

STD. 400 (REV. 01-2013)

<b>OAL FILE NUMBER</b>	NOTICE FILE NUMBER <b>Z-2015-0326-01</b>	REGULATORY ACTION NUMBER <b>2015-0612-03C</b>	EMERGENCY NUMBER
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For use by Office of Administrative Law (OAL) only

<p><b>NOTICE</b></p>	<p><b>REGULATIONS</b></p>
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**ENDORSED - FILED**  
 In the office of the Secretary of State  
 of the State of California

**JUL 23 2015**

*2:17 pm*

<b>AGENCY WITH RULEMAKING AUTHORITY</b> Office of Statewide Health Planning and Development	AGENCY FILE NUMBER (If any)
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**A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)**

1. SUBJECT OF NOTICE	TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other	4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
OAL USE ONLY: <input checked="" type="checkbox"/> ACTION ON PROPOSED NOTICE: <input checked="" type="checkbox"/> Approved & Submitted <input type="checkbox"/> Approved & Modified <input type="checkbox"/> Disapproved & Withdrawn		NOTICE REGISTER NUMBER <b>2015-152</b>	PUBLICATION DATE <b>4/10/2015</b>

**B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)**

1a. SUBJECT OF REGULATION(S) Patient Data Transmission Standards	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S) 2015-0203-07 E
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)	SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.) ADOPT AMEND <b>97177.15, 97244</b> REPEAL TITLE(S) <b>22</b>
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3. TYPE OF FILING			
<input type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input checked="" type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))	<input type="checkbox"/> Other (Specify) _____		

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)			
<input type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input checked="" type="checkbox"/> Effective on filing with Secretary of State	<input type="checkbox"/> §100 Changes Without Regulatory Effect	<input type="checkbox"/> Effective other (Specify) _____

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY			
<input type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input type="checkbox"/> State Fire Marshal	
<input type="checkbox"/> Other (Specify) _____			

7. CONTACT PERSON Beth Herse	TELEPHONE NUMBER 916-326-3613	FAX NUMBER (Optional)	E-MAIL ADDRESS (Optional) beth.herse@oshpd.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE <i>Stephen Pollitt</i>	DATE <b>2015-06-11</b>
TYPED NAME AND TITLE OF SIGNATORY Stephen Pollitt, ISO, Office of Statewide Health Planning and Development	

For use by Office of Administrative Law (OAL) only

**ENDORSED APPROVED**

**JUL 23 2015**

Office of Administrative Law

**NOTICE OF PROPOSED RULEMAKING**

Title 22, California Code of Regulations  
Sections 97177.15 and 97244

The Office of Statewide Health Planning and Development (“the Office”) proposes to permanently adopt the proposed regulations described below after considering all comments, objections, and recommendation regarding the proposed action.

The two sections relate to the transmission of confidential patient information to the Office, and were amended on an emergency basis in order to delete a regulatory requirement to use a data encryption system with security vulnerability.

**Public Hearing**

The Office has not scheduled a public hearing for this proposed action, however, the Office will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days before the close of the written comment period.

**Written Comment Period**

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action. The written comment period closes at 5:00 PM on May 26, 2015. No comments received after that time will be considered.

Submit comments to:

Stephen Pollitt  
Information Security Officer  
Office of Statewide Health Planning and Development  
400 R Street, Room 338  
Sacramento, CA 95811  
Phone: (916) 326-3620  
Email: [stephen.pollitt@oshpd.ca.gov](mailto:stephen.pollitt@oshpd.ca.gov)  
Web: <http://www.oshpd.ca.gov>

## Authority and Reference

Authority cited: Sections 128810 and 128755, Health and Safety Code.

Reference: Sections 128735, 128736, 128737, and 128745, Health and Safety Code.

## Informative Digest

### 1. Summary of Existing Law and Regulations and the Effect of the Proposed Rulemaking

Hospitals and freestanding ambulatory surgery clinics licensed by the California Department of Public Health are required by law to file certain patient-level information with the Office at specified intervals.

Health and Safety Code section 128735, subdivision (g), requires that each hospital file a Hospital Discharge Abstract Data Record for each patient discharged from the hospital. Health and Safety Code section 128736 requires that each hospital file an Emergency Care Data Record for each patient encounter in a hospital emergency department. Health and Safety Code section 128737 requires that each general acute hospital and licensed freestanding ambulatory surgery center file an Ambulatory Surgery Data Record for each patient encounter during which at least one ambulatory surgery procedure is performed. These three programs are often referred to as the patient data programs.

In addition, Health and Safety Code section 128745, subdivision (c), requires that each hospital at which Coronary Artery Bypass Graft (CABG) surgery is performed file a patient data record for each patient on whom CABG surgery is performed. This specific program is referred to as the California CABG Outcomes Reporting Program (CCORP), as the data are used to produce reports on outcomes of care.

Each of the patient data records reported to the Office in these four programs includes a set of data elements that are specified in statute and/or regulation. The data records include individually identifiable medical information.

The patient records are submitted to the Office electronically. The patient data programs use the MIRCal system for online reporting (22 CCR §97212) and the CABG program uses the CORC system for online reporting (22 CCR §97170). The Office many years ago also adopted regulations that specify the method of electronic data submission using these systems: Title 22, CCR, §97244 for MIRCal and Title 22, CCR, §97177.15 for CORC.

Until the emergency regulations went into effect, February 9, 2015, each of these sections specified use of a Microsoft Internet Explorer web browser that supports a secure Internet connection utilizing HTTPS and Secure Socket Layer (SSL) technology, an encryption technology.

SSL technology has become outdated and has been found to have security vulnerability. On January 8, 2015, the Office received a notice from the Department of Technology that in order to fully remediate the SSL security vulnerability, OTech would completely disable SSL. All OTech client departments, including the Office, will be required to instead use the replacement encryption technology, Transport Layer Security (TLS), which is now standard. This remediation began February 13, 2015.

With the emergency rulemaking, the Office deleted the outdated requirements to use SSL. The current MIRCAl and CORC systems require the use of data encryption and can be used both with SSL and with TLS, the more current standard. Because use of the MIRCAl and CORC systems for on-line reporting is separately mandated in regulations, and each of these systems requires data encryption, there is no need to list the encryption requirements in sections 97244 and 97177.15.

One other small change was made -- because older versions of the Microsoft Internet Explorer browser that are no longer supported by Microsoft may only accept SSL, the text was also modified to require that a Microsoft supported version of Internet Explorer be used; current versions will accept TLS.

## 2. Policy Statement Overview, Including Specific Benefits Anticipated

The Health and Safety Code provisions requiring that patient data be reported to the Office also require that the Office protect patients' rights of confidentiality. In light of these specific provisions, as well as the California Information Practices Act of 1977 (Civil Code section 1798 et seq.), the Office must at all times insure that the systems used to collect and store confidential patient information are secure consistent with current technological capabilities and healthcare industry practice.

The Office is proposing to permanently amend the two regulatory sections that require use of SSL encryption technology in order to avoid mandating use of an outdated technology with security vulnerabilities by facilities that are reporting identifiable patient medical information to the Office. The amended regulations provide greater protection of data confidentiality and patient privacy.

## 3. Evaluation of Inconsistency/Incompatibility with Existing State Regulations

As required by Government Code section 11346.5, subdivision (a)(3)(D), the Office evaluated the language contained in the proposed amendments. The Office has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations. These regulations relate only to existing programs.

### **Disclosures Regarding the Proposed Action**

The Office has made the following initial determinations:

Mandate on local agencies or schools districts: None

Cost or savings to any state agency: None

Cost to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 et seq.: None

Other non-discretionary cost or savings imposed on local agencies: None

Cost or savings in federal funding to the state: None

Significant effect on housing costs: None

Significant statewide adverse economic impact directly affecting business: The Office has made an initial determination that the action will not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Cost impacts on a representative private person or business: The Office is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Small Business: The Office has determined that the amendment may affect small business.

### Results of the Economic Impact Assessment

Repealing the mandate to use the outdated SSL encryption technology when filing patient data with the Office is not anticipated to impose any new costs on the reporting facilities.

Therefore, the Office concludes that this regulatory action will not affect the following:

- The creation of jobs within the state
- The elimination of jobs within the state
- The creation of new businesses within the state
- The elimination of existing businesses within the state
- The expansion of businesses currently doing business in the state
- The benefit to the public is that patient privacy will be more stringently protected.

### **Consideration of Alternatives**

In accordance with Government Code section 11346.5, subdivision(a)(13), the Office must determine that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the agency would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less

burdensome to affected private persons than the proposed action or would be more cost-effective to the affected private persons and equally effective in implementing the statutory policy or other provision of law.

### **Contact Persons**

Inquiries concerning the proposed administrative action may be directed to:

Stephen Pollitt  
Information Security Officer  
Office of Statewide Health Planning and Development  
400 R Street, Room 338  
Sacramento, CA 95811  
Phone: (916) 326-3620  
Email: [stephen.pollitt@oshpd.ca.gov](mailto:stephen.pollitt@oshpd.ca.gov)

The backup contact person for these inquiries is:

Beth Herse  
Attorney  
Office of Statewide Health Planning and Development  
400 R Street, Room 320  
Sacramento, CA 95811  
Phone: (916) 326-3610  
Email: [beth.herse@oshpd.ca.gov](mailto:beth.herse@oshpd.ca.gov)

### **Availability of Express Terms of the Proposed Action, Initial Statement of Reasons, and Information Upon Which the Proposal Action is Based**

The Office will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the address given for the contact persons. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the text of the proposed regulations, the initial statement of reasons, and an economic impact assessment contained in the initial statement of reasons. It also includes the emergency rulemaking documents. Copies may be obtained by contacting one of the contact persons listed above.

### **Availability of Substantial Changes to Original Proposal**

After considering all timely and relevant comments received, the Office may adopt the proposed regulations substantially as described in this notice. If the Office makes modifications which are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Office adopts the regulations as revised.

Please send requests for copies of any modified regulations to the listed contact person. The modified regulations will also be available on the website at <http://www.oshpd.ca.gov/LawsRegs/NewRegulations.html>. The Office will accept written comments on the modified regulations for 15 days after the date on which they are made available.

### **Availability of Final Statement of Reasons**

Upon its completion, copies of the Final Statement of Reasons will be available from the designated contact person. The Final Statement of Reasons will also be available through the Office's website at <http://www.oshpd.ca.gov/LawsRegs/NewRegulations.html>.

### **Availability of Documents on the Internet**

Copies of materials published or distributed through the Office's website can be accessed at <http://www.oshpd.ca.gov>. Materials related to this rulemaking can be accessed at <http://www.oshpd.ca.gov/LawsRegs/NewRegulations.html>.