THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE:. With an Executive Order aimed at federal agencies that provide coverage to nearly one in every four Americans with health insurance, President Bush August 22 took a major step forward in providing consumers with easy-to-use information about the quality and price of their health care. The information will enable consumers to make informed choices among doctors and hospitals, and it will help support doctors and hospitals that deliver high-quality care and avoid unnecessary health care costs, creating opportunities to improve care and lower its costs– additional details are 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. Legislation cited in the report can be accessed via http://www.thomas.loc.gov Regulations cited can be accessed via http://www.gpo.gov

CONGRESS TO DELAY ACTIONS ON HEALTH APPROPRIATIONS – Congress returned September 5th from its month-long August recess. Leaderships in the House and

Senate are maneuvering to keep tight focus on terrorism topics for the remainder of the 109th Congress which is scheduled to adjourn in early October, but which is very likely to return in a lame duck session after the November elections. The impetus for a post-election session is the need to finish FY 2007 appropriations bills most of which have not been taken up on the Senate floor. Pundits are also predicting that the Labor, Health and Human Services and Education Appropriations bills will not see floor action in either the House or Senate before the elections and that it, along with any other unfinished appropriations bills, is likely to be wrapped into a giant omnibus bill.

MEDICAL RESERVE CORPS NOW IN ALL 50 STATES -- The Medical Reserve Corps (MRC), a national network of locally based medical, public health, and other volunteers who help strengthen the public health system of their communities, has reached a new milestone. With the recent registration and approval of the North Dakota Public Health Emergency Volunteer Medical Reserve Corps in Bismarck, N.D., the MRC is now present in all 50 states, Washington, D.C., Guam, Palau, Puerto Rico, and the U.S. Virgin Islands.

The program is housed in the Office of the U.S. Surgeon General in the Department of Health and Human Services. It began as a demonstration project with 42 communities in July 2002. The following year, an additional 124 communities were added to the project. Since 2003, the program has grown to more than 460 MRC units in communities across the country with over 85,000 volunteers providing medical and public health support. MRC continues to expand its strength and reach as local, state and national officials and response partners recognize the program and its large pool of volunteers as an asset beyond measure.

"The MRC program has exceeded all expectations," said RADM Kenneth Moritsugu, Acting Surgeon General of the U.S. Public Health Service. "Its growth has been nothing short of extraordinary. Many communities in our nation are now healthier and safer because they have created an MRC unit."

MRC units are available to respond when disaster strikes their community. By working with preparedness, response, public health, and other partners on an ongoing basis, MRC units become part of the local response mechanisms. MRC volunteers train and exercise their skills to ensure that they can benefit the community when needed.

The MRC is a partner program with Citizen Corps, which is dedicated to hometown security. Citizen Corps, along with national service programs like AmeriCorps, Senior Corps, Learn and Serve, and the Peace Corps, works with USA Freedom Corps, an office of the White House charged with building a culture of service, citizenship, and responsibility in America. The MRC program is also proud to be a National Preparedness Month Coalition member. (See http://www.ready.gov for more information about National Preparedness Month)

MRC units across the country work to strengthen the public health infrastructure in their communities throughout the year, and respond to public health, natural, and manmade

disasters as needed. For more information on the MRC, visit www.medicalreservecorps.gov.

PRESIDENT DIRECTS FEDERAL AGENCIES TO PROVIDE HEALTH CARE QUALITY AND PRICE INFORMATION FOR CONSUMERS -- With an Executive Order aimed at federal agencies that provide coverage to nearly one in every four Americans with health insurance, President Bush August 22 took a major step forward in providing consumers with easy-to-use information about the quality and price of their health care. The information will enable consumers to make informed choices among doctors and hospitals, and it will help support doctors and hospitals that deliver high-quality care and avoid unnecessary health care costs, creating opportunities to improve care and lower its costs.

The Executive Order directs agencies that administer or support health insurance programs to take steps that will result in more complete and open information for consumers. The President said he hopes the Federal action will be followed by similar commitments in the private sector, and in state and local government. He directed Health and Human Services Secretary Mike Leavitt to work collaboratively with the health care sector to ensure that information provided to consumers is reliable and accurate.

The steps required by the order include the sharing of information about the quality of care delivered by doctors and hospitals, as well as the prices paid to these providers. The order also requires agencies and their health care contractors to promote the use of interoperable health information technology products, so that data can be easily shared. In addition, it requires agencies to offer insurance options that reward consumers who exercise choice among health providers based on value and quality of care.

Programs administered and sponsored by the federal government represent a significant portion of the nation's health care market, but until recently these programs have not been collaborating extensively with privately-led efforts to improve the availability of information to consumers. The Executive Order will result in increased quality and price information for all Medicare beneficiaries, those covered by Department of Defense health programs, Veterans Affairs Administration beneficiaries, and employees and their families covered under the Federal Health Benefits Program. Action by states will be needed to commit federally-supported Medicaid programs to the goals of the Executive Order.

The President said the Executive Order is a first step in a larger plan to provide open health quality and price information for all American consumers. He invited other employers to make similar commitments on behalf of their employees, including major private employers and states and local governments. And he pledged that the Administration will work with health care providers as well as labor unions, the insurance industry and others to support a reliable and comprehensive system of health quality and price information.

"People deserve to know what their health care costs, how good it is, and the choices available to them," HHS Secretary Mike Leavitt said. "The President's action is a major step forward in giving consumers easy-to-use information about the quality and price of their health care. This is fundamental to achieving a health care system that delivers good value."

Secretary Leavitt said the effort will begin with information available now and will grow in volume and sophistication over time. National "alliance" organizations bringing together payers and health care provider organizations have been at work for several years developing quality measures for ambulatory care (especially physician care), hospitals and other institutions. The goal of the President's initiative is to strengthen and build on these efforts and ultimately present consumers with information in a single, easy-to-use spreadsheet format.

In Medicare, early measures of quality have been available for hospitals, nursing homes and other institutions for several years. These quality measures are in the process of being expanded through the collaborative "alliance" process. Some quality information is also available at present through insurers and other sources. In addition, Medicare began this year posting information on the Web about the prices it pays for hospital care. Medicare plans to begin posting information about payment rates to physicians this fall.

Ultimately, under the President's plan, local information on the quality and cost of care for most Americans would be available from the collaboration of health care providers, public and private payers, and other stakeholders in different regions of the country. The collaboration by providers and payers would create an unprecedented broad and reliable foundation of information on the quality and price of services delivered by each health care provider. Quality and cost measures developed through this process would be made available to consumers.

A federally-sponsored program is currently underway in six geographic areas that will examine best practices for aggregating and sharing information.

Under the Executive Order, price and quality information would be made available for the particular benefit of those enrolled in the federally-administered or sponsored programs. However, much of this information will also be available in Web formats available to the general public.

QUICK DIAGNOSIS OF FLU STRAINS POSSIBLE WITH NEW MICROCHIP TEST -- Scientists from the University of Colorado at Boulder and the Centers for Disease Control and Prevention (CDC) have developed a microchip-based test that may allow more labs to diagnose influenza infections and learn more about the viruses causing illness. The FluChip successfully distinguished among 72 influenza strains-including the H5N1 avian influenza strain-in less than 12 hours. The research was led by University of Colorado scientist Kathy L. Rowlen, Ph.D., and was funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). It appears in the current issue of the Journal of Clinical Microbiology.

Laboratories across the United States can do basic tests to determine the type and subtype of an influenza virus within several hours. However, only the CDC and a handful of other labs internationally have the high-level biosafety facilities needed to perform specialized tests that reveal critical details about the virus's geographic origin and other features. Because the FluChip technology could be used in lower level biosafety facilities, it could expand influenza diagnostic capacity by allowing more labs to determine the geographic origin of a newly emergent virus and whether its source is human or nonhuman; learn how closely related a new virus is to ones that circulated previously; and detect genetic changes that may signal the virus is becoming more virulent.

"The ability to quickly and accurately identify strains of influenza would be invaluable to international flu surveillance efforts," says NIAID Director Anthony S. Fauci, M.D. "This is an encouraging advance."

"This state-of-the-art research is vital to our efforts to protect the nation's health, and it may provide a new tool in our toolbox in the fight against influenza," says CDC Director Julie Gerberding, M.D. "This is an excellent example of the advances we can achieve when governmental and academic researchers work together, and we look forward to future collaboration."

The FluChip is a type of microarray, commonly called a gene chip.
Although there are numerous variations, microarrays can be made by using a robotic arm to drop hundreds or thousands of spots of genetic material-DNA or RNA-of known sequence onto a microscope slide. The spots, called probes, are then exposed to a sample of unknown
composition: for instance, material taken from a person with an undiagnosed illness. Probes that match gene sequences of bacteria or viruses present in the sample result in capture of the target gene. By analyzing the pattern of captured targets, doctors can diagnose the cause of infection.

A key challenge in designing a gene chip for flu diagnosis is determining which flu virus gene sequences to use as probes, notes Dr. Rowlen. In a companion paper, the researchers describe a powerful new way to scan vast amounts of flu virus genetic information to find the most informative sequences. "Our goal was to develop an efficient method for mining large databases to identify regions of the flu genome that are largely the same from strain to strain as well as strain-specific sequences," Dr. Rowlen says.

Beginning with a pool of nearly 5,000 flu gene sequences, the investigators used the data mining process to select 55 flu RNA sequences for use as probes on the FluChip. Among them were probes chosen to enable detection of two of the most common flu strains currently circulating in humans, the H1N1 and H3N2 strains, as well as the avian flu strain H5N1.

The CDC provided flu isolates to the University of Colorado researchers to identify using the FluChip. The samples included flu strains that infect humans, horses, birds and swine.

CDC shared its technical expertise on influenza and worked alongside University of Colorado staff in CDC laboratories to process the influenza samples, test the FluChip technology and analyze the results. Combined results after two rounds of tests showed that the FluChip allowed users to obtain correct information about both type and subtype-considered a full characterization of a strain-from 72 percent of the samples. Full information on type-but only partial information on subtype-was obtained for 13 percent of the samples, while 10 percent of the samples could be identified by type only (no information about subtype). It took about 11 hours to conduct the tests and learn the identities of the strains, report the scientists.

"We were surprised and pleased at how well the chip performed in these early tests," says Dr. Rowlen. The researchers from CDC and University of Colorado are continuing to refine the FluChip and hope to bring the total time required to get full type and subtype characterization to under one hour.

Developing improved gene chips for flu diagnosis depends, in part, on the ready public availability of genomic sequence data, notes Karen Lacourciere, Ph.D., NIAID influenza program officer. In addition to flu genome sequence databases housed at the Los Alamos National Laboratory and CDC, the researchers also used information from the NIAID-supported Influenza Genome Sequencing Project. NIAID rapidly makes this sequence information publicly available through GenBank, an international, searchable online database funded by NIH. This resource is enhancing researchers' ability to select target sequences for next generation diagnostic chips, Dr. Lacourciere says.

The NIH and CDC are two of the 13 major components of the Department of Health and Human Services.

The National Institutes of Health (NIH)-The Nation's Medical Research Agency-includes 27 Institutes and Centers. It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments and cures for both common and rare diseases. For more information about NIH and its programs, visit http://www.nih.gov.

Since it was founded in 1946 to help control malaria, CDC has remained at the forefront of public health efforts to prevent and control infectious and chronic diseases, injuries, workplace hazards, disabilities, and environmental health threats. Today, CDC is globally recognized for conducting research and investigations and for its action oriented approach. For more information on CDC and its programs, visit www.cdc.gov.

CDC AND APHL MAKE INFLUENZA VIRUS SEQUENCE DATA PUBLICLY ACCESSIBLE --Scientists at the Centers for Disease Control and Prevention (CDC) have released genetic blueprints for over 650 genes of influenza viruses into a database accessible to researchers worldwide. The action marks the beginning of a collaboration between the CDC and the Association of Public Health Laboratories (APHL) that will allow for greater access to data on a variety of influenza virus samples obtained from patients in the United States, including avian influenza H5N1 if it should arrive here.

Through the new collaboration, CDC expects to provide genetic information for several hundred influenza viruses per year as a way to encourage more research on influenza. The sequence data will be available in nearly real time through Genbank, a public-access library for virus sequences managed by the National Institutes of Health, and through an influenza database housed at Los Alamos National Laboratories (LANL). The information added will include viruses from the annual flu season in the United States, any animal influenza viruses that infect humans and any novel strains that may emerge such as avian influenza H5N1. The new agreement will only apply to viruses isolated in the United States.

"CDC has long supported the timely and open sharing of influenza virus information to foster new research on influenza. We're excited that this historic collaboration with APHL provides a way to make international exchange of this information possible," said Dr. Nancy Cox, director of the CDC's Influenza Division. "With more information, the world's influenza experts can advance our understanding of the viruses circulating, potentially create new prevention strategies and treatments, and ultimately help us better protect the health of people around the world."

The sequence information, which is like a DNA fingerprint of each virus, allows researchers to determine more about a virus's origin and to compare it to other influenza viruses. This will help scientist determine whether the virus is susceptible to antiviral drugs and, in the case of avian influenza currently circulating in much of the world, to assess whether it's changing in a way that might make the virus more easily transmissible among people – a key property the virus would need to acquire to spark a pandemic. In addition, the sequences can be used to better identify the strains that should be included in the yearly flu vaccine.

Previously, the influenza sequences were available to a small number of influenza researchers who work together with WHO to recommend which influenza viruses should be included in influenza vaccines around the world. The sequence data will now be available through GenBank to anyone with Internet access.

APHL, the national association representing public health laboratories, collaborated with its members to gain approval from all 50 state laboratories to make sequence data from influenza viruses tested in these labs publicly available. APHL promotes effective programs and public policy to strengthen laboratory capacity to protect the health of US residents and to prevent and control disease globally.

"State health department laboratories analyze and subtype thousands of influenza viruses each year. If a novel virus is out there, we will likely be the first to detect it. This is why public health labs are a critical part of our country's early warning system for pandemic influenza, and why this collaboration with CDC is so important," said APHL President Dr. Jane Getchell.

State public health laboratories participate in national influenza surveillance efforts by subtyping viruses and routinely submitting some influenza viruses to CDC for more in-depth characterization. CDC asks public health labs to submit samples of influenza viruses from the beginning, peak and end of each flu season, as well as any samples that are unusual. Under the new agreement, if a novel strain is identified at CDC, the state laboratory which submitted it would be notified prior to the posting in Genbank or LANL databases.

CDC has been actively working with the World Health Organization to encourage sharing of viruses from countries with avian flu activity. After the Indonesian government recently agreed to make available the sequences for viruses from Indonesian bird flu patients, CDC placed total genome sequences for over 40 H5N1 viruses into a public-access database.

“We hope these initiatives will set the stage for other countries to adopt similar approaches to the release of Influenza virus sequence data that they manage” Dr. Cox said.