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May 21, 2001

Office of Regulations
Department of Health Services
714 P Street, Room 1000
P.O. Box 942732
Sacramento, CA 94234-7320
Fax: (916) 657-1459

RE: REPORTING OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) (R-19-00)

These comments are submitted on behalf of the California Academy of Preventive Medicine (CAPM), the state specialty society for physicians who practice in the fields of public health and preventive medicine. We oppose the proposed regulations to report HIV using unique identifiers (UIs)*, and raise legal questions about them. If, however, the Department decides to move ahead despite our opposition, we have proposals for amendments that would make the regulations less onerous to physicians and public health departments.

SUPERIORITY OF NAME-BASED REPORTING OVER UNIQUE IDENTIFIERS

CAPM favors the establishment of a totally name-based reporting system for HIV, which we believe would be superior for public health purposes. Over the past several years, our organization has opposed legislation that would have established reporting by UIs, and has supported legislation that would have established name-based HIV reporting (SB 1029). We are of the opinion that only name-based reporting facilitates public health preventive interventions, such as permitting public health departments to contact persons with HIV for assistance with partner notification, linkages with treatment and prevention case management, and assistance with medication compliance.

The preponderance of evidence, including the original HIV Testing Survey and the experiences of 33 states, shows that confidential name-based reporting is not a significant deterrent to HIV testing or treatment. Partner notification by public health specialists, which is facilitated by confidential reporting but not by UI reporting, can in

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* The regulation package uses the term "non-name code" 56 times. We have adopted the term "unique identifier," which has been more common in discussions about HIV reporting (although used in the package only twice).

fact recruit into testing the most directly at-risk persons, often before infection occurs. Direct health department outreach to reported individuals over time, which confidential reporting also facilitates but UI reporting makes difficult if not impossible, may help bring persons not yet in treatment into the health care system for state-of-the-art antiretroviral therapy that can prolong life and may reduce infectiousness. A name-based reporting system is also less expensive (by the Department's own analysis), less burdensome, and less time-consuming for both healthcare providers and health department workers than one requiring the construction of UIs for each case.

DIFFICULTIES WITH UNIQUE IDENTIFIERS AND THEIR COMPONENTS

* Digits from Social Security Numbers Would Make the System Fail:

Inclusion of digits from Social Security numbers in a UI raises barriers to complete reporting. Undocumented persons, a large population group, lack Social Security numbers. Many patients cannot remember their Social Security numbers. Many providers' offices do not record these numbers, and laboratories generally do not have access to them. The experience of the state of Texas with UIs requiring four digits from the Social Security number was that 50% of case reports lacked this information and could not be unduplicated; this was the major reason that Texas abandoned UIs in favor of names.

* Physicians Cannot Efficiently Produce Soundex Codes:

Soundex codes similarly are a barrier to complete reporting if done by physicians. San Francisco has recently completed a 6-month study that showed that laboratories were able to generate Soundex codes with the help of computer software, but that physicians (even with financial incentives) were not able to link these codes back to cases and to complete HIV case report forms. It is also pertinent to note that the UIs used in the San Francisco study were simpler than the 17-digit UIs required under the proposed regulations.

* The UIs Would Be a Burden to Providers and Local Health Departments:

The physicians on our Board are convinced that the 17-digit UIs proposed in the regulations would be intimidating to many healthcare providers, a time-consuming burden for physicians' offices, and highly subject to errors that would prevent the ability to eliminate duplicate reports. The 10-minute estimate for construction of each UI may be an underestimate, especially in the hands of untrained staff.

Laboratories would not be able to produce complete UIs, but would generate abbreviated UIs that health departments would ask physicians to match with cases in order to supply risk data. As noted above, physicians were unable to match back laboratories' UIs to cases in the San Francisco study. Physicians and laboratories would not be compensated for this burden, nor would local health departments receive adequate compensation for the expenses of dealing these UIs, including numerous contacts with providers about incomplete and inaccurate UIs.

* The Data That Would Be Produced Are Not Useful to the CDC:

The HIV/AIDS surveillance office of the Centers for Disease Control and Prevention (CDC) has confirmed in April 2001 that it is not currently able to use HIV surveillance data from the states that have UI reporting. The data cannot be utilized by the CDC's computers, and duplicates between states' reports cannot be detected and eliminated. These states report only aggregate data, as each state's UI coding system is different from the others' and from the CDC's own HIV/AIDS coding system. The proposed reporting system would therefore not, at least in the near future, incorporate California's HIV cases into an integrated epidemiological analysis as needed to determine HIV trends nationwide.

* The Goals Would Not Be Met, and Failure Would Be Extremely Costly:

Because of these problems, we expect that that the CDC standards of 85% completeness, 66% timeliness, and no more than 5% duplicates and 5% incorrectly matched case reports would be very difficult to meet under the proposed system. If they are not met, the effort will have been a costly waste, and California will lose vast amounts of Ryan White funds as well as surveillance funding for HIV beginning in FY 2005. Alternatively, the state will have to quickly adopt a new name-based system, which we should be working to develop now, particularly if legislation would be required.

In summary, the proposed system of reporting with UIs would be burdensome and costly, and would contain elements that would most likely cause it to fail. Texas was the largest state in which UIs have been tried and a similar system failed there; California's system would be three times as large and much more complex to administer, so success would be extremely doubtful. Moreover, even a UI system that might be successful from a data collection standpoint would be incapable of providing the public health prevention benefits that confidential name-based reporting can accomplish.

LEGAL CONCERNS

* Name Reporting May Not Be Illegal; If It Is, UI Reporting Is Illegal As Well:

On page 3 of the Initial Statement of Reasons, DHS staff dismissed the alternatives of name-based reporting, or a hybrid system in which names are reported but not retained after conversion to UIs, as being illegal in California. However, no legal citations or analysis were offered to justify this. Some of our members deal continually with the Health and Safety Code in public health work, and believe that the Health and Safety Code is ambiguous on this point. For example, Section 121015, subsection (a) prohibits physicians from providing identifying information to health officers in the context of partner notification, but does not specifically prohibit similar provision of information for other purposes such as surveillance. Subsection (d) refers to physicians who make reports of individuals testing positive, and specifies

that records on contacts be destroyed following notification, but does not similarly require the destruction of records on persons testing positive. Subsection (e) says that health officers shall keep confidential the identity of persons tested, implying that health officers may receive reports on individuals who test positive and that health departments may retain these reports.

UIs by definition contain identifying information, so if Section 121015 were truly deemed to make HIV reporting by name illegal, it would also mean that reporting of HIV infections by UIs is illegal. The legality of our long-existing AIDS reporting system would also be in doubt.

* <u>Penalties for Unauthorized Disclosure of HIV Results May Apply to UIs:</u>

Similarly, Section 120980 of the Code imposes penalties for unauthorized disclosure of "identifying characteristics of the persons to whom the (HIV) test results apply." This has not been interpreted as applying to AIDS reporting by healthcare providers. But if it were truly deemed to apply to HIV reporting by name, it would mean that reporting of UIs would constitute unauthorized disclosure as well, subject to civil and criminal penalties.

Because of these legal ambiguities, our Academy recommends that the department seek legislation with the full backing of the Administration, to clearly establish or legalize HIV reporting by name. Meanwhile, we suggest that the Department consider a consensus legal conference on the subject.

RECOMMENDATIONS IF REGULATIONS ARE ISSUED

Should the Department proceed with the issuance of regulations despite the above arguments, we propose several specific changes:

1. <u>Delete the Specific Prohibition on Communication of Names to Health Officers</u>:

We believe that it can serve valuable public health purposes for physicians and other health care providers to discuss HIV cases with health officers. Examples are to request consultation on whether a case is reportable, to request assistance in generating a UI, or to request that a health department worker contact a patient for linkages to services. But the draft regulations would specifically prohibit physicians from reporting cases by name unless they had met the criteria for AIDS, which would likely be interpreted as prohibiting such physician - health officer communication and might lead to the prosecution of physicians for following good public health practice.

Therefore, we specifically recommend that the following sentence in Section 2643.5(e) of the proposed regulations be deleted: "When reporting a confirmed HIV test, a health care provider shall not release a patient's personal information to the local Health Officer except for patients whose clinical conditions meet the AIDS reporting criteria, as specified in Article 1 of this Subchapter."

2. Add a Sunset Provision:

HIV surveillance systems will be evaluated by the CDC starting in 2002. After June 2004, the CDC plans to discontinue funding for surveillance systems that do not meet its strict criteria, and Ryan White funding will be based only on AIDS cases for those states. Therefore, we urge that the HIV reporting regulations have a sunset clause. This should call for an evaluation report by the department by January 1, 2004, with recommendations for future HIV reporting regulations. The reporting regulations issued this year should expire on June 30, 2004.

3. Evaluation Should Consider Partner Notification, Linkages to Services:

Evaluation of the success of the program should include the extent to which notification of the partners of persons reported is accomplished, and an analysis of the linkage of reported persons to medical and social services including prevention case management. This should be compared with the potential in a comparable name-based system.

4. Require Laboratories to Generate Complete UIs, Including Soundex Codes:

Laboratories must be able to generate whatever complete UIs are required for reporting. That way, local health departments would be able to directly use reports from labs, and labs could include the UIs with the test results so that health care providers could use the UIs and could match the UIs with names when supplying risk factor data at health department request.

Many small health care providers' offices have no computerized patient data. In contrast, labs are virtually all automated with computer databases. If Soundex codes are to be retained, they could be produced far more easily by labs than by physicians' or other health care providers' offices. The department would need to supply the appropriate software to the labs.

5. Eliminate Digits from Social Security Numbers:

Digits from Social Security numbers should not be part of any UI system. As noted above, they are not available for many patients, laboratories do not generally have them, and they were the major cause of failure of the Texas system.

6. Simplify the UI:

The overall length and complexity of the UI should be reduced.

7. Specify Non-Interference with Reporting and Data Sharing in Existing Law:

The Health and Safety Code currently contains several sections that permit or require communication of identifying information within correctional facilities, among health care providers caring for a patient, between a health care provider and the local health

officer, and between a local public health agency and other agencies or researchers. These include Sections 120985, 121010, 121015, 121025, 121055, 121060, 121065, 121070, 121085, 121090, and possibly others. While regulations do not supersede legislation, it is nevertheless important to clarify that any reporting regulations should not be interpreted such as to weaken or restrict the application of the above sections.

This provision should be added: "Nothing in these regulations shall be construed to restrict or interfere in any way with HIV partner notification, or with the communication of identifying information between a physician and the local health officer, or to other persons, where otherwise permitted or required by law."

CONCLUSION

Thank you for considering our comments. The Academy would be pleased to participate with other organizations in any advisory group to further revise the proposed reporting regulations so as to establish a more effective surveillance system than that provided in the current draft.

Sincerely,

[original signed by]

Richard Sun, MD, MPH
President, 2001-2002

At CAPM's annual meeting on May 4, 2001, the general membership voted that the CAPM Disease Prevention Strategy Committee draft comments on the proposed DHS regulations (R-19-00) for review by the CAPM Board of Directors. The Board approved the comments in this letter in a teleconference on May 18, 2001, and requested that the following parties receive copies of these comments.

cc: Diana M. Bontá, R.N., Dr.P.H.
Director
California Department of Health Services
P.O. Box 942732
Sacramento, CA 94234-7320

Grantland Johnson
Secretary
California Health and Human Services Agency
1600 Ninth Street, Suite 460
Sacramento, CA 95814

Jack Lewin, M.D.
Executive Vice President
California Medical Association
P.O. Box 7690
San Francisco, CA 94120-7690

California Conference of Local Health Officers (electronically at cclho@dhs.ca.gov)