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JAN 4 2013

**State of California  
Office of Administrative Law**

**CA DEPT OF PUBLIC HEALTH  
DIRECTOR'S OFFICE**

In re:

Department of Public Health

**NOTICE OF APPROVAL OF CHANGES  
WITHOUT REGULATORY EFFECT**

Regulatory Action:

California Code of Regulations, Title 1,  
Section 100

Title 17, California Code of Regulations

Adopt sections:

Amend sections: 2641.56

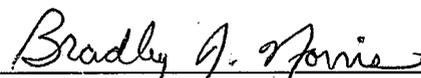
Repeal sections:

OAL File No. 2012-1127-02 N

In this "changes without regulatory effect" filing, the California Department of Public Health makes nonsubstantive amendments to an existing regulation defining "HIV/AIDS Confidentially Agreement" and to an existing form (previously incorporated by reference) which sets forth the required confidentiality agreement which must be signed by designated employees/contractors who have access to confidential HIV-related public health records. These provisions relate to requirements of Health and Safety Code section 121022(f).

OAL approves this change without regulatory effect as meeting the requirements of California Code of Regulations, Title 1, section 100.

Date: 1/3/2013



Bradley J. Norris  
Senior Staff Counsel

For: DEBRA M. CORNEZ  
Director

Original: Dr. Ron Chapman, MD, MPH

Copy: Mike Rainville

NOTICE PUBLICATION/REGULATION/REGISTRATION/COMMISSION

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-09)

OAL FILE NUMBERS

NOTICE FILE NUMBER Z-

REGULATORY ACTION NUMBER

2012-1127-02N

EMERGENCY NUMBER

NONSUBSTANTIVE

ENDORSED FILED IN THE OFFICE OF

2013 JAN -3 PM 1:13

2012 NOV 27 AM 11:50

OFFICE OF ADMINISTRATIVE LAW

Debra Bowen DEBRA BOWEN SECRETARY OF STATE

NOTICE

REGULATIONS

AGENCY WITH RULEMAKING AUTHORITY California Department of Public Health

AGENCY FILE NUMBER (If any) DPH 12-003

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, 4. AGENCY CONTACT PERSON, TELEPHONE NUMBER, FAX NUMBER (Optional), OAL USE ONLY, ACTION ON PROPOSED NOTICE, NOTICE REGISTER NUMBER, PUBLICATION DATE

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S) HIV/AIDS Confidentiality Agreement, 1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)

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.), TITLE(S) 17, ADOPT, AMEND 2641.56, REPEAL

3. TYPE OF FILING, Regular Rulemaking, Resubmittal of disapproved or withdrawn nonemergency filing, Emergency, Certificate of Compliance, Emergency Readopt, File & Print, Other, Changes Without Regulatory Effect, Print Only, 4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100), Effective 30th day after filing with Secretary of State, Effective on filing with Secretary of State, 5100 Changes Without Regulatory Effect, Effective other (Specify)

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

7. CONTACT PERSON Mike Rainville, TELEPHONE NUMBER (916) 445-7825, FAX NUMBER (Optional) (916) 319-9821, E-MAIL ADDRESS (Optional) Mike.Rainville@cdph.ca.gov

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, DATE 11/19/12, TYPED NAME AND TITLE OF SIGNATORY Kathleen M. Keeshen, Deputy Director and Chief Counsel

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

JAN 03 2013

Office of Administrative Law

California Department of Public Health

Reporting of Human Immunodeficiency Virus (HIV) Infection

Amend Section 2641.56 to read as follows:

**§ 2641.56. HIV/AIDS Confidentiality Agreement.**

"HIV/AIDS Confidentiality Agreement" means California Department of Public Health HIV/AIDS Confidentiality "Agreement by Employee/Contractor to Comply with Confidentiality Requirements" form (CDPH 8689 (05/07 10/12)), hereby incorporated by reference and available from the Department.

NOTE: Authority cited: Sections 120125, 120130, 121022, 131080 and 131200, Health and Safety Code. Reference: Sections 120175, 120775, 120820, 120885-120895, 120975, 120980, 121022, 121023, 121025, 121035, 121110, 131019, 131051, 131052, 131056 and 131080, Health and Safety Code.



CALIFORNIA DEPARTMENT OF PUBLIC HEALTH  
Title 17

Section Affected: 2641.56 and HIV/AIDS Confidentiality Agreement Form (CDPH 8689 (05/07)).

**Justification for Changes Without Regulatory Effect:**

Pursuant to California Code of Regulations (CCR), Title 1, Section 100, the California Department of Public Health (CDPH or Department) proposes a number of changes to its regulation section 2641.56 in Title 17 of the CCR and to the form currently titled "HIV/AIDS Confidentiality Agreement" (the "CDPH 8689" form), which is incorporated by reference in Section 2641.56. These changes are proposed as "Changes Without Regulatory Effect" under 1 CCR Section 100. Two of the proposed changes conform the Department's regulations to 2010 revisions to the California Health and Safety (H&S) Code Section 121025 (see 1 CCR Section 100(a)(6)). A number of the proposed changes revise grammar and punctuation (see 1 CCR Section 100(a)(4)). One of the proposed changes adds a statute as a reference citation (see 1 CCR Section 100(a)(5)). Other changes proposed under 1 CCR Section 100 as being "changes without regulatory effect" include: 1) eliminating an inconsistency between the current form signature requirements and H&S Code Section 121022(f); 2) modifying the form to reflect a 2009 CDPH, Office of AIDS (OA) program section name change; 3) revising the name and revision date of the form; and 4) other minor clarifying and conforming changes. None of the proposed changes materially alters any of the requirements, rights, responsibilities, conditions, prescriptions, or other regulatory elements of regulation Section 2641.56, the CDPH 8689 form, or any other CCR provision. Each of the specific changes proposed pursuant to 1 CCR Section 100 is discussed below.

**Chapter 4. Preventive Medical Service**

**Section 2641.56. HIV/AIDS Confidentiality Agreement.**

- Replace California Department of Public Health "HIV/AIDS Confidentiality Agreement" with "Agreement by Employee/Contractor to Comply with Confidentiality Requirements" in quotations in the first paragraph. This name change of the form better reflects the content and purpose of the form under H&S Code Section 121022(f). The name change of the form does not materially alter any of the requirements, rights, responsibilities, conditions, prescriptions, or other regulatory elements of any CCR provision.
- Change (CDPH 8689 (05/07)) to (CDPH 8689 (10/12)). This indicates when the form date was revised. This change in the form date does not materially alter any

of the requirements, rights, responsibilities, conditions, prescriptions, or other regulatory elements of any CCR provision.

- The reference note, citing H&S Code Section 121023, is added to reflect a new HIV reporting requirement per Senate Bill 1184 (Kuehl, Chapter 347, Statutes of 2008). This change is allowed by 1 CCR Section 100(a)(5) as a change in authority or reference citation.

#### **HIV/AIDS Confidentiality Agreement Form (CDPH 8689 (05/07)).**

- Change the title of the form from "HIV/AIDS Confidentiality Agreement" to "Agreement by Employee/Contractor to Comply with Confidentiality Requirements". This name change of the form better reflects the content and purpose of the form under H&S Code Section 121022(f). The name change of the form does not materially alter any of the requirements, rights, responsibilities, conditions, prescriptions, or other regulatory elements of any CCR provision.
- Add a comma (",") after "(HSC)" in first sentence of the first paragraph for correct punctuation. This change is allowed by 1 CCR Section 100(a)(4) as a revision in punctuation.
- Change the civil penalty amount for negligent disclosure from "\$2,500" to "\$5,000" per Assembly Bill (AB) 2541 (Portantino, Chapter 470, Statutes of 2010) amendments to H&S Code Section 121025(e)(1). This change is allowed by 1 CCR Section 100(a)(6) to make the regulatory provision consistent with a changed statute. The penalty amount in the existing form is now inconsistent with the amended penalty amount under H&S Code Section 121025(e)(1), and CDPH does not have authority to adopt a penalty amount which differs from the penalty amount set by statute.
- Change the civil penalty amount for willful or malicious disclosure from the range of "\$5,000-\$10,000" to "\$5,000-\$25,000" per AB 2541 (Portantino, Chapter 470, Statutes of 2010) amendments to H&S Code Section 121025(e)(2). This change is allowed by 1 CCR Section 100(a)(6) to make the regulatory provision consistent with a changed statute. The penalty amount in the existing form is now inconsistent with the amended penalty amount under H&S Code Section 121025(e)(2), and CDPH does not have authority to adopt a penalty amount which differs from the penalty amount set by statute.
- Change the acronym from "OA" to "CDPH/OA" because this clarifies that the Office of AIDS is an office of CDPH and not that of a local health department. This change clarifies without materially altering any of the requirements, rights, responsibilities, conditions, prescriptions, or other regulatory elements of any CCR provision.

- Change references from "Chief of the HIV/AIDS Case Registry Section" to "CDPH/OA Surveillance Section Chief." This reflects a 2009 CDPH section name change. The name "HIV/AIDS Case Registry Section" is no longer in use by CDPH. Changing these references to reflect the amended name of the section does not materially alter any of the requirements, rights, responsibilities, conditions, prescriptions, or other regulatory elements of any CCR provision.
- Delete "of this Confidentiality Agreement" from the last paragraph sentence and add the word "above" to the end of same sentence. This change will be consistent with the name change of the form and accurately reflect signee ~~acknowledgement of, and agreement to comply with, the terms and conditions of~~ this form. This change in wording does not materially alter any of the requirements, rights, responsibilities, conditions, prescriptions, or other regulatory elements of any CCR provision.
- Change "(printed)" to "(print)" beneath the "Employee" fill-in line for correct grammar. This change is allowed by 1 CCR Section 100(a)(4) as a revision in grammar.
- Change "(printed)" to "(print)" beneath the "Supervisor" fill-in line for correct grammar. This change is allowed by 1 CCR Section 100(a)(4) as a revision in grammar.
- ~~Add "Name of Employer" fill-in line under the "Supervisor" fill-in line. This addition allows CDPH to identify the employer of the signing supervisor. This change, merely requiring the addition of the employer's name, does not materially alter any of the requirements, rights, responsibilities, conditions, prescriptions, or other regulatory elements of any CCR provision.~~
- Delete fill-in lines for Chief name, Chief signature, and date. Delete "Chief name (printed)", "HIV/AIDS Case Registry Section", "Office of AIDS", and "California Department of Public Health". CDPH proposes these deletions to: 1) avoid the misinterpretation that the employee/contractor agreement may constitute a contract between that person and CDPH; and 2) delete a requirement that is inconsistent with statutory authority and beyond the authority granted to CDPH by applicable statutes.

H&S Code Section 121022(f) provides that the employee or contractor of a health agency is required to sign a confidentiality agreement which is to include information related to the penalties for a breach of confidentiality and the procedures for reporting a breach of confidentiality. H&S Code Section 121022(f) requires the Department (or the appropriate local health department) to review those confidentiality agreements annually, but does not direct or authorize the Department to execute those agreements. The proposed deletions are made to avoid causing a misconception that a contract is being entered into between the

employee/contractor and the Department; instead the form consists of an acknowledgement by the employee/contractor that they have been advised of the penalties for a breach of confidentiality and the procedures for reporting a breach of confidentiality, and an agreement by the employee/contractor to comply with these terms and conditions.

The deletion of signature-related requirements for the Chief of the HIV/AIDS Case Registry Section is made to remove an inconsistency between the form and the underlying statutory authority. H&S Code Section 121022(f) does not authorize CDPH to delay or negate the effectiveness of the employee-signed form by imposing its own signature requirement. The requirement for a signature by the Chief of the HIV/AIDS Case Registry Section should not have been included in the form by the California Department of Health Services (CDHS), CDPH's predecessor, when the form was initially adopted, as the justification given at that time (that signature by CDHS was necessary to monitor who has authorized access to confidential HIV-related public health records) is incorrect. CDPH does not use the signature to monitor or ensure compliance or to monitor who has authorized access to confidential HIV-related public health records. Instead, CDPH controls and monitors who has authorized access to confidential HIV-related public health records through separate records that, among other items, log receipt of the confidentiality forms; CDPH's determination of who will have authorized access does not depend on signature by the state. This change deletes the portion of the form that is inconsistent with statutory authority.

- Delete "THIS AGREEMENT IS NOT VALID UNTIL SIGNED BY THE CHIEF OF THE HIV/AIDS CASE REGISTRY". H&S Code Section 121022(f) provides that the employee or contractor of a health agency is required to sign a confidentiality agreement, but does not require or authorize the Department to execute those agreements; nor does H&S Code Section 121022(f) provide any authority for the Department to delay or invalidate a confidentiality agreement until signed by the Department or the Department's Chief of the HIV/AIDS Case Registry.

The justification for this deletion is the same as for the immediately preceding deletions.

- Add a period "(.)" at the end of the sentence "PLEASE RETAIN A COPY OF THIS DOCUMENT FOR YOUR RECORDS" for correct punctuation. This change is allowed by 1 CCR Section 100(a)(4) as a revision in in punctuation.
- Delete "(5/07)" and insert "(Revised 10/12)" to the form number footnote to reflect the revision date. This change in form date does not materially alter any of the requirements, rights, responsibilities, conditions, prescriptions, or other regulatory elements of any CCR provision.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH  
Title 17

Section Affected: 2641.56 and HIV/AIDS Confidentiality Agreement Form (CDPH 8689 (05/07)).

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**Chapter 4. Preventive Medical Service**

**Section 2641.56. HIV/AIDS Confidentiality Agreement.**

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RONALD W. CHAPMAN, MD, MPH  
Director

State of California—Health and Human Services Agency  
California Department of Public Health



EDMUND G. BROWN JR.  
Governor

DELEGATION OF AUTHORITY FOR ADOPTION OF REGULATIONS AND FILING OF STD 400

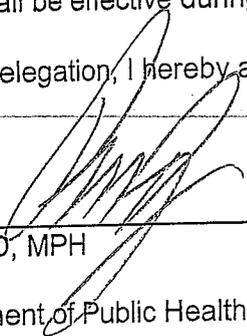
I, Ron Chapman, MD, MPH, Director of the Department of Public Health (CDPH), State of California, am empowered to adopt regulations for this Department pursuant to Article 2 (commencing with section 131200) of Chapter 2 of Part 1 of Division 112 of the Health and Safety Code, Government Code section 11152, and Title 1, California Code of Regulations, section 280.

I thereby delegate my authority and responsibilities for these matters to the following individuals:

- Kathleen Billingsley, RN, Chief Deputy Director of Policy and Programs, CDPH
- Daniel C. Kim, Chief Deputy Director of Operations, CDPH
- Kathleen M. Keeshen, Deputy Director and Chief Counsel Office of Legal Services, CDPH,

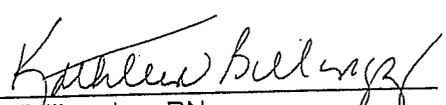
This delegation shall be effective during my term as Director or until withdrawn by me in writing.

In witness of this delegation, I hereby affix my signature to this delegation order.

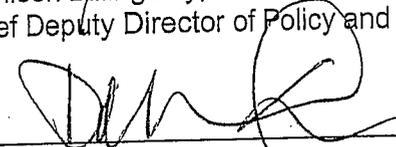
  
 \_\_\_\_\_  
 Ron Chapman, MD, MPH  
 Director  
 California Department of Public Health

Date: 6/13/11

We fully understand and accept this delegation.

  
 \_\_\_\_\_  
 Kathleen Billingsley, RN  
 Chief Deputy Director of Policy and Programs

Date: 6/13/11

  
 \_\_\_\_\_  
 Daniel C. Kim  
 Chief Deputy Director of Operations

Date: 6/13/11

  
 \_\_\_\_\_  
 Kathleen M. Keeshen  
 Deputy Director and Chief Counsel

Date: June 13, 2011