THE CSTE WASHINGTON REPORT

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June 27, 2002 Volume 6, Number 12

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EDITOR'S NOTE: Congress is responding to the President's proposal to create a Homeland Security Agency with hearings and deliberations. Of particular interest and importance to public health advocates is the future role and direction of public health funding within CDC and NIH and the mechanisms under which public health programs will operate. Review of the President's legislative proposal and Congressional response and reaction within key factions of the public health community is provided in this Washington Report.

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

LEGISLATIVE UPDATE: Homeland Security Legislative Proposal -- The White House presented its legislative proposal on the new Department of Homeland Security to Congress on June 18th. You can view it at:
http://www.whitehouse.gov/deptofhomeland/bill/index.html

Transferred to the new Department of Homeland Security are the following HHS administrative functions: Office of the Assistant Secretary for Public Health Emergency Preparedness; Office of Emergency Preparedness; National Disaster Medical System which works with the Metropolitan Medical Response System; and the National Stockpile – although the HHS Secretary would still manage it and determine its contents. Finally, and importantly for state and local public health, the new Department would also be responsible for all current HHS public health emergency preparedness activities – in other words, CDC's Bioterrorism Preparedness and Response Program and HRSA's Bioterrorism Hospital Preparedness Program. Except as directed by the President, the Secretary of Homeland Security would carry out these activities through HHS under agreements to be negotiated with the HHS Secretary. And the Homeland Security Secretary would be authorized to set the priorities for these preparedness and response activities.

Reaction -- Congress has begun to hold a series of hearings on the White House legislative proposal. A hearing on 6/25 before a Subcommittee of the House Energy and Commerce Committee featured Jan Heinrich, Director, Health Care-Public Health Issues for the General Accounting Office. Ms. Heinrich's testimony focused on Title V of the President's proposal, the public health/HHS sections of the bill. You can read the whole statement at: http://www.gao.gov/new.items/d02883t.pdf
While praising the proposal as having the potential to repair fragmentation, and improve coordination, she expressed the following concerns about the public health assistance programs: s"However, we have concerns about the proposed transfer of control from HHS to the new department for public health assistance programs that have both basic public health and homeland security functions. These dual-purpose programs have important synergies that we believe should be maintained. We are concerned that transferring control over these programs, including priority setting, to the new department has the potential to disrupt some programs that are critical to basic public health responsibilities. We do not believe that the President's proposal is sufficiently clear on how both the homeland security and the public health objectives would be accomplished."

Public health organizations are also beginning to express similar concerns about transferring control of public health preparedness programs to the new department while HHS retains only administration and implementation functions. Testimony provided this week by the American Society for Microbiology sounded this theme, as well as similar concerns about the research functions for terrorism preparedness now conducted at the NIH. NACCHO and the APHA have forwarded strong statements to key Members of Congress opposing transfer of authority for public health preparedness programs to the new Homeland Security Department, and ASTHO, CSTE and APHL are in the process of drafting their statements expressing similar misgivings while expressing support for an oversight and coordination role for the new department. Those statements will go to Congress and the Administration early next week. Meanwhile, CSTE Washington staff has been working quietly with key Congressional staff as they prepare questions for relevant witnesses appearing before the various oversight committees.

Legislative Timing -- Congress is moving quickly to finish work on legislation creating the new Homeland Security Department. Both the House and Senate hope to finish Committee work by the August recess, which begins July 29th, and schedule action on the floor in September.

ATSDR TO FUND LINKING CHRONIC DISEASE AND ENVIRONMENTAL DATA SOURCES – The Agency for Toxic Substances and Disease Registry (ATSDR) June 20 (67 FR 42001-42003) announced the availability of fiscal year (FY) 2002 funds for a cooperative agreement program to conduct research on the potential impact of environmental exposures on chronic disease outcomes. This program addresses the ``Healthy People 2010'' focus area of Environmental Health.

Measurable outcomes of the program will be in alignment with the following performance goals for ATSDR: (1) Ascertain the relationship between exposure to toxic substances and disease and (2) Build and enhance effective partnerships.

Assistance will be provided to official public health agencies of States or their bona fide agents or instrumentalities. This includes the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of the Marshall Islands, the Republic of Palau, and Federally recognized Indian Tribal governments. Also eligible are State organizations, including State universities, State colleges, and State research institutions, who must establish that they meet their respective State legislature's definition of a State entity or political subdivision to be considered an eligible applicant.Approximately $400,000 is available in FY 2002 to fund two to three awards. It is expected that the average award will be $150,000, ranging from $100,000 to $200,000. The award(s) are expected to begin on or \about September 1, 2002, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates are subject to change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds. Matching funds are not required for this program.

The application must be received on or before 5:00 p.m. Eastern Time July 30, 2002.

NIAID EXPANDS VACCINE TESTING NETWORK --The National Institute of Allergy and Infectious Diseases (NIAID) has awarded seven new contracts that will expand and reorganize its network of university-based sites conducting clinical trials of promising vaccine candidates and therapies for infectious diseases. The reconfigured Vaccine Treatment and Evaluation Units (VTEUs) will enable NIAID to fund more clinical trials focused on specific populations as well as larger trials of public health importance, including those related to biodefense and vaccine safety.

Established in 1962, the network is a national resource for vaccine development. VTEU investigators have tested and advanced vaccines for many diseases, including pneumonia,

influenza, cholera, whooping cough, malaria, and tuberculosis. Childhood vaccines and so-called combination vaccines — the delivery of several vaccines at the same time — have been and remain an important part of the network's research agenda. The first trial of an edible vaccine was conducted by VTEU researchers, and other novel vaccine delivery systems, such as an influenza vaccine delivered via a nasal spray, have been extensively tested through the network.

"For 40 years, the VTEUs have provided an important mechanism for conducting vaccine clinical trials in a variety of populations, including infants, children, adults, and specific high-risk populations," says NIAID Director Anthony S. Fauci, M.D. "More recently, part of this network's mission has been to evaluate vaccines against possible agents of bioterrorism."

An important strength of the VTEU network is its ability to rapidly recruit and retain volunteers. Through the VTEUs, NIAID quickly designed and implemented a multicenter clinical trial to evaluate the feasibility of diluting existing smallpox vaccine. Together, the VTEUs enrolled and vaccinated 680 volunteers in less than three months. Initial findings of this study were recently published in the New England Journal of Medicine. The results provide the government and vaccine advisory committees with essential information for making critical decisions about smallpox vaccination strategies.

In addition to rigorously evaluating vaccine safety during every trial, the VTEUs explore emerging hypotheses about vaccine-related adverse side effects. For example, one VTEU is studying thimerosal, a common vaccine preservative that contains a form of mercury. Thimerosal has recently been removed from vaccines routinely given to infants. To better understand what happens to thimerosal once it enters the body, the VTEU is assessing mercury levels in groups of infants who received routine immunizations either with or without thimerosal.

The new VTEU contracts will last five years; first-year funding is $23.3 million.

HHS ISSUES NEW MEDICAID MANAGED CARE REGULATION TO GUARANTEE STRONG PATIENT PROTECTIONS -- HHS Secretary Tommy G. Thompson today issued a final regulation to give Medicaid beneficiaries enrolled in managed care plans the same types of protection that participants in private plans would receive under patient rights' legislation now under consideration in Congress.

The regulation guarantees Medicaid beneficiaries access to emergency room care, a second opinion when needed, a timely right to appeal adverse coverage decisions and other patient protections. Under the new regulation, states have significant flexibility to decide how best to implement patient protections and use managed care in their Medicaid plans.

"This new rule ensures Medicaid beneficiaries get the rights and protections enjoyed by other Americans enrolled in managed care plans," Secretary Thompson said. "It also gives states the flexibility to implement these protections without jeopardizing health care services."

The final regulation builds on protections for Medicaid beneficiaries that were created under the Balanced Budget Act of 1997. About 22 million Medicaid beneficiaries, or 58 percent of all Medicaid enrollees, were enrolled in managed care programs at the end last year.

This rule also will change the federal requirements governing payments under state managed care programs, moving away from a formula using fee-for-service payments to a requirement that the methodology be actuarially sound. In addition, the final rule permits states with risk contracts to make graduate medical payments directly to academic medical centers.

The rule retains and expands upon all the protections already available to Medicaid beneficiaries under the 1997 statute. Under the rule, beneficiaries will have the following rights:

* Emergency Room Care. Health plans must pay for a Medicaid beneficiary's emergency room care whenever and wherever the need arises.
* Access to second opinion. All beneficiaries will be allowed to get a second opinion from a qualified health professional.
* Direct access for women's health services. Women will be allowed to directly access a woman's health specialist in the network for routine and preventive health care services as is available in Medicaid fee-for-service.
* Patient-Provider Communication. Managed care plans will be prohibited from establishing restrictions, such as gag rules, that interfere with patient-provider communications.
* Network Adequacy. Managed care plans will be required to ensure that they have the capacity to serve the expected enrollment in their service area.
* Marketing Activities. States will be required to approve marketing materials used by the managed care plans to enroll Medicaid beneficiaries. Plans are prohibited from using door-to-door, telephone, and other forms of "cold call" marketing.
* Grievance Systems. All managed care plans must have a system in place to accommodate enrollee grievances and appeals. Grievances must be resolved within state established timeframes that may not be longer than 90 days and must be resolved by managed care organizations within 45 days. However, expedited timeframes exist for resolving appeals when the life or health of the enrollee is in jeopardy.

Managed care plans serving Medicaid beneficiaries also must provide consumers with comprehensive, easy-to-understand information about the program in which they are enrolled.

The final rule will allow states, many of which have already implemented protections through state laws and regulations, to keep in place important aspects of their existing programs. The new rule also will require states to submit to HHS clear plans for providing beneficiaries with high quality care and to measure the quality of the care that is actually provided.