 weeks' gestation or at their first prenatal visit, if later. ⁴⁰

³⁸ See the ACOG guidance on Oral Health Care During Pregnancy and Through the Lifespan, available at: <https://www.acog.org/en/Clinical/Clinical%20Guidance/Committee%20Opinion/Articles/2013/08/Oral%20Health%20Care%20During%20Pregnancy%20and%20Through%20the%20Lifespan>

³⁹ See the USPSTF recommendation on Healthy Weight and Weight Gain in Pregnancy, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/healthy-weight-and-weight-gain-during-pregnancy-behavioral-counseling-interventions>

⁴⁰ See the USPSTF recommendation on Screening for Asymptomatic Bacteria in Adults, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/asymptomatic-bacteriuria-in-adults-screening>.

VI. OB/CPSP Preventive Criteria	
	Urine culture is recommended for bacteriuria screening in pregnancy and is the method for diagnosis. Pregnant women with asymptomatic bacteriuria usually receive antibiotic therapy, based on urine culture results and follow-up monitoring.
b) Rh Incompatibility Screening	<ul style="list-style-type: none"> • Rh incompatibility screening: 24-28 weeks gestation.⁴¹ • Rh incompatibility is a condition that occurs during pregnancy if a woman has Rh-negative blood and her baby has Rh-positive blood.
c) Diabetes Screening	<p>USPSTF recommends screening for gestational diabetes mellitus (GDM) in asymptomatic pregnant women after 24 weeks of gestation.⁴²</p> <ul style="list-style-type: none"> • <u>In the two-step approach</u>: the 50-g OGCT is performed between 24 and 28 weeks of gestation. A diagnosis of GDM is made when two or more glucose values fall at or above the specified glucose thresholds. • <u>One-step approach</u>: a 75-g glucose load is administered after fasting and plasma glucose levels are evaluated after 1 and 2 hours. Gestational diabetes is diagnosed if 1 glucose value falls at or above the specified glucose threshold. <u>Self-monitoring of blood glucose can be a useful tool in the management of pregnant woman with pre-existing and with gestational diabetes.</u>
d) Hepatitis B Virus Screening	<p>All pregnant women are screened for Hepatitis B during their first trimester or prenatal visit, whichever comes first.⁴³</p> <p>The screening tests for detecting maternal HBV infection is the serologic identification of HBsAg. Screening should be performed in each pregnancy, regardless of previous HBV vaccination or previous negative HBsAg test results.</p>

⁴¹ See the USPSTF recommendation on Rh(D) Incompatibility Screening, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/rh-d-incompatibility-screening>, and the NIH guidance on Rh Incompatibility, available at: <https://www.nhlbi.nih.gov/health-topics/rh-incompatibility>.

⁴² See the USPSTF recommendation on Gestational Diabetes Screening, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/gestational-diabetes-screening>.

⁴³ See the USPSTF recommendation on HBV Infection in Pregnant Women, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-b-virus-infection-in-pregnant-women-screening>.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2864180/>

VI. OB/CPSP Preventive Criteria

	<p>Following referral required for women with positive HBV:</p> <ul style="list-style-type: none"> • Case management during pregnancy • HBV DNA viral load testing • Referral to specialty care for counseling and medical management of HBV infection. <p>See Hepatitis B information on the CDC website, available at: https://www.cdc.gov/hepatitis/hbv/index.htm.</p>
<p>e) Hepatitis C Virus Screening</p>	<p>Per ACOG all pregnant women should receive Hepatitis C screening with blood assessment during the first prenatal visit.</p> <p>Pregnant woman with newly diagnosed HCV infection and abnormal serum aminotransferase and/or platelet levels should be referred for further medical assessment to rule out liver fibrosis or injury and so antiviral treatment can be initiated at the appropriate time.</p> <p>Providers should report HCV infection in a pregnant person to infant’s health care provider so that follow-up HCV testing can be conducted at the recommended time, and to the local health department so that ongoing risk factors can be assessed and relevant contacts can receive hepatitis A and hepatitis B testing and vaccination, as indicated, and can be linked, as appropriate, to preventive services.</p> <p>https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/05/routine-hepatitis-c-virus-screening-in-pregnant-individuals</p>
<p>f) Chlamydia Infection Screening</p>	<p>Per CDC, All pregnant women under 25 years old and older women with increased risk such as new or multiple sex partners, or a sex partner who has an STD, should be tested for chlamydia at their first prenatal visit pregnant women with chlamydial infection should have a test-of-cure four weeks after treatment and be retested within three months</p> <p>Retest during the 3rd trimester for women under 25 years of age or at risk.</p>

VI. OB/CPSP Preventive Criteria

	<p>See the CDC guidance on Chlamydia, available at: https://www.cdc.gov/std/chlamydia.</p> <p>See the CDC guidance on STD Tests, available at: https://www.cdc.gov/std/prevention/screeningreccs.htm.</p> <p>See the USPSTF recommendation on Chlamydia and Gonorrhea Screening, available at: https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/chlamydia-and-gonorrhea-screening.</p>
<p>g) Syphilis Infection Screening</p>	<p>Per CDC, all pregnant women should be tested for syphilis at the first prenatal visit.⁴⁴ High risk women need to be tested again during the third trimester (28 weeks gestation) and at delivery. This includes women who live in areas of high syphilis morbidity, are previously untested, had a positive screening test in the first trimester, or are at higher risk for syphilis (i.e., multiple sex partners, drug use, transactional sex, late entry into prenatal care or no prenatal care, meth or heroin use, incarceration themselves or of sex partners, unstable housing, or homelessness).</p>
<p>h) Gonorrhea Infection Screening</p>	<p>All pregnant women under 25 years old, and older pregnant women who are at increased risk, are screened for gonorrhea during their first prenatal visit.⁴⁵</p> <p>Specific microbiologic diagnosis of <i>N. gonorrhea</i> infection should be performed for all women at risk for or suspected of having gonorrhea.</p> <p>See the CDC guidance on Gonococcal Infections Among Adolescents and Adults, available at: https://www.cdc.gov/std/treatment-guidelines/gonorrhea-adults.htm.</p>

⁴⁴ See the CDC information on syphilis, available at: <https://www.cdc.gov/std/syphilis/stdfact-syphilis-detailed.htm>.

⁴⁵ See the CDC guidance on Gonococcal Infections Among Adolescents and Adults, available at: <https://www.cdc.gov/std/treatment-guidelines/gonorrhea-adults.htm>, and the USPSTF recommendation on Chlamydia and Gonorrhea Screening, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/chlamydia-and-gonorrhea-screening>.

VI. OB/CPSP Preventive Criteria	
i) Human Immunodeficiency Virus (HIV) Screening	<p>Per ACOG, all pregnant women should be informed that HIV test is part of the routine panel of the prenatal tests.⁴⁶</p> <p>If woman declines HIV testing this should be documented in the medical record.</p> <p>Repeat testing in the third trimester is recommended for woman known to be at high risk of acquiring HIV infection, and women who declined testing earlier in pregnancy.</p>
B. First Trimester Comprehensive Assessment	<p>A Comprehensive Perinatal Assessment must be completed each trimester and during the postpartum period. A Comprehensive Assessment tool must be used and updated every trimester and during the 12-month post-pregnancy period. The assessment tool must be consistent with CDPH's template tool, as confirmed by the local county or city Perinatal Health Coordinator.⁴⁷</p> <p>See the CPSP Integrated Initial 1, 2, and 3 Trimester Assessments and ICP, available link bottom of the page.</p>
1) Individualized Care Plan (ICP)	<p>ICP documentation includes specific obstetric, nutrition, psychosocial, and health education risk problems/conditions, interventions, and referrals.</p> <p>ICP must be developed based on the comprehensive assessment in each trimester and during the 12-month post-pregnancy period. The ICP must be updated based on the Comprehensive Assessments in each trimester, during the 12-month post-pregnancy period, and more frequently as needed. Documentation must be provided of the services offered and whether received.</p>
2) Nutrition Assessment	<p>A complete initial nutrition assessment should be performed at the initial visit or within four weeks thereafter and should be documented in the</p>

⁴⁶ See the ACOG Guidelines for Perinatal Care, available at: <https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx>, and the USPSTF recommendation on HIV Screening, available at:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening>

⁴⁷ See the CDPH CPSP webpage, available at: <https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/Pages/default.aspx>, and the Title 22 CPSP regulations, available at:

<https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/CDPH%20Document%20Library/CPSP-Title22CPSPRegulations.pdf>

VI. OB/CPSP Preventive Criteria	
	<p>pregnant woman medical record:</p> <ul style="list-style-type: none"> • anthropometric data • biochemical data • clinical data • dietary data
3) Psychosocial Assessment	<p>The psychosocial screening should be performed on a regular basis and documented in the woman's prenatal record.⁴⁸ The assessment should include the following:</p> <ul style="list-style-type: none"> ○ Depression assessment ○ Social and mental history ○ Substance use Disorder including alcohol and tobacco ○ Unintended pregnancy ○ Support systems ○ Documentation of referral as appropriate. <p>See the proposed changes for the 20202 Prenatal and Postpartum care HEDIS measures, available at: https://www.ncqa.org/wp-content/uploads/2019/02/20190208_08_Perinatal_Depression.pdf.</p>
a) Maternal Mental Health Screening	<p>Screening for maternal mental health conditions must be part of the Comprehensive Assessments at each trimester. Identified needs must be incorporated into the Individualized Care Plan and follow up services documented.</p> <p><i>Health and Safety Code (HSC) Section 123640: and AB-1477 Maternal mental health: Licensed health care practitioner who provides prenatal, postpartum or interpregnancy care for a patient shall ensure that the mother is offered screening or is appropriately screened for maternal mental health conditions. Counselling, referrals, or any interventions is documented.</i></p>

⁴⁸ See the ACOG Guidelines for Perinatal Care, available at: <https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx>, and the CDPH CPSP Provider Handbook, available at: <https://custom.cvent.com/C506006261F8428CB7CCB91AAA9A05B4/files/8a01c5b0dd744c0aa06f0dece9dec3f1.pdf>.

VI. OB/CPSP Preventive Criteria

“Maternal mental health condition” means a mental health condition that occurs during pregnancy or during the postpartum period and includes, but is not limited to, postpartum depression.

- USPSTF recommends screening for depression in the general adult population, including pregnant and postpartum women.
- CMS Technical Specifications include screening using validated tools and documentation of a follow-up plan if the depression screening is positive that aligns with USPSTF's referral and documentation of counseling or interventions with those found at risk for perinatal depression.
- Patient is screened for depression on the date of the encounter using an age-appropriate standardized tool AND, if positive, a follow-up plan is documented on the date of the positive screen.

Standardized Depression Screening Tool – A normalized and validated depression screening tool developed for the patient population in which it is being utilized. The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record.

- Edinburgh Postnatal Depression Scale (EPDS),
- Patient Health Questionnaire (PHQ) 9

Follow-Up Plan – Documented follow-up for a positive depression screening must include one or more of the following:

- Additional evaluation or assessment for depression
- Suicide Risk Assessment
- Referral to a practitioner who is qualified to diagnose and treat depression
- Pharmacological interventions
- Other interventions or follow-up for the diagnosis or treatment of depression

Additional information on CMS Technical Specifications, is available at:

<https://www.medicaid.gov/license/form/6466/4391>.

VI. OB/CPSP Preventive Criteria	
	See the USPSTF Grade A and B Recommendations, available at: https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/ .
b) Social Needs Assessment	<p>The comprehensive Assessments in each trimester must also provide social needs assessment includes housing, food, transportation, unintended pregnancy, support system available.⁴⁹</p> <p>Identified needs must be incorporated into the Individualized Care Plan, and follow up services documented</p>
c) Substance Use Disorder Assessment	<ul style="list-style-type: none"> • All pregnant women should be routinely asked about their use of alcohol, tobacco and drug, including prescription opioids and other medications used for nonmedical reasons. • If the woman acknowledges the use of alcohol, cocaine, opioids, amphetamines, or other mood-altering drugs or if chemical dependence is suspected, she should be counseled about the perinatal implications of their use during pregnancy and offered referral to an appropriate treatment program. <p>See the ACOG Guidelines for Perinatal Care, available at: https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx.</p>
3) Breastfeeding and other Health Education Assessment	<ul style="list-style-type: none"> • Health Education including breast feeding, preparation to breastfeed, language, cultural competence. And education needs must be assessed at least once during each trimester and more frequently as needed. Identified needs must be incorporated into the Individualized Care Plan, and follow up services documented. • Materials must be available in the appropriate threshold languages and must meet readability and suitability requirements for educational material distributed to Medi-Cal members.⁵⁰

⁴⁹ See the ACOG Guidelines for Perinatal Care, available at: <https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx>.

⁵⁰ See APL 18-016, Readability and Suitability of Written Health Education Materials, or any superseding APL.

VI. OB/CPSP Preventive Criteria	
4) Preeclampsia Screening	USPSTF recommends screening for preeclampsia in pregnant women with blood pressure measurements throughout pregnancy. ⁵¹
5) Intimate Partner Violence Screening	<ul style="list-style-type: none"> • USPSTF recommends that clinicians screen IPV in women of reproductive age and provide or refer women who screen positive to ongoing support services.⁵² • Provision of a Domestic Violence Screening is documented. • Assessment checklists, body diagrams and/or documentation in progress notes are acceptable. <p>Domestic violence screening includes:</p> <ul style="list-style-type: none"> • Medical screening • Documentation of physical injuries • Documentation of illnesses attributable to spousal/partner abuse • Referral to appropriate community service agencies⁵³
c. Second Trimester Comprehensive Assessment	<p>See the CDPH CPSP webpage, available at: https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/Pages/default.aspx.</p> <p>See the Title 22 CPSP Regulations, available at: https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/CDPH%20Document%20Library/CPSP-Title22CPSPRegulations.pdf.</p>
1) Individualized Care Plan (ICP)	<p>ICP documentation includes specific obstetric, nutrition, psychosocial, and health education risk problems/conditions, interventions, and referrals.</p> <p>ICP must be updated every trimester and more frequently as needed</p>

⁵¹ See the USPSTF recommendation on Preeclampsia Screening, available at:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/preeclampsia-screening>.

⁵² See the USPSTF recommendation on IPV, Elder Abuse, and Abuse of Vulnerable Adults Screening, available at:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/intimate-partner-violence-and-abuse-of-elderly-and-vulnerable-adults-screening>.

⁵³ HSC 1233.5

VI. OB/CPSP Preventive Criteria

2) Nutrition Assessment	<p>A nutrition reassessment using updated information should be offered to each client at least once every trimester and the individualized care plan should be revised accordingly.</p> <p>Nutrition ICP component should address:</p> <ul style="list-style-type: none">• The prevention and/or resolution of nutrition problems.• The support and maintenance of strengths and habits oriented toward optimal nutritional status• Dispensing, as medically necessary, prenatal vitamin/mineral supplement to each pregnant woman.• Treatment and intervention directed toward helping the patient understand the importance of, and maintain good nutrition during pregnancy and lactation, with referrals as appropriate.
3) Psychosocial Assessment	<p>The psychosocial screening should be performed on a regular basis and documented in the woman's prenatal record. The assessment should include the following:</p> <ul style="list-style-type: none">○ Depression assessment○ Social and mental history○ Substance use/abuse including alcohol and tobacco○ Unintended pregnancy○ Support systems○ Documentation of referrals as appropriate. <p>See the ACOG Guidelines for Perinatal Care, available at: https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx.</p> <p>https://www.ncqa.org/wp-content/uploads/2019/02/20190208_08_Perinatal_Depression.pdf</p>
a) Maternal Mental Health Screening	<p>Screening for maternal mental health conditions must be part of the Comprehensive Assessments at each trimester. Identified needs must be incorporated into the Individualized Care Plan and follow up services documented.</p>

VI. OB/CPSP Preventive Criteria

Health and Safety Code (HSC) Section 123640 and AB-1477 Maternal Mental Health: Licensed health care practitioner who provides prenatal, postpartum or interpregnancy care for a patient shall ensure that the mother is offered screening or is appropriately screened for maternal mental health conditions. Counseling, referrals or any interventions is documented.

“Maternal mental health condition” means a mental health condition that occurs during pregnancy or during the postpartum period and includes, but is not limited to, postpartum depression.

- USPSTF recommends screening for depression in the general adult population, including pregnant and postpartum women.
- CMS Technical Specifications includes screening using validated tools and documentation of a follow-up plan if the depression screening is positive that aligns with USPSTF's referral and documentation of counseling or interventions with those found at risk for perinatal depression.
- Patient screened for depression on the date of the encounter using an age-appropriate standardized tool AND, if positive, a follow-up plan is documented on the date of the positive screen.
 - Edinburgh Postnatal Depression Scale (EPDS),
 - Patient Health Questionnaire (PHQ) 9

Standardized Depression Screening Tool – A normalized and validated depression screening tool developed for the patient population in which it is being utilized. The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record.

Follow-Up Plan – Documented follow-up for a positive depression screening must include one or more of the following:

- Additional evaluation or assessment for depression
- Suicide Risk Assessment
- Referral to a practitioner who is qualified to diagnose and treat depression
- Pharmacological interventions

VI. OB/CPSP Preventive Criteria	
	<ul style="list-style-type: none"> • Other interventions or follow-up for the diagnosis or treatment of depression <p>For additional information on CMS Technical Specifications, see: https://www.medicaid.gov/license/form/6466/4391.</p> <p>See the USPSTF Grade A and B recommendations, available at: https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/.</p>
b) Social Needs Assessment	Social needs assessment including housing, food, transportation, unintended pregnancy, support system available. ⁵⁴
c) Substance Use Disorder Assessment	<ul style="list-style-type: none"> • All pregnant women should be routinely asked about their use of alcohol, tobacco, and drugs, including prescription opioids and other medications used for nonmedical reasons. • If the woman acknowledges the use of alcohol, cocaine, opioids, amphetamines, or other mood-altering drugs or if chemical dependence is suspected, she should be counseled about the perinatal implications of their use during pregnancy and offered referral to an appropriate treatment program. <p>See the ACOG Guidelines for Perinatal Care, available at: https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx</p> <p>See the USPSTF Grade A and B Recommendations, available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-and-b-recommendations.</p>
4) Breastfeeding and Other Health Education Assessment	<ul style="list-style-type: none"> • Health Education including breast feeding, language, cultural competence, and education needs must be assessed.

⁵⁴ See the ACOG Guidelines for Perinatal Care, available at: <https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx>.

VI. OB/CPSP Preventive Criteria	
	<ul style="list-style-type: none"> Materials must be available in the appropriate threshold languages and must meet readability and suitability requirements for educational material distributed to Medi-Cal members.⁵⁵
5) Preeclampsia Screening	USPSTF recommends screening for preeclampsia in pregnant women with blood pressure measurements throughout pregnancy. ⁵⁶
a) Low Dose Aspirin	The Provider should advise on the use of low-dose aspirin (81 mg/d) as preventive medication after 12 weeks of gestation in women who are at high risk for preeclampsia. ⁵⁷
6) Intimate Partner Violence Screening	<ul style="list-style-type: none"> USPSTF recommends that clinicians screen for IPV in women of reproductive age and provide or refer women who screen positive to ongoing support services.⁵⁸ Provision of a Domestic Violence Screening is documented. Assessment checklists, body diagrams and/or documentation in progress notes are acceptable. <p>Domestic violence screening includes:</p> <ul style="list-style-type: none"> Medical screening. Documentation of physical injuries or illnesses attributable to spousal/partner abuse. Referral to appropriate community service agencies.⁵⁹

⁵⁵ See APL 18-106, Readability and Suitability of Written Health Education Materials, or any superseding APL.

⁵⁶ See the USPSTF recommendation on Preeclampsia Screening, available at:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/preeclampsia-screening>.

⁵⁷ See the USPSTF Grande A and B recommendations, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-and-b-recommendations>.

⁵⁸ See the USPSTF recommendation on IPV, Elder Abuse, and Abuse of Vulnerable Adults Screening, available at:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/intimate-partner-violence-and-abuse-of-elderly-and-vulnerable-adults-screening>.

⁵⁹ HSC 1233.5

VI. OB/CPSP Preventive Criteria

<p>7) Diabetes Screening</p>	<p>The USPSTF recommends screening for gestational diabetes mellitus (GDM) in asymptomatic pregnant women after 24 and 28 weeks of gestation.⁶⁰</p> <ul style="list-style-type: none"> • In the 2-step approach, the 50-g OGCT is performed between 24 and 28 weeks of gestation in a non-fasting state. If the screening threshold is met or exceeded, patients receive the oral glucose tolerance test (OGTT). A diagnosis of GDM is made when 2 or more glucose values fall at or above the specified glucose thresholds. • 1-step approach, a 75-g glucose load is administered after fasting and plasma glucose levels are evaluated after one and two hours. Gestational diabetes is diagnosed if 1 glucose value falls at or above the specified glucose threshold.
<p>D. Third Trimester Comprehensive Assessment</p>	<p>See the CDPH CPSP webpage, available at: https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/Pages/default.aspx.</p> <p>See the Title 22 CPSP Regulations, available at: https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/CDPH%20Document%20Library/CPSP-Title22CPSPRegulations.pdf.</p>
<p>1) Individualized Care Plan (ICP) Update and Follow Up</p>	<p>ICP documentation includes specific obstetric, nutrition, psychosocial and health education risk problems/conditions, interventions, and referrals.</p> <p>See the CPSP Integrated Initial 1, 2, and 3 Trimester Assessments and ICP, available at: https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/CDPH%20Document%20Library/CPSP-CombinedInitialandTrimesterAssessmentandCarePlan.pdf.</p> <p>See the CPCP Postpartum Assessment and ICP, available at: https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/CDPH%20Document%20Library/CPSP-PostpartumAssessmentandCarePlan.pdf.</p>

⁶⁰ See the USPSTF recommendation on Gestational Diabetes Screening, available at:
<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/gestational-diabetes-screening>.

VI. OB/CPSP Preventive Criteria

<p>2) Nutrition Assessment</p>	<p>A nutrition reassessment using updated information should be offered to each client at least once every trimester and the individualized care plan should be revised accordingly.</p> <p>Nutrition ICP component should address:</p> <ul style="list-style-type: none"> • The prevention and/or resolution of nutrition problems. • The support and maintenance of strengths and habits oriented toward optimal nutritional status. • Dispensing, as medically necessary, prenatal vitamin/mineral supplement to each pregnant woman. • Treatment and intervention directed toward helping the patient understand the importance of, and maintain good nutrition during pregnancy and lactation, with referrals as appropriate. <p>https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/CDPH%20Document%20Library/CPSP-Title22CPSPRegulations.pdf</p>
<p>3) Psychosocial Assessment</p>	<p>Psychosocial assessment must be performed on a regular basis and documented in the woman’s prenatal record. The assessment should include the following:</p> <ul style="list-style-type: none"> • Depression Assessment • Social and Mental History • Substance use/abuse including alcohol and tobacco; unintended pregnancy • Support systems • Documentation of referrals as appropriate <p>See the CDPH CPSP Provider Handbook, available at: https://custom.cvent.com/C506006261F8428CB7CCB91AAA9A05B4/files/8a01c5b0dd744c0aa06f0dece9dec3f1.pdf.</p> <p>See the ACOG Guidelines for Perinatal Care, available at: https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx</p>
	<p><i>Practitioner who provides prenatal, interpregnancy, or postpartum care for a patient shall ensure that the mother is offered screening or is appropriately screened for</i></p>

VI. OB/CPSP Preventive Criteria

a) Maternal Mental Health Screening

maternal mental health conditions. Counselling, referrals or any interventions is documented.

*“Maternal mental health condition” means a mental health condition that occurs during pregnancy or during the postpartum period and includes, but is not limited to, postpartum depression.*⁶¹

- USPSTF recommends screening for depression in the general adult population, including pregnant and postpartum women.
- CMS Technical Specifications includes screening using validated tools and documentation of a follow-up plan if the depression screening is positive that aligns with USPSTF's referral and documentation of counseling or interventions with those found at risk for perinatal depression.
- Patient screened for depression on the date of the encounter using an age-appropriate standardized tool AND, if positive, a follow-up plan is documented on the date of the positive screen.

Standardized Depression Screening Tool – A normalized and validated depression screening tool developed for the patient population in which it is being utilized. The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record.

- Edinburgh Postnatal Depression Scale (EPDS),
- Patient Health Questionnaire (PHQ) 9

Follow-Up Plan – Documented follow-up for a positive depression screening must include one or more of the following:

- Additional evaluation or assessment for depression
- Suicide Risk Assessment
- Referral to a practitioner who is qualified to diagnose and treat depression
- Pharmacological interventions
- Other interventions or follow-up for the diagnosis or treatment of depression

⁶¹ HSC 123640

VI. OB/CPSP Preventive Criteria

	<p>For additional information on CMS Technical Specifications, see: https://www.medicaid.gov/license/form/6466/4391.</p> <p>See the USPSTF recommendation on Screening Depression in Adults, available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/depression-in-adults-screening.</p> <p>The USPSTF recommends that clinicians provide or refer pregnant and postpartum persons who are at increased risk of perinatal depression to counseling interventions.⁶²</p>
<p>b) Social Needs Assessment</p>	<p>The comprehensive assessments in each trimester must also provide social needs assessment including housing, food, transportation, unintended pregnancy, support system available.⁶³</p> <p>Identified needs must be incorporated into the Individualized Care Plan, and follow up services documented</p>
<p>c) Substance Use Disorder Assessment</p>	<ul style="list-style-type: none"> • All pregnant women should be routinely asked about their use of alcohol, tobacco and drug, including prescription opioids and other medications used for nonmedical reasons. • If the woman acknowledges the use of alcohol, cocaine, opioids, amphetamines, or other mood-altering drugs or if chemical dependence is suspected, she should be counseled about the perinatal implications of their use during pregnancy and offered referral to an appropriate treatment program. <p>The USPSTF recommends screening for unhealthy alcohol use in primary care settings in adults 18 years or older, including pregnant women, and providing persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce unhealthy alcohol use.</p>

⁶² See the USPSTF recommendation on Perinatal Depression, available at:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/perinatal-depression-preventive-interventions>.

⁶³ See the ACOG Guidelines for Perinatal Care, available at: <https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx>.

VI. OB/CPSP Preventive Criteria

	<p>See APL 21-014, Alcohol and Drug Screening, Assessment, Brief Interventions and Referral to Treatment, or any superseding APL for additional information. The USPSTF recommends that clinicians ask all pregnant persons about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation to pregnant persons who use tobacco.⁶⁴</p> <p>See the ACOG Guidelines for Perinatal Care, available at: https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx.</p> <p>See the USPSTF Grade A and B Recommendations, available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-and-b-recommendations.</p>
<p>4) Breastfeeding and other Health Education Assessment</p>	<ul style="list-style-type: none"> • Health Education including breast feeding, preparation to breastfeed, language, cultural competence, and education needs must be assessed at least once during each trimester and more frequently as needed. Identified needs must be incorporated into the Individualized Care Plan and follow up services documented. • Materials must be available in the appropriate threshold languages and must meet readability and suitability requirements for educational material distributed to Medi-Cal members.⁶⁵
<p>5) Preeclampsia Screening</p>	<p>USPSTF recommends screening for preeclampsia in pregnant women with blood pressure measurements throughout pregnancy.⁶⁶</p>

⁶⁴ See the USPSTF recommendation on Tobacco Smoking Cessation in Adults, Including Pregnant Persons, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions>.

⁶⁵ See APL 18-016, Readability and Suitability of Written Health Education Materials, or any superseding APL.

⁶⁶ See the ACIP recommendations on Routine Vaccination of Infants, Children, Adolescents, Pregnant Women, and Adults, available at: <https://www.cdc.gov/vaccines/vpd/dtap-dtap-td/hcp/recommendations.html>.

VI. OB/CPSP Preventive Criteria	
a) Low-Dose Aspirin	USPSTF recommends the use of low-dose aspirin (81 mg/d) as preventive medication after 12 weeks of gestation in women who are at high risk for preeclampsia. ⁶⁷
6) Intimate Partner Violence Screening	<ul style="list-style-type: none"> • USPSTF recommends that clinicians screen for IPV in women of reproductive age and provide or refer women who screen positive to ongoing support services.⁶⁸ • Provision of a Domestic Violence Screening is documented. • Assessment checklists, body diagrams and/or documentation in progress notes are acceptable. <p>Domestic violence screening includes:</p> <ul style="list-style-type: none"> • Medical screening. • Documentation of physical injuries or illnesses attributable to spousal/partner abuse. • Referral to appropriate community service agencies.⁶⁹
7) Diabetic Screening	<p>The USPSTF recommends screening for gestational diabetes mellitus (GDM) in asymptomatic pregnant women after 24 and 28 weeks of gestation.⁷⁰</p> <ul style="list-style-type: none"> • In the 2-step approach, the 50-g OGCT is performed between 24 and 28 weeks of gestation in a non-fasting state. If the screening threshold is met or exceeded, patients receive the oral glucose tolerance test (OGTT). A diagnosis of GDM is made when 2 or more glucose values fall at or above the specified glucose thresholds.

⁶⁷ See the USPSTF recommendation on Aspirin Use to Prevent Preeclampsia and Related Morbidity and Mortality, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/low-dose-aspirin-use-for-the-prevention-of-morbidity-and-mortality-from-preeclampsia-preventive-medication>.

⁶⁸ See the USPSTF recommendation on IPV, Elder Abuse, and Abuse of Vulnerable Adults Screening, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/intimate-partner-violence-and-abuse-of-elderly-and-vulnerable-adults-screening>.

⁶⁹ HSC 1233.5

⁷⁰ See the USPSTF recommendation on Screening for Gestational Diabetes, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/gestational-diabetes-screening>.

VI. OB/CPSP Preventive Criteria

	<ul style="list-style-type: none"> • 1-step approach, a 75-g glucose load is administered after fasting and plasma glucose levels are evaluated after one and two hours. Gestational diabetes is diagnosed if 1 glucose value falls at or above the specified glucose threshold. • <u>Self-monitoring of blood glucose can be a useful tool in the management of pregnant woman with pre-existing and with gestational diabetes.</u>
<p>8) Screening for Strep B</p>	<p>All pregnant women are screened for Group B Streptococcus (GBS) between their 35th and 37th week of pregnancy.</p> <p>Vaginal or rectal swab cultures at 36 – 37 weeks of gestation are positive for GBS, they should receive appropriate intrapartum antibiotic prophylaxis unless a prelabor cesarean birth is performed in the setting of intact membranes.</p> <p>Please refer to the following link for ACOG Frequently Asked Questions on Group B Streptococcus and pregnancy: https://www.acog.org/womens-health/faqs/group-b-strep-and-pregnancy.</p> <p>See the ACOG guidance on Prevention of Group B Streptococcal Early-Onset Disease in Newborns, available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/02/prevention-of-group-b-streptococcal-early-onset-disease-in-newborns?utm_source=vanity&utm_medium=web&utm_campaign=clinical.</p>
<p>9) Screening for Syphilis</p>	<p>Pregnant women with high risk for syphilis and women who live in areas with high syphilis morbidity should be re-tested for syphilis between 28 and 32 weeks and at delivery.</p> <p>Stat RPR should be performed at delivery for women with no prenatal care.</p> <p>https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/CS_Eval_Management_pregnant%20women.pdf</p>
<p>10) Tdap Immunization</p>	<ul style="list-style-type: none"> • Pregnant women should receive a single dose of Tdap during every pregnancy, preferably at 27 through 36 weeks gestation.

VI. OB/CPSP Preventive Criteria

	<ul style="list-style-type: none">• Tdap is recommended only in the immediate postpartum period before discharge from the hospital or birthing center for new mothers who have never received Tdap before or whose vaccination status is unknown.• Practitioners are required to ensure the provision of immunizations according to CDC's most recent ACIP guidelines, unless medically contraindicated or refused by the member. <p>See the CDC's ACIP recommendations on Routine Vaccination of Infants, Children, Adolescents, Pregnant Women, and Adults, available at: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/preeclampsia-screening1.</p> <p>See the CDC's ACIP guidelines on vaccines, available at: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html.</p> <p>Please note-the administration of pertussis is eligible for the Valued Based Payment (VBP) program. Please consult with the MCP for details.</p>
E. Prenatal care visit periodicity according to most recent ACOG Standards	<p>ACOG's <i>Guidelines for Perinatal Care</i> recommend the following prenatal schedule for a 40-week uncomplicated pregnancy:</p> <ol style="list-style-type: none">1) First visit by 6-8th week2) Approximately every 4 weeks for the first 28 weeks of pregnancy3) Every 2-3 weeks until 36 weeks gestation4) Weekly thereafter until delivery <p>If the recommended ACOG schedule is not met, documentation shows missed appointments, attempts to contact member and/or outreach activities.</p> <p>Refer the following link to ACOG for further details: https://www.acog.org/clinical</p>
F. Influenza Vaccine	<p>CDC and ACIP recommend that pregnant women gets vaccinated during any trimester of their pregnancy.</p> <p>Refer to the following link for further information on vaccination schedules:</p>

VI. OB/CPSP Preventive Criteria	
	<p>https://www.cdc.gov/vaccines/pregnancy/hcp-toolkit/guidelines.html</p> <p>https://www.cdc.gov/vaccines/hcp/acip-recs/rec-vac-preg.html</p> <p>See CDC guidance on pregnancy and vaccination, available at: https://www.cdc.gov/vaccines/pregnancy/pregnant-women/index.html</p> <p>See APL 18-004, Immunization Requirements, or any superseding APL for additional information.</p>
G. COVID Vaccine	<p>The American College of Obstetricians and Gynecologists (ACOG) recommends that all eligible persons greater than age 12 years, including pregnant and lactating individuals, receive a COVID-19 vaccine or vaccine series.</p> <p>Provider should document the discussion in the medical record if pregnant woman refused to receive the vaccine.</p> <p>During the subsequent office visits, obstetrician–gynecologists should address ongoing questions and concerns and offer vaccination again.</p> <p>https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care</p>
H. Referral to Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and assessment of Infant Feeding Status	<p>Pregnant and breastfeeding mothers must be referred to WIC.⁷¹</p> <ul style="list-style-type: none"> • Referral to WIC is documented in the medical record.⁷² • Infant feeding plans are documented during the prenatal period. • Infant feeding/breastfeeding status is documented during the postpartum period.⁷³ <p>Refer to the following link for information on the WIC program: https://m.wic.ca.gov/</p>

⁷¹ Public Law 103-448, Section 203(e)

⁷² 42 CFR 431.635

⁷³ PL 98-010, Breastfeeding Promotion

VI. OB/CPSP Preventive Criteria

Note: Although WIC determines eligibility for program participation, nearly all Medi-Cal beneficiaries are income eligible for WIC. Federal regulations specify that pregnant and breastfeeding women are given the highest priority for WIC Program enrollment.

I. HIV-related services *offered*

Per ACOG, repeat testing in the third trimester is recommended for women known to be at high risk of acquiring HIV infection, and women who declined testing earlier in pregnancy.

- The **offering** of prenatal HIV information, counseling, and HIV antibody testing is documented.⁷⁴
- Practitioners are **not required** to document that the HIV test was given or disclose (except to the member) the results (positive or negative) of an HIV test.
- Offering a prenatal HIV test is not required if a positive HIV test is already documented in the patient's record or if the patient has AIDS diagnosed by a physician.

See the ACOG Guidelines for Perinatal Care, available at:

<https://www.acog.org/clinical-information/physician-faqs/-/media/3a22e153b67446a6b31fb051e469187c.ashx>.

See the CDC STI Screening Recommendations, available at:

<https://www.cdc.gov/std/treatment-guidelines/screening-recommendations.htm>.

See the ACOG guidance on Prenatal and Perinatal HIV Testing, available at:

<https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Prenatal-and-Perinatal-Human-Immunodeficiency-Virus-Testing?IsMobileSet=false>.

See the USPSTF recommendation on HIV Screening, available at:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening>.

⁷⁴ HSC 125107

VI. OB/CPSP Preventive Criteria

J. AFP/Genetic Screening *offered*

The offering of blood screening tests prior to 20 weeks gestation counting from the first day of the last normal menstrual period is documented.⁷⁵ Genetic screening documentation includes:

- Family history
- Triple marker screening tests: Alpha Fetoprotein (AF), unconjugated estriol (UE), human chorionic gonadotropin (HCG)
- Member's consent or refusal to participate

For information on the Alpha-Fetoprotein Test, see:

<https://americanpregnancy.org/prenatal-testing/alpha-fetoprotein-test>

Note: Member's participation is voluntary. Testing occurs through CDPH Expanded AFP Program, and only laboratories designated by CDPH may be used for testing.

K. Family Planning Evaluation

- Women should be counseled about the risks and benefits of repeat pregnancy sooner than 18 months which have been associated with adverse perinatal outcomes, including preterm birth, low birth weight, and small size of gestational age, as well as adverse maternal outcomes.
- All postpartum women can be considered at risk for unintended pregnancy for that period of time.

Family Planning counseling, including counseling of interpregnancy intervals, contraceptive care, referral or provision of services is documented.⁷⁶ Prenatal discussions should include the woman's reproductive life plans, including the desire for and timing of any future pregnancies.

See the HHS guidance on Contraceptive Care Measures, available at:

<https://opa.hhs.gov/research-evaluation/title-x-services-research/contraceptive-care-measures>

⁷⁵ 17 CCR 6521-6532

⁷⁶ See PL 98-011, Family Planning Services in Medi-Cal Managed Care, or any superseding APL for additional information.

VI. OB/CPSP Preventive Criteria

See DHCS' Office of Family Planning webpage, available at:
<https://www.dhcs.ca.gov/services/ofp/Pages/OfficeofFamilyPlanning.aspx>

See APL 18-019, Family Planning Services Policy for Self-Administered Hormonal Contraceptives, or any superseding APL for additional information.

L. Comprehensive Postpartum Assessment

The weeks following birth are a critical period for a woman and her infant, setting the stage for long-term health and well-being. To optimize the health of women and infants, postpartum care should become an ongoing process, rather than a single encounter, with services and support tailored to each woman's individual needs. As of April 1, 2022, Medi-Cal's postpartum period is extended from 60 to 365 days, regardless of how the pregnancy ends.

- Per ACOG, women should contact their OB-GYN or other obstetric care providers within the first three weeks postpartum.
- The comprehensive postpartum visit should be scheduled between four weeks and six weeks after delivery.
- This initial postpartum assessment should be followed up with ongoing care as needed throughout the 12 month postpartum period, including with a comprehensive postpartum visit no later than 12 weeks after birth.

The comprehensive postpartum visit should include a full assessment of physical, social, and psychological well-being, including the following domains:

- Mood and emotional well-being
- Infant care and feeding
- Sexuality
- Contraception
- Birth spacing
- Sleep and fatigue
- Physical recovery from birth
- Chronic disease management
- Health maintenance

VI. OB/CPSP Preventive Criteria

Women with chronic medical conditions such as hypertensive disorders, obesity, diabetes, thyroid disorders, renal disease, and mood disorders should be counseled regarding the importance of timely follow-up with their OB-GYN or primary care providers for ongoing coordination of care.

During the postpartum period, the woman and her OB-GYN or other obstetric care provider should identify the health care provider who will assume primary responsibility for her ongoing care in her primary medical home.

See the ACOG guidance on Optimizing Postpartum Care, available at: <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/05/optimizing-postpartum-care>.

See the ACOG guidance on Postpartum Care, available at: <https://www.acog.org/news/news-releases/2018/04/acog-redesigns-postpartum-care>

See the CDPH CPSP Postpartum Assessment and ICP, available at: <https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/CDPH%20Document%20Library/CPSP-PostpartumAssessmentandCarePlan.pdf>.

<https://www.dhcs.ca.gov/services/medi-cal/eligibility/letters/Documents/I21-13.pdf#:~:text=Individuals%20in%20Medi-Cal%20with%20a%20SOC%20may%20be,for%20the%20rest%20of%20pregnancy%20and%20postpartum%20period.>

See PL 12-003, Obstetrical Care-Perinatal Services, or any superseding APL for additional information.

See ACOG information on Optimizing Postpartum Care, available at: <https://www.acog.org/More-Info/OptimizingPostpartumCare>.

Note: Postpartum care is eligible for the VBP program. Please consult with the MCP for details.

VI. OB/CPSP Preventive Criteria

	<p><u>For screening</u>: If the postpartum assessment visit is not documented a point will not be given. A point can be given if there is documentation in the medical record of missed appointments and attempts to contact member and/or outreach activities. If appointments are documented in a separate system from medical records, they must be readily accessible and meet the medical retention requirements.</p>
<p>1) Individualized Care Plan (ICP)</p>	<p>ICP documentation includes specific obstetric, nutrition, psychosocial and health education risk problems/conditions, interventions, and referrals.</p> <p>ICP must be developed based on the comprehensive assessment in each trimester and post-partum.</p> <p>See the CDPH CPSP Integrated Initial 1st, 2nd, and 3rd Trimester Assessments and ICP, available at: https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/CDPH%20Document%20Library/CPSP-CombinedInitialandTrimesterAssessmentandCarePlan.pdf.</p> <p>See the CDPH CPSP Postpartum Assessment and ICP, available at: https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/CDPH%20Document%20Library/CPSP-PostpartumAssessmentandCarePlan.pdf.</p>
<p>2) Nutrition Assessment</p>	<ul style="list-style-type: none"> • USPSTF recommends providing interventions during pregnancy and after birth to support breastfeeding. Nutrition Assessment should include mother and infant including support for breast feeding.⁷⁷ • Any needed interventions must be noted. • Documentation of referrals as indicated. Infant feeding/breastfeeding status is documented during the postpartum period.⁷⁸ <p>See the ACOG guidance on Optimizing Support for Breastfeeding as Part of Obstetric Practice, available at: https://www.acog.org/Clinical-Guidance-and-</p>

⁷⁷ See the USPSTF recommendation on Breastfeeding: Primary Care Interventions, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breastfeeding-primary-care-interventions>.

⁷⁸ See PL 98-010, Breastfeeding Promotion, or any superseding APL for additional information.

VI. OB/CPSP Preventive Criteria	
	<p>Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Optimizing-Support-for-Breastfeeding-as-Part-of-Obstetric-Practice?IsMobileSet=false.</p> <p>https://www.cdph.ca.gov/Programs/CFH/DMCAH/CPSP/CDPH%20Document%20Library/CPSP-PostpartumAssessmentandCarePlan.pdf</p>
3) Psychosocial Assessment	<p>Psychosocial Assessment includes mood and emotional wellbeing; sleep and fatigue.⁷⁹</p> <p>See the ACOG guidance on Optimizing Postpartum Care, available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/05/optimizing-postpartum-care.</p>
a) Maternal Mental Health Screening/Postpartum Depression screening	<p><i>Practitioner who provides prenatal or postpartum care for a patient shall ensure that the mother is offered screening or is appropriately screened for maternal mental health conditions. Counselling and intervention must be documented.</i></p> <ul style="list-style-type: none"> • USPSTF recommends that clinicians provide or refer postpartum persons who are at increased risk of postpartum depression to counseling interventions.⁸⁰ • CMS Technical Specifications includes screening using validated tools and documentation of a follow-up plan if the depression screening is positive that aligns with USPSTF's referral and documentation of counseling or interventions with those found at risk for postpartum depression. • Patient screened for depression on the date of the encounter using an age-appropriate standardized tool AND, if positive, a follow-up plan is documented on the date of the positive screen. <p><u>Standardized Depression Screening Tool</u> – A normalized and validated depression screening tool developed for the patient population in which it is being utilized. The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record.</p>

⁷⁹ See the ACOG guidance on Optimizing Postpartum Care, available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/05/optimizing-postpartum-care?utm_source=redirect&utm_medium=web&utm_campaign=otn.

⁸⁰ See the USPSTF recommendation on Perinatal Depression, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/abdominal-aortic-aneurysm-screening>.

VI. OB/CPSP Preventive Criteria

	<p><u>Follow-Up Plan</u> – Documented follow-up for a positive depression screening must include one or more of the following:</p> <ul style="list-style-type: none"> ○ Additional evaluation or assessment for depression ○ Suicide Risk Assessment ○ Referral to a practitioner who is qualified to diagnose and treat depression ○ Pharmacological interventions ○ Other interventions or follow-up for the diagnosis or treatment of depression <p>For additional information on CMS Technical Specifications, see: https://www.medicaid.gov/license/form/6466/4391.</p> <p>Edinburgh Postnatal Depression Scale (EPDS) is most commonly used and has been translated in 50 different languages.⁸¹</p>
<p>b) Social Needs Assessment</p>	<p>Social and Mental History (past and current). Follow up on pre-existing mental health disorders and social care needs such as housing, food, and transportation refer as appropriate.</p>
<p>c) Substance Use Disorder Assessment</p>	<p>Screen for tobacco and alcohol use and provide counseling; Screen for substance use disorder and refer as indicated.</p> <p>USPSTF recommends screening for unhealthy alcohol use in primary care settings in adults 18 years or older, including pregnant women, and providing persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce unhealthy alcohol use.⁸²</p> <p>See APL 21-014, Alcohol and Drug Screening, Assessment, Brief Interventions and Referral to Treatment, or any superseding APL for additional information.</p>

⁸¹ HSC 123640

⁸² See the USPSTF recommendation on Unhealthy Alcohol Use in Adolescents and Adults, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/unhealthy-alcohol-use-in-adolescents-and-adults-screening-and-behavioral-counseling-interventions>.

VI. OB/CPSP Preventive Criteria

	USPSTF recommends that clinicians ask all pregnant persons about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation to pregnant persons who use tobacco. ⁸³
4) Breastfeeding and other Health Education Assessment	<ul style="list-style-type: none">• Health Education on infant care and feeding including breast feeding, contraception, and birth spacing.• Materials must be in threshold language and must meet readability and suitability requirements for educational material distributed to Medi-Cal members.⁸⁴ <p>See the USPSTF recommendation on Breastfeeding, available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breastfeeding-primary-care-interventions.</p> <p>See APL 18-019, Family Planning Services Policy for Self-Administered Hormonal Contraceptives, or any superseding APL for additional information.</p>
5) Comprehensive Physical Exam	<p>The comprehensive postpartum visit should include a full assessment of physical, social, and psychological well-being, including the following domains:</p> <ul style="list-style-type: none">• Mood and emotional well-being• Infant care and feeding• Sexuality• Contraception• Birth spacing• Sleep and fatigue• Physical recovery from birth• Chronic disease management• Health maintenance

⁸³ See the USPSTF recommendation on Tobacco Smoking Cessation in Adults, Including Pregnant Persons, available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions>

⁸⁴ See APL 18-016, Readability and Suitability of Written Health Education Materials, or any superseding APL for additional information.

VI. OB/CPSP Preventive Criteria

Women with chronic medical conditions such as hypertensive disorders, obesity, diabetes, thyroid disorders, renal disease, and mood disorders should be counseled regarding the importance of timely follow-up with their OB-GYN or primary care providers for ongoing coordination of care.

During the postpartum period, the woman and her OB-GYN or other obstetric care provider should identify the health care provider who will assume primary responsibility for her ongoing care in her primary medical home.

It is recommended that all women have contact with their OB-GYN or other obstetric care providers within the first three weeks postpartum.

This initial assessment should be followed up with ongoing care as needed, concluding with a comprehensive postpartum visit no later than 12 weeks after birth.

See the ACOG guidance on Optimizing Postpartum Care, available at:

<https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/05/optimizing-postpartum-care>

Medical Record Review Tool

Health Plan: _____

Review Date: _____

Site ID: _____ Site NPI: _____

Reviewer name/title: _____

Address: _____

Reviewer name/title: _____

City and Zip Code: _____

Reviewer name/title: _____

Reviewer name/title: _____

Phone: _____ Fax: _____

Collaborating MCP(s): 1. _____

2. _____

No. of Physicians: _____

Contact person/title: _____

Provider Name	Credentials (MD, NP, PA, CNM, LM)	NPI

Electronic Medical Record (EMR): Yes ___ No ___



Paper/Hard Copy Medical Records: Yes ___ No ___ Shared Medical Records: Yes ___ No ___ Number of Records Reviewed: _____

Visit Purpose	Site-Specific Certification(s)	Provider Type	Clinic Type
<input type="checkbox"/> Initial Full Scope <input type="checkbox"/> Monitoring <input type="checkbox"/> Periodic Full Scope <input type="checkbox"/> Follow-up <input type="checkbox"/> Focused Review <input type="checkbox"/> Technical Assistance <input type="checkbox"/> Other _____ <div style="text-align: center; font-size: small;">(type)</div>	<input type="checkbox"/> AAAHC <input type="checkbox"/> JC <input type="checkbox"/> CHDP <input type="checkbox"/> NCQA <input type="checkbox"/> CPSP <input type="checkbox"/> None <input type="checkbox"/> Other _____	<input type="checkbox"/> Family Practice <input type="checkbox"/> Internal Medicine <input type="checkbox"/> General Practice <input type="checkbox"/> Pediatrics <input type="checkbox"/> OB/GYN as PCP _____ <input type="checkbox"/> Certified Nurse Midwife <input type="checkbox"/> Licensed Midwife	<input type="checkbox"/> Primary Care <input type="checkbox"/> Community <input type="checkbox"/> Hospital <input type="checkbox"/> FQHC <input type="checkbox"/> Rural Health <input type="checkbox"/> Solo <input type="checkbox"/> Group <input type="checkbox"/> Staff/Teaching <input type="checkbox"/> Other (Type) _____

Medical Record Scores						Scoring Procedure				Compliance Rate	
Note: When scoring for OB/CPSP Preventive, score the Adult or Pediatric Preventive criteria for the same record.						Scoring is based on <u>10</u> medical records.				Note: Any section score of < 80% requires a CAP for the entire MRR, regardless of the Total MRR score.	
	Points possible	Yes Pts. Given	No's	N/A's	Section Score %	1) Add points given in each section. 2) Add points given for all six (6) sections. 3) Subtract "N/A" points (if any) from total points possible to get "adjusted" total points possible. 4) Divide total points given by "adjusted" total points possible. 5) Multiply by 100 to determine compliance rate as a percentage.				Exempted Pass: 90% or above: (Total score is \geq 90% and all section scores are 80% or above)	
I. Format	(8) x 10 = 80					$\frac{\text{Points Given}}{\text{Total/ Adjusted Pts. Poss.}} = \frac{\text{Decimal Score}}{\text{Compliance Rate}} \times 100 = \text{Percentage}$				Conditional Pass: 80-89%: (Total MRR is 80-89% OR Any section(s) score is < 80%)	
II. Documentation	(8) x 10 = 90									Fail: 79% and Below	
III. Coordination of Care	(8) x 10 = 80									CAP Required	
IV. Pediatric Preventive	(34) x # of records									Other follow-up	
V. Adult Preventive	(30) x # of records									Next Review Due: _____	
VI. OB/CPSP Preventive	(59) x # of records										
	Points Possible	Yes Pts. Given	No's	N/A's							

Medical Records Reference:

Medical Record	CIN	Age Year/Month	Gender	Member's MCP Enrollment Date	PCP's MCP Effective Date	On Site (x)	Remote Access (x)
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

I. Format Criteria												
  RN/NP/MD/PA/CNM/LM												
Criteria met: Give one (1) point Criteria not met: 0 points Criteria not applicable: N/A	Wt.	MR #1	MR #2	MR #3	MR #4	MR #5	MR #6	MR #7	MR #8	MR #9	MR #10	Score
Individual Medical Record is established for each member.												
A. Member identification is on each page.	1											
B. Individual personal biographical information is documented.	1											
C. Emergency “contact” is identified.	1											
D. Medical records are maintained and organized.	1											
E. Member’s assigned and/or rendering primary care physician (PCP) is identified.	1											
F. Primary language and linguistic service needs of non-or limited-English proficient (LEP) or hearing/speech-impaired persons are prominently noted.	1											
G. Person or entity providing medical interpretation is identified.	1											
H. Signed Copy of the Notice of Privacy.	1											
Comments:	Yes											
	No											
	NA											

II. Documentation Criteria

  RN/NP/MD/PA/CNM/LM

Criteria met: Give one (1) point Criteria not met: 0 points Criteria not applicable: N/A	Wt.	MR #1	MR #2	MR #3	MR #4	MR #5	MR #6	MR #7	MR #8	MR #9	MR #10	Score
A. Allergies are prominently noted.	1											
B. Chronic problems and/or significant conditions are listed.	1											
C. Current <i>continuous</i> medications are listed.	1											
D. Appropriate consents are present:												
1) Release of Medical Records	1											
2) Informed Consent for invasive procedures	1											
E. Advance Health Care Directive Information is offered.	1											
F. All entries are signed, dated, and legible.	1											
G. Errors are corrected according to legal medical documentation standards.	1											
Comments:	Yes											
	No											
	N/A											

III. Coordination of Care Criteria

  RN/NP/MD/PA/CNM/LM

Criteria met: Give one (1) point Criteria not met: 0 points Criteria not applicable: N/A	Wt.	MR #1	MR #2	MR #3	MR #4	MR #5	MR #6	MR #7	MR #8	MR #9	MR #10	Score
A. History of present illness or reason for visit is documented.	1											
B. Working diagnoses are consistent with findings.	1											
C. Treatment plans are consistent with diagnoses.	1											
D. Instruction for follow-up care is documented.	1											
E. Unresolved/continuing problems are addressed in subsequent visit(s).	1											
F. There is evidence of practitioner <i>review</i> of specialty/consult/referral reports and diagnostic test results.	1											
G. There is evidence of <i>follow-up</i> of specialty consult/referrals made, and results/reports of diagnostic tests, when appropriate.	1											
H. Missed primary care appointments and outreach efforts/follow-up contacts are documented.	1											
Comments:	Yes											
	No											
	N/A											

IV. Pediatric Preventive Criteria NOTE: * denotes Pending AAP guidance.

 RN/NP/MD/PA/CNM/LM

Criteria met: Give one (1) point Criteria not met: 0 points Criteria not applicable: N/A	Wt.	MR #1	MR #2	MR #3	MR #4	MR #5	MR #6	MR #7	MR #8	MR #9	MR #10	Score
A. Initial Health Assessment (IHA) Includes H&P and Individual Health Education Behavioral Assessment (IHEBA)												
1) Comprehensive History and Physical	1											
2) IHEBA	1											
B. Subsequent Comprehensive Health Assessment												
1) Comprehensive History and Physical exam completed at age-appropriate frequency	1											
2) Subsequent Periodic IHEBA	1											
C. Well-child visit												
1) Alcohol Use Disorder Screening and Behavioral Counseling	1											
2) Anemia Screening	1											
3) Anthropometric Measurements	1											
4) Anticipatory Guidance	1											
5) Autism Spectrum Disorder Screening	1											
6) Blood Lead Screening	1											
7) Blood Pressure Screening	1											
8) Dental/Oral Health Assessment	1											
a) Fluoride Supplementation	1											
b) Fluoride Varnish	1											
9) Depression Screening	1											

IV. Pediatric Preventive Criteria NOTE: * denotes Pending AAP guidance.

 RN/NP/MD/PA/CNM/LM

Criteria met: Give one (1) point Criteria not met: 0 points Criteria not applicable: N/A	Wt.	MR #1	MR #2	MR #3	MR #4	MR #5	MR #6	MR #7	MR #8	MR #9	MR #10	Score
a) Suicide-Risk Screening*	1											
b) Maternal Depression Screening	1											
10) Developmental Disorder Screening	1											
11) Developmental Surveillance	1											
12) Drug Use Disorder Screening and Behavioral Counseling	1											
13) Dyslipidemia Screening	1											
14) Hearing Screening	1											
15) Hepatitis B Virus Infection Screening*	1											
16) Hepatitis C Virus Infection Screening	1											
17) Human Immunodeficiency Virus (HIV) Infection Screening	1											
18) Psychosocial/Behavioral Assessment	1											
19) Sexually Transmitted Infections (STIs) Screening and Counseling	1											
20) Sudden Cardiac Arrest and Sudden Cardiac Death Screening*	1											
21) Tobacco Use Screening, Prevention, and Cessation Services	1											
22) Tuberculosis Screening	1											
23) Vision Screening	1											
D. Childhood Immunizations												
1) Given according to Advisory Committee on Immunization Practices (ACIP) guidelines	1											
2) Vaccine administration documentation	1											

IV. Pediatric Preventive Criteria NOTE: * denotes Pending AAP guidance.

  **RN/NP/MD/PA/CNM/LM**

Criteria met: Give one (1) point
 Criteria not met: 0 points
 Criteria not applicable: N/A

	Wt.	MR #1	MR #2	MR #3	MR #4	MR #5	MR #6	MR #7	MR #8	MR #9	MR #10	Score
3) Vaccine Information Statement (VIS) documentation	1											
Comments:	Yes											
	No											
	N/A											

V. Adult Preventive Criteria

 RN/NP/MD/PA/CNM/LM

Criteria met: Give one (1) point Criteria not met: 0 points Criteria not applicable: N/A	Wt.	MR #1	MR #2	MR #3	MR #4	MR #5	MR #6	MR #7	MR #8	MR #9	MR #10	Score
A. Initial Health Assessment (IHA): Includes H&P and Individual Health Education Behavioral Assessment (IHEBA)												
1) Comprehensive History and Physical	1											
2) IHEBA	1											
B. Periodic Health Evaluation according to most recent United States Preventive Services Taskforce (USPSTF) Guidelines												
1) Comprehensive History and Physical Exam completed at age-appropriate frequency	1											
2) Subsequent Periodic IHEBA	1											
C. Adult Preventive Care Screenings												
1) Abdominal Aneurysm Screening	1											
2) Alcohol Use Disorder Screening and Behavioral Counseling	1											
3) Breast Cancer Screening	1											
4) Cervical Cancer Screening	1											
5) Colorectal Cancer Screening	1											
6) Depression Screening	1											
7) Diabetic Screening	1											
a) Comprehensive Diabetic Care	1											
8) Drug Disorder Screening and Behavioral Counseling	1											
9) Dyslipidemia Screening	1											
10) Folic Acid Supplementation	1											
11) Hepatitis B Virus Screening	1											

V. Adult Preventive Criteria

 RN/NP/MD/PA/CNM/LM

Criteria met: Give one (1) point Criteria not met: 0 points Criteria not applicable: N/A	Wt.	MR #1	MR #2	MR #3	MR #4	MR #5	MR #6	MR #7	MR #8	MR #9	MR #10	Score
12) Hepatitis C Virus Screening	1											
13) High Blood Pressure Screening	1											
14) HIV Screening	1											
15) Intimate Partner Violence Screening for Women of Reproductive Age	1											
16) Lung Cancer Screening	1											
17) Obesity Screening and Counseling	1											
18) Osteoporosis Screening	1											
19) Sexually Transmitted Infection (STI) Screening and Counseling	1											
20) Skin Cancer Behavioral Counseling	1											
21) Tobacco Use Screening, Counseling, and Intervention	1											
22) Tuberculosis Screening	1											
D. Adult Immunizations												
1) Given according to ACIP guidelines	1											
2) Vaccine administration documentation	1											
3) Vaccine Information Statement (VIS) documentation	1											
Comments:	Yes											
	No											
	N/A											

VI. OB/CPSP Preventive Criteria

  RN/NP/MD/PA/CNM/LM

Criteria met: Give one (1) point
 Criteria not met: 0 points
 Criteria not applicable: N/A

	Wt.	MR #1	MR #2	MR #3	MR #4	MR #5	MR #6	MR #7	MR #8	MR #9	MR #10	Score
A. Initial Comprehensive Prenatal Assessment (ICA)												
1) Initial prenatal visit	1											
2) Obstetrical and Medical History	1											
3) Physical Exam	1											
4) Dental Assessment	1											
5) Healthy Weight Gain and Behavior Counseling	1											
6) Lab tests												
a) Bacteriuria Screening	1											
b) Rh Incompatibility Screening	1											
c) Diabetes Screening	1											
d) Hepatitis B Virus Screening	1											
e) Hepatitis C Virus Screening	1											
f) Chlamydia Infection Screening	1											
g) Syphilis Infection Screening	1											
h) Gonorrhea Infection Screening	1											
i) Human Immunodeficiency Virus (HIV) Screening	1											
B. First Trimester Comprehensive Assessment												
1) Individualized Care Plan (ICP)	1											
2) Nutrition Assessment	1											

VI. OB/CPSP Preventive Criteria

  RN/NP/MD/PA/CNM/LM

Criteria met: Give one (1) point
 Criteria not met: 0 points
 Criteria not applicable: N/A

	Wt.	MR #1	MR #2	MR #3	MR #4	MR #5	MR #6	MR #7	MR #8	MR #9	MR #10	Score
3) Psychosocial Assessment												
a) Maternal Mental Health Screening	1											
b) Social Needs Assessment	1											
c) Substance Use Disorder	1											
4) Breast Feeding and other Health Education Assessment	1											
5) Preeclampsia Screening	1											
6) Intimate Partner Violence Screening	1											
C. Second Trimester Comprehensive assessment												
1) ICP	1											
2) Nutrition Assessment	1											
3) Psychosocial Assessment												
a) Maternal Mental Health Screening	1											
b) Social Needs Assessment	1											
c) Substance Use Disorder Assessment	1											
4) Breast Feeding and other Health Education Assessment	1											
5) Preeclampsia Screening	1											
a) Low Dose Aspirin	1											
6) Intimate Partner Violence Screening	1											
7) Diabetes Screening	1											

VI. OB/CPSP Preventive Criteria

  RN/NP/MD/PA/CNM/LM

Criteria met: Give one (1) point
 Criteria not met: 0 points
 Criteria not applicable: N/A

	Wt.	MR #1	MR #2	MR #3	MR #4	MR #5	MR #6	MR #7	MR #8	MR #9	MR #10	Score
D. Third Trimester Comprehensive assessment												
1) ICP Update and Follow Up	1											
2) Nutrition Assessment	1											
3) Psychosocial Assessment												
a) Maternal Mental Health Screening	1											
b) Social Needs Assessment	1											
c) Substance Use Disorder Assessment	1											
4) Breastfeeding and other Health Education Assessment	1											
5) Preeclampsia Screening	1											
a) Low Dose Aspirin	1											
6) Intimate Partner Violence Screening	1											
7) Diabetic Screening	1											
8) Screening for Strep B	1											
9) Screening for Syphilis	1											
10) Tdap Immunization	1											
E. Prenatal care visit periodicity according to most recent American College of Obstetricians and Gynecologists (ACOG) standards	1											
F. Influenza Vaccine	1											
G. COVID Vaccine	1											

VI. OB/CPSP Preventive Criteria

 RN/NP/MD/PA/CNM/LM

Criteria met: Give one (1) point
 Criteria not met: 0 points
 Criteria not applicable: N/A


	Wt.	MR #1	MR #2	MR #3	MR #4	MR #5	MR #6	MR #7	MR #8	MR #9	MR #10	Score
H. Referral to Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and assessment of Infant Feeding Status	1											
I. HIV-related services <i>offered</i>	1											
J. AFP/Genetic Screening offered	1											
K. Family Planning Evaluation	1											
L. Comprehensive Postpartum Assessment												
1) ICP	1											
2) Nutrition Assessment	1											
3) Psychosocial Assessment												
a) Maternal Mental Health Screening/Postpartum Depression screening	1											
b) Social Needs Assessment	1											
c) Substance Use Disorder Assessment	1											
4) Breastfeeding and other Health Education Assessment	1											
5) Comprehensive Physical Exam	1											
Comments:	Yes											
	No											
	N/A											

Facility Site Review Standards

Purpose: The Facility Site Review Standards provide the instructions, rules, regulations, parameters, and indicators for conducting Facility Site Reviews using the Facility Site Review tool. The site reviewer must use these Standards for measuring, evaluating, assessing, and making decisions.

Scoring: Site reviews include on-site inspection and interviews with site personnel. Reviewers are expected to use reasonable evidence available during the review process to determine if practices and systems on site meet review criteria. Critical Elements have a weight of two (2) points each and non-Critical Elements have a weight of one (1) point on the site review tool. Compliance levels include:

- 1) Exempted Pass: 90% or above *without deficiencies* in Critical Elements, Pharmaceutical or Infection Control
- 2) Conditional Pass: 80-89%, or 90% and above with deficiencies in either Critical Elements, Pharmaceutical or Infection Control
- 3) Fail: 79% and below

A corrective action plan (CAP) is required for a total score less than 90%, *OR* for a total score of 90% or above if there are deficiencies in Critical Elements, Pharmaceutical Services or Infection Control. Compliance rates are based on 169 total possible points, or on the total “adjusted” for Not Applicable (N/A) items. “N/A” applies to any scored item that does not apply to a specific site as determined by the reviewer. Reviewers are expected to determine how to ascertain information needed to complete the review. Review criteria that shall be reviewed *only* by a registered nurse (RN), nurse practitioner (NP), Certified Nurse Midwife (CNM), Licensed Midwife (LM), physician (MD), or physician assistant (PA) is labeled “ **RN/NP/CNM/LM/MD/PA**”.

Directions: Score full point(s) if review item is met. Score zero (0) points if item is not met. Do not score partial points for any item. Explain all “N/A” and “No” (0 point) items in the comment section. Provide assistance/consultation as needed for CAPs and establish follow-up/verification timeline.

- 1) Add the points given in each section.
- 2) Add points given for all six (6) sections to determine total points given for the site.
- 3) Subtract all “N/A” items from 170 total possible points to determine the “adjusted” total possible points. If there are no “N/A” items, calculation of site score will be based on 170 points.
- 4) Divide the total points given by 170 or by the “adjusted” total. Multiply by 100 to calculate percentage rate.

Scoring Example:

Step 1: Add the points given in each section.

Step 2: Add points given for all six (6) sections.

Example: 31 (Access/Safety)
27 (Personnel)
25 (Office Management)
40 (Clinical Services)
13 (Preventive Services)
34 (Infection Control)
170 (POINTS GIVEN)

Step 3: Subtract “N/A” points from 170 total points possible.

170 (Total points possible)
- 5 (N/A points)
165 (“Adjusted” total points possible)

Step 4: Divide total points given by the “adjusted” points, then multiply by 100 to calculate percentage rate.

$$\frac{\text{Points given}}{\text{“Adjusted” total}} \quad \text{or} \quad \frac{140}{165} = 0.8485 \times 100 = \mathbf{85\%}$$

Criteria	I. Access/Safety Standards
<p>A. Site is accessible and useable by individuals with physical disabilities.</p>	<p>Sites must have the following safety accommodations for physically disabled persons:</p> <p><u>Americans with Disabilities Act (ADA) Regulations:</u></p> <ul style="list-style-type: none"> • Site must meet city, county, and state building structure and access ordinances for persons with physical disabilities. A site/facility includes the building structure, walkways, parking lots, and equipment. • All facilities designed, constructed; or altered by, on behalf of, or for the use of a public entity must be readily accessible and usable by individuals with disabilities, if the construction or alteration was begun after January 26, 1992.¹ • Any alteration to a place of public accommodation or a commercial facility, after January 26, 1992, must be made to ensure that, to the maximum extent feasible, the altered portions of the facility are readily accessible to and useable by individuals with disabilities, including individuals who use wheelchairs.² <p>I.A.1) Clearly marked (blue) curb or sign designating disabled-parking space near accessible primary entrance.</p> <p><u>Parking:</u></p> <ul style="list-style-type: none"> • Parking spaces for persons with physical disabilities are located in close proximity to accessible building entrances. • Each parking space reserved for persons with disabilities is identified by a permanently affixed reflectorized sign posted in a conspicuous place. • If the provider has no control over availability of accessible parking within lot or nearby street spaces for persons with disabilities, the provider must have a plan in place for making program services available to persons with physical disabilities. <p>I.A.2) Pedestrian ramps have a level landing at the top and bottom of the ramp.</p> <p><u>Ramps:</u></p> <ul style="list-style-type: none"> • A clear and level landing is at the top and bottom of all ramps and on each side of an exit door. • Any path of travel is considered a ramp if its slope is greater than a 1-foot rise in 20 feet of horizontal run. • Ramps must be a minimum of 36-inches wide. Some areas require wider ramps.

¹ Title 28, Code of Federal Regulations (CFR), section 35.151. The CFR is searchable at: <https://www.ecfr.gov/search>.

² 28 CFR section 36.402.

Criteria	I. Access/Safety Standards
	<ul style="list-style-type: none"> • All edges must be protected to keep anyone from slipping off. • All ramps that are 5 feet long shall have a level top and bottom landings. • Ramps must have handrails on both sides if length is longer than 6 feet. <p>I.A.3) Exit and exam room doorway openings allow for clear passage of a person in a wheelchair.</p> <p><u>Exit Doors:</u></p> <ul style="list-style-type: none"> • All entrances and exterior and interior exit doors, regardless of the occupant load shall be made accessible to persons with disabilities. • Exam room and exit doorways have a minimum opening of 32 inches with the door open at 90 degrees that will allow for passage of wheelchairs. • Door hardware = operable with a single effort without requiring ability to grasp hardware. • Effort to operate doors = a maximum pressure of 5 pounds at interior doors. • Door hardware height = 30” – 44” above floor. • Exit doors include all doors required for access, circulation and use of the building and facilities, such as primary entrances and passageway doors. • Furniture and other items do not obstruct exit doorways or interfere with door swing pathway. <p>I.A.4) Accessible passenger elevator or reasonable alternative for multi-level floor accommodation.</p> <p><u>Elevators:</u></p> <ul style="list-style-type: none"> • If there is no elevator, a freight elevator may be used to achieve program accessibility if it is upgraded for general passenger use and if passageways leading to and from the elevator are well-lit, neat, and clean. <p>I.A.5) Clear floor space for wheelchair in waiting area and exam room.</p> <p><u>Clear Floor Space:</u></p> <ul style="list-style-type: none"> • Clear space in waiting/exam areas is sufficient (at least 30-in. x 48-in.) to accommodate a single, stationary adult wheelchair and occupant. • A minimum clear space of 60-inch diameter or square area is needed to turn a wheelchair. <p><u>Sanitary Facilities:</u></p> <p>I.A.6) Wheelchair accessible restroom facilities.</p> <ul style="list-style-type: none"> • A wheelchair accessible restroom stall allows sufficient space for a wheelchair to enter and permits the door to close.

Criteria	I. Access/Safety Standards
	<ul style="list-style-type: none"> • Sufficient knee clearance space underneath the sink allows wheelchair users to safely use a lavatory sink for hand washing. • If wheelchair-accessible restrooms are not available within the office site, reasonable alternative accommodation are provided such as a wheelchair-accessible restroom located within the building. Other reasonable alternatives may include, but is not limited to, urinal, bedpan, or bedside commode in a private area. <p>IA.7) Wheelchair accessible handwashing facilities or reasonable alternative.</p> <ul style="list-style-type: none"> • Restroom and hand washing facilities are accessible to able-bodied and physically disabled persons. • If wheelchair-accessible handwashing facilities are not available within the office site, reasonable alternative accommodation are provided such as sanitizers and wheelchair-accessible restroom located within the building. <p>Note:</p> <ul style="list-style-type: none"> • A public entity may not deny the benefits of its program, activities, and services to individuals with disabilities because its facilities are inaccessible.³ • Every feature need not be accessible, if a reasonable portion of the facilities and accommodations provided is accessible.⁴ • Reasonable Portion and/or Reasonable Alternatives are acceptable to achieve program accessibility. • Reasonable Portion applies to multi-storied structures and provides exceptions to the regulations requiring accessibility to all portions of a facility/site. • Reasonable Alternatives are methods other than site structural changes to achieve program accessibility, such as acquisition or redesign of equipment, assignment of assistants/aides to beneficiaries, provision of services at alternate accessible sites, and/or other site-specific alternatives to provide services.⁵ • Points shall not be deducted if Reasonable Portion or Reasonable Alternative is made available on site.

³ 28 CFR sections 35.149 – 35.150.

⁴ Title 24, California Code of Regulations (CCR), sections 2-419, California Administrative Code, the State Building Code. CCR is searchable at: <https://govt.westlaw.com/calregs/Search/Index>.

⁵ Title II-5.2000 of the ADA Technical Assistance Manual, available at: <https://www.ada.gov/taman2.html>.

Criteria	I. Access/Safety Standards
	<p>Specific measurements are provided strictly for “reference only” for the reviewer. Site reviewers are <i>NOT</i> expected to measure parking areas, pedestrian path of travel walkways and/or building structures on site.</p>
<p>B. Site environment is maintained in a clean and sanitary condition.</p>	<p>I.B.1) All patient areas including floor/carpet, walls, and furniture are neat, clean, and well maintained.</p> <ul style="list-style-type: none"> • The physical appearance of floors/carpets, walls, furniture, patient areas, and restrooms are clean and well maintained. <p>I.B.2) Restrooms are clean and contain appropriate sanitary supplies.</p> <ul style="list-style-type: none"> • Appropriate sanitary supplies, such as toilet tissue, hand washing soap, cloth/paper towels or antiseptic towelettes are made available for restroom use. • Environmental safety includes the “housekeeping” or hygienic condition of the site. • Clean means unsoiled, neat, tidy, and uncluttered. • “Well maintained” means being in good repair or condition.
<p>C. Site environment is safe for all patients, visitors and personnel.</p>	<p><u>Ordinances:</u></p> <ul style="list-style-type: none"> • Sites must meet city, county, and state fire safety and prevention ordinances. • Reviewers should be aware of applicable city and county ordinances in the areas in which they conduct reviews. <p>There is evidence staff has received safety training and/or has safety information available on the following:</p> <p>I.C.1) Fire safety and prevention.</p> <p>I.C.2) Emergency non-medical procedures (e.g. site evacuation, workplace violence).</p> <p><u>Emergency Action Plans:</u></p> <ul style="list-style-type: none"> • Non-medical emergencies include incidents of fire, natural disaster (e.g. earthquakes), workplace violence, etc. • Specific information for handling fire emergencies and evacuation procedures is available on site to staff. Personnel know where to locate information on site, and how to use information.⁶

⁶ 29 CFR section 1910.38
July 1 2022

Criteria	I. Access/Safety Standards
	<p>I.C.3) Lighting is adequate in all areas to ensure safety. Illumination: Lighting is adequate in-patient flow working and walking areas such as corridors, walkways, waiting and exam rooms, and restrooms to allow for a safe path of travel.</p> <p><u>I.C.4) (CE) Exit doors and aisles are unobstructed and egress (escape) accessible.</u> Access Aisle:</p> <ul style="list-style-type: none"> • Accessible pedestrian paths of travel (ramps, corridors, walkways, lobbies, elevators, etc.) between elements (seats, tables, displays, equipment, parking spaces, etc.) provide a clear circulation path. • The minimum clear passage needed for a single wheelchair is 36 inches along an accessible route but may be reduced to a minimum of 32 inches at a doorway. • Means of egress (escape routes) are maintained free of obstructions or impediments to full instant use of the path of travel in case of fire or other type of emergency. • Building escape routes provide an accessible, unobstructed path of travel for pedestrians and/or wheelchair users at all times when the site is occupied. • Cords (including taped cords) or other items are not placed on or across walkway areas. <p>I.C.5) Exit doors are clearly marked with “Exit” signs. Exits: Exit doorways are unobstructed and clearly marked by a readily visible “Exit” sign.⁷</p> <p>I.C.6) Clearly diagramed “Evacuation Routes” for emergencies are posted in a visible location at all elevators, stairs and exits. Evacuation Routes:</p> <ul style="list-style-type: none"> • Clearly diagramed “Evacuation Routes” for emergencies are posted in a visible location at all elevators, stairs and exits.⁸ <p>I.C.7) Electrical cords and outlets are in good working condition. Electrical Safety:</p> <ul style="list-style-type: none"> • Electrical cords are in good working condition with no exposed wires, frayed or cracked areas. Cords are not affixed to structures, placed in or across walkways, extended through walls, floors, and ceiling, or under doors or floor coverings.


⁷ 29 CFR 1910.37

⁸ 29 CFR 1910.33-39, 19 CCR 3.09 (a) (1) (B).

Criteria	I. Access/Safety Standards
	<ul style="list-style-type: none"> • Extension cords are not used as a substitute for permanent wiring. • All electrical outlets have an intact wall faceplate. • Sufficient clearance is maintained around lights and heating units to prevent combustible ignition. <p>I.C.8) Fire Fighting Equipment in accessible location. <u>Firefighting equipment:</u> <u>There is firefighting equipment that must be in accessible locations on site. At least one of the following types of fire safety equipment is on site:</u></p> <ul style="list-style-type: none"> • <u>Fire Extinguisher:</u> The employer shall provide portable fire extinguishers and shall mount, locate, and identify them so that they are readily accessible. Fire extinguishers are maintained in a fully charged and operable condition and kept in their designated places at all times except during use.⁹ • Smoke Detector with intact batteries. • Automatic Sprinkler System With a 10-inch clearance between sprinkler heads and stored materials. <p>I.C.9) An employee alarm system. <u>Employee Alarm System:</u></p> <ul style="list-style-type: none"> • Employers must install and maintain an operable employee alarm system that has a distinctive signal to warn employees of fire or other emergencies, unless employees can promptly see or smell a fire or other hazard in time to provide adequate warning to them.¹⁰ <p>OSHA: For those employers with 10 or fewer employees in a workplace, direct voice communication is an acceptable procedure for sounding the alarm provided all employees can hear the alarm. Such workplaces do not need a back-up system.</p> <p><u>Note:</u> Specific measurements are provided strictly for “<i>reference only</i>” for the reviewer. Site reviewers are <i>NOT</i> expected to measure parking areas, pedestrian path of travel walkways and/or building structures on site.</p>

⁹ 29 CFR 1910.157

¹⁰ 29 CFR 1910.37

Criteria	I. Access/Safety Standards
<p>D. Emergency health care services are available and accessible 24 hours a day, 7 days a week.</p> <p> RN/NP/CNM/LM/MD/PA</p>	<p>I.D. 1) Personnel are trained in procedures/action plan to be carried out in case of medical emergency on site.</p> <p><u>Site Specific Emergency Procedures:</u></p> <ul style="list-style-type: none"> • Staff can describe site-specific actions or procedures for handling medical emergencies until the individual is stable or under care of local emergency medical services (EMS). • There is a written procedure for providing immediate emergent medical care on site until the local EMS is on the scene. Although site proximity to emergency care facilities may be considered when evaluating medical emergency procedures, the key factor is the ability to provide immediate care to patients <i>on site</i> until the patient is stable or EMS has taken over care/treatment. • When the physician or non-physician medical practitioner (NPMP) is not on site, staff/MA may call 911, and CPR-certified staff may initiate CPR if needed. • Non-CPR-certified staff may only call 911 and stay with the patient until help arrives. <p>I.D.2) Emergency equipment is stored together in easily accessible location and is ready to be used.</p> <p><u>Emergency Medical Equipment:</u></p> <p>During business hours providers are prepared to provide emergency services for management of emergency medical conditions that occur on site <i>until</i> the emergent situation is stabilized and/or treatment is initiated by the local 911 Emergency Medical Service (EMS) system. Minimum emergency equipment is available on site to:</p> <ul style="list-style-type: none"> ○ Establish and maintain a patent/open airway. ○ Manage emergency medical conditions. <p>Emergency equipment and medication, appropriate to patient population served, are available in an accessible location and ready for use.</p> <ul style="list-style-type: none"> • An accessible location is one that is reachable by personnel standing on the floor, or other permanent working area, without locating/retrieving step stool, ladder or other assistive devices. • For emergency “Crash” cart/kit, contents are appropriately sealed and are within the expiration dates posted on label/seal. • Site personnel are appropriately trained and can demonstrate knowledge and correct use of all medical equipment they are expected to operate within their scope of work. <p>https://www.aafp.org/afp/2007/0601/p1679.html</p>

Criteria	I. Access/Safety Standards
	<p>I.D. 3) Emergency phone number contacts are posted, updated annually and as changes occur.</p> <p><u>Emergency Phone Number list:</u> Posted in an accessible and prominent location(s) and includes:</p> <ul style="list-style-type: none"> ○ Local emergency response services (e.g., fire, police/sheriff, ambulance). ○ Emergency contacts (e.g., responsible managers, supervisors). ○ Appropriate State, County, City, and local agencies (e.g., local poison control number). <p>The list should be dated, and telephone numbers updated annually and as changes occur.</p> <p>Emergency medical equipment appropriate to practice/patient population is available on site:</p> <p><u>I.D. 4) (CE) Airway management: oxygen delivery system, nasal cannula or mask, bulb syringe and Ambu bag:</u> Without the ability to adequately maintain the patient’s airway, all other interventions are futile. Minimum airway control equipment with various sizes of airway devices appropriate to patient population within the practice and examples of oxygen delivery systems include:</p> <ul style="list-style-type: none"> ○ Wall oxygen delivery system ○ Portable oxygen tank ○ Portable oxygen concentrator (POC) <p>All oxygen delivery systems must be able to be regulated up to 6 liters of oxygen per minute, maintained for a minimum of 15 minutes. This flow rate establishes a minimum total oxygen delivery capacity of 90 liters for these devices:¹¹</p> <ul style="list-style-type: none"> ○ Nasal cannula or mask ○ Bulb syringe ○ Ambu bag as appropriate to patient population served. Mask should be replaced when they no longer make a solid seal.

¹¹ See the Food and Drug Administration (FDA) guidelines for oxygen generators and oxygen equipment for emergency use, available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/review-guidelines-oxygen-generators-and-oxygen-equipment-emergency-use>

- Portable oxygen tanks are maintained at least $\frac{3}{4}$ full. There is a method/system in place for oxygen tank replacement. If oxygen tanks are less than $\frac{3}{4}$ full at time of site visit, site has a back-up method for supplying oxygen if needed **and** a scheduled plan for tank replacement.
- Oxygen tubing does not need be connected to oxygen tank, but must be kept in close proximity to tank.

Oropharyngeal airways are no longer required.

I.D.5) (CE) Emergency medicine for anaphylactic reaction management, opioid overdose, chest pain, asthma, and hypoglycemia:

Severe allergic reaction can cause urticaria (hives), hypotension, bronchospasm, wheezing, and pulmonary edema. Per the American Academy of Family Practice (AAFP), the minimum equipment to manage emergency anaphylactic reaction, asthma exacerbation, chest pain, opioid overdose, and hypoglycemia, based on the patient population served, shall include:

- Epinephrine 1mg/mL (injectable)
- Diphenhydramine 25 mg (oral) or 50 mg/ml (injectable)
- Naloxone¹²
- Chewable aspirin 81 mg¹³
- Nitroglycerin spray/tablet¹⁴
- Bronchodilator medication (solution for nebulizer or metered dose inhaler)
- Glucose (any type of glucose containing at least 15 grams)
- Appropriate sizes of ESIP needles/syringes¹⁵ and alcohol wipes

- The typical adult strength to address cardiac emergencies is 325 mg (four doses of 81 mg chewable aspirin or one dose of 325 non-enteric coated aspirin).
- If the site is seeing adults, the reviewer shall assess whether the appropriate number of chewable aspirin tablets of 81 mg is available (at least four tablets).

I.D.6) Medication dosage chart for all medications included with emergency equipment (or other method for determining dosage) is kept with emergency medications.

- There is a current medication administration reference (e.g. medication dosage chart) available for readily identifying the correct medication dosages (e.g. adult, pediatric, infant, etc.).
- Package inserts are not acceptable as dosage charts.
- All emergency medications in the emergency kit/ crash cart must have dosage charts.

Score should be either a **Yes or No only**


There is a process in place on site to:

¹² In 2018, the U.S. Surgeon General issued an advisory emphasizing the importance of health care professionals having naloxone (an opioid antagonist) on hand and being trained in how to use it. The U.S. Surgeon General’s advisory is available at: <https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html>. Also see the FDA’s approval of Narcan to reverse opioid overdose: <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/narcan-naloxone-nasal-spray-approved-reverse-opioid-overdose>, and articles regarding overdose preparedness for ambulatory clinics, available at: <https://www.aafp.org/fpm/2021/0100/p17.html> and <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5753997/>.

¹³ See the American Heart Association’s article on Aspirin and Heart Disease, available at: <https://www.heart.org/en/health-topics/heart-attack/treatment-of-a-heart-attack/aspirin-and-heart-disease>.

¹⁴ Pediatric offices only serving patients under 18 years old are not required to keep Nitroglycerin in their emergency kit. According to the FDA, “The safety and effectiveness of nitroglycerin in pediatric patients (under 18 years old) have not been established.” Also see page 8 of an article on Nitrostat, available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021134s007lbl.pdf.

¹⁵ If the emergency kit or “crash cart” has only non-safety needles/syringes, score that deficiency in Section VI., Infection Control, criteria B.2. See Infection Control Standards.

Criteria	I. Access/Safety Standards
	<p>I.D.7) Document checking of emergency equipment/supplies for expiration and operating status at least monthly. Documented evidence that emergency medication and equipment is checked at least monthly may include a log, checklist or other appropriate method(s).</p> <p>I.D.8) Replace/re-stock emergency medication, equipment, and supplies immediately after use. A receipt or documentation showing medication is ordered is acceptable for any medication shortage.</p> <p>Note: An “emergency medical condition” is a medical condition that manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in:</p> <ol style="list-style-type: none"> 1) placing the health of the individual (or unborn child of a pregnant woman) in serious jeopardy 2) serious impairment to bodily functions 3) serious dysfunction of any bodily organ or part <p>“Emergency services” means those services required for alleviation of severe pain, or immediate diagnosis and treatment of unforeseen medical conditions, which, if not immediately diagnosed and treated, would lead to disability or death.</p>
<p>E. Medical and lab equipment used for patient care is properly maintained.  RN/NP/CNM/LM/MD/PA</p>	<p>I.E.1) Medical equipment is clean. Medical and Laboratory Equipment: All equipment used to measure or assess patient health status/condition is clean.</p> <p>I.E.2) Written documentation demonstrates the appropriate maintenance of all medical equipment according to equipment manufacturer’s guidelines. Documentation:</p> <ul style="list-style-type: none"> • There is documented evidence that standard operating procedures have been followed for routine inspection/maintenance, calibration, repair of failure or malfunction, and testing and cleaning of all specialized equipment. • Appropriate written records include calibration or other written logs, work orders, service receipts, dated inspection sticker, etc.


Criteria	I. Access/Safety Standards
	<ul style="list-style-type: none"> • All equipment used to measure or assess patient health status/condition is functioning properly. All specialized equipment (e.g., ultrasonography equipment, electrocardiogram (EKG) machine, defibrillator, audiometer, hemoglobin meter, glucometer, scales, etc.) are adequately maintained according to the specified manufacturer's guidelines for the equipment or is serviced annually by a qualified technician. • Blood pressure cuffs, monitors, and other related equipment need not be calibrated unless required by the manufacturer. Manufacturer guidelines must be available on site, indicating that it is not necessary to calibrate the equipment. <p>Note: The term monitor includes, but not limited to, glucometers, EKG, BP monitors, hemocues, and audiometers.</p>

Criteria	II. Personnel Standards		
A.1. Professional health care personnel have current California licenses and certifications.	Medical Professional	License/Certification	Issuing Agency
	Certified Nurse Midwife (CNM)	RN License & Nurse-Midwife Certificate. Drug Enforcement Agency (DEA) Registration, <i>if appropriate</i>	CA Board of Registered Nursing DEA
	Certified Radiological Technologist (CRT)	CRT Certificate.	California Department of Public Health (CDPH), Radiologic Health Branch
	Doctor of Osteopathy (DO)	Physician's & Surgeon's Certificate DEA Registration	Osteopathic Medical Board of CA DEA
	Licensed Midwife (LM)	Licensed Midwife Certificate. Drug Enforcement Agency (DEA) Registration, <i>if appropriate</i>	Medical Board of CA DEA
	Licensed Vocational Nurse (LVN):	LVN License	CA Board of Vocational Nursing and Psychiatric Technicians
	Nurse Practitioner (NP)	RN License w/NP Certification & Furnishing Number DEA Registration, <i>if appropriate</i>	CA Board of Registered Nursing DEA
	Pharmacist (Pharm. D)	Pharmacist License	CA State Board of Pharmacy
	Physician/Surgeon (MD)	Physician's & Surgeon's Certificate DEA Registration	Medical Board of CA DEA
	Physicians' Assistant/ Associate (PA)	PA License DEA Registration, <i>if appropriate</i>	Physician Assistant Examining Committee/Medical Board of CA DEA
Radiological Technician	Limited Permit	CDPH, Radiologic Health Branch	

Criteria	II. Personnel Standards		
	Registered Dietitian (RD)	RD Registration Card	Commission on Dietetic Registration
	Registered Nurse (RN)	RN License	CA Board of Registered Nursing
<p>A.2. All required professional licenses and certifications, issued from the appropriate licensing/certification agency, are current.</p>	<p>Note: Effective June 27, 2010, MDs (does not apply to Osteopaths) shall provide notification to each patient that states the MD(s) on site is licensed and regulated by the Board, and includes the following:¹⁶</p> <p style="text-align: center;">NOTICE Medical doctors are licensed and regulated by the Medical Board of California (800) 633-2322 www.mbc.ca.gov.</p>		<p>Note: Effective August 11, 2011, PAs shall provide notification to each patient that states the PA(s) is licensed and regulated by the Physician Assistant Board , and includes the following:¹⁷</p> <p style="text-align: center;">NOTIFICATION TO CONSUMERS Physician Assistants are licensed and regulated by the Physician Assistant Board (916) 561-8780 www.pab.ca.gov</p>
	<p>II.A.2) Notification is provided to each member that the MD(s) is licensed and regulated by the Medical Board, and that the Physician Assistant(s) is licensed and regulated by the Physician Assistant Board.</p> <p>The notice to consumers above shall be provided by one of the following methods:</p>		

¹⁶ 16 CCR 1355.4, as mandated by Business and Professions Code (BPC) section 138.


¹⁷ 16 CCR 1399.547, as mandated by BPC section 138.

Criteria	II. Personnel Standards
	<ul style="list-style-type: none"> ○ Prominently posted sign in an area visible to patients in at least 48-pt Arial font. ○ A written statement signed and dated by the patient (or patient’s representative) and kept in the medical record, stating the patient understands that the MD is licensed and licensed and regulated by the board (for PA’s, that the PA is licensed and regulated by the PA Board). ○ A statement on letterhead, discharge instructions or other document given to the patient (or patient’s representative), where the notification is placed immediately above the signature line for the patient in at least 14-pt font.
<p>B. Health care personnel are properly identified.</p>	<p>II.B.1) Health care personnel wear identification badges/tags printed with name and title.</p> <ul style="list-style-type: none"> ● Health care personnel shall disclose, while working, their name and title on a name tag at least 18-point type. ● It is acceptable for health care personnel in a practice or an office, whose license is prominently displayed, to opt not to wear a nametag. <p>Note:</p> <ul style="list-style-type: none"> ● In the interest of public safety and consumer awareness, it shall be unlawful for any person to use the title “nurse” in reference themselves, in any capacity, except for an individual who is a registered nurse, or a licensed vocational nurse. ● “Health care practitioner” means any person who engages in acts that are the subject of licensure or regulation under Business and Professions Code (Sections 680-681). If a health care practitioner or licensed clinical social worker is working in a psychiatric setting or in a setting that is not licensed by the state, the employing entity or agency shall have the discretion to make an exception from the nametag requirement for the individual safety or therapeutic concerns.
<p>C. Site personnel are qualified and trained for assigned responsibilities.</p> <p> RN/NP/CNM/LM/MD/PA</p>	<p><u>Unlicensed Personnel:</u></p> <p>Medical assistants (MAs) are unlicensed health personnel, at least 18 years of age, who perform basic administrative, clerical, and non-invasive routine technical supportive services under the supervision of a licensed physician, surgeon, or podiatrist in a medical office or clinic setting.</p> <ul style="list-style-type: none"> ● “Supervision” means the licensed physician must be physically present in the treatment facility during the performance of authorized procedures by the MA.

Criteria	II. Personnel Standards
	<ul style="list-style-type: none"> • Per Business and Professions Code Section 2069 (a) (1), a supervising physician and surgeon at a "community clinic" licensed under Health and Safety Code section 1204(a) may, at their discretion, in consultation with the nurse practitioner, nurse midwife, or physician assistant provide written instructions to be followed by a medical assistant in the performance of tasks or supportive services. • The written instructions may provide that the supervisory function for the medical assistant in performing these tasks or supportive services may be delegated to the nurse practitioner, nurse midwife, or physician assistant and that those tasks may be performed when the supervising physician and surgeon is not on site. <p>II.C.1) Documentation of education/training for non-licensed medical personnel is maintained on site.</p> <ul style="list-style-type: none"> • Training may be administered under a licensed physician; or under an RN, LVN, PA, or other qualified medical assistant acting under the direction of a licensed physician. The supervising physician is responsible for determining the training content and ascertaining proficiency of the MA. Training documentation maintained on site for the MA must include the following: <ul style="list-style-type: none"> • Diploma or certification from an accredited training program/school, or • Letter/statement from the current supervising physician that certifies in writing: date, location, content, and duration of training, demonstrated proficiency to perform current assigned scope of work, and signature. <p><u>II.C.2) (CE) Only qualified/trained personnel retrieve, prepare or administer medications.</u></p> <p>Medication administration by an MA means the direct application of pre-measured medication orally, sublingually, topically, vaginally or rectally; or by providing a single dose to a patient for immediate self-administration by inhalation or by simple injection.</p> <ul style="list-style-type: none"> • All medications including vaccines must be verified with (shown to) a licensed person prior to administration. • Unlicensed staff (e.g. MAs) have evidence of appropriate training and supervision in all medication administration methods performed within their scope of work. • To administer medications by subcutaneous or intramuscular injection, or to perform intradermal skin tests or venipunctures for withdrawing blood, an MA must have completed at least the minimum number of training-hours established in CCR, Title 16, Section 1366.1.


Criteria	II. Personnel Standards
	<p>Note:</p> <ul style="list-style-type: none"> • MAs cannot administer anesthetics, including local anesthetic agents (such as Rocephin hydrated with Xylocaine). ¹⁸ • MAs may not place an intravenous needle, start or disconnect the intravenous infusion tube, administer medications or injections into an intravenous line, or administer anesthesia. • The supervising physician must specifically authorize all medications administered by an MA. “Authorization” means a specific written or standing order prepared by the supervising physician. <p>II.C.3) Site has a procedure in place for confirming correct patient, correct medication/vaccine, correct dosage, and correct route prior to administration.</p> <ul style="list-style-type: none"> • To help reduce the risk of medication errors, staff shall follow procedures for confirming the correct patient, correct medication/vaccine, correct dosage, and correct route prior to administration. <p>II.C.4) Only qualified/trained personnel operate medical equipment.</p> <p><u>Medical Equipment:</u></p> <ul style="list-style-type: none"> • Provider and/or staff can demonstrate appropriate operation of medical equipment used in their scope of work. Not all staff is required to be proficient in use of all equipment but at any given time, a staff must be prepared to operate equipment that is not routinely needed by every patient such as patient lifts and accessible scales. Health care personnel at the site must demonstrate that they can turn on the oxygen tank and tell when an oxygen tank needs to be replaced and/or refilled. <p>Note:</p> <ul style="list-style-type: none"> • Personnel on site must be qualified for their responsibilities and adequately trained for their scope of work. • Site staff should have a general understanding of the systems/processes in place, appropriate supervision, and knowledge of the available sources of information on site.

¹⁸ 16 CCR 1366.3(a) (1), also see information from the Medical Board of California on Medical Assistants, available at: <https://www.mbc.ca.gov/Licensing/Physicians-and-Surgeons/Practice-Information/Medical-Assistants.aspx>.
<https://www.mbc.ca.gov/FAQs/?cat=Licensees&topic=Medical%20Assistants>


Criteria	II. Personnel Standards
	<ul style="list-style-type: none"> Family members and personal care assistants, whether paid or unpaid, are not “unlicensed personnel” or otherwise captured within the scope of this tool.
<p>D. Scope of practice for non-physician medical practitioners (NPMP) is clearly defined.</p> <p> RN/NP/CNM/LM/MD/PA</p>	<p>II.D.1) Standardized Procedures provided for NPs and/or CNMs.</p> <ul style="list-style-type: none"> The scope of practice for NPs and CNMs is clearly defined including the delegation of the supervision of MAs when supervising physician is off premises. Documents may be utilized to determine and/or clarify practice procedures and supervisory processes on site. Reviewers are expected to verify that NP and/or CNM standardized procedures, and PA Practice Agreement and Supervision Physician’s Responsibility documentation are present on site. Reviewers are not expected to make in-depth evaluation of “appropriateness” of the NPMP’s scope of practice. <p><u>NPs:</u></p> <ul style="list-style-type: none"> NPs are prepared through education and experience to provide primary care and to perform advanced procedures. The extent of required supervision must be specified in the Standardized Procedures. Standardized procedures legally define the expanded scope of nursing practice that overlaps the practice of medicine. Standardized Procedures should identify the furnishing of drugs or devices, extent of physician or surgeon supervision, method of periodic review of competence, including peer review, and review of provisions in the Standardized Procedures. <p><u>CNM:</u></p> <ul style="list-style-type: none"> The certificate to practice nurse-midwifery authorizes the holder, under supervision of a licensed physician or surgeon, to attend cases of normal childbirth and to provide prenatal, intrapartum, and postpartum care, including family planning care for the mother, and immediate care for the newborn. The supervising and back-up physician or surgeon for the CNM must be credentialed to perform obstetrical care in the same delivering facility in which the CNM has delivery privileges.

Criteria	II. Personnel Standards
	<p>Note: CNMs and NPs operate under written Standardized Procedures that are collaboratively developed and approved by the supervising physician, the NP and administration within the organized health care facility/system in which standardized procedures will be used.</p> <p>II.D.2) A Practice Agreement defines the scope of services provided by PAs and Supervisory Guidelines define the method of supervision by the Supervising Physician.</p> <p>PA:</p> <ul style="list-style-type: none"> • Practice Agreement: <ul style="list-style-type: none"> a) Defines specific procedures identified in practice protocols or specifically authorized by the supervising physician, and must be dated and signed by physician and PA. b) The delegation of the supervision of MAs when supervising physician is off premises. c) An original or copy must be readily accessible at all practice sites in which the PA works. d) Failure to maintain a Practice Agreement is a violation of the PA Regulations and is grounds for disciplinary action by the Medical Board of California against a physician assistant’s licensure. • Supervising Physician’s Responsibility for Supervision of PAs’ Practice Agreement: Defines supervision responsibilities and methods required by Title 16, section 1399.545 of the Physician Assistant Regulations, and is signed by the physician. The following procedures must be identified: <ul style="list-style-type: none"> ○ Emergency transport of patients and back-up procedures (e.g., can call 911, name of hospital to transport patient included in Practice Agreement) for when the supervising physician is not on the premises. <p>Note:</p> <ul style="list-style-type: none"> • A Delegation of Services Agreement (DSA) in effect prior to January 1, 2020, shall be updated to meet the current requirements.¹⁹ • DSAs that still reflect components that are no longer required by BPC section 3502.3 should be enforced since the DSA is the currently established agreement between the PA and the supervising physician. • The reviewer should assess the site’s process for compliance with the DSA.


¹⁹ BPC 3502.3
July 1 2022

Criteria	II. Personnel Standards
	<ul style="list-style-type: none"> • Any deficiency shall result in a CAP requesting the site to adhere to the DSA components or establish a new Practice Agreement. <p>II.D.3) Standardized Procedures, Practice Agreements, and Supervisory Guidelines are revised, updated, and signed by the supervising physician and NPMP when changes in scope of services occur.</p> <ul style="list-style-type: none"> • Standardized Procedures, Practice Agreements shall undergo periodic review, with signed, dated revisions completed at each change in scope of work by supervising physician. • Frequency of the review to identify changes in scope of service shall be specified in writing. <p>II.D.4) Each NPMP that prescribes controlled substances has a valid DEA Registration Number.</p> <p>DEA: Each NP, CNM, and PA that prescribes controlled substances is required to have a valid DEA Registration Number.</p>
<p>E. Non-physician medical practitioners (NPMP) are supervised according to established standards.</p> <p> RN/NP/CNM/LM/MD/PA</p>	<p>The designated supervising physician(s) on site:</p> <p>II.E.1) Ratio to number of NPMPs does not exceed established ratios in any combination.</p> <p>NPMPs:</p> <ul style="list-style-type: none"> • The supervising physician holds ultimate responsibility for the practice of each supervised NPMP. • The maximum number of NPMPs who may be supervised by a single primary care physician (PCP) is limited to the following at any given time/shift in any of their locations:²⁰ <ul style="list-style-type: none"> ○ 4 NPs with furnishing license (there is no limit to the number of NPs the physician may supervise if the NP does not hold a furnishing license); ○ 4 CNMs; and ○ 4 PAs.

²⁰ BPC 3516(b), Welfare and Institutions Code (WIC) section 14132.966
July 1 2022

Criteria	II. Personnel Standards
	<p>This ratio is based on each physician, not the number of offices. A PCP, an organized outpatient clinic, or a hospital outpatient department cannot utilize more NPMPs than can be supervised within these stated limits.</p> <p>Physician Assistant Board (PAB) is at https://www.pab.ca.gov/ or the PAB office at 916-561-8780.</p> <p>II.E.2) The designated supervising or back-up physician is available in person or by electronic communication at all times when a NPMP is caring for patients. <u>Supervising Physician:</u></p> <ul style="list-style-type: none"> • “Supervision” means that a licensed physician and surgeon oversee the activities of, and accept responsibility for, the medical services rendered by a PA. • Supervising or back-up physician is available in person or by electronic communication at all times when a NPMP is caring for patients. <p>II.E.3) Evidence of NPMP supervision. <u>Evidence of NPMP Supervision:</u></p> <ul style="list-style-type: none"> • Standardized Procedures for NP or CNM should identify the furnishing of drugs or devices, extent of physician or surgeon supervision, method of periodic review of competence, including peer review, and review of provisions in the Standardized Procedures.²¹ • Standardized Procedures shall undergo periodic review, with signed, dated revisions completed at each change in scope of work. • Evidence of supervision of NPMP(s) are verifiable through on-site observation of supervisory processes, documentation, or supervisor/NPMP’s knowledge of the process.
<p>F. Site personnel receive safety training.  RN/NP/CNM/LM/MD/PA</p>	<p>II.F. There is evidence that site staff has received training on the following:</p> <ol style="list-style-type: none"> 1) Infection Control/Universal Precautions (annually) 2) Bloodborne Pathogens Exposure Prevention (annually) 3) Biohazardous Waste Handling (annually) <p>Training occurs <i>prior to</i> initial exposure to potentially infectious and/or biohazardous materials. Review and re-training sessions occur <i>at least annually</i>. Training content is appropriate (language, educational level, etc.) to personnel on site.</p>

Criteria	II. Personnel Standards
	<p>Training <i>minimally</i> includes the following:</p> <ul style="list-style-type: none"> ○ Universal/standard precautions ○ Use of personal protective equipment ○ Accessible copy of Bloodborne Pathogens Standard ○ Work practice controls/exposure prevention ○ Modes of transmitting bloodborne pathogens ○ Epidemiology/symptoms of HBV and HIV ○ Recognition of activities with exposure element ○ Handling and labeling of biohazardous waste(s) ○ Hepatitis B vaccination protocol and requirements ○ Explanation of emergency procedures ○ Post exposure reporting/evaluation/follow-up procedures ○ Decontamination of equipment/work areas ○ Site's written bloodborne pathogen exposure plan ○ Opportunity for discussion/questions <p>Personnel must know where to locate information/resources on site about infection control, the Bloodborne Pathogens Exposure Plan, and how to use the information. Evidence of training must be verifiable. Evidence of training may include:</p> <ul style="list-style-type: none"> ○ Informal in-services ○ New staff orientation ○ External training courses ○ Educational curriculum ○ Participation lists, etc. <p>Training documentation must contain:</p> <ol style="list-style-type: none"> 1) Employee's name 2) Job titles 3) Training date(s) 4) Type of training 5) Contents of training session 6) Names/qualifications of trainers <p>Records must be kept for three (3) years.</p>

Criteria	II. Personnel Standards
	<p>Note: Site personnel treat all blood and other potentially infectious materials (OPIM) as if these <i>are</i> infectious. Site personnel who are reasonably anticipated to have eye, skin, mucous membranes and potential exposure to blood and/or OPIM receive training as required by the Bloodborne Pathogens Standard.²²</p>
<p>G. Site personnel receive training on member rights.  RN/NP/CNM/LM/MD/PA</p>	<p>II.G. There is evidence that site staff has received information and/or training on the following:</p> <p><u>II.G.1) Patient Confidentiality</u></p> <ul style="list-style-type: none"> • Site personnel have received information and/or training about patient confidentiality and must be prepared to provide information on how patient confidentiality is protected at the site. • Evidence is verifiable for any occurrences of staff training which may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc. • If there is no verifiable evidence of staff training, staff is able to locate written patient confidentiality information on site and explain how to use information. <p><u>II.G.2) Informed Consent, including Human Sterilization</u></p> <ul style="list-style-type: none"> • Site personnel have received information and/or training on informed consent, including human sterilization. • Evidence is verifiable for any occurrences of staff training which may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc. • If there is no verifiable evidence of staff training, staff is able to locate written informed consent, including human sterilization information on site and explain how to use information. <p><u>II.G.3) Prior Authorization Requests</u></p> <ul style="list-style-type: none"> • Site personnel have received information and/or training on prior authorization requests.

Criteria	II. Personnel Standards
	<ul style="list-style-type: none"> • Evidence is verifiable for any occurrences of staff training which may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc. • If there is no verifiable evidence of staff training, staff is able to locate written prior authorization requests information on site and explain how to use information. <p><u>II.G.4) II.F.4) Grievance/Complaint Procedure</u></p> <ul style="list-style-type: none"> • Site personnel have received information and/or training on grievance/complaint procedure. Staff must be prepared to provide information to patient when requested. • Evidence is verifiable for any occurrences of staff training which may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc. • If there is no verifiable evidence of staff training, staff is able to locate written grievance/complaint procedures information on site and explain how to use information. <p><u>II.G.5) Child/Elder/Domestic Violence Abuse</u></p> <p><u>Abuse Reporting:</u> Site personnel have specific knowledge of local reporting requirements, agencies, and procedures, and know <i>where to locate</i> information on site and <i>how to use</i> information.</p> <p><u>Note:</u></p> <ul style="list-style-type: none"> • Health practitioners (e.g., physicians, surgeons, licensed nurses, licensed social workers, paramedics) in a health facility, (e.g., clinic, physician’s office, public health clinic) are legally mandated reporters of known or reasonably suspected cases of child abuse, elder abuse and domestic violence. • Legally mandated reporters must make telephone and written reports according to timeliness standards established by the designated local law enforcement agencies in each county. “Reasonably suspected” means having objectively reasonable suspicion based upon facts that could cause a reasonable person in a like position, drawing when appropriate on his or her training and experience, to suspect abuse (CA Penal Code 11164). • Failure to report by legally mandated reporters can result in criminal or civil prosecutions, punishable by monetary fines and/or county jail confinement.



Criteria	II. Personnel Standards
	<p>Any person entering employment, which makes him/her a mandated reporter, must sign a statement, provided and retained by the employer, that the employee has knowledge of the Child Abuse reporting law and will comply with its provision.²³</p> <p><u>II.G.6) Sensitive Services/Minors' Rights</u></p> <ul style="list-style-type: none"> • Site personnel have received information and/or training on sensitive services/minors' rights. Sensitive Services include family planning, pregnancy, sexually transmitted infections, etc. • PCP sites must have basic information on sensitive services that are appropriate to their practice office and be prepared to provide information to patients when needed. • Minor's Rights: California Family Code provides that a minor may, without parental consent, receive a number of sensitive services including outpatient mental health treatment and counseling for children 12 years and older. <p><u>II.G.7) Health Plan Referral Process/Procedures/Resources</u></p> <ul style="list-style-type: none"> • Site personnel have received information and/or training on health plan referral process/procedures/resources. • Evidence is verifiable for any occurrences of staff training which may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc. • If there is no verifiable evidence of staff training, staff is able to locate written health plan referral process/procedures/resources information on site and explain how to use information. <p><u>II.G.8) Cultural and Linguistic Training</u></p> <ul style="list-style-type: none"> • Site personnel have received information and/or training on cultural and linguistic appropriate services. • Evidence is verifiable for any occurrences of staff training which may include informal in-services, new staff orientation, external training courses, educational curriculum and participant lists, etc. • If there is no verifiable evidence of staff training, staff is able to locate written cultural and linguistic information on site and explain how to use information. Cultural and Linguistic



²³ Penal Code section 11166.5
July 1 2022

Criteria	II. Personnel Standards
	<p data-bbox="575 235 1835 302">Training- Culturally and Linguistically Appropriate Services (CLAS) mandates are Federal requirements for all recipients of Federal funds.²⁴</p> <p data-bbox="537 342 1272 375"><u>II.G.9) Disability Rights and Provider Obligations</u></p> <ul data-bbox="596 383 1898 561" style="list-style-type: none"> <li data-bbox="596 383 1835 483">• Site personnel have received information and/or training on patient rights and provider obligations under the Americans with Disabilities Act (ADA), Section 504 of the Rehabilitation Act of 1973, and/or Section 1557 of the Affordable Care Act <li data-bbox="596 492 1898 561">• Training content should include information about physical access, reasonable accommodations, policy modifications, and effective communication in healthcare settings. <p data-bbox="537 602 1787 634">https://www.hhs.gov/sites/default/files/ocr/civilrights/resources/factsheets/504.pdf</p> <p data-bbox="537 639 1598 672">https://www.hhs.gov/sites/default/files/section-1557-final-rule-faqs.pdf</p> <p data-bbox="537 677 1415 709">https://www.hhs.gov/sites/default/files/1557-fs-lep-508.pdf</p>


²⁴ See the National Standards on CLAS, available at:

<https://www.health.pa.gov/topics/Documents/Health%20Equity/CLAS%20Standards%20FactSheet.pdf>.



Criteria	III. Office Management Standards
<p>A. Physician coverage is available 24 hours a day, 7 days a week.</p>	<p>III.A.1) Clinic office hours are posted or readily available upon request. Current clinic office hours are posted within the office or readily available upon request.</p> <p>III.A.2) Provider office hour schedules are available to staff.</p> <p>III.A.3) Arrangement/schedule for after-hours, on-call, supervisory back-up physician coverage is available to site staff and members after-hours. Current site-specific resource information is available to site personnel and members about physician office hour schedule(s), local and/or Plan-specific systems for after-hours urgent care, emergent physician coverage available 24 hours a day, 7 days per week, and system for providing follow-up care.</p> <p>III.A.4) Contact information for off-site physician(s) is available at all times during office hours. When a physician is not on site during regular office hours, personnel are able to contact the physician (or covering physician) at all times by telephone, cell phone, pager, etc.</p> <p>III.A.5) Routine, urgent and after-hours emergency care instructions/telephone information is made available to patients.</p> <p>Note: One objective of effective clinic office management is to support the provision of appropriate, coordinated health care services. The review of clinic office management is to evaluate if effective systems are in place and whether site personnel appropriately follow established site-specific procedures.</p>
<p>B. There are sufficient health care personnel to provide timely, appropriate health Care services.</p> <p>  RN/NP/CNM/LM/MD/PA</p>	<p>III.B.1) Appropriate personnel handle emergent, urgent, and medical advice telephone calls.</p> <ul style="list-style-type: none"> • In addition to the physician, only appropriately licensed medical personnel such as a CNM, LM, NP, RN, or PA handles emergency, urgent, and medical advice/triage telephone calls.

Criteria	III. Office Management Standards
	<ul style="list-style-type: none"> • The California Board of Vocational Nursing and Psychiatric Technician Examiners has determined that the Licensed Vocational Nurse Practice Act does not permit the LVN to perform triage independently.²⁵ • The LVN may perform that part of the triage process that includes observation and data collection relative to basic physical assessment. • The LVN may not perform that part of the triage process that includes independent evaluation, interpretation of data, and determination of treatment priorities and levels of care. • Unlicensed personnel, such as medical assistants, may provide patient information or instructions only as authorized by the physician.²⁶ <p>Note: Telephone triage is the system for managing telephone calls during <i>and</i> after office hours.</p> <p>III.B.2) Telephone answering machine, voice mail system, or answering service is used whenever office staff does not directly answer phone calls.</p> <ul style="list-style-type: none"> • Telephone answering machine, voice mail system, or answering service is used whenever office staff does not directly answer phone calls. <p>III.B.3) Telephone system, answering service, recorded telephone information, and recording device are periodically checked and updated.</p> <ul style="list-style-type: none"> • Telephone system, answering service, recorded telephone information, and recording device are periodically checked and updated.
<p>C. Health care services are readily available.</p> <p> </p> <p>RN/NP/CNM/LM/MD/PA</p>	<p>III.C.1) Appointments are scheduled according to patients stated clinical needs within the timeliness standards established for Plan members.</p> <p>Note: Medi-Cal Managed Care Health Plans <i>require</i> the following timeliness standards for access to appointments:</p> <ul style="list-style-type: none"> ○ Urgent Care: 48 hours ○ Access to the first Prenatal Visit: 10 business days ○ Non-urgent (Routine) Care: 10 business days

Criteria	III. Office Management Standards
	<p>III.C.2) Patients are notified of scheduled routine and/or preventive screening appointments.</p> <ul style="list-style-type: none"> • The process established on site provides timely access to appointments for routine care, urgent care, prenatal care, pediatric periodic health assessments/immunizations, adult initial health assessments, specialty care, and emergency care. • Systems, practices, and procedures used for making services readily available to patients will vary from site to site. <p>III.C.3) There is a process in place verifying follow-up on missed and canceled appointments.</p> <ul style="list-style-type: none"> • An organized system must be evident (in use) for scheduling appointments appropriately, notifying, and reminding members of scheduled appointments, and following up on missed or canceled appointments. • Missed and/or canceled appointments and contact attempts must be documented in the patient's medical record.
<p>D. There is 24-hour access to interpreter services for non- or limited-English proficient (LEP) members.</p>	<p>III.D.1) Interpreter services are made available in identified threshold languages specified for location of site.</p> <ul style="list-style-type: none"> • Sites must provide 24-hour interpreter services for all members either through telephone language services or interpreters on site. <p>III.D.2) Persons providing language interpreter services, including sign language on site, are trained in medical interpretation.</p> <ul style="list-style-type: none"> • Site personnel used as interpreters have been assessed for their medical interpretation performance skills/capabilities. • Reviewer should ask for a written policy which includes the languages spoken by bilingual providers and staff. <p>Note: https://www.lep.gov; 22 CCR 51309.5</p> <ul style="list-style-type: none"> • If bilingual staff are asked to interpret or translate, they should be qualified to do so. Assessment of ability, training on interpreter ethics and standards, and clear policies that delineate appropriate use of bilingual staff, staff or contract interpreters and translators, will help ensure quality and effective use of resources.

Criteria	III. Office Management Standards
	<ul style="list-style-type: none"> • Those utilizing the services of interpreters and translators should request information about certification, assessments taken, qualifications, experience, and training. Quality of interpretation should be a focus of concern for all recipients. • Family or friends should not be used as interpreters, unless specifically requested by the member's circumstances. Minors, under 18 years old, accompanying members shall not be used as interpreters. • The Affordable Care Act of 2010, Section 1557: prohibits from using low-quality video remote interpreting services or relying on unqualified staff, translators when providing language assistance services. • A request for or refusal of language/interpreter services must be documented in the member's medical record. <p>Sign language interpreter services may be utilized for medically necessary health care services and related services such as:</p> <ul style="list-style-type: none"> ○ Obtaining medical history and health assessments ○ Obtaining informed consents and permission for treatments ○ Medical procedures ○ Providing instructions regarding medications ○ Explaining diagnoses ○ Treatment and prognoses of an illness ○ Providing mental health assessment ○ Therapy or counseling
<p>E. Procedures for timely referral/ consultative services are established on site.</p> <p> RN/NP/CNM/LM/MD/PA</p>	<p>Office practice procedures allow timely provision and tracking of:</p> <p>III.E.1) Processing internal and external referrals, consultant reports, and diagnostic test results.</p> <ul style="list-style-type: none"> • An organized, timely referral system is evident for making and tracking referrals, reviewing reports, providing/scheduling follow-up care and filing reports in medical records. • Referral informational resources are readily available for use by site personnel. • Site staff can demonstrate (e.g., "walk through") the office referral process from beginning to end <p>Systems, practices, and procedures used for handling referrals will vary from site-to-site.</p>

Criteria	III. Office Management Standards
	<p><u>III.E.2 (CE) Physician Review and follow-up of referral/consultation reports and diagnostic test results.</u></p> <ul style="list-style-type: none"> • There is a documented process of the practitioner review of diagnostic tests/consultations and subsequent outreach to follow-up with the patient to communicate results and provide next steps. • Practitioner review is evidenced by date and signature/initials on the report of the reviewing practitioner.
<p>F. Member grievance/complaint processes are established on site.</p>	<p>III.F.1) Phone number(s) for filing grievances/complaints are located on site.</p> <ul style="list-style-type: none"> • At least one telephone number for filing grievances is posted on site or is readily available upon request. <p>III.F.2) Complaint forms and a copy of the grievance procedure are available on site.</p> <ul style="list-style-type: none"> • Complaint forms and a copy of the grievance procedure are readily available on site and can be provided to members promptly upon request. • Includes The Department of Managed Health Care Help Center 1-888-466-2219 and Ombudsman 1-888-452-8609. <p>Note: A “grievance” is defined as any written or oral expression of dissatisfaction and shall include any complaint, dispute, and request for reconsideration or appeal made by an enrollee or their representative to a Plan or entity with delegated authority to resolve grievances on behalf of the Plan.</p>
<p>G. Medical records are available for the practitioner at each scheduled patient encounter.</p>	<p>III.G.1) Medical records are readily retrievable for scheduled patient encounters.</p> <ul style="list-style-type: none"> • The process/system established on site provides for the availability of medical records (paper and electronic), including outpatient, inpatient, referral services, and significant telephone consultations for patient encounters.

Criteria	III. Office Management Standards
	<p>III.G.2) Medical documents are filed in a timely manner to ensure availability for patient encounters.</p> <ul style="list-style-type: none"> • Medical records are filed in a timely manner that allows for ease of accessibility within the facility or in an appropriate health record storage facility if stored off-premises.²⁷
<p>H. Confidentiality of personal medical information is protected according to State and federal guidelines.</p> <p>  RN/NP/CNM/LM/MD/PA</p>	<p>III.H.1) Exam rooms and dressing areas safeguard patients' right to privacy.</p> <p><u>Privacy:</u></p> <ul style="list-style-type: none"> • Patients have the right to privacy for dressing/undressing, physical examination, and medical consultation. • Practices are in place to safeguard patient privacy. • Because dressing areas and examination room configurations vary greatly, reviewers will make site-specific determinations. <p>III.H.2) Procedures are followed to maintain the confidentiality of personal patient information.</p> <p><u>Confidentiality:</u></p> <ul style="list-style-type: none"> • Personnel follows site policy/procedures for maintaining confidentiality of individual patient information. • Individual patient conditions or information is not discussed in front of other patients or visitors, displayed or left unattended in reception and/or patient flow areas (this includes unattended electronic devices, patient registration sign-in sheets with more than one unique patient identifier). • There must be a confidentiality agreement between the provider and the cleaning service agency/persons if the medical records are kept in an open space and/or are unsecured. <p><u>Electronic Records:</u></p> <ul style="list-style-type: none"> • Electronic record-keeping system procedures have been established to ensure patient confidentiality, prevent unauthorized access, authenticate electronic signatures, and maintain upkeep of computer systems.

Criteria	III. Office Management Standards
	<ul style="list-style-type: none"> • Security protection includes an off-site backup storage system, an image mechanism with the ability to copy documents, a mechanism to ensure that recorded input is unalterable, and file recovery procedures. • Confidentiality protection may also include use of encryption, detailed user access controls, transaction logs, and blinded files. <p>III.H. 3) Medical record release procedures are compliant with State and federal guidelines. <u>Record Release:</u></p> <ul style="list-style-type: none"> • Medical records are not released without written, signed consent from the patient or patient’s representative, identifying the specific medical information to be released. • The release terms, such as to whom records are released and for what purposes, and the expiration date of the consent to medical record release should also be described. • This does not prevent release of statistical or summary data, or exchange of individual identifiable medical information between individuals or institutions providing care, fiscal intermediaries, research entities and State or local official agencies.²⁸ <p>III.H.4) Storage and transmittal of medical records preserves confidentiality and security. <u>Storage and transmittal:</u></p> <ul style="list-style-type: none"> • Health care services rendered under the Medi-Cal program or any other health care program administered by the department or its agents or contractors, shall confidentially and securely keep and maintain records of each service rendered under the Medi-Cal program or any other health care program administered by the department or its agents or contractors, the beneficiary or person to whom rendered, the date the service was rendered, and any additional information as the department may by regulation require. • FAX cover sheet shall have confidentiality statement. <p>III.H.5) Medical records are retained for a minimum of 10 years. <u>Record Retention:</u></p> <ul style="list-style-type: none"> • Records required to be kept and maintained under this section (including minors under 18 years old) shall be retained by the provider for a period of 10 years from the final date of the contract

Criteria	III. Office Management Standards
	period between the plan and the provider, from the date of completion of any audit, or from the date the service was rendered, whichever is later, in accordance with 42 CFR 438.3(u). ²⁹

²⁹ WIC 14124.1
July 1 2022

Criteria	IV. Clinical Services - Pharmaceutical Standards
<p>A. Drugs and medication supplies are maintained secured to prevent unauthorized access.</p>	<p><u>Deficiencies:</u> All deficiencies related to Pharmaceutical Services (e.g. medication maintenance, storage, safety, distribution, disposition, etc.) must be addressed in a corrective action plan.</p> <p>IV.A.1) Drugs are stored in specifically designated cupboards, cabinets, closets or drawers.</p> <p><u>Security:</u></p> <ul style="list-style-type: none"> • All drugs for dispensing are stored in an area that is secured at all times.³⁰ The Medical Board defines “area that is secure” to mean a locked storage area within a physician’s office. • Keys to locked storage area are available only to staff authorized by the physician to have access.³¹ • The Medical Board of California interprets “all drugs” to also include both sample and over-the-counter drugs.³² <p>IV.A.2) Drugs, drug samples, and over-the-counter drugs, hypodermic needles/syringes, all medical sharp instruments, hazardous substances and prescription pads are securely stored in a lockable space (cabinet or room) within the office/clinic.</p> <ul style="list-style-type: none"> • All drugs (including sample and over the counter), medication supplies, hazardous substances and prescription pads are securely stored in a lockable space (room, closet, cabinet, drawer) within the office/clinic.³³ (CA B&P Code, 4051.3) • A secure area means that drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. (42 CFR 482.13-CMS Manual System; 42 CFR Part 482.25) • Keys to the locked storage area are available only to staff authorized by the physician to have access.³⁴ (16 CCR, Chapter 2, Division 3, Section 1356.32) • During business hours, the lockable space may remain unlocked ONLY if there is no access to

³⁰ BPC 4172

³¹ 16 CCR 1356.3

³² 22 CCR 75032 and 75033


³³ BPC 4051.3

³⁴ 16 CCR 1356.32

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<p>this area by unauthorized persons and authorized clinic personnel remain in the immediate area at all times. At all other times, all drugs (including sample and over the counter), medication supplies, prescription pads and hazardous substances must be securely locked.</p> <p>IV.A.3) Controlled drugs are stored in a locked space accessible only to authorized personnel. Controlled substances:</p> <ul style="list-style-type: none"> • Controlled substances are stored separately from other drugs in a securely locked, substantially constructed cabinet accessible only to authorized personnel.³⁵ <p>IV.A.4) A dose-by-dose controlled substance distribution log is maintained.</p> <ul style="list-style-type: none"> • Written records are maintained of controlled substances inventory list(s) that includes: <ol style="list-style-type: none"> 1) Provider's DEA number 2) Name of medication 3) Original quantity of drug 4) Dose 5) Date 6) Name of patient receiving drug 7) Name of authorized person dispensing drug and 8) Number of remaining doses • Control substances include all Schedule I, II, III, IV, and V substances listed in the CA Health and Safety Code, Sections 11053-11058, and do not need to be double locked. • Personnel with authorized access to controlled substances include physicians, dentists, podiatrists, PAs, licensed nurses, and pharmacists and specifically authorized employees.³⁶ <p>IV.A.5) Written site-specific policy/procedure for dispensing of sample drugs are available on site.</p> <ul style="list-style-type: none"> • A list of drugs available for use in the clinic shall be maintained. Site should have written site-specific policies and procedures (P&Ps) for use of sample medications including governing activities of pharmaceutical manufacturers' representatives American Society of hospital

³⁵ 21 CFR 1301.75

³⁶ 21 CFR 1301.72

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<p>pharmacist (ASHP) Guidelines: Minimum Standard for pharmaceutical services in ambulatory care).³⁷</p> <ul style="list-style-type: none"> • Each clinic, which provides drug distribution services, shall have written policy and procedures for the safe and effective distribution, control, storage, use and disposition of drugs. <p>Note: During business hours, the drawer, cabinet or room containing drugs, medication supplies or hazardous substances may remain unlocked only if there is no access to area by unauthorized persons. Whenever drugs, medication supplies or hazardous substances are unlocked, authorized clinic personnel must always remain in the immediate area. At all other times, drugs, medication supplies, and hazardous substances must be securely locked. Controlled substances are always locked.</p>
<p>B. Drugs are handled safely and stored appropriately.  RN/NP/CNM/LM/MD/PA</p>	<p>Deficiencies: All deficiencies related to Pharmaceutical Services (e.g. medication maintenance, storage, safety, distribution, etc.) must be addressed in a corrective action plan (CAP).</p> <p>IV.B.1) Drugs are prepared in a clean area or “designated clean” area if prepared in a multi-purpose room. Drug Preparation: Drugs shall be drawn up in a designated clean medication preparation area that is not adjacent to potential sources of contamination, including sinks or other water sources. The drug preparation area should be cleaned and disinfected on a regular basis. CDC guidelines for drug preparation and safety: https://www.cdc.gov/injectionsafety/providers/provider_faqs_med-prep.html</p> <p>IV.B.2) Drugs for external use are stored separately from drugs for internal use. Storage:</p> <ul style="list-style-type: none"> • Drugs shall be separated by route of administration, especially ophthalmic and otic preparations. • Vaccines and other drugs should be stored separately from food, lab specimens, human specimens, cleaning supplies, and other items that may potentially cause contamination.

³⁷ The ASHP Guidelines for Minimum Standard for Ambulatory Care Pharmacy Practice is available at: <https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/anticoagulation/guidelines-minimum-standard-ambulatory-care-pharmacy.ashx?la=en&hash=ABF816352CAF1AB846B7C339A45AA74D80F820A6>.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<ul style="list-style-type: none"> • The Center for Disease Control (CDC) recommends avoiding storing other medications and biological products such as lab specimens/human specimens in a vaccine storage unit. <p>IV.B.3) Items other than medications in refrigerator/freezer are kept in a secured, separate compartment from drugs.</p> <ul style="list-style-type: none"> • Storing food, other medications, and biological products with vaccines put vaccines at risk for temperature fluctuation, excessive light exposure, administration errors, and contamination. <ul style="list-style-type: none"> ○ If food, other medications and biological products must be stored in the same refrigerator with vaccines, they must be in the sealed containers and stored below vaccines on the different shelves. • Drugs are stored under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug product are not affected.³⁸ • Room temperature where drugs are stored does not exceed 30°C (86°F).³⁹ • A drug or device is considered “adulterated” if it contains any filthy, putrid, or decomposed substance, or if it has been prepared, packed or held under unsanitary conditions.⁴⁰ • A drug is considered contaminated if it has been held under unsanitary conditions that may have been contaminated with filth or rendered injurious to health. • Drugs that are unused are considered by the Environmental Protection Agency (EPA) to be toxic wastes and must be disposed in accordance with 40 CFR, part 261. <p><u>American College of Physician guidelines</u> state sound management procedures include:</p> <ul style="list-style-type: none"> ○ Routinely checking for expiration dates. ○ Keeping medicines off the floor. ○ Labeling the sample medicines or writing prescribing information directly on the sample package. ○ Keeping a log of sample medicines given. In case of a recall, keeping a log allows to track down a patient to whom the recalled drug had been prescribed. ○ When a medication sample is given to a patient, the name and strength of the medication, instructions for use and the quantity or duration of therapy is always documented in the patient’s chart.

³⁸ 21 CFR 211.142

³⁹ 22 CCR 75037(d)

⁴⁰ Title 21, United States Code (USC), section 351. USC is searchable at: <https://uscode.house.gov/search/criteria.shtml>.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<p><u>ASHP guidelines</u> for minimum standard for pharmaceutical services in ambulatory care:</p> <ul style="list-style-type: none"> ○ Site should have written site-specific policies and procedures (P&Ps) for use of sample medications including governing activities of pharmaceutical manufacturers' representatives. ○ Each clinic, which provides drug distribution services, shall have written policy and procedures for the safe and effective distribution, control, storage, use and disposition of drugs.⁴¹ <p><u>Immunobiologics:</u>⁴²</p> <ul style="list-style-type: none"> ● Sites should have a written Vaccine Management Plan for routine and emergency vaccine management (required for Vaccines for Children (VFC) providers). ● Vaccines are refrigerated immediately upon receipt on site and stored according to specific instructions on the package insert for each vaccine. ● Diluent does not need refrigeration if vaccine is administered right after diluent is added. ● Vaccines are not stored in the doors, floors, vegetable bins, or under or near cooling vents of a refrigerator or freezer. <p>IV.B.4) Refrigerator thermometer temperature is 36°-46° Fahrenheit or 2°-8° Centigrade (at time of site visit).</p> <p><u>Refrigerator:</u> Vaccines are kept in a refrigerator maintained at 2-8°C or 36-46°F, and include, but are not limited to, DTaP, Td, Tdap, Hepatitis A, Hepatitis B, IPV, Pneumococcal, Rotavirus, Hib, Influenza (inactivated and FluMist), MCV, HPV, recombinant Zoster, or any combinations of these listed vaccines.⁴³</p> <p>IV.B. 5) Freezer thermometer temperature is 5° Fahrenheit or –15° Centigrade, or lower (at time of site visit).</p>

⁴¹ The ASHP Guidelines for Minimum Standard for Ambulatory Care Pharmacy Practice is available at: <https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/anticoagulation/guidelines-minimum-standard-ambulatory-care-pharmacy.ashx?la=en&hash=ABF816352CAF1AB846B7C339A45AA74D80F820A6>.

⁴² See the FDA's webpage on Vaccines, available at: <https://www.fda.gov/vaccines-blood-biologics/vaccines/questions-about-vaccines>.



⁴³ See the CDC Vaccine Recommendation and Guidelines of the Advisory Committee on Immunization Practices, available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/storage.html>, and the CDC Vaccine Storage and Handling Toolkit, available at: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<p>Freezer: Varicella and MMRV vaccines are stored in the freezer at -15°C or 5°F, or lower, and are always protected from light.</p> <ul style="list-style-type: none"> ○ MMR may be stored in a refrigerator or freezer; VFC recommends MMR be stored in the freezer with MMRV. ○ Never freeze vaccine diluents. <p>IV.B. 6) Site utilizes drugs/vaccine storage units that are able to maintain required temperature.</p> <p>CDC recommends for both temporary and long-term storage refrigerators and freezers using:</p> <ul style="list-style-type: none"> ○ Purpose-built units designed to either refrigerate or freeze (can be compact, under-the-counter style or large units). ○ Stand-alone household units. ○ Units dedicated to storage of biologics. <p>Measures should be in place to ensure that vaccine storage units are not accidentally physically disconnected from the power supply, such as “Do Not Disconnect” labels and not plugging units into surge protectors with an on/off switch.</p> <p>Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.⁴⁴</p> <p>IV.B. 7) Daily temperature readings of drugs/vaccines refrigerator and freezer are documented.</p> <p>Refrigerator and freezer temperatures are documented at least once a day (required twice daily for VFC providers).</p> <p>CDC recommends use of a continuous temperature monitoring device (digital data loggers).</p> <ul style="list-style-type: none"> ○ Digital data loggers (DDL) should have a minimum accuracy of +/- 1°F (0.5°C) ○ Equipped with buffered probe ○ Active temperature display outside of the unit ○ Capacity for continuous monitoring and recording where the data can be routinely downloaded ○ Calibrated at least every 2 years, to monitor vaccine storage unit temperatures

⁴⁴ See the CDC Vaccine & Immunization webpage, available at: <https://www.cdc.gov/vaccines/>.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<p>At least one back-up device should be readily available for emergency vaccine transport or when primary DDL is sent in for calibration.</p> <p>IV.B. 8) Has a written plan for vaccine protection in case of power outage or malfunction of the refrigerator or freezer.</p> <ul style="list-style-type: none"> • A written plan for vaccine protection in case of power outage or malfunction of the refrigerator or freezer is required. www.cdc.gov https://www.cdc.gov/disasters/poweroutage/vaccinestorage.html • Site personnel must be able to verbalize the procedures in the plan used to promptly respond to OUT OF RANGE TEMPERATURES. • Quarantine vaccines until guidance is obtained. • Action is taken when temperatures are identified to be outside of the recommended range. • Contacting VFC (http://eziz.org/vfc/overview/) or manufacturer are acceptable procedures. • For VFC providers, follow program requirements for documentation and reporting. <p>Consultation with CDC is available when necessary.⁴⁵ www.cdc.gov</p> <p>IV.B. 9) Drugs and vaccines are stored separately from test reagents, germicides, disinfectants, and other household substances.</p> <ul style="list-style-type: none"> • As these items may potentially cause contamination to verify that drugs are stored separately from test reagents, germicides, disinfectants, and other household substances. <p>IV.B.10) Hazardous substances are appropriately labeled.</p> <p>IV.B.11) Site has method(s) in place for drug and hazardous substance disposal. <u>Hazardous Substances Labeling and Disposal:</u></p> <ul style="list-style-type: none"> • Safety practices are followed in accordance with current/updated CAL-OSHA standards and 29 CFR 1910.1030.

⁴⁵ See the CDC General Best Practice Guidelines for Immunization: Best Practices Guidance of the ACIP, available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/storage.html>, the CDC Vaccine Storage and Handling Toolkit, available at: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>, the FDA Questions about Vaccines, available at: <https://www.fda.gov/vaccines-blood-biologics/vaccines/questions-about-vaccines>, and the CDC webpage on Vaccines and Immunizations, available at: <https://www.cdc.gov/vaccines/>.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<ul style="list-style-type: none"> • The manufacturer’s label is not removed from a container (bag, bottle, box, can, cylinder, etc.) only if the hazardous material or residues of the material remain in the container. • Containers for biohazard waste shall comply with United States Department of Transportation requirements when prepared for transport offsite from the facility. • A hazardous waste transporter transporting medical waste shall maintain a completed tracking document and provide a copy of that document to the medical waste generator (clinic, etc.). <p>All portable containers of hazardous chemicals and secondary containers into which hazardous substances are transferred or prepared require labeling. Labels must provide the following information:</p> <ol style="list-style-type: none"> 1) Identity of hazardous substance 2) Description of hazard warning: can be words, pictures, symbols 3) Date of preparation or transfer <p>Exception: Labeling is not required for portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the individual who performs the transfer.</p> <p>Note: The purpose of hazard communication is to convey information about hazardous substances used in the workplace. A hazardous substance is any substance that is a physical or health hazard.</p>
<p>C. Drugs are dispensed according to State and federal drug distribution laws and regulations.</p> <p> </p> <p>RN/NP/CNM/LM/MD/PA</p>	<p>Deficiencies: All deficiencies related to Pharmaceutical Services (e.g. medication maintenance, storage, safety, distribution, etc.) must be addressed in a corrective action plan.</p> <p>IV.C.1) There are no expired drugs on site.</p> <p>Expiration Date:</p> <ul style="list-style-type: none"> • The manufacturer’s expiration date must appear on the labeling of all drugs and formulas. • All prescription drugs not bearing the expiration date are deemed to have expired. • If a drug is to be reconstituted at the time of dispensing, its labeling must contain expiration information for both the reconstituted and unreconstituted drug. • Expired drugs may not be distributed or dispensed. • Per CDC – Medication Vials should be discarded whenever sterility is compromised or questionable.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<ul style="list-style-type: none"> • Per CDC “If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial”. • Per VFC “For multi-dose vials that do not require reconstitution, doses that remain after withdrawal of a dose can be administered until the expiration date printed on the vial unless otherwise specified by the manufacturer (Polio, meningococcal polysaccharide vaccine (MPSV4), PPSV, TIV, IPV, and yellow fever that are available in multi-dose vials)”.⁴⁶ <p>Both CDC and VFC recommend to follow the manufacturer’s product information.</p> <p>IV.C.2) Site has a procedure to check expiration date of all drugs (including vaccines and samples), and infant and therapeutic formulas.</p> <ul style="list-style-type: none"> • Site has a procedure to check expiration date of all drugs (including vaccines and samples) and infant and therapeutic formula AT LEAST monthly. <p>IV.C.3) All stored and dispensed prescription drugs are appropriately labeled.</p> <p><u>Prescription Labeling:</u></p> <ul style="list-style-type: none"> • Labels shall be carefully preserved, and all medications shall be stored in their original containers. • Each prescription medication dispensed is in a container that is not cracked, soiled, or without secure closures.⁴⁷ • Each commercial container of a controlled substance shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. • Drug container is labeled with the provider’s name, patient’s name, drug name, dose, frequency, route, quantity dispensed, and manufacturer’s name and lot number. • California Pharmacy Law <i>does not</i> prohibit furnishing a limited quantity of sample drugs if dispensed to the patient in the package provided by the manufacturer, no charge is made to the patient, and appropriate documentation is made in the patient’s medical record.⁴⁸

⁴⁶ See the CDC Frequently Asked Questions regarding Multi-dose vials, available at: https://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html, and the CDC Vaccine Storage and Handling Toolkit, available at: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>.

⁴⁷ 22 CCR 75037(A)

⁴⁸ BPC 4170 and 4171

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<p><u>Drug Distribution:</u></p> <ul style="list-style-type: none"> • Each clinic that provides drug distribution services has written policies and procedures for the safe and effective distribution control, storage, use and disposition of drugs. • In order to prevent inadvertent exposure to out-of-range temperatures, vaccines should never be re-distributed beyond the manufacturer/distributor-to-clinic distribution chain unless during an emergency. • In the event of necessary vaccine transport (emergency/power outage), vaccines must be packaged following CDC recommendations and include temperature monitoring devices during transport (approval is required for VFC providers prior to any vaccine transfer). <p><u>IV.C.4) (CE) Only lawfully authorized persons dispense drugs to patients.</u></p> <p><u>Drug Dispensing:</u></p> <ul style="list-style-type: none"> • Drug dispensing complies with all applicable State and federal laws and regulations. • Drugs are dispensed only by a physician, pharmacist, or other persons (e.g., NP, CNM, RN, PA) lawfully authorized to dispense medications upon the order of a licensed physician or surgeon. • Personnel such as MAs, office managers, and receptionists do not dispense drugs. • Drugs are not offered for sale, charged or billed to Medi-Cal members.⁴⁹ • A record of all drugs and formulas dispensed shall be entered in the patient's medical record. <p><u>Drug Administration:</u></p> <ul style="list-style-type: none"> • Basic safe practices for medication/vaccine administration, assess and document: <ol style="list-style-type: none"> 1) Patient's identity 2) Correct medication 3) Correct dose 4) Correct route 5) Appropriate time <p>CMS Manual System;⁵⁰</p> <ul style="list-style-type: none"> • Proper preparation is critical for maintaining the integrity of the vaccine during transfer from the vial to the syringe.

⁴⁹ BPC 4193

⁵⁰ 42 CFR 482.23(c)

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<ul style="list-style-type: none"> • Personnel can demonstrate or verbally explain procedure(s) used on site to confirm correct patient, medication/vaccine, dosage and route and vaccine are prepared and drawn only prior to administration. • Proper vaccine administration is critical to ensure that vaccination is safe and effective. • CDC recommends that all health care personnel who administer vaccines receive comprehensive, competency-based training on vaccine administration policies and procedures before administering vaccines. • Comprehensive, skills-based training should be integrated into existing staff education programs such as new staff orientation and annual education requirements. <p><u>IV.C.5) (CE) Drugs and Vaccines are prepared and drawn only prior to administration.</u></p> <p>ACIP discourages the routine practice of providers' prefilling syringes.</p> <ul style="list-style-type: none"> • Vaccines have a similar appearance after being drawn into a syringe, prefilling may result in administration errors. • Unused, provider prefilled syringes must be discarded if not used within the same day that they are filled. • Unused syringes that are prefilled by the manufacturer and activated (i.e., syringe cap removed, or needle attached) should be discarded at the end of the clinic day. <p>In certain circumstances in which a single vaccine type is being used (e.g., in preparation for a community influenza vaccination campaign), filling a small number (10 or fewer) of syringes may be considered (5). The doses should be administered as soon as possible after filling, by the same person who filled the syringes.</p> <p>The Center for Biologics Evaluation and Research (CBER) at the FDA offers information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions.⁵¹</p> <p><u>IV.C.6) Current Vaccine Information Sheets (VIS) for distribution to patients are present on site.</u></p> <p><u>Vaccine Immunization Statements:</u></p>

⁵¹ See the CDC's Vaccine Recommendations and Guidelines of the ACIP, available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html>.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<ul style="list-style-type: none"> • Since 1994, the National Childhood Vaccine Injury Act, Section 2126 of the Public Health Service Act, mandates that parents/guardians or adult patients be informed before vaccinations are administered. • Health care providers must present and offer a VIS to patients prior to any vaccine.⁵² As of 2009, CDC allows providers to present a current VIS (such as a laminated copy in a binder, etc.) to the patient/parent/guardian and allow time for the patient to read and ask questions. Staff should also offer a copy each time.⁵³ • The date the VIS was given (or presented and offered) <i>and</i> the publication date of the VIS must be documented in the patient’s medical record. • Federal law allows up to 6 months for a new VIS to be used. <p>The most current VIS are available from state and local health departments or can be downloaded from the CDC web site at: http://www.cdc.gov/vaccines/pubs/vis/default.htm or by calling the CDC Immunization Hotline at (800) 232-2522.</p> <p>VFC contains current VIS and provider notifications at: http://www.eziz.org/</p> <p>IV.C.7) If there is a pharmacy on site, it is licensed by the CA State Board of Pharmacy. Pharmacy:</p> <ul style="list-style-type: none"> • If a pharmacy is located on site and owned by the clinic, the license issued by the CA State Board of Pharmacy must be present on site. • Every pharmacy that dispenses a controlled substance must be registered with the DEA and be licensed by the CA State Board of Pharmacy. • A licensed pharmacist monitors drug distribution and policies and procedures for medication dispensing and storage. <p>Note: “Dispensing” of drugs means the furnishing of drugs or devices directly to a patient or upon a prescription from a physician, dentist, optometrist, podiatrist, veterinarian, or upon an order to furnish drugs or transmit a prescription from a certified nurse midwife, nurse practitioner, physician assistant or pharmacist acting within the scope of his or her practice.</p> <p>IV.C.8) Site utilizes California Immunization Registry (CAIR) or the most current version.</p>

⁵² 42 USC 300aa-26(D)(2)

⁵³ See the CDC’s Facts about VIS, which is available at: <https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html>.

Criteria	IV. Clinical Services - Pharmaceutical Standards
	<p><u>Immunization Registry Utilization:</u> Scoring must be No or Yes.</p> <ul style="list-style-type: none"> • DHCS requires documentation of immunizations in the California CAIR or the local registry. • If the clinic does not offer vaccines administration, the site staff shall be able to utilize the registry to access the member’s immunization record. <p>Contractor shall ensure that member-specific immunization information is periodically reported to an immunization registry (is) established in the Contractor’s Service Area(s) as part of the Statewide Immunization Information System. Reports shall be made following the Member’s initial health assessment and all other health care visits which result in an immunization being provided. Reporting shall be in accordance with all applicable State and Federal laws. DHCS Contract; CDC Recommendations at: www.cdc.gov/vaccines.</p>

Criteria	IV. Clinical Services – Laboratory Review
<p>D. Site is compliant with Clinical Laboratory Improvement Amendment (CLIA) regulations.</p>	<p>IV.D.1) Laboratory test procedures are performed according to current site-specific CLIA certificate.</p> <p><u>CLIA Certificates:</u></p> <ul style="list-style-type: none"> • All sites that perform laboratory testing for human health assessment, diagnosis, prevention, or treatment of disease has a current, unrevoked, unsuspended site-specific Clinical Laboratory Improvement Amendment (CLIA) certificate, or evidence of renewal. • Acceptable documentation such as the original certificate, copy of the original certificate, renewal receipt or other evidence of renewal submission is present on site or readily available upon request. The CLIA certificate or evidence of renewal should include the current site/clinic address. <p><u>Note:</u> Per 42 CFR, 493.35(b)(1-3), 493.43(b)(1-3) and 493.55(b)(1-3), laboratories must file a separate application for each laboratory location, with the following <u>exceptions</u>:</p> <ol style="list-style-type: none"> 1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address. 2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application, or 3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for laboratory sites within same physical location or street address. 4) A multi-site CLIA waiver can be used at all affiliated locations. A copy of the CLIA waiver must be at each individual location with the address of the main location on the waiver. A copy of the CLIA application must be reviewed by the CSR to verify the locations included for old and new locations. <p>The CLIA Certificate on site includes one of the following:</p> <ul style="list-style-type: none"> ○ Certificate of Waiver: Site can perform only exempt waived tests ○ Certificate for Provider-Performed Microscopy (PPM): Physicians, dentists, or NPMPs can perform PPM procedures and waived tests

Criteria	IV. Clinical Services – Laboratory Review
	<ul style="list-style-type: none"> ○ Certificate of Registration: Allows moderate and/or high complexity lab testing to be conducted until compliance with CLIA regulations are determined by survey ○ Certificate of Compliance: Lab has been surveyed and found in compliance with all applicable CLIA requirements ○ Certificate of Accreditation: Lab is accredited by an accreditation organization approved by CMS <p><u>Waived Tests:</u></p> <ul style="list-style-type: none"> ● If only waived tests are performed, site has a current CLIA Certificate of Waiver. ● There are no specific CLIA regulations regarding the performance of waived tests. ● Site personnel are expected to follow the test manufacturer’s instructions. ● Laboratories with certificates of waiver may not be routinely inspected by DHCS Laboratory Field Services Division but may be inspected as part of complaint investigations and on a random basis to determine whether only waived tests are being performed. <p><u>Moderate and High Complexity Tests:</u> Tests not listed as waived are divided into one of two categories, moderate complexity or high complexity, based on the complexity of the testing procedure. CLIA regulations for these categories list specific requirements for laboratory proficiency testing, patient test management, quality control, quality assurance, personnel, and inspections.</p> <p>IV.D.2) Testing personnel performing clinical lab procedures have been trained.</p> <p><u>Personnel Training:</u></p> <ul style="list-style-type: none"> ● Prior to testing biological specimens, personnel have been appropriately trained for the type and complexity of the laboratory services performed. ● Personnel have demonstrated the ability to perform all testing operations reliably and to report results accurately. ● Site personnel that perform CLIA waived tests have access to and can follow test manufacturer’s instructions. ● When requested, site personnel can provide a step-by-step verbal explanation or demonstration of test procedure and how to determine test results.

Criteria	IV. Clinical Services – Laboratory Review
	<ul style="list-style-type: none"> • The required training and certification are established by legislation for personnel performing moderate and high complexity tests.⁵⁴ <p>Reviewers are not expected to complete an in-depth evaluation of personnel performing moderate and high complexity tests.</p> <p>IV.D.3) Lab supplies (e.g. vacutainers, vacutainer tubes, culture swabs, test solutions) are inaccessible to unauthorized persons.</p> <p>IV.D.4) Lab test supplies are not expired. Lab supplies are disposed of by manufacturer’s expiration date.</p> <p>IV.D.5) Site has a procedure to check expiration date and a method to dispose of expired lab test supplies.</p> <p>Note: Any site that performs tests or examinations on human biological specimens derived from the human body is, by definition, “laboratories” under State and federal law, and includes locations such as nurses’ stations within hospitals, clinics, surgical centers, physician offices, and health fairs.</p> <p>The current listing of waived tests may be obtained at www.cms.gov or www.fda.gov includes an evaluation every two years (or sooner of complaint driven) by CDPH of personnel licenses/training, laboratory site inspection and demonstration of testing proficiency for moderate and high-complexity test sites.</p> <p>Contact CDPH Laboratory Field Services (510) 620-3800 or LFSrecep@cdph.ca.gov for CLIA certification, laboratory license, or personnel questions.</p>

⁵⁴ BPC 1200-1213
July 1 2022

Criteria	IV. Clinical Services – Radiology Review
<p>E. Site meets CDPH Radiological inspection and safety regulations</p>	<p>IV.E.1) Site has current CA Radiologic Health Branch Inspection Report and Proof of Registration if there is radiological equipment on site. <u>CDPH Radiologic Health Branch (RHB) Inspection Report:</u> If site has current documentation of one of the following, give the full 9 points and survey items 2-9 will not need to be surveyed. Acceptable documentation is:</p> <ul style="list-style-type: none"> ○ Inspection Report and Proof of Registration, or ○ Inspection Report and Proof of Registration and Short Form Sign-off sheet, or ○ Inspection Report and Proof of Registration and Notice of Violation form and approval letter for corrective action plan from the CA RHB <p>The Radiologic Inspection Report and Proof of Registration (receipt of payment or cancelled check), issued by the RHB, must be present if there is radiology equipment on site. If any violations are found, one of two documents are issued to the site:</p> <ul style="list-style-type: none"> ○ “Short Form Sign-off sheet” is issued for minimal problems that are easily corrected. ○ “Notice of Violation” form, requiring a site corrective action plan, is issued if there are more violations that are serious. All “Notice of Violation” corrective action plans must be accompanied by an approval letter from the CA RHB. <p>If documents are not available on site, or if reviewer is uncertain about the “status of documents on site, proceed to score all items 1-9.</p> <p>The following documents are posted on site:</p> <p>IV.E.2) Current copy of Title 17 with a posted notice about availability of Title 17 and its location.</p> <p>IV.E.3) “Radiation Safety Operating Procedures” posted in highly visible location.</p> <p>IV.E.4) “Notice to Employees Poster” posted in highly visible location.</p> <p>IV.E.5) “Caution, X-ray” sign posted on or next to door of each room that has X-ray equipment.</p> <p>IV.E.6) Physician Supervisor/Operator certificate posted and within current expiration date.</p>

Criteria	IV. Clinical Services – Radiology Review
	<p>IV.E.7) Technologist certificate posted and within current expiration date.</p> <p>The following radiological protective equipment is present on site:</p> <p>IV.E.8) Operator protection devices: radiological equipment operator must use lead apron or lead shield.</p> <p>IV.E.9) Gonadal shield (0.5 mm or greater lead equivalent): for patient procedures in which gonads are in direct beam.</p> <p><u>Radiological Equipment:</u> Equipment inspection, based on a “priority” rating system, is established by legislation. https://blink.ucsd.edu/files/safety-tab/rad/Title-17-CCR.pdf</p> <ul style="list-style-type: none"> • Mammography equipment is inspected annually, and must have federal FDA Certification on site and CA Mammography X-ray Equipment and Facility Accreditation Certification posted on the machine.⁵⁵ • High Priority equipment (e.g. fluoroscopy, portable X-ray) is inspected every three years. • Medium Priority equipment is inspected every 4-5 years depending on the volume of patients, frequency of x-ray equipment uses, and likelihood of radiation exposure. <p>If reviewer is uncertain about the “status of equipment inspection, call the RHB.</p> <p><u>Radiology Personnel:</u></p> <ul style="list-style-type: none"> • All certificates/licenses are posted and show expiration dates. • If there are many technicians, a list of names, license numbers, and expiration dates may be substituted. • The Certified Radiological Technologist (CRT) certificate permits the technologist to perform all radiology films except mammography and fluoroscopy, which require separate certificates. • The “Limited Permit” restricts the technician to one of the ten-(10) x-ray categories specified on the limited certificate: Chest, Dental laboratory, Dermatology, Extremities, Gastrointestinal, Genitourinary, Leg-podiatric, Skull, Torso-skeletal, and X-ray bone densitometry.

Criteria	IV. Clinical Services – Radiology Review
	<p>Note:</p> <ul style="list-style-type: none"> • Per RHB, dexascanners do not require lead aprons or gonadal shields, however, criteria 1-7 are still required. • RHB uses the ALARA (As Low As Reasonably Achievable) principle, which is the foundation of all radiation safety programs. The ALARA principle means to minimize exposure to radiation doses by employing all <i>reasonable</i> methods. • Dexascanners manufacturer guidelines do not require gonadal shielding or lead aprons due to very low radiation output, and potential for the shield to obscure the area being scanned, possibly rendering the scan non-diagnostic. With the focused beam, operators do not need aprons, the amount of exposure of “scattered” beams to an operator seated near the scanner is about the same level as that found in the natural environment. <p>A traditional x-ray machine used for bone density testing, is not a dexascanner, and <i>may</i> require shielding/apron.</p> <p>Note: The RHB of the Food, Drug, and Radiation Safety Division of CDPH enforces the Radiation Control Laws and Regulations designed to protect both the public and employees against radiation hazards. Enforcement is carried out through licensing, registration and periodic inspection of sources of radiation, such as radiation machines.</p> <p>For questions regarding radiologic safety (e.g. expired or no inspection letters on site), call CDPH RHB at (916) 327-5106. For Radiation Emergency Assistance, call 1-800-852-7550.</p> <p>Ref: CCR, Title 17, Chapter 5, Subchapter 4 regulations at https://www.cdph.ca.gov/rhb</p>

Criteria	V. Preventive Services Standards
<p>A. Preventive health care services and health appraisal examinations are provided on a periodic basis for the detection of asymptomatic diseases.</p>	<p>Examination equipment, appropriate for primary care services, is available on site:</p> <p>V.A.1) Exam tables and lights are in good repair. <u>Examination Table and Lights:</u></p> <ul style="list-style-type: none"> • Lights and exam tables shall be in good repair. “Good repair” means clean and well maintained in proper working order. • Examination tables must have a protective barrier such as paper which is changed between patients, to cover the exam surface. <p>V.A.2) Stethoscope and sphygmomanometer with various size cuffs (e.g. child, adult, obese, thigh).</p> <p>V.A.3) Thermometer with a numeric reading.</p> <p>V.A.4) Basic exam equipment: in addition to items mentioned above, offices should have the following:</p> <ul style="list-style-type: none"> ○ Percussion hammer ○ Tongue blades ○ Patient gowns <p>V.A.5) Scales: Standing balance beam and infant scales. <u>Scales:</u></p> <ul style="list-style-type: none"> • Infant scales are marked and accurate to increments of one (1) ounce or less and have a capacity of at least 35 pounds. • Standing floor scales are marked and accurate to increments of one-fourth (1/4) pound or less and have a capacity of at least 300 pounds. • Balance beam scales have an adjustment mechanism and zeroing weight to enable routine balancing at zero. • Electronic or digital scales have automatic zeroing and lock-in weight features. • Spring balance scales (e.g. bathroom scales) are unsatisfactory for clinical use as, over time, the spring counterbalance mechanism loses its accuracy.

Criteria	V. Preventive Services Standards
	<p>V.A.6) Measuring devices for stature (height/length) measurement and head circumference measurement. Measuring Devices: Equipment on site for measuring stature (length/height) and head circumference includes:</p> <ul style="list-style-type: none"> ○ Rigid 90° right angle headboard block that is perpendicular to the recumbent measurement surface. ○ Vertical to the wall-mounted standing measurement surface. ○ Flat, paper or plastic non-stretchable tape or yardstick, marked to one-eighth (1/8 in. or 1 mm) or less, attached to a firm, flat surface. The “0” of the tape is exactly at the base of the headboard for recumbent measurement, or exactly at foot level for standing measurement. ○ Moveable, non-flexible footboard at 90° right angle perpendicular to the recumbent measurement surface, or a flat floor surface for standing. ○ A non-stretchable tape measuring device marked to one-eighth (1/8 in. or 1 mm) or less for measuring head circumference (re-usable measuring device must be appropriately cleaned in between use). <p>V.A.7) Eye charts (literate and illiterate) and occluder for vision testing. Vision Testing:⁵⁶</p> <ul style="list-style-type: none"> ● Site has both literate (e.g., Snellen) and illiterate eye charts ● The current preferred optotypes (figures or letters of different sizes) for patients who cannot distinguish letters are the LEA or HOTV symbols (see figures below)

⁵⁶ See the Procedures for the Evaluation of the Visual System by Pediatricians, available at: <https://pediatrics.aappublications.org/content/137/1/e20153597>. Also see the American Association for Pediatric Ophthalmology and Strabismus Vision Screening Committee’s Pediatric Screening Guidance during the COVID-19 Pandemic, available at: <https://aapos.org/education/allied-health/covid>.



Criteria	V. Preventive Services Standards
	<div data-bbox="541 240 1163 678" data-label="Image"> </div> <ul data-bbox="548 764 1940 1094" style="list-style-type: none"> • Wall mounted eye charts should be height adjustable and positioned at the eye-level of the patient • Examiners shall stand their patients with their heels to the line unless the eye chart that is being used to screen specifically instructs the patient to be positioned elsewhere. “Heel” lines are aligned with center of eye chart at 10 or 20-feet depending on whether the chart is for the 10-foot or 20-foot distance. • Eye charts are in an area with adequate lighting and at height(s) appropriate to use • Effective occlusion, such as with tape or an occlusive patch of the eye not being tested, is important to eliminate the possibility of peeking. <p data-bbox="537 1138 905 1170">V.A.8) Ophthalmoscope.</p> <p data-bbox="537 1175 1188 1208">Ophthalmoscope is in good working condition.</p> <p data-bbox="537 1247 1388 1279">V.A.9) Otoloscope with adult and pediatric ear speculums.</p> <p data-bbox="537 1284 1629 1317">Otoloscope with multi-size ear speculums appropriate to the population served.</p> <p data-bbox="537 1356 1860 1388">V.A.10) A pure tone, air conduction audiometer is located in a quiet location for testing.</p>

Criteria	V. Preventive Services Standards
	<p><u>Hearing Testing:</u>⁵⁷</p> <ul style="list-style-type: none"> • The pure tone audiometer must have the minimum ability to: <ul style="list-style-type: none"> ○ Produce intensities between 0 to 80 dB ○ Have a headset with right and left earphones ○ Be operated manually ○ Produce frequencies at 1000, 2000, 3000, 4000, 6000, and 8000 Hz • Offices that provide pediatric preventive services should have a pure tone; air conduction audiometer available, audiometric testing is required at preventive health visits starting at 4 years of age. • PCP offices (such as Family Practitioners or General Practitioners) that refer all members to another provider for audiometric testing, must have a system in place that clearly demonstrates that the PCP office verifies that audiometric testing has been completed and that those results are returned to the PCP for review.
<p>B. Health education services are available to Plan members.</p>	<p><u>Health Education Services:</u> Services may include individual instruction, group classes, family counseling and/or other health educational programs and materials provided to members by the provider, health plan, or community sponsored programs.</p> <p>Health education materials and Plan-specific resource information are:</p> <p>V.B.1) Readily accessible on site or are made available upon request.</p> <p>V.B.2) Applicable to the practice and population served on site.</p> <p>V.B.3) Available in threshold languages identified for county and/or area of site location.</p> <p><u>Health Education Materials:</u></p>

⁵⁷ See the American Speech-Language-Hearing Association’s guidance on Audiograms, available at: <https://www.asha.org/public/hearing/audiogram/>.

Criteria	V. Preventive Services Standards
	<ul style="list-style-type: none"> • Must be available in the appropriate threshold languages and may be located in an accessible area on site (e.g., exam room, waiting room, health education room or area), or provided to members by clinic staff and/or by Plan upon request. • Must be available in accessible format which may include written information, audio and/or videotapes, computerized programs, and visual presentation aids for people with disabilities. • Should include general topics for health educational material such as: Immunizations, Pregnancy, Injury Prevention, Smoking Cessation, Dental Health, Nutrition, Physical Activity, STD/HIV Prevention, Family Planning, Asthma, Hypertension, and Diabetes. • Must meet the Medi-Cal Managed Care readability and suitability requirements for educational material distributed to Medi-Cal members.⁵⁸ <p><u>Plan-Specific Referral Information:</u> Plan-specific informing materials and/or resources are available on site in languages that are applicable to member population(s) primarily seen on site.</p> <ul style="list-style-type: none"> ○ For example, if primarily English and Spanish-speaking members are seen on site, then Plan-specific informing materials are available on site in those languages. ○ Although a site may not stock informing materials in each threshold language identified for the county, site personnel has access to contact resource information for locating Plan-specific informing materials in threshold languages not typically seen on site. ○ Interpreter services are provided in all identified threshold and concentration standard languages. <p><u>Note:</u> Threshold languages are the primary languages spoken by Limited English Proficient (LEP) population groups residing in a county. A numeric threshold of 3,000 eligible LEP Medi-Cal beneficiaries or a concentration standard of 1,000 residing in a single ZIP code or 1,500 in two contiguous ZIP codes establishes the threshold languages identified by DHCS for each county.</p>

⁵⁸ See All Plan Letter (APL) 18-016, "Readability and Suitability of Written Health Education Materials". APLs are searchable at: <https://www.dhcs.ca.gov/formsandpubs/Pages/AllPlanLetters.aspx>.

Criteria	VI. Infection Control Standards
<p>A. Infection control procedures for Standard/Universal precautions are followed.</p> <p>  RN/NP/CNM/LM/MD/PA</p>	<p><u>Deficiencies:</u> All deficiencies related to Infection Control must be addressed in a corrective action plan (CAP).</p> <p><u>Hand Washing Facilities:</u>⁵⁹</p> <ul style="list-style-type: none"> • Hand washing facilities are available in the exam room and/or utility room, and include an adequate supply of running potable water, soap and single use towels or hot air-drying machines. • Sinks with a standard faucet, foot-operated pedals, 4-6-inch wing-type handle, automatic shut-off systems or other types of water flow control mechanism are acceptable. • Staff can demonstrate infection control “barrier” methods used on site to prevent contamination of faucet handle, door handles and other surfaces until hand washing can be performed. • On occasions when running water is not readily available, an antiseptic hand cleanser, alcohol-based hand rub, or antiseptic towelettes is acceptable until running water is available.⁶⁰ <p>VI.A.1) Soap or antiseptic hand cleaner and running water are available in exam and/or treatment areas for hand washing.</p> <p><u>Soap or Antiseptic Hand Cleaner:</u> Hand washing prevents infection transmission by removing dirt, organic material and transient microorganisms from hands.</p> <ul style="list-style-type: none"> ○ Hand washing with plain (non-antimicrobial) soap in any form (e.g., bar, leaflet, liquid, powder, granular) is acceptable for general patient care (Association for Professionals in Infection Control and Epidemiology, Inc., 1995). ○ Antimicrobial agents or alcohol-based antiseptic hand rubs are used for hand washing when indicated to remove debris and destroy transient microorganisms (e.g., before performing invasive procedures, after contact with potentially infectious materials). ○ Plain and antiseptic hand wash products are properly maintained and/or dispensed to prevent contamination.


⁵⁹ See the World Health Organization’s Hand Hygiene guidelines, available at: [https://www.who.int/gpsc/5may/Hand Hygiene Why How and When Brochure.pdf](https://www.who.int/gpsc/5may/Hand_Hygiene_Why_How_and_When_Brochure.pdf).

⁶⁰ 29 CFR 1919.1030

Criteria	VI. Infection Control Standards
	<p>VI.A.2) A waste disposal container is available in exam rooms, procedure/treatment rooms, and restrooms. Waste Disposal Container:⁶¹</p> <ul style="list-style-type: none"> • Contaminated wastes (e.g. dental drapes, band-aids, sanitary napkins, soiled disposable diapers) are disposed of in regular solid waste (trash) containers, and are maintained to prevent potential contamination of patient/staff areas and/or unsafe access by infants/children. • Closed containers are not required for regular, solid waste trash containers. <p>VI.A.3) Site has procedure for effectively isolating infectious patients with potential communicable conditions. Isolation Procedures:⁶²</p> <ul style="list-style-type: none"> • Personnel can demonstrate or verbally explain procedure(s) used on site to isolate patients with potentially contagious conditions from other patients. • If personnel are unable to demonstrate or explain site-specific isolation procedures <i>and</i> cannot locate written isolation procedure instructions, site is considered deficient. • Isolation procedures may vary from site to site. <p>Note:</p> <ul style="list-style-type: none"> • Infection Control standards are practiced on site to minimize risk of disease transmission. • Site personnel are expected to apply the principles of “Standard Precautions” (CDC, 1996), used for all patients regardless of infection status. • Standard precautions apply to blood, all body fluids, non-intact skin, and mucous membranes, which are treated as potentially infectious for HIV, HBV or HCV, and other bloodborne pathogens. • “Universal precautions” refer to the OSHA mandated program that requires implementation of work practice controls, engineering controls, bloodborne pathogen orientation/education, and record keeping in healthcare facilities.

⁶¹ HSC 118275-118320. Also see the OSHA Standards for Bloodborne Pathogens, available at: <https://www.hercenter.org/rmw/osh-pps.php>.

⁶² See the CDC’s Guidelines for Isolation Precautions, available at: <https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>.

Criteria	VI. Infection Control Standards
<p>B. Site is compliant with OSHA Bloodborne Pathogens Standard and Waste Management Act.  RN/NP/CNM/LM/MD/PA</p>	<p><u>Deficiencies:</u> All deficiencies related to Infection Control must be addressed in a corrective action plan.</p> <p><u>VI.B.1) (CE) Personal Protective Equipment for Standard Precautions is readily available for staff use.</u> <u>Personal Protective Equipment (PPE):</u> PPE must be readily available.⁶³ PPE for protection against bloodborne pathogen hazards is available on site and must include:</p> <ol style="list-style-type: none"> 1) Gloves 2) Water repellent clothing barrier/gown 3) Face/eye protection (e.g., goggles/face shield) 4) Respiratory infection protection (e.g., mask) <p>PPE does not include general work clothes (e.g., uniforms, cloth lab coats) that will permit liquid to soak through.</p> <ul style="list-style-type: none"> • The storage of PPE should be adequate to protect the PPE from contamination, loss, damage, water or sunlight. • Proper storage often requires a dry and clean place that is not subject to temperature extremes. <p><u>VI.B.2) (CE) Blood, other potentially infectious materials, and Regulated Wastes are placed in appropriate leak proof, labeled containers for collection, handling, processing, storage, transport or shipping.</u> <u>Blood and Other Potentially Infectious Materials (OPIM):</u></p> <ul style="list-style-type: none"> • OPIM are all human body fluids, any unfixed tissue or organ (other than intact skin) from a human (living or dead), and HIV or HBV-containing blood, cells, tissue, organs, cultures, medium or solutions. • Containers for blood and OPIM are closable, leak proof, and labeled and/or color-coded. • Double bagging is required only if leakage is possible. <p><u>Labels:</u></p>

Criteria	VI. Infection Control Standards
	<ul style="list-style-type: none"> • A warning label is affixed to red-bagged regulated wastes, sharps containers, refrigerators/freezers containing blood or OPIM, containers used to store or transport blood or OPIM, and contaminated laundry or equipment for storage or transporting. • The international biohazard symbol with word “BIOHAZARD” or the words “Biohazardous Waste” label (fluorescent orange or red orange with contrasting lettering/symbols) is part of, or affixed to, the container. • Sharps containers are labeled with the words “Sharps Waste” or with the international biohazard symbol and the word “BIOHAZARD”. • Individual containers of blood or OPIM are exempted from warning labels if placed inside a labeled secondary container for storage, transport, or disposal. • Alternative marking or color coding may be used to label contaminated laundry or specimen containers if the alternative marking permits employees on site to recognize that container requires compliance with Universal Precautions. <p><u>VI.B.3) (CE) Needlestick safety precautions are practiced on site.</u></p> <p><u>Needlestick Safety:</u>⁶⁴</p> <ul style="list-style-type: none"> • Contaminated sharps are discarded immediately. • Sharps containers are located close to the immediate area where sharps are used and are inaccessible to unauthorized persons. • Sharps are not bent, removed from a syringe, or recapped. Recapping, bending, or removing contaminated needles is permissible only if there is no feasible alternative or if such actions are required for a specific medical procedure. If recapping, bending, or removal is necessary, employers must ensure that workers use either a mechanical device or a one-handed technique. Needleless systems, needles with Engineered Sharps Injury Protection (ESIP) devices, and non-needle sharps are used (incl. in emergency kits), unless exemptions have been approved by Cal/OSHA.⁶⁵ • Security of portable containers in patient care areas is always maintained. • Any device capable of cutting or piercing (e.g. syringes, hypodermic needles, needleless devices, blades, broken glass, slides, vials) are placed in a closable, puncture-resistant, labeled,

⁶⁴ See the OSHA Needlestick Safety Frequently Asked Questions, available at: <https://www.osha.gov/needlesticks/needlefaq.html>, and the OSHA Standards for Bloodborne Pathogens, available at: <https://www.hercenter.org/rmw/osha-bps.php>.

⁶⁵ 8 CCR 5193


Criteria	VI. Infection Control Standards
	<p>leak-proof container. If these requirements are met, containers made of various materials (e.g., cardboard, plastic) are acceptable.</p> <ul style="list-style-type: none"> • Containers are not overfilled past the manufacturer’s designated fill line, or more than ¾ full. • Supply of containers on hand is adequate to ensure routine change-out when filled. <p>VI.B.4) All sharp injury incidents are documented. <u>Sharps Injury Documentation:</u>⁶⁶</p> <ul style="list-style-type: none"> • Site has a method in place to document sharps injuries. • The Sharps Injury Log must contain, at a minimum, information about the injury, the type and brand of device involved in the injury (if known), the department or work area where the exposure occurred, and an explanation of how the incident occurred. • The incident must be recorded in the log within 14 business days of the date the incident is reported to the employer and maintained in such a manner to protect the confidentiality of the injured employee (e.g., removal of personal identifiers) and follow-up care is documented within 14 days of injury incident. • Sites with 10 or fewer employees are exempt from OSHA recordkeeping requirements and are exempt from recording and maintaining a Sharps Injury Log, however, it is recommended to have a method in place to document sharps injuries regardless of the number of employees. <p><u>Regulated Waste Storage:</u> Regulated wastes include:</p> <ul style="list-style-type: none"> ○ Biohazardous wastes, e.g., laboratory wastes, human specimens/tissue, blood/contaminated materials “known” to be infected with highly communicable diseases for humans and/or that require isolation. ○ Medical wastes, e.g., liquid/semi-liquid blood or OPIM, items caked with dry blood or OPIM and capable of releasing materials during handling, and contaminated sharps. <p>VI.B.5) Biohazardous (non-sharp) wastes are contained separate from other trash/waste.</p>

⁶⁶ See 8 CCR 5193, and the National Institute for Occupational Safety and Health’s guidance on Preventing Needlesticks and Sharps Injuries, available at: <https://www.cdc.gov/niosh/topics/bbp/sharps.html>.



Criteria	VI. Infection Control Standards
	<p>VI.B.6) Storage areas for regulated medical wastes are maintained secure and inaccessible to unauthorized persons.⁶⁷</p> <ul style="list-style-type: none"> • Regulated waste is contained separately from other wastes (e.g., contaminated wastes)* and placed in red biohazardous bags with Biohazard label and stored in a closed container that is not accessible to unauthorized persons. • If stored outside the office, a lock secures the entry door, gate or receptacle lid, and posted warning sign(s) in English and Spanish are visible for 25-feet: “CAUTION-BIOHAZARDOUS WASTE STORAGE AREA- UNAUTHORIZED PERSONS KEEP OUT” and CUIDADO-ZONA DE RESIDUOUS-BIOLOGICOS PELIGOROS-PROHIBIDA LE ENTRADA A PERSONAS NO AUTHORIZADAS”. <p>See HSC Sections 117915-117946, 49 CFR, Section 173.6; Core Infection Prevention and Control Practices -Centers for Disease Control and Prevention (CDC) The Healthcare Infection Control Advisory Committee (HICPAC), 2016.</p> <p>VI.B.7) Contaminated laundry is laundered at the workplace or by a commercial laundry service.</p> <p><u>Contaminated Laundry:</u></p> <ul style="list-style-type: none"> • Contaminated laundry (soiled with blood/OPIM) is laundered by a commercial laundry service, or a washer and dryer on site. • Contaminated laundry should not contain sharps, and when transported, should have the appropriate warning label. • Manufacturer’s guidelines are followed to decontaminate and launder reusable protective clothing. • Ensure that laundry areas have handwashing facilities and products and appropriate PPE available for staff. • Laundry requirements are “not applicable” if only disposable patient gowns and PPE are used on site.

⁶⁷ HSC 117600-118360, 29 CFR 1910.1030, CDC Guidelines for Isolating Precautions: Preventing Transmission of Infection Agents in Healthcare Settings, available at: <https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>.

Criteria	VI. Infection Control Standards
	<p>VI.B.8) Transportation of regulated medical wastes is only by a registered hazardous waste hauler or to a central location of accumulation in limited quantities (up to 35.2 pounds). Medical Waste Disposal: California adopted statutes into HSC affecting medical waste transporters in October 1993.⁶⁸</p> <ul style="list-style-type: none"> • Only medical waste transporters listed with CDPH can transport medical waste. • All medical waste transporters must carry paperwork issued by CDPH in each vehicle while transporting medical waste. • Medical wastes are hauled to a permitted offsite medical waste treatment facility, transfer station, or other registered generator by a registered hazardous waste transporter. • Limited-quantity exemption is not required for Small Quantity Generator (up to 35.2 pounds). However, a medical waste-tracking document that includes the name of the person transporting, number of waste containers (e.g., three sharps containers, or five biohazard bags), types of medical wastes, and date of transportation, is kept a minimum of 3 years for large waste generators and 2 years for small generators. <p>For the CDPH list of current medical waste transporters, visit: https://www.cdph.ca.gov/Programs/CEH/DRSEM/CDPH%20Document%20Library/EMB/MedicalWaste/Haulist_012921.pdf</p> <p>For information on the United States Postal Service mailability standards for medical waste (including sharps) refer to the Domestic Mail Manual, section 601.10.17: https://pe.usps.com/Archive/HTML/DMMArchive20100607/601.htm</p> <p>CDPH Medical Waste Management Program: https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/MedicalWaste.aspx</p> <p>CDPH Medical Waste Management Program Transporter Checklist: https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph8660.pdf</p> <p>CDPH Medical Waste Transporter Annual Verification: https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph8668.pdf</p>

Criteria	VI. Infection Control Standards
	<p>CDPH Medical Waste Transfer Stations and Offsite Treatment Facilities: https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/EMB/MedicalWaste/Transfer-and-Treatment.aspx</p> <p>CDPH Medical Waste Transporters Data Submission Protocol: https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph8666.pdf</p> <p>Department of Toxic Substances Control-Managing Hazardous Waste Transporters Registration https://dtsc.ca.gov/transporters/</p> <p>*Note: Contaminated wastes include materials soiled with blood during their use but are not within the scope of regulated wastes. Contaminated waste items need not be disposed as regulated waste in labeled red bags but can be discarded as solid waste in regular trash receptacle.</p>
<p>C. Contaminated surfaces are decontaminated according to Cal-OSHA standards.  RN/NP/CNM/LM/MD/PA</p>	<p><u>Deficiencies:</u> All deficiencies related to Infection Control must be addressed in a corrective action plan (CAP).</p> <p>VI.C.1) Equipment and work surfaces are appropriately cleaned and decontaminated after contact with blood or other potentially infectious material. <u>Routine Decontamination:</u></p> <ul style="list-style-type: none"> ○ Contaminated work surfaces are decontaminated with an appropriate disinfectant.⁶⁹ ○ Written “housekeeping” schedules have been established and are followed for regular routine daily cleaning. ○ Staff can identify cleaning and disinfection of surfaces and equipment, the disinfectant used and responsible personnel in between patients use. <p>VI.C.2) Routine cleaning and decontamination of equipment/work surfaces is completed according to site-specific written schedule. The written schedule for cleaning and decontamination of the work site as follows:</p> <ul style="list-style-type: none"> ○ Area cleaned/decontaminated

Criteria	VI. Infection Control Standards
	<ul style="list-style-type: none"> ○ Frequency of cleaning/decontamination ○ Employee responsible for determining and implementing the written schedule <p>All equipment and environmental and work surfaces shall be cleaned and decontaminated after contact with blood or OPIM no later than at the end of the shift.</p> <p>Cleaning and decontamination of equipment and work surfaces is required more often as specified below:</p> <ul style="list-style-type: none"> ○ Location within the facility ○ Type of surface or equipment to be treated ○ Type of soil or contamination present ○ Tasks or procedures being performed in the area <p>Contaminated work surfaces shall be cleaned and decontaminated with an appropriate disinfectant immediately or as soon as feasible when:</p> <ul style="list-style-type: none"> ○ Surfaces become overtly contaminated. ○ There is a spill of blood or OPIM. ○ Procedures are completed. ○ At the end of the work shift if the surface may have become contaminated since the last cleaning. <p><u>Spill Procedure:</u> Personnel can identify procedures for prompt decontamination of blood/body fluid spills, the disinfectant used, and the responsible person(s).</p> <p>Disinfectant solutions used on site are:</p> <p>VI.C.3) Approved by the Environmental Protection Agency (EPA).</p> <p>VI.C.4) Effective in killing HIV/HBV/TB.</p> <p>VI.C.5) Follow manufacturer instructions.</p> <p><u>Disinfectant Products:</u></p> <ul style="list-style-type: none"> ○ Products used for decontamination have a current EPA-approved status. ○ Effectiveness in killing HIV/HBV/TB is stated on the manufacturer's product label. ○ Decontamination products are used according to manufacturer's guidelines for decontamination and <u>contact times</u>.

Criteria	VI. Infection Control Standards
	<p><u>10% Bleach Solution:</u></p> <ul style="list-style-type: none"> ○ 10% bleach solution that is EPA registered and effective against TB, is changed/reconstituted every 24 hours (due to instability of bleach once mixed with water). ○ Surface is cleaned prior to disinfecting (due to presence of organic matter (e.g., dirt, blood, excrement) inactivates active ingredient, sodium hypochlorite). ○ Surface is air-dried or allowed appropriate time (stated on label) before drying. ○ Manufacturer’s directions, <i>specific</i> to every bleach product, are followed carefully. <p><u>Note:</u> “Contamination” means the presence or reasonably anticipated presence of blood or OPIM on any item or surface. “Decontamination” is the use of appropriate physical or chemical means to remove, inactivate or destroy bloodborne pathogens so that a surface or item is no longer capable of transmitting infectious particles and is rendered safe for handling, use or disposal.⁷⁰ Current EPA product lists and information is available from the EPA, Antimicrobial Division at (703) 305-1284, or at 29 CFR 1910.1030.</p>
<p>D. Reusable medical instruments are properly sterilized after each use.   RN/NP/CNM/LM/MD/PA</p>	<p><u>Deficiencies:</u> All deficiencies related to Infection Control must be addressed in a corrective action plan (CAP).</p> <p>VI.D.1) Written site-specific policy/procedures or manufacturer’s instructions for instrument/equipment sterilization are available to staff. If site uses an autoclave or cold chemical solution to achieve sterilization and/or high level disinfection (HLD) of instruments/equipment, site shall have specific policy/procedures or manufacturer’s instructions addressing instrument/equipment pre-treatment, cleaning and preparation, the management of chemical solutions, autoclave loading and operation, safety guidelines and precautions, and other required processes, which are available to staff to follow.</p> <p>Staff adheres to site-specific policy and/or manufacturer/product label directions for the following procedures:</p> <p>VI.D.2) Cleaning reusable instruments/equipment prior to sterilization. Cleaning Prior to Sterilization:</p>

⁷⁰ 8 CCR 5193. Also see CalOSHA’s Best Practices Approach for Reducing Bloodborne Pathogen Exposure, available at: https://www.dir.ca.gov/dosh/dosh_publications/BBPBest1.pdf.

Criteria	VI. Infection Control Standards
	<ul style="list-style-type: none"> • Prior to undergoing the sterilization process, soiled instruments/equipment are thoroughly cleaned using enzymatic detergent, rinsed, dried, and inspected for the presence of dried blood or other debris. <p><u>Cold chemical sterilization/high level disinfection:</u> <u>VI.D.3a) (CE) Staff demonstrate /verbalize necessary steps/process to ensure sterility and/or high-level disinfection of equipment.</u></p> <ul style="list-style-type: none"> • Personnel can demonstrate or verbally explain procedure(s) used for cleaning prior to sterilization, and to locate written directions on site. • Product efficacy tests (i.e. test strips) shall be performed according to manufacturer’s guidelines. <p><u>Cold Chemical Sterilization/High Level disinfection:</u></p> <ul style="list-style-type: none"> • Product manufacturer’s directions are strictly followed for instrument pre-soaking treatment, solution preparation, solution exposure procedures, safety precautions (e.g., room temperature, area ventilation), and post-sterilization processes. • Sterilization and or high-level disinfection exposure times and solution expiration date and time are available to staff. • Written procedures for cold sterilization and/or high-level disinfection is available on site to staff. <p><u>VI.D.3b) Confirmation from manufacturer item(s) is/are heat sensitive.</u></p> <ul style="list-style-type: none"> • Per CDC,⁷¹ the use of liquid chemical germicides to sterilize instruments ("cold sterilization") are limited. Sterility is not verified or assured with cold chemical sterilization. The first choice is always heat sterilization. The CDC refers to heat sterilization as "the method of choice when sterilizing instruments and devices. If an item is heat sensitive, it is preferable to use a heat-stable alternative or disposable item". • The use of a liquid chemical sterilant should be restricted to reprocessing devices that are heat-sensitive and incompatible with other sterilization methods. All other items should be heat sterilized or disposable.

⁷¹ See the CDC Guidelines for Disinfection and Sterilization, available at: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf>. Also see the CDC’s Guidelines on other sterilization methods, available at: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/other-methods.html>.

Criteria	VI. Infection Control Standards
	<p><u>VI.D.3c) (CE) Appropriate PPE is available, exposure control plan, Material Safety Data Sheets (MSDS) and clean up instructions in the event of a cold chemical sterilant spill.</u></p> <p><u>Cold Chemical Sterilants Spillage:</u> The OSHA Hazard Communication Standard requires manufacturers and importers of hazardous chemicals to develop MSDS for each chemical or mixture of chemicals.^{72, 73}</p> <ul style="list-style-type: none"> ○ Employers must have the data sheets for cold chemical sterilants readily available to employees who work with the products to which they could be exposed. ○ Staff should attend training classes in safety awareness about the use and exposure to cold chemical sterilants used on site. ○ Personnel are familiar with and can recognize signs and symptoms of exposure to cold chemical sterilants used on site. ○ Staff must be aware of the procedures for clean up in the event of spillage. ○ Staff can demonstrate or verbally explain procedure(s) used on site for chemical spill cleanup. ○ If personnel are unable to demonstrate or explain site-specific chemical spill cleanup procedures <i>and</i> cannot locate written chemical spill cleanup procedure instructions, site is considered deficient. ○ Cleanup procedures may vary from site to site depending on the cold chemical sterilants used. ○ The appropriate PPE for cold chemical sterilants clean up must be readily available. <p>National Institute for Occupational Safety and Health (NIOSH) with the Centers for Disease Control and Prevention. Environmental Health and Safety guidelines for disinfectants and sterilization methods. MSDS for cold chemical sterilants. The American National Standard (ANSI)/Advancing Safety in Medical Technology (AAMI) ST58:2013.</p> <p><u>Control Methods and Work Practices:</u> are in place to prevent or reduce exposure to the cold chemical sterilants. Cold chemical sterilants have toxic properties and are hazardous.</p>

⁷² 29 CFR 1910.1200, 1915.99, 1917.28, 1918.90, 1926.59, and 1928.21.

⁷³ See CDC guidelines on sterilizing heat sensitive dental instruments, available at: <https://oshareview.com/2013/10/cdc-guidelines-sterilizing-heat-sensitive-dental-instruments-dental-infection-control/>. 29 CFR 1910.1030(d)(3)(i), 29 CFR 1910.1030(d)(3)(ii), 29 CFR 1910.1030(d)(4)(ii)(A), 29 CFR 1910.1030(d)(4)(iii)(B), 29 CFR 1910.132, 29 CFR 1910.134. See the CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, available at: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/index.html>.

Criteria	VI. Infection Control Standards
	<ul style="list-style-type: none"> • Cold chemical sterilants must be used strictly in accordance with the manufacturer’s directions. Always consult the manufacturer for safety precautions and MSDS information. • The appropriate PPE must be used to avoid inhalation or skin contact exposure to during the cold chemical sterilization/high level disinfection process. <p>Examples of cold chemical sterilants include:</p> <ul style="list-style-type: none"> ○ Glutaraldehyde (Cidex) ○ Peracetic acid ○ Hydrogen peroxide-based solutions <p>Glutaraldehyde is a common cold chemical sterilants. Exposure to glutaraldehyde can cause the following health effects: throat and lung irritation, breathing difficulty, nose irritation, nosebleed, burning eyes and conjunctivitis, rash, hives, headaches, and nausea.</p> <p>Exposure to glutaraldehyde may be prevented or reduced by using the following control methods and work practices:</p> <ul style="list-style-type: none"> ○ Use local exhaust ventilation. ○ Keep glutaraldehyde baths under a fume hood where possible.⁷⁴ ○ Avoid skin contact (use appropriate PPE-gloves and aprons made of nitrile or butyl rubber wear goggles and face shields). ○ Use only enough sterilants to perform the required sterilization procedure. ○ Seal or cover all containers holding the sterilants. ○ Attend training classes. <p>Autoclave/Steam Sterilization:</p> <p>VI.D.4a) Staff demonstrate/verbalize necessary steps/process to ensure sterility.</p> <ul style="list-style-type: none"> • Autoclave manufacturer’s directions are strictly followed for instrument pre-cleaning, machine loading, operation safety precautions, minimum time-temperature criteria, and post sterilization processes. • Written operating procedures for autoclave are available on site to staff. • Documentation of sterilization loads include date, time and duration of run cycle, temperature, steam pressure, and operator of each run.

⁷⁴ For more information on glutaraldehyde exposure and safety tips, refer to the CDC guidance, available at:

<https://www.cdc.gov/niosh/docs/2001-115/default.html>.

Criteria	VI. Infection Control Standards
	<ul style="list-style-type: none"> • If instruments/equipment are transported off-site for sterilization, equipment handling, and transport procedures are available on site to staff. • Documentation of instruments and personnel transporting must be maintained. <p>VI.D.4 b) Autoclave maintenance per manufacturer’s guidelines. <u>Autoclave Maintenance:</u> Autoclave is maintained and serviced according to manufacturer’s guidelines. Documentation of maintenance should include:</p> <ul style="list-style-type: none"> ○ Mechanical problems ○ Inspection dates ○ Results/outcome of routine servicing ○ Calibration ○ Repairs, etc. <p><u>Note:</u> If the manufacturer’s guidelines are not present on site, then the autoclave is serviced annually by a qualified technician. A dated sticker on the autoclave or a service receipt is acceptable documentation of appropriate maintenance.</p> <p><u>VI.D.4c) (CE) Spore testing of autoclave/steam sterilizer with documented results (at least monthly).</u> <u>Spore Testing:</u></p> <ul style="list-style-type: none"> • Autoclave spore testing is performed <i>at least monthly</i>, unless otherwise stated in manufacturer’s guidelines. • Documentation of biological spore testing includes: <ul style="list-style-type: none"> ○ Date ○ Results ○ Types of spore test used ○ Person performing/documenting test results • Written procedures for performing routine spore testing and for handling positive spore test results are available on site to staff. • For positive spore tests, the autoclave is removed from service immediately until inspection is completed and a negative retest occurs. Procedures include: <ul style="list-style-type: none"> ○ Report problem ○ Repair autoclave ○ Retrieve all instruments sterilized since last negative spore test

Criteria	VI. Infection Control Standards
	<ul style="list-style-type: none"> ○ Re-test autoclave ○ Re-sterilize retrieved instruments ● Biologic spore test products vary and are designed for use based on specific autoclave type. Biologic control testing challenges the autoclave sterilization cycle with live, highly resistant, nonpathogenic spores. If spores are killed during processing, it is assumed that all other microorganisms are also killed and that the autoclave load is sterile. <p>Note: Documentation of monthly spore testing must be maintained onsite even for sterilization that is performed offsite.</p> <p><u>VI.D.4.d) (CE) Management of positive mechanical, chemical, and biological indicators of the sterilization process.</u></p> <p><u>Autoclave/Steam Sterilization Mechanical, Chemical, and Biological Indicators:</u>⁷⁵</p> <ul style="list-style-type: none"> ● Sterilization failure can occur for reasons such as slight variation in the resistance of the spores, improper use of the sterilizer, and laboratory contamination during the culture. ● Per CDC, the autoclave/steam sterilization procedure should be monitored routinely by using a combination of: <ul style="list-style-type: none"> ○ <u>Mechanical Indicator</u>: monitor sterilization process with a daily assessment of cycle time and temperature by examining the temperature record chart and an assessment of pressure via the pressure gauge (e.g., graphs, gauges, printouts) ○ <u>Chemical Indicator</u>: are usually either heat-or chemical-sensitive inks that change color when one or more sterilization parameters (e.g., steam-time, temperature, and/or saturated steam; ETO-time, temperature, relative humidity and/or ETO concentration) are present. ○ <u>Biological</u>: spore test – an indicator to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items <p>Staff should adhere to site-specific protocol and/or manufacturer/product label for management of positive indicator(s).</p>

⁷⁵ See the CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, available at: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf>.

Criteria	VI. Infection Control Standards
	<p>VI.D.4.e) Sterilized packages are labeled with sterilization date and load identification information.</p> <p><u>Package and storage of sterilized items:</u></p> <ul style="list-style-type: none"> • Following the sterilization process, medical and surgical devices must be handled using aseptic technique in order to prevent contamination. • Storage areas for sterilized packages are clean, dry and separated from non-sterile items by a functional barrier (e.g., shelf, cabinet door, and drawer). • Sterilized package labels include: <ul style="list-style-type: none"> ○ Date of sterilization ○ Load run identification information ○ Initials of staff member ○ General contents (e.g. suture set) each item in a sterile package need not be listed on the label if a master list of package contents is available elsewhere on site <p>VI.D.4.f) Storage of sterilized packages.</p> <p><u>Storage of sterilized packages:</u>⁷⁶</p> <ul style="list-style-type: none"> • Storage areas for sterilized packages are clean, dry and separated from non-sterile items by a functional barrier (e.g., shelf, cabinet door, and drawer). • Maintenance of sterility is event related, not time related. • Sterilized items are considered sterile until use, unless an event causes contamination. • Sterilized items are not considered sterile if package is opened, wet/moist, discolored or damaged, and should be kept removed from sterile package storage area. • Site has a process for routine evaluation of sterilized packages.

⁷⁶ See the CDC Summary of Recommendations regarding Disinfection and Sterilization, available at: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html>, and the CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, available at: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf>.

Facility Site Review Tool

Date: _____ Health Plan Name or Code: _____ IPA: _____

Last Review Date: _____ Site ID: _____ Site NPI: _____

Reviewer name/title: _____ Provider Address: _____

Reviewer name/title: _____ City and Zip Code: _____

Reviewer name/title: _____ Phone: _____ Fax: _____ Current Fire Clearance: _____

Contact person/title: _____

No. of staff on site: _____ Physician _____ NP _____ CNM _____ LM _____ PA _____ RN _____ LVN _____ MA _____ Clerical _____ other

Visit Purpose		Site-Specific Certification(s)		Provider Type		Clinic Type	
<input type="checkbox"/> Initial Full Scope	<input type="checkbox"/> Monitoring	<input type="checkbox"/> AAAHC	<input type="checkbox"/> JC	<input type="checkbox"/> Family Practice	<input type="checkbox"/> Internal Medicine	<input type="checkbox"/> Primary Care	<input type="checkbox"/> Community
<input type="checkbox"/> Periodic Full Scope	<input type="checkbox"/> Follow-up	<input type="checkbox"/> CHDP	<input type="checkbox"/> NCQA	<input type="checkbox"/> Pediatrics	<input type="checkbox"/> OB/GYN	<input type="checkbox"/> Hospital	<input type="checkbox"/> FQHC
<input type="checkbox"/> Focused	<input type="checkbox"/> Ed/TA	<input type="checkbox"/> CPSP	<input type="checkbox"/> None	<input type="checkbox"/> General Practice	<input type="checkbox"/> Specialist	<input type="checkbox"/> Rural Health	<input type="checkbox"/> Solo
<input type="checkbox"/> Other _____	(type)	<input type="checkbox"/> PCMH				<input type="checkbox"/> Medical Group	<input type="checkbox"/> Staff/Teaching
		<input type="checkbox"/> Other _____				<input type="checkbox"/> Other _____	(type)

Site Scores						Scoring Procedure		Compliance Rate	
	Total Points Poss.	Points Given	No Points	N/As	CE*				
I. Access/Safety	31					1) Add points given in each section. 2) Add total points given for all six sections. 3) Adjust score for "N/A" criteria (if needed), by subtracting N/A points from 169 total points possible. 4) Divide total points given by "adjusted" total points. 5) Multiply by 100 to get the compliance (percent) rate. $\frac{170}{\text{N/A Points}} = \frac{\text{Adjusted Points}}{\text{Adjusted Points}}$ $\frac{\text{Points Total / Decimal Given Adjusted Points}}{\text{Compliance Score}} \times 100 = \text{Rate}$		<input type="checkbox"/> Exempted Pass: 90% or above (without deficiencies in Critical Elements, Pharmaceutical Services, or Infection Control)	
II. Personnel	27							<input type="checkbox"/> Conditional Pass: 80-89%, or 90% and above with deficiencies in Critical Elements, Pharmaceutical Services, or Infection Control	
III. Office Management	25							<input type="checkbox"/> Fail: 79% and Below	
IV. Clinical Services	40							<input type="checkbox"/> CAP Required	
V. Preventive Services	13							<input type="checkbox"/> Other follow-up	
VI. Infection Control	34							Next Site Review Due: _____	
Totals	170								


*CE = Critical Elements. Indicate any CEs for easy reference to generate a CAP.

I. Access/Safety Criteria	Yes	No	N/A	Wt.	Site Score
<p>A. Site is accessible and useable by individuals with physical disabilities. Title 24, California Code of Regulations (CCR) (CA Building Standards Code); Title 28 Code of Federal Regulations (CFR) §35 (American Disabilities Act of 1990, Title II, Title III) All facilities designed, altered, or constructed after January 26, 1992, for the use of public entity must be readily accessible and usable by persons with disabilities.</p> <p>Sites must have the following safety accommodations for physically disabled persons:</p> <p>1) Clearly marked (blue) curb or sign designating disabled-parking space near accessible primary entrance.</p> <p>2) Pedestrian ramps have a level landing at the top and bottom of the ramp.</p> <p>3) Exit and exam room doorway openings allow for clear passage of a person in a wheelchair.</p> <p>4) Accessible passenger elevator or reasonable alternative for multi-level floor accommodation.</p> <p>5) Clear floor space for wheelchair in waiting area and exam room.</p> <p>6) Wheelchair accessible restroom facilities.</p> <p>7) Wheelchair accessible handwashing facilities or reasonable alternative.</p>					



Comments: (Write comments for all “No” (0 points) and “N/A” scores.)


I. Access/Safety Criteria, continued	Yes	No	N/A	Wt.	Site Score
<p>B. Site environment is maintained in a clean and sanitary condition. 28 CCR §1300.80; 22 CCR §75062</p> <p>1) All patient areas including floor/carpet, walls, and furniture are neat, clean, and well maintained.</p> <p>2) Restrooms are clean and contain appropriate sanitary supplies.</p>					
<p>C. Site environment is safe for all patients, visitors, and personnel. 8 CCR §3220, §2299-2989; 22 CCR §53230; 24 CCR, §2, §3, §9; 28 CCR §1300.80; 29 CFR §1910.37, §1910.38, §1910.157, §1910.301, §1926.34</p> <p>There is evidence staff has received safety training and/or has safety information available on the following:</p> <p>1) Fire safety and prevention.</p> <p>2) Emergency non-medical procedures (e.g. site evacuation, workplace violence).</p> <p>3) Lighting is adequate in all areas to ensure safety.</p> <p>4) <u>Exit doors and aisles are unobstructed and egress (escape) accessible.</u></p> <p>5) Exit doors are clearly marked with “Exit” signs.</p> <p>6) Clearly diagramed “Evacuation Routes” for emergencies are posted in a visible location at all elevators, stairs and exits.</p> <p>7) Electrical cords and outlets are in good working condition.</p> <p>8) Fire Fighting Equipment in accessible location</p> <p>9) An employee alarm system.</p>					

Comments: (Write comments for all “No” (0 points) and “N/A” scores.)



I. Access/Safety Criteria, continued	Yes	No	N/A	Wt.	Site Score
D. Emergency health care services are available and accessible 24 hours a day, 7 days a week. 8 CCR §3220; 22 CCR §51056, §53216, §75031; 28 CCR §1300.67, §1300.80; American Academy of Family Practice (AAFP) 					
1) Personnel are trained in procedures/action plan to be carried out in case of medical emergency on site.	1)	1)	1)	1	
2) Emergency equipment is stored together in easily accessible location and is ready to be used.	2)	2)	2)	1	
3) Emergency phone number contacts are posted, updated annually, and as changes occur.	3)	3)	3)	1	
Emergency medical equipment appropriate to practice/patient population is available on site:					
4) <u>Airway management: oxygen delivery system, nasal cannula or mask, bulb syringe and Ambu bag.</u>	4)	4)	4)	2	
5) <u>Emergency medicine for anaphylactic reaction management, opioid overdose, chest pain, asthma, and hypoglycemia. Epinephrine 1mg/ml (injectable) and Diphenhydramine (Benadryl) 25 mg (oral) or Diphenhydramine (Benadryl) 50 mg/ml (injectable), Naloxone, chewable Aspirin 81 mg, Nitroglycerine spray/tablet, bronchodilator medication (solution for nebulizer or metered dose inhaler), and glucose (any type of glucose containing at least 15 grams). Appropriate sizes of ESIP needles/syringes and alcohol wipes.</u>	5)	5)	5)	2	
6) Medication dosage chart for all medications included with emergency equipment (or other method for determining dosage) is kept with emergency medications.	6)	6)	6)	1	
There is a process in place on site to:					
7) Document checking of emergency medication, equipment and supplies for expiration and operating status at least monthly.	7)	7)	7)	1	
8) Replace/re-stock emergency medication, equipment and supplies immediately after use.	8)	8)	8)	1	

Comments: (Write comments for all “No” (0 points) and “N/A” scores.)





I. Access/Safety Criteria, continued	Yes	No	N/A	Wt.	Site Score
<p>E. Medical and lab equipment used for patient care is properly maintained. 28 CCR §1300.80; 21 CFR §800-1299; 22 CCR §75062; §53230  </p> <p>1) Medical equipment is clean.</p> <p>2) Written documentation demonstrates the appropriate maintenance of all medical equipment according to equipment manufacturer’s guidelines.</p>	<p>1)</p> <p>2)</p>	<p>1)</p> <p>2)</p>	<p>1)</p> <p>2)</p>	<p>1</p> <p>1</p>	
<p>Comments: Write comments for all “No” (0 points) and “N/A” scores.</p>	TOTALS				



II. Personnel Criteria	Yes	No	N/A	Wt.	Site Score
<p>A. Professional health care personnel have current California licenses and certifications. CA Business & Professional Code (BPC) §2050, §2099.5, §2506, §2725, §2746, §2835, §3500, §4110; CCR, Title 16, §1355.4, §1399.547</p> <p>1) All required Professional Licenses and Certifications, issued from the appropriate licensing/certification agency, are current.</p> <p>2) Notification is provided to each member that the MD(s) is licensed and regulated by the Medical Board, and that the Physician Assistant(s) is licensed and regulated by the Physician Assistant Committee.</p>	<p>1)</p> <p>2)</p>	<p>1)</p> <p>2)</p>	<p>1)</p> <p>2)</p>	<p>1</p> <p>1</p>	
<p>B. Health care personnel are properly identified. BPC §680</p> <p>1) Health care personnel wear identification badges/tags printed with name and title.</p>	<p>1)</p>	<p>1)</p>	<p>1)</p>	<p>1</p>	
<p>C. Site personnel are qualified and trained for assigned responsibilities. BPC §2069; 16 CCR §1366 - 1366.4 </p> <p>1) Documentation of education/training for non-licensed medical personnel is maintained on site.</p> <p><u>2) Only qualified/trained personnel retrieve, prepare, or administer medications.</u></p> <p>3) Site has a procedure in place for confirming correct patient/medication/vaccine dosage and route prior to administration.</p> <p>4) Only qualified/trained personnel operate medical equipment.</p>	<p>1)</p> <p>2)</p> <p>3)</p> <p>4)</p>	<p>1)</p> <p>2)</p> <p>3)</p> <p>4)</p>	<p>1)</p> <p>2)</p> <p>3)</p> <p>4)</p>	<p>1</p> <p>2</p> <p>1</p> <p>1</p>	

Comments: (Write comments for all “No” (0 points) and “N/A” scores.)



II. Personnel Criteria, continued	Yes	No	N/A	Wt.	Site Score
<p>D. Scope of practice for non-physician medical practitioners (NPMP) is clearly defined. 16 CCR §1379, §1399.540, §1399.545, §1474; BPC §2725, §2746.5, §2746.51, §2836.1 </p> <p>1) Standardized Procedures provided for Nurse Practitioners (NP) and/or Certified Nurse Midwives (CNM).</p> <p>2) A Practice Agreement defines the scope of services provided by Physician Assistants (PA) and Supervisory Guidelines define the method of supervision by the Supervising Physician.</p> <p>3) Standardized Procedures, Practice Agreements and Supervisory Guidelines are revised, updated <u>and</u> signed by the supervising physician and NPMP when changes in scope of services occur.</p> <p>4) Each NPMP that prescribes controlled substances has a valid Drug Enforcement Administration Registration Number.</p>	<p>1)</p> <p>2)</p> <p>3)</p> <p>4)</p>	<p>1)</p> <p>2)</p> <p>3)</p> <p>4)</p>	<p>1)</p> <p>2)</p> <p>3)</p> <p>4)</p>	<p>1</p> <p>1</p> <p>1</p> <p>1</p>	
<p>E. NPMPs are supervised according to established standards. BPC §3516(b); Welfare and Institutions Code (WIC) 14132.966; 16 CCR §1379; §1399.545 </p> <p>The designated supervising physician(s) on site:</p> <p>1) Ratio to number of NPMPs does not exceed established ratios in any combination. a) 1:4 NPs b) 1:4 CNMs c) 1:4 PAs</p> <p>2) The designated supervising or back-up physician is available in person or by electronic communication at all times when a NPMP is caring for patients.</p> <p>3) Evidence of NPMP supervision.</p>	<p>1)</p> <p>2)</p> <p>3)</p>	<p>1)</p> <p>2)</p> <p>3)</p>	<p>1)</p> <p>2)</p> <p>3)</p>	<p>1</p> <p>1</p> <p>1</p>	

Comments: (Write comments for all “No” (0 points) and “N/A” scores.)

II. Personnel Criteria, continued	Yes	No	N/A	Wt.	Site Score
<p>F. Site personnel receive safety training annually 8 CCR §5193; CA Health and Safety Code (HSC) §117600; CA Penal Code §11164, §11168; 29 CFR §1910.1030, 8 CCR §3342  </p> <p>There is evidence that site staff has received annual training on the following:</p> <p>1) Infection Control/Universal Precautions (annually)</p> <p>2) Blood Borne Pathogens Exposure Prevention (annually)</p> <p>3) Biohazardous Waste Handling (annually)</p>	<p>1)</p> <p>2)</p> <p>3)</p>	<p>1)</p> <p>2)</p> <p>3)</p>	<p>1)</p> <p>2)</p> <p>3)</p>	<p>1</p> <p>1</p> <p>1</p>	
<p>G. Site personnel receive training on member rights. 22 CCR §51009, §51305.1, §53452, §53858; 28 CCR §1300.68; 42 CFR §438.206 (6); 42 CFR §438.224; 42 CFR §438.10 (g); HSC 124260, 1374.16; CA Penal Code §11164, §1166.5, §11168, Family Code 6920, 6924, 6930; National Youth law  </p> <p>There is evidence that site staff has received training on the following:</p> <p>1) Patient confidentiality</p> <p>2) Informed Consent, including human sterilization</p> <p>3) Prior Authorization requests</p> <p>4) Grievance/Complaint Procedure</p> <p>5) Child/Elder/Domestic Violence Abuse</p> <p>6) Sensitive Services/Minors' Rights</p> <p>7) Health Plan referral process/procedures/resources</p> <p>8) Cultural and linguistics</p> <p>9) Disability Rights and Provider Obligations</p>	<p>1)</p> <p>2)</p> <p>3)</p> <p>4)</p> <p>5)</p> <p>6)</p> <p>7)</p> <p>8)</p> <p>9)</p>	<p>1)</p> <p>2)</p> <p>3)</p> <p>4)</p> <p>5)</p> <p>6)</p> <p>7)</p> <p>8)</p> <p>9)</p>	<p>1)</p> <p>2)</p> <p>3)</p> <p>4)</p> <p>5)</p> <p>6)</p> <p>7)</p> <p>8)</p> <p>9)</p>	<p>1</p> <p>1</p> <p>1</p> <p>1</p> <p>1</p> <p>1</p> <p>1</p> <p>1</p> <p>1</p>	
<p>Comments: Write comments for all “No” (0 points) and “N/A” scores.</p>	TOTALS				

III. Office Management Criteria	Yes	No	N/A	Wt.	Site Score
<p>A. Physician coverage is available 24 hours a day, 7 days a week. 22 CCR §56500, §53855</p> <p>The following are maintained current on site:</p> <p>1) Clinic office hours are posted or readily available upon request.</p> <p>2) Provider office hour schedules are available to staff.</p> <p>3) Arrangement/schedule for after-hours, on-call, supervisory back-up physician coverage is available to site staff.</p> <p>4) Contact information for off-site physician(s) is available at all times during office hours.</p> <p>5) Routine, urgent and after-hours emergency care instructions/telephone information is made available to patients.</p>	<p>1)</p> <p>2)</p> <p>3)</p> <p>4)</p> <p>5)</p>	<p>1)</p> <p>2)</p> <p>3)</p> <p>4)</p> <p>5)</p>	<p>1)</p> <p>2)</p> <p>3)</p> <p>4)</p> <p>5)</p>	<p>1</p> <p>1</p> <p>1</p> <p>1</p> <p>1</p>	
<p>B. There are sufficient health care personnel to provide timely, appropriate health care services. 22 CCR §53855; 28 CCR §1300.67.1, §1300.80  </p> <p>1) Appropriate personnel handle emergent, urgent, and medical advice telephone calls.</p> <p>2) Telephone answering machine, voice mail system, or answering service is used whenever office staff does not directly answer phone calls.</p> <p>3) Telephone system, answering service, recorded telephone information, and recording device are periodically checked and updated.</p>	<p>1)</p> <p>2)</p> <p>3)</p>	<p>1)</p> <p>2)</p> <p>3)</p>	<p>1)</p> <p>2)</p> <p>3)</p>	<p>1</p> <p>1</p> <p>1</p>	

Comments: (Write comments for all “No” (0 points) and “N/A” scores.)



III. Office Management Criteria, continued	Yes	No	N/A	Wt.	Site Score
<p>C. Health care services are readily available. 22 CCR §56000(2); 28 CCR §1300.67.2.2 </p> <p>1) Appointments are scheduled according to patients stated clinical needs within the timeliness standards established for Plan members.</p> <p>2) Patients are notified of scheduled routine and/or preventive screening appointments.</p> <p>3) There is a process in place verifying follow-up on missed and canceled appointments.</p>	<p>1)</p> <p>2)</p> <p>3)</p>	<p>1)</p> <p>2)</p> <p>3)</p>	<p>1)</p> <p>2)</p> <p>3)</p>	<p>1</p> <p>1</p> <p>1</p>	
<p>D. There is 24-hour access to interpreter services for non- or limited-English proficient (LEP) members. 22 CCR §53851; 28 CCR 1300.67.04</p> <p>1) Interpreter services are made available in identified threshold languages specified for location of site.</p> <p>2) Persons providing language interpreter services, including sign language on site, are trained in medical interpretation.</p>	<p>1)</p> <p>2)</p>	<p>1)</p> <p>2)</p>	<p>1)</p> <p>2)</p>	<p>1</p> <p>1</p>	
<p>E. Procedures for timely referral/consultative services are established on site. 22 CCR §53851; 28 CCR §1300.67, §1300.80 </p> <p>Office practice procedures allow timely provision and tracking of:</p> <p>1) Processing internal and external referrals, consultant reports, and diagnostic test results.</p> <p>2) <u>Physician Review and follow-up of referral/consultation reports and diagnostic test results.</u></p>	<p>1)</p> <p>2)</p>	<p>1)</p> <p>2)</p>	<p>1)</p> <p>2)</p>	<p>1</p> <p>2</p>	
<p>F. Member Grievance/Complaint processes are established on site. 22 CCR §53858, §56260</p> <p>1) Phone number(s) for filing grievances/complaints are located on site.</p> <p>2) Complaint forms and a copy of the grievance procedure are available on site.</p>	<p>1)</p> <p>2)</p>	<p>1)</p> <p>2)</p>	<p>1)</p> <p>2)</p>	<p>1</p> <p>1</p>	

Comments: (Write comments for all “No” (0 points) and “N/A” scores.)



III. Office Management Criteria, continued	Yes	No	N/A	Wt.	Site Score
G. Medical records are available for the practitioner at each scheduled patient encounter. 22 CCR §75055; 28 CCR §1300.80 1) Medical records are readily retrievable for scheduled patient encounters. 2) Medical documents are filed in a timely manner to ensure availability for patient encounters.	1) 2)	1) 2)	1) 2)	1 1	
H. Confidentiality of personal medical information is protected according to State and federal guidelines. 1) Exam rooms and dressing areas safeguard patients' right to privacy. 2) Procedures are followed to maintain the confidentiality of personal patient information. 3) Medical record release procedures are compliant with State and federal guidelines. 4) Storage and transmittal of medical records preserves confidentiality and security. 5) Medical records are retained for a minimum of 10 years.	1) 2) 3) 4) 5)	1) 2) 3) 4) 5)	1) 2) 3) 4) 5)	1 1 1 1 1	
Comments: Write comments for all "No" (0 points) and "N/A" scores.	TOTALS				

<p style="text-align: center;">IV. Clinical Services: Pharmaceutical Services Criteria</p>	Yes	No	N/A	Wt.	Site Score
<p>A. Drugs and medication supplies are maintained secure to prevent unauthorized access. BPC §4172; 22 CCR §75032, §75033, §75037(a-g), §75039; 21 CFR §1301.72, §1301.75, §1301.76, §1302; 16 CCR §1356.3; HSC §11053-11058</p>					
<p>1) Drugs are stored in specifically designated cupboards, cabinets, closets or drawers.</p>	1)	1)	1)	1	
<p>2) Prescription drug samples, and over-the-counter drugs, hypodermic needles/syringes, all medical sharp instruments, hazardous substances, and prescription pads are securely stored in a lockable space (cabinet or room) within the office/clinic.</p>	2)	2)	2)	1	
<p>3) Controlled drugs are stored in a locked space accessible only to authorized personnel.</p>	3)	3)	3)	1	
<p>4) A dose-by-dose controlled substance distribution log is maintained.</p>	4)	4)	4)	1	
<p>5) Written site-specific policy/procedure for dispensing of sample drugs are available on site.</p>	5)	5)	5)	1	

Comments: (Write comments for all “No” (0 points) and “N/A” scores.)

IV. Clinical Services: Pharmaceutical Services Criteria, continued	Yes	No	N/A	Wt.	Site Score
B. Drugs are handled safely and stored appropriately. 22 CCR §75037(a-g), §75039; 21 CFR §211.137; 21 USC §351; HSC §117600-118360; 40 CFR, part 261; Current CDC Recommendations  					
1) Drugs are prepared in a clean area or “designated clean” area if prepared in a multi-purpose room.	1)	1)	1)	1	
2) Drugs for external use are stored separately from drugs for internal use.	2)	2)	2)	1	
3) Items other than medications in refrigerator/freezer are kept in a secured, separate compartment from drugs.	3)	3)	3)	1	
4) Refrigerator thermometer temperature is 36°-46° Fahrenheit or 2°-8° Centigrade (at time of site visit).	4)	4)	4)	1	
5) Freezer thermometer temperature is 5° Fahrenheit or –15° Centigrade, or lower (at time of site visit).	5)	5)	5)	1	
6) Site utilizes drugs/vaccine storage units that are able to maintain required temperature.	6)	6)	6)	1	
7) Daily temperature readings of drugs/vaccines refrigerator and freezer are documented.	7)	7)	7)	1	
8) Has a written plan for vaccine protection in case of power outage or malfunction of the refrigerator or freezer.	8)	8)	8)	1	
9) Drugs and vaccines are stored separately from test reagents, germicides, disinfectants, and other household substances.	9)	9)	9)	1	
10) Hazardous substances are appropriately labeled.	10)	10)	10)	1	
11) Site has method(s) in place for drug and hazardous substance disposal.	11)	11)	11)	1	

Comments: (Write comments for all “No” (0 points) and “N/A” scores.)

IV. Clinical Services: Pharmaceutical Services Criteria, continued	Yes	No	N/A	Wt.	Site Score
C. Drugs are dispensed according to State and federal drug distribution laws and regulations. BPC §4024, §4076, §4170, §4171, §4173, §4174; 22 CCR §75032, §75033, §75036, §75037(a-g), §75038, §75039; 16 CCR §1718.1; 21 CFR §211.137; 42 USC 6A §300AA-26; CDC Recommendations; DHCS Contract; All Plan Letter 18-004; BPC §4000 et seq (Pharmacy Law); §4170; HSC §11000-11651 (Uniform Controlled Substances Act)  					
1) There are no expired drugs on site.	1)	1)	1)	1	
2) Site has a procedure to check expiration date of all drugs (including vaccines and samples), and infant and therapeutic formulas.	2)	2)	2)	1	
3) All stored and dispensed prescription drugs are appropriately labeled.	3)	3)	3)	1	
4) <u>Only lawfully authorized persons dispense drugs to patients.</u>	4)	4)	4)	2	
5) <u>Drugs and Vaccines are prepared and drawn only prior to administration.</u>	5)	5)	5)	2	
6) Current Vaccine Information Sheets (VIS) for distribution to patients are present on site.	6)	6)	6)	1	
7) If there is a pharmacy on site, it is licensed by the CA State Board of Pharmacy.	7)	7)	7)	1	
8) Site utilizes California Immunization Registry (CAIR) or the most current version.	8)	8)	8)	1	

Comments: (Write comments for all “No” (0 points) and “N/A” scores.)



<p align="center">IV. Clinical Services: Laboratory Services Criteria</p>	Yes	No	N/A	Wt.	Site Score
<p>D. Site is compliant with Clinical Laboratory Improvement Amendment (CLIA) regulations. 22 CCR §51211.2, §51137.2; BPC §1200-1214, §1229, §1220; 42 USC 263a; Public Law 100-578; www.cms.gov; www.fda.gov</p>					
<p>1) Laboratory test procedures are performed according to current site-specific CLIA certificate.</p>	1)	1)	1)	1	
<p>2) Testing personnel performing clinical lab procedures have been trained.</p>	2)	2)	2)	1	
<p>3) Lab supplies (e.g. vacutainers, vacutainer tubes, culture swabs, test solutions) are inaccessible to unauthorized persons.</p>	3)	3)	3)	1	
<p>4) Lab test supplies are not expired.</p>	4)	4)	4)	1	
<p>5) Site has a procedure to check expiration date and a method to dispose of expired lab test supplies.</p>	5)	5)	5)	1	

Comments: (Write comments for all “No” (0 points) and “N/A” scores.)



V. Preventive Services	Yes	No	N/A	Wt.	Site Score
A. Preventive health care services and health appraisal examinations are provided on a periodic basis for the detection of asymptomatic diseases. 22 CCR §53851; 28 CCR §1300.67					
Examination equipment, appropriate for primary care services, is available on site:					
1) Exam tables and lights are in good repair.	1)	1)	1)	1	
2) Stethoscope and sphygmomanometer with various size cuffs (e.g. child, adult, obese/thigh).	2)	2)	2)	1	
3) Thermometer with a numeric reading.	3)	3)	3)	1	
4) Basic exam equipment: percussion hammer, tongue blades, patient gowns.	4)	4)	4)	1	
5) Scales: standing balance beam and infant scales.	5)	5)	5)	1	
6) Measuring devices for stature (height/length) measurement and head circumference measurement.	6)	6)	6)	1	
7) Eye charts (literate and illiterate) and occluder for vision testing.	7)	7)	7)	1	
8) Ophthalmoscope.	8)	8)	8)	1	
9) Otoscope with multi-size ear speculums appropriate to the population served.	9)	9)	9)	1	
10) A pure tone, air conduction audiometer is located in a quiet location for testing.	10)	10)	10)	1	

Comments: (Write comments for all “No” (0 points) and “N/A” scores.)

V. Preventive Services: Health Education Criteria	Yes	No	N/A	Wt.	Site Score
B. Health education services are available to Plan members. 22 CCR §53851; 28 CCR 1300.67 Health education materials and Plan-specific resource information are: 1) Readily accessible on site or are made available upon request. 2) Applicable to the practice and population served on site. 3) Available in threshold languages identified for county and/or area of site location.	1) 2) 3)	1) 2) 3)	1) 2) 3)	1 1 1	
Comments: Write comments for all “No” (0 points) and “N/A” scores.	TOTALS				

VI. Infection Control Criteria, continued	Yes	No	N/A	Wt.	Site Score
C. Contaminated surfaces are decontaminated according to Cal-OSHA Standards. 8 CCR §5193; HSC §118275  					
1) Equipment and work surfaces are appropriately cleaned and decontaminated after contact with blood or other potentially infectious material.	1)	1)	1)	1	
2) Routine cleaning and decontamination of equipment/work surfaces is completed according to site-specific written schedule.	2)	2)	2)	1	
Disinfectant solutions used on site are:					
3) Approved by the Environmental Protection Agency (EPA).	3)	3)	3)	1	
4) Effective in killing HIV/HBV/TB.	4)	4)	4)	1	
5) Follow manufacturer instructions.	5)	5)	5)	1	

Comments: (Write comments for all “No” (0 points) and “N/A” scores.)

VI. Infection Control Criteria, continued	Yes	No	N/A	Wt.	Site Score
<p>D. Reusable medical instruments are properly sterilized after each use. 22 CCR §53230, §53856; CDC guideline for disinfection and sterilization; Food and Drug Administration: Reprocessing medical equipment in health care setting.  </p>					
<p>1) Written site-specific policy/procedures or manufacturer’s instructions for instrument/equipment sterilization are available to staff.</p>	1)	1)	1)	1	
<p>Staff adheres to site-specific policy and/or manufacturer/product label directions for the following procedures: 2) Cleaning reusable instruments/equipment prior to sterilization.</p>	2)	2)	2)	1	
<p>3) Cold chemical sterilization/high level disinfection: <u>a) Staff demonstrate/verbalize necessary steps/process to ensure sterility and/or high-level disinfection of equipment.</u></p>	3a)	3a)	3a)	2	
<p>b) Confirmation from manufacturer item(s) is/are heat sensitive.</p>	3b)	3b)	3b)	1	
<p><u>c) Appropriate PPE is available, exposure control plan, Material Safety Data Sheets and clean up instructions in the event of a cold chemical sterilant spill.</u></p>	3c)	3c)	3c)	2	
<p>4) Autoclave/steam sterilization.</p>					
<p>a) Staff demonstrate/verbalize necessary steps/process to ensure sterility.</p>	4a)	4a)	4a)	1	
<p>b) Autoclave maintenance per manufacturer’s guidelines.</p>	4b)	4b)	4b)	1	
<p><u>c) Spore testing of autoclave/steam sterilizer with documented results (at least monthly).</u></p>	4c)	4c)	4c)	2	
<p><u>d) Management of positive mechanical, chemical, and biological indicators of the sterilization process.</u></p>	4d)	4d)	4d)	2	
<p>e) Sterilized packages are labeled with sterilization date and load identification information.</p>	4e)	4e)	4e)	1	
<p>f) Storage of sterilized packages.</p>	4f)	4f)	4f)	1	
<p>Comments: Write comments for all “No” (0 points) and “N/A” scores.</p>	TOTALS				