

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 09/29/2015
NAME OF PROVIDER OR SUPPLIER Clinicas de Salud del Pueblo, Inc.		STREET ADDRESS, CITY, STATE, ZIP CODE 900 Main St. Brawley, CA 92227-2630 IMPERIAL COUNTY	

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The following reflects the findings of the Department of Public Health during a complaint/breach event visit.

Complaint Intake Number:
CA00392581 - Substantiated

Representing the Department of Public Health
Surveyor ID # 22930, HFEN

The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility

NOV 23 2016

Event ID: JC9U11	9/29/2016	9:40:40AM
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>Lisa Astiola-Davis</i>	TITLE Compliance Director	(X6) DATE November 18, 2016

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 10

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	Health and Safety Code Section 1280.15(a) A clinic, health facility, home health agency, or hospice licensed pursuant to Section 1204, 1250, 1725, or 1745 shall prevent unlawful or unauthorized access to, and use or disclosure of, patients' medical information, as defined in Section 56.05 of the Civil Code and consistent with Section 1280.18. For purposes of this section, internal paper records, electronic mail, or facsimile transmissions inadvertently misdirected within the same facility or health care system within the course of coordinating care or delivering services shall not constitute unauthorized access to, or use or disclosure of, a patient's medical information. The department, after investigation, may assess an administrative penalty for a violation of this section of up to twenty-five thousand dollars (\$25,000) per patient whose medical information was unlawfully or without authorization accessed, used, or disclosed, and up to seventeen thousand five hundred dollars (\$17,500) per subsequent occurrence of unlawful or unauthorized access, use, or disclosure of that patient's medical information. For purposes of the investigation, the department shall consider the clinic's, health facility's, agency's, or hospice's history of compliance with this section and other related state and federal statutes and regulations, the extent to which the facility detected violations and took preventative action to immediately correct and prevent past violations from recurring, and factors outside its control that restricted the facility's ability to comply with this section. The department shall have full discretion to consider all factors when determining whether to investigate and the		This Plan of Correction constitutes my written allegation of compliance for the deficiencies cited. However, submission of this Plan of Correction is not an admission or agreement by the provider of the facts alleged or conclusion set for on the statement of deficiency. This Plan of Correction is submitted to meet requirements established by state and federal law. This organization proactively protects the confidentiality and privacy of all patient information and provides training to workforce members on its privacy policies in an unceasing effort to improve and safeguard the information of patients. The SMAPI involved attended training, and orientation to the specific job duties and responsibilities to protect the confidentiality of patient health information as well as signed an attestation to comply with the requirements as cited in this facility's Workstation Use and Non-Disclosure Agreement, Corporate Compliance Handbook and Code of Conduct. All employees are required to sign a HIPAA Privacy Security Agreement prior to receiving their unique credentials for accessing this facilities computer resources. Responsible Person: Chief Information Officer	9/30/2013 9/30/2013

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	<p>amount of an administrative penalty, if any, pursuant to this section.</p> <p>Health and Safety Code section 1280.15, subdivision (a) provides that a clinic, health facility, home health agency, or hospice licensed pursuant to Section 1204, 1250, 1725, or 1745 shall prevent unlawful or unauthorized access to, and use or disclosure of, patients' medical information, as defined in subdivision (g) of Section 56.05 of the Civil Code and consistent with Section 1280.18. For purposes of this section, internal paper records, electronic mail, or facsimile transmissions inadvertently misdirected within the same facility or health care system within the course of coordinating care of delivering services shall not constitute unauthorized access to, or use or disclosure of, a patient's medical information. The department, after investigation, may assess an administrative penalty for a violation of this section of up to twenty-five thousand dollars (\$25,000) per patient whose medication information was unlawfully or without authorization accessed, used, or disclosed, and up to seventeen thousand five hundred dollars (\$17,500) per subsequent occurrence of unlawful or unauthorized access, use, or disclosure of that patient's medical information. For purposes of the investigation, the department shall consider the clinic's, health facility's, agency's, or hospice's history of compliance with this section and other related state and federal statutes and regulations, the extent to which the facility detected violations and took preventative action to immediately correct and</p>		<p>Immediate Measure and Corrective Action: Patient1, Patient2, Patient3 were notified via telephone to explain and apologize. Identity theft and credit monitoring services were offered for a period of two years. Responsible Person: Compliance Officer</p> <p>Immediate Measure and Corrective Action: SMAPI's access to this facility's electronic health record system was immediately suspended to prevent further access to the medical records of Patient1, Patient2, and Patient3, or any other patient. Responsible Persons: Chief of Operations and the Chief Information Officer.</p> <p>Immediate Measure and Corrective Action: SMAPI was immediately terminated from employment tasks and duties. Responsible Person: Chief of Operations</p> <p>Immediate Measure and Corrective Action: The RN Nurse Supervisor met with facility staff to reinforce the importance of HIPAA and specifically that access to information is for authorized purposes only. Responsible Person: RN Supervisor</p>	<p>1/22/2014</p> <p>1/22/2014</p> <p>1/22/2014</p> <p>1/29/2014</p>

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	<p>prevent past violations from recurring, and factors outside its control that restricted the facility's ability to comply with this section. The department shall have full discretion to consider all factors when determining whether to investigate and the amount of an administrative penalty, if any, pursuant to this section.</p> <p>The above regulation was not met as evidenced by:</p> <p>Based on interview and record review, the facility failed to ensure that patient medical records were kept confidential and health information was protected for three sampled patients (Patients 1, 2, and 3) when Patient 1, Patient 2, and Patient 3's medical information was accessed and reviewed by one student medical assistant/phlebotomist intern (SMAPI) who was not directly involved with any of the patients' care and did not have a professional purpose to access the records. The failure to protect each patient's medical information led to a violation of the patients' rights and permitted unauthorized access to the patients' medical information.</p> <p>Findings:</p> <p>On 5/5/14 at 11:15 A.M., the surveyor entered the clinic to conduct an investigation on the reported breach of medical information by a healthcare worker. According to the Chief Operation Officer (COO) and Registered Nurse (RN) 1, the clinic was made aware of the breach when Patient 1 filed a</p>		<p>Immediate Measure and Corrective Action: All workforce members were re-educated via e-mail on HIPAA requirements and responsibility to access information per regulations and this facility's policy. The purpose was to remind and bring awareness to disciplinary action including termination for noncompliance. HIPAA topics are sent via email to all staff periodically. Responsible Person: Compliance Officer</p> <p>Immediate Measure and Corrective Action: All workforce members were mandated to demonstrate understanding and compliance with HIPAA Privacy by acknowledging reading and receipt with their respective signatures on forms titled "HIPAA Privacy/ Security Agreement for Members of the Workforce" and the "HIPAA Confidentiality Pledge." Both documents attached for your review. Responsible person: Compliance Officer</p>	<p>2/5/2014, 4/8/2014, and 5/7/2014</p> <p>5/9/2014</p>

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	<p>* On 12/27/13 at 3:48 P.M., three times. * On 1/10/14 at 3:45 P.M., four times.</p> <p>Patient 1's medical information that was accessed by the SMAPI included a History and Physical (H&P), dated 12/20/12, which contained history of present illness, past medical and surgical procedures, diagnostic tests, gynecological (female reproductive system) and obstetric (childbirth) information, social history, a review of systems, skin findings, screening summary, vital signs, medications to include dose, route and frequency, allergies, labs, diagnostic services, visit type, and date of birth.</p> <p>Patient 2's medical information had been accessed:</p> <p>* On 12/10/13 at 11:08 A.M., three times. * On 12/10/13 at 11:09 A.M., three times. * On 12/10/13 at 11:29 A.M., three times * On 12/11/13 at 1:13 P.M., four times. * On 1/3/14 at 3:33 P.M., three times.</p> <p>Patient 2's medical information that was accessed by the SMAPI included a History and Physical (H&P), dated 12/10/13, which contained history of present illness, medications, allergies, review of systems, vital signs, weight, screening summary, physical exam, assessment, plan, referral to dermatology (a branch of medicine concerned with the diagnosis and treatment of skin disorders), and name of provider.</p> <p>Patient 3's medical information had been</p>		<p>Effective May 9, 2014, the Corporate Quality Assurance committee comprised of the CMO, RN Supervisor, Clinic Administrator, COO, CCO, and Medical Assistant Lead implemented under the supervision of the RN Supervisor to monitor appropriate access of patient health records. The RN Supervisor or designated quality assurance representative will perform the following systemic changes: randomly checking the appropriate access of workforce members using the EHR Event Audit log.</p> <p>Any deficiencies will be corrected and will be reported immediately to the appropriate agency. All staff is encouraged and mandated per policy to report suspected activity.</p> <p>RN Supervisors and lead team members will also survey computer use of clinical staff in person and at random to ensure that staff is only accessing patient information that they need in order to perform their job duties. Compliance and outcome of random in-person surveys will be reported to the COO and CQI Team Responsible Person: RN Supervisor and COO</p> <p>5/9/2014</p>

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	<p>accessed:</p> <ul style="list-style-type: none"> * On 12/11/13 at 1:11 P.M., three times. * On 12/11/13 at 1:13 P.M., four times * On 12/11/13 at 1:14 P.M., six times. * On 12/12/13 at 4:20 P.M., three times. * On 12/19/13 at 11:38 A.M., four times. * On 1/10/14 at 12:01 P.M., four times. * On 1/20/14 at 2:42 P.M., three times. <p>Patient 3's medical information that was accessed by the SMAPI included an H&P, dated 12/10/13, which contained a history of present illness, family history, pediatric social history, active medications to include medication name, dose, route and frequency, allergies, review of systems, vital signs, screening summary, physical exam findings, assessment, plan, referrals, nurse practitioner name, visit type and date of birth.</p> <p>On 5/5/14 at 12:30 P.M., a review of the clinic's form titled Workstation Use and Non-Disclosure Agreement dated 7/8/09, indicated, in part, "All persons accessing [clinic's name] information systems must recognize their responsibility in ensuring the privacy and security of "confidential information" in their trust. Therefore, each person being granted access to [clinic's name] systems must read and comply with all [clinic's name] Policies. As a condition to receiving access to information, I, the undersigned, agree to comply with the following terms: 3. I will not access information that I am not legally authorized to, including by not limited to information about any</p>		<p>The RN Supervisor and COO are responsible for ensuring the auditing process is completed and that compliance is sustained.</p> <p>Responsible Person:RN Supervisor and Chief of Operations</p>	5/9/2014

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	<p>family member, friend or co-worker. 5. I will not access or request data on patients for whom I have not clinical/professional relationship and/or legitimate [clinic's name] business purpose," and this agreement was signed by SMAPI on 9/30/13.</p> <p>A review of the clinic's policy titled "Confidentiality Policy", dated 10/11/12, was conducted. The policy's purpose stipulated "To protect 'confidential information' that is critical to [clinic name], operations. Confidential information includes, but is not limited to, financial information, patient identifiable information, employee identifiable information, intellectual property, financially nonpublic information, contractual information, any information of a competitive advantage nature, and from any source or in any form (i.e. paper magnetic or optical media, conversations, film, etc.), may be considered confidential. The value and sensitivity of information is protected by law and by the strict policies of [clinic name]. The intent of these laws and policies is to assure that confidential information will remain confidential through its collection, use, storage, and destruction within [clinic name]." The policy indicated that "All board members, officers, employees, contractors, volunteers, students and others with privileges at [clinic name] are responsible for protecting the privacy and security of all confidential information handled, learned, heard or viewed in the course of his/her work or association with [clinic name].</p> <p>Both the CCO and the COO acknowledged that Patients 1, 2, and 3's medical information had not been kept confidential when SMAPI accessed each</p>			

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	<p>patient's EHR without prior authorization or having a professional need.</p> <p>A telephone interview with the Chief Executive Officer (CEO) was conducted on 11/10/14 at 10:50 A.M. The CEO acknowledged that Patients 1, 2, and 3's medical information had not been kept confidential when SMAPI accessed each patient's EHR without prior authorization or having a professional need.</p> <p>A telephone interview with Patient 1 was conducted on 11/10/14 at 3:10 P.M. Patient 1 stated she had a suspicion when an estranged family member called to inquire about a recent visit to the clinic for Patient 3. According to Patient 1, a second incident occurred sometime in January 2014. Patient 1 stated during the second incident SMAPI had been observed in the lab when the patient took Patient 3 to the clinic for blood work. Per Patient 1, 30 minutes after they left the clinic, the estranged family member called to ask what was wrong with Patient 3 and what was the reason for blood work. At that point, Patient 1 stated it was confirmed that SMAPI had disclosed patient medical information without authorization. Patient 1 stated that patient medical information had also been disclosed to a childhood friend who reported the information to the patient. Patient 1 then feared that SMAPI had disclosed this medical information to other people in the community. Patient 1 further stated felt the unauthorized access was unfair, not right, and their rights had been violated especially since all three patients' medical information had been disclosed to additional people in the</p>			

*DISCLOSURE
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	<p>community.</p> <p>On 9/29/15 at 3:45 P.M., an exit conference call was held with the CCO. The CCO acknowledged that a medical information breach had occurred when the SMAPI accessed and viewed Patients 1, 2, and 3's medical information without prior authorization and a business need.</p>			

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