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ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES: ARE APRNS IN THE LOOP?

Windy Carson-Smith, Publisher and CEO

In the first week of December the Senate Judiciary Committee conducted a hearing on e-prescribing and the DEA ban on e-prescribing of controlled substances. Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, said abuse of prescription drugs now exceeds abuse of cocaine, heroin, hallucinogens, Ecstasy and inhalants, combined. "In the absence of appropriate controls," he said, "allowing electronic prescriptions for controlled substances would certainly exacerbate a growing epidemic of prescription drug abuse in the United States."□

Pointing to the potential advantages of e-prescribing for controlling health care costs and improving medication safety, Coburn accused Rannazzisi of following a bureaucratic rule that says, "Never do what's best when you can do what's safe."□

Senators supporting the expansion of e-prescribing to controlled substances include Jeff Bingaman (D-NM), Norm Coleman (R-MN), John Ensign (R-NV), John Kerry (D-MA), Mel Martinez (R-FL), Bill Nelson (D-FL), Olympia Snowe (R-ME), Debbie Stabenow (D-MI), John Sununu (R-NH), and Sheldon Whitehouse (D-RI).

Health and Human Services Secretary Mike Leavitt said the Medicare bill indicated that a bill is being drafted in the Senate Finance Committee to require physicians to implement health information technology that meets department standards in order to be eligible for higher payments from Medicare.□

Leavitt's statement was not specific about what kinds of health IT should be required, but in a blog on the HHS Web site he cited the benefits of e-prescribing, noting:

"The technology necessary to electronically receive and fill prescriptions exists in most

pharmacies in the United States. However, only a small percentage of doctors use it. The benefits are unchallengeable. E-prescribing is not only more efficient and convenient for consumers, but widespread use would eliminate thousands of medication errors every year. At the AHIC meeting, we announced standards that will help to get us there. We are starting with standards for providing medication history and for formularies so that providers have the information they need to write correct prescriptions. These two standards alone could go a long way to eliminating errors."

However, the focus has been on moving the medical community toward e-prescribing, without regard for advanced practice nurses who prescribe controlled substances. The American Nurses Association (ANA), in response to this deficiency in the debate, moved toward trying to include advanced practice nurses into proposed legislation and practice by meeting with the White House to discuss inclusion of NPs into any proposed e-prescribing legislation or regulation.

Although the DEA continued to express concerns about altering the existing system to allow for e-prescribing of controlled substances, Mr. Rannazzisi, has stated in his testimony that:

"HHS has finalized initial regulations establishing standards for an electronic prescription drug program under Medicare Part D. The standards were not designed to provide safeguards against the diversion of controlled substances. The responsibility for establishing these regulatory safeguards against diversion of controlled substances falls upon DEA as the agency charged with administering and enforcing the Controlled Substances Act."

DECISION POSTPONED ON LIMITED SERVICE CLINICS

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STATE HOUSE NEWS SERVICE

State House, Boston, Dec. 12, 2007...State public health officials on Wednesday raised a litany of questions about proposed limited service health clinics and postponed their decision until January on whether to allow such clinics in Massachusetts stores.

The 14-member state Public Health Council, which includes seven doctors, raised questions about disrobing at clinics, selling tobacco products in clinic settings, and conflict of interest issues arising from the clinics being located in the same building as a pharmacy that owns it.

Supporters of such clinics say they represent a new and convenient venue for basic health care and could potentially help control rising health care costs. Skeptics have raised questions about limits on the type of care to be provided in such clinics and the continuity of relationships between patients and their physicians.

Council members suggested mandating the use of hand sanitizers and questioned whether insurance companies are adequately prepared to cover clinic costs when clinic patients are referred to other providers.

Other members questioned whether the individuals running the clinics will have enough experience dealing with both children and adults, and requested better specification in the regulations on the location toilets and janitor's closets in clinics. Council members also wished to maintain control of regulation violation hearings.

The state Department of Public Health (DPH) will attempt to address the questions and revise the regulations, which have become a subject of extensive debate within the medical community, particularly among community health centers and primary care doctors, fearful of losing patients and the fracturing of care and records.

Elected officials have also weighed in. Boston Mayor Thomas Menino says clinics would lead to greater racial and ethnic health disparities. Senate President Therese Murray and Sen. Richard Moore (D-Uxbridge), and his co-chair Rep. Patricia Walrath (D-Stow) on the Health Care Financing Committee, have voiced support for clinics.

The proposed rules ban the treatment of children 24 months and under in the clinics. Child immunizations would not be allowed and patients would not be permitted to disrobe and put on a gown, though council members said the definition of disrobement was unclear.

The proposed rules also require each clinic to keep records on the premises and have a taped message that directs patients to a toll-free number connecting them to a practitioner. The rules also require the clinic to maintain a roster of primary care practitioners and community health centers willing to accept a referral from the clinic.

The proposed regulations came about after CVS Corp. submitted a proposal last year to open a "Minute Clinic" in Weymouth, with eventual plans to expand to 125 clinics statewide. CVS initially hoped for exemptions from current state regulations. DPH officials instead chose to draft the new regulations.

Though the company has no immediate plans to open its own version of limited service clinics in Massachusetts, Wal-Mart Stores, Inc., a major CVS competitor, said in September testimony to DPH that they would like an exemption since they operate in other states more along the lines of a "group practice." DPH officials today rejected talk of an exemption. Wal-Mart has 45 stores in Massachusetts.

At the "Minute Clinics," visits take about 15 minutes and cost about \$59, according to CVS officials.

"The concept has already been well-proven," said Michael Howe, CEO of CVS subsidiary "Minute Clinic," noting that there are already about 400 clinics in 24 states.

Howe said the company has no change in plans after hearing the concerns. "The suggestions at this point are going to have to be vetted," he said after the move to hold off on a vote.

Asked if any of the suggestions from council members appeared to be deal breakers, DPH Commissioner John Auerbach, who chairs the council, said, "None of them struck me that way, no."

Raising the conflict of interest issue, some council members said patients could be referred directly into the pharmacy system and influence the pharmacy's business practices, and vice versa.

Albert Sherman, a Public Health Council veteran and a vice chancellor at UMass Medical School in Worcester, said conflict of interest violations are unavoidable. "They happen and they will happen no matter how you write it, because it's human nature," he said. "You have a real conundrum here."

Public health officials said they had looked at other states, such as Minnesota, and seen no evidence of such abuse, though patients may use the nearby pharmacy simply out of convenience. "There was no evidence of any inappropriate prescribing practice," said Paul Dreyer, director of the Bureau of Health Care Safety and Quality.

Other council members noted the lack of requiring a private waiting area for patients. "I think this is a significant issue," said Dr. Alan Woodward, former president of the Massachusetts Medical Society. "Just to have them walking around is not being appropriate as far as a conscientious infectious disease management policy."

Dreyer said areas would be examined on a case-by-case basis.

RHODE ISLAND NURSE PRACTITIONERS STRATEGIES TO ADDRESS WELLPOINT'S NEW POLICY

Lisah Carpenter, Lobbyist, RI Nurse Practitioner Association

This article is a summary of events that occurred recently in New Hampshire from the point at which the NH Nurse Practitioner Association (NHNPA) was first made aware that Anthem BCBS in NH (Anthem) had begun implementing a new credentialing policy to mandate a collaborating or supervising physician signature for all ARNPs, to Wellpoint, Inc.'s (Wellpoint) decision to rescind the policy. It focuses on the advocacy strategy applied by NHNPA.

Early Alert: It began quietly enough, with an email on Tuesday, August 14, from one of our members, "Subject: Anthem. Please call me when you get my fax. Anthem is NOW requiring a supervising physician for all ARNPs in NH!" The email came from an ARNP who had recently opened her own primary care family practice.

Seeking Clarity: Over the next 24 hours, a number of emails were sent back and forth between the ARNP's office, her Anthem provider representative and NHNPA. We needed to get the facts straight: Does the policy intend to include all ARNPs in NH? Does it apply to ARNPs who are employees, or only to those who own their own practices (primary care, mental health, consulting services)? Why in NH? Why now?

Anthem's answer via the provider representative: This is a national policy being implemented across the country, per a decision by Wellpoint, the parent company in California. It applies to all ARNPs, irrespective of their practice setting, and is being rolled out as providers seek to renew their credentials. No signature, no provider contract, no reimbursement. Period.

Articulating the Problem: We quickly drafted a set of talking points that enumerated what we viewed as the short and long-term consequences of Anthem/Wellpoint's new policy in NH, emphasizing the duration of ARNP independent practice in NH (since 1991), the current shortage of primary care and mental health providers across the state, and the added stress that would be exerted on existing providers and facilities. On Wednesday, August 15, NHNPA also blitzed its membership and national organizations to determine whether other states had yet been hit, and how widespread notification had been within NH.

Setting Goals: Our immediate goals were to temporarily enjoin the contract/network termination of any ARNP, and to prevent the closure of any practice. Our long-term goal was for Anthem/Wellpoint to rescind the policy in NH, preferably nationally. Our strategy ran along several lines simultaneously: 1) to exert pressure as high up within the company, as quickly as possible; 2) to exert pressure as high up within state government as quickly as possible; and, 3) to evaluate all legislative and legal options.

Activating the Grassroots: By the end of the first week, we realized that numerous ARNPs had received notification, some of whom felt forced, financially, to comply with the new policy. Others knew nothing about it, because their office staff had simply had the forms signed and returned. ARNP offices that were resisting had already received follow-up notices and were beginning to receive phone calls from Wellpoint representatives, threatening removal from the network. No other state was reporting similar notification. We asked our members to alert their office managers to the problem, attempt to hold off on compliance, and call Wellpoint's contact person in MA, to object to the new policy. Later that day the voicemail box at Wellpoint was reported to be full – it is critically important to note that NHNPA's membership responded when the call to action was posted to the listserve.

Identifying the Power Structure: The following week, our first outside call went to a contact whom we felt understood the issues, had enormous credibility with insurers and policymakers alike, and had relationships deep within the health insurance world; hoping she might plant the seed with Anthem's decision-makers that this policy would have devastating consequences in NH. Our second call went to the NH insurance commissioner, and the third call went to the governor. On August 22 we received word

that implementation of the new policy was put on hold until further review by the Wellpoint team in California; and, two days later, the insurance commissioner called to tell us that he had just returned from a meeting with Anthem, in which they told him the matter would be resolved. Then we waited.

Firming Up the Base: While waiting for Anthem/Wellpoint to make a decision, we took steps to keep the issue alive. We took every opportunity to talk about the problem. In the full flush of a presidential primary season, we accepted invitations to political gatherings that we knew would attract influential people in the health care world, and we talked up the problem – the reaction was gratifying. Everyone with whom we spoke, from hospital executives to policymakers to provider colleagues, clearly understood the critical role played by ARNPs in the delivery of safe, high quality health care throughout the state, and no one could understand why any insurer would implement a policy in direct conflict with the independent practice authority granted in the nurse practice act, especially when access to primary care and mental health services was suffering due to deepening shortages. Finally, we contacted legislators and the attorney general’s office, in the event that legislation might be needed and/or a restraint of trade claim could be raised.

Setting Plan B into Motion: On September 20, days before the legislative deadline, with no word from Anthem/Wellpoint, a bill was filed to prohibit health carriers from restricting ARNP practice authority through their credentialing process.

Resolution: It is impossible to know where the turning point was for this company, but on Friday, September 28, we received official word that Anthem/Wellpoint had decided to rescind its policy. NHNPA is enormously grateful to everyone involved. In this case, we were very fortunate to be in a small state, with direct access to the right people. The experience has been a good reminder of the vulnerability of our practice authority. This time, however, we felt the power of longevity on our side – ARNPs are most definitely here to stay!

HHS ISSUES FIRST DEPARTMENT-WIDE REPORT ON PERSONALIZED HEALTH CARE

Health and Human Services (HHS) Secretary Mike Leavitt today released the first department-wide report on the goal of personalized health care and said work in biomedical science, health information technology and health care delivery should be aligned to produce “the right treatment, at the right time” for each individual patient.

The report, *Personalized Health Care: Opportunities, Pathways, Resources*, presents a long-range plan for achieving much more individualized treatment for patients, especially by using genetic information and health information technology (IT). Together, health information and IT can give clinicians better information about each patient and more support in choosing “best care” options for treatment.

“Health care professionals have always aimed at making medical care as individualized as possible. But in truth, our ability to deliver the right care for each person has been limited,” Secretary Leavitt writes in a foreword to the report.

The report was produced as part of Secretary Leavitt’s priority initiative on personalized health care. It describes how the exploding knowledge of the human genome will increase the capacity to predict, detect, preempt and treat disease, by enabling physicians to “look beneath” visible symptoms and see signs and causes of disease at the molecular level. The report also describes how health IT can make patient information accessible securely, while maintaining confidentiality, as well as how it can support high quality care. Health IT can even help clinicians and researchers ascertain which treatments are most effective and for whom, by using broad-scale data derived from day-to-day medical practice.

The report includes descriptions of the opportunities presented by science and technology. It also outlines pathways where work is needed. Additionally, the report presents the first inventory of some 50 related programs underway throughout HHS.

Secretary Leavitt said the combination of genomic medicine, health IT, and better use of medical evidence will make possible much more effective health care -- such as learning which medicines, at what dosages, work best for which patients.

“Personalized health care means knowing what works, knowing why it works, knowing who it works for, and applying that knowledge for patients,” he writes. “These goals may sound elementary, but a generation of effort lies ahead of us in achieving them.”

Secretary Leavitt emphasized that personalized medicine, especially the use of genomic data, will require further attention to using information correctly, including protecting the privacy of identifiable personal health information and protection against misuse of that information. The Secretary also noted that the Bush Administration, since 2001, has supported enactment of federal law to protect against misuse of genomic information in employment and health insurance.

Some highlights of related activities in HHS include:

- Genome-wide Association Studies, sponsored especially by the National Institutes of Health (NIH), to identify genetic elements in disease. New findings from these studies are now being reported at a rapidly accelerating pace.
- Efforts by the Centers for Disease Control and Prevention (CDC) to describe population-wide genomic characteristics and to help lay the groundwork for using genomic elements in health care.
- Programs under the National Cancer Institute (NCI) to improve understanding of the causes of cancer and to improve treatment through scientific advancement as well as new programs for sharing “best treatment” information.
- HHS-supported efforts in health IT to develop technical standards and provide for secure exchange of medical data, aimed at supporting the President’s goal of electronic health records for most Americans by 2014.

- New guidance and planning by the Food and Drug Administration (FDA) to lay the groundwork for rapid development of useful new products, and for integrating genomic information into drug prescribing and disease diagnosis.
- Efforts by NIH, CDC, the Agency for Healthcare Research and Quality (AHRQ), the Health Resources and Services Administration (HRSA) and the Indian Health Service (IHS) to accelerate the translation of scientific discoveries and “best practice” information into clinical practice.

The report is available on the HHS web site at <http://www.hhs.gov/myhealthcare>

**FOOD AND DRUG ADMINISTRATION, AGENCY INFORMATION
COLLECTION ACTIVITIES: PROPOSED COLLECTION: COMMENT
REQUEST: MENTAL MODELS STUDY OF COMMUNICATION WITH
HEALTH CARE PROFESSIONALS ABOUT THE RISKS AND BENEFITS OF
PROVIDING PRESCRIPTION USE FOR PREGNANT AND NURSING WOMEN
WITH CHRONIC CONDITIONS**

Comment submission date, written or electronic comments due by February 11, 2008. The proposed information collection will help FDA advance public by identifying misperception and knowledge gaps about how health care providers use information to make decisions about the use of prescription drugs for the targeted patient groups. Knowledge of these misperceptions and gaps provides opportunities for FDA to target its communications more precisely to such gaps and areas of misperception in health providers’ mental models regarding treatment decisions.

The project will use “mental modeling” a qualitative research method that compares a model of the decision-making processes of a group or groups to a model of the same decision-making processes developed from expert knowledge and decision-making. In the study the decision models of certain health care providers concerning treatment options for pregnant and nursing women will be compared to a decision model concerning such treatment options that was derived from the knowledge and experience of FDA reviewers responsible for product labeling. FDA will use telephone interviews to determine from the health providers the factors that influence their treatment decisions for pregnant women with chronic conditions.

The protocol requires one-on-one telephone discussions with about 25 members of 2 categories of providers:

- (1) Those who directly care for pregnant and nursing women, including obstetricians, OB/GYNs, nurse midwives, and general practitioners; and
- (2) Those who directly care for women of reproductive age with significant chronic health conditions (e.g. allergists, psychiatrists or cardiologists)

The protocol as well as sampling size does not allow the FDA to determine whether distinctions exist between nurse and physician “mental modeling”. Likewise, the FDA protocol does not incorporate all or a statistical significant sampling of nurse providers

within the research protocol. Nurses and nursing organizations should provide substantial and extensive comment on this model.

RECENT REPORTS

Unsettling Scores: A Ranking of State Medicaid Programs. (2007) Public Citizen ranks state Medicaid programs by eligibility, scope of services, quality of service and reimbursement. <http://www2.citizen.org/hrg/medicaid/>

Discharge rounds in the 80-hour workweek: importance of the trauma nurse practitioner.

Haan JM, Dutton RP, Willis M, Leone S, Kramer ME, Scalea TM. *J Trauma*. 2007; 63:339-343.

<http://psnet.ahrq.gov/resource.aspx?resourceID=5952>

To License or Not: States and Midwifery, National Conference of State Legislators, *State Health Notes*, vol. 28, Issue 502, October 29, 2007

<http://www.ncsl.org/programs/health/shn/2007/sn502a.htm>

The impact of safety organizing, trusted leadership, and care pathways on reported medication errors in hospital nursing units.

Vogus TJ, Sutcliffe KM. *Med Care*. 2007; 45:997-1002.

<http://psnet.ahrq.gov/resource.aspx?resourceID=5997>

Aiming Higher: Results from a State Scorecard on Health Systems Performance.

This report by the Commonwealth Fund compares health systems in all 50 states, ranking states based on 32 performance indicators for health care access, quality, equity and healthy living, and avoiding hospital admissions and costs.

http://www.commonwealthfund.org/usr_doc/StateScorecard.pdf?section=4039

Can your nurses stop a surgeon?

Weinstock M. *Hosp Health Netw*. September 2007.

<http://psnet.ahrq.gov/resource.aspx?resourceID=5943>

Statistics You Can Use, DBTAC Southeast ADA Center. For more information and copies of the report, contact DBTAC, 490 Tenth Street, Atlanta, Georgia 30318, 404-385-0636, 800-949-4232(v/tty) 404-385-0641 (fax), sedbtacproject@law.syr.edu and www.sedbtac.org

Health IT implementation stories: HANDS care plan tool seeks to improve nurse communication at handoff in AHRQ-funded study.

AHRQ National Resource Center for Health Information Technology.

<http://psnet.ahrq.gov/resource.aspx?resourceID=5938>

Patient safety in nursing practice.

Farquhar M, Collins Sharp BA, Clancy CM. AORN J. 2007; 86:455-457.
<http://psnet.ahrq.gov/resource.aspx?resourceID=5948>

New York City puts hospital error data online.

Kershaw S. New York Times. September 7, 2007;Metro Desk section:B1.
<http://psnet.ahrq.gov/resource.aspx?resourceID=5923>

Guilty, afraid, and alone — struggling with medical error.

Delbanco T, Bell SK. N Engl J Med. 2007;357:1682-1683.
<http://psnet.ahrq.gov/resource.aspx?resourceID=6082>

AANP responds to August 9, 2007 Wall Street Journal article "States Boost Scrutiny of Drug Store Clinics" which questions the ability of nurse practitioners to provide health care services in the retail clinic setting. To read the response in its entirety: <http://www.aanp.org/NR/rdonlyres/ecoxfz5qywwtv3gur7spjeyrdzlsbkifzsyxoubta56vzyu p7f3pwnstxymllytemnuw6srgz5fx3hwms46okc3rdf5b/WSJ+Ltr%2e1.pdf>

Improving Hispanic Elders' Health: Community Partnerships for Evidence-Based Solutions.

DHHS' new initiative to improve the health and quality of life of Hispanic elders encourages Hispanic families to take advantage of new Medicare benefits, including prescription drug coverage, flu shots, diabetes screening and self-management, cardiovascular screening, cancer screening and smoking cessation programs. Communities around the country are invited to apply for pilot project funding.

2008 SPEAKING ENGAGEMENTS

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| March 5, 2008 | National Association of Clinical Nurse Specialists
"State Legislative Update"
Atlanta, Georgia |
| April 8, 2008 | American Bar Association, HIV/AIDS Law and Practice Conference
"Nurse HIV Testing, Employment and Corporate Practice"
Dallas, Texas |
| June 23-24, 2008 | Center for American Nurses (CAN)
"Nurse Staffing and Acuity Legislation: An Overview", LEAD 2008, Washington, DC |
| August 9, 2008 | American Association of Diabetes Educators
"Expanding the Role: Who's Managing Diabetes?"
Washington, DC |

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