THE CSTE WASHINGTON REPORT

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September 6, 2002 Volume 6, Number 16

INSIDE THIS ISSUE

EDITOR'S NOTE: Congress returns this month to a crowded legislative agenda with limited time to act before the mid-term elections in November. Must do items include the appropriations bills to fund federal agencies for Fiscal Year 2003, this year delayed by significant differences between the Congress and the White House on policy and fiscal priorities. Some observers are predicting enough stalemates before the elections to force a lame duck Congressional session to complete action on the appropriations measures. Public health priorities are again caught in the legislative crunch, with advocates for public health pushing hard to keep public health programs from the cost cutting expected before the Congress is done with its work this session.

The CSTE Washington Report is provided as an information resource for members of the Council of State and Territorial Epidemiologists on federal legislation and regulation affecting public health and epidemiology in the U.S. Regulations cited can be accessed via http://www.gpo.gov

APPROPRIATIONS UPDATE – The House Labor-HHS-Education Appropriations Subcommittee postponed its tentatively planned mark up this week, but plans to mark up next week unless a bill is taken up directly on the House floor bypassing the Committee

process. There is considerable political concern among Moderate Republicans, who are more supportive of the health and education programs funded in the Labor-HHS-Education Appropriations bills, that an agreement struck with a group of conservative House Members and the House leadership before the August recess will force them to vote for a bill that reflects the President's budget request. The President's budget request, while providing a generous $3.7 billion increase for the National Institutes of Health, and continuing $940 million for State and Local bioterrorism preparedness, cuts many health programs and level funds others while also under funding education programs. Among the CDC programs the President's budget cuts are: Chronic Disease Prevention and Health Promotion (-$56 million, or 7.5%); Environmental Health (-$1.1 million, 0.71%); Infectious Disease (-$9.5 million, 2.7%); Injury Prevention and Control (-$4.6 million, 3.07%); Occupational Safety and Health (-$28 million, 9.8%). The HIV/AIDS, STD, TB Prevention, Preventive Health Block Grant, and Immunization programs were essentially level funded.

The Chairman of the House Appropriations Committee, Rep. Bill Young (R-FL) hopes to demonstrate to the leadership that a bill that reflects the President's budget request does not have enough votes to pass on the House floor and so introduced a bill earlier this week (HR 5320) that he is urging be taken straight to the floor for that test. The leadership has reported that, indeed, it does not have the votes to pass the bill, but is expected to force Labor-HHS-Education Subcommittee Chairman Regula (R-OH) to mark up a bill that is either the President's budget request, or a bill that cuts NIH, or other generously funded programs to distribute funds to under funded health programs. Either bill is a difficult choice for policy-makers. Public health groups are spearheading an effort targeting Moderates to vote against any Labor-HHS-Education Appropriations bill that reflects either the President's budget request, or that cuts in some health programs to distribute funding to others and to work for increasing the overall allocation for the Labor-HHS-Education Appropriations bill.

The Senate has completed Committee work on its Labor-HHS-Ed Appropriations bill (S. 2766; Report 107-216) before the August recess. The Senate bill includes an estimated $6 billion more than the President's budget request.

LEGISLATIVE UPDATE – Homeland Security: The Senate is debating its version of the Homeland Security bill on the Senate floor this week and for the next couple of weeks. Under the Committee passed version of the bill now being debated the CDC bioterrorism grant program and related activities are not transferred to the new department. This is also the case with the House passed bill (HR 5005; see the July 26th Washington Report, Vol. 6, No. 14). The major issue in the Senate is the President's request for flexibility in hiring, transferring, promoting, and firing federal workers in the new department that now enjoy civil service protections in their home agencies. The House bill incorporates the flexibility the President is seeking. National Health Tracking Act: This bill (S. 2054), sponsored in the Senate by Sen. Hillary Clinton (D-NY) and in the House by Nancy Pelosi (D-CA; HR 4596) is currently being redrafted to incorporate comments from CSTE, CDC, and other organizations. The bill seeks to set up state

surveillance systems that will track priority chronic diseases like asthma, birth defects, and cancer and relevant environmental, behavioral, socioeconomic, demographic, and other risk factors. The state grant program would be authorized at $100 million for FY 2005-2009. It creates a federal commission which will establish minimum standards and procedures regarding priority chronic conditions and relevant environmental and other risk factors. The bill also expands the EIS program at CDC to include environmental health officers who can aide states in investigating urgent incidents involving environmental hazards and exposure or elevated incidence or prevalence of chronic disease. The bill also expands the current biomonitoring program at the CDC. Finally the bill creates Centers of Excellence to study the links between environmental exposure and chronic disease and train environmental health professionals. CSTE is expecting to receive the new draft for review and comment soon, possibly next week. The HELP Committee still hopes to mark up the bill before the end of the 107th Congress. The House companion measure has had no Committee action to date.

HHS NAMES MEMBERS TO COUNCIL ON PUBLIC HEALTH PREPAREDNESS -- HHS Secretary Tommy G. Thompson August 23 named the 21 members of the Secretary's Council on Public Health Preparedness, which will advise the department on appropriate actions to prepare for and respond to public health emergencies, including acts of bioterrorism.

D. A. Henderson, M.D., the Secretary's principal science advisor for public health preparedness, will chair the Council on Public Health Preparedness. The panel's first meeting will take place Aug. 26-27 in Washington.

"This diverse group of very experienced professionals will be an invaluable resource in the ongoing effort to strengthen our nation's bioterrorism preparedness and response," Secretary Thompson said. "As we continue to build our public health capabilities for emergencies, their input will be an important element in our planning."
Information on the members named to the advisory council follows:

* **D. A. Henderson, M.D., M.P.H.,** founding director of the Center for Civilian Biodefense Studies at the Johns Hopkins University Bloomberg School of Public Health. He is currently Secretary Thompson's principal science advisor for Public Health Preparedness.
* **Georges C. Benjamin, M.D.,** secretary of the Maryland Department of Health and Mental Hygiene.
* **Gail H. Cassell, Ph.D.,** vice president for scientific affairs and Distinguished Lilly Research Scholar for Infectious Diseases at Eli Lilly and Company in Indianapolis, Ind.
* **James Chin, M.D.,** clinical professor of epidemiology at the University of California at Berkeley's School of Public Health in Stockton, Calif.
* **Francis Cigarroa, M.D.,** president of the University of Texas Health Sciences Center in San Antonio, Texas.

* **Colleen Conway-Welch, Ph.D., M.S.N.,** professor and dean of the Vanderbilt University School of Nursing in Nashville, Tenn.
* **Donald Fisher, Ph.D.,** president and chief executive officer of the American Medical Group Association in Alexandria, Va.
* **Timothy T. Flaherty, M.D.,** board member of the American Medical Association Board of Trustees. He is from Neenah, Wis.
* **Kathleen F. Gensheimer, M.D., M.P.H.,** state epidemiologist for Maine's Department of Human Services in Augusta, Maine.
* **Mary Gilchrist, Ph.D.,** director of the University of Iowa Hygienic Laboratory in Iowa City, Iowa.
* **Margaret Hamburg, M.D.,** Nuclear Threat Initiative's vice president for Biological Programs in Washington, D.C.
* **Dennis G. Maki, M.D.,** professor of medicine and head of the Infectious Diseases Department of Medicine at the University of Wisconsin Medical School in Madison, Wis.
* **Robert A. Malson, J.D.,** District of Columbia Hospital Association president in Washington, D.C.
* **Thomas L. Milne,** executive director of the National Association of County and City Health Officials in Washington, D.C.
* **Frederick A. Murphy, D.V.M., Ph.D.,** professor at the University of California, Davis School of Veterinary Medicine in Davis, Calif.
* **Michael T. Osterholm, Ph.D., M.P.H.,** director of the University of Minnesota's Center for Infectious Disease Research and Policy in Minneapolis, Minn.
* **William L. Roper, M.D., M.P.H.,** dean of the University of North Carolina at Chapel Hill School of Public Health in Chapel Hill, N.C.
* **Paul B. Roth, M.D.,** dean of the School of Medicine and associate vice president for clinical affairs for the Health Science Center at the University of New Mexico in Albuquerque, N.M.
* **Andrew A. Sorensen, Ph.D.,** president of the University of South Carolina in Columbia, S.C.
* **Michael Stocker, M.D., M.P.H.,** is chief executive officer of Empire Blue Cross and Blue Shield in New York City, N.Y.
* **Ed Thompson, M.D., M.P.H.,** state health officer for the Mississippi State Department of Health in Jackson, Miss.

The agenda for the committee's first meeting will include bioterrorism preparedness and response programs, states' preparedness programs, lessons learned from the last fall's anthrax mail attacks, research and development efforts, development of new products related to bioterrorism and public health emergency response planning.

MODIFICATIONS TO THE STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION -- FINAL RULE

Overview: *The Department of Health and Human Services on August 14th published final modifications to the Privacy Rule to ensure that the Rule provides strong privacy protection without hindering access to quality health care. Based on the comments received on the notice of proposed rulemaking, the Department modified a number of provisions of the Privacy Rule.*

The Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule) took effect on April 14, 2001. The Privacy Rule creates national standards to protect individuals' personal health information and gives patients increased access to their medical records. As required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Privacy Rule covers health plans, health care clearinghouses, and those health care providers who conduct certain financial and administrative transactions electronically. Most covered entities must comply with the Privacy Rule by April 14, 2003. Small health plans have until April 14, 2004 to comply with the Rule.

Final Modifications:

Marketing -- The final Rule requires a covered entity to obtain an individual's prior written authorization to use his or her protected health information for marketing purposes except for a face-to-face encounter or a communication involving a promotional gift of nominal value. The Department defines marketing to distinguish between the types of communications that are and are not marketing, and makes clear that a covered entity is prohibited from selling lists of patients and enrollees to third parties or from disclosing protected health information to a third party for the marketing activities of the third party, without the individual's authorization. The Rule clarifies that doctors and other covered entities communicating with patients about treatment options or the covered entity's own health-related products and services are not considered marketing. For example, health care plans can inform patients of additional health plan coverage and value-added items and services, such as discounts for prescription drugs or eyeglasses.

Consent and Notice -- The Department makes changes to protect privacy while eliminating barriers to treatment by strengthening the notice requirement and making consent for routine health care delivery purposes (known as treatment, payment, and health care operations) optional. The Rule requires covered entities to provide patients with notice of the patient's privacy rights and the privacy practices of the covered entity. The strengthened notice requires direct treatment providers to make a good faith effort to obtain patient's written acknowledgement of the notice of privacy rights and practices. The final Rule promotes access to care by removing mandatory consent requirements that would inhibit patient access to health care while providing covered entities with the option of developing a consent process that works for that entity. The Rule also allows consent requirements already in place to continue.

Uses and Disclosures Regarding Food and Drug Administration (FDA)-Regulated Products and Activities -- The final Rule permits covered entities to disclose protected

health information, without authorization, to a person subject to the jurisdiction of the FDA for public health purposes related to the quality, safety or effectiveness of FDA-regulated products or activities such as collecting or reporting adverse events, dangerous products, and defects or problems with FDA-regulated products. This assures that information will continue to be available to protect public health and safety, as it is today.

Incidental Use and Disclosure -- The final Rule acknowledges that uses or disclosures that are incidental to an otherwise permitted use or disclosure may occur. Such incidental uses or disclosures are not considered a violation of the Rule provided that the covered entity has met the reasonable safeguards and minimum necessary requirements. For example, if these requirements are met, doctors' offices may use waiting room sign-in sheets, hospitals may keep patient charts at bedside, doctors can talk to patients in semi-private rooms, and doctors can confer at nurse's stations without fear of violating the rule if overheard by a passerby.

Authorization -- The final Rule clarifies the authorization requirements to the Privacy Rule to, among other things, eliminate separate authorization requirements for covered entities. Patients will have to grant permission in advance for each type of non-routine use or disclosure, but providers will not have to use different types of forms. These modifications also consolidate and streamline core elements and notification requirements.

Minimum Necessary -- The final Rule exempts from the minimum necessary standards any uses or disclosures for which the covered entity has received an authorization. The Rule previously exempted only certain types of authorizations from the minimum necessary requirement, but since the rule will only have one type of authorization, the exemption is now applied to all authorizations. Minimum necessary requirements are still in effect to ensure an individual's privacy for most other uses and disclosures.
The Department clarifies in the preamble that the minimum necessary standard is not intended to impede disclosures necessary for workers' compensation programs. The Department will actively monitor to ensure that worker's compensation programs are not unduly affected by the Rule.

Parents and Minors -- The final Rule clarifies that state law, or other applicable law, governs in the area of parents and minors. Generally, the Privacy Rule provides parents with new rights to control the health information about their minor children, with limited exceptions that are based on state or other applicable law and professional practice. For example, where a state has explicitly addressed disclosure of a minor's health information to a parent, or access to a child's medical record by a parent, the final Rule clarifies that state law governs. In addition, the final Rule clarifies that, in the special cases in which the minor controls his or her own health information under such law and that law does not define the parents' ability to access the child's health information a licensed health care provider continues to be able to exercise discretion to grant or deny such access as long as that decision is consistent with the state or other applicable law.

Business Associates -- The final Rule gives covered entities (except small health plans) up to an additional year to change existing written contracts to come into compliance with the business associate requirements. The additional time will ease the burden of covered entities renegotiating contracts all at once. The Department has also provided sample business associate contract provisions.

Research -- The final Rule facilitates researchers' use of a single combined form to obtain informed consent for the research and authorization to use or disclose protected health information for such research. The final Rule also clarifies the requirements relating to a researcher obtaining an IRB or Privacy Board waiver of authorization by streamlining the privacy waiver criteria to more closely follow the requirement of the "Common Rule," which governs federally funded research. The transition provisions have been expanded to prevent needless interruption of ongoing research.

Limited Data Set -- The final Rule permits the creation and dissemination of a limited data set (that does not include directly identifiable information) for research, public health, and health care operations. In addition, to further protect privacy, the final Rule conditions disclosure of the limited data set on a covered entity and the recipient entering into a data use agreement, in which the recipient would agree to limit the use of the data set for the purposes for which it was given, and to ensure the security of the data, as well as not to identify the information or use it to contact any individual.

Other provisions:

* *Hybrid Entities* -- The final Rule permits any entity that performs covered and non-covered functions to elect to use the hybrid entity provisions and provides the entity additional discretion in designating its health care components.

* *Health Care Operations: Changes in Legal Ownership* -- The final Rule clarifies the definition of "health care operations" to allow a covered entity who sells or transfers assets to, or consolidates or merges with, an entity who is, or will be, a covered entity upon completion of the transaction, to use and disclose protected health information in connection with such transaction, which include due diligence and transferring records containing protected health information as part of the transaction.

* *Group Health Plan Disclosures of Enrollment and Disenrollment Information* -- The final Rule allows a group health plan, a health insurance issuer, or HMO acting for a group health plan to disclose to a plan sponsor, such as an employer, information on whether the individual is enrolled in or has disenrolled from a plan offered by the sponsor without amending the plan documents.

* *Accounting of Disclosures* -- The final Rule exempts disclosures made pursuant to an authorization from the accounting requirements. The authorization process itself adequately protects individual privacy by assuring that the individual's permission is given both knowingly and voluntarily. The final Rule also exempts from the accounting

requirements incidental disclosures, and disclosures that are part of a limited data set. The Rule provides a simplified alternative approach for accounting for multiple research disclosures that includes providing a description of the research for which an individual's protected health information may have been disclosed and the researcher's contact information.

* *Disclosure for Treatment, Payment, or Health Care Operations of Another Entity*- The final Rule clarifies that covered entities can disclose protected health information for the treatment and payment activities of another covered entity or a health care provider, and for certain health care operations of another covered entity.

* *Protected Health Information: Exclusion for Employment Records* - The final Rule clarifies that employment records maintained by a covered entity in its capacity as an employer are excluded from the definition of protected health information. The modifications do not change the fact that individually identifiable health information created, received, or maintained by a covered entity in its health care capacity is protected health information.

The final Rule also includes technical corrections and additional clarifications related to various sections of the existing rule. The final Rule is designed to ensure that protections for patient privacy are implemented in a manner that maximizes privacy while not compromising either the availability or the quality of medical care.

On July 6, 2001, the Department issued its first guidance to answer common questions and clarify certain of the Privacy Rule's provisions. The Department is committed to assisting covered entities come into compliance with the Rule. Therefore, the Department will update the guidance to reflect the modifications adopted in this final Rule. The revised guidance will be available on the HHS Office for Civil Rights Privacy Web site at http://www.hhs.gov/ocr/hipaa/.