THE CSTE WASHINGTON REPORT

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INSIDE THIS ISSUE

EDITOR'S NOTE:. -- CDC's National Center for Health Statistics is issuing a new Health E-Stat today entitled "Electronic Medical Record use by Office-based Physicians: United States, 2005." The E-Stat is the latest look at the growing trend towards electronic record-keeping in the medical community. Some of the key findings in the report include: Nearly one in four (23.9 percent) of physicians reported using full or partial electronic medical records (EMRs) in their office-based practice in 2005 - a 31 percent increase from the 18.2 percent reported in 2001 -- additional information is included 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 ACTS ON HEALTH BILLS BEFORE ADJOURNMENT -- Bills of interest that have recently passed the House or Senate, been reported out of Committee:

"Combating Autism Act of 2005" (S. 843/H.R. 2421; report no. 109-318) – This bill passed the Senate under unanimous consent on August 3, 2006. Introduced respectively by Sen. Rick Santorum (R-PA) and Rep. Mary Bono (R-CA), the bill amends the Public Health Service Act to combat autism through research, screening, intervention and education. Below are key excerpts from the bill regarding a $15 million CDC surveillance grant program primarily directed to state and local health departments. The House bill has had no action.

> SEC. 399AA. DEVELOPMENTAL DISABILITIES SURVEILLANCE AND RESEARCH PROGRAM.
> `(a) Autism Spectrum Disorder and Other Developmental Disabilities-
> `(1) IN GENERAL- The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants or cooperative agreements to eligible entities for the collection, analysis, and reporting of State epidemiological data on autism spectrum disorder and other developmental disabilities. An eligible entity shall assist with the development and coordination of State autism spectrum disorder and other developmental disability surveillance efforts within a region. In making such awards, the Secretary may provide direct technical assistance in lieu of cash.
> `(2) DATA STANDARDS- In submitting epidemiological data to the Secretary pursuant to subsection (a), an eligible entity shall report data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention, after consultation with relevant State and local public health officials, private sector developmental disability researchers, and advocates for individuals with autism spectrum disorder or other developmental disabilities.
> `(3) ELIGIBILITY- To be eligible to receive an award under paragraph (1), an entity shall be a public or nonprofit private entity (including a health department of a State or a political subdivision of a State, a university, or any other educational institution), and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

National Uniformity for Food Act (H.R. 4167/S. 3128; report no. 109-379) – This bill passed the House on March 8, 2006 on a vote of 283-139. The Senate Health, Education, Labor and Pensions Committee held a hearing on July 27th. Introduced by Rep. Mike Rogers (R-WI) and Sen. Richard Burr (R-NC), the bill amends the bill amends the federal Food, Drug, and Cosmetic Act to provide for uniform food safety warning notification requirements. A Congressional Research Service summary on the introduced version of the bill is provided below. Two amendments were adopted to the bill on the House floor: a) requirements or exemptions from uniformity for state warning requirements will be expedited in three cases: (1) where the requested warning relates to cancer-causing agents; (2) where the requested warning related to reproductive effects or birth defects; and (3) where the requested warning is intended to provide information that will allow parents or guardians to understand, monitor, or limit a child's exposure to cancer-causing agents or reproductive or developmental toxins; b) National Uniformity for Food Act is prevented from affecting any State law, regulation, proposition or other action that establishes a notification requirement regarding the presence or potential effects of mercury in fish and shellfish.

Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to prohibit any state or political subdivision from establishing or continuing in effect for any food in interstate commerce any requirement that is not identical to specified FFDCA provisions (that would result in materially different requirements), including those related to adulterated foods, unsafe food additives, new animal drugs, and warnings concerning food safety. Allows state enforcement of identical provisions unless the Secretary of Health and Human Services has determined that such state provisions should not be enforced.

Allows a state to petition for an exemption or to establish a national standard regarding any requirement under FFDCA or the Fair Packaging and Labeling Act relating to food regulation. Allows the Secretary to provide such an exemption if the requirement: (1) protects an important public interest that would otherwise be unprotected; (2) would not cause any food to be in violation of any federal law; and (3) would not unduly burden interstate commerce.

Allows a state to establish a requirement that would otherwise violate FFDCA provisions relating to national uniform nutrition labeling or this Act if the requirement is needed to address an imminent hazard to health that is likely to result in serious adverse health consequences and if other requirements are met.

Declares that this Act does not preempt certain state and local laws relating to labeling or a consumer advisory relating to food sanitation imposed on a food establishment or recommended by the Secretary.

Declares that the Act takes effect only if the Secretary certifies to Congress that implementation will pose no additional risk to the public health or safety from terrorist acts relating to the food supply.

PREEMIE bill, "Prematurity Research Expansion and Education (S. 707/H.R. 2861; report no. 109-298) -- The Senate bill passed the Senate on August 1st under unanimous consent and it has been referred to the Energy and Commerce Committee. The bill, introduced by Sen. Alexander (R-TN) is designed to reduce preterm labor and delivery and the risk of pregnancy-related deaths and complications due to pregnancy, and to reduce infant mortality caused by prematurity.

Pandemic and All-Hazards Preparedness Act (S. 3678; report no. 109-319) – This bill was formally reported out of the Senate Health, Education, Labor and Pensions Committee on August 2, 2006. Introduced by Sen. Richard Burr (R-NC), the bill amends the Public Health Service Act with respect to public health security and all-hazards preparedness and response and enjoys strong bipartisan support. Sen. Burr hopes to bring it to the Senate floor under an expedited procedure (no debate, no amendments), but that did not happen prior to the August Congressional recess. There is no comparable House bill.

Ryan White HIV/AIDS Treatment Modernization Act (S. 2823; no written report) – This bill was formally reported out of the Senate Health, Education, Labor and Pensions Committee on August 3, 2006. Introduced by HELP Committee Chairman Mike Enzi (R-WY), the bill reauthorizes the Ryan White CARE Act. There is no companion measure in the House, and no Committee action on a bill (H.R. 5009) reauthorizing the

Ryan White CARE Act introduced by Rep. Dave Weldon (R-FL). Below is an Congressional Research Service summary of the Senate bill as introduced:

> The bill amends the Public Health Service Act to maintain a metropolitan area's eligibility to receive an AIDS emergency relief grant until such area fails to meet eligibility requirements for three consecutive years.
>
> Amends the formula for awarding grant funds to consider the number of HIV/AIDS (currently, AIDS) cases.
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> Requires the return of unexpended grant funds to the Secretary of Health and Human Services or the submission of an application for the use of such funds.
>
> Directs grantees to expend not less than 75% of grant funds received on core medical services. Allows the Secretary to grant waivers to such requirement under certain circumstances.
>
> Establishes a transitional grant program for metropolitan areas with lower numbers of AIDS cases.
>
> Requires the Secretary to develop and maintain a list of classes of core AIDS Drug Assistance Program (ADAP) antiretroviral medications. Requires states to ensure that such medications are the minimum required treatments to be included in any ADAP program.
>
> Limits the amount by which a grant to an eligible metropolitan area can decrease each year.
>
> Provides for supplemental grants to states that demonstrate a need for supplemental financial assistance.
>
> Allows the Secretary to award grants to assist states in providing eligible individuals appropriate access to pharmaceutical therapies.
>
> Establishes a grant program for the provision of family-centered care involving outpatient or ambulatory care for women, infants, children, and youth with HIV/AIDS.
>
> Provides for activities to evaluate and address the disproportionate impact of HIV/AIDS and disparities in access, treatment, care, and outcome on racial and ethnic minorities.

Brownfields reauthorization (H.R. 5810; report no. 109-608, Part I) – This bill was formally reported out of the Transportation and Infrastructure Committee on July 18th. It has also been referred to the House Energy and Commerce Committee which has not yet acted on it. The Senate does not have a comparable bill. Introduced by Rep. Don Young (R-AK), the bill amends the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 to authorize funding for brownfields revitalization activities and State response programs, and other purposes.

NEW REGULATIONS TO FACILITATE ADOPTION OF HEALTH INFORMATION TECHNOLOGY -- HHS Secretary Mike Leavitt August 1 announced final regulations that will support physician adoption of electronic prescribing and electronic health records technology.

"Electronic health records help doctors provide higher quality patient care, improved efficiency and with less hassle," Secretary Leavitt said. "By removing barriers, these regulation changes will help physicians get these systems in place and working for patients faster."

Electronic prescribing enables a physician to transmit a prescription electronically to the patient's choice of pharmacy or ancillary provider. It can improve patient safety by decreasing prescription errors due to hard-to-read physician handwriting and communication errors, automating the process of checking for drug interactions and allergies and eliminating duplicative laboratory and diagnostic tests.

Electronic prescribing also enables physicians and pharmacies to obtain from drug plans information about the patient's eligibility and medication history. Having access to this information at the point of care makes writing, transmitting, and filling prescriptions quicker and easier, and also makes it possible for physicians to make informed decisions about the availability of lower-cost, therapeutically appropriate alternatives to the prescribed medication.

Electronic health records technology, when interoperable among health care providers in various settings, offers benefits similar to the benefits of electronic prescribing in terms of reducing medical errors, coordinating care and improving efficiency.

Interoperable electronic health records will allow information to be more portable, moving with consumers from one point of care to another. In addition, the implementation of interoperable electronic health records technology is a critical step in achieving secure and seamless information exchange and improving our health care system.

The final rules displayed today by the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG) create new exceptions and safe harbors to two key federal fraud and abuse laws for arrangements involving the donation of certain electronic health information technology and services.

The CMS rule creates two new exceptions to the physician self-referral law, which prohibits a physician from referring Medicare patients for certain designated health services (DHS) to entities with which the physician has a financial relationship, unless an exception applies. The law also prohibits the health care entity from billing for Medicare services that are furnished as a result of a prohibited referral.

Similar to the CMS rule, the OIG rule establishes two new safe harbors under the federal anti-kickback statute. Arrangements involving the provision of items and services that meet the requirements of the safe harbors are exempt from enforcement action under the federal anti-kickback statute related to electronic prescribing as well as electronic health records systems.

The rules finalize an exception and safe harbor for the provision of electronic health records information that is more expansive than the exception and safe harbor proposed by CMS and OIG on Oct. 11, 2005. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) mandated exception and safe harbor for arrangements involving the provision of electronic prescribing technology and services were finalized as proposed.

The exceptions and safe harbors establish the conditions under which:

1. Entities furnishing DHS (and certain other entities under the safe harbor) may donate to physicians (and certain other recipients under the safe harbor) interoperable electronic health records software, information technology and training services.
2. Hospitals and certain other entities may provide physicians (and certain other recipients under the safe harbor) with hardware, software, or information technology and training services necessary and used solely for electronic prescribing.

"These final rules will improve care by giving doctors and other health care providers needed support for interoperable health records that enable them to increase quality and improve efficiency," said CMS Administrator Mark B. McClellan, M.D., Ph.D. "Medicare plays a critical role in this important initiative, and we are committed to its success."

"These important regulations will help promote the adoption of essential health information technology while protecting the federal health care programs and beneficiaries from fraud and abuse," said HHS Inspector General Daniel Levinson.

The exception under the physician self-referral law for arrangements involving the donation of electronic health records technology will protect the provision of software or information technology and training services that are necessary and used predominantly to create, maintain, transmit or receive the electronic health records of the donor’s or physician’s patients.

The scope of donors and recipients under the final rules is considerably broader than in the proposed rules. Donations protected under the exception may be made to any physician by entities furnishing DHS. The exception requires compliance with criteria similar to those listed in the electronic prescribing exception, as well as additional criteria, such as those requiring cost sharing and selection of physician recipients of donated technology.

The corresponding OIG safe harbor is similar. However, consistent with underlying statutory differences, the safe harbor covers a broad array of providers, suppliers, practitioners and health plans when they provide electronic health records technology to physicians and others engaged in the delivery of health care.

Among other conditions, the final rules for arrangements involving the donation of electronic health records technology include a cost-sharing requirement. Recipients are required to pay 15 percent of the cost of the electronic health records technology items and services. In addition, consistent with the President's goal of adoption of electronic health records technology by 2014, the exception and safe harbor protecting arrangements involving the donation of electronic health records will sunset on Dec. 31, 2013.

The electronic prescribing exception was mandated by the MMA and signed into law by President Bush on Dec. 8, 2003. As part of the MMA, Medicare will require Prescription Drug Plans (PDPs) and Medicare Advantage (MA) organizations participating in the new prescription drug benefit to support electronic prescribing. Electronic prescribing will be voluntary for physicians and pharmacies. Although participation by physicians in electronic prescribing is optional, the exception and safe harbor are designed to encourage the adoption of effective electronic prescribing programs and will make electronic prescribing more attractive to physicians.

These CMS and OIG final rules represent a coordinated effort to advance Secretary Mike Leavitt's goal to improve the health care of Medicare beneficiaries through the use of electronic prescribing and electronic health records systems.

MORE PHYSICIANS USING ELECTRICAL MEDICAL RECORDS -- CDC's National Center for Health Statistics is issuing a new Health E-Stat today entitled "Electronic Medical Record use by Office-based Physicians: United States, 2005."

The E-Stat is the latest look at the growing trend towards electronic record-keeping in the medical community. Some of the key findings in the report include:

Nearly one in four (23.9 percent) of physicians reported using full or partial electronic medical records (EMRs) in their office-based practice in 2005 - a 31 percent increase from the 18.2 percent reported in 2001.

Physicians in the Midwest (26.9 percent) and West (33.4 percent) were more likely to use EMRs than those in the Northeast (14.4 percent).

Physicians in metropolitan statistical areas (nearly 24.8 percent) were more likely to use EMRs than were those in non-metropolitan areas (16.9).

Only one in ten (9.3 percent) physicians, however, used EMRs with all four of the basic functions (computerized orders for prescriptions, computerized orders for tests, reporting of test results, and physician notes) considered necessary for a complete EMR system.

The entire E-Stat can be accessed at the CDC/NCHS web site at www.cdc.gov/nchs.

GENETICALLY ALTERED BACTERIA COULD BLOCK MALARIA TRANSMISSION- - Scientists have discovered a way to help stop the spread of malaria by genetically altering a bacterium that infects about 80 percent of the world's insects. Malaria is primarily transmitted through mosquito bites and kills more than a million people every year.

The ubiquitous Wolbachia bacteria are able to alter male insects so that they can only reproduce with female insects also infected with the bacteria, resulting in more infected offspring. Researchers believe that by using genetically altered Wolbachia bacteria, they could spread genes that leave mosquitoes unable to transmit the malaria parasite. Their research was published in the journal Genetics.

There are several National Academies reports on malaria control. The Institute of Medicine report *Battling Malaria: Strengthening the U.S. Military Malaria Vaccine Program* examines how to better integrate the military's malaria vaccine R&D programs and discusses areas that need further research. *Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance* offers recommendations on maximizing the effectiveness of antimalarial drugs, emphasizing the use of artemisinin-based combination therapies and the creation of a global subsidy that would make these effective combination treatments affordable and widely available in nations heavily afflicted by the disease.

Microbial Threats to Health: Emergence, Detection, and Response discusses the current state of knowledge and policy pertaining to emerging and re-emerging infectious diseases and urges the U.S. government play a significant role in building the capacity of poor countries to monitor, prevent, and respond to disease outbreaks. The National Research Council report *Malaria Control During Mass Population Movements and Natural Disasters* reviews recent scientific literature relevant to establishing malaria control programs in situations involving forced migration, conflict, and other emergencies.

FDA'S NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH PUBLISHES STUDY ON DISTINGUISHING POTENTIAL HOAX MATERIALS FROM BIOTERROR AGENTS -- Researchers at the Food and Drug Administration (FDA) National Center for Toxicological Research (NCTR) are developing a quick, cost-effective way to screen for and identify bioterror agents and other substances used in hoax incidents.

The testing method uses a technology called mass spectrometry. This technique identifies and quantifies compounds, based on the structure and chemical properties of their molecules, quickly and with a very high degree of accuracy.

The testing process works in a way similar to the FBI's fingerprint library for criminals. A researcher can take patterns generated by a mass spectrometer's analysis of a substance

to be identified and compare them to a database of known substances, for immediate recognition.

"Our new technique, along with fingerprinting, offers a rapid and valuable assessment of a range of bioterror and hoax samples," said NCTR's Dr. Jon Wilkes, Ph.D., the lead author of the study. "We hope to see the testing put into place by government and industry in the near future. Anytime we can run tests more quickly, we can benefit public health and safety." NCTR will continue to build the "finger print" data base.

This project serves as a prime example of scientific work conducted under the FDA's Critical Path Initiative -- work that is intended from its conception for widespread use.

Although other testing methods, such as DNA testing, are available, they are costly and involve lengthy processes that can delay by days detection of micro-organisms that can cause disease. This new technique is very fast, taking about 7 minutes for each sample on the mass spectrometer following three to eight hours of sample preparation time. Sample preparation is beyond the scope of this paper.

Although this new test (screening technique) can not distinguish living from nonliving microbiological organisms (whether cells are dead or alive), the test can process a large number of samples rapidly. The per test cost is as little as $2 each whereas DNA methods cost from $15 to $50 per test and take from 24 hours from start to finish including sample growth or culture.

The speed and cost-effectiveness of the tests make their use feasible for FDA enforcement work as well as for industry. Researchers found that the testing method could be used to distinguish biological and chemical samples of all sorts, addressing the analytical needs of the food industry, law enforcement and military authorities as well as regulatory agencies

Already, NCTR has examined the mass spectrometric fingerprints of a variety of chemical and biological materials that could be used in a biological attack. These include two types of food poisoning bacteria -- *Vibrio parahaemolyticus*, (associated with illness from eating oysters) and *Salmonella enterica,* (bacteria often found in poultry causes gastrointestinal illness) -- and inert substances such as flour and corn starch.

Mass spectrometry generally is used to characterize a pure substance. This use of this technique to evaluate complex mixtures such as bacteria or food is more novel.

NCTR is working with an industrial partner under an FDA Cooperative Research and Development Agreement (CRADA) to commercialize the method for food manufacturing quality control as well as counter-terror applications.

FDA recently published the research article about the new testing method in the journal *Rapid Communications Mass Spectrometry*, "Pyrolysis Mass Spectrometry for Distinguishing Potential Hoax Materials from Bioterror Agents." Dr. Wilkes is the leader

of FDA's counterbioterror team in the Divisions of Systems Toxicology and Microbiology at NCTR. The authors include his FDA colleagues Fatemeh Rafii, Ph.D., John B. Sutherland, Ph.D., Mr. Larry G. Rushing, and Dan A Buzatu, Ph.D., all of whom have been conducting research in this area at NCTR since l995.

The article is available online at:
http://www3.interscience.wiley.com/cgi-bin/fulltext/112693175/HTMLSTART.